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

FSIS DIRECTIVE

7237.1
Rev. 1
Amend. 1

8/9/94

LABELING OF INGREDIENTS

I. PURPOSES

The purposes of this directive are to:

A. clarify information contained in FSIS Directive 7237.1, dated 2/22/94, and provide FSIS policy changes;

B. provide FSIS personnel with information on changes in the FDA regulations on ingredient labeling that apply when FDA-standardized foods, FDA-certified color additives, or protein hydrolysates are used as ingredients in meat and poultry products,

C. give official establishments the opportunity to make changes when designing new labels,

D. serve as a guide for use with applicable parts of the MPI Regulations.

II. CANCELLATION

FSIS Directive 7237.1, dated 2/22/94.

III. REASONS FOR REISSUANCE

Requests were received for clarification of the intent of FSIS Directive 7237.1, dated 2/22/94, and to extend the time provided for compliance with the policy outlined in the directive. Because of the extensive changes, this directive has been rewritten in its entirety.

IV. REFERENCES

MPI Regulations, Parts 317, 318, 319, and 381.
FDA Regulations, 21 CFR, Parts 73, 74, 101, 102, 130, 131, 133, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 166, 168, and 169.

V. DEFINITIONS

FDA	Food and Drug Administration
FLD	Food Labeling Division
MPI	Meat and Poultry Inspection
PMC	Proprietary Mix Committee

VI. POLICY/BACKGROUND

A. FSIS regulates the labeling of meat and poultry products while FDA has responsibility for all other food labeling, including food ingredients. When FDA regulated foods and food ingredients are used as components and ingredients in meat and poultry products, FSIS follows FDA's requirements for labeling of those foods and ingredients with very few exceptions.

B. On January 6, 1993, FDA published regulations amending its ingredient labeling requirements for standardized foods, color additives, and protein hydrolysates. FDA amended the regulations in response to the Nutrition Labeling and Education Act of 1990. The regulations are intended to provide consumers with more information on the ingredients in their foods to assist in making sound personal food choices. The amended regulations require the listing of the common or usual names of all ingredients in standardized foods and all FDA-certified color additives. These FDA regulations were effective in May 1993. The regulations also require the listing of the common and usual names of protein hydolysates and the identity of the source from which the protein was derived. The time period for compliance with these FDA regulations has been extended to August 8, 1994.

C. Because FDA maintains regulatory authority to determine the common or usual names of ingredients, FSIS's policy regarding the labeling of FDA-standardized foods, FDA-certified color additives and protein hyrolysates, when used as components or ingredients in meat and poultry products, will parallel FDA's regulatory changes as published on January 6, 1993. Changes to the MPI regulations resulting form this policy, (e.g., changing the common or usual name of "hydrolyzed vegetable protein" whenever it appears), will be published in the Federal Register. Similar changes will be made to FSIS policy issuances (e.g., the Standards and Labeling Policy Book), as appropriate. However, implementation of the policies in this directive is not contingent upon publication of such changes. FSIS's intent is that all labels for meat and poultry will be modified to conform to FDA's regulations by August 8, 1995. Until that time, labels approved by the Food Labeling Division (FLD), Regulatory Programs, will be approved with the condition that changes will be made to conform to FDA's regulations by August 8, 1995.

D. The intent of the subject FDA ingredient labeling changes is to provide more ingredient information for the consumer. FDA has always required the ingredients in non-standardized FDA-foods and food ingredients to be fully disclosed on the labels of such products. FSIS has followed this requirement with certain exceptions, e.g., soy

sauce and Worcestershire sauce, used in the formulation of meat and poultry products. As a matter of conformance with the intent of FDA's regulations, FSIS will also require the full disclosure of the ingredients in all non-standardized FDA foods on the labels of meat and poultry products.

E. Consistent with the intent to provide consumers with explicit ingredient information, FSIS intends to amend its policy regarding the use of cured meat, e.g., bacon and ham, as ingredients in meat and poultry products. Currently, when cured meat ingredients are used at less than 10 percent of a meat or poultry product formulation, the ingredients do not need disclosure on the labels of the products. On August 8, 1995, FSIS will require complete disclosure of all ingredients in cured meat products used as ingredients, regardless of their label of use in the formulations of meat and poultry products.

F. FSIS extended the compliance date to August 8, 1995, based on concerns that the original date (i.e., July 6, 1994) by which the Agency expected compliance with FDA's regulations provided insufficient time for meat and poultry processors to modify their labels. FDA has extended the time period for compliance with the final portion of its regulations (i.e., on protein hydrolysates) to August 8, 1994, when all FDA labels must reflect the new ingredient labeling rules. However, more time is required to, in turn, modify meat and poultry labels.

VII. PROCEDURES

A. Establishments voluntarily amending labels to conform to the subject FDA regulations should submit labels to FLD, Regulatory Programs, Washington, DC, for approval. Verification for conformance with FDA's regulations on labeling of ingredients is determined only at the time of meat and poultry product label approval. Presently, there is no requirement for enforcement of the subject regulations by inspection personnel. If inspection personnel have specific questions about ingredients on particular labels, those questions may be directed to the Branch Chief, Food Standards and Ingredients Branch, Product Assessment Division, Regulatory Programs, at (202) 254-2588.

B. Labels conforming to the ingredient labeling requirements must be submitted to FLD, Regulatory Programs, for review and approval by August 8, 1995. Manufacturers are encouraged to familiarize themselves with the ingredient labeling procedures and may begin to submit their new labels in accordance with the labeling ingredient requirements.

VIII. FURTHER GUIDANCE

If there are technical questions concerning this directive, please contact the Branch Chief, Food Standards and Ingredients Branch, Product Assessment Division, Regulatory Programs, at (202) 254-2588.

/s/ Robert W. Gonter
for

Deputy Administrator
Office of Policy, Program Development
and Evaluation