

Module 6: The Revised PBIS

Goal To identify the changes made to PBIS to support HACCP-based inspection.

Objectives After completing this module, participants will be able to:

1. Describe the new structure and components.
2. Describe the differences between the new Inspection System Procedure (ISP) Guide and the old ISG.
3. Describe the changes to the Plant Profile.
4. Complete an Establishment/Shift Inspection Procedure Worksheet.
5. Explain how to properly complete a Procedure Schedule.
6. Explain how to properly complete a Noncompliance Record (NR).
7. Describe the Noncompliance Determination Guide (NDG).
8. Define noncompliance trend indicators.

I. INTRODUCTION

A modernized approach to inspection requires changes in the performance-based inspection system (PBIS) and the activities FSIS has conducted under that system — in particular, the tasks in the Inspection System Guide (ISG).

Therefore, for establishments that are subject to the HACCP system regulations, FSIS has replaced the ISG and portions of PBIS directives with directive 5400.5 and its attachments. Inspection program personnel are to follow the instructions in this directive in every establishment that is subject to the HACCP system regulations.

Two components of PBIS will guide inspection program activities. These components are used to determine whether an establishment is complying with regulatory requirements – in particular, in making determinations about compliance with the HACCP system regulations, Sanitation Standard Operating Procedures (SSOP) regulations, and other consumer protection requirements.

The first PBIS component is the Inspection System Procedure (ISP) Guide, which replaces the ISG.

The second PBIS component is the automated data processing (ADP) system that schedules work to be done by inspection personnel, incorporates inspection findings into a central database, and creates reports from the database that can be used to support supervisory and management decision making.

Several PBIS forms that are used to update the ADP system and document inspection findings have been either replaced or modified. The instructions for completing these forms have also changed.

A PBIS comparison chart has been included as an attachment to this handout. It can be used as a quick reference to the changes to PBIS policies, activities, and forms.

Inspection personnel must keep in mind that both versions of PBIS will be in use until HACCP is implemented in all plants in the year 2000. PBIS, in its present form, will be used in non-HACCP plants, while PBIS, in its new form, will be used in plants under the HACCP system regulations. Therefore, it's possible that inspectors with patrol assignments could use both the old PBIS techniques and the new PBIS techniques during a single day.

II. INSPECTION SYSTEM PROCEDURE (ISP) GUIDE

Overview

The ISP provides the in-plant procedures that the Agency currently views as appropriate in enforcing the new HACCP regulatory requirements and

administering the inspection mandates. The ISP Guide lists the applicable regulatory requirements and FSIS directives.

The names of the hierarchical categories in the ISP guide are different from those in the ISG. The categories in the ISP Guide are Activities, Elements, and Procedures. Comparatively, the categories in the ISG were Processes, CCPs, and Tasks.

The eight Activities are:

Activity Number	Activity
01	Sanitation Standard Operating Procedures
02	[Reserved]
03	Hazard Analysis and Critical Control Point
04	Economic/Wholesomeness
05	Sampling
06	Other Requirements
07	[Reserved]
08	Emergency Elements [Reserved]

Each Activity has one or more elements. For instance, the elements for HACCP are:

03 Hazard Analysis and Critical Control Point

Elements

03A	HACCP Basic Compliance Checks
03B	Raw Product-Ground
03C	Raw Not Ground
03D	Thermally Processed/Commercially Sterile
03E	Not Heat Treated-Shelf Stable
03F	Heat Treated-Shelf Stable
03G	Fully Cooked-Not Shelf Stable
03H	Heat-Treated But Not Fully Cooked-Not Shelf Stable
03I	Product with Secondary Inhibitors-Not Shelf Stable
03J	Slaughter.

NOTE: The elements 03B through 03J represent the nine HACCP processes.

There are only three verification procedures within the HACCP Activity--03. Element 03A contains one procedure (03A01) that is used to verify BASIC compliance of a HACCP plan. The BASIC compliance procedure (03A01) is an unscheduled procedure that is performed at the time of HACCP implementation

and as appropriate thereafter such as whenever the plant changes or modifies its HACCP plan or following annual reassessment.

The other two HACCP verification procedures (procedure 01 and 02) are found in each of the elements 03B through 03J. The HACCP procedure 01 instructs inspection personnel to **randomly select** and verify compliance of one or more HACCP regulatory requirements at **one or more CCPs** identified in the plant's HACCP plan. Whereas, the HACCP procedure 02 instructs inspection personnel to verify compliance of all regulatory requirements at **ALL CCPs** within the plant's HACCP plan for a specific production of product.

Although, in comparison, the requirements and description of HACCP procedures 01 and 02 are different, all the 01 procedures are the same for elements 03B through 03J; only the procedure code is different. For example, the regulatory requirements, references, and description for procedure 03B01 are the same for procedures 03C01, 03D01, 03E01, etc. Likewise, all the 02 procedures are the same for elements 03B through 03J; again, only the procedure code is different. For example, procedure 03B02 is the same procedure as 03C02, 03D02, 03E02, etc.

After-The-Fact Detection vs. Systems Approach

The objective of the procedures in the ISP guide is different than that of the tasks in the ISG. Many task descriptions in the ISG direct the inspector's attention to a particular step or point in the process. Because the tasks are so narrow in focus, they only provide the inspector with a snapshot of what is happening in the process at the time they are performed and not the overall process. When a problem is found, it is more indicative of the regulatory requirements not being met rather than the process being out of control. Hence, the current inspection system relies more on after-the-fact detection of problems rather than verifying the effectiveness of the establishment's process controls.

The procedures in the ISP guide were written to reinforce FSIS's regulatory oversight role and to be compatible with the systems approach. They center on the establishment preventing problems in the process rather than inspection detecting them. Many ISG tasks weren't compatible with the new regulations and had to be removed. Other food safety related tasks, and non-food safety related tasks for facilities, equipment, water, rodent and pest control, and labeling tasks were merged or combined into one or fewer procedures. For instance, the twelve rodent and pest control tasks are now one procedure. Thus, there are significantly fewer ISP guide procedures than ISG tasks. Forty-eight procedures now make up the ISP in comparison to five hundred and forty tasks that made up the ISG.

The **food safety** regulatory requirements that were addressed by the tasks in the ISG are now addressed by the SSOP and HACCP procedures in Activities 01

and 03. **Economic adulteration, wholesomeness, and other** regulatory requirements that were addressed by the tasks in the ISG are now addressed by procedures in Activities 04 and 06. For example, the temperature to which a battered and breaded product is cooked (food safety) is verified using the appropriate HACCP element in Activity 03. Whereas, the requirement that batter and breading not exceed 30% in the finished product (economic) is verified using procedure 04A04.

04 Economic/Wholesomeness

The ISG tasks that deal with verifying product requirements traditionally recognized as “**prevention/control of economic adulteration**” have been revised and consolidated in the ISP as Element 04A. Likewise, the ISG tasks that encompass the “**labeling and standards requirements**” have been revised and consolidated in the ISP as Element 04B. Inspection responsibilities for performing “**finished product standards, AQL, boneless meat defect criteria, pork skins, and moisture**” now make up Element 04C in the ISP.

05 Sampling

Activity 05 addresses “**sampling (economic, residue, and directed)**” and the new pathogen reduction requirements for *E. coli* testing and *Salmonella* performance standards.

06 Other Requirements

“**Other Requirements,**” as outlined in Activity 06 of the ISP, consist of six elements. Procedures in this activity are designed for verifying **other consumer protection** regulatory requirements. Keep in mind that the regulatory requirements that fall under the provisions of the SSOPs and/or HACCP **are not** included in these elements but are captured in Activity 01 and 03, respectively.

Further Defining Activity 04 and 06 Procedures in Comparison to Activity 01, 03, and 05 Procedures

Inspection personnel perform verification procedures in activities 04 and 06 to determine whether a specific product, facility, or equipment is in compliance with **other** regulatory requirements. On the other hand, inspection personnel perform verification procedures in activities 01, 03, and 05 to determine whether an establishment is complying with the **food safety systems** (SSOPs, HACCP, and Pathogen Reduction) as required by FSIS regulations.

Evaluation Tasks vs. Verification Procedures

Many tasks in the ISG had an evaluation component that required inspection personnel to only evaluate records to determine if on file, timely, accurate, and

complete. This evaluation component does not exist in the ISP guide. Except for sample collection procedures, every procedure in the ISP guide requires inspection personnel to perform a verification activity.

There are two SSOP verification procedures (01B01 and 01C01) that instruct inspection personnel to review records only.

With the exception of these two SSOP procedures, when performing any of the other procedures in the ISP, inspection personnel may review applicable records, take on-site measurements, or make direct observations. Inspection personnel may choose to perform any *one* of these activities, or use any combination of these activities to verify that the requirements have been met when they perform each procedure. For example, when performing the 03B01 procedure, an inspector may choose to review only records for his/her random selection of CCPs. Likewise, when performing the 03B02 procedure, an inspector may choose to review only records to verify that all CCPs meet all of the HACCP regulatory requirements.

Maintaining the ISP Guide

The Regulation Development and Analysis Division (RDAD) and the Inspection Systems Development Division (ISDD) are responsible for managing and coordinating development of ISP changes, which generally will occur in conjunction with rulemaking proceedings or other Agency policy issuances. Resolution of differences and clearance of draft ISP guide changes will be part of the regular policy review process for FSIS issuances.

Agency personnel who believe changes are needed should make their suggestions, through regular supervisory channels, to their Deputy Administrators. Deputy Administrators should forward their recommendations to RDAD.

III. PLANT PROFILE

There are two important PBIS documents that inspection personnel should complete prior to (i.e., during the awareness phase) the implementation date of the Pathogen Reduction-Hazard Analysis and Critical Control Point regulations. The first document is FSIS Form 5400-1, the plant profile.

This document will continue to provide information that is needed to implement and maintain PBIS and keep FSIS's Common Online Reference for Establishments file current. The general instructions for completing and maintaining the profile have not changed. The Plant Profile, however, had to be modified because the information being entered in some blocks is no longer applicable for inspection activities in establishments subject to the HACCP system regulations. For example, the traditional, TQC, and PQC inspection

boxes, the approval date box for a QC program, and the PEA, IRE, and ERAIE boxes were removed from the inspection system block, the Partial Quality Control programs block, and the other indicators block of the form. Other blocks were modified so that pertinent information about the establishment HACCP system could be captured. For instance, the process activities in the processing data block were replaced with the nine HACCP processes. Specific instructions for completing the plant profile are in FSIS Directive 5400.5, Attachment 1.

IV. ESTABLISHMENT/SHIFT PROCEDURE PLAN

Overview

The second document that inspection personnel should complete is FSIS Form 5400-5, the Establishment/Shift Inspection Procedure worksheet. For daily procedure schedules to be generated in an establishment subject to the HACCP system regulations, an establishment/shift procedure plan that reflects current product/processes/operations must be entered into the ADP component of PBIS. Establishments with more than one shift will need a procedure plan for each shift. Procedure plan worksheets will not be completed for each inspector when multiple inspectors are assigned to the same shift. Remember with PBIS prior to HACCP implementation, monitoring plans were completed for each inspector on the shift that was assigned PBIS responsibilities.

The Establishment/Shift Inspection Procedure worksheet replaces the Establishment/Shift Monitoring Plan worksheet. The new worksheet lists all of the ISP guide procedures that the agency currently views as appropriate for administering the new inspection mandates. There are no “core” procedures that are common to all plants appearing in bold print and pre-marked with an arrow, as is the case with the present monitoring plan worksheet.

Developing the Establishment/Shift Procedure Plan

To develop procedure plans for establishments coming under the Pathogen Reduction/Hazard Analysis and Critical Control Point regulations, inspection personnel will use the instructions for developing a procedure plan that are part of this module.

Enter the establishment number and shift at the top of the inspection procedure worksheet. Using the ISP guide, inspection personnel will review each procedure listed on the form and if it applies to the establishment’s operations for that shift, they will place an “X” in the space provided.

Inspection personnel will use their extensive knowledge of the establishment’s operations and the establishment’s existing monitoring plan(s) to complete the Establishment/Shift Inspection Procedure worksheet. The workshop on page 32 of this module provides inspection personnel with an example of how to complete

the Establishment/Shift Inspection Procedure worksheet.

The determination of which HACCP procedures are applicable will depend on the type of products being produced in the establishment. All meat and poultry products fall into one of the nine HACCP elements or processes in the ISP guide. The process that is used to produce the product or the final condition of the product when it leaves the establishment is the key to whether or not a particular HACCP procedure is marked on the worksheet. For example, if the final product shipped from the establishment was raw and not ground, then the HACCP element addressing raw and not ground products would apply and both procedures for element 03C would be marked, i.e., 03C01 and 03C02.

NOTE: If any of the procedures for HACCP elements 03B through 03J were marked, then the HACCP basic compliance check, element 03A, would be selected and its single procedure marked on the worksheet.

Maintaining the Establishment/Shift Procedure Plan

After completing the worksheets, inspection personnel are to submit them to their District Office. Personnel in the District Office will enter all identified procedure codes into the ADP system. After the initial procedure plans are developed from the completed worksheets, they will need to be maintained so that they reflect the current operations for each shift at a particular establishment. Maintenance of the establishment/shift procedure plans involves review and possible revision of the worksheet. As outlined in FSIS Directive 5400.5, the instructions for adding procedures to a plan, deleting procedures from a plan, and the review of the preprinted worksheet are basically the same as those under the old PBIS, except that inspection personnel are to review the preprinted worksheet for accuracy upon rotation in addition to the annual review.

V. CONDUCTING INSPECTION SYSTEM PROCEDURES

Procedure Schedule (PS) Overview

The IIC will continue to receive a schedule that identifies the in-plant procedures to be performed each day. The procedures that appear on the schedule are randomly selected from those marked as applicable on the establishment/shift procedure plan and will vary from day to day. The schedule, however, is now FSIS Form 5400-2, Procedure Schedule, rather than FSIS Form 8800-2, Inspector Assignment Schedule. The procedures that appear on the procedure schedule or PS are scheduled based on food safety priority.

Only **one** PS will be generated per shift per establishment. Schedules will no longer be created for each off-line slaughter and/or processing assignment in an establishment. When there are two or more inspectors assigned to the plant/shift, the IIC and inspectors will jointly review the work to be performed and

decide who will perform it. Should agreement not be reached, the immediate supervisor will assign the work.

The PS looks different than the Inspector Assignment Schedule. The column structure is gone. Because only one schedule is generated per shift and schedules are not generated for each inspector assigned PBIS responsibilities, the inspector(s) name is not needed. The inspector name space has been removed from the heading of the form. The activity and element will be preprinted above the procedure code and descriptor. The procedure code and 80 character descriptor will be preprinted on the form. The term risk is no longer used. "Priority" represents the public health significance assigned to the procedure. The higher the number the greater the public health significance. Procedures with the greatest public health significance have priority values above 5. Other regulatory requirements, such as net weight and labeling compliance checks, will have values of 5 or less. "Page" refers to the page number from the ISP guide. "Rate" represents the number of days the procedure should be scheduled over a year. Performed, not performed and noncompliance trend indicators, when applicable, have replaced the acceptable, minor, major, critical, and not performed code inspection results.

Multiple Establishment Duties

FSIS Form 5400-3B, Establishment Schedule Summary, which replaced the Inspector Assignment Schedule Summary, summarizes the inspection sites for a workweek and is issued as a cover sheet for the weekly set of procedure schedules. It is only issued to inspection personnel who are responsible for conducting in-plant activities at more than one establishment. The Establishment Schedule Summary will list the establishments in numeric order, but inspection personnel will determine the order in which the establishments are visited. Deciding the order of establishment visits should be based on the:

- Establishment's operating hours;
- Establishment's compliance/noncompliance history;
- Need to randomize the timing of inspection visits;
- Need to perform specific scheduled procedures, e.g., pre-operational sanitation;
- Need to perform administrative duties, e.g., breaking seals and releasing brands; and
- Need to respond to emergency situations

Procedure Priorities and Substitutions

Inspection personnel are to review the PS and identify the procedures with the greatest food safety significance. These procedures have the highest priority number. A quick tour of the establishment should also be conducted to determine what operations are being conducted and if any of the scheduled procedures cannot be performed. Inspection personnel may elect to perform an unscheduled procedure in place of a scheduled procedure that could not be performed because the product was not available or the operation was not being conducted.

They also continue to have the ability to modify the schedule by performing unscheduled procedures instead of scheduled procedures to assure process control and that adulterated/misbranded product is not being produced or shipped which is consistent with the Agency's food safety priorities and purposes of achieving FSIS's regulatory objectives. Professional judgement, experience and knowledge of establishment conditions should be used when deciding to perform an unscheduled procedure instead of a scheduled procedure.

Whenever inspection personnel perform an unscheduled procedure, they are to complete a blank PS, FSIS Form 5400-3. As always, procedures with high food safety priority, scheduled or unscheduled, take precedence over other procedures.

Performing Procedures

When inspection personnel perform procedures, they are to:

- Follow the procedure description in the ISP guide;
- Respond to identified and suspected instances of insanitary conditions, other types of adulteration, and misbranding;
- Document their findings of noncompliance with regulatory requirements;
- Advise establishment management when they find noncompliance with regulatory requirements;
- Verify that the establishment's immediate and further planned actions are taken as documented on "open" noncompliance records (NR); and
- Perform other functions, as appropriate, which may include administrative duties such as filing FSIS issuances and removing official devices.

Completing the PS

The inspection result for a scheduled procedure will either be performed, not performed, or a noncompliance trend indicator will be circled. **Only one inspection result should be entered on the schedule for a procedure.**

When a scheduled procedure is performed, there are two possible outcomes. The results of the procedure will either indicate compliance or noncompliance with the regulations. If the results of the procedure indicate compliance with regulatory requirements, circle “performed” on the schedule. **All sampling procedures**, whether scheduled **or** unscheduled, where FSIS inspection personnel select, process, and mail samples to the laboratory **will be recorded as performed.**

If the results of a scheduled procedure indicate noncompliance with regulatory requirements, rather than circling performed, circle the most appropriate trend indicator. Circling the trend indicator serves three purposes: it identifies the regulatory requirement that wasn’t met, i.e., categorizes the noncompliance, it indicates that the procedure was performed, and it is used to track patterns of noncompliance. For example, if the procedure revealed that an establishment employee did not initial and date an entry on a record required by their HACCP plan, then the recordkeeping trend indicator would be circled. An in-depth explanation of how to select noncompliance trend indicators is provided in the noncompliance determination guide section of this module.

If the scheduled procedure is not performed, circle “not performed” on the schedule. The reason for not performing the procedure or “Not performed code” isn’t needed any more.

If the scheduled procedure is not applicable to the establishment due to error in completing the Establishment/Shift Inspection Procedure worksheet or the product/process has been discontinued, enter the letter “K” next to “not performed”.

Completing the Blank PS

Unscheduled procedures will be recorded on a blank PS, FSIS Form 5400-3. The establishment number/shift and the visited date are recorded on the top of the form.

The inspection result for an unscheduled procedure will either be performed or a noncompliance trend indicator will be entered. Again, only **one** inspection result should be entered on the blank schedule for the procedure.

When the results of the unscheduled procedure do not indicate noncompliance with the regulations, enter the code for the procedure and the result code “a” in

the result code column of the form. When the results of the unscheduled procedure indicate noncompliance with the regulations, enter the code for the procedure and the result code for the appropriate trend indicator.

The reason for performing an unscheduled procedure or “Unscheduled code” isn’t needed any more.

The inspection procedures for verifying BASIC compliance of SSOPs, HACCP plans, and *E. coli* procedures **are always** performed as unscheduled procedures. There is no trend indicator for noncompliance with basic regulatory requirements. Enter procedure code 01A01, 03A01, or 05A01, as appropriate, and leave the result code column blank on the form. The procedure code will indicate to the District Office that there is noncompliance with the basic regulatory requirements. Attachment 2 of this handout is a table that identifies the procedures in each Activity and the noncompliance trend indicator result codes used for each Activity.

VI. NONCOMPLIANCE RECORD (NR)

Overview

A Noncompliance Record, or NR, and Noncompliance Record Continuation Sheet, FSIS Forms 5400-4 and 5400-4a, respectively, serves as FSIS’s official record of noncompliance with one or more regulatory requirements. The NR also serves as written notification to plant management about noncompliance observed during the performance of procedures.

The NR replaces the PDR in HACCP plants. Inspection personnel will complete an NR each time the performance of a procedure results in a finding of noncompliance with regulatory requirements. The Noncompliance Record Continuation Sheet is completed when more than one inspector performs sanitation procedures in elements 01B and 01C and when additional space is needed to describe the noncompliance.

NRs should be filed in two sections. An “open” NR section and a “closed” NR section.

When an NR is issued, inspection personnel provide establishment management with the original and first copy. Place the second copy in the “open” NR section. When establishment management returns the NR, with their proposed immediate and further planned actions, file the original in the “open” section and destroy the second copy. The NR remains open until the establishment has brought itself into compliance with regulatory requirement(s) that resulted in the issuance of the NR.

Inspection personnel are to review the open NR file daily. As part of performing procedures, inspection personnel are to determine if the establishment's immediate action is acceptable (if not already determined) and if their further planned actions, including preventive measures, are sufficient to prevent recurrence of noncompliance (s) in the "open" file. Sometimes, situations may involve the "further planned actions" verification being determined over a longer period of time; hence, inspection personnel will need to monitor these situations on an on-going basis.

When the establishment has brought itself into compliance with the regulatory requirement(s) that resulted in issuance of an NR, complete the appropriate blocks on the original NR, and transfer it to the "closed" section of the NR file.

Inspection personnel are to continue holding weekly conferences to discuss noncompliance findings (if any) and action (s) taken by the establishment to bring itself into compliance.

Completing NR and NR Continuation Sheet

Like the PDR, the NR is a legal record documenting a plant's failure to comply with regulatory requirements. That's why it's extremely important to complete it accurately.

Although the NR looks similar to the PDR, several improvements were made.

The numbered blocks on the NR and NR Continuation Sheet are to be completed as follows:

1. **Date**--Enter the date noncompliance occurred. The date can be entered numerically, e.g., 1-29-98.
2. **Record No.**--Number the NRs completed in a given establishment sequentially, by year (i.e., 1-97, 2-97, 3-97, etc., regardless of who completes the NR or the shift).
3. **Est. No.**--Enter as a 5-digit number followed by a red meat or poultry designator and the shift number (e.g., 00345 M/2).
4. **To (Name and Title)**--Enter the name and title of the responsible establishment official. For a HACCP system noncompliance, always enter the name of the person who signed the HACCP plan. For a SSOP regulation noncompliance, always enter the name of the person who signed the SSOPs.

5. Personnel Notified--Enter the name(s) of the establishment management personnel who was/were notified about the noncompliance.
6. Relevant Regulations--Cite the specific regulation or regulations that the establishment failed to comply with. For example, if the establishment failed to take corrective action in response to a deviation from a critical limit, then 417.2 (c) (5) and 417.3 (a) would be entered. Don't enter every regulation listed in the procedure reference column of the ISP unless they are all specific to the noncompliance.
7. Relevant Section/Page of Establishment Procedure/Plan--Enter the section or page of the establishment's procedure or plan when the noncompliance represents the failure to comply with the written provisions of their procedure or plan. For example, if the establishment failed to take corrective action in response to a deviation from a critical limit, the section or page of the HACCP plan that lists the corrective actions they should have taken would be entered. Place an "X" in the appropriate box to reference the type of procedure or plan. *E. coli* and alternate processing procedure noncompliance are considered "other". When the noncompliance is not related to a procedure or plan, enter N/A.
8. ISP Code--Enter the code of the procedure performed.
9. Noncompliance Classification Indicators--Mark the trend indicator that best describes the noncompliance. This should be the same trend indicator that is circled on the PS. Remember that basic compliance procedures don't have trend indicators.
10. Description of Noncompliance--Noncompliance replaced the word deficiency but the block is completed in the same manner. That is, each noncompliance is described in clear, concise detail, including the exact problem, location and effect on product. If more space is needed to describe the noncompliance use a NR Continuation Sheet.

NOTE: In non-HACCP plants, the PDR Continuation Sheet is used only when multiple inspectors perform on-site verification of pre-operational sanitation inspection. If inspectors need extra space, they write on the back or on a blank sheet of paper.

The NR in HACCP plants also has a continuation sheet, but it has more uses. The NR Continuation Sheet will still be used when multiple inspectors conduct verification of pre-operational sanitation inspection. But it may also be used when the inspector needs extra space to document noncompliance. Inspectors don't have to write on the back

of the NR or on another piece of paper. When using the NR Continuation Sheet for extra space, inspectors can just check the box next to the word attachment in the top right corner of the sheet, and complete blocks 1-3.

11. Signature of Inspection Program Employee--The inspector or IIC signs the NR after blocks 1 through 10 have been completed.
- 12 & 13 Plant Management Response--These blocks have been renamed. The terms "immediate action" and "further planned action" have replaced "corrective action" and "preventive measures" but the blocks are completed in the same manner. When the establishment elects to respond verbally or in writing, the immediate action is the action the plant is taking to correct the noncompliance including appropriate product disposition. The further planned action is the action the plant plans to take to bring itself back into compliance including measures to prevent recurrence.
- 14 & 15 Signature of Plant Management and Date--If establishment management responds in writing on block 12 or block 13, an establishment official should sign and date the NR.
- 16 & 17 Verification Signature of Inspection Program Employee and Date--Sign after establishment has brought itself into compliance with the regulatory requirement (s) that resulted in the issuance of the NR and if necessary the NR Continuation Sheet.

VI. NONCOMPLIANCE DETERMINATION GUIDE (NDG)

Overview

FSIS has developed new regulatory actions for enforcing the HACCP system requirements that replace the Corrective Action System. This means those key components of the Corrective Action System, like Progressive Enforcement Action (PEA) and the Deficiency Classification Guide (DCG) don't apply in HACCP plants.

Inspection personnel will use the new enforcement actions instead of PEA when the HACCP system regulations are implemented. Enforcement protocols for each of the new regulatory areas are discussed in Modules 7,8, and 9.

Under HACCP, an establishment's failure to comply with a regulatory requirement will be identified and documented as "noncompliance" rather than a deficiency. Noncompliance is not classified as minor, major, or critical, so the DCG is not applicable. In the past inspection personnel documented deviations when QC standards weren't met. They won't do that anymore. The term

“deviation” is defined differently in HACCP establishments. **Deviation is used in a HACCP establishment to describe a failure to meet a critical limit.** For example, if a plant’s critical limit isn’t met for cooking roast beef, a deviation has occurred. The establishment must take corrective action when a deviation occurs. Stated differently, management must take corrective action when the critical limit in their HACCP plan isn’t met. If the corrective action defined in their HACCP plan isn’t taken, then noncompliance exists.

A noncompliance determination guide, or NDG, has been developed that replaces the DCG. The NDG identifies and describes the noncompliance trend indicators for each of the various PBIS activities in the ISP guide. Inspection personnel are to apply the NDG in all regulatory areas.

Noncompliance Trend Indicators

When inspection personnel determine that the establishment has failed to comply with one or more regulatory requirements, they need to use the NDG when deciding which trend indicator to circle on the PS or which block to mark on the NR. Trend indicators categorize the specific types of noncompliance identified in HACCP establishments. For example, if the performance of a procedure revealed that an establishment employee did not initial and date an entry on a record required by their HACCP plan, then the inspector would mark the recordkeeping trend indicator on the PS and NR. Likewise, if the performance of a procedure revealed that the establishment did not take appropriate corrective action in response to a deviation from a critical limit, then the inspector would mark the corrective action trend indicator on the PS and NR.

The trend indicators don’t have any associated severity. In other words, one trend indicator does not represent a more serious failure to comply with the regulations than another indicator.

The purpose of trend indicators is to improve the Agency’s ability 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.

Like the basic compliance elements, the residue and economic sampling elements, 05B and 05C, won’t have trend indicators. Sample results that indicate noncompliance will be documented on a NR and reported by the procedure code.

Compliance/Noncompliance Categories and Use of the Trend Indicators

Failures to comply with food safety-related regulations are divided into two categories:

- 1) Basic Compliance/Noncompliance, and
- 2) Other Requirements Compliance/Noncompliance

Note: The Other Requirements Compliance/Noncompliance includes failures to comply with any “other” food safety-related requirement not addressed by the basic compliance check and failures to comply with “other” consumer protection regulatory requirements.

The sections that follow will identify example noncompliance(s) that are applicable to each category and the trend indicators that are used to document the regulatory requirement(s) that was not met.

1. Basic Compliance/Noncompliance

There are only three procedures in the ISP guide that cover basic compliance requirements.

Procedures 01A01, 03A01, 05A01, focus on whether or not the establishment has instituted (developed) the procedures or plans required by FSIS regulations. “Basic Noncompliance” exists when an establishment does not have the required plan or procedures or recordkeeping at all, or what the establishment has clearly does not meet regulatory requirements.

There aren’t any trend indicators for basic noncompliance; the results are reported by the procedure code. Simply writing the procedure code on the blank procedure schedule automatically indicates that the inspector is documenting a basic noncompliance.

SSOP Examples

Procedure 01A01 is the basic procedure for SSOP requirements. Certain components are required in each SSOP. For example, basic noncompliance exists if:

- A plant’s written SSOP does not identify the procedures to be conducted prior to the start of operations.
- A plant’s written SSOP does not specify the frequency for each procedure

HACCP Examples

Procedure 03A01 addresses the basic requirements for HACCP plans. Certain components are required in each HACCP plan. For example, basic noncompliance exists if:

- There isn't a critical limit identified in the HACCP plan for a critical control point.
- The hazard analysis does not contain a flow diagram.
- The HACCP plan does not identify the corrective actions to be taken when a critical limit is exceeded.

E. coli Examples

Procedure 05A01 addresses the basic requirements for *E. coli* testing. Specific information is required in the establishment's written specimen collection procedure. For example, basic noncompliance exists if:

- A plant's written *E. coli* specimen collection procedure does not include the location of sampling or how sampling randomness will be achieved.
- A plant's written *E. coli* specimen collection procedure does not identify the establishment employee designated to collect samples.

2. Other Requirements Compliance/Noncompliance

a. "Other" Food-Safety Related Requirements

These requirements relate to how the establishment actually executes and implements the procedures or plans required by the regulations. Inspection personnel perform procedures to determine if the establishment implementing its SSOP, HACCP plan or *E. coli* procedure as written. When the establishment doesn't operate according to its written SSOP, its HACCP plan or its *E. coli* procedure, an "Other Requirements" food safety-related noncompliance exists.

1) SSOP Regulations Trend Indicators

One of four trend indicators must be circled on the PS and marked on the NR, when inspection personnel determine that an establishment is not following its written SSOPs. The four trend indicators correspond to the regulatory requirements in Part 416. The trend indicators are described in FSIS Directive 5400.5. They are:

- **Monitoring (416.13)**

This indicator addresses the establishment's actions, observations and records for implementation of the SSOP. Monitoring noncompliance is when the plant fails to monitor their pre-operational and operational sanitation procedures daily. It would also be used if the plant fails to monitor operational sanitation at the frequency stated in the SSOP.

- **Corrective Action (416.15)**

This indicator addresses the establishment's corrective actions and records when the SSOP fails to prevent contamination or adulteration of product. It should be marked in cases of noncompliance where the plant does not take all of the corrective actions required by section 416.15 of the regulations. For example, the plant fails to clean and sanitize contaminated equipment they found during pre-op monitoring prior to using it. It may also be marked when corrective actions taken are not appropriate to restore sanitary conditions, or do not include measures to prevent the recurrence of direct contamination or adulteration of products

- **Recordkeeping (416.16)**

This indicator should be marked in cases of noncompliance when the records required by 416.16 aren't maintained including records of corrective actions taken. For example, SSOP records are not initialed and dated, the records are not maintained daily, they're not kept for the required period of time, or the plant fails to record the results of a monitoring check, when it is determined that the monitoring has occurred. If there were an instance of noncompliance where the plant is not maintaining any records at all, the results of the procedure would be documented under procedure code 01A01 as basic noncompliance.

- **Implementation**

Inspection program personnel who find that an establishment's noncompliance with requirements for SSOP implementation involves more than one of these areas (e.g., monitoring, corrective action, and recordkeeping) should use the implementation trend indicator. This trend indicator applies to single as well as multi-inspector assignments.

For example, in a multi-inspector assignment, if two inspectors perform an SSOP verification procedure and one inspector found recordkeeping noncompliance and the other inspector found corrective action noncompliance, then the trend marked on the NR for the procedure would be implementation.

NOTE: Keep in mind, the proceeding examples used to clarify the use of the SSOP trend indicators are not all inclusive.

2) HACCP System Regulations Trend Indicators

One of four trend indicators must be circled on the PS and marked on the NR, when inspection personnel determine that an establishment is not following their written HACCP plan. The four trend indicators correspond to the regulatory requirements in Part 417. The trend indicators are described in FSIS Directive 5400.5. They are:

- **Monitoring**

This indicator addresses the establishment's actions, observations and records for monitoring CCPs. **This indicator should be marked in cases of noncompliance when the establishment fails to monitor as prescribed in the HACCP plan.** For example, the plant is not monitoring a critical limit at a CCP, is monitoring but not at the frequency stated in the plan, records a value that is not an actual or quantifiable value for a critical limit at a CCP, or is not following the procedure methodology for monitoring as stated in the plan. In cases where the establishment is not monitoring at all, the noncompliance would be recorded under the basic procedure 03A01.

- **Corrective Action**

This indicator addresses the establishment's corrective actions and records when a deviation occurs. **It should be marked in cases of noncompliance where the plant does not take corrective actions required by the HACCP plan.** It may also be checked in cases of noncompliance where it is evident that the plant did not identify the cause of the deviation and control the CCP. It may also be marked when corrective actions taken are not appropriate to correct the deviation. This indicator should also be marked in circumstances where a critical limit was exceeded and no corrective action was taken, or corrective action was not taken in accordance with section 417.3 of the regulations.

It should also be marked in cases of noncompliance where the establishment did not perform reassessment of its HACCP plan when required.

- **Recordkeeping**

This indicator should be marked in **cases of noncompliance when the records required by the HACCP plan aren't properly maintained.** It's primarily used where the noncompliance indicates sloppy recordkeeping practices. For example, the HACCP record (s): is/are not signed and dated; the plant fails to record the results of a monitoring check; the production code, slaughter production lot, or product identity is missing; is not legible, or not retained for the required period of time. It should also be marked in an instance of noncompliance where the plant does not have documentation that supports the

HACCP plan, i.e., the plant does not have scientific, technical or regulatory data to support the selection of each CCP, critical limit, monitoring procedure or verification procedure. This indicator should be marked in cases of noncompliance when no pre-shipment review of records is conducted. If there were an instance of noncompliance where the plant is not maintaining any records at all, the results of the procedure would be documented under procedure code 03A01 as basic noncompliance.

- **Verification**

This indicator addresses the establishment's actions, observations and records for verifying the implementation of their HACCP plan. It should be marked in cases of noncompliance **where the establishment is not performing verification activities as described in its HACCP plan, such as the calibration of process monitoring equipment is not conducted as defined in the HACCP plan.** It is also marked in cases where an establishment is not following the alternative frequency for sampling of *E. coli* as described in its HACCP plan.

NOTE: Keep in mind, the preceding examples used to clarify the use of the HACCP trend indicators are not all inclusive.

3) *E. coli* Regulations Trend Indicator

Only one trend indicator must be circled on the PS and marked on the NR, when inspection personnel determine that an establishment is not following their written *E. coli* procedure.

Other

This indicator should be marked in cases of noncompliance where the establishment is not collecting samples at the required location in the slaughter process, is not collecting samples at the required frequency, or is not sampling randomly as per the written procedure. FSIS Form 5000-4 provides a checklist of "other" requirements for *E. coli* sampling.

NOTE: Keep in mind, the preceding examples used to clarify the use of the *E. coli* trend indicator are not all inclusive.

b. "Other" Consumer Protection Regulatory Requirements

The FMIA and PPIA require establishments operating under federal inspection to produce safe, wholesome, and properly labeled products in a sanitary environment in accordance with regulations. The Pathogen Reduction/HACCP regulations require establishments to develop a system of preventive controls to improve the safety of their products. The regulatory requirements for consumer

protection activities such as economic adulteration, wholesomeness (non-public health), and misbranding, and other regulatory requirements such as facilities, equipment, and water requirements have not changed due to the implementation of the Pathogen Reduction/HACCP regulations.

Industry must still prevent contamination, adulteration, misbranding, and comply with **all** regulatory requirements. When contamination or adulteration occurs, the establishment management must bring the establishment into compliance by controlling the immediate situation and preventing recurrence of the noncompliance.

Inspection personnel are still responsible of ensuring that adulterated or misbranded product does not enter commerce. When the establishment fails to meet regulatory requirements for facilities, equipment, water, sewage, standards of identity, labeling, or net weight, an “Other Consumer Protection Noncompliance” exists. **The trend indicators for Other Consumer Protection address both product and facility noncompliance.**

NOTE: Keep in mind, the following examples used to clarify the use of the product and facility trend indicators are not all inclusive.

1) Product Trend Indicators

For product regulations addressed by the 04 Activity and element 06A (export) there are three indicators. They are:

- **Economic**

This indicator should be used for noncompliance found when performing **procedures in the 04 elements** prior to the labeling or branding of a finished product. In other words, it is used for product **in-process** noncompliance. Economic adulteration is the term generally associated with this type of noncompliance since the product does not meet a specified regulatory standard or requirement and is not yet ready to be offered for sale. Hence, **economic** is the indicator used to categorize noncompliance when products in the process of being prepared do not meet an “other” regulatory requirement. For example, it should be marked when a boneless meat procedure is performed and wholesomeness defects are found which exceed boneless meat reinspection criteria. Similarly, it should be marked when the number of nonconformances found during the performance of a FPS test exceed the regulatory limit. It should also be marked in cases of noncompliance where a scale used for determining net weight is found to be inaccurate and no product is being weighed, or when during the production process a product has been found to contain more solution than allowed by regulation.

- **Misbranding**

This indicator should be used for noncompliance found when performing procedures in the 04 or 06A elements after the product is labeled, branded or packaged. Misbranding has a very specific meaning in the FMIA and PPIA. It applies to product that bears false or misleading labeling in any particular, if it is offered for sale, in a container, package, etc. Therefore, this indicator by definition only applies to products that are packaged, labeled, and offered for sale that contain in whole or in part aspects that are misleading, false, or are not in compliance with regulatory standards. For example, it should be marked for noncompliance with labeling, net weight, and product standard of identity or composition requirements.

- **Protocol**

This indicator **only applies** to establishments that are using an alternative method for producing product or conducting a process that's not food safety related **and** differs from regulatory requirements. This establishment will have a written protocol or procedure on file that was reviewed (not approved) by FSIS personnel. This trend indicator will be marked when the establishment is not following their written protocol or alternate procedure.

NOTE: The protocol indicator **IS NOT** used when the establishment fails to follow the written provisions of a QC procedure or QC program. If the establishment's failure to follow their QC procedure or QC program is also a failure to meet a regulatory requirement, that regulatory failure will be documented using the most appropriate trend indicator. For example, if the establishment's statistically valid individual sample upper control limit for batter/breading pick-up is 33%, and the inspector determines that this limit was exceeded without management taking corrective action as stated in their program, and because the regulatory limit of 30% was also exceeded, then noncompliance exists. The noncompliance in this case is that the establishment did not take appropriate corrective action and exceeded the regulatory limit of 30% batter/breading.

If the batter/breading regulatory failure was determined in-process, then it would be documented using the "economic" trend indicator. However, if the batter/breading regulatory failure was determined in-process but part of the product lot was boxed and labeled, then it would be documented using the "misbranding" trend indicator.

2) Facility Trend Indicators

For facility regulations addressed by elements 06D through 06G, there are four indicators. **The indicator should be selected based on the root cause of the noncompliance.** The indicators are:

- **Lighting**

This indicator should be used for noncompliance with lighting requirements. For example, it should be marked when lighting intensities are not met.

- **Structural**

This indicator should be used for documenting noncompliance that occurs in the establishment structure, floors, walls, ceilings, doors, establishment owned vehicles used to ship product, or with **any** other facility regulatory requirement. For example, it should be marked when certain conditions exist such as the presence of condensation that is not contaminating or adulterating product (e.g., condensation is not over product, product traffic areas, product contact zones, etc.). It should be marked when holes are found in the production area flooring, walls, and ceilings, or when inedible or condemned product areas aren't separate and distinct from edible product areas.

- **Outside premises**

This indicator should be used for noncompliance with outside premise requirements. For example, it should be marked when accumulations of rubbish are found outside the plant.

- **Product Based**

This indicator should be used for noncompliance where there is a potential for product involvement that **does not** result in misbranding, mislabeling, **direct** product contamination or insanitary conditions covered by the SSOPs. For example, it should be marked when product residue (fat, meat tissues, etc.) from the previous day's operations is found on the leg of a table in the production area but all equipment surfaces examined while performing 01B02 are clean and sanitary. This material will not cause direct product contamination but could lead to indirect product contamination. Thus, this is a facilities noncompliance rather than an SSOP noncompliance.

This indicator is also used when product noncompliance is found during the performance of procedures in Activity 06.

VIII. SUMMARY

This portion of the training has familiarized you with the changes that have been made to several components of the Performance Based Inspection System. The policies, procedures, forms, and instructions for PBIS under HACCP are addressed in FSIS Directive 5400.5. Inspection program personnel are to follow the policies, procedures, and instructions in this directive in every establishment that's subject to the HACCP system regulations. The exiting PBIS policies,

procedures, and instructions will remain in effect for those establishments not subject to the HACCP system regulations.

ATTACHMENT 1

PBIS COMPARISON CHART

Establishments not under HACCP	Establishments under HACCP
Policy/Procedure: FSIS Directives 5400.1, 5400.2, 8800.1, 8800.3, and 8810.1	Policy/Procedure: FSIS Directive 5400.5
<p style="text-align: center;">ISG</p> <p>“Process” 13 processes</p> <p>“CCP”</p> <p>“Task” 540 tasks</p> <p>both evaluation tasks and verification tasks</p> <p>references QC programs</p>	<p style="text-align: center;">ISP</p> <p>“Activity” 8 activities</p> <p>“Element”</p> <p>“Procedure” 48 procedures</p> <p>only verification procedures</p> <p>does not reference QC programs except in Activity 04</p>
Plant Profile	Plant Profile—with block modifications
<p>Establishment/Shift Monitoring Plan—reviewed at least annually</p> <p>Lists all of the processes, CCPs and tasks</p> <p>Identifies “core” tasks</p> <p>One Establishment/Shift Monitoring Plan per assignment</p>	<p>Establishment/Shift Procedure Plan—reviewed at least annually or upon rotation</p> <p>Lists all of the procedures</p> <p>No “core” procedures identified</p> <p>One Establishment/Shift Procedure Plan per plant per shift regardless of # of inspection program personnel assigned</p>

Inspector Assignment Schedule Summary	Establishment Summary Schedule
Inspector Assignment Schedule	Procedure Schedule
Inspection results recorded as acceptable, minor, major, or critical	Inspection results recorded as performed, not performed, or noncompliance with trend indicator
Inspector name recorded	No Inspector name recorded
One schedule per assignment/ Inspector	One schedule per shift/establishment
Requires unscheduled code for unscheduled task	Unscheduled codes eliminated
Requires not performed code when task is not performed	Not performed codes eliminated
Corrective Actions/PEA	Enforcement Protocols
Use of Deficiency Classification Guide	Use of Noncompliance Determination Guide
Deficiencies classified as minor, major or critical	Noncompliance = noncompliance
QC Deviations are documented	QC Deviations are not documented
Deficiencies are documented on the Process Deficiency Record (PDR)	Noncompliance findings are documented on the Noncompliance Record (NR)
Defect Identification	System Failure vs. isolated noncompliance
Plant identifies corrective and preventive actions	Plant identifies immediate and further planned actions
Repetitive deficiencies or deviations for the same task or in the same CCP initiate PEA	Noncompliance trend indicators (possible system failure with withholding action and suspension)
MIS Reports	MIS Reports

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD	1. Date	2. Record No.	3. Establishment No.
---	---------	---------------	----------------------

4. To (Name and Title)

5. Personnel Notified

6. Relevant Regulation(s)

7. Relevant Section/Page of Establishment Procedure/Plan →	HACCP	SOP	OTHER
--	-------	-----	-------

8. ISP Code

9. NONCOMPLIANCE CLASSIFICATION INDICATORS

Plant Process	A. <input type="checkbox"/> SSOP	<input type="checkbox"/> Monitoring	<input type="checkbox"/> Corrective Action	<input type="checkbox"/> Recordkeeping	<input type="checkbox"/> Implementation
	B. <input type="checkbox"/> HACCP	<input type="checkbox"/> Monitoring	<input type="checkbox"/> Corrective Action	<input type="checkbox"/> Recordkeeping	<input type="checkbox"/> Plant Verification
C. <input type="checkbox"/> Product		<input type="checkbox"/> Economic	<input type="checkbox"/> Misbranding	<input type="checkbox"/> Protocol	
D. <input type="checkbox"/> Facility		<input type="checkbox"/> Lighting	<input type="checkbox"/> Structural	<input type="checkbox"/> Outside Premises	<input type="checkbox"/> Product Based
E. <input type="checkbox"/> E. COLI		<input type="checkbox"/> Other			

10. Description of Noncompliance:

11. Signature of Inspection Program Employee

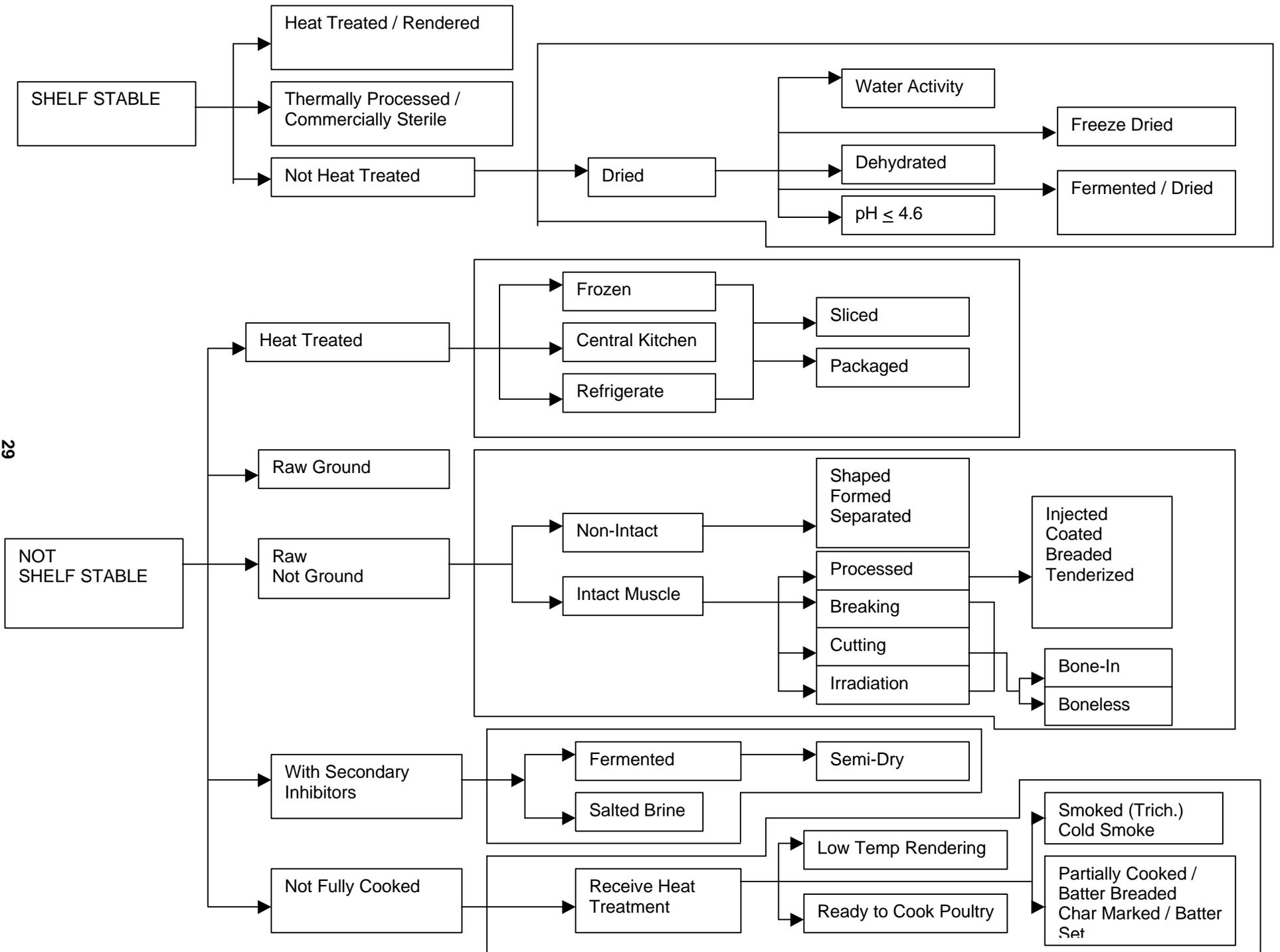
You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. Plant Management Response: (immediate action(s)):

13. Plant Management Response (further planned action(s)):

This document serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory and administrative action.

14. Signature of Plant Management	15. Date
16. Verification Signature of Inspection Program Employee	17. Date



ATTACHMENT 2

ISP – Procedure Codes Noncompliance – Trend Indicators Result codes					
SSOP	HACCP	Economic/ Wholesomeness	<i>E. coli</i>	Sampling	Other Requirements
01B01	03B01	04A01	05A01	05A03	06D01
01B02	03B02	04A02	05A02	05B01	06D02
01C01	03C01	04A03		05B02	06D03
01C02	03C02	04A04		05C01	06E01
	03D01	04B01			06F01
	03D02	04B02			06F02
	03E01	04B03			06G01
	03E02	04B04			
	03F01	04C01			
	03F02				
	03G01				
	03G02	Other			
	03H01	06A01			
	03H02				
	03I01				
	03I02				
	03J01				
	03J02				

Noncompliance Indicators

c) Monitoring d) Corrective Action e) Recordkeeping o) Implementation	c) Monitoring d) Corrective Action e) Recordkeeping f) Plant Verification	g) Economic h) Misbranding i) Protocol	m) Basic n) Other		j) Lighting k) Structural l) Outside Premises p) Product Based
--	--	--	----------------------	--	---

- a) performed
- b) not performed

<u>Procedure Codes</u>
01A01 03A01
a) performed or for noncompliance leave results column blank on PS, FSIS Form 5400-3

THE ESTABLISHMENT/SHIFT PROCEDURE PLAN WORKSHOP

You will need the following materials to complete this workshop.

1. The Instructions for Developing an Establishment/Shift Procedure Plan.
2. The general information about the example establishment “**Bargain Packing**”, Inc. (page 35) and **Bargain Packing’s** current ADP Establishment/Shift Monitoring plan worksheet (pages 36-38) and monitoring plan (pages 39-45).
3. A new Establishment/Shift Inspection Procedure Worksheet, FSIS Form 5400-5, (page 46).

Note: *Since “**Bargain Packing**”, Inc. is a small establishment coming under the HACCP system regulations in January 1999, inspection personnel will need to develop a establishment/shift procedure plan(s) for it.*

To complete this workshop, you will need to:

Read the Instructions for Developing an Establishment/Shift Procedure Plan on pages 33 and 34.

Read the general information about Bargain Packing on page 35.

Review Bargain Packing’s current plan worksheet (pages 36-38) and monitoring plan (pages 39-45).

Enter 00038--M/1 for the HACCP establishment number and shift at the top of FSIS Form 5400-5 on page 46.

Read the Compliance Standards/Glossary and Procedure Description columns of the ISP for each procedure listed on FSIS Form 5400-5 and place an “X” in the block behind the procedure code if it pertains to the processes/operations conducted at “**Bargain Packing, Inc.**”

Note: **If you are not sure whether a particular procedure in Activity 04 or 06 is applicable to Bargain Packing’s current operations, you may refer to the Guidelines for Procedures in Activities 04 and 06 on pages 6-8 of Module 9d.**

INSTRUCTIONS FOR DEVELOPING A ESTABLISHMENT/SHIFT PROCEDURE PLAN

Overview

Inspection personnel will need to develop procedure plans for those establishments subject to the Pathogen Reduction/HACCP system regulations on January 25, 1999. A procedure plan must be developed for each shift the establishment operates.

PBIS creates daily procedure schedules from the ISP procedures identified on the establishment/shift procedure plan. Therefore, it is extremely important that the procedures marked on the Establishment/Shift Inspection Procedure Worksheet reflect current processes/operations conducted on the shift.

Inspection personnel must use their knowledge of the establishment's current operations to make an accurate assessment of which procedures are valid for the establishment. **They should review the plant profile, the establishment's current monitoring plan(s), and any other information that will assist them in identifying the operations conducted at the establishment.**

Selecting HACCP Elements and Procedures

The determination of which HACCP elements and procedures are applicable will depend on the type of products being produced in the establishment. All meat and poultry products fall into one of the nine HACCP elements or processes in the HACCP Activity—03. The process that is used to produce the product or the final condition of the product when it leaves the establishment is the key to whether or not a particular HACCP element is selected. For example, if the final product shipped from an establishment was raw and not ground, then HACCP element 03C would be selected. If the final product shipped from an establishment was fully cooked but not shelf-stable then element 03G would be selected. For slaughter/processing combination establishments, the HACCP element 03J would always be selected and any other appropriate HACCP element(s) that addresses THE FINAL CONDITION OF A PRODUCT (S) leaving the establishment would also be selected.

Note: Many establishments produce a variety of products, therefore, several Activity 03 HACCP elements may be applicable in the establishment.

For all Activity 03 HACCP elements, other than element 03A, both procedures (01 and 02) for the specific element should be marked on the Establishment/Shift Inspection Procedure worksheet. If any of the procedures for HACCP elements 03B through 03J are marked, then the HACCP basic compliance element 03A would be selected and its single procedure, 03A01, marked on the worksheet.

Note: Inspection personnel should refer to the Guidelines for Procedures in Activities 04, Economic/Wholesomeness, and 06, Other Requirements in Module 9d of the Pathogen Reduction/HACCP technical training, if they are having difficulty determining whether or not a particular procedure in Activity 04 or 06 is applicable to the establishment's current processes/operations.

Developing a New Procedure Plan

To develop a procedure plan:

- Request a blank Establishment/Shift Inspection Procedure Worksheet, FSIS Form 5400-5, from the District Office,
- Enter the establishment number and shift at the beginning of the form,
- Read the Compliance Standards/Glossary and Procedure Description columns of the ISP for each procedure listed on FSIS Form 5400-5,
- Place an "X" in the block behind the procedure code if it pertains to the processes/operations conducted at the establishment, and
- Submit the completed form to the District Office.

Bargain Packing, Inc.
Federal Establishment Number 00038--M/00042--P
2222 West Nowhere Ave.
Somewhere, U.S.A. 00000
Telephone No. (101) 438-4323

General Information

This is a one-shift pork slaughter/processing combination plant that operates from 0630 hours to 1500 hours Monday through Friday. The establishment slaughters 800 swine per week. The products produced are pork cuts (roasts, chops, ribs, etc.) boneless pork (boning/cutting), fresh pork sausage, tenderized/marinated meat and poultry cuts, and pork hearts, livers, and kidneys. Tissue/organs are collected for research/ pharmaceutical purposes.

There are no Custom Exempt or Retail Exempt operations. The plant **does not** perform ID Services or Voluntary Inspection or Export product. There is no rail siding.

The IIC is a GS-9 and performs all processing duties. A slaughter inspector performs slaughter duties, and a SVMO is available on an “as needed basis” for carcass disposition.

During the awareness phase, inspection personnel learned that the establishment has the following HACCP plans.

- Slaughter,
- Raw Product—Ground, and
- Raw—Not Ground

The establishment has the following procedures/quality control programs.

- On-Line Boneless Meat Reinspection,
- Marination of red meat, and
- Marination of poultry

Establishment/Shift Monitoring Plan Worksheet
 Asgn-Est/Shift: 30BR-00038 M/1

Inspector:

Tasks				
01A01a1 []	01C08a2 []	03D01a2 [«»]	04A02a2 [«»]	06B01a1 []
01a2 [«»]	09a1 [«»]		03a1 [«»]	01a2 []
02a1 []	09a2 [«»]	03E01a1 []	03a2 [«»]	03a1 []
02a2 [«»]	10a1 []	01a2 [«»]		03a2 []
03a1 []	10a2 []	02a2 [«»]	04B01a1 [«»]	05a1 []
03a2 [«»]	11a1 []	03a2 [«»]	01a2 [«»]	05a2 []
04a2 [«»]	11a2 [«»]	04a2 []	02a1 []	07a1 []
05a2 [«»]		05a1 []	02a2 [«»]	07a2 []
06a1 []	01D01a1 [«»]	05a2 [«»]	03a1 [«»]	08a1 []
06a2 [«»]	01a2 [«»]	06a2 []	03a2 [«»]	08a2 []
07a1 []	02a1 []	07a1 []		09a1 []
07a2 [«»]	02a2 [«»]	07a2 []	05A01a1 []	09a2 []
08a1 []		08a1 []	01a2 [«»]	11a1 []
08a2 [«»]	02B07a1 []	08a2 []	01c1 []	11a2 []
09a1 []	07a2 [«»]	09a1 []	01c2 []	12a1 []
09a2 [«»]	08a1 []	09a2 []	02a1 [«»]	12a2 []
10a1 []	08a2 [«»]	10a1 []	02a2 [«»]	
10a2 [«»]	09a1 []	10a2 []	03a1 [«»]	06C01a1 []
11a1 []	09a2 [«»]		03a2 [«»]	01a2 []
11a2 [«»]		03F01a1 []		02a1 []
12a2 [«»]	02D01a2 [«»]	01a2 [«»]	05B01a1 []	02a2 []
13a1 []		02a2 []	01a2 [«»]	04a1 []
13a2 []	02E01a2 [«»]		01b2 [«»]	04a2 []
14a2 [«»]	02a2 [«»]	03G01a1 []	02a1 []	05a1 []
15a2 [«»]		01a2 []	02a2 [«»]	05a2 []
	02F01a2 [«»]	02a1 []	03a1 []	
01B02a1 []	02a2 [«»]	02a2 []	03a2 [«»]	06D01a1 []
02a2 [«»]				01a2 []
03a1 []	03A01a1 []	03H01a1 []	06A01a1 [«»]	02a1 []
03a2 []	01a2 [«»]	01a2 []	01a2 [«»]	02a2 []
	02a1 []	02a1 []	03a1 []	03a1 []
01C01a1 [«»]	03a1 []	02a2 []	03a2 [«»]	03a2 []
01a2 [«»]	03a2 []	03a1 []	04a1 []	04a1 []
02a1 []		03a2 []	04a2 []	04a2 []
02a2 []	03B01a2 [«»]		05a1 []	05a1 [«»]
03a1 []	02a2 [«»]	03I01a1 []	05a2 []	05a2 [«»]
03a2 []	03a1 [«»]	01a2 []	06a1 []	06a1 []
04a1 []	03a2 [«»]	02a1 []	06a2 []	06a2 []
04a2 [«»]		02a2 []	07a1 []	06b1 []
05a1 [«»]	03C01a2 []	03a2 []	07a2 []	06b2 []
05a2 [«»]	02a2 [«»]		08a1 []	07a1 []
07a1 [«»]	03a1 []	04A01a1 [«»]	08a2 []	07a2 []
07a2 [«»]	03a2 []	01a2 [«»]		08a1 []
08a1 []		02a1 [«»]		08a2 []

FSIS Form 8800-4 (12/94)

Date: 06/17/1998

«» Indicates Task currently in Monitoring Plan

Core Tasks Boldfaced

Directions: Add tasks by placing an "X" in the box to the right. Remove tasks no longer applicable by drawing a single line through the task code.

Establishment/Shift Monitoring Plan Worksheet
 Asgn-Est/Shift: 30BR-00038 M/1

Inspector:

Tasks				
06E01a1 [] 01a2 []	06J04a1 [] 04a2 [] 05a1 [] 05a2 []	06K14a2 [] 15a1 [] 15a2 [] 16a1 [] 16a2 [] 17a1 [] 17a2 [] 18a1 [] 18a2 [] 19a1 [] 19a2 []	06N10a1 [] 10a2 [] 11a1 [] 11a2 [] 12a1 [] 12a2 [] 13a1 [] 13a2 []	06S03a1 [] 03a2 [] 04a1 [] 04a2 [] 05a1 [] 05a2 [] 06a2 [] 07a1 [] 07a2 [] 08a1 [] 08a2 [] 09a1 [] 09a2 [] 10a1 [] 10a2 [] 11a1 [] 11a2 [] 12a1 [] 12a2 [] 13a2 [] 14a1 [] 14a2 [] 15a2 [] 16a2 [] 17a1 [] 17a2 [] 18a1 [] 18a2 [] 19a2 [] 20a1 [] 20a2 [] 21a1 [] 21a2 [] 22a1 [] 22a2 [] 23a1 [] 23a2 [] 24a1 [] 24a2 [] 25a1 [] 25a2 [] 26a1 [] 26a2 [] 27a1 []
06F01a1 [] 01a2 [] 02a1 [] 02a2 [] 03a1 [] 03a2 []	06a1 [] 06a2 [] 07a1 [] 07a2 [] 08a1 [] 08a2 [] 09a1 [] 09a2 [] 11a1 [] 11a2 []	06L02a1 [] 02a2 [] 03a1 [] 03a2 [] 04a1 [] 04a2 [] 05a1 [] 05a2 []	06P01a1 [] 01a2 [] 02a1 [] 02a2 [] 04a2 []	
06G01a1 [] 01a2 [] 02a1 [] 02a2 []	06K01a1 [] 01a2 [] 02a1 [] 02a2 [] 03a1 [] 03a2 [] 04a1 [] 04a2 [] 04b1 [] 04b2 [] 05a1 [] 05a2 [] 06a1 [] 06a2 [] 07a1 [] 07a2 [] 08a1 [] 08a2 [] 09a1 [] 09a2 [] 10a1 [] 10a2 [] 11a1 [] 11a2 [] 12a1 [] 12a2 [] 13a1 [] 13a2 [] 14a1 []	06M01a1 [] 01a2 [] 02a1 [] 02a2 [] 03a1 [] 03a2 []	06Q01a1 [] 01a2 [] 03a1 [] 03a2 [] 04a1 [] 04a2 [] 05a1 [] 05a2 [] 06a1 [] 06a2 [] 07a1 [] 07a2 [] 08a1 [] 08a2 [] 09a1 [] 09a2 [] 10a1 [] 10a2 [] 11a1 [] 11a2 [] 12a1 [] 12a2 []	
06H01a1 [] 01a2 [] 02a1 [] 02a2 [] 03a1 [] 03a2 [] 04a1 [] 04a2 [] 04b1 [] 04b2 [] 05a1 [] 05a2 [] 06a1 [] 06a2 []		06N01a1 [] 01a2 [] 01b1 [] 01b2 [] 03a1 [] 03a2 [] 04a1 [] 04a2 [] 05a1 [] 05a2 [] 06a1 [] 06a2 [] 08a1 [] 08a2 [] 09a1 [] 09a2 []		
06I01a1 [] 01a2 [] 03a1 [] 03a2 [] 03b1 [] 03b2 [] 04a2 [] 05a2 []			06R01a2 [] 02a1 [] 03a2 []	
06J01a1 [] 01a2 [] 02a2 [] 03a1 [] 03a2 []			06S01a1 [] 02a2 []	

FSIS Form 8800-4 (12/94)

Date: 06/17/1998

«» Indicates Task currently in Monitoring Plan

Core Tasks Boldfaced

Directions: Add tasks by placing an "X" in the box to the right. Remove tasks no longer applicable by drawing a single line through the task code.

Establishment/Shift Monitoring Plan Worksheet
 Asgn-Est/Shift: 30BR-00038 M/1

Inspector:

Tasks				
06S27a2 []	07A04a2 [«»]	09A01a1 []	11G01a2 []	12B09a2 []
28a1 []		01a2 [«»]		10a1 []
28a2 []	07B01a2 [«»]	02a1 []	11H01a2 []	10a2 []
29a1 []	02a1 []	02a2 []		
29a2 []	02a2 []	03a1 []	11I01a2 []	12C01a2 []
30a1 []	02b1 []	03a2 []		02a2 []
30a2 []	02b2 []		11J01a2 []	
31a1 []	02c1 []	09B01a1 []		
31a2 []	02c2 []	01a2 [«»]	11K01a2 []	
32a1 []	03a1 []	02a1 [«»]		
32a2 []	03a2 []	02a2 [«»]	11L01a2 []	
33a1 []	04a1 []	03a2 []		
33a2 []	04a2 []		11M01a2 []	
34a1 []	05a1 []	10A01a1 []		
34a2 []	05a2 []	01a2 [«»]	11N01a2 []	
35a1 []	06a2 [«»]	02a1 []		
35a2 []		02a2 [«»]	11O01a2 []	
36a1 []	07C02a1 []			
36a2 []	02a2 [«»]	10B01a1 [«»]	11P01a2 []	
37a1 []	03a1 []	01a2 [«»]		
37a2 []	03a2 [«»]	02a1 []	11Q01a2 []	
38a1 []	04a1 []	02a2 []		
38a2 []	04a2 []	03a1 []	11R01a2 []	
39a1 []		03a2 []		
39a2 []	07D01a1 [«»]	04a2 []	11S01a2 []	
40a1 []	01a2 [«»]	04b2 []		
			11T01a2 [«»]	
06T01a1 []	08A01a2 [«»]	10C01a1 []		
01a2 []	02a2 []	01a2 [«»]	11U01a1 []	
02a1 []			01a2 []	
02a2 []	08B01a1 []	11A01a2 [«»]		
03a1 []	01a2 [«»]		11V01a2 []	
03a2 []		11B01a2 []		
04a1 []	08C01a1 []	02a2 [«»]	12A01a2 []	
04a2 []	01a2 []			
05a1 []		11C01a2 []	12B01a2 []	
05a2 []	08D01a1 []		02a2 []	
06a1 []	01a2 []	11D01a2 []	03a2 []	
06a2 []	02a1 []		04a2 []	
	02a2 []	11E01a2 []	05a2 []	
07A01a2 [«»]	03a1 []		06a2 []	
02a2 [«»]	03a2 []	11F01a2 [«»]	07a2 []	
03a2 []			08a1 []	
04a1 []			08a2 []	

FSIS Form 8800-4 (12/94)

Date: 06/17/1998

«» Indicates Task currently in Monitoring Plan

Core Tasks Boldfaced

Directions: Add tasks by placing an "X" in the box to the right. Remove tasks no longer applicable by drawing a single line through the task code.

Monitoring Plan
Establishment: 30BR-00038 M/1
Bargain Packing Inc.

CCP Code: 01A FACILITIES
Frequency: 13

Page #	Task Code	Risk	Time	Task Description
1-1	01A01a2	5	21	Verif floor/walls imperv,gd repair; ovhd struct moist-resist,gd repair,leakproof
1-1	01A02a2	5	21	Verif rails away frm stationary objct; high to keep prod frm contact floor/struc
1-2	01A03a2	7	21	Verif handwsh facil incl soap&towels avail in all processing rooms
1-2	01A04a2	2	21	Verif facil adequate for production volume, avoiding overly
1-2	01A05a2	3	21	Verif facil for product reconditioning available where needed, identified
1-3	01A06a2	7	21	Verif adeq toil/urin, lockers, showers (slau pits), lavatories avail
1-3	01A07a2	4	21	Verif storage facil in good repair, adequate for type, quantity of material
1-4	01A08a2	5	21	Obsv all plant areas in view for adequate lighting, protected, in good repair
1-4	01A09a2	3	21	Verif outside premises properly surfaced, drained
1-5	01A10a2	5	21	Ck inspection stations for required specifications/water
1-5	01A11a2	5	21	Ck antemortem facilities allow animal to be observed
1-6	01A12a2	5	21	Ck facilities/equipment for stunning are avail and comply
1-6	01A14a2	5	21	Ck final inspection sites for required specifications
1-6	01A15a2	5	21	Ck U.S. Suspect facilities are adequate - supplies avail

CCP Code: 01B EQUIPMENT MAINTENANCE
Frequency: 13

Page #	Task Code	Risk	Time	Task Description
1-7	01B02a2	5	8	Obsv equip sample for adequate maintenance program

CCP Code: 01C WATER AND ICE SUPPLY
Frequency: 13

Page #	Task Code	Risk	Time	Task Description
1-9	01C01a1	2	4	Ck water potability certificate current and accurate
1-9	01C01a2	4	26	Ck water clear, free of visib contam, smell&taste CK;prvt well on blueprn/leg ac
1-10	01C04a2	5	26	Obsv water supply sys for pressure/ample, adeq hot water, dead-end pipes
1-11	01C05a1	5	4	Eval avail pit records (backflow preventers/back-siphonage devices)
1-11	01C05a2	5	26	Ck 1/more back-siphon devc for location and functioning
1-12	01C07a1	2	4	Ck that current water cert for ice manuf is on file
1-12	01C07a2	3	26	Obsv ice to dtm if FSIS requirements met
1-13	01C09a1	4	4	Eval avail rec (appr nonpotable water use, water re use)
1-13	01C09a2	4	26	Ck appr nonpot wat usc, wat re-use prog on file; proced followed
1-14	01C11a2	5	26	Verif 180 degree water or appr disinfectant avail

CCP Code: 01D SEWAGE
Frequency: 7

Page #	Task Code	Risk	Time	Task Description
1-15	01D01a1	2	4	Eval avail pit records (sewage and drainage)
1-15	01D01a2	2	24	Use blprnt, obsv area of sewage&drain sys, grease basins/drain ponds for accept
1-15	01D02a2	4	24	Verif waste facilities adequate for quantity & type of material

Monitoring Plan
Establishment: 30BR-00038 M/1
 Bargain Packing Inc.

CCP Code: 02B OPERATIONAL SANITATION
Frequency: 35

Page #	Task Code	Risk	Time	Task Description
2-1	02B07a2	5	10	Ck locker/rest/lunch rooms; handwsh facil for suppl, proper clean/monit/maintain
2-1	02B08a2	3	10	Inspect open lockers to determ if kept clean, in good repair
2-2	02B09a2	5	10	Tour outside prem to determ if accumulations of materials proper stored/removed

CCP Code: 02D SANITATION SOP'S
Frequency: EO

Page #	Task Code	Risk	Time	Task Description
2-3	02D01a2	8	97	Determ Est has met reg req'nts for devlpment and maintenance of sanitation SOP

CCP Code: 02E PRE-OPERATIONAL SANITATION VERIFICATION
Frequency: 260

Page #	Task Code	Risk	Time	Task Description
2-4	02E01a2	8	31	Verif Est SSOP recds ensur monit effect pre-op; corr action init'd to prev contam
2-5	02E02a2	8	31	Rev SSOP inclu recds/proced; obs sanit cond; proc-ck 1/more area; slau-insp unit

CCP Code: 02F OPERATIONAL SANITATION VERIFICATION
Frequency: 260

Page #	Task Code	Risk	Time	Task Description
2-6	02F01a2	8	16	Verif Est SSOP recds ensur monit effect op; corr action init'd to prev contam
2-7	02F02a2	8	16	Rev SSOP inclu recds/proced; obs sanit cond; ck 1/more area ensur Est cond clean

CCP Code: 03A ANTE-MORTEM
Frequency: 260

Page #	Task Code	Risk	Time	Task Description
3-1	03A01a2	5	21	Verif all antemortem presentation stnds are met

CCP Code: 03B HUMANE HANDLING
Frequency: 156

Page #	Task Code	Risk	Time	Task Description
3-3	03B01a2	2	10	Verif livestock is humanely handled
3-3	03B02a2	6	10	Verif animals condemn on antemort IDed/humanely killed, as required
3-4	03B03a1	2	4	Eval avail rec (approved stunning methods)
3-4	03B03a2	2	10	Ck stunning methods are acceptable/effective

CCP Code: 03C BLEEDING
Frequency: 156

Page #	Task Code	Risk	Time	Task Description
3-5	03C02a2	5	5	Ck accept blood samp collected fr @ elig anim; all req info w/samp

Monitoring Plan
Establishment : 30BR-00038 M/1
Bargain Packing Inc.

CCP Code: 03D IDENTITY
Frequency: 156

Page #	Task Code	Risk	Time	Task Description
3-6	03D01a2	8	10	Verif carcass/part ID inclu traceback info maintained in-house

CCP Code: 03E SANITARY DRESSING
Frequency: 156

Page #	Task Code	Risk	Time	Task Description
3-7	03E01a2	8	12	Ck adeq of carc/part handl/dress to ensure sanit dress
3-7	03E02a2	5	12	Verif sternum split and all viscera removed for prop insp
3-7	03E03a2	8	12	Verif lactat diseas mamma glands prop'ly removed; spillage trimmed
3-8	03E05a2	8	12	Verif contam equip and facil clean/sanit bet carc when req

CCP Code: 03F PLANT PRESENTATION
Frequency: 260

Page #	Task Code	Risk	Time	Task Description
3-10	03F01a2	5	8	Verif presentation adeq for proper insp; perf 2 tests/shift min

CCP Code: 04A PEST AND RODENT CONTROL PROGRAM
Frequency: 52

Page #	Task Code	Risk	Time	Task Description
4-1	04A01a1	5	5	Eval avail records to determ if pest control program on file & maintained
4-1	04A01a2	7	24	Obsv plant premises to determ if pest&rodent control program effective
4-1	04A02a1	6	5	Eval records to determ if map showing pest control devices on file & accurate
4-1	04A02a2	6	24	Ck all/sample pest control stations against map for accuracy, maintenance
4-2	04A03a1	7	5	Eval avail plt records (no rodent or insect activity)
4-2	04A03a2	7	24	Ck production area or sample for rodent or insect activity; if detected, take pr

CCP Code: 04B PESTICIDES AND RODENTICIDES
Frequency: 13

Page #	Task Code	Risk	Time	Task Description
4-2	04B01a1	5	5	Eval pesticide list to determ if timely, accurate, complete
4-2	04B01a2	4	8	Review samp of pesticide lbs for proper ID, FSIS approved, proper use
4-3	04B02a2	5	8	Ck to determ prop storge of pesticides/insecticides, closed containers, control
4-3	04B03a1	7	5	Eval avail plt records (pesticide applic)
4-3	04B03a2	7	8	Obsv evidence of pesticide applic for complce with FSIS requirements

CCP Code: 05A RECEIVING
Frequency: 13

Page #	Task Code	Risk	Time	Task Description
5-1	05A01a2	5	16	Select sample to determ if prod whlsm/identified; temp poultry; ck recvng needs
5-3	05A02a1	5	7	Eval available records (letters of Guaranty)
5-3	05A02a2	3	16	Ck 1/more ingr for curnt guaran, ingr clean/ID; dry milk prod frm apprvt plt
5-4	05A03a1	2	7	Evaluate available records (ID of incoming nonfood chemicals)
5-4	05A03a2	2	16	Ck 1/more incon nonfood chem w. Prop Sub List or current auth lettr PAD;eval rec

Monitoring Plan
Establishment: 30BR-00038 M/1
Bargain Packing Inc.

CCP Code: 05B STORAGE
Frequency: 26

Page #	Task Code	Risk	Time	Task Description
5-5	05B01a2	6	12	Obsv 1/more meat/poult storage areas to determ if conditions acceptable
5-5	05B01b2	5	12	Verif that lot of applicable prod segregated in cooler/freezer per QC program
5-6	05B02a2	5	12	Obsv dry storage for acceptability; sample restrict ingred & compare w. inventory
5-6	05B03a2	1	12	Ck that chemicals properly used, stored, labeled

CCP Code: 06A SAUSAGE PROCESSING
Frequency: 156

Page #	Task Code	Risk	Time	Task Description
6-1	06A01a1	7	8	Evaluate available records (sausage formulation)
6-1	06A01a2	6	16	Ck prod ingred for ID/prop wght; calc min meat component, max restrict ingred
6-3	06A03a2	6	16	Ck casings at stuff op; ck flushed or preflushed nat casings prop handled

CCP Code: 06D BONING/CUTTING/BREAKING
Frequency: 52

Page #	Task Code	Risk	Time	Task Description
6-16	06D05a1	6	4	Evaluate available records (on-line/lot-based reinspection boneless meat)
6-16	06D05a2	5	24	Perf bnls nt reinsp on 1/more samp; obsv pint technique/disposit; confirm rework

CCP Code: 06L CONTAMINATED PRODUCT
Frequency: EO

Page #	Task Code	Risk	Time	Task Description
6-50	06L02a1	7	4	Evaluate available records (foreign particle contamination)
6-50	06L02a2	6	10	Obsv ID, control and re-exam of suspected/contaminated prod
6-50	06L03a1	6	4	Evaluate available records (disposition)
6-50	06L03a2	5	10	Observe denaturing and tanking of all unacceptable prod
6-51	06L04a2	6	10	Ck raw mat/fin prod wholesome, prop ID, not adulat/contam
6-51	06L05a2	7	10	Verif washing/trimming/recond done acceptably or as per approved QC prog

CCP Code: 06N MISCELLANEOUS POULTRY PROCESSING
Frequency: 52

Page #	Task Code	Risk	Time	Task Description
6-56	06N03a1	7	8	Evaluate available records (solution formulation)
6-56	06N03a2	6	16	Verif formulation 1 solution; ck ingred wt; calc restrict ingred level
6-56	06N04a1	6	8	Evaluate available records (addition of solution)
6-56	06N04a2	5	16	Obsv solutn appl, weighing prod, select 1/more batch/piece, weigh bef/aft, calc % gn

CCP Code: 06Q MISCELLANEOUS MEAT PROCESSING
Frequency: 104

Page #	Task Code	Risk	Time	Task Description
6-68	06Q03a1	6	8	Evaluate available records (solution formulation)
6-68	06Q03a2	5	15	Verif formulation of 1/more solutions; ck ingred wts; calc restrict ingred level
6-68	06Q04a1	6	8	Evaluate available records (addition of solution)
6-68	06Q04a2	5	15	Obs solut appl, weighing prod, select 1/more batch/piece; weigh bef/aft; calc % gn

Page: 4

Date: 06/17/1998

Monitoring Plan
Establishment: 30BR-00038 M/1
Bargain Packing Inc.

CCP Code: 07A MARKING AND BRANDING
Frequency: 13

Page #	Task Code	Risk	Time	Task Description
7-1	07A01a2	5	15	Review brand imprints/inventory of security items/security of brand storage dev
7-1	07A02a2	5	15	Ck if approved branding ink is used
7-2	07A04a2	5	15	Verif 1/more cont plainly/permanently marked w/req info

CCP Code: 07B LABELING
Frequency: 26

Page #	Task Code	Risk	Time	Task Description
7-3	07B01a2	5	16	Select finished prod labels as directed thru label audit sampling program
7-6	07B06a2	5	16	Ck one or more samples of diff product labels to determ if approved/correct/prop

CCP Code: 07C NET CONTENT
Frequency: 52

Page #	Task Code	Risk	Time	Task Description
7-8	07C02a2	5	24	Ck 1/more scales for accuracy; calc avg weight of sample of empty containers
7-8	07C03a2	5	24	Ck scale; perform net wt/draind wt insp accord to field manual

CCP Code: 07D PACKAGING
Frequency: 13

Page #	Task Code	Risk	Time	Task Description
7-11	07D01a1	5	4	Evaluate available records (packaging material acceptability & use)
7-11	07D01a2	5	12	Ck rndm boxes packg materl to determ if acceptabl/properl used/covered by letter

CCP Code: 08A RETAINED PRODUCT
Frequency: EO

Page #	Task Code	Risk	Time	Task Description
8-1	08A01a2	5	8	Verify prop ID facil available for retained prod pending disposit;refrig if need

CCP Code: 08B RETURNED PRODUCT
Frequency: 13

Page #	Task Code	Risk	Time	Task Description
8-2	08B01a2	5	18	Ensure ret'd prod in designat area;reinsp separated prod;obsv plant condemn prod

CCP Code: 09A STORAGE
Frequency: 13

Page #	Task Code	Risk	Time	Task Description
9-1	09A01a2	5	8	Ck storage room temp;condit of 1/more boxes to determ if prop handled/closed/lbd

Monitoring Plan
Establishment: 30BR-00038 M/1
Bargain Packing Inc.

CCP Code: 09B SHIPPING
Frequency: 13

Page #	Task Code	Risk	Time	Task Description
9-3	09B01a2	5	8	Ck 1/more vehicles to determ if clean/properly equipped
9-3	09B02a1	5	8	Evaluate available records (disclosure of transactions)
9-3	09B02a2	5	8	Ck 1/more records to determ if all transactions fully & correctly disclosed

CCP Code: 10A CONDEMNED AND INEDIBLE FACILITIES
Frequency: 13

Page #	Task Code	Risk	Time	Task Description
10-1	10A01a2	5	10	Cbs facil/plant prac for handl condemn/inedbl to elim cross-contam:req security
10-1	10A02a2	5	10	Ck 1/more contain for uniform, distinct mark: no rust/corros

CCP Code: 10B PRODUCT CONTROL
Frequency: 52

Page #	Task Code	Risk	Time	Task Description
10-2	10B01a1	5	4	Evaluate available records (ID & use of containers)
10-2	10B01a2	5	8	Ck condmn prod in H2O-tight contain labl "US Condmn";inedbl in contain so marked

CCP Code: 10C DENATURANTS
Frequency: 52

Page #	Task Code	Risk	Time	Task Description
10-4	10C01a2	8	7	Cbsv condmn/inedbl prod storage for approved methods/no cross-contamination

CCP Code: 11A RESIDUE SAMPLING
Frequency: 13

Page #	Task Code	Risk	Time	Task Description
11-1	11A01a2	5	65	Random select samples for residue determination

CCP Code: 11B PROCESSED PRODUCTS MONITOR SAMPLING
Frequency: EO

Page #	Task Code	Risk	Time	Task Description
11-2	11B02a2	5	65	Rndm select diagnostic sample

CCP Code: 11F PROCESSED PRODUCTS MONITOR SAMPLING
Frequency: 7

Page #	Task Code	Risk	Time	Task Description
11-3	11F01a2	5	65	Rndm select fresh pork saus sample, process, mail to desig lab

Monitoring Plan
Establishment: 30BR-00038 M/1
Bargain Packing Inc.

CCP Code: 11T PROCESSED PRODUCTS MONITOR SAMPLING
Frequency: EO

Page #	Task Code	Risk	Time	Task Description
11-4	11T01a2	5	65	Collect/process/mail sample upon computer request or from CS/AQ/RO/Headquarters

CCP Code: 98H ADDITIONAL CCP PROCEDURES
Frequency: 104

Page #	Task Code	Risk	Time	Task Description
0-0	98H01a2	7	16	Temp addl verification insp req - refer to supporting documentation

Establishment/Shift Procedure Worksheet
HACCP Est/Shift:

Procedures			
01A01 []	04B03 []		
01B01 [] 02 []	04 []		
01C01 [] 02 []	04C01 []		
03A01 []	05A01 [] 02 [] 03 []		
03B01 [] 02 []	05B01 [] 02 []		
03C01 [] 02 []	05C01 []		
03D01 [] 02 []	06A01 []		
03E01 [] 02 []	06B01 []		
03F01 [] 02 []	06D01 [] 02 [] 03 []		
03G01 [] 02 []	06E01 []		
03H01 [] 02 []	06F01 [] 02 []		
03I01 [] 02 []	06G01 []		
03J01 [] 02 []			
04A01 [] 02 [] 03 [] 04 []			
04B01 [] 02 []			

FSIS Form 5400-5 (9/97)

Date:

Directions: Add procedures by placing an "X" in the box to the right. Remove procedures no longer applicable by drawing a line through the procedure code.

Noncompliance Classification (Trend) Indicator Workshop.

Complete the following statements.

The trend indicator that should be used if:

- ◆ the establishment fails to monitor their operational sanitation procedures daily is _____.
- ◆ the establishment has a sanitation noncompliance that results in direct product contamination and they fail to take corrective action per 416.15 is _____.
- ◆ the establishment fails to authenticate SSOP records is _____.
- ◆ two or more inspection personnel conducting pre-op sanitation find noncompliance with different trend indicators is _____.

- ◆ the establishment fails to monitor as per the HACCP plan is _____.
- ◆ the establishment fails to perform verification as per the HACCP plan is _____.
- ◆ the establishment fails to take corrective action as per the HACCP plan is _____.
- ◆ the HACCP records are not properly maintained is _____.
- ◆ economic adulteration is determined to occur prior to labeling or branding is _____.
- ◆ noncompliance is found when the product has been labeled/branded/packaged is _____.
- ◆ the establishment has an alternative method for conducting a process and does not follow it is _____.
- ◆ the establishment is not meeting facility light requirements is _____.
- ◆ the establishment is not maintaining floors and ceilings is _____.