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

FSIS DIRECTIVE

7221.1
Amend. 1

08-19-96

PRIOR LABELING APPROVAL

PURPOSE

This directive provides guidelines for inspectors. The guidelines will help inspectors to ensure that the modifications to the Food Safety and Inspection Service (FSIS) food labeling prior approval program regulations are implemented effectively and without disruption to the inspection process. The modified regulations streamline several aspects of the label approval, oversight, and enforcement process. The regulations are effective July 1, 1996.

These regulatory changes will:

1. institute a single label review;
2. permit companies to make minor labeling changes without resubmitting each label for prior approval;
3. permit companies to produce certain simple labels without submission to the Agency; and
4. reduce inspectors' paperwork and recordkeeping burdens.

Single review will reduce the paperwork burden for both FSIS employees and producers, as well as accelerate the label approval process. Inspectors will continue to inspect labels for regulatory compliance but will be able to spend more time on activities directly related to food safety, public health, and economic adulteration. Generic approval of a variety of new labels and minor labeling changes will also allow companies to be more responsible to changes in consumers' preferences for healthier foods and other market demands.

Labeling accuracy is expected to be maintained for several reasons. First, the regulations provide for increased Agency review of complex labels submitted for prior approval. Second, a multifaceted audit program is being created to complement the existing prior approval system. Third, companies' labeling accuracy will be an integral part of the Agency's assessment of establishment performance.

Companies must continue to adhere to the labeling standards incorporated in the Federal meat and poultry products inspection regulations and policies. They will be fully accountable for the content and production of all labels, whether generically approved, modified without resubmission, or submitted for FSIS for review and approval.

Finally, an oversight audit activity is being implemented in conjunction with the new regulations. The audits will allow FSIS to systematically monitor product labeling across the country, identify the most significant violations, periodically identify and refer technical labeling discrepancies for establishment correction, and assess trends that can be helpful in developing effective labeling requirements and product standards.

CANCELLATIONS

This directive cancels FSIS Directive 7227.1, dated 3/4/87, FSIS Directive 7231.2, dated 3/7/86, FSIS Directive 7231.3, dated 10/23/92, FSIS Directive 7234.1, Rev. 1, dated 1/25/89, FSIS Directive 7239.4, Rev. 1, dated 3288, and Policy Memo 096.

ESTABLISHMENT RESPONSIBILITIES

Establishments are responsible for ensuring that labeling used for meat and poultry products is not false or misleading. Establishments are responsible for correcting all labeling to comply with the Federal meat and poultry products inspection regulations and policies.

Sketch labeling (as defined in 9 CFR 317.4 and 381.132) must be submitted in duplicate to FLD for approval, except for labeling that may be generically approved. Labels that may be generically approved are listed in 9 CFR 317.5 and 381.133. Final labeling submitted to FLD for approval will not be approved by FLD, except for temporary approval.

Establishments may print a final label and use the label under a generically approved category without further authorization from FSIS. Establishments do not have to present a copy of the generically approved labeling or labeling approved by FLD to the Inspector-in-Charge (IIC) prior to use.

A corporation may submit one labeling application (in duplicate form) to FLD for a product produced in multiple establishments owned by the corporation.

Establishments are required to maintain records of all labeling used in accordance with 9 CFR 320 of the meat inspection regulations for meat products and 9 CFR Part 381, Subpart Q of the poultry products inspection regulations for poultry products. Labeling records must be made available to FSIS field personnel and any authorized USDA official upon request. If a corporation conducts business at multiple locations, labeling records may be kept at the headquarters office. When an FLD audit is being conducted, labeling records must be available within 24 hours. Each record must consist of the actual product's label, (including generic labeling and sketch approvals by FLD, if appropriate), the product formulation, and processing procedures, in accordance with 9 CFR 317.4, 317.5, 318.132, and 381.133.

The 24-hour time allowance does not pertain to providing formulation information to inspection personnel for the purpose of verifying product formulation or composition

performed under PBIS Process 06. In accordance with 9 CFR 318.6 and 381.180, whenever products are formulated, official establishments must provide inspectors accurate information upon request on all procedures involved in product preparation, including product composition and any changes in those procedures that are essential for inspection verification of the process. No specific format is required, however, the information must be as complete as needed for inspectors to perform PBIS Process 06 tasks.

FSIS no longer requires a specific labeling record filing system. Labeling records for generic labeling do not have to be completed on the labeling application form, FSIS Form 7234-1, Application for Approval of Labels, Marking, or Device. However, labeling submitted to FLD for approval must continue to be completed on FSIS Form 7234-1.

Establishments are responsible for transferring approved labels, wrappers, or containers bearing the official mark (with or without the establishment number) between official establishments. Establishments must also furnish inspectors accurate information on all procedures involved in product preparation, including product composition, and any changes in such procedures. Records must be maintained to properly identify product origin in the event of a product control problem, e.g., voluntary product recall.

Establishment management may appeal an inspection decision to the Program employee's supervisor having jurisdiction over the subject matter of the appeal.

INSPECTOR RESPONSIBILITIES IN DOMESTIC ESTABLISHMENTS

Inspection personnel will return existing labeling files to all establishments when the final prior labeling approval system regulations become effective on July 1, 1996. Inspection personnel will no longer be required to maintain labeling files as of July 1, 1996, and will not be directly involved in the submission or approval of labels.

Inspection personnel will continue to monitor product formulation and processing procedures using the appropriate Inspection System Guide (ISG) Process 06, Product Handling and Preparation Tasks, to ensure that all labeling conforms to the general labeling requirements.

Inspectors will verify that labels contain the mandatory features and accurately reflect the finished product by using revised ISG task code 07B01a2 when directed by FLD through the new label audit sampling program. ISG task code 07B01a2 has been modified to be performed only as directed through the new FLD label audit sampling program and will no longer be routinely scheduled. Like task code 11TO1a2, task code 07B01a2 is a "Directed Sample Request" task. However, there may be times when inspectors observe product labels that do not include the mandatory features or the label does not accurately reflect the finished product. In such cases, the inspector should document these incidents as "unscheduled tasks" using the same task code, 07B01a2, retain all suspect product, document a Process Deficiency Record, classify

the deficiency as “major,” and record the appropriate unscheduled code descriptor in the “major” column on the inspector’s assignment schedule.

07B Labeling

07B01a2	Labels contain Mandatory features. Labels accurately reflect the Finished product. There are no health, safety, or serious economic adulteration issues associated with the product.	316.13(g) 317.1-17 381.115-140 381.170 MPI Bulletins 418 And 83044 FSIS Directives 6030.1 7110.1 7220.2 7234.1 7235.1 7310.7	Select finished product labels as directed to verify that the labels contain the mandatory features and that the label accurately reflects the finished product. Send copies of the labels and requested information to FLD per the FLD sampling audit program.

When an inspector receives an audit request, the ISG task code 07B01a2 is performed as directed through the label audit sampling program. The inspector will select the finished product labels to determine if the following mandatory features appear on the finished product label in accordance with 9 CFR 317.2:

1. name of the product
2. ingredients statement, if needed
3. inspection legend and establishment number
4. handling statements, e.g., keep refrigerated, keep frozen, etc., if needed
5. net quantity of contents statement, if needed
6. signature line (manufacturer’s or distributor’s name and address)
7. nutrition labeling, if needed

Inspection personnel will also verify that the labeling accurately reflects the finished product to ensure that the product does not create an health, safety, or economic adulteration problem, and send copies of the labels and requested information to FLD as instructed on the label audit sampling program request.

When necessary, inspection personnel will be directed to provide labeling information for use by FSIS headquarters to audit generically approved labeling. This is one part of a multifaceted compliance monitoring plan to ensure labeling accuracy. There will be a nationally directed monitoring/surveillance plan that will provide for an overall assessment of all aspects of meat and poultry product labels. This program will include selecting samples from the establishment, the marketplace, and FSIS headquarters component (already reviewed and approved by FLD).

If all of the mandatory features appear on the label and the label accurately reflects the finished product, inspection personnel will mark the IIC's schedule "Acceptable." If all of the mandatory features do not appear on the label or the label does not accurately reflect the finished product, inspection personnel will mark the IIC's schedule "Major" and retain the product.

Questions pertaining to labeling deficiencies should be directed to the inspector's immediate supervisor.

RESPONSIBILITIES FOR IMPORTED PRODUCT

All current labeling approvals on file at U.S. ports of entry on July 1, 1996, will be returned to the foreign establishments. The management of establishments certified under foreign inspection systems must maintain copies of all labeling used, along with the relevant product formulations and processing procedures, in accordance with 9 CFR 317.4(a).

Foreign establishments are responsible for ensuring the accuracy of labeling for all product exported to the United States. Foreign inspection systems will verify that each establishment maintains complete labeling records and practices that result in compliance with current FSIS labeling regulations and policy. Where appropriate, foreign countries will declare a protein fat free (PFF) group number on the health certificate for product amendable to PFF analysis in accordance with 9 CFR 318.19(a)(2). Also, Group II protein data must be supplied on the health certificate for sausage products which contain Group II protein ingredients as defined in 9 CFR 318.22.

Prior to exporting meat and poultry products to the United States, foreign establishments will submit label sketches (in triplicate form) in those circumstances where labeling is required to be submitted to FLD for approval, in accordance with 9 CFR 317.4. FLD will retain one copy of the approved sketch, return one copy to the submitting party, and send one copy to International Programs (IP). IP will send the approvals to the foreign government's inspection system.

FSIS Foreign Programs Officers will verify a foreign inspection system's labeling controls by reviewing their labeling records (e.g., FLD sketch labeling approvals and generically approved labeling). When a shipment is presented for reinspection at the U.S. port of entry, FSIS import inspectors will ensure that the labeling contains all mandatory features and accurately reflects the finished product.

/s/ Craig A. Reed

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