Import: Unpasteurized Egg Products Inspection
Shell Eggs-Breaking

Objectives

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

1. Identify the steps to take in inspecting a shipment of imported unpasteurized egg product.
2. Identify the documents that must accompany each egg product shipment.
3. Explain the requirements for seals on imported egg product shipments.
4. Identify the regulatory requirements for labeling and physical examination of imported egg products.
5. Explain the inspection activities for shell eggs imported for breaking.
6. Discuss briefly the refused entry policy.

References

1. FSIS Directive 5030.1, Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants
2. FSIS PHIS Directive 9900.1, Imported Product Shipment Presentation
3. FSIS PHIS Directive 9900.2, Import Re-inspection of Meat, Poultry, and Egg Products
4. FSIS PHIS Directive 9900.5, Label Verification of Imported Meat, Poultry, and Egg Products
5. FSIS PHIS Directive 9900.8, Meat, Poultry, Egg Products Refused Entry into the United States
6. FSIS Notice 70-20, Egg Products Inspection Regulatory Changes
7. FSIS Notice 71-20, Import Reinspection Activities
8. 9 CFR 590, Inspection of Eggs and Egg Products

Import Reinspection

Reinspection of Imported Egg Products

The Egg Product Inspection Act (EPIA) (21 U.S.C. 1046) prohibits the importation of egg products unless they are processed under an approved inspection system of the government of the foreign country of origin and comply with the other pertinent requirements of the EPIA and regulations as are applied to domestic products. Under § 590.910 of the egg products import regulations (9 CFR 590.910), egg products imported into the United States (U.S.) must be from foreign countries that comply with the EPIA and its applicable regulations.
FSIS requires that all egg products that are offered for import be presented for reinspection before the product is used in the production of domestic product (9 CFR 590.925). The Importer of record (IOR) or its agent (this is typically a Customs Broker) files an entry with U.S. Customs and Border Protection (CBP) to apply for inspection of imported products prior to the arrival of the consignment of products, as per 9 CFR 590.920(b). When the importer files its entry with CBP, this will provide FSIS with prior notification.

When applying for import inspection, the IOR or its agent applies for the inspection of product that is to be offered for import in advance of the anticipated arrival of each consignment. Applicants must submit an electronic import inspection application (FSIS Form 9540-1, *Import Inspection Application (Meat, Poultry, and Egg Products)* (version 2/26/2014; refer to Attachment 1) through the CBP Automated Commercial Environment. Paper applications can also be submitted, but the applicant needs to complete all the appropriate blocks in the form, regardless.

**Note:** a computer fillable [FSIS Form 9540-1](#) is also available on the FSIS Web site.

Importers or brokers will continue to submit a paper copy of the current import application, FSIS Form 9540-1, to the Import inspection personnel (IIP) at the designated official import inspection establishment identified on the application where the product will be presented for reinspection no later than the time of filing with CBP. Refer to [PHIS Implementation Letter to Importers](http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/phis-import-component/phis-implementation-letter-to-importers) on the FSIS Web site (http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/phis-import-component/phis-implementation-letter-to-importers).

For applications that are incomplete or contain inaccurate information, the applicant will be asked to correct the application before import reinspection may proceed.

IPP review the documents to ensure that the shipment is properly certified by the foreign country and to verify that each lot is accompanied by the proper certification, in accordance with 9 CFR 590.915. Inspection certification data may be submitted either electronically from government to government (eCert) into the Public Information System (PHIS) or with a paper inspection certificate (non-eCert). There are currently two countries authorized to export egg products to the U.S.: Canada and The Netherlands.

For example, when Canada exports to the U.S., a foreign inspection certificate – CFIA Form 2684 (*Certificate of Inspection for Processed Eggs;* refer to Attachment 2) – is required to accompany all imported egg products and must contain the following information (§ 590.915(e)):
• the date
• the foreign country of export and the producing foreign establishment number
• the species used to produce the product and the source country and foreign establishment number, if the source materials originate from a country other than the exporting country
• the product’s description including the process category, the product category, and the product group
• the name and address of the importer or consignee
• name and address of the exporter or consignor
• the number of units (pieces or containers) and the shipping or identification mark of the units
• the net weight of each lot, and
• any additional information the Administrator requests to determine whether the product is eligible to be imported into the U.S.

In addition, 9 CFR 590.915 requires:

• A certification that the products were produced under the approved regulations, requirements, and continuous Government inspection of the exporting country.
• Name (including signature) and official title of the person authorized to issue foreign inspection certificates for egg products exported to the United States.
• The certificate must also bear the official seal of the foreign government agency responsible for the inspection of the product (as an example, refer to Attachment 2). This certificate must be in English.

As mentioned earlier, the egg products foreign inspection certificate must certify that the product was produced under the approved regulations.

**Reinspection Verification Activities – Unpasteurized Liquid Egg Products**

As stated before, upon arrival at the U.S. port of entry, egg product shipments must be presented at an official import inspection facility for reinspection by IIP or inspection program personnel (IPP) before they are allowed into U.S. commerce. The location of reinspection will be as indicated on the FSIS Form 9540-1 (see Attachment 1).

Egg products are reinspected using the criteria identified in FSIS PHIS Directive 9900.2. At the Port of Entry:
Pasteurized egg products – all pasteurized egg product shipments must stop at an official import inspection establishment for reinspection.

Non-pasteurized egg products – non-pasteurized egg products are not required to stop at an official import inspection establishment prior to proceeding directly to an official egg products plant in the U.S. that conducts a pasteurization process. When the FSIS Form 9540-1 and official inspection certificate is received, OFO Recall Management and Technical Analysis Staff (RMTAS) is to enter the data into PHIS and obtain a reinspection assignment. FSIS reinspection will occur at the official egg products plant designated on the FSIS Form 9540-1. IPP are to refer to FSIS Directive 5030.1, Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants, Chapter III, Section IV.

Canada is currently the only country exporting unpasteurized egg products to the United States. The exporter (Canada) is responsible for notifying FSIS about the shipment, including the details about the shipment.

When a shipment (tanker truck) of unpasteurized egg product from Canada (Est. XXXX) is destined to arrive to an egg products plant the IPP at the plant receiving the shipment must access the PHIS Import Home page (using the import inspector role) to retrieve the lot and to pull the type of inspection (TOI) assignments for the lot. There are three TOIs that IPP need to complete at an inspection level of normal:

- Certification
- Label Verification
- Product Exam-3.

IPP at the egg products plant will follow instructions as per Directive 5030.1, as well as the applicable import directives. As mentioned above, IPP are to (refer to FSIS Directive 9900.2, Section XIX) complete the following TOIs:

1. Certification TOI – Verify that the shipment has been properly certified by the Canadian Food Inspection Agency (CFIA) as follows:

   - The shipment is accompanied by an inspection certificate issued by CFIA (officially sealed document; CFIA Form 2684 – Certificate of Inspection for Processed Eggs; Attachment 2). Remember, this paperwork is provided to the egg products inspectors by the driver of the tanker.
   - The information on FSIS Form 9540-1 (Import Inspection Application is accurate
   - The inspection certificate complies with 9 CFR 590.915, and
• The seals on the transport vehicle are intact, and the seal numbers on the transport vehicle match the seal numbers that are identified on the inspection certificate or on official letterhead containing CFIA’s official seal

**Note:** IPP are to review FSIS Form 9540-1 (which includes the details of the shipment; see Attachment 1) and the CFIA inspection certificate (see completed sample, Attachment 2), which must accompany each load to assure that the shipment is properly certified by the foreign country.

2. **Label Verification TOI** – Verify that the labeling on the product complies with 9 CFR 590.955 and that the product matches the information presented on the inspection certificate.

IPP should refer to the following regulations for guidance on reviewing labels of imported egg products: 9 CFR 590.950 and 590.955. In addition, IPP are to verify compliance with labeling regulations for imported egg products presented for reinspection by examining the labeling features on shipping and immediate containers, as defined in Directive 9900.5. Labels of imported products must adhere to the same requirements as labels for domestically produced egg products (9 CFR 590.910).

3. **Product Exam-3 TOI** – Perform a product examination as per 9 CFR 590.925(b) and 590.930(g), as well as 590.424(b), following instructions per FSIS Directive 9900.2.

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

When IPP are entering the results in the Import Reinspection – Product Exam-3 page in PHIS, the web page is different from the Certification and Labeling TOI (refer to FSIS Directive 5030.1). It has three parts or widgets, as shown below.
The first widget applies, for the most part, to Meat & Poultry, but the section on which we need to focus is the “Additional Information” section, where there are two mandatory fields. Hence, the PHIS Import Reinspection – Product Exam-3 page now requires the inspector to complete the require fields. According to Directive 9900.2, Section V (Sampling Plans and Defect Tables for Physical Inspections), gives instructions to IPP to follow Table 1 when determining the sampling plan and defect criteria for a specific product when a physical inspection has been assigned. For egg products the associated sampling plan is SP5. Thereafter, section XIX (Physical Inspection of Egg Products) gives the procedures to follow to conduct reinspection of the imported product.

While executing the Product Examination TOI the IPP will refer to Attachment 1 (Sampling Defect Tables – Inspection) and use the sampling plan SP5 when a physical inspection 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).

When looking at the SP5 (refer to the footnote) sampling plan in Attachment 1, the egg products tanker that arrives at the plant is a bulk package, i.e., the tanker is the immediate container and represents one sampling 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 about 12 pounds (approximately 1.5 gallons by volume). The numbers that should be entered in the PHIS Import Reinspection – Product Exam-3 page mandatory fields are “12” in the Weight Sample box and “1” in the Number of Units Taken box.

In case the inspector finds any public health (PH) or other consumer protection (OCP) defect (i.e., off-condition, chemical or physical hazards, etc.) after examining the product, then the inspector will 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 defect details in the “Remarks” section in PHIS Import Reinspection – Product Exam-3 page. IPP are to refuse entry on the lot if a public health defect is determined.

**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. Therefore, it is essential that these description are as detailed as possible.

If IPP encounter problems with shipment certification or labeling, as well as the circumstances of a shipment that does not arrive as scheduled (Failure-to-Present – FTP; refer to FSIS Directive 9900.1, Section V), they are to notify the District Office (DO) and await instructions through supervisory channels.

Once IPP complete the reinspection of unpasteurized egg products by completing the assigned TOIs (i.e., label verification, certification, and product examination – organoleptic examination), then the IPP can release the lot in PHIS. IPP will retain CFIA Form 2684 (*Certificate of Inspection for Processed Eggs*) in the government files.

**Verification Activities – Imported Shell Eggs for Breaking**

Shell eggs for breaking can be imported into the U.S. from any country recognized by the USDA’s Animal and Plant Health Inspection Service (APHIS) as free of pests and animal disease issues. Jurisdiction over imported shell eggs is shared by APHIS, FDA, and the USDA’s Agricultural Marketing Service (AMS).

**Note:** For incoming shipments of imported shell eggs for breaking originating from HPAI positive poultry flocks or HPAI affected zones, CBP will issue VS Form 16-78 "Report of Entry, Shipment of Restricted Imported Animal Products and By-Products, and Other Materials." VS Form 16-78 is used to document the movement of the restricted material associated with these shipments from the port of entry to the APHIS-
approved FSIS egg products plant. Imported eggs from HPAI zones can only go to an APHIS-approved egg products plant that conducts both breaking and pasteurization. (Link to database: https://vsapps.aphis.usda.gov/vsps/public/AESearch.do?method=unspecified)

FDA has regulatory authority over imported shell eggs under the Federal Food, Drug, and Cosmetic Act. Foreign producers must comply with the requirements of FDA’s “Egg Rule” found in 21 CFR Part 118 – Prevention of *Salmonella* Enteritidis in Shell Eggs during Production, Storage, and Transportation. If the eggs are for breaking only, they must comply with only the registration requirements and the refrigeration requirements in 21 CFR 118.

**Note:** These regulations require that shell eggs that will go to an official USDA egg products plant for breaking and pasteurization must be refrigerated at 45°F or below ambient temperature beginning 36 hours after time of laying up until they reach the official USDA egg products plant in the U.S.

AMS oversees the importation of shell eggs for breaking and table eggs destined for the ultimate consumer. AMS is responsible for checking imported shell eggs to ensure that they are properly labeled, and that restricted eggs are disposed of properly. AMS notifies FDA when an application is submitted to import shell eggs into the U.S. and notifies FDA before it releases any lots of imported shell eggs into domestic commerce. An application to import shell eggs into the U.S. must be submitted using AMS Form LPS-222 (“Import Request (Shell Eggs);” refer to Attachment 3) containing all the information from the foreign health certificate. AMS will confirm that the load arrives as intended at the port of entry and conduct verification procedures related to seals, labeling, and that the information on the AMS Form LPS-222 is correct. Once AMS completes its verification procedures, these loads are eligible to be sent to an egg products plant for breaking.

Canada, France, Germany, Honduras, Italy, Latvia, Lithuania, Mexico, Portugal, Spain, and The Netherlands are the countries that export shell eggs to the USA for breaking.

Once the imported shell eggs for breaking are reinspected and released by AMS, they are considered “in-commerce” (domestic shell eggs). IPP at egg products plants who receive this type of shell eggs are to review the appropriate documentation and verify that the plant complies with the applicable record requirements in 9 CFR 590.200 (i.e., looking for the supplier information).

**IPP responsibilities in egg products plants receiving imported shell eggs originating from Canada intended for breaking (Notice 27-16)**

When shipments of imported shell eggs from Canada intended for breaking proceed directly to official egg products plants, AMS will notify the applicable DO
management that the shipment is being transported to an egg products plant in that district. The DO is to notify IPP of the expected arrival of the shipment.

Upon arrival of the imported shell eggs at the official plant, IPP are to:

- Request a copy of AMS Form LPS-222 and VS Form 16-78 (if applicable; will accompany shipments that have originated from HPAI positive poultry flocks or HPAI affected zones) from the driver or DO
- Verify that the government (CBP) or commercial seal(s) are intact and that the seal number(s) matches the seal number(s) recorded on Form LPS-222 or VS Form 16-78 (when issued)
- Verify that the number of containers in the shipment matches the number recorded on Form LPS-222 and VS Form 16-78 (when issued)
- Verify that the plant complies with the applicable records requirements in 9 CFR 590.200 and 590.950(b)

After verifying all the items above, IPP are to send an e-mail to ImportedBreakingStock@fsis.usda.gov containing the information delineated in FSIS Notice 27-16, Part IV.E. If IPP encounter any problems (i.e., seal is not intact and/or seal number or the number of containers does not match the seal number or the number of containers recorded on applicable forms) during their verification activities, IPP are to

- apply a U.S. Retain tag and hold the affected shipment of imported shell eggs and segregate
- send an e-mail to the above e-mail address and their immediate supervisor and DO following instruction as per FSIS Notice 27-16
- Wait for further instruction from their immediate supervisor and DO for any further actions regarding the disposition determination of the affected shipment

**Documenting results in PHIS**

IPP are to schedule a Routine or Directed Review Egg Plant Data task for every imported shell eggs shipment received and document the results of their verification activities by stating that they verified 9 CFR 590.200. If IPP scheduled an additional directed task, click on the reason “Instructed by Supervisor.”

**Hold on Distribution (9 CFR 590.930)**

All imported egg products will be conditionally released from CBP only after inspection of the product has occurred. If the product is moved from the port of entry to an official plant for reinspection, it must be under official seal. The
District Office must be notified immediately if product fails to report for reinspection by the close of the estimated date of arrival.

**Refused Entry**

Imported egg products that do not comply with U.S. requirements are not allowed to enter U.S. commerce and are to be identified as “United States Refused Entry” product (9 CFR 590.945). Egg products that must be identified as such are defined in Directive 9900.8. As per Directive 9900.8, inspection personnel are to:

- Ensure that the refused entry product is under FSIS control until properly identified as “United States Refused Entry.”
- Notify import establishment/egg products plant management of each refused entry

In the case of imported unpasteurized egg products that were refused entry, IPP need to immediately contact their supervisor who then will give notice to the District Office/Recall Management Technical Analysis Division (RMTAD) in Headquarters as soon as possible; further guidance will be provided to the inspector by supervisory channels. RMTAD still receive emails at importinspection@fsis.usda.gov.
Import Inspection Application 1
**Import Unpasteurized Egg Products Inspection**  
**Shell Eggs-Breaking**  
**04/11/2021**

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**FSIS Form 8540-1 (continuation sheet)**

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<th>LOT NO.</th>
<th>SHIPPING IDENTIFICATION MARK</th>
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<th>PRODUCTION DATE(S)</th>
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<td></td>
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</tbody>
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<table>
<thead>
<tr>
<th>NET WEIGHT OF LOT (LB/NSBM)</th>
<th>SHIPPING UNIT PACKAGE TYPE NAME</th>
<th>NUMBER OF UNITS</th>
<th>IMMEDIATE UNIT PACKAGE TYPE NAME</th>
<th>NUMBER PER SHIPPING UNIT</th>
<th>SEAL NUMBER(S)</th>
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<th>PROCESSING EST NO.</th>
<th>SOURCE COUNTRY(S)</th>
<th>PROCESS CATEGORY</th>
<th>PRODUCT GROUP</th>
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</table>

<table>
<thead>
<tr>
<th>SPECIES (DOMESTIC)</th>
<th>ADDITIONAL SPECIES (IF APPLICABLE)</th>
<th>DESCRIPTION OF PRODUCT</th>
</tr>
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<tbody>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>SUPPLEMENTAL PRODUCT CODES (CTN, INTENDED USE CODE, UPC)</th>
<th>ESTIMATED DATE OF ARRIVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

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**Virtual Egg Products, Webinar**

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The following is guidance for applicants/custom brokers importing meat, poultry or egg products to the United States. The FSIS form 9540-1 has been modified to capture more detailed information about shipments.

Block:
1. Country of Origin. Enter the name of the country that issued the inspection certificate for the export of the product.
2. Inspection Certificate Number. Enter the serial number, including dashes/slashes, from the foreign country inspection contained on the inspection certificate.
3. Exporting Establishment Number. Enter the official number of the foreign facility that the product was exported from the inspection certificate.
4. U.S. Port of Entry/ CBP Port Code. This is the name of the port of entry and the associated CBP port code designation where the entry is filed with U.S. Customs and Border Protection (CBP). Example: When the entry is filed at the Port of Philadelphia for merchandise unloaded at Long Beach, CA, enter "Philadelphia, PA - 1101" as the U.S. Port of Entry and Port Code.
5. U.S. Port of Unloading/CBP Port Code. This is the name of the U.S. port of entry and the associated CBP port code for merchandise unloaded at Long Beach, CA, enter "Los Angeles/Long Beach, CA - 1104" as the U.S. Port of Unloading and Port Code.
6. FSIS Establishment Number. This is the official number assigned by FSIS to the establishment where the product will move for FSIS import inspection.
7. Name and Address of FSIS Establishment. The name and address of the FSIS establishment where the product is to be moved for FSIS import inspection.
8. Name (first/last), Business Name and Address of Customs Broker or Applicant, as applicable (including zip code). Self explanatory.
30. Description of the Product. Enter the name or description of the product from the inspection certificate. For example, lamb legs, beef short loin, etc.
31. Supplemental Product Code. Enter the GTIN, Intended Use Code, UPC, or other product code that is used in commerce for the product.
32. Estimated Date of Arrival. Enter the date that the product is expected to arrive at the FSIS establishment for import inspection.
33. Printed Name of Customs Broker or Applicant. Enter actual name of person signing this application.
34. Signature. Signature of person filing this application.
35. Date. Enter the date the application is completed.

1/ For American Samoa, either Pago Pago, AS Seaport - 0001 or Pago Pago, AS Airport - 0002
Attachment 2 – Example: Completed Foreign Certificate of Inspection for Processed Egg (CFIA Form 2684)

<table>
<thead>
<tr>
<th>Canada</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CERTIFICATE OF INSPECTION FOR PROCESSED EGGS</strong></td>
</tr>
<tr>
<td><strong>CERTIFICAT D’INSPECTION POUR OEUFS-PRODUITS</strong></td>
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</tbody>
</table>

**Foreign Certificate 1**

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<th>Description</th>
<th>Value</th>
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<tbody>
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<tr>
<td><strong>Inspection Location</strong></td>
<td>Canada</td>
</tr>
<tr>
<td><strong>Certification Number</strong></td>
<td>00000</td>
</tr>
<tr>
<td><strong>Date</strong></td>
<td>02/14/2021</td>
</tr>
<tr>
<td><strong>Reason for Exportation</strong></td>
<td>For Processing</td>
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<tr>
<td><strong>Inspection Authority</strong></td>
<td>Canada</td>
</tr>
<tr>
<td><strong>Description of Product</strong></td>
<td>Processed Eggs</td>
</tr>
<tr>
<td><strong>Certificate No.</strong></td>
<td>22400</td>
</tr>
<tr>
<td><strong>Final Weight</strong></td>
<td>49.400 lbs</td>
</tr>
<tr>
<td><strong>Inspection Authority</strong></td>
<td>Canada</td>
</tr>
</tbody>
</table>

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**Import Unpasteurized Egg Products Inspection Shell Eggs-Breaking**

04/11/2021
Attachment 3 – AMS Form LPS-222, Import Request (Shell Eggs)