

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

FSIS DIRECTIVE

5030.1,
Revision 1

4/13/18

INSPECTION METHODOLOGY UTILIZING THE PUBLIC HEALTH INFORMATION SYSTEM FOR THE VERIFICATION OF REGULATORY COMPLIANCE IN EGG PRODUCTS PLANTS

CHAPTER I - GENERAL

I. PURPOSE

This directive is being reissued to clarify instructions to inspection program personnel (IPP) regarding how they are to verify that egg products plants are meeting the regulatory requirements of 9 CFR 590. Also, the Public Health Information System (PHIS) egg products task library (Attachment 2) includes modifications to the listing of regulations that IPP are to verify when conducting verification tasks and clarifying instructions for verification of the Big 8 Formulation and Monthly Volume Reporting tasks in PHIS based upon data analysis results. IPP are to note that in PHIS they will see the term “establishment” used for egg product plants. The directive also provides instructions on how to use PHIS to schedule and document inspection activities.

KEY POINTS:

- *Provides updated screenshots and instructions for imported unpasteurized liquid egg products received at an official egg products plant*
- *Provides updated instructions for completing Noncompliance Records (NRs), as well as modifications to the Trends of Noncompliance section, Meeting Agendas, Memorandums of Interview (MOIs), PHIS task library (Attachment 2), and other types of documentation within PHIS*

II. CANCELLATION

FSIS Directive 5030.1, Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants, 4/17/14

III. BACKGROUND

FSIS conducts inspection activities at egg products plants as required under the Egg Products Inspection Act (EPIA). FSIS egg products inspection regulations are in 9 CFR 590. Under the EPIA, an egg product is adulterated if it has “been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.” IPP are to verify that sanitary conditions in the plant are such that adulteration of product does not occur by verifying that the regulations are met.

IV. WEEKLY MEETINGS

DISTRIBUTION: Electronic

OPI: OPPD

A. IPP are to have weekly meetings with plant management to discuss issues of concern. The meetings may involve discussing individual noncompliance, developing trends of noncompliance, findings on the part of the IPP that show compliance but warrant discussion, or other topics that arise. IPP may use PHIS Inspection Verification 'Meeting Agenda' feature to prepare the meeting agenda. IPP are to share a copy of the meeting agenda with plant management when requested. In addition, plant management may wish to share information or concerns at the weekly meetings. See [FSIS Directive 5010.1](#), *Food Safety Related Topics for Discussion During Weekly Meetings with Establishment Management*, for suggested topics for weekly meetings.

NOTE: IPP have access to an 'Inspection Notes' feature in PHIS that allows inspectors to capture information in between weekly meetings that can be included in the meeting agenda and used to create the MOI. IPP are not to use the MOI as a means to document daily conversations with plant employees.

B. On a periodic basis, about once a month as scheduled using the PHIS 'Update Plant Profile' task, IPP are to ask plant management at the weekly meeting whether it has made any changes in the production process or other changes that could affect the safety of the product. If IPP learn that plant management has made a change in its process, based on the nature of the change, IPP are to perform the appropriate verification activities outlined in this directive. If IPP are unsure how to proceed, they are to contact their supervisor for guidance. IPP are to update the applicable sections of the plant profile in PHIS as necessary to ensure that it accurately reflects the plant's operations and programs. See [FSIS Directive 5030.2](#), *Managing the Establishment Profile in the Public Health Information System (PHIS) for Egg Products Inspection*, for instructions on maintaining the plant profile.

C. IPP are to take notes at the weekly meetings and may document the notes in an MOI generated from the meeting agenda feature in PHIS. The MOI is to include the date of the meeting, who was at the meeting, and details about the specific topics discussed including answers to any questions asked during the meeting. IPP are to provide plant management with a copy of the MOI. If plant management objects to anything written in the MOI, IPP are to follow the instructions in [FSIS Directive 5010.1](#). IPP are to attach any documents provided by the plant in the weekly meeting and reference the attachment in the MOI.

V. PHIS VERIFICATION METHODOLOGY

A. [FSIS Directive 13,000.1](#), *Scheduling In-plant Inspection Tasks in the Public Health Information System (PHIS)*, contains instructions on how to schedule tasks and use the task calendar in PHIS. In situations where IPP are unable to complete all tasks in a given month, they are to use the priority scale (See Attachment 1 – Task Priority List) to decide which tasks are more important to complete.

B. The Task Priority List (Attachment 1) ranks the various inspection and sampling procedures in order of priority, with 1 being the most important and 6 being least important. IPP are to ensure that when tasks cannot be completed, they focus on performing the most important tasks. In other words, if IPP are unable to complete all tasks, they are to drop the least important (priority 6) ones first. IPP are to focus on accurately and thoroughly performing and completing higher priority tasks as instructed through this directive.

C. IPP are to verify regulatory requirements in one or more areas of the plant. IPP are to gather information regarding what they see occurring in the operation and use professional knowledge and good judgment when determining whether the plant has met the regulatory requirements. IPP are also to assess the information available in the plant by considering all available information and then making a determination as to whether the observed situation creates insanitary conditions or causes

adulteration of product (9 CFR 590.500-590.575), prevents FSIS from performing inspection (9 CFR 590.132), or violates other specific regulatory requirements. When IPP determine that the plant has failed to meet the regulatory requirement, they are to evaluate what is known for a fact and then take appropriate action (9 CFR 590.426).

D. IPP are to use the following thought process when performing verification duties:

1. Gather all available information, including any relevant records generated by the plant;
2. Observe plant conditions;
3. Observe product and verify temperature measurements for applicable regulatory requirements;
4. Assess the significance and meaning of the information gathered;
5. Determine whether the information supports a finding of regulatory compliance; and
6. Document findings in PHIS. Refer to Chapter IV, Section II of this directive.

E. To assess the significance and meaning of the information gathered, IPP are to consider what each piece of information taken separately, or with other findings, means to ensure that products are not adulterated (9 CFR 590.420(c)). IPP are to consider information that they have gathered in the context of past findings and to look for any patterns or trends in the findings. IPP are to consider the following:

1. Are conditions in the plant getting worse over time?
2. Are the same or similar problems occurring repeatedly or consistently occurring on a seasonal basis?
3. Is the plant responding effectively and in a timely manner to problems that do arise (9 CFR 590.504)?

F. To determine whether the information supports a finding of regulatory noncompliance, IPP are to determine, based on all the available information, whether one of the following findings emerges from the evidence that the plant:

1. Is not maintaining sanitary conditions (9 CFR 590.504(a));
2. Has produced or shipped adulterated product (9 CFR 590.504(b), (d), and (o)); or
3. Is not meeting other requirements.

NOTE: There can be conditions in the plant that are less than perfect but that would not represent noncompliance with the regulations because they are not creating insanitary conditions, adulterating product, or preventing FSIS personnel from performing inspection activities.

G. When IPP document noncompliance, they are to describe why the findings led them to a determination of noncompliance. If IPP are uncertain whether the information supports a particular determination, they are to discuss the issue with their immediate supervisor.

H. If IPP have concerns about circumstances that may indicate systemic problems, or there is reason

to believe that product may have become adulterated, IPP are to bring these issues to the attention of their supervisor immediately.

VI. SUPERVISORY RESPONSIBILITIES

A. The supervisor plays a key role in ensuring that decisions made by IPP are consistent with FSIS statutory authority and Agency policy, and that they perform their duties in accordance with prescribed inspection methods and procedures addressed in this directive.

B. Supervisory personnel are to ensure that IPP correctly apply inspection methodology, make informed decisions, properly document findings, and take appropriate enforcement actions, as instructed in this directive.

C. Supervisory personnel are to refer to the current version of the [FSIS Guide for Conducting In-Plant Performance System \(IPPS\) Assessments](#) for additional guidance and instructions.

CHAPTER II - SANITATION

I. GENERAL

A. IPP are to use the verification methodology described in Chapter I, Section V, above, to inspect unpasteurized and pasteurized egg products and to verify that the plant maintains the sanitary condition of the premises and equipment (9 CFR 590.504(a)).

B. IPP are to have knowledge of the egg products inspection regulations in order to recognize non-compliant situations.

C. IPP are to conduct verification activities listed below as many times in a shift as necessary to ensure that operations are conducted in a sanitary manner.

II. VERIFYING SANITATION REQUIREMENTS

A. IPP are to perform sanitation verification tasks as a routine task at the designated frequency specified under Section III. A. IPP may also initiate a sanitation verification task as a directed task when conditions suggest that an insanitary condition may occur, or when they observe noncompliance with the sanitation regulatory requirements.

B. There are three general types of sanitation verification tasks IPP may perform to verify that a plant is meeting the regulatory requirements for sanitation. Each task type includes a recordkeeping verification component and a review and observation (e.g., "hands-on") component. The general type of sanitation tasks are:

1. Pre-Operational Sanitation Verification: IPP are to use the Pre-Operational Sanitation Verification task 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).
2. Operational Sanitation Verification: IPP are to use the Operational Sanitation Verification task 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 590.504-590.575).
3. Facility Sanitation Verification: IPP are to use the Facility Sanitation Verification task to verify

that the plant is meeting the facilities/sanitation regulatory requirements (9 CFR 590.504-590.575) and to verify that the plant is operating under sanitary conditions such that adulteration of product will not occur.

C. Each time they perform the sanitation verification tasks, IPP are to verify one or more of the sanitation regulatory requirements (9 CFR 590.500-590.575). Over the course of time, IPP are to verify all sanitation regulatory requirements.

D. When time allows, IPP are to verify multiple sanitation regulatory requirements in one or more areas of the plant each time they perform the sanitation verification task.

E. In many cases, IPP will be able to verify that plants meet one or more sanitation requirements while observing the plant during other verification activities. Whenever IPP are observing conditions and operations in the plant as part of their verification activities or other duties, they are to be aware of the sanitary conditions and verify that the plant is meeting the sanitation requirements by maintaining the facilities, equipment, and utensils in a sanitary manner and by following practices that protect product from adulteration (9 CFR 590.504(a)). IPP are to be aware that they have the authority to take appropriate regulatory action when they observe insanitary conditions, including non-product contact surfaces, while performing pre-operational or operational sanitation verification.

F. If IPP determine that the plant is meeting the sanitation regulatory requirements in a particular area of the facility; they are to document those findings of compliance in PHIS in accordance with Chapter IV of this directive. If IPP find that the plant has not complied with the sanitation regulatory requirements, then IPP are to assess the situation and determine whether the situation creates insanitary conditions, causes adulteration of product, or prevents FSIS personnel from performing inspection. There may be conditions in the facility that are less than perfect, but they would not represent noncompliance with the sanitation regulatory requirements unless they are creating insanitary conditions, adulterating product, or preventing FSIS personnel from performing inspection activities. IPP are to use professional knowledge and good judgment when determining whether the plant meets sanitation requirements.

G. If the plant is not meeting the regulatory requirements, IPP are responsible for documenting how the plant is not doing so in PHIS and initiating the appropriate action (9 CFR 590.426). Refer also to Chapter IV, Section II of this directive.

H. When IPP are to determine whether the plant maintains food contact surfaces, both pre-operational and in operation, in sanitary condition, they are to evaluate the conditions in the plant. IPP should ask questions such as, but not limited to, the following:

1. Are product contact surfaces being contaminated or adulterated? (9 CFR 590.504(n) and 590.552(a));
2. 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));
3. Is the breaker operator performing the function in a sanitary manner? (9 CFR 590.522(b));
4. 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));
5. 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);

6. 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));
7. Are strainers and filters providing effective removal of shell fragments from collected liquid egg products? (9 CFR 590.522(v));
8. 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));
9. 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)); and
10. Are egg shells being adequately removed from the processing area and not accumulating on equipment or floors? (9 CFR 590.522(g))

I. When IPP verify that the plant meets facilities sanitation requirements, they are to evaluate the conditions observed in the plant. In order to determine compliance, IPP are to ask question such as, but not limited to, the following:

1. 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));
2. Are functional hand wash facilities available to each breaking machine operator, and are the operators sanitizing their hands or gloves (when worn)? (9 CFR 590.522(b));
3. 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));
4. 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));
5. 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));
6. 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));
7. 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));
8. 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));
9. 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));
10. 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));

11. Is the water supply protected against contamination and pollution? (9 CFR 590.500(h));
12. Is the waste water from processing equipment being piped directly to drains? (9 CFR 590.500(g)); and
13. 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))

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 are to document the noncompliance and take the appropriate enforcement action (e.g., apply USDA Retain-Reject Tag to product or equipment).

K. 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 contact the District Office (DO) through the appropriate chain of command.

III. PRE-OPERATIONAL AND OPERATIONAL SANITATION VERIFICATION TASKS

IPP are to:

1. Perform one routine Pre-Operational Sanitation verification task daily;
2. Perform one routine Operational Sanitation verification task in an assignment during each shift;
3. Perform the Facilities Sanitation verification task when it appears in the PHIS inspection task list as a routine task; and
4. Perform additional "inspector directed" sanitation verifications as warranted by conditions observed at the plant. For example, if during the performance of verifications unrelated to sanitation (refer to Chapter III), inspection personnel observe insanitary conditions, they are to perform the appropriate Sanitation verification task. IPP are also to perform sanitation tasks as directed by their supervisor.

IV. PRE-OPERATIONAL SANITATION VERIFICATION PROCEDURES

A. When performing hands-on pre-operational sanitation inspection on a daily basis, IPP are to 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.

B. IPP are to 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-operational inspection (e.g., how many pieces of equipment or how many production areas they will inspect on a particular day). IPP can use, but are not limited to, the following questions to help determine what they will inspect:

1. Which pieces of equipment will directly contact exposed product?
2. Which pieces of equipment are the hardest to clean?
3. Which pieces of equipment are easiest to clean?
4. How recently has the sanitary condition of equipment in the processing areas been verified by FSIS?
5. Is there a history of pre-operational sanitation noncompliance documented by FSIS?
6. 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?

C. During the performance of the review and observation component of the pre-operational sanitation procedure, IPP are to:

1. 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);
2. In very small facilities that have a limited amount of equipment at which to look, IPP are to follow the same thought process when determining what equipment to look at during the performance of the pre-operational sanitation verification;
3. 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); and
4. 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.

D. In determining regulatory compliance, IPP are to 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-operational sanitation conditions, IPP are to use professional judgment in determining whether the plant's pre-operational 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).

E. IPP are to focus on the following factors in making this determination:

1. 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);
2. The condition of surfaces or equipment that may harbor contaminants (e.g., CIP pipes, holding tanks, the underside of food contact belts, or conveyors/equipment that can contain product residues); and
3. 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.

F. When IPP find product contact surfaces unclean prior to operations, they are to take an action under 9 CFR 590.426 to prevent contamination or adulteration of product. IPP are to maintain any control actions until the plant has restored sanitary conditions.

G. IPP are to document the results of their verification activities, including any noncompliance, following the instructions in Chapter IV of this directive.

H. When determining whether noncompliance exists, IPP are only to 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.

I. 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, they are to document noncompliances on a single Pre-Operational 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 procedure, they are to record the Pre-Operational Sanitation procedure 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 surface during Pre-Operational Sanitation verification procedures, IPP are to 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.

V. OPERATIONAL SANITATION VERIFICATION

A. IPP are to verify operational sanitation regulatory requirements by performing the Operational Sanitation verification task that appears on the PHIS task list.

B. When IPP verify that processing activities meet regulatory requirements (9 CFR 590.500-590.575), they are to evaluate the processing procedures and associated activities observed in the facility. IPP are to verify that processing operations in the plant are such that adulteration of product does not occur. IPP do this by ensuring that the regulations associated with processing are met. To determine compliance, IPP are to ask question such as, but not limited to, the following:

1. 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));
2. 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));
3. 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 590.522(m));
4. 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));

5. 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));
6. 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));
7. Are the shell eggs that have received a spray rinse adequately dry at the time of breaking? (9 CFR 590.516(b)); and
8. 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))

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

D. Using the information gathered during these verification activities, IPP are to determine whether noncompliance exists. IPP are to use any findings as prompts 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:

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

E. IPP are to document the results of their verification activities, including any noncompliance, per the instructions in Chapter IV of this directive.

F. If IPP observe contamination of product or direct food contact surfaces and insanitary conditions of facilities, equipment, or utensils while performing the Operational Sanitation verification task, they are to 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 of product or food contact surfaces (e.g., non-food contact surfaces) while performing an Operational Sanitation verification procedure, they are to record the Operational Sanitation procedure results of regulatory compliance and record the noncompliance under a separate Facilities Sanitation verification task. When they find insanitary conditions associated with non-food contact surfaces during Operational Sanitation verification procedures, IPP are to initiate a directed Facilities Sanitation verification task to document noncompliance even if they had not planned to perform a routine Facilities Sanitation task that day.

CHAPTER III – VERIFICATION REQUIREMENTS

I. FOOD SAFETY VERIFICATION REQUIREMENTS

A. IPP are to verify food safety regulatory requirements by performing the Food Safety verification

tasks that appear on the PHIS task list. The Food Safety verification tasks will appear on the plant's inspection task list according to the specific Food Safety process categories (See [FSIS Directive 5030.2](#), *Managing the Plant Profile for Egg Products*, Chapter II).

B. When IPP verify that egg products plants meet food safety requirements, they are to evaluate the food safety procedures and associated activities observed in the plant. IPP are to verify that the plant meets the applicable food safety regulatory requirements (9 CFR 590.500-580) to ensure that products are not adulterated. In order to determine compliance, IPP should ask questions such as, but not limited to, the following:

1. Are dirty and leaker shell eggs being precluded from entering, and being broken in, the breaking room? (9 CFR 590.510(c));
2. Have shell eggs that entered the breaking room with fecal, mold, or foreign material contamination on the shell contaminated the breaker cracker head or separator cups after transfer? (9 CFR 590.504(m) and 590.510(c));
3. If the plant breaks checks and eggs with a portion of the shell missing, are they free of adhering dirt and foreign material and the shell membrane not ruptured? (9 CFR 590.510(c)(1));
4. If the plant breaks eggs damaged during candling or transfer that have a portion of the shell and shell membranes missing, are they clean, is the yolk unbroken, and are the contents of the egg contained within the shell (not extruding over the outside shell)? (9 CFR 590.510(c)(2));
5. Is the plant ensuring that eggs with meat or blood spots are being removed in an acceptable manner prior to breaking those eggs? (9 CFR 590.510(c)(3));
6. Are liquid egg products meeting the minimum temperature and holding time requirements to achieve complete pasteurization throughout the entire pasteurization run? (9 CFR 590.570(b));
7. Is the plant conducting *Salmonella* testing on liquid, frozen, or dried egg products? (9 CFR 580(b));
8. Is the plant immediately notifying IPP of *Salmonella* positive test results? (9 CFR 590.580(c));
9. Is the plant supplying the test results on all egg products analyzed for *Salmonella*? (9 CFR 590.580(c));
10. Are the ingredients/substances added in the processing of egg products clean, approved for their intended use, at the correct concentration or percentage, and fit for human food? (9 CFR 590.504(j));
11. Are ineligible eggs or eggs contaminated with feces or foreign material being removed and segregated from the eggs being broken such that they are not contaminating the egg products being produced? (9 CFR 590.504(b)); and
12. During the final organoleptic examination of liquid, dried, and frozen egg products, are foreign material, any off-conditions, or unsatisfactory odors detected? (9 CFR 590.5(Adulteration) and 590.504(b)).

C. Each Food Safety task has two components: a recordkeeping component and a review and

observation component. IPP are to use either of these components, or a combination of the two, to verify regulatory compliance. For example, IPP may review the recording charts (recordkeeping component) of the continuous pasteurizer recording device (paper chart or electronic) or observe the plant employee documenting the results (observation part of the review and observation component) on the recording chart (9 CFR 590.570(a) and (b)). IPP can then calculate and verify the holding time and flow rate (review part of the review and observation component) to determine if the plant is in compliance with the time/temperature requirements for pasteurization for the product being produced.

D. During the recordkeeping component of a verification task, IPP are to gather information by reviewing the required charts, data recording devices, or testing results associated with food safety, e.g., 9 CFR 590.570, 590.575, and 590.580, as well as any additional relevant records generated by the plant.

NOTE: Plants engaged in the transportation, shipment, production, and receipt of eggs and egg products are required to maintain records in accordance with 9 CFR 590.200 for a period of two (2) years. Heat treatment records associated with dried whites shall be maintained for 1 year (9 CFR 590.575(d)).

E. During the review and observation component of a verification task, IPP are to gather information by:

1. Making observations about whether the plant's continuous recording device is recording the actual time/temperature measurements as required by 9 CFR 590.570(a) and (b);
2. Observing the plant employee taking other measurements; or
3. Observing product or conditions within the plant.

F. When IPP document a food safety verification task in PHIS, IPP are to select on the "Activity" tab Review and Observation, Recordkeeping, or Both as the verification (also referenced as components) activity when claiming a task.

II. VERIFICATION OF THE NON-FOOD SAFETY CONSUMER PROTECTION REGULATORY REQUIREMENTS

A. IPP are to verify that plants comply with regulatory requirements designed to protect the consumer in ways other than ensuring food safety.

B. When PHIS schedules a routine non-food safety consumer protection task, IPP are to perform the appropriate verification task. This task includes verifying that plants are complying with labeling requirements (9 CFR 590.411), observing preparation or processing procedures to verify plant compliance (9 CFR 590.500-590.580), reviewing plant records associated with product formulation, condition, and temperature (e.g., examining lots of frozen egg products) to verify compliance with 9 CFR 590.504(l), 590.536(b) and 590.539, and verifying the records and loads of domestic unpasteurized liquid egg products to verify compliance with 9 CFR 590.200 and 590.424.

C. IPP are to perform a directed non-food safety consumer protection task when, during the performance of food safety verification activities, they observe conditions or activities that cause them to suspect that the plant is not meeting non-food safety regulatory requirements. Similarly, if while performing a scheduled non-food consumer protection verification task IPP have food safety concerns, they are to perform the appropriate food safety task as an unscheduled task and take any necessary enforcement actions. For example, if an inspector is performing final inspection of product to determine whether it meets the time/temperature requirements for frozen product (9 CFR

590.536(b)) and upon organoleptic examination determines that the product is off-condition or has an unsatisfactory odor (9 CFR 590.5 (Adulteration) and 590.504(b)), he or she is to perform the applicable food safety task directed as instructed in Chapter III of this directive to verify the applicable regulatory requirements and to determine whether the product is adulterated and document noncompliance if appropriate.

D. IPP are to conduct a final condition examination of the finished product (9 CFR 590.504(l)). IPP examine product to determine whether the product complies with regulatory requirements such as product standards (21 CFR part 160), regulatory minimum or maximum limits of ingredients or components ([FSIS Directive 7120.1](#), *Safe and Suitable Ingredients Used in the Production of Meat, Poultry and Egg Products*), or whether product intended for freezing fails to meet the time and temperature requirements (9 CFR 590.536). If IPP find that product exceeds any of the maximum limits, falls below the minimum requirements, or fails to meet any of the other non-food safety regulatory requirements, there is regulatory noncompliance. For example, during the final condition inspection of a lot of frozen product, IPP do not need to conduct an examination of all containers of the lot but rather a smaller selected sample that represents the entire lot (e.g., a minimum of two containers). If IPP observe any containers of the representative sampling size that fail to meet the time/temperature requirements for pasteurized egg products intended to be frozen (9 CFR 590.536(b)), it would mean that the entire lot is affected and thus fails to meet the regulatory time/temperature requirements.

NOTE: The applicable non-food safety tasks include: General Labeling – Egg Products, Economic/Wholesomeness of Egg Products, and Other Inspection Requirements (EP).

III. VERIFICATION ACTIVITIES UNDER GENERAL LABELING, PRODUCT STANDARDS/IDENTITY, AND NET WEIGHTS

A. IPP are to select one or more products in current production and verify that the applicable labels, containers, and packaging material bearing USDA identification meet the requirements in 9 CFR 590.411.

NOTE: IPP are to be aware that plants are responsible for obtaining label approval by submitting those requests to the Labeling and Policy Development Staff (LPDS) and maintaining labeling records. IPP are also to be aware that the plant is required to make these records available to IPP upon request to review and substantiate compliance with applicable labeling requirements as per 9 CFR 590.220 and 590.411.

B. IPP are to review plant records and product labels and observe plant operations to verify that the product complies with the regulations by determining whether:

1. The plant maintains records to establish that the applicable labels have been submitted to, and approved by, LPDS;
2. The product meets any applicable product standards of identity to ensure that the label is not false or misleading;

NOTE: 9 CFR 590.411 includes, by reference, the requirements for specific standardized egg products under the Federal Food, Drug, and Cosmetic Act, found in 21 CFR 160.

3. The net weight of the product is accurately reflected on its label (9 CFR 590.411);
4. All ingredients have been added in amounts that come within the maximum or minimum level specified (e.g., color preservatives);

5. Ingredients are accurately declared on the product label in order of descending proportions by weight;
6. All required labeling features listed in 9 CFR 590.411 are displayed on the label (e.g., product name, ingredients statement, address line, lot number, net contents, official identification, plant number, and nutritional labeling, unless an exemption applies); and
7. Product formulations and processing procedures are documented to ensure that labels conform to the requirements (9 CFR 590.411).

C. IPP are to verify the presence and accuracy of plant records (9 CFR 590.411) substantiating that each lot produced:

1. Complies with applicable standards of identity or product identity;
2. Contains ingredients, including non-egg ingredients, that are food grade;
3. Meets egg solids requirements;
4. Has batch records that correspond with the volume of packaged product produced; or
5. Meets other requirements as indicated on the product label (e.g., special claims, shelf-life claims).

D. IPP are to issue an NR when product does not comply with a non-food safety regulatory requirement and are to notify the plant orally of the finding. IPP are to consider all relevant factors when determining the amount of affected product. Factors IPP are to consider include such items as the plant's lot identification procedures, receiving records, and production records, as well as the average amount of product produced per shift or per production line. When necessary, IPP are to consult with their supervisor for assistance in determining the amount of affected product.

E. IPP are to take appropriate control actions (9 CFR 590.426), such as retention of product, rejection of equipment or facilities, stopping lines, or refusing to allow the processing of specifically identified product, if they determine that misbranded or adulterated product would enter commerce. Additionally, FSIS may rescind or refuse approval of false or misleading marks, labels, or forms of any container for use with egg products.

F. IPP are to issue an NR when they determine that the process is out of control, resulting in economically adulterated or misbranded product. IPP are to associate (that is, link) the NRs when noncompliances are from the same cause, as described in Chapter IV of this directive.

IV. IPP RESPONSIBILITIES FOR IMPORTED UNPASTEURIZED LIQUID EGG PRODUCT RECEIVED AT AN OFFICIAL EGG PRODUCTS PLANT

A. Personnel in Headquarters (i.e., RMTAD) will send notification via e-mail to inform FLS and in-plant inspection personnel information regarding incoming shipments of imported unpasteurized liquid egg products prior to arrival at the official egg products plant.

B. After being notified by plant management that a shipment of imported unpasteurized liquid egg products has arrived at the official egg products plant, IPP are to log into PHIS under the Import Inspector Role to retrieve the lot information.

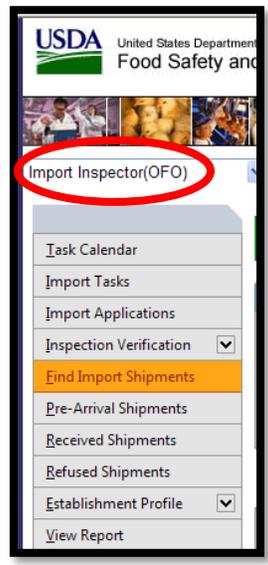


Figure 1

B. Under the Import Inspector Role, IPP are to retrieve the lot information and verify the shipment information in the PHIS system by:

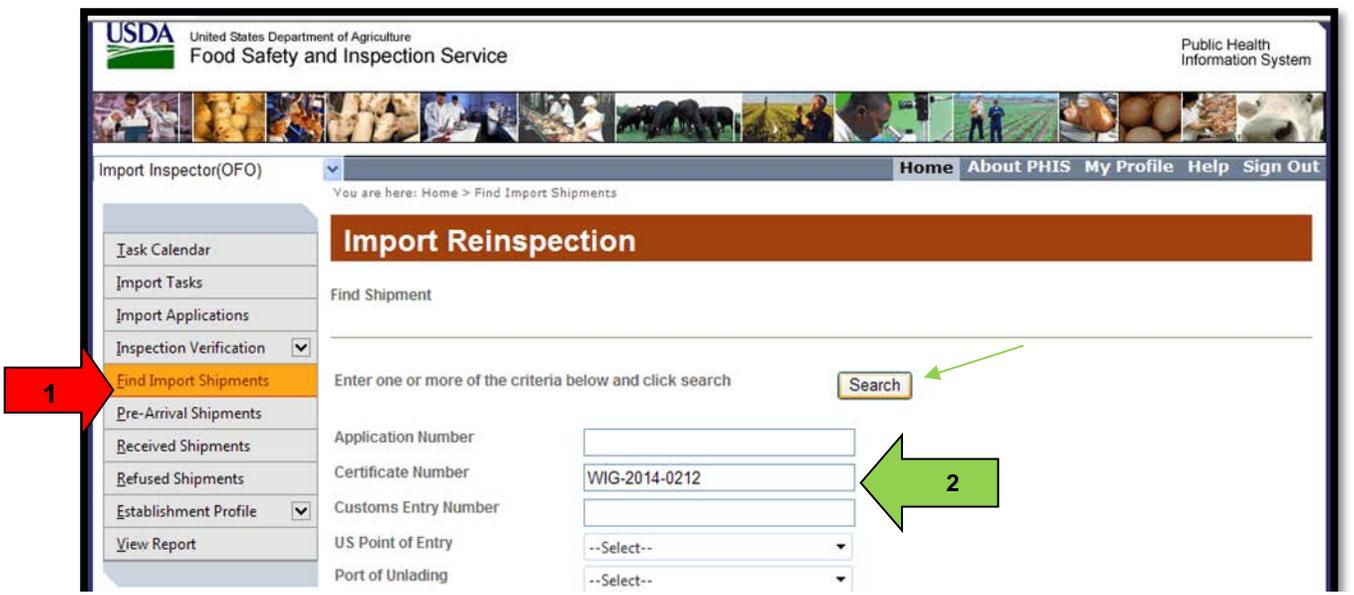


Figure 2

1. Clicking on the **Find Import Shipments** on the navigation menu. Doing so will open the Import Reinspection – Shipments page;
2. Entering the certificate number from CFIA Form 2648 that accompanied the shipment in the certificate number box and click on the **Search** button; and

Inspector Shipments page

Figure 3

3. Reviewing the list of shipments on the Import Reinspection – Shipments page, (categorized by the application number) and clicking on the arrow next to the application number (which is the number that is automatically generated in PHIS when the application was originally initiated in the system) that is associated with the certificate number that was entered. This action expands the application list to show the lots (Lot ID) associated with the inspection certificate. Note that the Lot status is shown as “Received” as illustrated on the screenshot below (Figure 3a).

Figure 3a

C. After the Lot status is shown as being “Received,” IPP are to click the blue arrow icon next to the lot ID number (Figure 3a). By executing this action, the Import Reinspection – Lot Manager page is presented which shows the inspection assignment, known as “Types of Inspections” (TOIs) to which

the IPP will be conducting (See Figure 4). The TOIs that IPP will be performing are: **Certification, Label Verification, and Product Exam-3.**

Inspector Lot Manager page – Shows TOIs assigned

The screenshot displays the 'Inspector Lot Manager' interface. On the left is a navigation menu with options like 'Task Calendar', 'Import Tasks', and 'Find Import Shipments'. The main content area is titled 'Import Reinspection' and shows details for an application with number 250590. A red arrow points to the 'View Application | Edit Application' links. Below the application details are buttons for 'Lot Tracking', 'Refused Entry', and 'Add Unscheduled TOI'. A table lists assigned TOIs: Certification, Label Verification, and Product Exam - 3, all with a status of 'Assigned'. Below this is a 'Pending Actions' table showing 'Lot Reinspection' assigned on 01/30/2014. At the bottom is a 'Lot Event Log' table showing 'Receive Lot' and 'Draw Assignments' performed by 'NOVELLA BLOSSOM' on 01/30/2014.

You are here: Home > Shipment List > Lot Manager

Import Reinspection

Lot Manager [View Application](#) | [Edit Application](#)

Application No: 250590 Inspection Certificate: WIG-2014-0212
 Submitted: 1/30/2014 Applicant: Chris Guillas
 Importer: Bob Denver Country of Origin: CANADA
 Customs Entry: M7619985338
 Lot ID: 1 Date Presented: 01/30/2014
 Lot On Hold: No Shipping Mark: WIG-2014-2012
 Lot Status: Received

TOI	Inspection Level	Status	SME-Status Decision	Additional Information
Certification	Normal	Assigned		
Label Verification	Normal	Assigned		
Product Exam - 3	Normal	Assigned		

Action	Assigned	Location	Date Assigned
Lot Reinspection		G496	01/30/2014

Lot Event	Performed By	Import Est.	Date	Description
Receive Lot	NOVELLA BLOSSOM		01/30/2014	
Draw Assignments	NOVELLA BLOSSOM		01/30/2014	

Figure 4

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE IMPORT INSPECTION APPLICATION (Meat, Poultry & Egg Products)		1. COUNTRY OF ORIGIN CANADA	2. INSPECTION CERTIFICATE NUMBER WIG-2014-0211
		3. EXPORTING ESTABLISHMENT NUMBER 0042E	
4. U.S. POINT OF ENTRY/CBP PORT CODE 17 / Pembina ND - 7 3401		5. U.S. PORT OF UNLADING/CBP PORT CODE /	
6. IMPORT EST./EGG BREAKING EST. NO. G496	7. NAME & ADDRESS OF FSIS IMPORT EST./EGG BREAKING EST. Estherville Foods, Inc. 105 N. 4th St. Estherville, IA 51334		
8. NAME & ADDRESS OF CUSTOMS BROKER OR APPLICANT Chris Guillas Livingston International 670 Young St. Tonawanda, NY 14150		8a. REFERENCE NUMBER 8b. BROKER/APPLICANT PHONE NUMBER 7196965650 8c. FACSIMILE NUMBER 8d. E-MAIL ADDRESS cguillas@burnbraefarms.com	
9. NAME & ADDRESS OF CONSIGNEE Bob Denver Egg Clearing House 122 Broadway 2nd Floor Dover, NH 03821		10. IMPORTER OF RECORD NUMBER 11. NAME & ADDRESS OF IMPORTER OF RECORD William Dawson Estherville Foods, Inc. 105 N. 4th St. P.O. Box 158 Estherville, IA 51334	
BLOCKS 12 THROUGH 33 REPEAT FOR EACH LOT ON THE INSPECTION CERTIFICATE			
12. LOT NO. 1	13. SHIPPING MARK WIG-2014-0211	14. CUSTOM ENTRY NUMBER(S) M7619985338	15. PRODUCTION DATE(S) FROM: TO:
16. NET WEIGHT OF LOT (pounds) 48000	17. SHIPPING UNIT PACKAGE TYPE NAME Foodtainer	18. NUMBER OF UNITS 1	19. IMMEDIATE UNIT PACKAGE TYPE NAME Foodtainer
		20. NUMBER PER SHIPPING UNIT 1	21. SEAL NUMBER(S) WIG-2014-0211
22. PROCESSING EST. NO. 0042E		23. SOURCE COUNTRY(S) (if different from block 1)	24. SOURCE EST. NO. 0410000000
25. HTS CODE		26. PROCESS CATEGORY Eggs/Egg Products	
27. PRODUCT CATEGORY Egg Products		28. PRODUCT GROUP Whole egg (w/wo added ingredients) - Unpasteurized (Liquid) (Tanker)	
29. SPECIES (Dominant) Chicken		29A. ADDITIONAL SPECIES (if applicable)	
30. DESCRIPTION OF PRODUCT Whole egg - Unpasteurized Liquid		31. SUPPLEMENTAL PRODUCT CODE	
32. BILL OF LADING NUMBER(S)		33. ESTIMATED DATE OF ARRIVAL 2/1/2014	
<small>IN CONSIDERATION of the U.S. Director of Customs and Border Protection granting me/us permission to transfer the packages of foreign food product described on this form which are offered for entry into the United States, I/we agree, under bond filed with said director of Customs and Border Protection and subject to penalties prescribed in laws enacted by Congress and regulations issued there under by the Secretary of Homeland Security, to hold the said food product intact at the location indicated above until it has been inspected and passed by a food inspector from the Food Safety and Inspection Service or has been otherwise disposed of under the supervision of a U.S. Customs and Border Protection Officer or a FSIS Inspector.</small>			
34. PRINTED NAME OF CUSTOMS BROKER OR APPLICANT Chris Guillas		35. SIGNATURE	36. DATE 1/30/2014

Figure 4a

D. Once the Import Reinspection – Lot Manager page is opened, IPP are to click on the “View Application” (See Figure 4) to access FSIS Form 9540-1, *Import Inspection Application* (See Figure 4a) which contains the imported shipment product information that was electronically submitted by HQ personnel.

1. IPP are to close the application by clicking on the “X” located in the upper right-hand corner of the screen in order to return to the Import Reinspection – Lot Manager page.

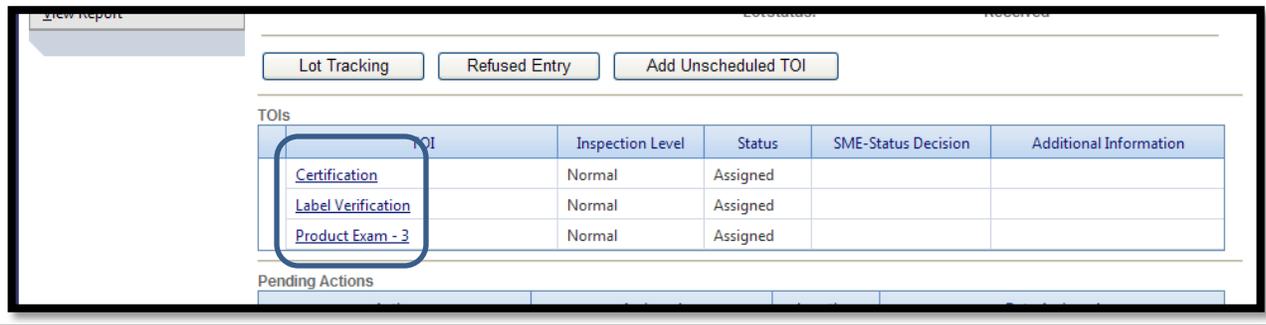


Figure 5

E. From the Import Reinspection – Lot Manager page, IPP are to access the assignments under the TOIs widget (as shown in Figure 5) by conducting the following steps:

NOTE: IPP are to review the electronically submitted FSIS Forms 9540-1, *Import Inspection Application*, and also the hard copy of the foreign inspection certificate that accompanies the imported unpasteurized liquid egg products shipment, CFIA Form 2648, *Certificate of Inspection for Processed Eggs (green form)* to be able to complete the TOIs.

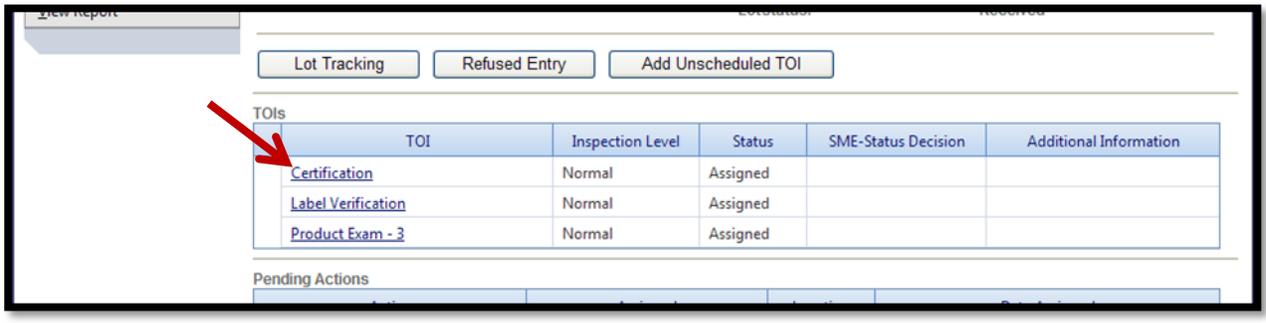


Figure 5a

1. Click on **Certification link** in the TOI widget to record the results of the certification verification for the shipment of domestic and imported unpasteurized liquid egg products in accordance with 9 CFR 590.915;

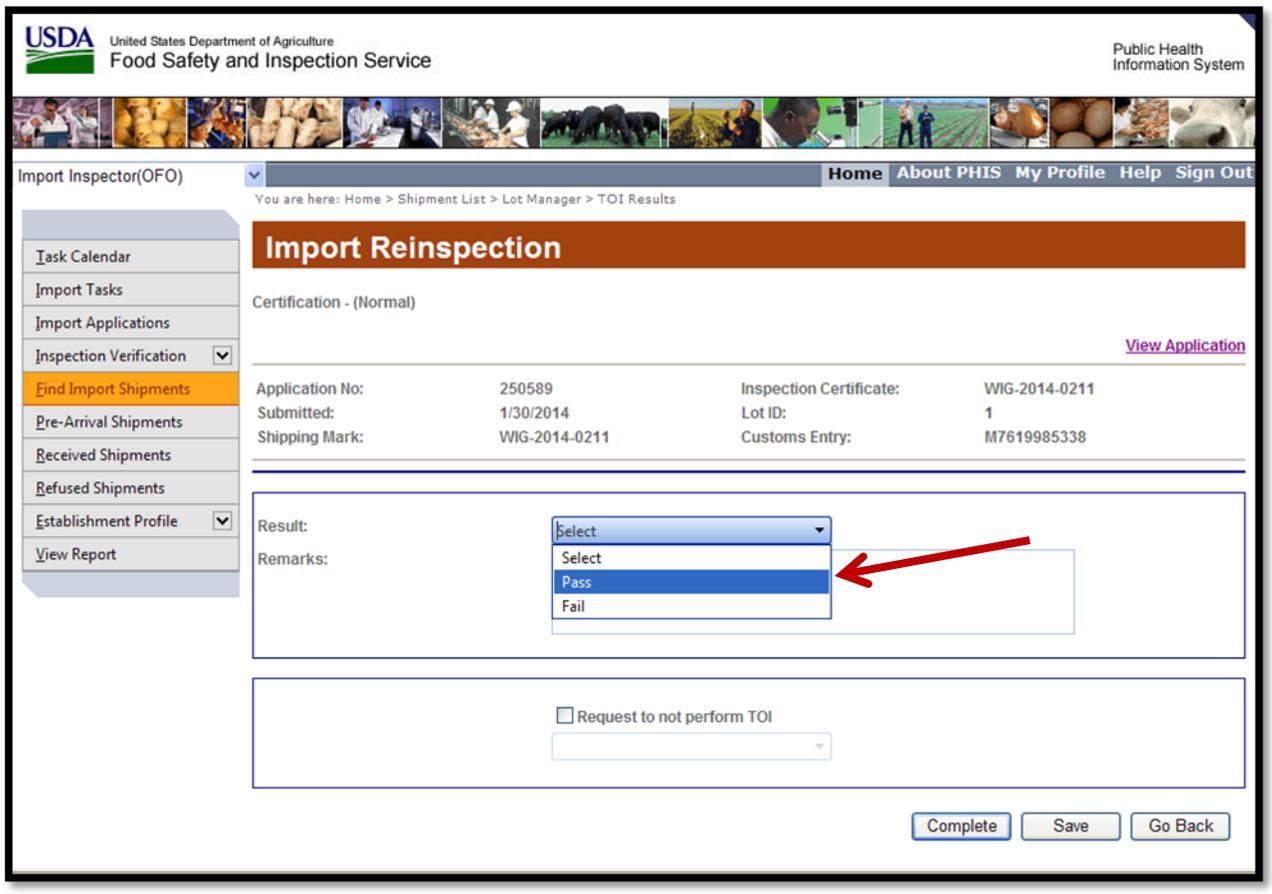


Figure 5b

- a. Inspector Certification TOI page – select either Pass or Fail as applicable for certification TOI;

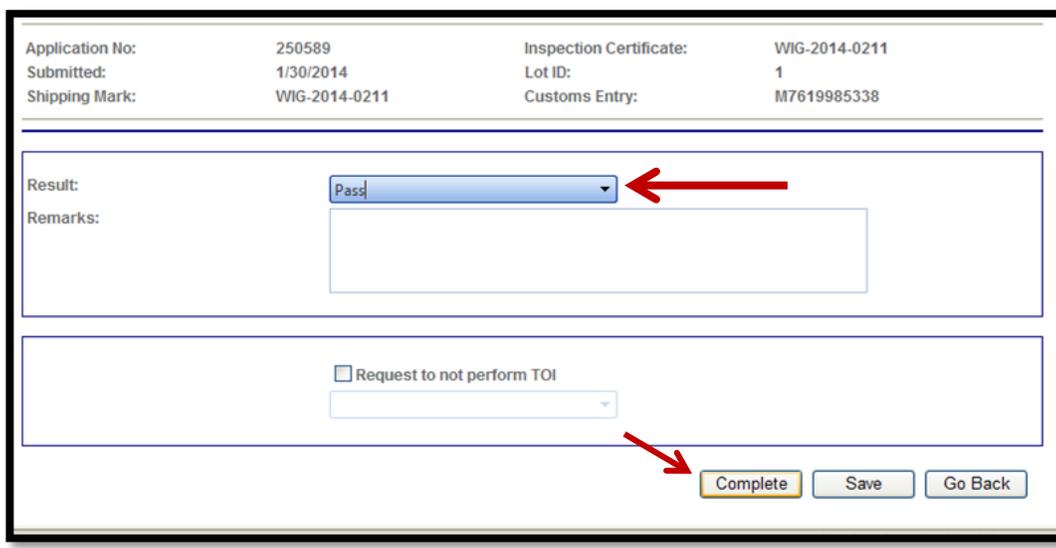


Figure 5c

- b. After verifying the certification accompanying the imported shipment of unpasteurized

liquid egg products are compliant with 9 CFR 590.915, IPP are to select “Pass” and enter any information related to the inspection of the lot under the “remarks” section; and

- c. Then click **Complete** button to finalize this action (Figure 5c). As can be seen in Figure 5d it will show the status as “COMPLETE and Passed” for the certification widget.
- d. If during the performance of the assigned TOIs, IPP discover that the imported egg products do not comply with the U.S. regulatory requirements, IPP are to immediately inform the DO through supervisory channels for guidance and disposition of the lot.

You are here: Home > Shipment List > Lot Manager

Import Reinspection

Lot Manager [View Application](#) | [Edit Application](#)

Application No:	250589	Inspection Certificate:	WIG-2014-0211
Submitted:	1/30/2014	Applicant:	Chris Guillas
Importer:	William Dawson	Country of Origin:	CANADA
Customs Entry:	M7619985338		
Lot ID:	1	Date Presented:	01/30/2014
Lot On Hold:	No	Shipping Mark:	WIG-2014-0211
		LotStatus:	Received

TOIs

	TOI	Inspection Level	Status	SME-Status Decision	Additional Information
COMPLETE	Certification	Normal	Passed		
	Label Verification	Normal	Assigned		
	Product Exam <input type="button" value="Label Verification"/>	Normal	Assigned		

Figure 5d

You are here: Home > Shipment List > Lot Manager

Import Reinspection

Lot Manager [View Application](#) | [Edit Application](#)

Application No:	250589	Inspection Certificate:	WIG-2014-0211
Submitted:	1/30/2014	Applicant:	Chris Guillas
Importer:	William Dawson	Country of Origin:	CANADA
Customs Entry:	M7619985338		
Lot ID:	1	Date Presented:	01/30/2014
Lot On Hold:	No	Shipping Mark:	WIG-2014-0211
		LotStatus:	Received

TOIs

	TOI	Inspection Level	Status	SME-Status Decision	Additional Information
COMPLETE	Certification	Normal	Passed		
	Label Verification	Normal	Assigned		
	Product Exam Label Verification	Normal	Assigned		

Figure 6

2. IPP are to click on **Label Verification link** in the TOI widget to record the results of the label verification for the shipment of imported, unpasteurized liquid egg products. IPP are to verify that the product meets the labeling requirements as outlined in 9 CFR 590.950 and 590.955 and matches the information provided in the CFIA Form 2648. IPP are to follow the same steps under Part E, section 1, subsections a through c as illustrated under Figure 5b and 5c.

You are here: Home > Shipment List > Lot Manager

Import Reinspection

Lot Manager [View Application](#) | [Edit Application](#)

Application No:	250589	Inspection Certificate:	WIG-2014-0211
Submitted:	1/30/2014	Applicant:	Chris Guillas
Importer:	William Dawson	Country of Origin:	CANADA
Customs Entry:	M7619985338		
Lot ID:	1	Date Presented:	01/30/2014
Lot On Hold:	No	Shipping Mark:	WIG-2014-0211
		LotStatus:	Received

TOIs

	TOI	Inspection Level	Status	SME-Status Decision	Additional Information
COMPLETE	Certification	Normal	Passed		
COMPLETE	Label Verification	Normal	Passed		
	Product Exam - 3	Normal	Assigned		

Figure 6a

- a. After IPP complete the action of indicating that the Label Verification has met the regulatory requirements, the Import Reinspection – Lot Manager page will show the status as “COMPLETE and Passed” as shown in Figure 6a.

You are here: Home > Shipment List > Lot Manager

Import Reinspection

Lot Manager [View Application](#) | [Edit Application](#)

Application No:	250589	Inspection Certificate:	WIG-2014-0211
Submitted:	1/30/2014	Applicant:	Chris Guillas
Importer:	William Dawson	Country of Origin:	CANADA
Customs Entry:	M7619985338		
Lot ID:	1	Date Presented:	01/30/2014
Lot On Hold:	No	Shipping Mark:	WIG-2014-0211
		LotStatus:	Received

TOIs

	TOI	Inspection Level	Status	SME-Status Decision	Additional Information
COMPLETE	Certification	Normal	Passed		
COMPLETE	Label Verification	Normal	Passed		
	Product Exam - 3	Normal	Assigned		

Figure 7

3. IPP are to Perform an organoleptic examination of the product received as per 9 CFR 590.424(b), 590.925(b), and 590.930(g), along with Section V (Sampling Plans and Defect Tables for Physical Inspections) of [FSIS Directive 9900.2, Import Reinspection of Meat, Poultry, and Egg Products](#). To enter the results in PHIS, IPP are to click on **Product Exam-3** link which takes IPP to the Import Reinspection – Product Exam-3 page as shown in Figure 7a.

Import Reinspection

Product Exam - 3 - (Normal) [View Application](#)

Application No:	250589	Inspection Certificate:	WIG-2014-0211
Submitted:	1/30/2014	Lot ID:	1
Shipping Mark:	WIG-2014-0211	Customs Entry:	M7619985338

<u>Public Health - Critical</u>			
Specified Risk Material	<input type="text"/>	Ingesta	<input type="text"/>
Fecal	<input type="text"/>	Off Condition	<input type="text"/>
Under Processed	<input type="text"/>	Other Chemical or Physical Hazards	<input type="text"/>
Other Harmful Material	<input type="text"/>		
<u>QCP - Non-Critical</u>			
Other Pathological	<input type="text"/>	Other	<input type="text"/>
<u>Additional Information</u>			
Weight of Samples*	<input type="text"/>	Number of Units Taken*	<input type="text"/>

Result:

Remarks:

Figure 7a

- a. When IPP access the Product Exam-3 page as shown in Figure 7a, they are to complete the required fields. IPP are to follow [FSIS Directive 9900.2](#), Section V (Sampling Plans and Defects Tables for Physical Inspections), Table 1, when determining the sampling plan and defect criteria for a specific product when physical inspection has been assigned. The associated sampling plan for egg products is SP5. IPP are to follow the procedures as outlined in section XIX (Physical Inspection of Egg Products) of [FSIS Directive 9900.2](#) to conduct reinspection of the imported product.
- b. While executing the Product Examination TOI, IPP are to refer to Attachment 1 (Sampling Defect Tables – Inspection) and use the sampling plan SP5 when a physical examination has been assigned for egg products. As per Attachment 1, the corresponding sampling plan SP5 references the matching Defect criteria Product Examination-3 (PE3) which is delineated in Attachment 2, (Defect Classifications – PE3).

NOTE: Product examination is an organoleptic, physical type of inspection in which IPP look for defects such as extraneous materials (i.e., wood, glass, chemical, and insects) and off-condition odors. The defects are classified either as a public health (PH) concern or as other consumer protection (OCP) concern (i.e., quality).

- c. The egg products tanker that arrives at the plant is a bulk package, (i.e., the tanker is the immediate container and represents one sample unit). When product is bulk packaged, in this case the egg products tanker, the sample unit to be collected for the organoleptic examination should weigh approximately 12 pounds or 1.5 gallons by volume. The numbers that should be entered in the Product Exam-3 page under the mandatory fields (marked with asterisk*) are “12” in the ‘**Weight Sample**’ box and “1” in the ‘**Number of Units Taken**’ box.

Import Reinspection

Product Exam - 3 - (Normal) [View Application](#)

Application No:	250589	Inspection Certificate:	WIG-2014-0211
Submitted:	1/30/2014	Lot ID:	1
Shipping Mark:	WIG-2014-0211	Customs Entry:	M7619985338

<u>Public Health - Critical</u>			
Specified Risk Material	<input type="text"/>	Ingesta	<input type="text"/>
Fecal	<input type="text"/>	Off Condition	<input type="text"/>
Under Processed	<input type="text"/>	Other Chemical or Physical Hazards	<input type="text"/>
Other Harmful Material	<input type="text"/>		
<u>OCP - Non-Critical</u>			
Other Pathological	<input type="text"/>	Other	<input type="text"/>
<u>Additional Information</u>			
Weight of Samples*	<input type="text"/>	Number of Units Taken*	<input type="text"/>

Result:	<input type="text" value="Select"/>
Remarks:	<input style="height: 20px;" type="text"/>

Figure 7b

- d. If IPP observe any PH or OCP defect (i.e., off-condition, chemical, or physical hazards, etc.) after examination of the product, then IPP are to enter “1” in the “Off-Condition” or “Other Chemical/Physical Hazard” box – Public Health Critical widget in PHIS, following the defect criteria description under the Product Examination (PE3) table (Attachment 2 – Defect Classification). IPP are to clearly and accurately describe the defects details in the “Remarks” section. IPP are to refuse entry on the lot if a public health defect is determined and notify the DO and await instructions through supervisory channels.

NOTE: These descriptions are the official record of the defect and in the case of a failed TOI, they are used as the official description of the issue conveyed to the foreign government.

You are here: Home > Shipment List > Lot Manager

Import Reinspection

Lot Manager [View Application](#) | [Edit Application](#)

Application No:	250589	Inspection Certificate:	WIG-2014-0211
Submitted:	1/30/2014	Applicant:	Chris Guillas
Importer:	William Dawson	Country of Origin:	CANADA
Customs Entry:	M7619985338		
Lot ID:	1	Date Presented:	01/30/2014
Lot On Hold:	No	Shipping Mark:	WIG-2014-0211
		LotStatus:	Received

TOIs

	TOI	Inspection Level	Status	SME-Status Decision	Additional Information
COMPLETE	Certification	Normal	Passed		
COMPLETE	Label Verification	Normal	Passed		
COMPLETE	Product Exam - 3	Normal	Passed		

Figure 7c

- e. After IPP initiate the action of indicating that the Product Exam – 3 has met the regulatory requirements, the Import Reinspection – Lot Manager page will confirm the status as “COMPLETE and Passed” as shown in Figure 7c.

You are here: Home > Shipment List > Lot Manager

Import Reinspection

Lot Manager

[View Application](#) | [Edit Application](#)

Application No: 250589 Inspection Certificate: WIG-2014-0211
 Submitted: 1/30/2014 Applicant: Chris Guillas
 Importer: William Dawson Country of Origin: CANADA
 Customs Entry: M7619985338
 Lot ID: 1 Date Presented: 01/30/2014
 Lot On Hold: No Shipping Mark: WIG-2014-0211
 Lot Status: Received

TOIs

	TOI	Inspection Level	Status	SME-Status Decision	Additional Information
COMPLETE	Certification	Normal	Passed		
COMPLETE	Label Verification	Normal	Passed		
COMPLETE	Product Exam - 3	Normal	Passed		

Pending Actions

Action	Assigned	Location	Date Assigned
Lot Reinspection		G496	01/30/2014

Lot Event Log [Lot Reinspection](#)

Lot Event	Performed By	Import Est.	Date	Description
Receive Lot	NOVELLA BLOSSOM		01/30/2014	
Draw Assignments	NOVELLA BLOSSOM		01/30/2014	

Figure 8

USDA United States Department of Agriculture
 Food Safety and Inspection Service

Public Health Information System

Import Inspector(OFO) Home About PHIS My Profile Help Sign Out

You are here: Home > Shipment List > Lot Manager > Complete Reinspection

Import Reinspection

Complete Reinspection

[View Application](#)

Application No: 250589 Inspection Certificate: WIG-2014-0211
 Submitted: 1/30/2014 Lot ID: 1
 Shipping Mark: WIG-2014-0211 Customs Entry: M7619985338

Release Acceptable Units

Figure 8a

- Once IPP have completed all three TOIs assignments, IPP are to click on **Lot Reinspection link** under the Pending Actions as shown in Figure 8 which will open the Import Reinspection

– Complete Reinspection page. After this page has been opened, IPP are to place checkmark in the **Release Acceptable Units** box and then click on **Complete** box to finalize this action (as shown in Figure 8a).

5. If there are no impending imported lots that require inspection, IPP can either log out of PHIS by clicking on “Sign Out” or can switch user roles (e.g., Consumer Safety Inspector) to continue conducting and performing tasks in PHIS.

CHAPTER IV – DOCUMENTATION

I. DOCUMENTING VERIFICATION RESULTS IN PHIS

- A. IPP are to use PHIS to document the results of their verification tasks, including findings of regulatory compliance and regulatory noncompliance. For additional instructions on how to use PHIS to document inspection results, please refer to the [PHIS User Guide](#) and [FSIS Directive 13,000.1](#).

B. After IPP have completed a verification task, they are to record the results of the task by scheduling the task and recording the results in the task results page. They are to make the appropriate entries regarding the task and their findings of regulatory compliance or noncompliance by checking appropriate boxes, making appropriate selections from lists, or typing in text as prompted by PHIS.

C. PHIS will prompt IPP to select the specific regulatory requirements that they verified during the inspection task from a list and record their finding of compliance or noncompliance for each one.

D. When IPP find noncompliance, they are to:

1. Notify a representative of plant management as soon as possible (before documenting the findings);
2. Document the noncompliance in PHIS, mark the noncompliance as “final” (see section II, below), print the NR, and present it to plant management. Note that PHIS will allow IPP to document one or more instances of noncompliance as separate documents within a single NR. IPP are to finalize each individual noncompliance and present it to plant management as soon as practical, if they have not finished the inspection task. If IPP find subsequent noncompliances during the remainder of the inspection task, those may be documented separately;
3. Verify that the plant takes necessary actions to return to compliance with the applicable regulations found noncompliant;
4. When the plant has returned to compliance with all regulations with which it was not found not to be in compliance in the NR, IPP are to mark the NR and the associated inspection task as “completed”;
5. When IPP enter inspection results in PHIS, the system will allow IPP to enter information by selecting from appropriate choices wherever possible. In some cases, the possible selections for these data fields will be reflected by the information entered in the PHIS plant profile;
6. If IPP observe that the available selections do not match the plant’s operations, they are to review the plant profile and make any necessary updates. IPP are to refer to FSIS Directive 5030.2 for information about the plant profile and instructions on how to update the profile.

II. DOCUMENTING NONCOMPLIANCE IN PHIS

A. When IPP find noncompliance with one or more regulatory requirements, they are to complete the NR in the PHIS electronic format following the instructions below and in the [PHIS User Guide](#). The date, NR number, inspection task, and plant number are automatically entered by PHIS.

NOTE: The instructions below coincide with the flow for PHIS and are not in order of the numbered blocks on the printed NR.

B. If PHIS is not operational, IPP may complete and issue a paper copy of the NR (FSIS Form 5400-4). However, once PHIS becomes operational again, IPP are to record the applicable procedure and results and document the NR in PHIS.

NOTE: Block 7 on the printed NR is associated with information added from the PHIS task “Activity” tab.

C. *Relevant Regulations* — (Block 6 on printed NR) IPP are to select one or more of the regulatory citations offered on the noncompliance page in PHIS. PHIS will offer the regulatory citations based on the earlier recording of the regulations verified on the task results page. IPP are to verify that the regulatory citation includes all of the specific regulations and requirements that the plant did not meet. If a particular regulatory citation is not available in PHIS, IPP are to type it in the description text block. If IPP believe that the regulatory citation should be available for a particular inspection task, they are to submit the suggestion to PDS through askFSIS.

D. *Description of Noncompliance*—IPP are to include the following elements in their description:

1. A description of each noncompliance in clear, concise terms, including the problem, time of occurrence, location, and effect on the product, if any. The description needs to clearly explain how the IPP’s findings support the determination that the plant did not meet regulatory requirements.
2. An explanation of how IPP notified plant management of the noncompliance (e.g., written or oral).
3. IPP are to review recent similar NRs and select one NR to associate to the new NR in PHIS if the NRs should be linked based on instructions in this paragraph. The selected NR number appears in block 6a of the printed NR. When there is a developing trend of noncompliance, IPP are to include the number of the previous NR with the same cause and a description of how the NR derived from the same cause is included in the description block. When applicable, IPP are to describe any unsuccessful further planned actions taken by the plant to address the noncompliances. IPP may document the identified trend in the meeting agenda feature of PHIS for discussion at the next meeting with establishment management (refer to the [PHIS User Guide](#) for additional instructions on the meeting agenda and MOI features of PHIS). IPP are to discuss developing trend of noncompliance with plant management at the weekly meeting (See Chapter I, Section IV, *Weekly Meetings*).

E. *Affected Product Information*—IPP are to record approximate weight and product name, lot number, or other information available to identify the specific amount of product affected by the noncompliance, if any.

F. *Product adulteration*-IPP are to use the product adulteration check box on the noncompliance page to indicate if the documented noncompliance resulted in any adulterated product being produced.

G. *Retain Tags/Rejected Tags*-If IPP took a regulatory control action (US Retain/Reject tag) in response to the noncompliance, they are to enter the tag numbers.

H. Example of information to be included in the description of noncompliance:

At approximately 0600 hours, after the plant's pre-operational inspection and before the start of production, I performed a pre-operational Sanitation verification procedure. I observed the following instances of noncompliance: Heavy organic matter of liquid egg residue from previous day's production located inside multiple pipes, inlet valves, and gaskets of the High Temperature Short Time (HTST) pasteurization system. Because these surfaces are all actual or potential product contact surfaces, organic matter and product residue in these areas could cause product to become contaminated at the start of operations. I applied U.S. "Reject" tag # B 1469277 to the HTST pasteurization system. A similar noncompliance was documented on NR 05 -13, dated February 13, 2013. The preventive measures of including procedures for cleaning the HTST pasteurization system, pipes, valves, and gaskets in a manner that will prevent organic residue formation were not implemented or were ineffective in preventing recurrence. (9 CFR 590.522(a))

I. *'Either Addressed To or Other Addressed To is required' (Block 4. To (Name and Title) on printed NR)*-- PHIS will provide a list of names from the PHIS Plant Profile Contact tab information to select from or enter the name and title of the responsible plant official, if not listed. IPP are to enter the name of the plant official responsible for responding to the NRs.

J. *Personnel Notified* – Enter the names of the plant management personnel who were notified about the noncompliance. IPP are to select one or more names from the list offered in PHIS. If IPP notified someone other than one of the listed contacts, they are to enter that name in the field.

K. *Signature of Inspection Program Employee* -- IPP are to sign the paper NR form after the noncompliance has been finalized and printed.

L. *Plant Management Response* -- On the printed NR, this block may be completed by the plant.

M. *Signature of Plant Management and Date* -- If plant management responds in writing on block 12 or block 13, a plant official should sign and date the NR.

N. *Verification Signature of Inspection Program Employee and Date* -- Once a plant has returned to compliance for all the regulatory noncompliances documented in the NR, IPP are to navigate to that NR in PHIS and designate it as completed. IPP sign and date the paper NR.

NOTE: The NR can only be marked completed after IPP have verified that the plant has brought itself into compliance with the regulatory requirement that was not met and resulted in the issuance of the NR.

O. The plant is not required to indicate its corrective and preventive measures on the NR, and IPP may need to verify corrective actions by direct observation and reviewing records prepared by the plant.

III. TRENDS OF NONCOMPLIANCE

A. When IPP document a noncompliance and consider whether the noncompliance is associated

with previous instances of noncompliances at that plant, they are to be aware that the word “Link” on the ‘Noncompliance Record (NR) – Noncompliances’ screen is used to associate noncompliances as described in this part.

B. IPP are to associate two or more NRs when they indicate an ongoing trend of related noncompliances or systemic problems with the plant’s food safety system. The following characteristics may help IPP to identify NRs that may be associated, but these factors, by themselves, do not justify associating the NRs:

1. Two or more NRs have the same regulatory citation;
2. Two or more NRs resulted from the same type of inspection task; or
3. Two or more similar NRs occurred within a reasonably close period of time.

C. IPP are to associate NRs when they demonstrate one or more of the following trends:

1. One NR indicates that the plant’s corrective actions for a previous NR were not implemented or did not prevent recurrence of the same noncompliance; or

EXAMPLE: IPP documented noncompliance with 9 CFR 590.515(a)(4) this week at Plant A when they observed that the wash water for the shell egg washer was not changed approximately every 4 hours. Upon reviewing the NR history prior to the weekly meeting, IPP noted another noncompliance with 9 CFR 590.515(a)(4) last week that also documented the same issue. After reviewing the plant’s proposed corrective actions from the previous noncompliance, IPP find that the plant did not implement its proposal to increase the frequency of changing wash water to every 3 hours. IPP concluded that the plant failed to implement the corrective actions, resulting in the recurrence, so they associate the two NRs.

2. Two or more NRs demonstrate repetitive failures of the same aspect of the plant’s food safety operations.

EXAMPLE: IPP documented noncompliance with 9 CFR 590.510(c) this week at Plant C when they observed that the transfer room operator was allowing ineligible leakers and dirty eggs to enter the breaking room (9 CFR 590.5). The plant determined that the employee monitoring the shell eggs exiting the washer had not been properly trained in how to identify and remove all ineligible shell eggs exiting the washer. The preventive measure was to re-train the employee. Upon reviewing the NR history in preparation for the weekly meeting, IPP noted a noncompliance with 9 CFR 590.510(c) from the previous week. In that case, the breaking machine operator was not stopping the machine and removing the contents of broken shell eggs that were of inedible interior quality. The plant had determined that that employee was also not properly trained to handle the equipment and re-trained the employee. Even though these two noncompliances involved different employees at different locations in the plant, IPP decided to associate them because they both indicated that the plant had a loss of process control, and that the plant’s employees had not been properly trained for their assigned duties.

D. When IPP determine that an NR is associated with one or more previous NRs, they are to record the association and briefly describe why they determined that the NRs were associated in the “Inspection Notes” feature of PHIS. If IPP are uncertain whether particular noncompliances are associated, they are to request assistance from their supervisor.

E. The FLS is to ask the following questions regarding trends of noncompliance:

1. Do the NRs indicate a trend of ongoing related noncompliances or systematic problems with the plant's food safety operations?
2. How much time has elapsed between associated NRs?
3. Are there NRs over the past three months that should have been associated with other NRs?
4. Do the NRs establish that there is a persistent problem in the plant's approach to addressing noncompliances (e.g., the plant's procedures led to repeated noncompliances)?

F. Based on the answers to these questions, the FLS is to determine whether IPP are correctly identifying and documenting any trends of noncompliance, and whether a comprehensive food safety assessment should be recommended.

IV. DATA ANALYSIS

PHIS tracks inspection activities that are used to verify the plant's compliance with the egg products inspection regulations. The Data Analysis and Integration Group (DAIG) within the [Office of Data Integration and Food Protection \(ODIFP\)](#) will create a PHIS report that tracks whether inspection activities have been completed. This report will include identifying noncompliance by the type of activity.

V. QUESTIONS

Refer questions regarding this directive to the Policy Development Staff through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Directive 5030.1**
Question Field: Enter question with as much detail as possible
Product Field: Select **General Inspection Policy** from the drop-down menu
Category Field: Select **Regulations/Agency Issuances** from the drop-down menu
Policy Arena: Select **Domestic (U.S.) only** from the drop-down menu

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.



Assistant Administrator
Office of Policy and Program Development

Attachment 1: Prioritization of Procedures

- Priority 1 High
 - Reserved for emergency directed procedures
- Priority 2 High
 - Verification and Follow up Sampling for
 - *Salmonella* (as directed)
 - Pre-operational and Operational Sanitation verification tasks
- Priority 3 Medium
 - Other Sampling (i.e., residues)
 - Facilities/Sanitation verification task
 - Review of Plant Data task
 - Monthly Volume Reporting task
 - Big 8 Formulation Verification task
 - Food Defense Procedures
- Priority 4 Medium
 - Unpasteurized Egg Products Food Safety verification task
 - Pasteurized Not Shelf Stable Egg Products Food Safety verification task
- Priority 5 Low
 - Dried Egg Products Food Safety verification tasks
 - Review/Update plant profile and plant meetings
- Priority 6 Low
 - Economic wholesomeness verification task
 - Other Inspection Requirements task
 - Labeling verification task
 - General/Product Identity/Net weights
 - Export tasks

Attachment 2: PHIS Task Library for Egg Products Verification Tasks

Pre-Operational Sanitation Egg Products

Verification Instructions/Guidance: IPP perform Pre-Operational sanitation verification by inspecting direct food contact surfaces in one or more areas of the plant (e.g., conducting “hands on” inspection) to ensure that the plant adheres to the egg products regulatory requirements for sanitation on equipment and facilities.

Regulations	Regulatory Descriptions
590.504(n)	Utensils and equipment shall be clean and sanitized at start of operations and kept sanitary during all processing operations
590.515(a)(1)	Shell egg cleaning equipment kept in good repair and cleaned after each day’s use or more frequently if necessary
590.522(aa)(2)	Systems for pumping egg liquid directly from egg breaking machines - requirements
590.522(aa)(3)	Mechanical egg breaking equipment shall be cleaned and sanitized prior to use and every 4 hours or more often as needed during operations to maintain sanitary conditions
590.522(d)	Clean breakers required at startup and after lunch periods. Rotate table equipment with clean equipment every 2 ½ hours
590.522(y)	Liquid egg holding vats and containers (including tank trucks) used for transporting liquid egg shall be cleaned after each use and cleaned and sanitized prior to use
590.522(z)	Tables, shell conveyors, and containers for inedible egg product shall be cleaned at end of each shift
590.532(a)	Equipment/facility requirements for tanks and vats for holding liquid eggs
590.536(a)	Freezing rooms kept clean and free from objectionable odors
590.539(f)	Crushers and other equipment used in defrosting operation shall be dismantled at end of each shift, and washed, rinsed and sanitized
590.542	Spray process drying operations sanitation meets requirements
590.547	Albumen flake process drying sanitation requirements
590.548	Drying, blending, packaging, and heat treatment rooms and facilities requirements
590.552(a)(1)	Cleaning of equipment used in egg processing operations in contact with liquid eggs or exposed edible products to eliminate organic matter and inorganic residues
590.552(a)(2)	Equipment shall be cleaned at frequency specified under sanitary requirements for particular kind of operation and type of equipment involved
590.552(a)(3)	C.I.P. (cleaned-in-place) shall be considered acceptable provided cleaning methods and procedures used are equivalent to that of dismantled equipment

Operational Sanitation – Egg Products

Verification Instructions/Guidance: IPP are to verify that the plant adheres to sanitation and operational requirements of the regulations to ensure that processing activities during the production of egg products does not result in the adulteration of product.

Regulations	Regulatory Descriptions
590.10	Administrator may waive provisions of the regulations
590.440	Processing Ova
590.500(d)	Materials/equipment not in use shall be stored in a sanitary manner
590.504(a)	Operations involving processing, storing, and handling of egg products shall be in accord with clean and sanitary methods and conducted as rapidly as practicable
590.504(b)	Any shell egg or egg product not processed or not fit for human food be removed and segregated
590.504(i)	Utensils and equipment contaminated during processing shall be removed and not used again until clean and sanitized
590.504(n)	Utensils and equipment shall be clean and sanitized at start of operations and kept sanitary during all processing operations
590.504(p)	Air that contacts product or product contact surfaces shall come from approved filtered outside air sources
590.508	Candling and transfer-room operations
590.515(a)(1)	Shell egg cleaning equipment kept in good repair and cleaned after each day's use or more frequent if necessary
590.515(a)(2)	Temperature of the wash water shall be 90°F or higher, at least 20°F warmer than the egg and maintained throughout cleaning cycle
590.515(a)(4)	Wash water changed approximately every 4 hours or more often to maintain sanitary conditions
590.515(a)(5)	Replacement water continuously added to maintain overflow
590.515(a)(7)	Washing operation is continuous as eggs not allowed to stand/soak in water
590.515(a)(8)	Prewetting process
590.515(b)	Shell eggs not be washed in breaking room or any room where edible products are processed
590.516	Sanitizing and drying of shell eggs prior to breaking
590.522(a)	Breaking room shall be dust-free condition, free from flies, insects, and rodents
590.522(aa)	Mechanical egg breaking machine shall be operated in a sanitary manner and at a rate to inspect and segregate each egg and insure removal of all loss and inedible eggs
590.522(aa)(1)	Contaminated mechanical egg breaking equipment shall be cleaned, sanitized or replaced with clean equipment
590.522(aa)(2)	Systems for pumping egg liquid directly from egg breaking machines - requirements
590.522(aa)(3)	Mechanical egg breaking equipment shall be cleaned and sanitized prior to use and approximately every 4 hours or more often as needed during operations to maintain sanitary conditions
590.522(b)	Breaking room personnel wash hands thoroughly with odorless soap and water

- each time they enter breaking room and prior to receiving clean equipment after breaking inedible egg
- 590.522(c) Paper towels/tissues used at breaking tables. Cloth towels not permitted
- 590.522(d) Clean breakers required at startup and after lunch periods. Rotate table equipment with clean equipment every 2 ½ hours
- 590.522(e) Cups overflowing not permitted
- 590.522(f) Visual and organoleptic examination of shell egg broken
- 590.522(g) Removal of shell particles, meat and blood spots and other foreign material with approved instrument
- 590.522(h) Adequate cleaning and sanitizing of equipment after inedible egg is broken
- 590.522(j) Inedible or loss eggs contacting any cup or other liquid egg receptacle shall be rejected
- 590.522(k) Drip trays shall be emptied at least once for each 15 dozen eggs or every 15 minutes
- 590.522(m) Ingredients and additives used in or for processing egg products must be handled in clean and sanitary manner
- 590.522(p) Leaker trays washed and sanitized whenever soiled and at end of shift
- 590.522(q) Shell egg containers whenever dirty shall be cleaned and drained; cleaned, drained, and sanitized at end of each shift
- 590.522(r) Belt-type shell egg conveyors shall be cleaned and sanitized approximately every 4 hours in addition to continuous cleaning
- 590.522(s) Cups, knives, racks, separators, trays, spoons, liquid egg pails and other breaking equipment, except for mechanical egg breaking equipment shall be cleaned and sanitized every 2 ½ hours, at the end of each shift and prior to use
- 590.522(t) Utensils and dismantled equipment shall be drained and air dried on approved metal racks
- 590.522(u) Dump tanks, drawoff tanks, and churns cleaned approximately every 4 hours. Pasteurization equipment cleaned at end of day's use or more often if necessary
- 590.522(v) Devices used for removal of shell particles and other foreign material shall be cleaned and sanitized each time necessary but at least once each 4 hours of operation
- 590.522(w) Breaking room equipment cannot be stored on floor
- 590.522(x) Metal containers and lids for other than dried products shall be thoroughly washed, rinsed, sanitized and drained immediately prior to filling
- 590.522(y) Liquid egg holding vats and containers (including tank trucks) used for transporting liquid egg shall be cleaned after each use and cleaned and sanitized prior to use
- 590.522(z) Tables, shell conveyors, and containers for inedible egg product shall be cleaned at end of each shift
- 590.539(a) Defrosting of frozen egg products done in sanitary manner
- 590.539(d)(1) Frozen eggs packed in metal or plastic may be placed in running tap water (70°F or lower) without submersion
- 590.539(e) Handling containers and removing egg product done under sanitary methods
- 590.539(f) Crushers and other equipment used in defrosting operation shall be dismantled at end of each shift and washed, rinsed, and sanitized
- 590.539(f)(1) Intermittent use of crushers shall be flushed after each use and again before placed in use
- 590.539(f)(2) Floors and work tables are to be kept clean
- 590.542 Spray process drying operations sanitation meets requirements

590.547	Albumen flake process drying sanitation requirements
590.548	Drying, blending, packaging, and heat treatment rooms and facilities requirements
590.552(a)(1)	Cleaning of equipment used in egg processing operations in contact with liquid eggs or exposed edible products to eliminate organic matter and inorganic residues
590.552(a)(2)	Equipment shall be cleaned at frequency specified under sanitary requirements for particular kind of operation and type of equipment involved
590.552(a)(3)	C.I.P. (cleaned-in-place) shall be considered acceptable provided cleaning methods and procedures used are equivalent to that of dismantled equipment
590.552(b)(1)(ii)	Sanitizing by use of hypochlorites or other solutions cannot exceed 200 ppm. of available chlorine on equipment surfaces and solution shall be changed if strength is below 100 ppm.
590.552(b)(2)	Shell eggs that are sanitized and equipment that contacts edible products shall be rinsed with clean water after sanitizing if other than hypochlorites sanitizing agents unless approved by Administrator

Sanitation and Establishment Facilities - Egg Products

Verification Instructions/Guidance: IPP use this procedure to verify compliance with the facility and sanitation requirements in one or more areas of the plant.

Regulations	Regulatory Descriptions
590.136	Facilities and equipment furnished by management for use by inspectors
590.146	Drawings and specifications of facility (new and revised)
590.500(a)	Plant free from odor, dust, and objectionable air
590.500(b)	Premises shall be free from refuse, waste materials, odors, rodents and insects
590.500(c)	Building shall be in sound construction and good repair to prevent entrance of vermin
590.500(d)	Materials/equipment not in use shall be stored in a sanitary manner
590.500(e)	Doors and windows are designed and installed to prevent entrance of rodents, flies, other insects, dust and dirt
590.500(f)	Doors/openings required to be rodent-proof construction
590.500(g)	Efficient drainage and plumbing system for the plant and premises
590.500(h)	Water supply (hot and cold) shall be ample, clean, and potable with adequate pressure throughout the plant
590.500(i)	Floors, walls, ceiling, partitions, posts, doors, and other parts of structures shall be of such material, construction and finish to permit thorough cleaning
590.500(j)	Room and compartment in which shell eggs or egg products are handled or processed shall be constructed and designed to insure operating conditions are free from objectionable odors and vapors and maintained in sanitary condition
590.500(k)	Precautions to exclude dogs, cats, and vermin from the plant
590.500(l)(1)	Sufficient number of adequately lighted dressing rooms and toilet rooms, ample in size, separate from rooms and compartments which shell eggs or egg products are handled, processed, or stored
590.500(l)(2)	Toilet facilities required
590.500(m)	Lavatory accommodations and hand washing facilities
590.500(n)	Suitable facilities for cleaning and sanitizing utensils and equipment throughout the plant
590.500(o)	Refuse room requirements
590.502	Equipment and utensils; PCB-containing equipment
590.504(f)	Employees shall wash hands and maintain in clean condition when handling egg products or utensils/containers that may contact egg product
590.504(h)	Approved use of detergents, insecticides or other chemicals to not deleterious affect the eggs or egg products
590.504(j)	Any substance or ingredient added in processing of egg products shall be clean and fit for human food
590.504(k)	Packages or containers shall be of sanitary design and sound condition
590.504(n)	Utensils and equipment shall be clean and sanitized at start of operations and kept sanitary during all processing operations
590.504(p)	Air that contacts product or product contact surfaces shall come from approved filtered outside air sources
590.504(q)	All liquid and solid waste in official plant shall be disposed to prevent product adulteration
590.506	Candling and transfer-room facilities and equipment

590.508	Candling and transfer-room operations
590.515(a)(1)	Shell egg cleaning equipment kept in good repair and cleaned after each day's use or more frequently if necessary
590.515(a)(3)	Approved cleaning compound shall be used in wash water
590.515(a)(6)	Waste water from egg washing operation piped directly to drains
590.520(a)	At least 30 foot candle on all working surfaces; at least 50 foot candle at breaking and inspection stations
590.520(b)	Surface of ceiling and walls are water-resistant and smooth
590.520(c)	Floor water-resistant, free from cracks, rough surfaces, and sloped for adequate drainage
590.520(d)(1)	Ventilation shall provide for a positive flow of outside filtered air through the room
590.520(d)(2)	Ventilation shall provide air of suitable working temperature through the room
590.520(e)	Hand washing facilities requirements in breaking room
590.520(f)	Containers used for packaging egg products not acceptable as liquid egg buckets
590.520(g)	Identification of container for disposal of rejected liquid
590.520(h)	Strainers, filters, centrifugal clarifiers, or other mechanical devices required for removal of shell particles and foreign material
590.520(i)	Separate drawoff room required with filtered positive air ventilation system for packaging egg product
590.522(aa)(2)	Systems for pumping egg liquid directly from egg breaking machines - requirements
590.522(n)	Liquid egg containers not allowed to pass through candling room
590.522(o)	Test kits used provided by plant to determine strength of sanitizing solution
590.530(a)	Liquid egg cooling facility requirements
590.532(a)	Equipment/facility requirements for tanks and vats for holding liquid eggs
590.532(b)	Liquid egg holding tanks or vats equipped with suitable thermometers and agitators
590.532(c)	Inlets to holding tanks/vats to prevent excessive foaming
590.532(d)	Gaskets used meet sanitary standards
590.534	Freezing facilities and air circulation requirements
590.536(a)	Freezing rooms kept clean and free from objectionable odors
590.536(c)	Proper handling/stacking of containers
590.538	Defrosting facilities requirements
590.539(f)(2)	Floors and work tables are to be kept clean
590.540	Spray process drying facilities meets requirements
590.546	Albumen flake process drying facilities requirements
590.548	Drying, blending, packaging, and heat treatment rooms and facilities requirements
590.549	Dried egg storage
590.550	Washing and sanitizing rooms or area facilities requirements
590.552(b)(1)(i)	Chemicals and compounds used for sanitizing shall be approved by Administrator prior to use
590.560(a)	Personnel facilities, including toilets, lavatories, lockers, and dressing rooms shall be adequate and meet the State and local requirements for food processing plants
590.560(b)	Toilets and dressing rooms shall be kept clean and adequately ventilated to eliminate odors and kept adequately supplied with soap, towels, and tissues.
590.560(c)	No person affected with or carrier to any communicable disease in

	transmissible stage or with boils, sores, infected wounds, or wearing cloth bandages on hands shall be permitted to come in contact with eggs in any form or equipment used to process such eggs
590.560(d)	Workers shall wear clean outer uniforms when contacting liquid or dried eggs, containers, or equipment
590.560(e)	Plant personnel handling exposed edible product shall wash hands before beginning work and upon returning to work after leaving work room
590.560(f)	Expectorating or other unsanitary practices are not permitted
590.560(g)	Use of tobacco, wearing of jewelry, nail polish, or perfumes not permitted in any area where edible product is exposed
590.560(h)	Hair nets or caps requirement in breaking and packaging rooms
590.570(a)	Pasteurization facilities requirements.

Unpasteurized Egg Products - Food Safety

Verification Instructions/Guidance: IPP verify that food safety requirements for raw liquid unpasteurized egg products are met, and that the plant adheres to proper food safety requirements of the regulations to ensure that any eggs and egg products not fit for human food do not enter commerce.

Regulations	Regulatory Descriptions
590.5_Adulterated	Adulterated
590.240	Detaining product
590.422	Condemnation of adulterated product
590.424	Reinspection of product
590.45	Eggs and Egg Products Not Intended for Human Food
590.504(b)	Any shell egg or egg product not processed or not fit for human food shall be removed and segregated
590.504(j)	Any substance or ingredient added in processing of egg products shall be clean and fit for human food
590.504(o)(2)	Shipment of nonpasteurized or <i>Salmonella</i> -positive egg product to receive pasteurization, repasteurization, or heat treatment at another official plant
590.510(b)	Shell eggs having strong odors shall be candled and broken separately
590.510(c)(1)	Checks and eggs with portion of the shell missing
590.510(c)(2)	Eggs with clean shells damaged in candling or transfer
590.510(c)(3)	Eggs with meat or blood spots
590.510(d)	All loss or inedible eggs shall be placed in a designated container and handled as required in 9 CFR 590.504(c)
590.510(e)	Incubator reject eggs shall not be brought into the official plant

Shelf Stable Egg Products - Food Safety

Verification Instructions/Guidance: IPP verify that food safety requirements for all heat treated-shelf stable egg products are met, and that the plant adheres to proper food safety requirements of the regulations to ensure that any eggs and egg products not fit for human food do not enter commerce.

Regulations	Regulatory Descriptions
590.5_Adulterated	Adulterated
590.10	Administrator may waive provisions of the regulations
590.45	Eggs and Egg Products Not Intended for Human Food
590.240	Detaining product
590.422	Condemnation of adulterated product
590.424	Reinspection of product
590.504(b)	Any shell egg or egg product not processed or not fit for human food shall be removed and segregated
590.504(j)	Any substance or ingredient added in processing of egg products shall be clean and fit for human food
590.504(o)(1)	Egg products shall be sampled for <i>Salmonella</i> to assure adequate pasteurization
590.510(b)	Shells having strong odors shall be candled and broken separately
590.510(c)	Shell eggs, when presented for breaking
590.510(c)(1)	Checks and eggs with a portion of the shell missing
590.510(c)(2)	Eggs with clean shells damaged in candling or transfer
590.510(c)(3)	Eggs with meat or blood spots
590.510(d)	Loss or inedible eggs placed in dedicated container
590.510(e)	Incubator reject eggs
590.570(a)	Pasteurization facilities requirements
590.570(b)	Pasteurization operations – time/temperature requirements of liquid egg products
590.570(c)	Other methods of pasteurization approved by the Administrator
590.575(a)	Heat treatment of dried whites container requirements
590.575(b)(1)	Minimum requirements for heat treatment of spray dried albumen to not less than 130°F and held continuously at such temperature not less than 7 days and until salmonella negative
590.575(b)(2)	Minimum requirements for heat treatment of pan dried albumen not less than 125°F and held continuously at such temperature not less than 5 days and until <i>Salmonella</i> -negative
590.575(b)(3)	Other methods for heat treatment of spray dried or pan dried may be approved by Administrator upon receipt of satisfactory methods to assure <i>Salmonella</i> - negative products
590.575(d)	Records requirements for heat treatment of dried whites
590.575(e)	Processed and tested dried whites may be labeled “Pasteurized”
590.580(a)	Laboratory tests and analyses of liquid, frozen or dried egg products requirements
590.580(b)	Sampled and analyzed by FSIS-approved lab and method from the final package form
590.580(c)	Laboratory results provided immediately upon receipt to IPP

Pasteurized Not Shelf Stable - Egg Products - Food Safety

Verification Instructions/Guidance: IPP verify that food safety requirements for all heat treated-not shelf stable egg products are met, and that the plant adheres to proper food safety requirements of the regulations to ensure that any eggs and egg products not fit for human food do not enter commerce.

Regulations	Regulatory Descriptions
590.5_Adulterated	Adulterated
590.10	Administrator may waive provisions of the regulations
590.45	Eggs and Egg Products Not Intended for Human Food
590.240	Detaining product
590.422	Condemnation of adulterated product
590.424	Reinspection of product
590.504(b)	Any shell egg or egg product not processed or not fit for human food shall be removed and segregated
590.504(j)	Any substance or ingredient added in processing of egg products shall be clean and fit for human food
590.504(o)(1)	Egg products shall be sampled for <i>Salmonella</i> to assure adequate pasteurization
590.510(b)	Shell eggs having strong odors shall be candled and broken separately
590.510(c)	Shell eggs, when presented for breaking
590.510(c)(1)	Checks and eggs with a portion of the shell missing
590.510(c)(2)	Eggs with clean shells damaged in candling or transfer
590.510(c)(3)	Eggs with meat or blood spots
590.510(d)	Loss or inedible eggs placed in dedicated container
590.510(e)	Incubator reject eggs
590.570(a)	Pasteurization facilities requirements
590.570(b)	Pasteurization operations – time/temperature requirements of liquid egg products
590.570(c)	Other methods of pasteurization approved by the Administrator
590.580(a)	Laboratory tests and analyses of liquid, frozen or dried egg products requirements
590.580(b)	Sampled and analyzed by FSIS-approved lab and method from the final package form
590.580(c)	Laboratory results provided immediately upon receipt to IPP

Economic/Wholesomeness of Egg Products

Verification Instructions/Guidance: IPP verify that egg products are produced in a safe, wholesome manner and do not become adulterated. (Examples include: Final condition examination on all product types, liquid, frozen, and dried, that have been processed and packaged in final package form, inspection of domestic pasteurized/unpasteurized liquid egg products received, and reinspection of all egg product types.)

Regulations	Regulatory Descriptions
590.10	Administrator may waive provisions of the regulations
590.24	Egg products plants requiring continuous inspection
590.26	Egg products entering or prepared in official plants
590.40	Continuous inspection not provided
590.45	Eggs and Egg Products Not Intended for Human Food
590.240	Detaining product
590.420	Continuous inspection requirement
590.422	Condemnation of adulterated product
590.424	Reinspection of product
590.430(a)	Limitation on entry of eggs and egg products
590.430(b)	Processing of inedible egg products separate from edible products
590.435	Wholesomeness and approval of materials
590.440	Processing Ova
590.504(b)	Any shell egg or egg product not processed or not fit for human food be removed and segregated
590.504(g)	Objectionable product or material separate from where shell eggs or egg products are processed, stored, or handled
590.504(h)	Approved use of detergents, insecticides, or other chemicals that do not have a deleterious effect on the eggs or egg products
590.504(j)	Any substance or ingredient added in processing of egg products shall be clean and fit for human food
590.504(l)	Wholesomeness of egg products
590.504(m)	Egg products processed in a manner to ensure removal of blood, meat spots, shell particles, and foreign material
590.510	Classifications of shell eggs used in the processing of egg products
590.530(c)	Cooling and temperature requirements for liquid egg products as specified in Table 1 of this section
590.530(d)	Upon written request liquid cooling and holding temperatures not otherwise provided in this section may be approved
590.530(g)	Previously frozen egg or egg product cannot be added to liquid product for cooling requirements
590.536(b)(2)	Pasteurized egg products intended to be frozen shall be reduced to 10°F or lower within 60 hours from time of pasteurization
590.536(e)	Organoleptic examination of frozen egg products found unfit shall be denatured and removal of official identification mark
590.539(a)	Defrosting of frozen egg products done in sanitary manner
590.539(b)	Organoleptic inspection of each frozen egg product container for condition or odor prior to being emptied into crusher or receiving tank. Off-condition/objectionable odor product shall be denatured.
590.539(c)	Frozen whites used for dried albumen defrosted at room temperature

590.539(d)	Frozen whole eggs, whites, and yolks may be tempered or partially defrosted not to exceed 48 hours at room temperature, no higher than 40°F, or not to exceed 24 hours at room temperature provided no portion exceeds 50°F while in or out of container
590.539(e)	Handling containers and removing egg product done under sanitary methods
590.542	Spray process drying operations sanitation meets requirements
590.570(b)	Pasteurization operations – time/temperature requirements of liquid egg products
590.570(c)	Other methods of pasteurization approved by the Administrator
590.575(b)(1)	Minimum requirements for heat treatment of spray dried albumen to not less than 130°F and held continuously at such temperature not less than 7 days and until <i>Salmonella</i> -negative
590.575(b)(2)	Minimum requirements for heat treatment of pan dried albumen not less than 125°F and held continuously at such temperature not less than 5 days and until <i>Salmonella</i> -negative
590.575(b)(3)	Other methods for heat treatment of spray dried or pan dried may be approved by Administrator upon receipt of satisfactory methods to assure <i>Salmonella</i> - negative products

General Labeling – Egg Products

General Labeling

Verification Instructions/Guidance: IPP verify that egg products bear a label; marking products and their containers' labeling; marking device, and containers entering official plants; and reinspection and preparation of egg products.

Labeling – Product Standards

Verification Instructions/Guidance: IPP are to select an appropriate product and verify compliance by reviewing plant records (including formulation) and labels or observing the preparation of products and comparing the findings to the appropriate regulatory standards.

Labeling – Net Weights

Verification Instructions/Guidance: IPP are to select an egg product and verify net weight regulatory requirements by reviewing plant records and conducting net weight checks, scale calibrations, or tare weight checks.

Regulations	Regulatory Descriptions
590.5_Misbranded	Misbranded
590.10	Administrator may waiver provisions of the regulations
590.410	Shell egg and egg products labeling requirements
590.411	Requirement of formulas and approval of labels for use in official egg products plants.
590.412	Form of official identification symbol and inspection mark
590.414	Products bearing the official inspection mark
590.415	Use of other official identification
590.417	Unauthorized use or disposition of approved labels

590.418	Supervision of marking and packaging
590.419	Reuse of containers bearing official identification
590.440	Processing Ova
590.504(c)	Proper labeling of loss and inedible eggs or egg products with approved denaturant
590.504(o)(2)	Shipment of nonpasteurized or <i>Salmonella</i> -positive egg product to receive pasteurization, repasteurization, or heat treatment at another official plant
590.575(e)	Processed and tested dried whites may be labeled "Pasteurized"
590.800	Identification of restricted eggs
590.840	Identification of inedible, unwholesome, or adulterated egg products
590.860	Identification wording shall be legible and conspicuous
590.940	Marking of egg products offered for importation
590.950	Labeling requirements of containers of eggs or egg products for importation
590.955	Labeling requirements of shipping containers of eggs or egg products for importation
590.956	Relabeling requirements of imported egg products

Other Inspection Requirements (EP)

Verification Instructions/Guidance: IPP perform this task to verify miscellaneous requirements for inspection such as the presence and adequacy of inspection facilities (blueprints), accessibility to plant facilities; refrigeration and labeling of shell eggs for ultimate consumer; and time/temperature parameters for freezing and defrosting egg products.

Regulations	Regulatory Descriptions
590.10	Administrator may waiver provisions of the regulations
590.24	Egg products plants requiring continuous inspection
590.26	Egg products entering or prepared in official plants
590.35	Eggs and egg products outside official plants
590.40	Continuous inspection not provided
590.45	Eggs and Egg Products Not Intended for Human Food
590.50	Refrigeration and Labeling requirements of Shell Eggs for the ultimate consumer
590.124	Schedule of operations of official plants
590.132	Access to plant facilities
590.136	Facilities and equipment furnished by management for use by inspectors
590.146	Drawings and specifications of facility (new and revised)
590.200	Records requirements
590.220	Information to be furnished to inspectors
590.420	Continuous inspection requirement
590.422	Condemnation of adulterated product
590.424	Reinspection of product
590.426	Retain tag/regulatory control action
590.430(a)	Limitation on entry of eggs and egg products
590.430(b)	Processing of inedible egg products separate from edible products
590.520(a)	At least 30 foot candle on all working surfaces; at least 50 foot candle at breaking and inspection stations
590.539(d)	Frozen whole eggs, whites, and yolks may be tempered or partially defrosted not to exceed 48 hours at room temperature, no higher than 40°F, or not to exceed 24 hours at room temperature provided no portion exceeds 50°F while in or out of container
590.539(d)(1)	Frozen eggs packed in metal or plastic may be placed in running tap water (70°F or lower) without submersion
590.539(d)(2)	Defrosted liquid held at 40°F or less (except for pasteurized or stabilized by glucose removal as per 9 CFR 590.530) and not held more than 16 hours prior to processing or drying
590.544	Spray process powder definitions and requirements

Review of Egg Plant Data

Verification Instructions/Guidance: IPP are to perform a weekly review of plant data, verify records associated with domestic and imported shell eggs intended for breaking, and verify data and plant's validation process associated with shelf-life claims on the label of products.

Regulations	Regulatory Descriptions
590.200	Records requirements
590.220	Information to be furnished to inspectors
590.580(c)	Laboratory results provided immediately upon receipt to IPP

Big 8 Formulation Verification

Verification Instructions/Guidance: IPP are to verify that plants are accurately controlling and labeling the eight most common ("Big 8") food allergens as per [FSIS Directive 7230.1 Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common \("Big 8"\) Food Allergens](#). IPP are to answer specific questions related to this task in PHIS under the 'Questionnaire' tab.

Regulations	Regulatory Descriptions
317.2(f)	List of ingredients
320.6	Information & reports required from official establishment operators
381.118	Ingredients statement
416.4(d)	Product processing, handling, storage, loading, unloading, and during transportation must be protected
417.2(a)(1)	Hazard analysis
417.2(c)(1)	List food safety hazards
417.2(c)(4)	List of procedures & frequency
417.3(b)	Deviation not covered (unforeseen hazard)
417.4(b)	Reassessment of hazard analysis
417.5(a)(1)	Written hazard analysis
418.2	Notification of adulterated or misbranded product in commerce
590.411	Requirement of formulas and approval of labels for use in official egg products plants

NOTE: 9 CFR 590.411 will be the only regulation that egg products inspectors would verify when completing this task. The other regulations are not applicable to egg products plants and therefore, IPP would checkmark the 'mandatory' regulations as N/A under the N/A column and the other ('non-mandatory') regulations IPP would not checkmark the box under the 'verified' column at all, the box would be left 'blank'.

Monthly Volume Reporting Egg Products

Verification Instructions/Guidance: IPP are to perform this task monthly to verify the product volumes for all egg products produced applicable to the plant, which may include the quantity of shell eggs broken, total liquid or frozen egg produced, total dried egg solids, and other egg products produced in

the plant. IPP are to enter that information under the 'Questionnaire' tab.

NOTE: IPP are to complete the monthly volume reporting task as early in the month as possible and record the previous month's production volume data. For example, when conducting the June Monthly Volume Reporting Egg Products task enter the plant's monthly volume during the month of May. When conducting the July Monthly Volume Reporting Egg Products task, enter the plant's monthly volume manufactured during the month of June. Also, the monthly volume report represents the entire product volume produced by the plant on all production shifts. IPP should schedule and perform the task once during the month, reporting on the previous month's production. IPP are to consult with their supervisor to determine which shift is responsible to conduct the task for each month.