# Sanitation
# SSOP and SPS

During this session of training we are going to discuss Sanitation Standard Operating Procedures (SSOPs), Sanitation Performance Standards (SPS), and Good Manufacturing Practices (GMPs). All of these play an important role in Pathogen Reduction and are programs used in conjunction with Hazard Analysis Critical Control Point (HACCP). In general these programs cover sanitation, both pre-operational and operational, throughout the entire establishment. All of these programs, SSOP, SPS, GMP, and HACCP, when implemented properly, will ensure that the establishment is producing a safe unadulterated product for consumers. The United States Department of Agriculture, Food Safety Inspection Service regulations §CFR 416.1-17 address the requirements of SPS and SSOPs. These regulations were implemented on January 25, 1997. Following the outline of the regulations we will begin with SPS.

Performance standards define the results to be achieved by sanitation, but not the specific means to achieve those results. Establishments have flexibility to determine what is appropriate and sufficient in maintaining sanitary conditions and preventing the adulteration of product; therefore, they can meet the sanitation performance standards in different ways. The performance standards are based on current science and are consistent with the Hazard Analysis and Critical Control Point philosophy of placing the responsibility for ensuring food safety on establishments.

Good Manufacturing Practices (GMP's) can be used to address many, if not all, aspects of the SPS requirements. If an establishment chooses to use GMP's as part of their SSOP then they must have written programs and document the implementation of those procedures.

**§ 416.1 General rules.**

Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.

**§ 416.2 Establishment grounds and facilities.**

(a) *Grounds and pest control.*
The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.

(b) *Construction.*
(1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.

(2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.

(3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.
(4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.

(c) *Light.*
Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.

(d) *Ventilation.*
Ventilation adequate to control odors vapors and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.

(e) *Plumbing.*
Plumbing systems must be installed and maintained to:
(1) Carry sufficient quantities of water to required locations throughout the establishment;
(2) Properly convey sewage and liquid disposable waste from the establishment;
(3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;
(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor;
(5) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing; and
(6) Prevent the backup of sewer gases.

(f) *Sewage disposal.*
Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.

(g) *Water supply and water, ice, and solution reuse.*
(1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.

(2) Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.

(3) Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse of water that which has come into contact with raw product may not be used on ready-to-eat product.

(4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g) (1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section.

(5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.

(6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.

(h) *Dressing rooms, lavatories, and toilets.*
(1) Dressing rooms, toilet rooms, and urinals must be sufficient in number; ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.

(2) Lavatories with running hot and cold water, soap, and towels, must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.

(3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

**§ 416.3 Equipment and utensils.**

(a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.

(b) Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.

(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

**§ 416.4 Sanitary operations.**

(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review.

(d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

**§ 416.5 Employee hygiene.**

(a) *Cleanliness.*
All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.

(b) *Clothing.*
Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.

(c) *Disease control.*
Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition are corrected.

**§ 416.6 Tagging insanitary equipment, utensils, rooms or compartments.**

When an FSIS program employee finds that any equipment, utensil, room, or compartment at an official establishment is insanitary or that its use could cause the adulteration of product, he will attach to it a ''U.S. Rejected'' tag. Equipment, utensils, rooms, or compartments so tagged cannot be used until made acceptable. Only an FSIS program employee may remove a ''U.S. Rejected'' tag.

**§ 416.11 General rules.**

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

**§ 416.12 Development of Sanitation SOP's.**

(a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).
(b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.
(c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.
(d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

**§ 416.13 Implementation of SOP's.**

(a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.
(b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.
(c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's.

**§ 416.14 Maintenance of Sanitation SOP's.**

Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

**§ 416.15 Corrective Actions.**
(a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the

implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s).
(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

**§ 416.16 Recordkeeping requirements.**

(a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made accessible available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site, provided such records can be made available to FSIS within 24 hours of request.

**§ 416.17- Agency Verification**

Government inspection personnel shall verify the adequacy and effectiveness of the SSOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

1. Reviewing the SSOP's
2. Reviewing the daily records documenting the implementation of the SSOP's and the procedures specified therein and any corrective actions taken or required to be taken
3. Direct observation of the implementation of the SSOP's and the procedures specified therein and any corrective actions taken or required to be taken
4. Direct observation or testing to assess the sanitary conditions in the establishment

To verify the initial adequacy of the establishments SSOP, or when modifications are made, there are several questions that should be asked. These questions include:

1. Does the establishment have a written SSOP that describes the procedures the establishment conducts daily to prevent direct contamination of product?

2. Does the SSOP identify which of the procedures are pre-operational procedures?

3. Does the SSOP identify which of the procedures are operational procedures?

4. Does the SSOP address (at a minimum) the cleaning of food contact surfaces of facilities, equipment and utensils?

5. Does the SSOP specify the frequency with which the establishment will conduct each procedure?

6. Does the SSOP identify the establishment employees responsible for implementing and maintaining specified procedures?

7. Does the establishment identify records that are used daily to document the implementation and monitoring of the SSOP and corrective actions when taken?

8. Has an individual with overall authority on-site or higher level official signed and dated the SSOP?

If there any problems identified during the review of the SSOP, then government inspectors must document those problems and request a corrective action from establishment management. Once the SSOP has been found to be adequate, then government inspectors must monitor the daily implementation of the program.

The on-going verification can be accomplished different ways. This training recommends that the approach to on-going verification is divided into two categories; direct observation and records review.

Direct observation is accomplished by conducting either a hands-on review of facilities, equipment, and utensils or by observing the establishment employees conducting their monitoring of sanitation, taking corrective action, and recordkeeping (shadowing). It is highly recommended that a mixture of both direct observation methodologies be used to verify that the establishment is following their program.

Inspectors should be taking with them a flashlight and a sufficient number of the tags when conducting either of these procedures.

If inspectors are conducting a pre-operational hands-on review of the facilities, equipment, and utensils, they should be allowing the establishment to conduct their own monitoring prior to starting the hands-on review. Inspectors should be comparing what they identify during their hands-on to what the establishment identified during their monitoring.

If inspectors have identified problems that affect product and/or product contact surfaces and were not identified by the establishment, they should be taking an enforcement action against the establishment; such as tagging equipment, facilities, or utensils and documenting all problems observed and the fact that the establishment monitoring failed to identify the problems. They must request that the establishment provide corrective actions sufficient to address all parts of 416.15.

The records review portion of verification must occur daily. To conduct this review the inspector must review records that demonstrate the establishment is conducting procedures identified in the SSOP, documenting results, and are taking appropriate corrective actions sufficient to address all parts of 416.15. If the establishment is failing to complete these tasks then the inspector must document this failure and request corrective actions from the establishment.

It is recommended that during a standard work week, that inspectors conduct hands-on direct observation at least 2 times and that records are reviewed daily. If problems are identified by inspectors

every time they conduct the hands-on direct observations, that they increase the frequency as needed to ensure that products are being produced that are safe from contamination. If non-conformances continue to exist, it is recommended that the government inspector "shadow" or observe the plant inspector performing hands-on direct observation. During this time the government inspector will be able to determine if the plant personnel are executing their inspection procedures adequately. If plant personnel are not inspecting adequately or executing their SSOP as designed, this is a nonconformance and would be documented as such.

Inspectors must document in some way that they are conducting these reviews even if there are not any problems identified. If inspectors continue to identify problems they may request assistance from supervisors or request an investigation.