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

# FSIS NOTICE	02-09	1/6/09

REQUIREMENTS RELATED TO SANITATION STANDARD OPERATING PROCEDURES (SANITATION SOPs) PREVENTIVE MEASURES

I. PURPOSE

FSIS is issuing this notice to clarify the policy underlying a recently published askFSIS question and answer on Sanitation SOPs.

II. BACKGROUND

An askFSIS question and answer states:

Is an establishment required to determine, and document, preventive measures when the establishment or FSIS finds an unclean food contact surface during pre-operational (pre-op) sanitation monitoring?

No. When an unclean food contact surface, equipment, or utensil is found during pre-op by the establishment, before any product has passed over the unclean surface, the establishment needs to clean the surface, but there is no noncompliance. The establishment's system worked as designed. The establishment should generate an appropriate record in accordance with 416.16.

If FSIS were to have found the unclean surface, the Agency would expect the plant clean the surface and would document noncompliance under 01B02 , citing 9 CFR 416.13(c) for the establishments failure to adequately monitor the implementation of the Sanitation SOP and also citing 9 CFR 416.1, because of the insanitary condition. In addition, FSIS would expect the establishment to consider how to make appropriate improvements in the execution of its pre-operational procedures because the establishment must be maintained in a manner sufficient to prevent the creation of insanitary conditions. Preventive measures would not need to be documented, however, unless product has been adulterated or contaminated by the unclean surface, equipment, or utensil.

When the establishment or FSIS finds noncompliance because of unclean food contact surfaces before the start of operations, inspection program personnel (IPP) are not to require the establishment to provide preventive measures unless product has been contaminated or adulterated by the unclean surface, which is unlikely to be the case. The requirement for preventive measures only applies when the Sanitation SOPs fail to prevent contamination or adulteration of product. During the pre-operational period, it is almost always the case that product is not coming into contact with surfaces, and therefore 9 CFR 416.15 would not be relevant.

III. IPP RESPONSIBILITIES

For pre-operational noncompliance under the 01B02 procedure code, inspection program personnel are to verify that the establishment re-establishes and documents the restoration of sanitary conditions under 9 CFR 416.16. The Sanitation SOPs record of a finding of pre-operational sanitation inspection noncompliance without direct product contamination or adulteration would not need to include preventive measures. Nonetheless, IPP are to link repeated pre-operational sanitation noncompliances with the same or similar cause (See FSIS Directive 5000.1, Chapter IV) and to make a determination that the Sanitation SOPs that are performed prior to operations (see 9 CFR 416.12(c)) are inadequate if there are repeated pre-operational failures (see 9 CFR 416.14).

IPP are to cite all relevant regulations on the NR. However, the current version of PBIS does not have 9 CFR 416.1 available to cite in the relevant regulations section of the NR. In addition to citing 9 CFR 416.16, IPP may cite 9 CFR 416.13(c), for failing to conduct pre-operation sanitation adequately, and 9 CFR 416.4(a), for not adequately cleaning a food contact surface, and recount in the description the requirement in 9 CFR 416.1 that the establishment must operate in a manner that will not create insanitary conditions.

IV. IMPLICATIONS OF THIS NOTICE FOR FSIS DIRECTIVE 5000.1

In response to this notice, FSIS will revise FSIS Directive 5000.1 Verifying an Establishment's Food Safety System. In the interim, this notice clarifies parts of the directive as follows.

The first note in FSIS Directive 5000.1, Chapter I section XVIII B. is incorrect as related to pre-operational sanitation non-compliances. The note states:

> **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).

With the clarification in this notice, this note will likely only apply to operational sanitation. In pre-operational situations, inspection program personnel still are to take any necessary regulatory control action (e.g., rejecting equipment). For pre-operational sanitation, because, generally, no direct product contamination or adulteration of product occurs, inspection program personnel can "close out" the NR once they have verified that the establishment has restored sanitary conditions and has documented any corrective actions taken.

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.

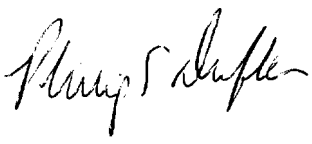
With this notice, the Agency acknowledges that this note will likely only apply to operational sanitation. In pre-operational situations, IPP are to take any necessary regulatory control action (e.g., rejecting equipment); however, unless product is involved, the action is to be released when sanitary conditions are restored by the establishment.

Also, in 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.

With the clarification in this notice, this note will likely only apply to operational sanitation. In virtually all pre-operational situations, IPP do not have to verify whether further planned actions where documented.

Refer questions regarding this notice or posted askFSIS Q&As to the Policy Development Division through askFSIS at http://askfsis.custhelp.com or by telephone at 1-800-233-3935.



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