

## Sanitation Requirements

### Objectives

After completing this module, participants will be able to do the following:

1. Identify general facility and sanitation requirements in egg products plants.
2. Identify facility and sanitation requirements for specific rooms and operations typically found in plants, including candling, transfer, breaking, cooling, holding, freezing, defrosting, drying, washing and sanitizing, and pasteurization rooms.
3. Identify the health and hygiene of plant employee requirements.
4. Identify tanker sanitation requirements.
5. Explain how IPP verify sanitation regulatory requirements

#### Note:

Effective 10/29/2021 or early opt-in, some of the 9 CFR 590 regulations will be replaced by 9 CFR Part 416 Sanitation Performance Standards (SPS) and Sanitation Standard Operating Procedures (SSOP).

### Introduction

Sanitation is crucial to producing safe and wholesome products. For example, in pasteurization of liquid egg products, it is critical that the pasteurizer, which is a clean-in-place (CIP) system, is properly cleaned and sanitized because when egg products are pasteurized the outcome should be a product that tests negative for *Salmonella*.

For an egg products plant to comply with the sanitation regulatory requirements, they should:

- Take the appropriate measures to maintain sanitary conditions targeting the facility/equipment, as well as the processing environment, including those areas that can impact food safety.

FSIS Directive 5030.1 provides instruction as to how inspection program personnel (IPP) are to verify that egg product plants are meeting the sanitation regulatory compliance of 9 CFR part 590.

### Plant Requirements

General plant requirements as described in §590.500 include:

- The plant must be free from objectionable odors, dust, or smoke-laden air.

- Facilities and outside premises should be maintained to eliminate odors and the harborage of vermin.
- Buildings must have sound construction and be kept in good repair. In rooms that hold edible products, windows that open directly to the outside must have protection to prevent flies, vermin, dirt, or dust from entering.
- There must be adequate plumbing and drainage for transporting water to all parts of the plant where water is required. Sewage removal must be rapid and not lead to backups or insanitary conditions.
- Floors, walls, ceilings and other parts of the plant need to be made of materials that are impervious to moisture and can be thoroughly cleaned.
- There must be an adequate number of welfare facilities and dressing rooms and these must have the following:
  - adequate lighting
  - separation from production areas
  - separate ventilation
  - single service towels (or, in some cases, electric hand dryers)
  - hot and cold running water
  - unscented soap that will not interfere with organoleptic inspection
  - operation by means other than hand controls
- There must be adequate and convenient facilities to wash and to sanitize utensils and equipment.
- Rooms where refuse is collected and stored must be
  - completely enclosed
  - separately located from production areas, with no direct entrance into production or edible storage areas

**NOTE:** If the plant wants to use an alternative system (i.e., procedures, equipment, and processing techniques), the plant must first get approval (9 CFR 590.10 – waiver; refer to FSIS Directive 11,000.2, *Verification Activities for the Use of New Methodology in Meat and Poultry Establishments and Egg Products Plants*).

## **Facility and Sanitation Requirements for Specific Rooms and Operations**

### **Candling and Transfer Room (§590.506)**

The transfer and candling rooms have specific requirements to assure the shell egg is handled in a sanitary manner and to allow for the detection of ineligible eggs while still in the shell.

Specific requirements include the following:

- Candling devices must be provided to enable detection of eggs that are ineligible prior to breaking.
- The room where candling is performed must be darkened enough to assure the candling operation will be accurate.
- Floor construction must allow for thorough cleaning and provide adequate drainage.
- The rooms must be equipped with an approved exhaust system.
- Equipment and utensils must be designed and made of materials that allow thorough cleaning and sanitizing.

### **Breaking Room (§590.520)**

The specific requirements for breaking rooms address the fact that this is where the liquid unpasteurized egg is first exposed to the environment. This room also houses many complex pieces of machinery, which, if not properly maintained, could allow for cross contamination of product.

- Proper lighting is essential to egg breaking operations because it is a key element of the organoleptic inspection process. A minimum of 30 foot-candles of light are required in all working areas in the breaking room, except at inspection stations and where the shell eggs are broken, which require 50 foot-candles of light.
- Ceilings and walls must be water resistant and easily cleanable. Floors must be waterproof, reasonably free of cracks or rough surfaces, properly sloped, and have adequate drainage.
- The breaking room must have a positive flow of outside filtered air through the room and the temperature of the room must be adequate for operations.
- The breaking room must also have an adequate number of hand-washing facilities with these features:
  - convenient location(s)
  - warm water
  - unscented soap
  - clean towels or other facilities for drying hands
  - washing stations operated by means other than hand controls

- All equipment and utensils used must be designed and constructed in a way that allows the egg product to be processed in a clean and sanitary manner. (§590.502)

### **Liquid Egg Cooling (§590.530)**

This operation requires the following:

- The surface of walls, floors, and ceilings must be kept clean and not allow condensation to form.
- Equipment must be of approved construction and designed to hold the correct amount of product.
- Liquid egg containers must be covered while in use.

### **Liquid Egg Holding (§590.532)**

Areas for holding liquid eggs are similar to those used for cooling liquid egg products. Specific requirements for liquid egg holding are as follows:

- Tanks and vats must be of approved construction, usually stainless steel, and must be fitted with covers.
- Tanks and/or silos may be located partially outside of processing rooms, but they must terminate in processing rooms.
- Thermometers and agitators are required equipment for these liquid egg storage tanks.

### **Freezing Facilities (§590.534)**

Whether freezing is on or off premise, these are the specific requirements for these facilities:

- The facility must be capable of freezing all liquid egg products in the required time.
- All freezing rooms require proper and adequate air circulation.
- If off-premise sites are used, they must be approved before use.

### **Defrosting Facilities (§590.538)**

The construction of vats or tanks and equipment used to hold and defrost product must allow for easy and thorough cleaning.

### **Spray Drying Facilities (§590.540)**

Drying performed in some facilities has specific requirements not only for construction and sanitation but also for how the dryers must operate.

Requirements for dryers include the following:

- Dryers must be of a continuous discharge type.
- Dryers must not allow for the accumulation of dried egg product in the drier, bags, and conveyors.
- Dryers must have smooth construction, including welds, and allow for thorough cleaning.
- An approved air filtering system must be located on the intake side of the unit.
- The air supply must be free of odors, dust, and dirt.
- The heating style and source must be equipped with proper filtration equipment.
- Pumps and preheating units must be made of stainless steel or the equivalent.

590.542 provides the sanitation requirements for the spray process drying operations

### **Washing and Sanitizing Rooms (§590.550)**

Rooms where equipment and utensils are cleaned and sanitized must:

- Have the same construction and cleaning requirements of previous rooms mentioned.
- Be adequately sized to handle the equipment and utensils.
- Have an exhaust system to remove odors.

Some plants may not have a specific room to clean and to sanitize equipment and utensils. In this case, the following precautions must be taken:

- The area must be segregated from the breaking room.
- The area must be well ventilated with airflow that travels away from the breaking room.

## **Pasteurization (§590.570)**

The area and machinery where pasteurization occurs must have:

- Proper and approved construction to assure all products will be properly pasteurized.
- Equipment that meets the regulatory requirements for its design and includes:
  - A holding tube
  - An automatic flow diversion valve
  - Thermal controls
  - Recording devices

## **Clean-in-Place systems (§590.552) – otherwise known as C.I.P.**

Cleaning requirements:

- Cleaned to eliminate organic matter and inorganic residues.
- Equipment cleaned per sanitary requirements (frequency).
- CIP equivalent to thorough manual washing and sanitizing – may require bacteriological tests and periodic dismantling of equipment.

Sanitizing requirements:

- Chemicals/compounds shall have Administrator's approval prior to use.
- Maximum 200 ppm available chlorine of sanitizing solution
  - Hypochlorite or other approved sanitizing solutions

**Note:** Sanitized shell eggs & equipment which contacts edible products shall be rinsed with clean water after sanitizing if other than hypochlorite used as sanitizing agent unless otherwise approved by Administrator.

## **Health and Hygiene of Personnel (§590.560)**

### **Introduction**

The health and hygiene of plant employees is vital to assure that wholesome product is produced. If a plant's facilities are unsanitary or its workers become a vector for disease, the plant's product may be compromised.

The regulations outline specific requirements for the sanitation of facilities and the health and hygiene of personnel.

### **Facilities**

1. Facilities including lavatories, lockers, and dressing rooms must be adequate in size and must meet all state, county, and city requirements for food processing plants.
2. These facilities must be kept clean and must be adequately ventilated to eliminate odors. Specifically, toilets must be ventilated directly to the outside.
3. These facilities must be adequately supplied with soap, towels, and tissues.

### **Plant Employees**

1. No person who is affected with any communicable disease in the transmissible stage or who is a carrier of a disease, or who has boils, sores, or infected wounds may come in contact with egg product or equipment in any form.
2. Workers must wear clean outer garments.
3. If workers handle exposed product, they must wash their hands before beginning work and upon returning to work after leaving the work room (590.504(f) also applies).
4. Workers may not use tobacco in any form while working in any area at the plant where edible product is exposed.
5. Spitting or other unsanitary practices are forbidden.
6. Workers may not wear jewelry, nail polish, or perfumes in any areas where edible product is exposed.
7. All people in breaking and packaging rooms must wear caps or hairnets properly.

**Note:** Recent policy was issued (FSIS Directive 5060.1, *Hygiene and Biosecurity Practices*) providing instructions to IPP to fully comply with the same sanitation and hygiene regulations that the plant personnel must adhere to; and to fully comply with the sanitary and hygiene procedures and biosecurity measures put in place by an official egg products plant that are required of all their employees.

## Tanker Sanitation Requirements (590.504(k); 590.522(y))

Before filing tanker trucks and similar equipment, the interior of the tanker, inlet caps, dome gaskets, air vents, dismantled outlet valves, and “O” rings are to be inspected for cleanliness and adequate sanitizing. Tanker owners, drivers, and plant management should be informed that only tankers that meet the following requirements may be loaded:

- Interior is clean and sanitized.
- Outside is clean around the domes, air vents, and outlet valves.
- Sanitary gaskets are in good condition.
- Tanker is capable of being sealed so liquid cannot be added or removed without breaking the seals.

There are plants that have procedures in place to differentiate those tankers that have been cleaned and sanitized.

## Verifying Sanitation Requirements

There are three general types of sanitation verification tasks that IPP must perform to verify that a plant is meeting the regulatory requirements for sanitation. Each task includes a recordkeeping verification component and a review and observation component. The (3) types of sanitation tasks are:

- Pre-Operational Sanitation Verification (perform (1) routine task daily)
- Operational Sanitation Verification Task (perform (1) routine per shift)
- Facility Sanitation Verification Task (perform when it appears on task list as a routine task)

IPP may perform additional “inspector directed” sanitation verification tasks as warranted by conditions observed in the plant. Each time the IPP perform the sanitation verification tasks, IPP should verify one or more of the sanitation regulatory requirements (9 CFR 590.500-575). Over the course of time, they are to verify **all** sanitation regulatory requirements.

When time allows, IPP should verify multiple sanitation regulatory requirements in one or more areas of the plant, each time they perform a sanitation verification task. In some cases, IPP will be able to verify one or more sanitation requirements while performing other verification activities.



When IPP determine whether the plant maintains food contact surfaces during **both** pre-operational and operational, IPP must evaluate the conditions in the plant. IPP should ask questions such as, but not limited to, the following:

- Are product contact surfaces being contaminated or adulterated? (9 CFR 590.504(n) and 590.552(a))
- Has the breaking machinery run for a considerable time between rinse downs such that dried egg material or shells have collected on the product flow away trays? (9 CFR 590.504(n))
- Is the breaker operator performing the function in a sanitary manner? (9 CFR 590.522(b))
- Are containers for trash and inedible eggs removed from the candling rooms as often as necessary to prevent off odors or insanitary conditions in the transfer room operation? (9 CFR 590.508(b))
- Are shell eggs being properly classified and segregated so as to allow only eligible eggs to enter the breaking room and be broken? (9 CFR 590.510)
- Has the shell egg washer run for a considerable time or the wash water not been changed such that sanitary conditions are no longer maintained? (9 CFR 590.515(a)(4))
- Are strainers and filters providing effective removal of shell fragments from collected liquid egg products? (9 CFR 590.522(v))
- If it maintains such procedures, is the plant adhering to its clean-in-place (CIP) procedures to ensure that the equipment is clean and sanitized prior to operations? (9 CFR 590.552(a)(3))
- Are the air-lines operational and the air from a filtered source when the breaking machine is operational and directed at the breaking machine operator to aid in the organoleptic examination of individual shell eggs being broken? (9 CFR 590.504(p) and 590.522(f))
- Are eggs shells being adequately removed from the processing area and not accumulating on equipment or floors? (9 CFR 590.522(g))

### **Performing the Pre-operational Sanitation Verification Task**

The pre-operational sanitation verification task is used to verify that plants maintain sanitary conditions of food contact surfaces and equipment to prevent

contamination or adulteration of egg products prior to operations as required in 9 CFR 590.504(n).

When performing hands-on pre-operational sanitation inspection on a daily basis, IPP must use a risk-based approach when selecting the areas and equipment that they will inspect. IPP may need to adjust their thought process periodically based upon their verification findings.

IPP must gather information to assist them in selecting equipment or areas of the plant for pre-operational sanitation verification and for determining the extent of their pre- op inspection (e.g., how many pieces of equipment or how many production areas they will inspect on a particular day). IPP must ask, but are not limited to, the following questions to help determine what they will inspect:

- Which pieces of equipment will directly contact exposed product?
- Which pieces of equipment are the hardest to clean?
- Which pieces of equipment are easiest to clean?
- How recently has the sanitary condition of equipment in the processing areas been verified by FSIS?
- Is there a history of pre-op noncompliance documented by FSIS?
- How many pieces of equipment or areas of the plant do IPP need to observe to have confidence that the plant begins operations under sanitary conditions?

During the performance of the review and observation component of the pre-op task, IPP must:

- Look at selected pieces of equipment rather than all pieces of equipment. Rotate inspection of equipment so that over time all equipment has been inspected (e.g., if a plant has five product flow pumps, IPP can inspect a different pump each day).
- In very small facilities that have a limited amount of equipment at which to look, IPP must follow the same thought process when determining what equipment to look at during the performance of the pre-op verification.
- Select a representative sample (e.g., one or two of each) when there are large numbers of simple equipment such as pans, buckets, trays, gaskets, or filters, rather than looking at a single piece of equipment (e.g., tanker inspection).

- Avoid repetitive inspection of equipment following incidental contamination findings, such as one small piece of a shell egg or particulate matter on that piece of equipment.

In determining regulatory compliance, IPP must assess the cleanliness of areas or equipment that, if insanitary, would present the greatest risk of transferring pathogens, such as *Salmonella* spp. or *Listeria monocytogenes*, sometimes found in extended shelf life product, or contaminants to product (e.g., direct food contact surfaces that are difficult to clean or that may serve as harborage sites). When assessing pre-op sanitation conditions, IPP must use professional judgment in determining whether the plant's pre-op measures have resulted in a clean and sanitary environment (i.e., breaking equipment is clean and free of egg solids, all pipes and gaskets are clean and have been sanitized prior to use).

IPP must focus on the following factors in making this determination:

- The condition of the equipment or surfaces that can have the greatest effect on the safety of the product (e.g., check the cleanliness of the breaking equipment, cups, knives, racks, trays, and hard-to-clean food contact surfaces).
- The condition of surfaces or equipment that may harbor contaminants (e.g., CIP pipes, holding tanks, the underneath side of food contact belts, or conveyors/equipment that can contain product residues).
- Conditions that may affect overall sanitation of the equipment and the area, for example, whether one small shell egg fragment or product residue could affect the sanitation of the food contact surface or contaminate or adulterate product.

When IPP find product contact surfaces unclean prior to operations, IPP must take an action under 9 CFR 590.426 and 9 CFR 500.2(a) to prevent contamination or adulteration of product. IPP must maintain any regulatory control actions until the plant has restored sanitary conditions.

IPP must document the results of their verification activities, including any noncompliance, following the instructions in Chapter IV of Directive 5030.1. When determining whether noncompliance exists, IPP must take into account what they have observed and not engage in speculation. For example, debris build-up on a food contact surface will come in contact with product during operations and thus is to be considered in assessing sanitary conditions. In contrast, debris build-up on a nearby wall or piece of non-food contact equipment may eventually come in contact with product but not definitely. Thus, the latter condition is not to be cited as a noncompliance.

If IPP observe unclean food contact surfaces and insanitary conditions associated with a non-food contact surface, facility, or equipment while

performing the pre-operational sanitation verification task, IPP must document noncompliance on a single pre-op sanitation NR by recording a result of noncompliance for each applicable regulatory citation. If IPP observe only insanitary conditions associated with non-food contact surfaces of the facilities, equipment, or utensils, while performing a pre-operational sanitation verification task, IPP must record the pre-operational sanitation task results of regulatory compliance and record the noncompliance under a separate facilities sanitation verification task. When they find insanitary conditions associated with a non-food contact surfaces during pre-operational sanitation verification task, IPP must initiate a directed facilities sanitation verification task to document the noncompliance even if they had not planned to perform a routine facilities sanitation task that day.

### **Performing the Operational Sanitation Verification Task**

The operational sanitation verification task is used to verify that the plant meets all operational sanitation regulatory requirements to prevent the contamination of food contact surfaces or adulteration of products during operations (9 CFR 590.504-575).

When verifying that processing activities meet regulatory requirements (9 CFR 590.500-575), IPP must evaluate the processing procedures and associated activities observed in the facility. IPP must verify that processing operations in the plant are such that adulteration of product does not occur. IPP must verify that the regulations associated with processing are met. To determine compliance, IPP must ask questions such as, but not limited to, the following:

- Is liquid product being contaminated by shell fragments collecting in the product flow away trays on the breaking machines? (9 CFR 590.522(g), 590.522(aa)(2) and 590.504(m))
- Is excess egg white foam collecting in the flow away tray such that it is creating an insanitary condition for passing liquid product? (9 CFR 590.522(aa)(2))
- Are ingredients added in the processing of egg products clean, fit for human food, used in the correct percentages, and approved for their intended use? (9 CFR 590.504(j) and 9 CFR 590.522(m))
- Whenever an inedible egg is broken, is the plant removing, cleaning, and sanitizing the affected breaking equipment to prevent adulteration of product? (9 CFR 590.522(h))
- Is the temperature of the wash water maintained at 90°F or higher, and at least 20°F warmer than the egg, throughout the cleaning cycle? (9 CFR 590.515(a)(2))

- Is the wash water being changed approximately every four (4) hours or more often as needed to maintain sanitary conditions and at the end of each shift? (9 CFR 590.515(a)(4))
- Are the shell eggs that have received a spray rinse adequately dry at the time of breaking? (9 CFR 590.516(b))
- Prior to breaking, is the plant utilizing a spray rinse of available chlorine or its equivalent (between 100 ppm but not to exceed 200 ppm) on its shell eggs? (9 CFR 590.516(a))

IPP must take appropriate action when there is direct product contamination or adulteration of product. IPP must not release product or equipment affected by the control action and should not mark the NR as “completed” in PHIS until they have verified that the plant has restored sanitary conditions and has completed the proper product disposition(9 CFR 590.426).

Using the information gathered during these verification activities, IPP must determine whether noncompliance exists. IPP must use any findings as clues to direct them to points in the egg products processing operation where an insanitary condition is created as a result of the loss of process control and reflects regulatory noncompliance. Such findings may include:

- A noncompliance related to cross-contamination of egg products because of breaking ineligible eggs and failure to clean and sanitize equipment;
- The design or use of facilities, equipment, or utensils resulting in a noncompliance;
- A noncompliance related to employee hygiene practices that may contaminate food contact surfaces or product; or
- A failure to maintain process control through the implementation of in-plant procedures that are designed to prevent product contamination.

IPP must document the results of their verification activities, including noncompliance per the instructions in Chapter IV of Directive 5030.1.

If IPP observe contamination or adulteration of product or direct food contact surfaces and insanitary conditions of facilities, equipment, or utensils while performing the operational sanitation verification task, IPP must document both of the noncompliances on a single NR by recording a result of noncompliance for each applicable regulatory citation. If IPP observe only insanitary conditions that did not result in direct contamination or adulteration of product or food contact surfaces (e.g., non-food contact surfaces) while performing a operational

Sanitation verification task, IPP must record the operational sanitation task results of regulatory compliance and record the noncompliance under a separate facilities sanitation verification task. When IPP find insanitary conditions associated with non-food contact surfaces during operational sanitation verification task, IPP must initiate a directed facilities sanitation verification task to document noncompliance even if IPP had not planned to perform a routine facilities sanitation task that day.

### **Performing the Facility Sanitation Verification Task**

The facility sanitation verification task is used to verify that the plant is meeting the facilities/sanitation regulatory requirements (9 CFR 590.500-575) and to verify that the plant is operating under sanitary conditions such that adulteration or contamination of product will not occur.

IPP must verify whether the plant is compliant or noncompliant with the facilities sanitation requirements. IPP must evaluate the conditions observed in the plant. In order to determine compliance, IPP should ask questions such as, but not limited to, the following:

- Is the light intensity at the point of inspection at the breaking machine operator station at least 50 foot candle? (9 CFR 590.520(a))
- Are functional hand wash facilities available to each breaking machine operator, and are the operators sanitizing their gloved hands? (9 CFR 590.522(b))
- Is there sufficient ventilation that provides a positive flow of outside filtered air through the room to evacuate off odors and vapors that may accumulate in the room? (9 CFR 590.500(a) and 590.500(j))
- Are the doors and windows designed and installed to prevent the entrance of rodents, flies, other insects, dust, and dirt? (9 CFR 590.500(e))
- Are the doors leading into rooms where edible product is processed of solid construction and fitted with self-closing devices? (9 CFR 590.500(e))
- Are there a sufficient number of adequately lighted dressing rooms and toilet rooms, ample in size, and separate from rooms and compartments in which shell eggs or egg products are handled, processed, or stored? (9 CFR 590.500(l)(1))
- Are the floors, walls, ceiling, partitions, posts, doors, and other parts of structures constructed and made of materials that facilitate their use and allow for thorough cleaning? (9 CFR 590.500(i))

- Are the welfare facilities (toilet and dressing rooms) kept clean and adequately ventilated to eliminate odors and supplied with soap, towels, and tissues? (9 CFR 590.560(b))
- Are the floors sloped to the drains, and are the floor drains equipped with traps and constructed to minimize clogging? (9 CFR 590.500(g))
- Is the water supply (both hot and cold) used for egg processing and handling operations clean and potable with adequate pressure and facilities for distribution throughout the plant? (9 CFR 590.500(h)) Is the water supply protected against contamination and pollution? (9 CFR 590.500(h))
- Is the wastewater from processing equipment being piped directly to drains? (9 CFR 590.500(g))
- Is every room or compartment that handles or processes any shell eggs or egg products maintained in a clean and sanitary condition? (9 CFR 590.500(j))

Insanitary conditions may be isolated (e.g., damaged box with exposed product, product residue in containers from previous day's production) and only affect a limited area of the plant. As such, they will not affect the sanitary condition of other product or equipment. In such cases, IPP must document the noncompliance and take the appropriate enforcement action (e.g., apply USDA Retain-Reject Tag to the product or the equipment).

In other instances, the insanitary conditions may be such that the product produced in the plant may have been prepared, packaged, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. For example, if an inspector finds gross rodent infestation in a plant, then the product prepared, packed, or held under those conditions may have become contaminated with filth, and IPP may need to immediately withhold the marks of inspection (9 CFR 590.420(c) and 9 CFR 500.3(a)(4)) and contact the District Office through the appropriate chain of command.

## Summary

FSIS Directive 5030.1, Chapter II, Sections I – V, gives instruction on how the inspector is to go about verifying the sanitary conditions of the plant and its processes and includes a list of questions to help the IPP in their GAD process. The IPP must use professional knowledge and good judgement when determining whether the plant meets sanitation requirements.

If IPP determine that the plant is meeting the sanitation regulatory requirements in a particular area of the facility, IPP must document those findings in PHIS.

If the plant is not meeting the regulatory requirements, IPP are responsible for documenting the noncompliance in PHIS, issuing an NR, and initiating the appropriate action (9 CFR 590.426 or 9 CFR 500), if warranted.

**Note: If an egg products plant chooses to implement the sanitation requirements (9 CFR part 416) included in the final rule prior to their implementation dates, IPP are to use FSIS Directive 5000.1, Rev. 5, Verifying an Establishment's Food Safety System to verify an egg products plant's compliance with those requirements.**







