

PART 905—[AMENDED]

Accordingly, the provisions of § 905.306 are amended by revising the following entries in Table I paragraph (a), applicable to domestic shipments, and Table II paragraph (b), applicable to export shipments, to read as follows:

§ 905.306 Orange, grapefruit, tangerine and tangelo regulation 6.

(a) * * *

TABLE I

Variety	Regulation period	Minimum grade	Minimum diameter (inches)
(1)	(2)	(3)	(4)
Grapefruit: Seedless, white.	1/23/84-8/19/84.	Improved No. 2 (External), U.S. No. 1 (Internal).	3½e
	On and after 8/20/84.	Improved No. 2 (External), U.S. No. 1 (Internal).	3½e
Oranges: Temple.	1/16/84-8/19/84.	U.S. No. 1 Golden.	2½e
	On and after 8/20/84.	U.S. No. 1	2½e

(b) * * *

TABLE II

Variety	Regulation period	Minimum grade	Minimum diameter (inches)
(1)	(2)	(3)	(4)
Oranges: Temple.	1/16/84-8/19/84.	U.S. No. 1 Golden.	2½e
	On and after 8/20/84.	U.S. No. 1	2½e

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674)

Dated: January 16, 1984.

Russell L. Hawes,

Acting Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 84-1513 Filed 1-18-84; 8:45 am]

BILLING CODE 3410-02-M

7 CFR Parts 959 and 979**Expenses and Rates of Assessment for Specified Marketing Orders**

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation authorizes expenses of the committees functioning under Marketing Orders 959 and 979. Funds to administer these programs are

derived from assessments on handlers of the fruits and vegetables regulated under the orders.

EFFECTIVE DATES: August 1, 1983—July 31, 1984 (§ 959.224); October 1, 1983—September 30, 1984 (§ 979.206).

FOR FURTHER INFORMATION CONTACT: Robert F. Matthews, Vegetable Branch, F&V, AMS, USDA, Washington, D.C. 20250; (202) 447-5764.

SUPPLEMENTARY INFORMATION: This rule has been reviewed under Secretary's Memorandum 1512-1 and Executive Order 12291 and has been designated a "nonmajor" rule.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) William T. Manley, Deputy Administrator, Agricultural Marketing Service, has certified that this action will not have a significant economic impact on a substantial number of small entities.

These marketing orders are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674). These actions are based upon the recommendations and information submitted by each committee established under the respective marketing orders, and upon other information. It is found that the expenses and rates of assessment, as hereinafter provided, will tend to effectuate the declared policy of the act.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice and engage in public rulemaking and good cause exists for not postponing the effective date until 30 days after publication in the Federal Register (5 U.S.C. 553). Each order requires that the rate of assessment for a particular fiscal period shall apply to all assessable fruits and vegetables handled from the beginning of such period. To enable the committee to meet current fiscal obligations, approval of the expenses is necessary without delay. It is necessary to effectuate the declared policy of the act to make these provisions effective as specified and handlers have been apprised of such provisions, and the effective time.

List of Subjects in 7 CFR Parts 959 and 979

Marketing agreements and orders, Onions, Melons, Texas.

Sections 959.223 (M.O. 959) and 979.205 (M.O. 979) are removed and new sections are added as follows: (The following sections prescribe annual expenses and assessment rates and will not be published in the Code of Federal Regulations.)

PART 959—ONIONS GROWN IN SOUTH TEXAS**§ 959.224 Expenses and assessment rate.**

Expenses of \$230,150 by the South Texas Onion Committee are authorized, and an assessment rate of \$0.03 per 50-pound container or equivalent quantity is established for the fiscal period ending July 31, 1984. Unexpended funds may be carried over as a reserve.

PART 979—MELONS GROWN IN SOUTH TEXAS**§ 979.206 Expenses and assessment rate.**

(a) Expenses of \$118,600 by the South Texas Melon Committee are authorized, and an assessment rate of \$0.01 per carton of melons is established for the fiscal period ending September 30, 1984.

(b) In accordance with the provisions of § 979.42, late payment charges of one and one-half percent per month shall be charged on the unpaid balance for each past due account. An account is past due 30 days after the billing date. Unexpended funds may be carried over as a reserve.

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674)

Dated: January 16, 1984.

Russell L. Hawes,

Acting Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 84-1512 Filed 1-18-84; 8:45 am]

BILLING CODE 3410-02-M

Food Safety and Inspection Service**9 CFR Parts 301, 317, 320 and 381**

[Docket No. 82-018F]

Policy Governing Inspection of Packaging Materials

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the Federal meat and poultry products inspection regulations to clarify the Food Safety and Inspection Service (FSIS) policy on the use by federally inspected establishments of various packaging materials for meat and poultry products. Inspectors are authorized to prevent the use of any packaging materials that might lead to the adulteration of product. The current FSIS policy of providing an advisory evaluation of packaging materials prior to use, to ensure they will be permitted to be used in the establishment, has been misinterpreted to be a mandatory premarket approval procedure. The

policy therefore requires clarification and revision. This final rule defines "packaging material" and requires that official establishments 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 amended, and all applicable food additive regulations; that inspectors 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 reason to believe otherwise; that FSIS continue to evaluate packaging materials upon request; and that FSIS institute a monitoring program to ensure written guaranties can be substantiated.

EFFECTIVE DATE: July 17, 1984.

FOR FURTHER INFORMATION CONTACT: Charles Edwards, Chief, Product Safety Branch, Food Ingredient Assessment Division, Science, Food Safety and Inspection Service, U.S. Department of Agriculture, Bldg. 306, BARC East, Beltsville, MD 20705, (301) 344-2566.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

The Agency has made a determination that this final rule is not a major rule under Executive Order 12291. It will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. This regulation provides that federally inspected meat and poultry establishments obtain and keep on file a written guaranty from packaging suppliers that packaging is in compliance with the FFDCA and all applicable food additive regulations. This will result in a more simple, timely, and economical way than is now available for official establishments to demonstrate to inspectors that packaging materials comply with the food additive laws.

Effect on Small Entities

The Administrator, FSIS, has determined that this final rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act, Pub. L. 95-354 (5 U.S.C. 601). The

rule may have a very minor impact on costs to those official establishments where no records of packaging materials used are currently kept. Thus, the increased cost to small entities within this class is not expected to be significant. Otherwise, no increased cost to official establishments is expected.

Background

The Poultry Products Inspection Act (PPIA) and the Federal Meat Inspection Act (FMIA) authorize Federal inspectors in official establishments subject to either Act to prevent product which may be adulterated from entering into commerce (21 U.S.C. 451 *et seq.* and 601 *et seq.*). Product may become adulterated in a number of ways, including by migration of substances from containers.

A meat or poultry-product is adulterated if it bears or contains any food additive which is unsafe within the meaning of section 409 of the FFDCA (21 U.S.C. 453(g)(2)(c) and 601(m)(2)(c)). Section 409 of the FFDCA provides that all food additives are unsafe unless found by the Food and Drug Administration (FDA) to be safe for their intended use (21 U.S.C. 438). FDA lists approved food additives and other substances that might become components of food, together with conditions of use for such products, in its regulations (21 CFR Parts 170-189). These listings include indirect food additives such as packaging materials which may become components of the foods due to their contact with the foods. Therefore, packaging or other food contact materials that might become components of food and that are intended for use in federally inspected establishments must comply with all applicable regulations promulgated under the FFDCA or be deemed "unsafe."

Furthermore, a meat or poultry product may be adulterated under the PPIA and FMIA "if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health" (21 U.S.C. 453(g)(6) and 601(m)(6)).

Thus, Federal inspectors in official establishments are authorized to inspect packaging materials intended for use with food products subject to the FMIA and the PPIA. Although there are currently no regulations in Title 9 of the Code of Federal Regulations that deal specifically with packaging materials for meat and poultry products, § 17.16 of the Meat and Poultry Inspection Manual explains the inspectors' authority in this regard by stating: "Generally, packages and packaging materials need not be

sampled; however, if the inspector has reason to doubt their acceptability, he requires the plant or supplier to show a letter of acceptance, and permits use of materials on the basis of such letter."

Under current policy, if an inspector questions the safety of a packaging material, the Food Ingredient Assessment Division (FIAD), Science, FSIS, evaluates the material's chemical acceptability and advises the inspector and establishment of its findings. There is no regulatory requirement for prior review and approval of packaging materials, and packaging materials may be sold to and used by official establishments without any prior approval by any central USDA authority. However, a Federal inspector may inspect and disallow the use of a packaging material, and may retain any product contained in it if he/she has reason to doubt the chemical acceptability of the packaging material.

Since 1972, FSIS has provided as a free service to industry a prior evaluation of packaging materials and other resinous or polymeric materials which may be used in a food contact setting. This service resulted from discussions in the late 1960's with the packaging industry concerning ways to confirm acceptance of materials when inspectors question their acceptability. Prior evaluation (not approval) of those materials in that context can be advantageous to all involved. This can help to prevent unnecessary confrontations and costly delays for the food industry that may result when an inspector questions the acceptability of a packaging material. FIAD's written response serves as evidence to the inspector that the material is in compliance with the FFDCA and all applicable food additive regulations. If not in compliance, the materials are unsafe within the meaning of the FFDCA, the use of which would result in an adulterated product.

To obtain the service, the supplier of the material must advise FIAD of the intended use and provide a statement of composition for the material to be evaluated. The evaluation process requires approximately 6 weeks at the end of which FIAD provides a written response indicating whether or not it can confirm that the material meets the appropriate regulatory criteria. These responses can then be provided to Federal inspection officials as proof of acceptance.

During 1981, the American Paper Institute (API) expressed its belief that the FSIS system for prior evaluation of packaging materials is excessive and undesirably limits competition and

innovation to the detriment of the packaging industry and consumers. This view was also expressed early in 1982 by the American Meat Institute and the National Broiler Council.

On May 18, 1982, FSIS received a petition from the API, the Paperboard Packaging Council (PPC), and the Fibre Box Association (FBA) requesting that FSIS amend its policy governing the evaluation of packaging materials.

The petitioners assert that "for many years a letter from FSIS confirming regulatory compliance has been necessary, as a practical matter, to market packaging products for use with meat and poultry" because "USDA inspectors have often made continued plant operation conditional on the availability of USDA letters of acceptance for such packaging." The petitioners stated that the current FSIS system of voluntary prior evaluation of packaging materials imposes unnecessary delays and inefficiencies on the marketing process. They contend that the delays caused by the system often result in the loss of commercial opportunities.

The petitioners requested that FSIS "adopt a packaging program that does not require premarket review for packaging" and issue a statement of policy discontinuing the issuance of letters of acceptability and indicating that USDA inspectors "may not prohibit the entry of packaging from USDA inspected plants merely because such packaging is not accompanied by such a letter."

FSIS concluded that although the petition may have been based on the misconception that the current assessment program is mandatory, the petition was for the most part meritorious. Therefore, on November 10, 1982, FSIS published in the *Federal Register* (47 FR 50914) a proposed rule clarifying the fact that any premarket assessment of packaging material is strictly voluntary and instituting a simple procedure whereby the supplier of the packaging shall provide an accompanying written guaranty that the materials used in the packaging comply with FDA regulations.

This guaranty would be kept on file by the establishments and would be accepted by Federal inspectors to establish that the materials are in compliance with the FFDCA and applicable food additive regulations. The use by FSIS of this guaranty will be consistent with the provisions regarding guaranties under Sections 301(h) and 303(c) (2) and (3) of the FFDCA (21 U.S.C. 331(h) and 333(a) (2) and (3)). Guarantors, therefore, may refer to FDA's regulations concerning guaranties

and their suggested forms (21 CFR 7.12 and 7.13). Furthermore, FSIS would undertake a monitoring program involving a series of limited surveys of official establishments, conducted on a random basis, to determine what packaging materials are being used. FSIS would then request an inspector from each of the selected establishments to collect information on a specific number of packaging materials. From the information received, FSIS would review the materials to assure compliance with applicable food additive regulations.

Discussion of Comments

FSIS received 43 comments in response to the proposed rule—25 from suppliers and component manufacturers of packaging materials, 9 from packaging material trade associations, 3 from meat and poultry processors, and 6 from meat and poultry trade associations. All commenters supported the intent of the proposed rule, with 14 recommending changes either substantive in nature or merely for clarification. The following is a summary of the issues raised by the commenters and FSIS's response to each:

Letter of Guaranty

1. *Comment.* Seven commenters believed that the phrase "all applicable food additive regulations" could be misinterpreted to preclude the use of lawful substances (e.g., GRAS (generally recognized as safe), prior-sanctioned, and nonmigrating substances) which are not covered by a specific food additive regulation. They suggested that the wording be changed to "compliance with the Federal Food, Drug, and Cosmetic Act, as amended, and all applicable food additive regulations."

Response. FSIS believes that this suggestion is valid. It was not FSIS's intent to exclude GRAS, prior-sanctioned, nor nonmigrating substances. Therefore, wording of the final rule has been amended, as suggested, to avoid that misinterpretation.

2. *Comment.* Three commenters stated that the specific means of assurance should not be mandated. The manufacturer should be free to use the letter of guaranty, assurance letter, guaranty form, suitable invoice stamp, or similar written communication.

Response. The intent of the proposed rule was to obtain a guaranty from the supplier of finished packaging materials. The form of such guaranty is not as important as the content. The text of the proposed rule used the phrase "letter of guaranty" and the content of such

"letters of guaranty" was specified. As long as the required information is provided, FSIS sees no reason why it must be supplied in a mandated format. Therefore, to remove the implication that the guaranty must be in the form of a letter, FSIS has changed the phrase "letter of guaranty" to read "guaranty" in the final rule.

3. *Comment.* One commenter recommended that suppliers be permitted to provide letters of guaranty from component manufacturers to fulfill the requirement of supplying a guaranty. Another commenter suggested that the convertor (one who converts unfinished materials into a finished product) be required, along with the packaging manufacturer, to supply a guaranty.

Response. Responsibility for providing a guaranty for the finished packaging material rests with the suppliers under whose trade name and firm name the material is presented at the official establishments. Such suppliers should obtain from their component manufacturers and convertor any assurances that they deem appropriate in order to provide that guaranty. However, it is not appropriate that suppliers of the finished material provide guaranties from their component manufacturers to USDA. This would create additional paperwork and confusion. Establishments would be required to retain several papers for a single material. Therefore, FSIS advises that guaranties from component manufacturers will not fulfill the guaranty requirement of the final rule. Also, FSIS will not require a guaranty from the convertor unless the material is marketed to the official establishment under that firm's name and brand name or code designation. To avoid any confusion as to who shall supply the guaranty, FSIS has revised the final rule to refer only to "suppliers" of the packaging material rather than "manufacturers." This is in keeping with the requirement that responsibility for providing the guaranty rests with the suppliers.

4. *Comment.* One commenter believed that guaranties required from packaging manufacturers need only be given for those packaging material components which, in the intended use of the packaging material, come into direct contact with food. The commenter recommended that USDA apply this concept (FDA's functional barrier concept) for inks. It was stated that inks separated by a functional barrier should be excluded from the need for certification of compliance with food additive regulations. However, an opposing commenter suggested that

USDA publish a list of acceptable printing inks and continue its evaluation of printing inks.

Response. The "functional barrier" concept is applied by FSIS to food products under its jurisdiction. However, FDA regulations concerning packaging materials explicitly require consideration of food type and conditions of use as factors in determining safe use. Therefore, the "functional barrier" concept is applied by FSIS in light of all the circumstances surrounding the use of the packaging material.

Suppliers of packaging materials should base guaranties given for their finished packaging materials (including inks used on such materials) on compliance of the materials with the FFDCA. Therefore, printing inks in contact with meat or poultry must consist of appropriately regulated substances, prior-sanctioned substances, GRAS substances, substances not reasonably expected to become a component of the food, or substances otherwise lawfully permitted in food packaging materials. Inks that are separated from meat or poultry by an effective barrier to migration of ink components need not comply with the food additive regulations if, under the conditions of use, they are not expected to be food additives within the meaning of the FFDCA. However, suppliers should be prepared to verify that the inks are not food additives. Suppliers, as a good manufacturing practice, should not use toxic ink components, even if such inks are not intended to be food additives, because of the possibility of accidental contamination. FSIS will continue working with FDA to assure consistent policies in this area and to resolve any printing ink issues that may arise.

5. Comment. Two commenters suggested that guaranties should specify the packaging material use for which the guaranty is given, in order to avoid unauthorized use and to insure that there is no misunderstanding among manufacturers, official establishments, and inspectors.

Response. FSIS agrees. Existing requirements limit certain materials to specified amounts and use conditions. Both the nature of a material and its use must be clearly understood in order to determine whether it is acceptable. Suppliers must necessarily include the use conditions specified for approval under the FFDCA in order to give a guaranty on any given material. To make this quite clear, the final rule has been amended to require that guaranties specify the applicable conditions of use. Such conditions shall include

temperature limits and any other pertinent limits specified under the FFDCA and food additive regulations.

6. Comment. One commenter contended that the use of the term "guaranty" is inappropriate as it would create a second class of guaranties. The present class refers to substances intended as food or direct additives to food. The commenter suggested the use of another term such as letter of compliance.

Response. The term "guaranty" is commonly used and well understood in the food industry in connection with food additives. The FFDCA has express provisions regarding guaranties which are found in sections 301(h) and 303(c) (2) and (3) (21 U.S.C. 331(h) and 333(a) (2) and (3)). Under the FFDCA, the term "food additive" is defined as "... any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food) * * *." The definition of "food additive" includes indirect additives, such as packaging material components, as well as direct additives. Therefore, the term "guaranty" is properly used in reference to indirect additives and is commonly used within the meat and poultry inspection program to designate a supplier's written assurance that substances comply with the FFDCA. Thus, FSIS determines that the use of the term "guaranty" is appropriate as set forth in this final rule. However, for clarity, FSIS has revised the final rule by defining "guaranty" in §§ 317.20(b) and 381.144(b) as a "statement of assurance."

7. Comment. One commenter stated that the introductory sentence in § 317.20(b) of the proposed rule implies that a letter of guaranty should accompany each shipment, and recommend some clarification.

Response. The proposed §§ 317.20(b) and 381.144(b) indicate that packaging materials must be accompanied or covered by a guaranty. This was not intended to imply that a written guaranty must actually accompany each shipment. However, if the guaranty does not accompany the shipment, the material must be covered by a continuing guaranty previously given. Since, as the commenter further stated, the implication is dispelled as the regulation continues, FSIS concludes that there is no need to reword the text of the final rule.

8. Comment. One commenter contended that multiplant firms (official establishments) should be allowed to maintain guaranty letters at a central location as long as they are available for the inspector within 24 hours.

Response. The guaranty is intended to provide assurance that uses of packaging materials comply with the FFDCA and all applicable regulations. FSIS inspectors are to accept such guaranties to establish that materials do comply. Therefore, it is anticipated that inspectors will routinely require that files of guaranties be available for review. The capability of plants to make copies available within 24 hours as the commenter suggested is doubtful. This invites confrontations between plant management and inspectors which this rule is intended to eliminate. From a practical standpoint, FSIS does not believe this suggestion is feasible. FSIS recommends that plants with central purchasing functions consider implementing systems which make copies of all applicable guaranties available at each plant.

Monitoring Program

9. Comment. One commenter opposed the requirement for the "complete chemical composition" as part of the monitoring program and suggested requiring instead "detailed proof of compliance with FDA regulations."

Response. The monitoring program is intended to verify suppliers' guaranties for their packaging materials. In order to confirm a material's approval for use under the FFDCA, FSIS will in any case need the complete chemical composition; i.e., a complete listing of ingredients used in the manufacture of the packaging material. It should be noted that under the monitoring program, FSIS will not require the chemical composition of the packaging prior to selection for review. As indicated in § 317.20(d), 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. The suggestion of requiring "detailed proof of compliance with FDA regulations" may cause confusion in that it does not differentiate between the guaranty and FSIS's need for specific compositional information. Therefore, FSIS concludes that the requirement for complete chemical composition will stand as proposed.

10. Comment. One suggestion was made that the regulation be written to state that packaging materials monitoring will be "conducted on a random basis."

Response. FSIS's intent is that the monitoring be random. However, FSIS reserves the authority to monitor problems revealed by the random monitoring on a selective basis. FSIS believes this is necessary in order to fulfill its responsibility to insure that materials used to package meat and poultry are approved under the FFDCA. Therefore, the description of the packaging monitoring program will remain as proposed.

Lists of Acceptable/Unacceptable Materials

11. *Comment.* Four commenters opposed the listing of packaging materials that are found to be unacceptable. They believed that there is no need for a listing because the FFDCA provides adequate remedies and penalties. The major concerns were marketing problems due to the system of being listed, competitor's misuse of the listings, and errors in the listing.

Response. Penalties under the FFDCA may be applied only by FDA. FSIS receives its authority and responsibility under the FMIA and PPIA. FSIS concludes that the listing is necessary to provide inspection personnel with timely information concerning unacceptable packaging materials. The listing will be distributed through the FSIS issuance system (e.g., MPI Bulletin or FSIS Notice). The listing of packaging materials which could adulterate meat and poultry products will serve as an interagency communication of administrative findings made under this regulation. Sections 317.20(e) and 381.144(e) state that before approval to use a packaging material is finally denied, the official establishment, as well as the supplier, shall be given 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 will be held to resolve the dispute. Approval to use the materials pending the outcome will be denied only if the Administrator determines that there is an imminent hazard to public health. Furthermore, the provisions of § 317.20 (d) and (e) and 381.144 (d) and (e) allow ample opportunity for suppliers to avoid having their materials listed.

12. *Comment.* One commenter suggested that FSIS publish a list of acceptable packaging materials.

Response. Establishing a list of acceptable materials would nullify the intent of this rule. Publication of such a list would tend to perpetuate the misperception that premarket approval is mandatory. Therefore, FSIS does not consider it appropriate to publish a list

of packaging materials currently recognized as acceptable.

Voluntary Evaluation Service

13. *Comment.* One commenter stated that voluntary evaluation should be limited to components of packaging materials which may reasonably be expected to come into direct contact with food. The commenter also stated that continuing the voluntary evaluation may lead users of packaging materials to believe that they are better protected from liability with FSIS acceptance letters. On the other hand, two commenters supported retention of the voluntary prior evaluation service.

Response. The purpose of this rule is to clarify FSIS's intent that any premarket assessment of packaging materials is voluntary. FSIS has determined that its voluntary prior-evaluation program is perceived as mandatory and that this perception fosters over-reliance by inspectors on acceptance letters. However, there is a need for official establishments to be able to provide inspectors with tangible assurances of the safety of packaging materials. Therefore, the rule provides for written guaranties which inspectors will accept as assurance that packaging materials comply with the FFDCA. The monitoring program is intended to verify such guaranties. These provisions are intended to eliminate the misperception concerning mandatory prior evaluation by providing another means by which assurances can be made by inspectors. It is not intended to curtail a service to the industry which many may find useful. Therefore, it is not appropriate that FSIS discontinue its voluntary evaluation program.

Current Procedures

14. *Comment.* Twelve commenters expressed the view that the present system has resulted in delays because of misinterpretation of requirements by industry, customers, or inspectors. One of these commenters also stated that part of the problem (i.e., misinterpretation as mandatory prior evaluation requirement) has resulted from the inability to reference a USDA regulation or policy statement.

Response. FSIS agrees that misperceptions concerning voluntary prior evaluation and the absence of a regulation or policy statement concerning the inspection of packaging materials has contributed to delays in the marketing process. This regulation's clear statement of FSIS policy should alleviate this problem. The provisions in this rule are consistent with current practices within the food industry and will continue to provide the necessary

assurance that meat and poultry products are not adulterated by packaging materials.

Miscellaneous

15. *Comment.* Two commenters recommended that, if the proposed rule is made a final rule, FSIS allow official establishments a grace period of 6 months to obtain the required guaranties.

Response. FSIS agrees that some phase-in period is necessary. To allow for an orderly phase-in, FSIS has made this final rule effective 180 days after publication. The Agency believes that suppliers of packaging materials have a responsibility to use this period to help make the requirements of this regulation known to the regulated industry and to take the action necessary to assure that the regulated industry is not disrupted because guaranties are not in place.

16. *Comment.* FSIS should make it clear that the rule is applicable to packaging materials only and not to all materials used in establishments (e.g., aprons, gloves, and surface coatings).

Response. This rule applies only to packaging materials. The term "packaging material" means any cloth, paper, plastic, or metal material used to form a container, wrapper, label, or cover for meat and poultry products. The provisions of this rule are not applicable to personal equipment such as gloves, aprons, and smocks, nor to surface coatings applied to equipment or structural surfaces. These items will continue to be handled as in the past. The final rule has been amended to include a definition for "packaging material."

Final Rule

After careful consideration of the comments received on the proposed rule, FSIS has determined to adopt the proposal as published, with the modifications previously discussed herein.

This rule does not limit the inspectors' authority to question the safety or sanitation of a packaging material if the inspector determines that cause exists for suspecting it is out of compliance, nor does it preclude any appropriate action under the FMIA or PPIA in the event of possible adulteration or misbranding of product.

Information collection requirements contained in this regulation have been approved by the Office of Management and Budget under the provisions of 44 U.S.C. Chapter 35 and have been assigned OMB #0583-0015.

List of Subjects**9 CFR Part 301**

Meat inspection, Meat and meat food products.

9 CFR Part 317

Meat inspection, Packaging and containers.

9 CFR Part 320

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 381

Poultry products inspection, Packaging and containers, Reporting and recordkeeping requirements.

1. The authority citation for Parts 301, 317 and 320 reads as follows:

Authority: 34 Stat. 1260, 79 Stat. 903, as amended, 81 Stat. 584, 84 Stat. 91, 438; 21 U.S.C. 71 *et seq.*, 601 *et seq.*, 33 U.S.C. 1254.

PART 301—[AMENDED]

2. Section 301.2 is amended by adding a new paragraph (xxx) to read as follows:

§ 301.2 Definitions.

(xxx) *Packaging material.* Any cloth, paper, plastic, metal, or other material used to form a container, wrapper, label, or cover for meat products.

PART 317—[AMENDED]

3. A new § 317.20 (9 CFR 317.20) is added to the Federal meat inspection regulations to read as follows:

§ 317.20 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 their 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 must 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 any 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 material 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 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.

PART 320—[AMENDED]

4. Section 320.1 of the Federal meat inspection regulations (9 CFR 320.1) is amended by adding a new paragraph (b)(5) and a reference to the OMB Control Number to read as follows:

§ 320.1 Records required to be kept.

(b) * * *

(5) Guaranties provided by suppliers of packaging materials under § 317.20.

(Approved by the Office of Management and Budget under OMB #0583-0015)

PART 381—[AMENDED]

5. The authority citation for Part 381 reads as follows:

Authority: 71 Stat. 441, as amended, 76 Stat. 663, 86 Stat. 819, as amended; 21 U.S.C. 451 *et seq.*, 7 U.S.C. 450, 33 U.S.C. 1254.

6. Section 381.1 is amended by adding a new paragraph (b)(59) to read as follows:

§ 381.1 Definitions.

(b)(59) *Packaging material.* Any cloth, paper, plastic, metal, or other material used to form a container, wrapper, label, or cover for poultry products.

7. A new § 381.144 is added to Subpart N of the poultry products inspection regulations to read as follows:

§ 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 must 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.

8. Section 381.175 of the poultry products inspection regulations (9 CFR 381.175) is amended by adding a new paragraph (b)(2) and a reference to the OMB Control Number to read as follows:

§ 381.175 Records required to be kept.

(b) * * *

(2) Guaranties provided by suppliers of packaging materials under § 381.144. (Approved by the Office of Management and Budget under OMB #0583-0015)

Done at Washington, DC, on January 9, 1984.

Donald L. Houston,
Administrator, Food Safety and Inspection Service.

[FR Doc. 84-1442 Filed 1-18-84; 8:45 am]

BILLING CODE 3410-DM-M

DEPARTMENT OF THE TREASURY**Comptroller of the Currency****12 CFR Part 29**

[Docket No. 84-1]

Adjustable-Rate Mortgages

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Final rule.

SUMMARY: The Office of the Comptroller of the Currency ("Office") is revising its Adjustable-Rate Mortgage ("ARM") regulation (12 CFR Part 29) to exempt ARM loans with open-end credit features from the periodic disclosure requirements specified in § 29.7 (b) and (c). This revision will enhance the ability of national banks to design ARM loans with open-end credit features without unduly reducing disclosures to borrowers. The disclosure requirements for closed-end ARMs remain unchanged.

EFFECTIVE DATE: January 19, 1984.

FOR FURTHER INFORMATION CONTACT: Nancy Jones or David Nebhut, Financial Economists, Economic and Policy Analysis Division (202) 447-1924, or Jonathan L. Levin, Senior Attorney, Legal Advisory Services Division (202)

447-1880, Office of the Comptroller of the Currency, Washington, D.C. 20219.

SUPPLEMENTARY INFORMATION:

Special Analyses

The Secretary of the Treasury has certified that this regulation will not have a "significant impact on a substantial number of small businesses," as that phrase is used in the Regulatory Flexibility Act; therefore, no regulatory flexibility analysis has been prepared. The revised regulation eases the burden of existing requirements. The effect of the revisions is expected to be beneficial rather than adverse, and small entities are generally expected to share the benefits of the revisions with larger institutions.

A Regulatory Impact Analysis is not required because the Office has determined that the regulation is not a "major rule" as defined by Executive Order 12291. The regulation will not have an annual effect on the economy of \$100 million or more, will not result in a major increase in costs or prices to consumers, individual industries, Federal, state, or local government agencies, or geographic regions, nor will it have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises.

The Office has determined that a delayed effective date is unwarranted in that the revisions to the ARM regulation relieve restrictions on the ability of national banks to offer new loan programs of benefit to the public.

Background and Analysis

On October 17, 1983, the Office published a proposed rule that would have revised the periodic disclosure requirements specified in § 29.7 (b) and (c) for ARM loans with open-end credit features (48 FR 47001). The Office proposed that, for open-end ARMs, notice of any interest-rate changes when accompanied by payment changes, and payment changes for reasons other than an interest-rate change, be made at least fifteen days before payment at the new level is due. Through that Notice of Proposed Rulemaking the Office also solicited public comment on the advisability of requiring national banks to make prior disclosures to borrowers of rate and/or payment changes for ARM loans with open-end credit features.

Under 12 CFR 29.7(b) of the ARM regulation, as adopted on March 7, 1983 (48 FR 9506), certain information is required to be disclosed to borrowers

not later than one business day after an interest-rate change is implemented and, if such interest-rate change is accompanied by a payment change, at least 25 days before a payment at the new level is due. Section 29.7(c) of the ARM regulation requires that certain items be disclosed to borrowers at least 25 days before a payment change may take effect if, under the bank's adjustable-rate mortgage program, a payment change may occur for reasons other than an interest-rate change.

The periodic disclosure requirements contained in Part 29 were designed for closed-end, long-term ARM loans. For such ARM plans, the Office has received no information indicating that the required disclosures are unduly burdensome for banks. In contrast, the timing requirements of the periodic disclosure notice present severe technical difficulties for banks interested in offering open-end ARMs with standard billing cycles.

ARMs with open-end credit features, unlike closed-end ARMs, are designed to accommodate repeated advances from, and payments to, an established line-of-credit throughout the billing cycle. Typically, borrowers are required to make a minimum periodic payment based upon the interest charged for the billing cycle just ended and the outstanding loan balance. Ordinarily, the bank does not know the outstanding balance until the billing cycle has ended and the payment for the preceding month has been received. This may not allow sufficient time for both processing charges and credits and then notifying the borrower 25 days before the next payment is due as required by Part 29. Where the bank provides a grace period in each billing cycle for the receipt of late payments, the timing of disclosures becomes all the more difficult.

Furthermore, the requirement that banks provide notice of interest-rate changes not accompanied by payment changes within one business day of implementation effectively precludes the use of an interest-rate index that changes more frequently than monthly or on an irregular basis. This raises the interest-rate risk to the bank and may result in a higher interest rate being charged to the borrower than if the bank were able to change the interest rate more frequently.

For ARM plans with open-end credit features, other Federal agencies rely upon the disclosure requirements applicable to open-end credit plans under Federal Reserve Regulation Z (12 CFR part 226). The National Credit Union Administration does not impose periodic disclosure requirements on ARMs made by Federal credit unions

(12 CFR 701.21-6B). To facilitate ARMs with open-end credit features for Federal savings and loan associations, the Federal Home Loan Bank Board recently removed its requirement that prior notice of an adjustment to the payment, the balance, or the interest rate be given to adjustable-rate open-end credit borrowers (12 CFR 545.33; 48 FR 23061 May 23, 1983).

General Summary of Comments

The Office received 26 comment letters in response to its proposed revisions to 12 CFR 29.7 (b) and (c) for ARMs with open-end credit features. Letters were received from 21 national and state-chartered banks, two law firms (one commenting on behalf of 45 banks), a trade association, a diversified financial services company, and a private citizen.

All but one of the respondents favored reducing or eliminating the periodic disclosure requirements in the regulation with respect to open-end ARMs in order to improve the ability of banks to offer such loan programs. The remaining respondent advocated retaining the existing periodic disclosure requirements for open-end ARMs.

Nineteen of the respondents, approximately three-quarters of those commenting, recommended that the final rule exempt open-end ARMs from § 29.7 (b) and (c). These respondents felt that the timing of periodic disclosures under Part 29 is not compatible with the ordinary structure of open-end credit plans. Many of them indicated that the disclosures required under Federal Reserve Regulation Z ensure adequate notification to borrowers without reducing desirable flexibility in product design. A number of these respondents contended that retention of any periodic disclosure requirements for open-end ARMs would place national banks at a competitive disadvantage to Federal savings and loan associations because the Federal Home Loan Bank Board regulations do not impose periodic notice requirements on open-end ARMs.

Three respondents proposed variations of the Office's proposal to reduce advance notice of payment changes from 25 to 15 days. One respondent favored the adoption of the revisions as proposed.

Two respondents recommended that the definition of an adjustable-rate mortgage, contained in § 29.1 of the regulation, be expanded to include non-purchase-money loans secured by real estate. They argued that such a revision would be consistent with the stated intent of the Office to facilitate open-end ARMs.

In issuing the proposed rule the Office did not intend to expand the coverage of the ARM regulations. The Office intended only to solicit public comment on revising periodic disclosure requirements applicable to ARM loans with open-end credit features. Accordingly, loans secured by a lien on a one- to four-family dwelling that do not involve the financing or refinancing of the purchase of the dwelling remain outside the scope of Part 29.

Final Rule

The final rule exempts ARMs that satisfy the definition of "open-end credit" under Federal Reserve Regulation Z (12 CFR 226.2(a)(20)) from the periodic disclosure requirements contained in 12 CFR 29.7 (b) and (c). Such loans will continue to be subject to the disclosure requirements specified in § 29.7 (a), (d), and (e) and to the disclosure requirements applicable to open-end credit contained in Regulation Z. The disclosure requirements for closed-end ARMs remain unchanged.

The exemption of open-end ARMs from the periodic disclosure requirements of the ARM regulation will have several benefits. The exemption will facilitate the offering of such plans by banks and will subject banks to the same disclosure requirements as those governing Federal savings and loan associations, credit unions, and most other housing lenders. Borrowers will benefit from the increased number and types of institutions able to offer open-end ARM loans. At the same time, borrowers will continue to receive timely disclosures by way of periodic statements issued by banks in compliance with Regulation Z.

Under the final rule the nature of the disclosure items made to borrowers under Regulation Z will change little from those which would be received were § 29.7 (b) and (c) to continue to be applicable to open-end ARMs. Regulation Z requires a lender to provide periodic disclosures for all open-end credit accounts which show a debit or credit balance of more than \$1 at the end of a billing cycle or which have had a finance charge imposed during the billing cycle. The notice must include the following items:

- The previous balance;
- An identification of transactions that occur during the billing cycle;
- Any credits made to the account during the billing cycle;
- The periodic rate(s) used to calculate the finance charge, the corresponding annual percentage rate(s), and (as applicable) the fact that the periodic rate(s) may vary;

- The balance(s) on which the finance charge was computed;
- The amount of the finance charge;
- The annual percentage rate(s);
- Any other charges, other than finance charges, imposed during the billing cycle;
- The closing date of the billing cycle and the outstanding balance on that date; and
- If a free-ride period is provided, the date by which payment must be made to avoid additional finance charges.

The periodic disclosure requirements under § 29.7 (b) and (c) contain four items that are not required to be disclosed under Regulation Z: The past index value, the current index value, the previous interest rate, and foregone interest-rate increases. Interest rate adjustments must be based on the movements of an index that is initially disclosed and is readily verifiable by the borrower, and under Regulation Z, each periodic statement will disclose the current interest rate. Therefore, the Office believes that the burden imposed on banks by adding to the disclosure requirements of Regulation Z is not justified by a correspondingly appreciable benefit to borrowers.

Exemption of open-end ARMs from the 25-day prior notification requirement for payment changes and the one business-day notification requirement for interest-rate changes should have no adverse effect on borrowers. Regulation Z provides for timely notification to open-end credit borrowers. More specifically, § 226.5(b)(2)(ii) of Regulation Z requires the creditor to mail or deliver periodic statements at least 14 days before the date by which, or the time period within which, the new balance or any portion of the new balance must be paid in order to avoid additional finance or other charges. Also, § 226.6(a)(2) requires the creditor to furnish the borrower with variable rate disclosures before the first transaction is made under the open-end credit plan. If such disclosures are not made, a subsequent rate increase is considered a change in terms that, under § 226.9(c), requires the creditor to mail or deliver to the borrower a written notice at least 15 days before the effective date of such change.

Furthermore, the extensive disclosures required under § 29.7(a) of the ARM regulation at the initiation of every ARM loan will continue to provide borrowers with essential information concerning the nature and terms of their open-end ARMs, as well as the impact on their payments of changes in the outstanding loan balance and interest rate.

List of Subjects in 12 CFR Part 29

National banks, Adjustable-rate mortgages.

Accordingly, for the reasons set forth above, Part 29 is amended by amending § 29.7 (b) and (c) as follows:

1. The authority citation for Part 29 reads as follows:

Authority: 12 U.S.C. 1 et seq.; 12 U.S.C. 93a; and 12 U.S.C. 371.

The information collection requirements contained in this Part have been assigned OMB Control No. 1557-0139.

2. By amending 12 CFR 29.7 (b) and (c) by revising the introductory text as follows:

§ 29.7 Disclosure.

(b) Timely notice in writing of interest-rate changes which contains the information set forth in paragraphs (b)(1) through (b)(6) of this section shall be provided to the borrower. For purposes of this subsection, timely notice means notice sent to the borrower not later than one business day after an interest-rate change is implemented, and, if such interest-rate change is accompanied by a payment change, at least 25 days before a payment at the new level is due, *except that* this subsection shall not apply to adjustable-rate mortgage loans qualifying as "open-end credit," as that term is defined under 12 CFR 226.2(a). The bank shall notify the borrower in writing of the following items:

(c) Timely notice in writing of payment changes which contains the information set forth in paragraphs (c)(1) through (c)(4) of this section shall be provided to the borrower. For purposes of this subsection, timely notice means that for payment changes occurring for reasons other than an interest-rate change, including, but not limited to, a limit on negative amortization, notice be sent to the borrower at least 25 days before a payment at the new level is due, *except that* this subsection shall not apply to adjustable-rate mortgage loans qualifying as "open-end credit," as that term is defined under 12 CFR 226.2(a). The bank shall notify the borrower in writing of the following items:

Doyle L. Arnold,

Acting Comptroller of the Currency.

[FR Doc. 84-1503 Filed 1-18-84; 8:45 am]

BILLING CODE 4810-33-M