

OPI: RP/PAD

PACKAGING MATERIALS MONITORING

I. PURPOSE

This directive provides guidelines for complying with the packaging monitoring requirements contained in Sections 317.24(d) and 381.144(d) of the MPI Regulations.

II. CANCELLATION

FSIS Directive 7410.2, dated 9/20/85

III. REASON FOR REISSUANCE

This revision updates references to MPI Regulations, Sections 317.24 (formerly designated as 317.20) and 381.144(d); FSIS Directive 11,000.2 (formerly Part 8.34 of the MPI Manual). It revises FSIS Form 11,300-11 (formerly FSIS Form 6800-11). This revision also 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, and 381.144; FSIS Directive 11,000.2 dated 4/28/87; FSIS Directive 7410.1, Rev. 1, dated 7/1/93;

V. ABBREVIATIONS AND FORM

The following will appear in their abbreviated form in this directive:

FFDCA Federal Food, Drug, and Cosmetic Act
IIC Inspector In Charge
PAD Product Assessment Division
CPB Compounds and Packaging Branch
IO Inspection Operations

FSIS Form 11,300-11--Packaging Material Monitoring

VI. POLICY

MPI Regulations, Sections 317.24 and 381.144, note that official establishments must receive from the suppliers of their packaging materials and retain in their files, written guaranties that the materials comply with the FFDCA, as amended, and all applicable food additive regulations. Such guaranties establish that the described packaging materials are in compliance unless the inspector has specific reasons to believe otherwise.

FSIS will monitor the use of packaging materials in official establishments to ensure that the written guaranties can be substantiated.

VII. INSPECTOR'S RESPONSIBILITIES

A. The IIC shall:

1. Receive FSIS Form 11,300-11, (See Attachment 1), which will be forwarded to randomly selected establishments by the CPB.

2. Select a specified number of packaging material(s) (one material per monitoring form) during the timeframe indicated on the monitoring form. If possible, different kinds of materials (e.g., cans, plastic film, etc.) should be selected and the material(s) should be currently in use at the establishment and covered by a guaranty.

3. Provide the necessary information as indicated on the monitoring form. Most of this information can be taken directly from the guaranty. If no material is used at the establishment, *** the IIC should write "NONE" in Item 1 *** and complete Item 6.

4. Use the self-addressed envelope that accompanies the monitoring form and return it completed to CPB. A sample of the packaging material should not be submitted.

5. Allow continued use of a material during the review period. Selection of a material for review does not affect a material's acceptability. If the acceptability of a packaging material cannot be confirmed, the IIC at the establishment where the material was selected for review will be notified by Headquarters IO office. Subsequently, an FSIS listing of selected materials will be issued to inform all other establishments.

VIII. REVIEW REQUIREMENTS

A. CPB will review the information provided by the IIC on FSIS Form 11,300-11. If CPB does not have the complete chemical composition of a packaging material that has been selected, a letter (See Attachment 2) will be sent to establishment management with copies to the IIC and the pack-aging material supplier. CPB will assign a Monitoring Control Number to each monitoring form. This number must be included on all correspondence from establishment management or the material supplier in order to track the progress of the *** evaluation of the selected packaging material.

B. CPB will review additional information requested in Attachment 2 that would verify the basis for the supplier's guaranty.

1. The establishment/supplier will have a minimum of 30 days to submit the information. The information should include, but not necessarily be limited to: manufacturing firm's name, brand name or code designation for the material, complete chemical composition, and intended use of the selected material. The Monitoring Control Number, as shown at the bottom of Attachment 2, should be included on all correspondence from the establishment or packaging supplier concerning that packaging material.

2. If CPB does not receive a reply from the packaging material supplier within the timeframe specified, a final notice (See Attachment 3) will be sent to establishment management with copies to the IIC and the packaging material supplier.

3. If no response to the final notice is received and the safety and/or acceptability of the material cannot be confirmed, continued use of the packaging material may be denied in accordance with the procedures in MPI Regulations, Sections 317.24(e) and 381.144(d). If use of a packaging material is denied, the IIC at the establishment where the material was selected for review will be notified by Headquarters IO office. Subsequently, an FSIS listing will be issued to inform all other establishments.

C. Inspectors shall not take action to prevent use of the material until official notification is issued.

IX. NOTIFICATION OF UNACCEPTABLE MATERIALS

If the use of a material is denied by the Administrator, the IIC at the establishment where the material was selected for review will be immediately notified by the Headquarters IO office. Also, FSIS will periodically issue to inspectors a listing, by distinguishing brand name or code designation and by the supplier's name and address, of packaging materials that have been reviewed and have failed to meet the requirements of the FFDCAs, as amended. Materials listed are those not permitted for use in official establishments. If a subsequent review of any material indicates that it meets the requirements of the FFDCAs, a letter will be issued to the packaging material supplier superseding the listing. This letter will serve as proof of acceptability until a subsequent listing is issued.

A. Upon receipt of notification by the Headquarters IO office or the FSIS listing, the IIC will take the following actions:

1. Follow instructions given in the notification of unacceptable materials, which will be sent by the Headquarters IO Office.

2. Review the FSIS listing to determine if any listed materials are in use at the establishment. The inspector should not allow materials listed in the FSIS listing to be used in

official establishments unless notified otherwise. Unless an imminent hazard to public health exists, no product recalls or repackaging should be required. The disposition of materials already in the establishment, which appear in the FSIS listing, and of food products packaged in such materials, will be handled on a case-by-case basis in the notification.

Craig A. Reed
Deputy Administrator
Inspection Operations

Attachments

- 1 -- FSIS Form 11,300-11 (Reference hard copy of FSIS Directive 7410.2, Rev. 1)
- 2 -- Example--FSIS Letter to Establishment
- 3 -- Example--Final FSIS Letter to Establishment

Attachment 2

Manager, Establishment #	Date
Establishment Name	
Establishment Address	
Establishment Address	

Dear Establishment Manager:

In accordance with MPI Regulations, Sections 317.24 and 381.144, the Food Safety and Inspection Service (FSIS) monitors the use of food contact packaging materials in official establishments to assure that they conform to the requirements of the Federal Food, Drug, and Cosmetic Act and all applicable food additive regulations. This establishment was selected at random to participate in the monitoring program.

On (Date) _____, the Federal Inspector at this establishment selected (Material Name) supplied by (Supplier's Name) for review. FSIS has no information on file concerning this packaging material. Therefore, we will need the complete chemical composition and intended use from the supplier in order to ensure that the written guaranty from the supplier listed above can be substantiated.

All major and minor constituents in the formulation must be listed by proper chemical name as they appear in the appropriate regulations (Title 21, Code of Federal Regulations). Dyes and pigments must be identified by their 5-digit Colour Index Constitution number or structural formula. Each ingredient should be further identified by its CAS registry number when available. Chemical formulations and other proprietary information are held in a confidential file and used only to evaluate the material. Please have your packaging material supplier submit the complete composition of the above material to the address below within 30 days. If the information is

not provided within the time indicated, the guaranty will be considered invalid and use of this material in official establishments may be denied.

USDA, FSIS, RP, PAD
Compounds and Packaging Branch
Bldg. 306, BARC-East
Beltsville, Maryland 20705

All correspondence concerning this request must include the monitoring control number below or a copy of this letter.

* (monitoring control #) *

If you have any problems, please call the Compounds and Packaging Branch at (301) 504-8566.

Sincerely,

John M. Damare, Chief
Compounds and Packaging Branch
Product Assessment Division
Regulatory Programs

cc: Inspector in Charge
Packaging Material Supplier

Attachment 3 Manager,

Establishment #
Establishment Name
Establishment Address
Establishment Address

F I N A L N O T I C E - (date)

Dear Establishment Manager:

In accordance with MPI Regulations, Sections 317.24 and 381.144, the Food Safety and Inspection Service (FSIS) monitors the use of food contact packaging materials in official establishments to assure that they conform to the requirements of the Federal Food, Drug, and Cosmetic Act and all applicable food additive regulations. This establishment was selected at random to participate in the monitoring program.

On (Date) , the Federal Inspector at this establishment selected (Material Name) supplied by (Supplier's Name) for review. FSIS has no information on file concerning this packaging material. Therefore, we will need the complete chemical composition and intended use from the supplier in order to ensure that the written guaranty from the supplier listed above can be substantiated.

All major and minor constituents in the formulation must be listed by proper chemical name as they appear in the appropriate regulations (Title

21, Code of Federal Regulations). Dyes and pigments must be identified by their 5-digit Colour Index Constitution number or structural formula. Each ingredient should be further identified by its CAS registry number when available. Chemical formulations and other proprietary information are held in a confidential file and used only to evaluate the material. Please have your packaging material supplier submit the complete composition of the above material to the address below within 30 days. If the information is not provided within the time indicated, the guaranty will be considered invalid and use of this material in official establishments may be denied.

USDA, FSIS, RP, PAD
Compounds and Packaging Branch
Bldg. 306, BARC-East
Beltsville, Maryland 20705

All correspondence concerning this request must include the monitoring control number below or a copy of this letter.

* (monitoring control #) *

If you have any problems, please call the Compounds and Packaging Branch at (301) 504-8566.

Sincerely,

Failure to respond to this final notice within 30 days will result in invalidation of the guaranty for this material.

John M. Damare, Chief
Compounds and Packaging Branch
Product Assessment Division
Regulatory Programs

cc: Inspector in Charge
Packaging Material Supplier