

SUPERVISORY REVIEW GUIDE FOR THE EVALUATION PROCESS OF THE SSOP REGULATORY REQUIREMENT

I PURPOSE

The purpose of this document is to provide guidance for supervisory oversight of the in-plant Sanitation Standard Operating Procedures (SSOP) discussed in FSIS Directive 11,100.3. Guidance will focus on sections V. and VI. of the directive which pertain to initial evaluation (meeting regulatory requirements for a written SSOP on January 27, 1997) and documentation and enforcement procedures if requirements are not met. Discussion on section V. provides additional information for consideration when performing the evaluation task. Counsel on section VI. identifies procedures for Area Supervisors/District Managers, Import District Managers and Circuit Supervisors, Multi-IPPS, and IFOs to enact when a IIC or import inspector initiates a suspension action. Procedures discussed for the supervisory oversight of the initial evaluation, documentation, and enforcement of SSOPs are also applicable for oversight of regulatory requirements 304.3(a) and 281.22(a) and revision of the SSOP. A separate guide will be issued on the supervision of the SSOP verification process described under section VII of FSIS Directive 11,100.3.

II BACKGROUND

The "Changing Role of Supervisors" segment of the Pre-HACCP/Culture Change Supervisory Training Program presented the concept that supervisors should work "on" the system instead of work "in" the system. Additionally, it stated that supervisors should approach their jobs in a "pro-active" rather than a "re-active" way. These two notions are very different from how frontline supervisors have approached the technical and professional oversight of employee's work in the past. This guide describes how supervisors will work "on" the system in a "pro-active" way utilizing four of the primary roles from the Supervisory Blueprint; (1) Leader, (2) Evaluator/Decision-maker, (3) Communicator, and (4) Program Advocate in implementing and maintaining supervision of employees carrying out the SSOP EVALUATION PROCESS.

Implementation of the SSOP on January 27, 1997, will provide import field supervisors, multi-IPPS supervisors, circuit supervisors, area supervisors, and soon to be District Managers and Assistants, with an immediate opportunity to apply these primary roles.

III APPLICATION

A. Initial Evaluation

The important role of supervisors in the SSOP evaluation process actually begins prior to January 27, 1997. Communication with Inspectors-In-Charge, as well as industry officials, on the awareness, meaning and application of the five SSOP requirements is integral to having a full understanding of the requirements. Supervisors should open dialogue and answer any questions inspection personnel and plant management officials may have on the SSOP requirements upon completion of the employee and supervisory Pre-HACCP/Culture Change Training Programs. **Please do not interpret this guidance document as instruction to enter into pre-approval of a plant's SSOP Plan; instead, this guidance is to ensure that inspection personnel and plant management officials comprehend the five SSOP requirements and the consequences associated with not complying with them.**

The following information is provided to help supervisors effectively communicate the five SSOP requirements and serve as a program advocate for these requirements.

1. The first requirement is to determine if the plant has a written plan describing daily procedures the establishment will conduct before and during operations and the frequency at which they will be conducted to prevent direct contamination or adulteration of product(s).

Specificity and detail on how the plant wants to accomplish this component is up to the plant. The emphasis of this requirement is the prevention of direct contamination or adulteration of product. Plants should be developing procedures which they can realistically carry out given their size, management and empowerment philosophy, and nature of operations. The goal is to prevent direct product contamination and have procedures to immediately react to occurrences of direct product contamination. Inspection personnel should not expect perfection or that everything will go right 100% of the time. FSIS expects plants to monitor their preventive procedures and act if direct product contamination occurs. FSIS will decide on the effectiveness of a plant's ability to prevent and react to direct product contamination during the verification process NOT the evaluation process.

SSOPs that are received in a foreign language will need to be translated before any determination as to compliance with the five requirements is made. In such cases, the IIC can allow the plant to operate until such time as a translated copy of the plan is presented for review. The deadline for receipt of a translated copy into English should be agreed upon between the IIC and plant. The IIC should contact their supervisor for actions to take if the agreed upon deadline is not met. IICs will perform process verification of the SSOP during this time period.

2. The second requirement is that the plan is signed and dated by an official with overall on-site authority or a higher level official of the establishment. The plan must be signed upon initiation and when modified.

Plants have flexibility in determining who the signature individual will be as long as they meet the requirement that it is signed and dated by an official with overall on-site authority or a higher level official of the establishment. There is no requirement that this person be listed on the Grant of Inspection, PBIS plant profile, or plant blueprints. There is no requirement that the plant provide proof that this person has overall authority or an explanation required if this person maintains a corporate position. The verification process will be used to determine if the person designated as the responsible official does in fact have the stated authority.

Plant management that inadvertently forgets to sign the SSOP as required by the regulation 416.12(b), and can correct this problem by signing the SSOP, should be afforded the opportunity to sign without initiation of a suspension action.

3. The third requirement is that the SSOP Plan identify pre-operational sanitation procedures and distinguish them from sanitation activities to be carried out during operations. These pre-operational procedures at a minimum must address the cleaning of food contact surfaces of facilities, equipment, and utensils.

This requirement may raise many questions by industry as to how specific in detail they are to get. Plants may, but are not required to, go into great detail in listing each specific piece of equipment for cleaning and monitoring in the written SSOP. An inadvertent omission of equipment or small utensil is not a reason for finding that the SSOP does not meet the requirements or suspending operations. The IIC should notify the plant of any perceived minor omissions and request they revise the SSOP.

In addition, there is no requirement for plants to describe in detail the mixing of chemical cleaners or applying sanitizers in their plan. Plants are expected to utilize chemicals under the conditions of use

listed in the *Proprietary Substances and Nonfood Compound* publication. Their acceptance will continue to be verified under Inspection System Guide task codes 05A031 and 05A032 and not part of an inspector evaluation of the SSOP Plan.

Methods used by a plant to monitor and maintain pre-operational sanitation procedures, and the frequency for doing so, may be met under this requirement or under requirement one. Effectiveness of pre-operational sanitation procedures will be determined through the verification process NOT the evaluation process.

4. The fourth requirement is that the written SSOP identify the individuals who are responsible for implementing and maintaining daily sanitation activities. Plants may identify these individual(s) by name or job title. There is no requirement that these individuals or positions have separate lines of authority from the production process. Production employees, lead line personnel, department forepersons, etc., may be identified to meet this requirement. Identification of these employees or positions will most likely occur in small plant operations.

Additionally, while the employee identified as responsible for implementation and maintenance of procedures in the SSOP may be the employee who actually performs such activities, he or she instead may be the employee in charge of ensuring that the sanitation procedures are carried out. All that is required is that the SSOP identify the employee(s) responsible for implementation and maintenance of the procedures in the SSOP. The establishment does not need to identify the employee(s) who actually perform sanitation procedures. Also, an establishment's SSOP may have more than one employee responsible for implementation and maintenance of sanitation procedures. Effectiveness of responsible employees in implementing and maintaining daily sanitation activities will be determined through the verification process NOT through the evaluation function.

5. The fifth and last requirement is that establishments maintain daily records that demonstrate they are carrying out the sanitation procedures outlined in their SSOP plan, including the corrective actions taken. Plant management has flexibility in designing such records. There is no set format required, only that a record is maintained. Records may be maintained on a computer in lieu of hard copy as long as they are accessible to inspection personnel.

Section 416.16 of the regulations requires plants to maintain daily records sufficient to document the implementation and monitoring of the SSOP and any corrective action taken. It does not specifically state the record must be part of the written SSOP. Therefore, if a record is not identified in the written SSOP, but the plant has posted or identified a SSOP record to the IIC, then this requirement has been met. Record retention periods are also defined in the regulations and thus are not required to be included in the written SSOP Plan.

Another crucial point needs to be communicated to the IICs when performing the evaluation task. IICs shall not determine that a plant has failed to comply if all the requirements of section 416 of the regulation have been included in the written SSOP but the IIC questions the validity or usefulness of identified procedures, monitoring activity, or implementation ability. Effectiveness of the SSOP in the prevention and/or correction of direct product contamination will be determined through verification inspection methodology.

In addition, IICs should contact you the supervisor if they have any questions as to whether the five requirements of the SSOP have not been met or if they need any additional information before determining that the plant has not complied and implemented a suspension action. This approach is consistent with the Pre-HACCP/Culture Change Training Program. IICs are empowered and responsible for evaluating the adequacy of a plant's SSOP Plan and for taking appropriate enforcement action. As a

leader, frontline supervisors are expected to assess the appropriateness of an employee's actions utilizing some or all of the sanitational leadership styles--direct, coach, support, and delegate - presented in the Managing the Journey segment of the Pre-HACCP/Culture Change Supervisory Training Program.

D. Documentation

When the IIC decides that a plant's SSOP Plan is not in compliance with the regulation, he/she must clearly identify the reason(s) for such action on the Process Deficiency Record (PDR), FSIS form 8820-1. Failure of the plant to supply a written plan or address one or more of the five requirements must be specifically identified on the PDR. The documentation on the PDR will provide the basis for informing the area/district office or Import District Manager of a plant's failure to meet a condition of inspection resulting in a suspension action.

E. Enforcement Perspective

1. General

Enforcement actions identified in FSIS Directive 11,100.3, section VI., for failure to comply with the five components required under section 416 of the regulations take effect on January 27, 1997. Operating within the leader and evaluator/decision-maker roles, supervisors will be required to assess inspection personnel enforcement actions, provide counsel to employees on enforcement strategies, and implement the following enforcement proceedings.

2. Field Supervisors Role by Organizational Level

a. Area Supervisor/District Manager and Import District Manager

This level of management is to discern from the IIC's report and documentation of a suspension action that requirements in 416.12 and/or 416.16 of the regulations have not been met and plant's management's intent to take appropriate corrective action.

Plants that fail to comply with all five requirements of section 416 of the regulations and refuse to take immediate corrective action demonstrate an unwillingness and/or inability to comply with the regulatory requirements. In such cases, the Area Supervisor/District Manager or Import District Manager will sustain the suspension action and follow the procedures contained in FSIS Directive 11,100.3, VI, C and D.

Where plant management proposes to implement appropriate corrective action, the Area Supervisor/District Manager or Import Manager will direct the circuit supervisor, multi IPPS supervisor, or import field office supervisor to meet in person or telephonically, whichever is most expeditious, with plant management.

b. Circuit Supervisor, Multi-IPPS, and IFO Supervisor

This level of management will take the following actions when directed to meet with plant management by the Area Supervisor/District Manager or Import District Manager:

(1) Assess the plant's proposed corrective action to comply with the requirements of section 416 of the regulations. If acceptable, require plant management to identify a time frame for compliance. The Circuit Supervisor, Multi IPPS or IFO Import Supervisor may request compliance personnel assistance to assess corrective actions if they so desire.

(2) Consult with the IIC/import inspector to determine there is no evidence of insanitary conditions which could lead to direct contamination or adulteration of product.

(3) Allow the establishment to operate under the following conditions (a) plant management identifies acceptable corrective actions that will be enacted within a specified time frame; and (b) the IIC reports no circumstances are present which could lead to direct contamination or adulteration of product. Document your decisions and notify the Area Supervisor/District Manager or Import District manager of this action. Provide copies of the documentation to the Area Supervisor/District Manager or Import District Manager and IIC/import inspector.

c. Area Supervisor/District Manager and Import District Manager

The Area Supervisor/District Manager or Import District Manager, after consultation with the Evaluation and Enforcement Division, District Enforcement Operations, shall notify the plant in writing, as promptly as circumstances permit, the disposition of enforcement actions -- including the reason for the suspension action; the obeyance actions taken as a result of the plant's corrective actions; and FSIS's intent to reinstate the suspension action if the establishment does not comply within the time frame specified in their identified corrective action. Provide a copy of this notification to the circuit supervisor/IFO Import Supervisor, multi-IPPS if appropriate, and IIC/import inspector.

d. IIC/import inspector

The IIC/import inspector shall notify his/her supervisor if corrective actions are not completed within the specified time frames.

3. Final Determination

a. The circuit supervisor, multi-IPPS supervisors, and IFO import supervisor will consult with the area supervisor/district manager or import district supervisor will consult with their area supervisor/district manager or import district manager when the IIC/import inspector advises them that a plant has not completed the specified corrective actions within the identified time frames.

b. The Area Supervisor/District Manager or Import District Manager and compliance officials shall determine the appropriate enforcement action and send a letter to the plant management officials accordingly. A copy of this letter will be provided to all supervisors and the IIC/import inspector.

4. Suspension Action

If suspension actions are initiated under FSIS Directive 11,100.3, section VI. for failure to comply with the regulations, the IIC should allow the shipment of products which have been inspected and passed products produced prior to January 27, 1997.