§ 381.140 Relabeling poultry products.

When it is claimed by the operator of an official establishment that some of its labeled poultry product, which has been transported to a location other than an official establishment, is in need of relabeling because the labeling has become mutilated or damaged, or for some other reason needs relabeling, the requests for relabeling the poultry product shall be sent to the Administrator and accompanied with a statement of the reasons therefor and the quantity of labeling required. Labeling material intended for relabeling inspected and passed product shall not be transported from an official establishment until permission has been received from the Administrator. The relabeling of inspected and passed product shall be done under the supervision of an inspector pursuant to the regulations in part 362 of this chapter. The establishment shall reimburse the Inspection Service for any cost involved in supervising the relabeling of such product as provided in said regulations.

§§ 381.141–381.143 [Reserved]

§ 381.144 Packaging materials.

(a) Edible products may not be packaged in a container which is composed in whole or in part of any poisonous or deleterious substances which may render the contents adulterated or injurious to health. All packaging materials must be safe for the intended use within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act, as amended (FFDCA).

(b) Packaging materials entering the official establishment must be accompanied or covered by a guaranty, or statement of assurance, from the packaging supplier under whose brand name and firm name the material is marketed to the official establishment. The guaranty shall state that the material’s intended use complies with the FFDCA and all applicable food additive regulations. The guaranty shall identify the material, e.g., by the distinguishing brand name or code designation appearing on the packaging material shipping container; must specify the applicable conditions of use, including temperature limits and other pertinent limits specified under the FFDCA and food additive regulations; and must be signed by an authorized official of the supplying firm. The guaranty may be limited to a specific shipment of an article, in which case it may be part of or attached to the invoice covering such shipment, or it may be general and continuing, in which case, in its application to any article or other shipment of an article, it shall be considered to have been given at the date such article was shipped by the person who gives the guaranty. Guaranties consistent with the Food and Drug Administration’s regulations regarding such guaranties (21 CFR 7.12 and 7.13) will be acceptable. The management of the establishment must maintain a file containing guaranties for all food contact packaging materials in the establishment. The file shall be made available to Program inspectors or other Department officials upon request. While in the official establishment, the identity of all packaging materials must be traceable to the applicable guaranty.

(c) The guaranty by the packaging supplier will be accepted by Program inspectors to establish that the use of material complies with the FFDCA and all applicable food additive regulations.

(d) The Department will monitor the use of packaging materials in official establishments to assure that the requirements of paragraph (a) of this section are met, and may question the basis for any guaranty described under paragraph (b) of this section. Official establishments and packaging suppliers providing written guaranties to those official establishments will be permitted an opportunity to provide information to designated Department officials as needed to verify the basis for any such guaranty. The required information will include, but is not limited to, manufacturing firm’s name, trade name or code designation for the material, complete chemical composition, and use. Selection of a material for review does not in itself affect a
material's acceptability. Materials may continue to be used during the review period. However, if information requested from the supplier is not provided within the time indicated in the request—a minimum of 30 days—any applicable guaranty shall cease to be effective and approval to continue using the specified packaging material in official establishments may be denied. The Administrator may extend this time where reasonable grounds for extension are shown, as, for example, where data must be obtained from suppliers.

(e) The Administrator may disapprove for use in official establishments packaging materials whose use cannot be confirmed as complying with the FFDCA and applicable food additive regulations. Before approval to use a packaging material is finally denied by the Administrator, the affected official establishment and the supplier of the material shall be given notice and the opportunity to present their views to the Administrator. If the official establishment and the supplier do not accept the Administrator's determination, a hearing in accordance with applicable rules of practice will be held to resolve such dispute. Approval to use the materials pending the outcome of the presentation of views or hearing shall be denied if the Administrator determines that such use may present an imminent hazard to public health.

(f) Periodically, the Administrator will issue to inspectors a listing, by distinguishing brand name or code designation, of packaging materials that have been reviewed and that fail to meet the requirements of paragraph (a) of this section. Listed materials will not be permitted for use in official establishments. If a subsequent review of any material indicates that it meets the requirements of paragraph (a), the material will be deleted from the listing.

(g) Nothing in this section shall affect the authority of Program inspectors to refuse a specific material if he/she determines the material may render products adulterated or injurious to health.

[49 FR 2236, Jan. 19, 1984]