
FSIS DIRECTIVE

7410.1
Rev. 1

7-1-93

PACKAGING MATERIALS

I. PURPOSE

This directive provides guidelines for enforcing the packaging regulations contained in Sections 317.24 and 381.144 of the MPI Regulations.

II. CANCELLATION

FSIS Directive 7410.1, dated 6/29/84

III. REASON FOR REISSUANCE

This revision updates references to MPI Regulations, Section 317.24, (formerly designated as 317.20), and FSIS Directive 11,000.2 (formerly Part 8.34 of the MPI Manual). Also, this revision updates the phone number, mailing address, and organization structure for the Product Assessment Division, Compounds and Packaging Branch (formerly Food Ingredient Assessment Division, Product Safety Branch), Regulatory Programs.

IV. REFERENCES

21 CFR 7.12 and 7.13 FDA Regulations;
MPI Regulations, Sections 301.2, 317.24, 381.1, 381.144;
FSIS Directive 11,000.2 dated 4.28/87

V. [RESERVED]

VI. POLICY

Official establishments must receive from the suppliers of their packaging materials and retain in their files, written guaranties that the materials are in compliance with the Federal Food, Drug and Cosmetic Act (FFDCA), as emended, and all applicable food additive regulations. Inspectors will view such guaranties as establishing that the described packaging materials are in compliance with the FFDCA and all applicable food additive regulations unless the inspector has specific reasons to believe otherwise. FSIS will institute a monitoring program to ensure written guaranties can be substantiated.

VII. REQUIREMENT FOR GUARANTY

A. What Requires a Guaranty. The packaging material regulations are intended to cover only those materials which may become components of food due to their contact with meat or poultry products (i.e., indirect food additives). Therefore, establishments are required to obtain from suppliers and keep on file a guaranty for all food contact packaging materials in the establishment. Some examples of food contact packaging materials are:

- Absorbent Pads
- Insert Labels
- Glass Jars
- Cans
- Giblet Wrap

B. What Does Not Require a Guaranty.

1. Packaging Materials (no food contact).

- a. Since the regulations are intended to only cover those materials which may become indirect food additives through contact, a guaranty is not required for materials not in direct contact with meat or poultry products. Some materials meet the definition of packaging material in Sections 301.2(ddd) and 381.1(b)(59) of the MPI Regulations, but are not indirect food additives and therefore are not covered by these packaging material regulations. Examples of these are shipping cartons which are not the immediate container, netting placed over sealed plastic wrap, labels applied to cans or other containers after the food is sealed inside, and strapping or tape used where food contact is not expected.
- b. A guaranty is not required at the receiving establishment for packaging material used on meat and poultry products coming from another official establishment, even if it is reused at the destination establishment. If the packaging material is reused, its use must be in

accordance with FSIS Directive 11,000.2. Such materials should be covered by a guaranty at the establishment of origin (i.e., the point at which the meat or poultry product was first packaged).

- c. A guaranty is not required for packaging materials containing ingredients, such as antioxidants or binders, received at an establishment.
2. Other Materials. A guaranty is not required for materials which do not meet the definition of packaging materials, even though there may be food contact. Though not covered under the packaging regulations, such materials may be regulated under other sections of the regulations. For example, equipment and utensils are covered under Sections 308.5 and 381.53 of the MPI Regulations. Examples of such exclusions are:

Apparel – coats, aprons, gloves, boots, head covers

Utensils – knives

Equipment and Parts – belts, gaskets, cutting boards

Construction and Repair Material – wall board, ceiling panels, floor coverings, coatings

Additives – scald additives, smoke flavorings, branding inks, dry ice

Nonfood Compounds – cleaners, water treatments, pesticides

Continue to handle these materials as in the past.

VIII. WHAT TO LOOK FOR IN THE GUARANTY

A. Source.

1. The guaranty must be from the supplier of the packaging material. USDA-issued acceptance letters may not be substituted for a guaranty. Generally, the firm supplying the guaranty (i.e., supplier) will be the firm under whose name the material is marketed to the official establishment. The firm and brand names on the guaranty must be traceable to the material which it covers. Some material, such as aluminum roll stock, is used to form different sizes and shapes of containers. A separate guaranty is not needed for each size or shape. A guaranty provided by the roll stock supplier is sufficient.
2. The guaranty for packaging materials fabricated within an establishment may come from the official establishment itself. An example would be aluminum roll stock for trays which is coated and formed after it is received at the establishment. Since the establishment has modified the aluminum roll stock by coating it, the establishment must guarantee the final form of the material.

- B. Format. A guaranty need not be in any specific format, but must include the following information:
1. Statement that the material complies with the FFDCA and any applicable regulations.
 2. Brand name or “code” designation of the material. The term code is not intended to suggest a universal coding system. A code may be any combination of letters or numbers that is used by the supplier to identify a specific packaging material.
 3. Name of the supplier.
 - a. A supplier may be any one of a number of firms; the manufacturer, a distributor, or even the establishment itself (See VIII.(A). (2).)
 - b. The supplier will generally be the firm whose name appears on the packaging material shipping container or other documentation (e.g., bill of lading) accompanying the packaging material.
 4. Conditions of use for the material, including temperature and other pertinent limits. This information is required to avoid improper use and to insure that there is no misunderstanding among suppliers, establishments, and inspectors about the use(s) covered by a guaranty. Existing acceptance criteria limit certain materials to specific use conditions (e.g., maximum processing temperature or use only with certain types of food such as nonacid foods). Therefore, a guaranty must include the use condition and limitations under which the guaranty is valid (e.g., to contain meat at room temperature and below or to contain poultry products processed at temperatures not exceeding 100 degrees C.).
 5. Signature of an official of the supplier should include typed or printed name and title. The signing official need not be an officer of the supplying firm.

C. Traceability.

1. The identity of all packaging materials in the establishment must be traceable to the applicable guaranty.
2. Do not look for a brand or supplier identification on each container (e.g., can or jar). Instead, look for a brand name or supplier identification on shipping cases, invoices, or bills of lading which can be traced to a particular container. In instances when the identification does not appear on the shipping container (e.g., bulk shipments or palletized shipments of cans), establishments will be held responsible for maintaining traceability,

segregating shipments, or otherwise associating packaging materials with the applicable guaranty.

3. Guaranties need not cover specific size, shape, or thickness of container or wrapper. Rather, they cover the material from which such packages are fabricated. Individual packages need only be traceable to the stock material. This is particularly true for cans, trays, or boxes made within the establishment. For example, the same aluminum roll stock may be used within the establishment to form different sizes and/or shapes of trays. A separate guaranty is not required for each size and/or shape tray. A guaranty covering the roll stock is sufficient.

IX. WHAT TO DO WHEN PROBLEMS ARE ENCOUNTERED

Problems other than those discussed below should be handled as in the past. Even if guaranties are complete and correct, inspectors should continue to inspect and disallow the use of packaging materials and retain products contained in them if there is reason to believe the materials may render the products adulterated or injurious to health.

A. Problems That May Occur With Guaranties:

1. No guaranty letter is available or traceable for a packaging material.
2. Guaranty has missing information.
3. Conditions of use are different from those guaranteed.

B. Inspectors in Charge. Check for problems as described in Paragraph IX. A. above and call the Area Supervisor for guidance in resolving any problem concerning compliance with the regulations. Do not retain the packaging material or product packaged in it on your own volition pending resolution of a problem with the guaranty.

C. Circuit Supervisors. Check for problems as described in Paragraph IX A. above during visits to the establishments and call the Area Supervisor for guidance in resolving any problems concerning compliance with the regulations. Do not retain the packaging material or product packaged in it on your own volition pending resolution of a problem with the guaranty.

D. Area Supervisors.

1. Use your discretion to determine appropriate action to resolve problems as described in Paragraph IX. A. above when possible.
2. Keep a log of calls to include the date, brief description of the problem, and action taken to resolve the problem.

3. When problems cannot be resolved within the context of policy described in this directive, contact the Compounds and Packaging Branch for consultation. Questions should be directed to:

Compounds and Packaging Branch, PAD, RP
Food Safety and Inspection Service
U.S. Department of Agriculture
Bldg. 306, BARC-East
Beltsville, MD 20705
Telephone: (301) 504-8566, FTS 504-8566

Wilson Horne

Deputy Administrator
Inspection Operations