



# **FSIS Directive 5000.1**

## **Verifying an Establishment's Food Safety System - Revision 4**

**OPPD/PDS Thursday District Correlation**



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

## FSIS DIRECTIVE

5000.1  
Rev. 4

3/4/14

### VERIFYING AN ESTABLISHMENT'S FOOD SAFETY SYSTEM

**NOTE:** *Although this directive is being reissued, fundamental changes in approach are not made in this revision. Agency personnel should read III. REASON FOR RE-ISSUANCE below for information on the reasons for reissuance of this directive. Agency personnel are to focus on understanding the information reflected there.*

#### CHAPTER I - GENERAL

##### I. PURPOSE

A. This directive provides comprehensive instructions to inspection program personnel (IPP) on how they are to protect the public health by properly verifying an establishment's compliance with the pathogen reduction, sanitation, and the Hazard Analysis and Critical Control Point (HACCP) regulations. This directive also provides comprehensive direction for import inspection personnel to verify compliance with sanitation regulations in official import inspection establishments and for taking enforcement actions. This directive provides documentation procedures under the Public Health Information System (PHIS).

**NOTE:** In this directive, the term IPP refers to Consumer Safety Inspectors and Public Health Veterinarians.

B. Import inspection personnel are to refer only to the following chapters of this directive as they relate to Sanitation Performance Standards (SPS) and documentation/enforcement at an official import establishment:

- Chapter I – General
- Chapter II – Sanitation
- Chapter V – Documentation and Enforcement
- Chapter VI – Rules of Practice

**NOTE:** In the chapters identified above import inspection personnel are to use the same sections referenced for IPP interchangeably.

##### KEY POINTS:

- *Removes the hazard analysis verification task instructions, which have been reissued in FSIS Directive 5000.6*
- *Adds instructions related to the HACCP reassessment documentation requirements*
- *Changes terminology to use the term "HACCP Verification task" for consistency*
- *Adds notes to describe features in PHIS and clarify PHIS tasks*
- *Uses PHIS terminology that is consistent with that used in other directives and notices*

**DISTRIBUTION:** Electronic

OPI: OPPD

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*Agency personnel should read III. REASON FOR RE-ISSUANCE below for information on the reasons for reissuance of this directive.*

*Agency personnel are to focus on understanding the information reflected there.*

*NOTE: this is a revision to FSIS PHIS Directive 5000.1 not the obsolete FSIS Directive 5000.1 Rev 3.*



## **FSIS Directive 5000.1**

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The Agency is reissuing this directive to:

- address changes implemented in PHIS not reflected in the previous version of this directive and to include the standard PHIS terminology used in other directives and notices.

For example: HACCP Implementation Procedure is now referenced as the HACCP Verification task. IPP perform tasks in PHIS, not procedures.



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The Agency is reissuing this directive to:

- remove instructions for the hazard analysis verification (HAV) task now in FSIS Directive 5000.6, *Performance of the Hazard Analysis Verification Task*.

Note: The entire section related to this task was removed in this revision and is only mentioned briefly in reference to the other Directive



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The Agency is reissuing this directive to:

- provide instructions to IPP to verify that establishments comply with the regulations to document HACCP plan reassessment.
- New regulation in 9 CFR 417.4(a)(3)(ii)



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IPP are to be aware of the information added or changed to help clarify the policy for:

Chapter 1 - the entrance meeting and weekly meetings

- During entrance meeting discuss any previous agreements associated with sample notification
- Describes the Meeting Agenda feature in PHIS and how it may be used to create MOI
- Describe the Inspection Notes feature and how it can be used.



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IPP are to be aware of the information added or changed to help clarify the policy for:

Chapter II Part II – addition of new notes to clarify the requirements

- about making facility compliance determination
- about lighting requirements
- about in-line water mixing devices



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IPP are to be aware of the information added or changed to help clarify the policy for:

Chapter II Part III – description of the Activity tab, use of the actual task name, and new notes

- Clarify how the Activity tab is to be used for Sanitation SOP tasks and overtime designation
- Clarified when Sanitation SOP records need to be available for FSIS review



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IPP are to be aware of the information added or changed to help clarify the policy for:

Chapter III – Removal of information associated with the HAV task, the term “HACCP implementation” is changed to “HACCP verification”, “procedures” changed to “tasks”, new description of the Activity tab, addition at the end of this Chapter addressing the change to the reassessment documentation requirement

- Added that all records associated with specific production need to be reviewed prior to shipment of product.



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#### Chapter III

IPP are to verify the reassessment requirement as part of the HAV task. However, if during the performance of a HACCP verification task, IPP discover that the establishment performed a reassessment that is not documented as required in 9 CFR 417.4(a)(3)(ii), IPP are to document the noncompliance under the HACCP verification task being performed if a HAV task is not being performed.

*Under 9 CFR 417.4(a)(3)(ii)- Each establishment must make a record of each reassessment required in the regulations and must document the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment. For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination.*



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IPP are to be aware of the information added or changed to help clarify the policy for:

#### Chapter IV

- species slaughtered under voluntary inspection (9 CFR Part 352 and Part 362) are exempt from generic *E. coli* testing.
- Establishments can reference any of the FSIS Laboratory Guidebook methods as the method they use to meet intent of the regulatory requirement.



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IPP are to be aware of the information added or changed to help clarify the policy for:

Chapter V –

- instructions for documenting noncompliance now follow the flow for PHIS
- reference sanitary dressing directive information
- change from link to associate
- reference Directive 13,000.3 appeals and not limited to 48 hours
- how to direct questions



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Questions ??????