

# Labeling

## Objectives

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

1. Understand FSIS's role in label oversight.
2. Understand the procedures plants use for submitting a label request and label change.
3. List the information required on a label.
4. Understand nutrition labeling and standards of identity for egg products.
5. Cite the procedures for requesting and using temporary labels, as well as transferring labels.
6. Understand what constitutes the official marks of inspection.
7. Explain how the inspection results will be recorded in PHIS.

## References

1. 9 CFR 590.410 – 419
2. USDA User Guide for Industry: Label Submission and Approval System (LSAS)
3. A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products
4. 21 CFR Part 160 – FDA, HHS; Subpart B – Food for Human Consumption, Part 160 Eggs and Egg Products
5. USDA/AMS Memorandum; Subject: Supervision of Egg Products Formulation and Solids Verification, dated May 12, 1994.

## Overview of Labeling Responsibilities

An egg products plant's responsibility is to produce products that are properly packaged and labeled, including that the labels are not false or misleading in content, ingredients, marking, or any other labeling feature. The role of inspection program personnel (IPP) is to ensure these requirements are met. This module provides details, definitions, and guidance on how IPP carry out their role in ensuring plants are correctly labeling their products.

Specific IPP responsibilities include the following:

- Verify that product labels have the correct information.
- Retain improperly labeled product and document the appropriate information and actions taken, including noncompliance, in PHIS.
- Provide information requested by the Labeling and Program Delivery Staff (LPDS) concerning plant labels.
- Verify product formulations and processing procedures to ensure that labels conform to the requirements.
- Verify the presence and accuracy of plant records with regard to the following:
  - Egg Solids Verification
  - Ingredients & Non-egg ingredients are Food Grade
  - Ingredients used and amounts (not to exceed allowable maximums)
  - Batch records coincide with volume of packaged product
- Verify the Standards of Identity (21 CFR Part 160) or Product Identity.

## Labels

### Label Oversight

Plant management is solely responsible for maintaining the label approval file. However, this information must be made available upon request for IPP to review and to substantiate that each lot produced complies with applicable requirements. All improperly labeled products must be retained pending reprocessing or relabeling.

All egg products labels, containers, and packaging material bearing USDA identification must be approved and used in accordance with the regulations below:

- Label Approval Process (9 CFR part 412)
- Egg Products Inspection Regulations (9 CFR Part 590.410-419)
- FDA Eggs and Egg Products Regulations (21 CFR Part 160)

According to 9 CFR 590.5, the term *Label* means a display of any printed, graphic, or other method of identification upon the shipping container, if any, or upon the immediate container, including but not limited to, an individual consumer package of eggs and egg products, or accompanying such product

## Label Approval Process for Plants

If a plant wishes to get approval to use a label, it must follow this process:

1. Ensure the label has correct information (see “Required Information on Labels” below) and indicate which labels will identify products intended for direct consumer sales (e.g., consumer packaged product compared to bulk packaged egg products not for sale or distribution to household consumers).

Products labeled for retail distribution must comply with FDA regulations for nutrition labeling (21 CFR Part 101). If the packaged egg product is for institutional use, the product is not required to bear nutritional labeling unless a nutrition or health claim is made. All tests and nutrition information made on labels must be maintained on file by the plant.

2. If the product label being submitted for approval indicates that the product contains two or more egg or non-egg ingredients, the label request must include the product formulation. The ingredient statement must include all ingredients in descending order of proportion by weight. If the ingredient is less than 2% of the total formulation, it may be shown as “Contains 2 percent or less of the ingredient(s).” This statement must be located after the ingredient statement or the product identity.
3. Applications for label approval are submitted to the Labeling and Program Delivery Staff (LPDS) a number of ways.
  - a. Label submissions can be sent via regular mail and express-mail services, hand-carried by a company representative and delivered to FSIS through a courier (label expediting firm, consultant, law firm, etc.) In addition, small and very small companies may fax labels to LPDS for evaluation.

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- b. Electronic Label Submission and Approval System (LSAS)  
When using LSAS, the submitter creates an egg label application and selects the Type of Product = Egg.
- c. The plant submits two copies of each label proof for approval.

FSIS Form 7234-1 “Application for Approval of Labels, Marking, or Device or both

- Form 7234-1 for egg products is generated with the LSAS.
- Labels are approved by LPDS.
- For experimental formulations, protocols, or procedures, the plant must submit supporting documentation with the label approval request to OPPD.

### **Distribution of Approved Label Requests**

For label approval requests submitted by an official plant, the original and one copy of the approval notice, with attached proof(s), will be sent to the requestor at the applicable plant. The plant will then give the original notice and attached proofs to IPP for review.

For requests submitted by other than an official plant, the approval will be sent to the submitting firm only.

If the label includes language such as “Distributed by” or “Packed For,” the plant must provide FSIS Form 7234-1 and proof for verification prior to producing the product.

If a label is disapproved, it will be sent directly to the submitting firm only.

**Note:** If a plant is only repackaging an egg product, not processing it, the label should have the number of the processing plant and ‘Packed For’ on the label. When the label is submitted to LPDS, they expect the plant to include how the product is controlled when repackaged.

### **Final Label Approval**

IPP are to compare the final label and proof to ensure they are the same. This is to be completed before the plant uses the label. If IPP do not receive a copy of the label, they should request a copy from the plant. If the plant’s label is incorrect, IPP should not allow it to be used on the egg product. Finally, IPP need to reconfirm that there are no changes when the label is printed.

## Label Changes

As of December 28, 2020, generic labeling is allowed in egg product plants.

**Note:** If a label is submitted with an 'open' net weight statement, the plant may change this open statement without approval. Another example of a change that could be made without resubmitting the label would be a color change to the label if the original labels have been submitted in black and white.

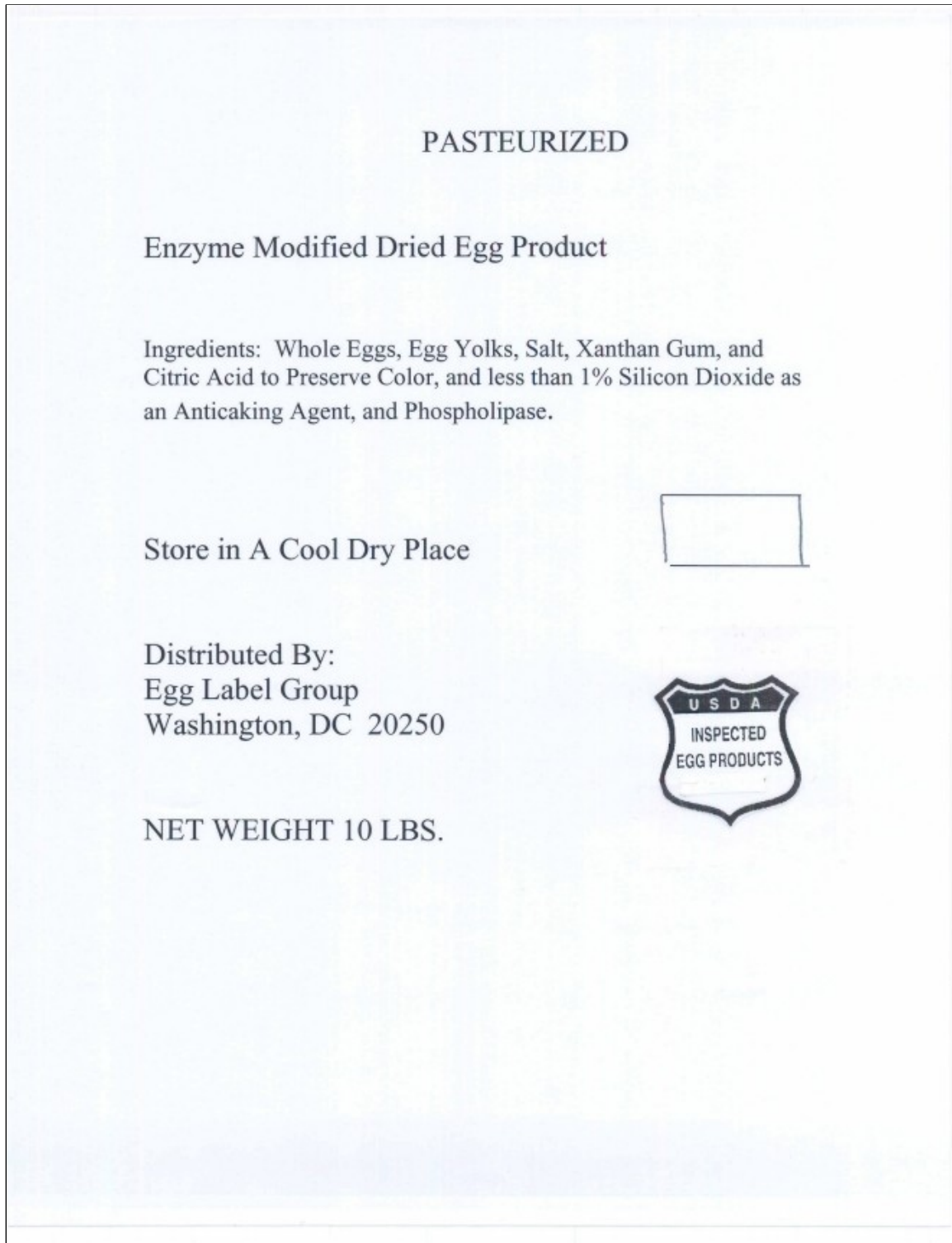
When making approved changes, the incorrect information must be neatly obliterated and the correct information neatly printed or stamped on the label, being careful not to interfere with other printed material. Self-adhesive stamps may be used.

## Required Information on Labels

1. Product Name: This will include the state of the product (dried, frozen, and so on). The font size for the product name must be equal to the most prominent printing on the label.
2. Trade Name (optional): A trade name may be used in conjunction with the product identity.
3. Ingredients: Ingredients must be listed on the principal display by their common or usual name in order of descending proportion by weight.
4. The lot number or an alternative code indicating date of production, in accordance with 9 CFR 590.200(a).
5. The Official Mark: The official mark must be shown. The plant number may be omitted from the official identification if applied elsewhere on the container. If the plant number is applied outside the mark, the plant number must be preceded by the letter G or the word plant, as per 9 CFR 590.413.
6. Name and Place of Business of Manufacturer, Packer, or Distributor
7. Net Weight Statement

**Note:** Additional information on the label may include claims regarding nutritional labeling, shelf life, and use-by or sell-by dates.

## Example of Product Label



Product Label Figure 1

### **Obsolete Labels**

IPP do not need to report obsolete labels.

### **Lot Number or Production Code Number**

The lot number or production code number must be legibly applied to each primary container and shipping container when egg products are packaged. It may be placed on the label or container.

The lot number shall be shown as a Julian date, representing the day the product was packaged followed by the last digit of the year. The lot number must always include four digits. The plant may use an alternative coding system, in accordance with 9 CFR 590.200(a)(3) and 590.411(c)(3).

### **Master Shipping Labels**

If a shipping container contains two or more individual cartons, boxes, or bags, their labels must include all of the same information shown on the primary container. Additionally, the number of primary containers and net weight must be declared on the lower 30% of the principal display panel.

### **Pressure Sensitive (Strip) Labels**

Certain strip labels may be used without LPDS approval in conjunction with previously approved labels if they do not cover any required labeling information. Pressure sensitive labels are used to show the packers or distributor's name and address and/or to show product identity for whole eggs, egg yolks, or whites without added ingredients. Pressure sensitive labels for identification of products with added ingredients must be submitted to LPDS for approval.

## Temporary Approvals

Temporary approval may be granted by the LPDS to modify and use labels previously printed with minor errors. For example, a Brand name change or change of state such as frozen to liquid.

If more labels exist after the number or time limit has expired, the company may request an extension.

## Labels for Unpasteurized Products

Unpasteurized products packaged for storage either in the plant or for shipment to another federal plant for further processing are to bear a label stating that the product requires further processing in another official plant. As per 9 CFR 590.410, IPP are to verify that bulk shipments of unpasteurized or microbial pathogen-positive egg products produced in official plants bear a label containing the words “date of loading,” followed by a suitable space in which the date the container, tanker truck, or portable tank is loaded must be inserted. The label must be conspicuously located, printed and affixed on material that cannot be detached or effaced due to exposure to weather. As per 9 CFR 590.411-415, IPP are to verify that unpasteurized or microbial pathogen-positive egg products shipped from an official plant are marked with a label saying, “EGG PRODUCTS FOR FURTHER PROCESSING IN AN OFFICIAL PLANT.”

**Note:** There is no official mark on this product.

## Labels for Edible Egg Products

IPP are to verify that containers, portable tanks, and bulk shipments of edible egg products produced in official plants are labeled in accordance with 9 CFR 590.411 through 590.415 and bear the official identification shown in Figure 1 of 9 CFR 590.413. \*NOTE: The mark of inspection is now found in 9 CFR 413. As per 9 CFR 590.410, IPP are to verify that the labels of packages of egg products produced from shell eggs that have been treated with ionizing radiation reflect that treatment on the finished product labeling. Label products containing ova in accordance with 9 CFR 590.411 and 9 CFR 590.440.

## Official Identification

The official shield must be printed on the primary display panel of the label using the exact design and wording outlined in 9 CFR 590.412. Some specific guidance includes the following:

- The plant number may be printed on the shield or elsewhere on the container.



- When the plant number is not printed within the shield, the letter G may be used to denote plant instead of using the word plant.
- The shield may not be used on any label that does not bear all the mandatory labeling information.
- If product is for institutional use only, it may be packaged in unlabeled or partially labeled primary containers. Such containers must show the production code date and plant number.
- Any label that includes other than just the code, date, and plant number must be submitted to the labeling division for approval.
- All master shipping containers for unlabeled or partially labeled primary containers must bear all required labeling information.

### **Negative *Salmonella* Statement**

The statement “SALMONELLA NEGATIVE AS DETERMINED BY USDA METHOD OF ANALYSIS” may be shown on the labels if the product was sampled and analyzed for the presence of *Salmonella* and results are available. This product may not move until the results are back. This label claim is approved by LPDS but must be verified by inspectors. If the claim is not being used appropriately, inspectors should contact LPDS with that information to determine if the label needs to be rescinded.

### **Kosher**

When kosher labeling is used, IPP will verify that the plant has received authorization from the rabbinical organization to use the kosher symbol.

### **Water Declaration**

When potable water is added to egg products as a carrier, a certification that the water performs a useful function must be included as part of the product formula and submitted to Labeling Staff for approval.

The percentage of water must be declared on the label in the ingredient statement in descending order of proportion.

Water is not required to be declared on the label of liquid or frozen egg products under the following conditions:

- when used to reconstitute nonfat milk to a minimum of 10% milk solids and shown on the label as reconstituted skim or nonfat milk, or skim or nonfat milk

- when used to reconstitute corn syrup solids to approximately 80% solids
- when used as a carrier of an approved chemical essential to the method of an approved pasteurization process
- if water is added as a carrier to liquid eggs which will be dried

### **Country of Origin**

Egg products imported from approved foreign countries must be labeled to show the country of origin unless reprocessed. Note that Canada and the Netherlands are currently the only countries approved to export egg products to the United States.

### **Relabeling of Product**

If a product that has already been officially inspected and labeled is relabeled with another approved label, the product must bear the original code date.

Dried product repackaged into a new primary container may bear the current code date.

If the product is relabeled in an official plant other than where packed, the new label may show either plant number. However, if the company name and address shown on the label is not that of the packing plant, terminology such as “distributor” “distributed by” or “packed for” must be used.

It is important that records be maintained when the product is relabeled for recall purposes.

### **Transfer of Approved Labels**

Approved labeling materials may be transferred from one official plant to another official plant and used without LPDS approval under these circumstances:

- no plant number is shown (applied by packing plant);
- original plant number is neatly obliterated and new plant number is legibly applied preceded by the letter G or word “plant” outside the official shield; (the plant are expected to convert from P to G);
- if the packing plant’s name and address is not shown, clarifying terminology such as “distributor” “distributed by” or “packed for” is used.

If applicable, the approved formulation and minimum pasteurization treatment for the product must be made available to IPP at the plant where the product will be processed and packed.

IPP at the receiving plant will grant approval for use of the transferred labels by dating and initialing a copy of the label they reviewed.

Modifications of labels are not permitted without temporary approval from LPDS.

## **Nutrition Labeling**

The nutrition labeling requirements for egg products are prescribed in FDA Regulation 21 CFR 101.3. This is the basis for 9 CFR 590.411(e). Nutrition labeling is required on most consumer size packages of egg products. Nutrition labeling is not required on institutional size packages unless a nutrient content claim is made on the label (e.g., low fat).

### *Nutrient Content*

Certain foods are considered significant sources of specific essential nutrients and thus require specific labeling information to allow the consumer to be aware of what he or she is eating.

So, for any food that has a *Standard of Identity* and that a consumer would expect to be a significant source of essential nutrients, that food must not be processed in a manner that would leave it lacking any essential nutrients that would be expected to be present in the food.

If a process removes from food any of the essential nutrients considered to be a significant source of that nutrient, then that process is deemed to be one that produces a nutritionally inferior food product. The EPIA defines a nutritionally inferior egg product to be “adulterated” if it is not labeled in a manner that would disclose that inferiority, e.g., “Avidin reduced egg whites”.

## **Label Claims**

When plants use label claims (e.g., organic), they must provide documents to show how the claim is verified. If the process changes, the plant must resubmit the label with the updated information (e.g., change in the source).

## **Products Standards and Identity**

### **Product Standards and Identity for Eggs and Egg Products**

Egg products must adhere to specific standards to ensure they are, in fact, egg products. These standards are found in 21 CFR Part 160 located in the Egg Product Index.

#### *Whole Eggs*

Liquid or frozen whole eggs are eggs of the domestic hen, broken from shells with yolks and whites in their natural proportion as so broken (21 CFR 160.110 &

160.115). A combination of whites and yolks in other than natural proportions, such as “accidentally broken” whole eggs, may be identified as whole eggs as long as the solid content is standardized to 24.2% or greater.

There is an AskFSIS Q&A (Adjustment of Total Egg Solids) that clarifies policy in relation to adjusting total egg solids. The issue was about an egg products plant that breaks eggs but the total egg solids content of the whole egg in natural proportion is less than 23.6%. Can the plant raise the total egg solids of broken whole eggs to meet a buyer’s specification (total egg solids of 23.6%) and still label the product as “whole egg”? The answer is YES, which can be accomplished by either withholding whites or adding egg yolks.

If a product specification requires that egg yolks be added to whole eggs, thus raising the egg solids to above 28% or in a proportion other than natural proportion whole eggs, the product must be identified as “whole eggs and egg yolks”.

If the liquid or frozen whole eggs have added salt or sugar (and no other ingredients), then they may be identified as Salted or Sugared Whole Eggs, or Salted/Sugared Whole Eggs with approximately (amount to be added) % Salt/Sugar.

The finished dried weight of dried whole eggs broken from a domestic hen must contain at least 95% total egg solids by weight if the product has had glucose removed or has had anti-caking agents added to it. In these cases, the label must include a statement about the removal of glucose (for example, “Glucose removed for stability”) or about the addition of anti-caking agents (21 CFR 160.105).

### *Egg Whites*

Liquid or frozen egg whites must meet the applicable standard of identity (21 CFR 160.140 and 160.150). Approved whipping aids may be added but must be declared as part of the product identity. Adding the function of the ingredient is not mandatory.

Dried egg whites must meet the applicable standards of identity as per 21 CFR 160.145. The glucose content must be reduced prior to drying, and optional whipping agents may be added and declared in the label. In addition, if the lysozyme and avidin content is reduced prior to drying, the process needs to be accomplished as per 21 CFR 173.25 and a statement “lysozyme and avidin reduced” should be included on the label.

### *Egg Yolks*

Liquid or frozen egg yolks from eggs of domestic hens that are separated from the whites. This product must contain not less than 43% egg solids (21CFR 160.180and 160.190).

If salt or sugar is added, the label must identify the salt or sugar with an approximate percentage.

Dried eggs meeting the definition of egg yolks may be labeled “Glucose removed for stability” or “Stabilized, glucose removed” (21 CFR 160.185). Anti-caking agents may be added up to maximum limits and must be included on the label.

The finished dried product shall contain not less than 95% total egg solids by weight.

### *Egg Solids Requirements*

Plants that process yolks or standardized whole eggs must have acceptable equipment for determining the solid content of each lot.

Alternatively, a composite sample must be taken during production and submitted to a commercial or USDA laboratory for analysis for egg solid content. The plant must have available each day for IPP to review the results of such testing, demonstrating that each day's production of applicable product(s) complies with minimum solids requirements.

During routine inspection tours, IPP will verify that egg solids are being accurately determined and recorded by the plant. To help the IPP to assure that egg products are produced in compliance with the egg solids requirements, refer to the USDA/ARS Memorandum dated May 12, 1994, which is included in this module as an addendum.

## **Compounds and Ingredients**

One of the duties of IPP is to monitor the use of all compounds in the official plant and to assure that compounds and non-egg ingredients are being properly used. The plant must provide documentation that validates the conditions for use and the safety of the ingredients and compounds used. They may demonstrate this with several resources, including Letters of Guarantee or Safety Data Sheets.

Plant management must have available, for the IPP's review, the records (including test data) substantiating that each lot produced complies with applicable product identity, ingredients, egg solids, and/or other requirements as indicated in the product label.

## **Documenting Results in PHIS**

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 standard. The results will be documented using the routine General Labeling – Egg Products routine task in PHIS. IPP are to document noncompliance when it is observed and inform plant management when any noncompliance is identified. IPP verify that plant management takes appropriate corrective and preventive measures.

NOTE:

LPDS will no longer issue the PY-221 form nor provide an egg products approval number as a result of the implementation of regulations dating December 28, 2020 for egg products plants. IPP are to be aware that plants must comply with the label approval provisions of 9 CFR Part 412.1 and are responsible for obtaining label approval as required under 9 CFR 412.1(e) 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, 412, and 590.411. Egg products are also now under the generic ruling like meat and poultry products!!

Please see an update guideline for more guidance.

\*\*Final Rule Guidance

<https://www.fsis.usda.gov/wps/wcm/connect/2927e3b5-d441-4c34-9826-3c22a5684213/egg-products-presentation.pdf?MOD=AJPERES>

## Labeling True or False Quiz



Work with your group to determine whether the following statements are true or false. Refer to your handout to check your answers.

1. Inspection program personnel are responsible for comparing the final label to the label approval notice to ensure that they are the same.
2. Modifications may be made to labels without approval from the Labeling and Program Delivery Staff.
3. Labels must include the name and place of business of the manufacturer or distributor of the product.
4. Labels on primary containers must contain all of the same information as shipping containers.
5. Inspection program personnel must verify that strip labels completely cover any other labels on the product.
6. Inspection program personnel are responsible for verifying that product in the plant is being processed in the manner indicated on product labels.
7. Unpasteurized products shipped in a tanker from one official plant to another must bear a statement "UNPASTEURIZED."
8. It is not acceptable, under any circumstances, to transfer labeling materials from one official plant to another.

