VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS

FOOD SAFETY CONSUMER PROTECTION
Meat Inspection Service
MONTPELIER, VT
Chuck Ross, Secretary



MIS DIRECTIVE

7221.1, Revision 1

1/6/2014

Adopted from FSIS Directive 7221.1 Rev1

PRIOR LABELING APPROVAL

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) for conducting the General Labeling task in the Public Health Information System (PHIS).

KEY POINTS:

• IPP are to verify establishments receive necessary label approval and compliance with labeling requirements through the General Labeling task in PHIS.

II. CANCELLATION

FSIS Directive 7221.1 amend. 1., Prior Labeling Approval, dated 08/19/1996

III. LABEL APPROVAL

- A. Prior Label Approval: All labels are to be approved before use. Prior approval in the form of sketch approval or temporary approval from the Vermont Meat Inspection Office is to be obtained for labels described in 9 CFR 412.1(c).
- B. Sketch Label Approval: A sketch label is a printer's proof or other version that clearly shows all required label features, size, location, and indication of final color. VT Meat Inspection approves sketch labels after companies submit them, and VTMIS finds the label features meet regulatory requirements. Sketch approval is required for all labels described in 9 CFR 412.1(c).
- C. Final Label Approval: A final label is a label that is applied to product before leaving the establishment..

IV. BACKGROUND

- A. IPP are to be aware that establishments are responsible for ensuring that labels used for meat and poultry products is not false or misleading, and for ensuring that labels comply with the Federal meat and poultry products inspection regulations and policies.
- B. IPP are to be aware that sketch labels (as defined in 9 CFR 412.1(d)), along with a completed form and all supporting documentation are to be submitted to the office for evaluation. Label submissions may be mailed or faxed in duplicate. If a label is approved by the office, establishments may print a final label, create a final label record in accordance with 9 CFR 320.1(b)(11) and 9 CFR Part 381.175(b)(6), and use

the label in commerce.

C. Final labels that are not in compliance with Federal meat and poultry products inspection regulations may still be granted temporary approval under the conditions listed in 9 CFR 412.1(f). The final label along with a completed form and all supporting documentation, including support for conformity to the conditions in 9 CFR 412.1(f), are to be submitted to the office for temporary approval.

V. IPP VERIFICATION ACTIVITIES IN OFFICIAL ESTABLISHMENTS

A. IPP in meat and poultry establishments are to continue to perform the General Labeling task when scheduled in PHIS. When scheduled, IPP are to randomly select one or more labels for verification from products in production at the assigned establishment.

B. IPP are to verify that the establishment is maintaining records of the selected labels in accordance with 9 CFR 320.1(b)(11) for meat products and 9 CFR Part 381.175(b)(6) for poultry products. Labeling records are to be made available to field personnel and any authorized VAAFM official within 24 hours of request. Each labeling record should include: a copy of the final label that is in use, the product formulation, the processing procedure for the product, and any supporting documentation needed to show that the label is consistent with the Federal meat and poultry regulations and policies on labeling as described in 9 CFR 412.1. The final label is to comply with modifications and conditions of use put forth by the meat inspection office in the label approval [9 CFR 412.1(a)].

C. IPP are to verify regulatory compliance of the final label by reviewing it for the presence of all applicable required features listed in Table 1.

Table 1: Required Labeling Features			
Feature	Reference	Location	Applies to
Product Name	9 CFR 317.2(c)(1) or 381.117	Principal display panel	All products
Inspection Legend	9 CFR 317.2(c)(5) or 381.123	Principal display panel	All products
Handling Statement (e.g. "Keep Frozen")	9 CFR 317.2(k) or 381.125(a)	Principal display panel	Products requiring shandling to maintain wholesomeness
Net Weight Statement	9 CFR 317.2(h) or 381.121	Principal display panel	Product sold at reta the net weight is ap retail
Ingredients Statement*	9 CFR 317.2(f) or 381.118	Information panel or Principal display panel	Products with multiplingredients

Address Line	9 CFR 317.2(g) or 381.112	Information panel or	All products
	1-1	Principal display panel	
Nutrition Facts Panel	by 9 CFR 317.300 or	Information panel or	Products not exemp
	381.400	Principal display panel	CFR 317.400 or 38
Safe Handling Instructions	9 CFR 317.2(l) or 381.125(b)	Information panel or	Products with a not
		Principal display panel	eat meat or poultry
			component

*NOTE: All ingredients used in the product must be listed in the ingredients statement. Product is considered adulterated if an allergen is not listed in the ingredients statement. IPP are to contact their supervisor for guidance if at any time they have reason to believe that product failing to declare one of the "big 8" allergens [wheat, crustacean shellfish (e.g. crab, lobster, shrimp), eggs, fish, peanuts, milk, tree nuts (e.g. almonds, pecans, walnuts), and soybeans] or other ingredients of public health concern has entered commerce. FSIS ingredient and allergen compliance guidelines are available online.

VI. DETERMINING AND DOCUMENTING NONCOMPLIANCE

A. IPP are to document the results of their verification, including any noncompliance, in PHIS in a manner that accords with Chapter VI of FSIS PHIS Directive 7000.1, Verification of Non-food Safety Consumer Protection Regulatory Requirements.

- B. When a labeling record does not include approval for that label, IPP are to document the noncompliance on a Noncompliance Record (NR) in PHIS, citing 9 CFR 412.1 as the relevant reference. IPP are to retain any product bearing a label that requires, but has not received, approval. The establishment may take corrective action by obtaining label approval through the office or by replacing the noncompliant labels with labels that have received prior approval and are in compliance with Federal meat and poultry inspection regulations and policies.
- C. When a label is not in compliance with regulatory requirements, IPP are to document the noncompliance on an NR in PHIS, citing the relevant reference from Table 1. IPP are to retain any product bearing that label. The establishment may take corrective action by obtaining temporary label approval through the meat inspection office, bringing the labels into compliance with a pressure-sensitive sticker, or replacing the noncompliant labels with compliant labels.
- D. There may be times when an inspector is not performing the General Labeling task but observes a product label that is not in compliance with meat and poultry regulations. For example, if during the course of duty, IPP find that an ingredient is not declared on the final label, the net weight is incorrect, or the order of predominance of the ingredients on the label is inaccurate, IPP are to initiate a directed General Labeling task, retain affected product, and document the noncompliance in PHIS as described above.

VII. SUPERVISORY RESPONSIBILITIES

Katherine M. Marlamara DVM

A. Supervisors are to ensure that IPP are familiar with reviewing, and know how to review, labels and labeling records.

B. When "big 8" allergens or other ingredients of public health concern are not properly declared, a recall may be warranted. Refer to FSIS Directive 8080.1, *Recall of Meat and Poultry Products* for additional information on the recall of meat and poultry products.

XII. QUESTIONS

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Meat Inspection Service