



Application for Continuous Inspection Service in Official Egg Products Plants

Presented by
Policy Development Staff

Overview of Discussion

- ▶ Application for Continuous Inspection
 - Official Egg Products Plants
 - Form 5200-2
 - Instructions provided
 - Attach blueprint!
- ▶ Includes Approval of Drawings and Specifications



Authority

The Authority is found in:

- ▶ EGG PRODUCTS INSPECTION ACT
(21 U.S.C. 1031–1056)
- ▶ REGULATIONS GOVERNING the INSPECTION of EGGS
and EGG PRODUCTS (9 CFR Part 590)
- ▶ REGULATIONS GOVERNING the VOLUNTARY
INSPECTION and GRADING of EGG PRODUCTS (9
CFR Part 592)



Authority

- ▶ Mandatory Inspection Program for Egg Products
 - 9 CFR 590
- ▶ Voluntary Inspection Program for Egg Products
 - ▶ 9 CFR 592
- ▶ Egg products exempt from continuous inspection:
 - Examples include: Egg substitutes, cooked eggs (e.g., omelets, pucks, patties) & hard boiled

Under FSIS Authority

- ▶ **Mandatory Inspection Program**
 - Egg products:
 - The Secretary of Agriculture has authority over egg products processing plants
 - What is an egg product?
 - Dried, frozen, or liquid eggs, with or without added ingredients
 - What is an egg products plant?
 - A place of business where eggs are processed:
 - Broken, filtered, mixed, blended
 - Pasteurized
 - Produced frozen, liquid, dried, in packaging, in bulk liquid

What is an Egg Product?

- ▶ The term “egg product” means any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under such conditions as he may prescribe to assure that the egg ingredients are not adulterated and such products are not represented as egg products.

What is Egg Product Processing?

- ▶ Breaking Eggs
- ▶ Filtering
- ▶ Mixing
- ▶ Stabilizing
- ▶ Blending
- ▶ Pasteurizing / Heat treatment
- ▶ Cooling
- ▶ Freezing
- ▶ Drying
- ▶ Packaging

Also Interpreted to mean

- ▶ Labeling

Under FSIS Authority

- ▶ Voluntary Inspection Program
- ▶ FSIS Form 5200-6

What is Inspected under Item 16?

- Processing of product containing eggs;
- Sampling Products;
- Quantity and Condition inspection of products
- Supervise the Official Marking of packages of product eligible for the Official Mark identification
- Standards and methods as approved
- At the request of the Applicant

Under FSIS Authority

- ▶ Voluntary Inspection Program
- ▶ FSIS Form 5200-6
 - What is Inspected under Item 16?
 - Examples of products produced for voluntary inspection:
 - Hard cooked eggs
 - Frozen cooked omelets or patties
 - With no meat or poultry components
 - Very few plants – use this item 16 Voluntary Inspection Program

Application for Federal Inspection

- ▶ FSIS Form 5200-2
 - Egg Products Section I, Item 3 (Egg Products)
 - Blueprint attached, Item 16
 - Type of Operation, Section II
 - Item 21 B
 - Processes..... Checkmark ALL THAT APPLY!!!

Item 16 – Attach Blueprint

- ▶ Regulation 9 CFR 590.146
- ▶ Regulatory requirements summarized
 - Initial plant survey – new to egg products as an official plant
 - Drawings submitted by applicant (blueprint) per Item 16
 - Acceptance of the drawings by FSIS

Item 16 – Attach Blueprint

For a New plant....

- Initial plant survey – new egg products as an official plant
- Drawings submitted by applicant (blueprint)
- Acceptance of the drawings by FSIS
- **Change in procedure of reviewing drawings coming in 2014**

Change in procedure for approving drawings

- ▶ PDS will no longer review drawings/blueprints.
- ▶ No approval letters will be issued by PDS.
- ▶ District Offices will be responsible for assigning personnel to perform the review, and acceptance of drawings/blueprints
 - Most likely the FLS will be the “primary” designee to review the drawings/blueprints.

Approval of official plant according to the following procedure

- ▶ Initial Survey:
 - District Office will designate FLS responsible for new plant.
 - FLS conducts initial inspection of premises to determine adequacy for service in accordance with regulatory requirements. Provide application Form 5200-2 and Drawings Guide to applicant.
- ▶ Drawings and specifications to be submitted by applicant:
 - Supplemental information- air filtration
 - Room Specifications
 - Water potability certificates
 - Sewage treatment permits if rural
 - Equipment design acceptance standards if applicable
 - 3-A Sanitary Standards,
 - USDA, AMS, Dairy Processing Equipment

Item 16 – Attach Blueprint continued

- ▶ Regulation 9 CFR 590.146
- ▶ Regulatory requirements summarized
 - Communicate acceptance of the drawings to DO so the application process can continue
 - New plant number assigned
 - Final plant survey conducted
 - Prepare for inauguration of service

Acceptance of the drawings by FSIS

- FLS communicates acceptance of drawings and specifications to District Office so the processing of the Application for Service can continue.
- *DO provides “NO-Objection” letter to applicant related to drawings.
- *Final plant survey is conducted by FLS then provides recommendation via FSIS Form 5200-4.
- *DO coordinates inauguration of service by issuing Form 5200-1 as applicant reports start of operations date.
- *Inauguration of new service begins with Grant of Inspection 5200-1.
- *New plant included in list of Active Plants by DO

Acceptance of the drawings, con't

- ▶ In 1998, the Technical Service Center in Omaha began provided the drawing/blueprint review service for the DO.
- ▶ In 2014, the Policy Development Staff will no longer provide the drawing and blueprint review service.

Acceptance of the drawings by FSIS

- ▶ In transition – 2014
 - This presentation provides guidance on drawing/blueprint review process
 - Review of drawings to be performed by FLS
 - Provisional acceptance communicated to Applicant via the DO in writing of “no-objection letter”
 - Coordination of initial survey, drawing review, final survey and inauguration of service by the DO

Acceptance of the drawings by FSIS

- ▶ How should the FLS, Inspector and DO track approvals?
 - By individual plant number and by dates
 - Communication – NO Objection Letter from DO to Applicant & Inspector replace “Approval Letters” generated by PDS in Omaha.
 - Plants–hold on to their own drawings and communication
 - “Central Filing System” no longer maintained in Omaha

Review of Drawings

- ▶ Two documents are helpful
 - Drawing–blueprint Guide – used by plant
 - Checklist – used by FLS for final survey
- ▶ Review the Regulatory requirements of CFR 590.146
- ▶ Expectations in detail in next slides:

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Review of Drawings

- ▶ Expectations:
 - Provide sanitary processing environment
 - Provide separate dry and wet processing environments
 - Adequate ventilation –
 - “Positive air flow” where exposed egg products
 - How does “positive air flow” interact with exhaust?
 - Provides “clean” rooms for exposed product

Review of Drawings

- ▶ Expectations: (continued)
 - Separate raw and pasteurized (ready to eat) product processing environments
 - Adequate employee traffic patterns limit cross contamination issues
 - Floor slope and drain systems adequate to limit standing / pooling water and egg
 - Intact structures–building maintenance
 - Adequate product storage capacity

Review of Specifications

- ▶ Expectations: (continued)
 - Walls and ceilings impervious to water/condensation
 - Insect and rodent control, inside and out
 - Potable water
 - Sewage treatment
 - Lighting
 - Refuse areas, inedible areas

Review of Specifications

- ▶ Expectations: (continued)
 - Adequate welfare facilities for employees
 - Supplemental information –
 - “Fill in the gaps” and “Catch all”
 - Third party certifications of acceptable equipment such as 3-A Certificates, AMS Dairy Division Certification, Self declaration–company letterhead
 - Example: Adequately filtered compressed air used in direct product contact

Acceptable Upon Review

- ▶ Communicate acceptance/approval to District Office so they may continue processing the Application for Federal Service FSIS Form 5200-2.
- ▶ The bottom line is that any previously accepted drawing, piece of equipment or processing operation that appears to be unacceptable, insanitary or produces unwholesome or adulterate product is no longer acceptable. So regardless of any previous acceptance expressed....each new day stands on its own merits. If there is a problem....FSIS can expect it to be corrected. No unacceptable practice, operation or facility should be allowed to continue to operate.

Unacceptable Upon Review

- ▶ Communicate unacceptable review or unacceptable initial survey to District Office so they place a hold on processing the Application for Federal Service FSIS Form 5200-2.

Unacceptable Upon Review

- ▶ Communicate unacceptable review to District Office and Applicant
 - the Applicant can provide adequate changes or additional supplemental information,
 - a provisional approval can be communicated so processing the Application can resume pending acceptable follow-up survey

Later Modifications to Plant

- ▶ When changes or remodeling of existing and previously approved plant are significant.....
 - Company submits new drawings and specifications to FLS with Inspector input
 - Review drawings and specifications
 - If no unanswered questions – Acceptance

Later Modifications to Plant

- ▶ When changes or remodeling of existing and previously approved plant are significant.....(continued)
 - Conduct final survey – can be delegated to Inspector
 - Communicate to company acceptance of modifications
 - Company maintains drawings, e-mails, documents, No-Objection Letter from DO

Later Modifications to Plant

- ▶ When changes or remodeling of existing and previously approved plant are significant.....(continued)
 - If modifications produce new products at the facility, communicate to District Office so that verification of plant profile and sampling requests are up to date
 - If modifications discontinue some processing operations, adjustments will be required

Later Modifications, Acceptance

- ▶ If the examination of the drawings, supplemental information and room specification show that they meet regulatory requirements, approval will be given. The set of the accepted drawings will be maintained by the plant submitting the prints. Plant management is to make their file of accepted prints readily available to the egg products inspector and the Frontline Supervisor when requested.

Later Modifications – Acceptance con't

- ▶ A final review and acceptance of the submitted drawings will be determined by the Frontline Supervisor. A final survey of the finished facility will also be conducted by the supervisor or the designee followed by the communication of conformance with provisions of a “No-objection” letter and conformance with regulatory requirements.

Later Modifications – Acceptance, con't

- ▶ Acceptance of drawings of a new plant requesting inspection service, or for changes in an existing plant, does not constitute operating approval. A final survey must be made by the Frontline Supervisor or a designee to determine if the plant construction and facilities are in accordance with the accepted drawings and the regulations. On new and existing plants, a written communication to that effect will then be provided to the applicant by the District Office.