



FSIS Notice 02-09

Requirements Related to Sanitation Standard Operating Procedures Preventive Measures

OPPD/PDD

PDD Monthly OFO District Manager Meeting
Thursday January 8, 2008



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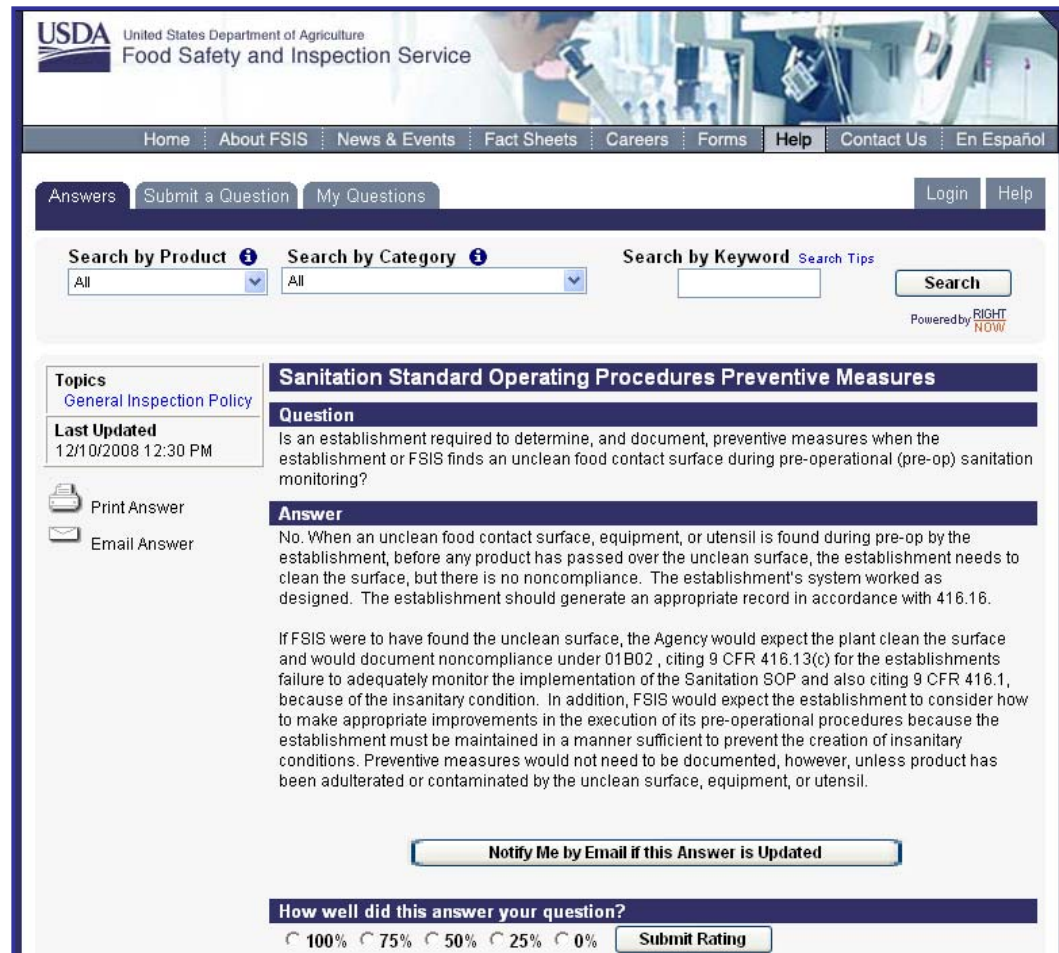
I. PURPOSE

Clarify the policy underlying published askFSIS question and answer on Sanitation SOPs and preventive measures.

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II. BACKGROUND

Q&A Posting to askFSIS



The screenshot shows the askFSIS website interface. At the top, there is a navigation bar with links for Home, About FSIS, News & Events, Fact Sheets, Careers, Forms, Help, Contact Us, and En Español. Below this is a search bar with three options: Search by Product (set to All), Search by Category (set to All), and Search by Keyword. A 'Search' button is present, along with a 'Powered by RIGHT NOW' logo. The main content area features a 'Topics' sidebar with 'General Inspection Policy' and a 'Last Updated' timestamp of 12/10/2008 12:30 PM. The main article is titled 'Sanitation Standard Operating Procedures Preventive Measures' and includes a 'Question' section asking if an establishment is required to document preventive measures for sanitation monitoring. The 'Answer' section explains that such documentation is required when noncompliance is found, citing 9 CFR 416.13(c) and 416.16. A 'Print Answer' and 'Email Answer' button are located to the left of the answer. At the bottom of the article, there is a 'Notify Me by Email if this Answer is Updated' button and a rating section with radio buttons for 100%, 75%, 50%, 25%, and 0%, and a 'Submit Rating' button.

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Key Points:

- Policy *ONLY* applies to ISP Element 01B
- Policy premise (*a proposition that forms the basis of an argument or from which a conclusion is drawn*)
 - Prior to operations no product is on the production floor
 - Product cannot become contaminated or adulterated prior to operations

NOTE: If prior to operations product does become contaminated or adulterated as a result of being on the production floor, then 9 CFR 416.15 applies.

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Key Points:

- Prior to operations establishment compliance
 - Sanitation SOP is functioning if establishment monitoring activity finds unclean direct food contact surfaces
 - establishment restores sanitation prior to operations starting
 - no product is adulterated or contaminated
 - establishment documents the result (9 CFR 416.16)
 - implementation of the procedures prior to operations (9 CFR 416.12(c)),
 - monitoring and
 - actions taken to correct the insanitary condition due to failed implementation of procedures on the daily Sanitation SOP record

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Key Points:

- Noncompliance prior to operations (01B02)
 - FSIS finds unclean food contact surfaces before the start of operations
 - FSIS reviews records and the establishment has not documented required information on the daily record
- Noncompliance prior to operations (01B01)
 - FSIS reviews records and the establishment has not documented required information on the daily record

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III. IPP RESPONSIBILITIES

- 01B02 noncompliance finding:
 - verify that the establishment re-establishes and documents the restoration of sanitary conditions under 9 CFR 416.16
 - pre-operational sanitation inspection noncompliance without direct product contamination or adulteration does not require preventive measures
 - link repetitive pre-operational sanitation noncompliances with the same or similar cause (See FSIS Directive 5000.1, Chapter IV)
 - IPP determine if procedures prior to operations (see 9 CFR 416.12(c)) are inadequate if repeated pre-operational failures (implementation of procedure and monitoring)
 - IPP determine if the establishment is evaluating the effectiveness of their Sanitation SOP (see 9 CFR 416.14)

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III. IPP RESPONSIBILITIES

- 01B02 noncompliance
 - cite all relevant regulations
 - cite 9 CFR 416.16
 - cite 9 CFR 416.13(c) if failing to conduct pre-operation sanitation adequately
 - cite 9 CFR 416.4(a) if not adequately cleaning a food contact surface,
 - Block 10 Description recount 9 CFR 416.1 in that the establishment must operate in a manner that will not create insanitary conditions.

Note: Current version of PBIS does not have 9 CFR 416.1 available to cite in the relevant regulations section of the NR.

Note: Using SPS regulations on a Sanitation SOP noncompliance is a change from current FSRE training.



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IV. IMPLICATIONS FOR FSIS DIR 5000.1

- Required changes -
 - The first note in FSIS Directive 5000.1, Chapter I section XVIII B. is incorrect as related to pre-operational sanitation noncompliances.

NOTE: CSIs are to take the appropriate control action (see Chapter IV) when there is direct product contamination or other adulteration of product. CSIs are not to release product *or equipment affected by the control action* and are not to “close out” the noncompliance record (NR) until they have verified that the establishment has restored sanitary conditions, has completed the proper product disposition, and has implemented preventive measures (see 9 CFR 416.15).

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IV. IMPLICATIONS FOR FSIS DIR 5000.1

- Policy consequence to Chapter I section XVIII B. Note
 - only apply to operational sanitation.
 - 01B02 IPP take any necessary regulatory control action (e.g., rejecting equipment).
 - 01B02 NR with no direct product contamination or adulteration of product IPP can “close out” the NR once they have verified that the establishment has restored sanitary conditions and has documented any corrective actions taken.

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IV. IMPLICATIONS FOR FSIS DIR 5000.1

- Required changes -
 - Also, in FSIS Directive 5000.1, Chapter I section XVIII B 2., it states:

When the CSI finds direct contact surfaces unclean or direct contamination or adulteration of product, he or she should take a regulatory control action. That regulatory control action should not be relinquished until the establishment has proposed an acceptable preventive measure.

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IV. IMPLICATIONS FOR FSIS DIR 5000.1

- Policy consequence to Chapter I section XVIII B 2.
 - only apply to operational sanitation
 - IPP are to take any necessary regulatory control action (e.g., rejecting equipment); however, unless product is involved, the action is to be released when sanitary conditions are restored by the establishment.

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IV. IMPLICATIONS FOR FSIS DIR 5000.1

- Required changes -
 - FSIS Directive 50001., Chapter IV, Section III, D. it states:

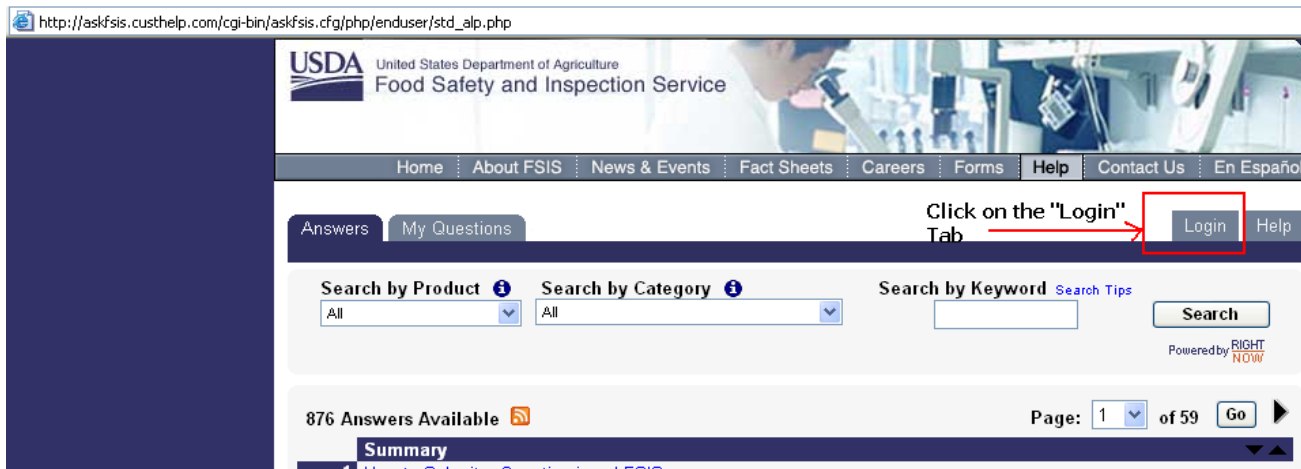
NOTE: If the establishment has found the noncompliance and taken the corrective actions required, there is no noncompliance. The CSI should verify that the establishment is implementing the corrective actions specified in 9 CFR 416.15 when the establishment finds direct contamination or adulteration of products or contact surfaces. If the establishment finds that the responsible individual did not initial and date the record and implemented immediate and further planned actions and records these actions, the CSI should not document this as noncompliance.

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IV. IMPLICATIONS FOR FSIS DIR 5000.1

- Policy consequence to Chapter IV, Section III, D.
 - only apply to operational sanitation
 - IPP do not have to verify whether further planned actions where documented

- Refer questions regarding this notice or posted askFSIS Q&As to the PDD
 - askFSIS at <http://askfsis.custhelp.com> or



– 1-800-233-3935.