Actions	Compliance times	Procedures
(1) Check your maintenance records to determine whether this AD applies to your airplane by doing the following: (i) Check the maintenance records to determine whether a 0513166 series plastic control wheel is installed. The owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7) may check the maintenance records. (ii) If, by checking the maintenance records, the pilot can positively show that no 0513166 series plastic control wheels are installed, then the inspection, testing, and replacement requirements of this AD do not apply. The AD is complied with after you make an entry into the aircraft records that shows compliance with this portion of the AD, in accordance with section 43.9 of the Federal Aviation Regulations (14 CFR 43.9).	Required within 100 hours time-in-service (TIS) after the effective date of this AD.	No special procedures required to check the maintenance records.
(2) For any affected airplane where at least one 0513166 series plastic control wheel is installed, do the following: (i) Inspect each control wheel for cracks; and (ii) Conduct a pull test on each control wheel	Before further flight after the maintenance records check or within 100 hour TIS after the effective date of this AD, and reinspect afterward at intervals not to exceed 12 months until all control wheels are replaced with FAA-approved control wheels that are not 0513166 series plastic control wheels.	Do this following the instructions of Cessna Service Letter No. 64–8, dated February 14, 1964.
(3) Replace any cracked control wheel or any control wheel that does not pass any pull test, with an FAA-approved control wheel that is not a 0513166 series plastic control wheel.	Do this replacement before further flight after the inspection where the cracked or failed control wheel is found.	Do the replacements following the instructions in the applicable maintenance or service manual.
(4) Do not install, on any affected airplane, a 0513166 series plastic control wheel.	As of the effective date of this AD	Not Applicable.
(5) You may replace all control wheels with wheels that are not part number 0513166, as terminating action for the repetitive inspection and test requirement of this AD.	You may replace all control wheels at any time, except for those control wheels that are cracked or do not pass a pull test. Such wheels must be replaced prior to further flight, as required by paragraph (d)(3) of this AD.	Do the replacements following the instructions in the applicable maintenance or service manual.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Wichita Aircraft Certification Office (ACO), approves your alternative. Send your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note 2: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. You should include in the request an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Eual Conditt, Aerospace Engineer, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946–4128; facsimile: (316) 946–4407.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may get the service information referenced in the AD from Cessna Aircraft Company, Product Support, P.O. Box 7706, Wichita, Kansas 67277; or you may examine this document at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on January 11, 2001.

Marvin R. Nuss,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1665 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 00N–1633]

RIN 0910-AB95

Marking Requirements for and Prohibitions on the Reimportation of Imported Food Products That Have Been Refused Admission into the United States

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the food import regulations to require food products which, for safety reasons, are refused entry into the United States to be marked ''UNITED STATES REFUSED ENTRY.'' The proposed rule would also prohibit persons from refusing to affix this mark on refused food, from importing or

offering to import a previously refused food, and from altering, removing, tampering with, or concealing a mark. The proposed rule is intended to protect the public health against unsafe imported food products and to facilitate the examination of imported products.

DATES: Submit written comments by April 9, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy, Planning, and Legislation (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381) authorizes FDA to examine foods, drugs, devices, and cosmetics imported or offered for import into the United States and to refuse admission to products under certain conditions. Imported products are subject to the same statutory and regulatory requirements as domestic products. For example, a domestic food product must not be adulterated or misbranded. Similarly, an imported food that is intended for sale in the United States must not be adulterated or misbranded.

FDA's examination of imports often begins with a review of records to determine whether additional scrutiny is warranted. FDA may, based on its review of the records, permit the goods to proceed, visually examine or take samples of the goods for laboratory analysis, or verify the registration, listing, declarations, and certifications for the product. For food products, visual examinations may be inadequate for detecting suspected microbiological contamination, pesticide residues, and other toxic elements, so FDA may take samples of an imported food product for further examination. If the examination shows that the food product appears to be in compliance with U.S. requirements, FDA releases the shipment to proceed into U.S. commerce. If the food product appears to be not in compliance, the importer has an opportunity to provide evidence or testimony that the food product complies with U.S. requirements or to submit a plan to recondition the food product to bring it into compliance if such reconditioning is possible. If, after the importer has had an opportunity to present its views or if reconditioning failed to bring the food into compliance, the food product is not in compliance, FDA may refuse admission to the food product. If refused products are not reexported within 90 days of refusal, the U.S. Customs Service (Customs Service) will have the products destroyed.

Additionally, under section 304 of the act (21 U.S.C. 334), FDA may initiate seizure and condemnation proceedings against any article of food that is adulterated or misbranded, or which may not be introduced into interstate commerce under section 404 of the act (21 U.S.C. 344). A court may, after seizure and condemnation of an imported article, order the article to be destroyed or permit the article to be reexported (see *United States* v. *Food, 2,998 Cases*, 64 F.3d 984 (5th Cir. 1995)). The Customs Service also has seizure procedures (see 19 U.S.C. 1595a).

In recent years, the demand on FDA's resources for reviewing food imports has increased significantly. For example, in 1985, approximately 950,000 line items of goods were offered for import into the United States. (A line item corresponds to a specific item on an invoice or shipping papers.) By 1998, the number of line items had increased to over 3 million (see statement by William B. Schultz, Deputy Commissioner for Policy, Food and Drug Administration, before the Permanent Subcommittee on Investigations, Senate Committee on Government Affairs, September 24, 1998). FDA's ability to inspect a sufficient proportion of imports has been severely hampered by this increase. Currently, FDA examines or samples less than 2 percent of imported foods for compliance with FDA requirements.

FDA is aware that some unscrupulous importers use various measures to subvert this process in order to introduce unsafe food products into the United States. In April 1998, the General Accounting Office (GAO) issued a report entitled ''Food Safety: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable'' (GAO/RCED–98–103). The GAO report stated that some importers evade import controls and are able to introduce contaminated, adulterated, or unsafe food into the United States even when FDA refused to admit the food and the Customs Service ordered the food to be reexported or destroyed. In particular, the GAO report noted that FDA does not require that refused foods be marked as ''refused entry.''

Additionally, in 1998, the Senate Governmental Affairs Committee's Permanent Investigations Subcommittee held hearings on the safety of food imports. The Committee heard testimony about various methods used to avoid food safety inspections and to introduce adulterated food into the United States. These methods included reimporting refused goods through another U.S. port (''port shopping'') and substituting trash or other items for adulterated food products for which FDA has refused entry so that the trash and other items, rather than the adulterated food products, were destroyed or reexported (Ref. 2) (statement of ''Former Customs Broker''). Placing a clearly identifiable mark on food imports that have been refused admission for safety reasons would help curtail the reintroduction of unsafe food products into the United States.

On July 3, 1999, the President issued a memorandum to the Secretary of Health and Human Services and the Secretary of the Treasury (the Secretaries) on the safety of imported foods. The memorandum identified food safety as a high priority and, among other things, directed the Secretaries to take all actions available to ''prohibit the reimportation of food that has been previously refused admission and has not been brought into compliance with United States laws and regulations (so called 'port shopping'), and require the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons....''

II. Description of the Proposed Rule

A. Introduction

FDA is proposing to amend its import regulations to create a new § 1.98 entitled ''Marking Requirements for and Prohibitions on the Reimportation of Food Products That Have Been Refused Admission into the United States.'' The proposal would require importers or consignees to mark food (including animal feed) that FDA refuses to admit, for safety reasons, into the United States. The mark should make it more difficult for imported food products that have been refused admission into the United States to evade import controls and would complement FDA's efforts to monitor food imports more effectively. The proposed rule would also prohibit importers from reimporting refused shipments.

FDA and the Customs Service held two public meetings to discuss imported food safety on February 10, 2000, in Los Angeles, CA, and on February 17, 2000, in Washington, DC. Several comments were made concerning marking refused food imports, and FDA addresses those

comments as part of this description of the proposed rule.

B. Who Must Affix the Mark?

If you are an importer or consignee of a shipment of imported food that FDA has refused to admit for safety reasons, you would be subject to the rule. (For purposes of this rule, the reference to ''safety reasons'' means that consuming the imported food could adversely affect a person's health.) Under proposed § 1.98(a), if FDA has refused to admit your imported food into the United States for safety reasons, you must mark the refused food as ''UNITED STATES REFUSED ENTRY.'' An FDA employee or FDA-designated official (such as an FDA-commissioned official) would supervise the marking process.

In contrast, if FDA refused admission of your imported food for other nonsafety reasons, you would not be subject to this rule. For example, if FDA refused to admit your imported food because it was labeled in a foreign language, you would not have to mark the refused food product. If, however, FDA refused to admit your imported food because it contained an unsafe ingredient, you would have to mark the refused product in accordance with the regulation.

C. What Must the Mark Look Like?

Proposed § 1.98(b) would require you to make the mark in capital letters at least 2.5 centimeters (cm) or 1 inch high. The mark would state ''UNITED STATES REFUSED ENTRY.'' The mark's language and format are similar to those used by the U.S. Department of Agriculture on meat and meat food products that have been refused admission into the United States (9 CFR 327.26(c)).

Some comments during a public meeting suggested that the mark include some indication of why the food product was refused entry instead of stating simply that the food was refused entry. FDA has not included this suggestion in the proposed rule because the text of the proposed mark, ''UNITED STATES REFUSED ENTRY,'' is applicable to all products that are refused entry for safety reasons and is similar to a mark used by the U.S. Department of Agriculture. If FDA required the mark to explain the reasons for the refusal, importers and consignees would need multiple marks (to cover the various possible reasons for refusing entry) or would need to use ''fill in the blank'' marks which could then be illegible (if the reasons are handwritten) or difficult to use (if the reasons are machine-printed). Nevertheless, FDA welcomes additional comment on this point.

Proposed § 1.98(b)(1) would require the mark to be permanent, clear, and conspicuous. This will help ensure that the mark is noticeable. For example, if the mark is affixed to a bill of lading, you could place the mark diagonally across the center of the document and use colored ink. However, the proposal would not specify any particular method of marking. In other words, you can use adhesive labels, ink stamps, or any other marking tool or device so long as the mark is at least 2.5 cm or 1 inch high, uses the correct language, is clear and conspicuous, and is permanently affixed to the refused imported food's container (where possible) and to shipping documents accompanying the imported food before it leaves the port of entry.

Another comment at a public meeting suggested that the mark be in ''invisible ink'' that FDA would be able to see through the use of some scanning device. Some individuals expressed concern about how a visible mark would affect the refused product's ability to enter a foreign country or return to the exporting country. This proposed rule does not include the use of ''invisible ink.'' One important benefit of the mark is that it is supposed to be clear and conspicuous; this will make it easier for FDA and the Customs Service to detect attempts to bring refused food products back into the United States. If the mark could only be seen by using some unspecified device, FDA and the Customs Service might find it difficult to determine whether the mark was correctly applied, to see the mark on goods that are being reintroduced into the United States in spite of an earlier refusal, or to readily distinguish between foods that should be admitted into the United States from foods that have already been refused entry. FDA invites comment on this point.

FDA also invites comments on whether the rule should use or allow for different size requirements due to the variety of food packages and product sizes and whether the rule should require any particular form of marking.

D. Where Must the Mark Go?

Proposed § 1.98(b)(1) would require you to affix the mark permanently to the packing container holding the refused food and on invoices, bills of lading, and any other documents accompanying the food when it is exported from the United States. The proposal would explain that, for purposes of thois rule, a packing container is any container used to pack one or more immediate containers of the refused food and that an immediate container is any container which holds an imported food for sale to the ultimate consumer. For example, assume that you have a box that holds 24 cans of imported food. the box would be the packing container, and each can would be an immediate container. You would, under the proposal, mark the box rather than mark each can. FDA would not require you to mark every individual retail unit (unless the immediate container also happens to be the packing container, such as a large bag of rice or flour). If the mark cannot be permanently affixed to a packing container (as with bulk agricultural commodities, such as a railcar of wheat, a truckload of potatoes, or a tanker of corn syrup) you would only have to place the mark on documents accompanying the food when it leaves the United States.

Several comments at the public meeting said the mark should go on cargo containers used to transport large amounts of imported food products. Others suggested using seals on cargo containers instead of merely marking the containers. FDA interpreted these comments concerning cargo containers as applying the mark or seal on items such as rail cars, containers to be attached to trucks, and other large, reusable containers. FDA has not included the comments' suggestions in this proposed rule. By proposing to require the mark to be clear, conspicuous, and permanent, FDA intends to make it difficult for a person to ''port shop'' or to conceal refused food. If the mark were placed on a large, reusable cargo container (such as a tractor trailer or rail car), it would be easy to defeat the rule simply by moving the refused food from the marked cargo container to an unmarked container. For example, if the mark is on a container attached to a truck instead of the packing containers holding the refused food product, the intent behind the rule could be defeated by shifting the refused food product from the marked tractor trailer to an unmarked one. In contrast, if the mark is on the packing containers (such as boxes or wrapped shipping palettes) holding the refused food, it will be more difficult, both in terms of time and cost, to open and repackage the refused food, and thus evade the rule's purpose. FDA invites additional comment on this point.

E. When Must You Affix the Mark?

Proposed § 1.98(b)(2) would require you to affix the mark, under the supervision of an FDA employee or person designated by FDA, before the food is exported. This is to ensure that

you place the mark, as required, on the refused food before the food leaves the United States.

F. Enforcement Issues

If this rule is finalized with a prohibition on the reimportation of refused food, reimportation of refused food in violation of this rule would constitute a violation of 19 U.S.C. 1595a which would then permit the Customs Service to seize, forfeit, and destroy the goods after following the appropriate procedures. Thus, proposed § 1.98(c) would prohibit you from: (1) Importing or offering to import any food that has been previously refused admission into the United States and marked as ''UNITED STATES REFUSED ENTRY;'' and (2) altering, removing, tampering with, or concealing a mark. If you refuse to affix a mark on a refused food import, FDA and the Customs Service might deny permission to re-export the refused food product, order the product to be destroyed, and take other regulatory action against you and the refused food. The Customs Service might also assess civil money penalties under 19 U.S.C. 1592 or 1595a(b) if you alter, remove, tamper with, or conceal a mark.

G. Authority Citation Changes

FDA is also proposing to amend the authority citation for 21 CFR part 1 to include references to sections 704 of the act (21 U.S.C. 374) and 801 of the act and section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264). These statutory provisions provide additional legal authority to issue the proposed rule (as explained in section III of this document).

III. Legal Authority

Section 801(a) of the act states that FDA shall refuse to admit imported food into the United States if the imported food has been manufactured, processed, or packed under insanitary conditions, is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or is adulterated or misbranded. Sections 402 and 403 of the act (21 U.S.C. 342 and 343) describe when a food is adulterated and misbranded respectively. Section 701(a) of the act (21 U.S.C. 371(a)) authorizes the agency to issue regulations for the efficient enforcement of the act, while section 701(b) of the act authorizes FDA and the Department of the Treasury to jointly prescribe regulations for the efficient enforcement of section 801 of the act.

The proposed rule is within FDA's authority at sections 402, 403, 701, and 801 of the act. Because marking refused goods would permit FDA to more efficiently enforce section 801 of the act, FDA is authorized to impose marking requirements on such food products. The mark would help ensure that food products that fail to meet the conditions for admission into the United States do not enter or reenter interstate commerce.

Section 704 of the act authorizes FDA to conduct inspections for the efficient enforcement of the act. Assuming that the proposed rule is later finalized, FDA may need to conduct inspections to help enforce the rule. Thus, while section 704 of the act does not provide independent authority to mark refused food imports, it is relevant to FDA's enforcement of the rule.

The proposed rule is also authorized by sections 301 of the PHS Act (42 U.S.C. 241) and 361 of the PHS Act. Section 301 of the PHS Act authorizes FDA to ''render assistance'' to appropriate public health authorities in the conduct of or to promote coordination of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of disease. Section 361 of the PHS Act authorizes FDA to issue regulations to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. Marking food products that have been refused entry into the United States would assist foreign public health officials to determine whether to take regulatory action against a particular product. The mark would alert foreign countries that the food product has already been refused admission into the United States. Marking such food products would also help prevent the introduction, transmission, or spread of communicable diseases into the United States by making it more difficult for such rejected food products to enter the United States through a different port or to escape detection.

IV. Environmental Impact

FDA has determined under 21 CFR 25.30(a), 25.30(k), and 25.32(g) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that the marking requirements proposed in this document are not subject to review by the Office of Management and Budget (OMB) because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). Rather, the proposed statements are ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the proposed rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VII. Analysis of Impacts

A. Introduction

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 considers a rule to be a ''significant regulatory action'' if (among other things) it may have an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. OMB has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. For reasons explained later in this section, FDA concludes that the proposed rule, if finalized, would not have a significant economic impact on a substantial

number of small entities. Therefore, a regulatory flexibility analysis is not required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires that agencies prepare a written assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the proposed rule because the proposed rule is not expected to result in any 1 year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $110 million.

B. The Rationale Behind This Proposed Rule

The introduction to this proposed rule explains the reasons, such as ''port shopping'' and the President's July 3, 1999, memorandum on the safety of imported foods that prompted FDA, in conjunction with the Customs Service, to issue this regulation. FDA refers readers to that discussion if they seek details regarding the reasons for this proposal and the problems concerning the reimportation of previously refused imported food.

C. Regulatory Options Considered

As described earlier, the proposed rule would require importers and consignees whose food products have been refused admission in to the United States for safety reasons to mark such products as ''UNITED STATES REFUSED ENTRY.'' This will make it easier for FDA and the Customs Service to detect attempts to re-introduce previously-refused imported food into the United States.

In drafting this rule, FDA considered and rejected several alternatives. For example, one option would be to order the destruction of all refused food imports. While this would deter ''port shopping'' and similar illegal practices, this alternative is not feasible because it would require Federal resources to be diverted to supervising or otherwise ensuring that the refused food imports are stored until they can be destroyed and that they are actually destroyed. Additionally, the standard of proof to support the destruction of violative products is greater than the standard of proof for refusing to admit imported products, so ordering the destruction of refused food imports would increase, rather than decrease, the demands on government field resources. This alternative would also be extremely costly to importers since many refused shipments can be exported and legally sold or reconditioned for sale in other countries.

Another alternative would be a ''no action'' option. This alternative was unacceptable because it would allow illegal practices, such as port shopping, to continue and would result in the reentry of previously refused food imports into the United States. Consumers who ingested those unsafe food imports would, in turn, be subject to foodborne illnesses. Consequently, a ''no action'' alternative would not further efforts to protect the public health.

Another alternative would be to mark some, but not all, food refused for safety reasons. This alternative would be less costly, but would also be less efficient and less practical. This alternative was unacceptable because it would create an opportunity for some refused food imports to reenter the United States through port shopping (and to harm consumers) and because an unmarked, but previously-refused, food import would be difficult to detect compared to a previously-refused and marked food import. Additionally, marking some, but not all, refused food would inevitably create arguments as to FDA's criteria for deciding which refused foods should or should not be marked and whether a specific food import met that criteria.

For example, if the alternative was to mark refused food depending on its geographic origin (under a theory that some foreign nations regulate exported food more rigorously than others so that the United States could relax its safeguards for foods from those countries), the result would be both inefficient and unfair. To illustrate this point, assume that country A has a food regulatory system while country B has a less demanding regulatory system. If an alternative would mark unsafe food from country B, but not mark a similar, unsafe food from country A, such an alternative would make it possible for unsafe food from country A to be port shopped, thereby defeating the intent of the rule. Marking would then depend on geographic origin rather than the safety of the food itself.

As another example, if the alternative were to mark refused food imports based on their potential risk, such as marking refused foods which, if consumed, would cause death or serious illness in humans, such an approach would be impractical and difficult to apply. To illustrate this point, assume that an imported food product appears to be contaminated because mold is visible on the product. If marking depended on whether the moldy food would cause death or serious illness, arguments would inevitably arise concerning the identification of the mold, its toxicological properties (if any), the methodology or references used to analyze the mold or to determine the seriousness of the health risk associated with the mold, etc.

D. Benefit-Cost Analysis

1. Strategic Action by Importers

Although the vast majority of importers and consignees comply with the act, some attempt to circumvent Federal law and introduce unsafe food into U.S. commerce through illegal means such as port shopping. For these importers and consignees, measures such as those contained in this proposed rule are necessary to deter illegal conduct.

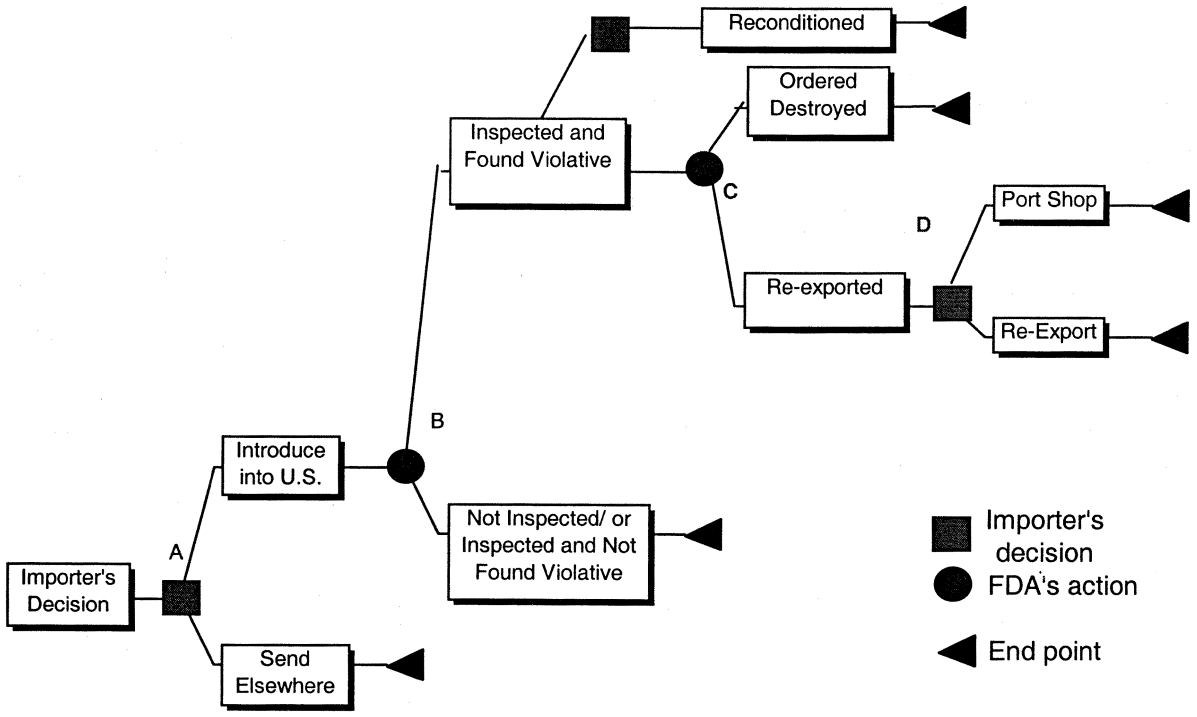
An importer's or consignee's decision on how to dispose of its cargo is influenced by changes in the expected profits associated with each of its choices. Requiring importers and consignees to mark ''UNITED STATES REFUSED ENTRY'' on imported food which has been refused admission for safety reasons changes the expected profits associated with the initial decision to attempt to import unsafe food. A mark also affects the expected profits associated with the decision to recondition, re-export, or port shop after a shipment is found violative.

The decision process of an importer of potentially unsafe food can be represented visually by a decision tree (see figure 1). This illustrates how requiring ''UNITED STATES REFUSED ENTRY'' on refused imports will alter an importer's or consignee's incentives. The same tree shows the possible outcomes and decisions an importer or consignee can make at each stage of the importation process. At point A, an importer or consignee with violative food first decides whether to attempt to import the food into the United States. This decision will be influenced by the price the importer or consignee can get for the food if it is successfully imported, the probability the cargo will be inspected, and the cost to the importer or consignee if the food is inspected and found violative. At point B, whether the cargo is inspected is a function of factors such as the port of entry, FDA's inspection rate, and the type of product. If it is found violative, the importer may choose to recondition the food to correct the violations. At point C, FDA refuses admission of the food. If the food is not destroyed, at

point D the importer or consignee may have the option of re-exporting to a foreign country or port shopping.

Illustration 1:

A Dynamic Representation of the Introduction of Food into Commerce in the United States



2. The Rule's Effect on Deterrence

Labeling refused imported foods as''UNITED STATES REFUSED ENTRY'' alters the incentive structure that importers and consignees face when deciding whether to introduce their product into United States commerce. In particular, there are four ways that the rule would increase the deterrence value of the FDA inspection system.

a. Port shopping will be reduced. One primary goal of this rule would be to reduce port shopping. Placing a mark on a refused food import will reduce the probability that the refused food import will be re-imported into the United States. The cost of port shopping will increase because resources would have to be expended to repackage a product that has been marked. Thus, port shopping will become relatively less attractive to importers and consignees.

b. Decrease in the value of re-exported items. The value of a product destined for reexport will decrease if it is marked ''UNITED STATES REFUSED ENTRY.'' After the product has been marked, the importer or consignee has two costly choices: (1) Relabel containers or repackage the product into containers that do not bear the mark after the product leaves the United States, or (2) sell the goods abroad with the mark intact. It is likely that such a mark would be viewed less than favorably by food safety inspectors and importers in international markets. Thus, the expected profit from selling goods that are marked would be lower than if the mark did not exist, so this loss is in addition to the loss of value from refusal alone. Either of the importer's or consignee's choices (repackage or sell with the mark intact) would lower the expected profit of reexporting.

c. Reconditioning will become a more favored alternative. The expected profit from reconditioning a refused food import is not likely to change with this rule. Consequently, since the expected profits from port shopping and re-exporting refused food imports are expected to fall, reconditioning the cargo becomes economically more attractive. FDA expects that more importers and consignees will choose to recondition their product.

d. Decrease in the introduction of unsafe food into the United States. As with reconditioning, the expected profit from initially sending a potentially unsafe product to a foreign port is not expected to change significantly with this rule. Therefore, as the expected profit from attempting to import unsafe food into the United States is lowered (because the cost of re-importing and re-exporting unsafe food is increased), the incentive to ship one's product directly to a foreign (non-United States) market is increased. The net result of such a dynamic is that more unsafe food products will either be directly shipped to foreign markets or reconditioned at the point of export.

3. Benefits From The Rule

a. Health benefits. As described earlier, the proposed rule, if finalized, would decrease the number of unsafe imported food products reaching the U.S. consumer. The rule should

discourage attempts to introduce or reintroduce unsafe imported food into the United States and encourage the reconditioning of imported food that FDA has refused to admit for safety reasons. Consequently, U.S. consumers would benefit through a reduction in the number of foodborne illnesses due to unsafe imported foods. Because FDA cannot quantify the amount of illegal re-importation of refused foods, the agency cannot make a definitive prediction of the value of the reduced illnesses arising from this proposed rule. Although foods that represent a direct and serious danger to public health are, in most cases, destroyed,[1] refused food eligible for re-exportation may also present a health hazard. Typical reasons for refusal include illegal food or color additives, pesticide contamination, foreign objects, poor sanitation, and unregistered manufacturers or processes not filed. Each of these reasons for refusal may represent a health risk. Illegal food or color additives can cause allergic reactions in sensitive individuals. These allergic reactions can range from mild contact dermatitis to a severe allergy attack. Also, long-term exposure to some illegal color additives has been linked to cancer. Sanitation problems indicate the food was held in unsanitary conditions, which may indicate more serious problems such as contamination with microbial pathogens. Pesticide contamination may represent a long-term cancer risk. A single exposure to a violative pesticide level is very unlikely to result in cancer, but prolonged exposure over years may lead to increased risk. ''Process not filed'' indicates that FDA has not approved the canning process the manufacturer uses. Without FDA approval, it is not known if the firm is using a canning process that may result in botulism contamination. Although the probability of contamination is low, botulism is a very severe illness that has a high mortality rate.

Table 1 of this document shows some possible illnesses and injuries that can result from unsafe foods and includes their symptoms and an average cost per case. The quality-adjusted life days (QALD) (Ref. 8) column represents the lost utility per day to a consumer from an illness, essentially the loss to the consumer due to symptoms and problems associated with the illness. The QALD's are valued in dollars by multiplying the number of lost days by the value of statistical day, $630 (see 64 FR 36516 at 36523, (July 6, 1999)). This value of a statistical life day is drawn from the economic literature (Ref. 10). The medical cost column is the direct, medical cost of illness, which includes hospitalization and doctor visits. Most illnesses arising from *E. Scherichia coli* O157:H7 or *Salmonella* are self-limiting and short in duration, but some illnesses due to *Salmonella* or *E. coli* O157:H7 can be quite serious. *E. coli* in some cases can result in kidney damage or death. Salmonella can sometimes trigger chronic arthritis and in a very small percentage of cases can result in death.

TABLE 1.—COST OF SOME ILLNESSES POTENTIALLY AVERTED BY THE RULE

Potential Harm	Symptoms	QALD Loss	Dollar Value of Lost QALD's	Medical Costs	Total Cost
Allergens: Contact dermatitis	Reddening, swelling, itching of skin	2.10	$1,325	$125	$1,450
Allergens: Allergic reaction	Difficulty breathing, asthma, rash, possible shock	1.03	$646	$550	$1,196
Objects in food: Simple dental injury	Toothache, headache	0.23	$145	$0	$145
Objects in food: Complex dental injury	Simple, plus infection	3.47	$2,187	$3,540	$5,727
Objects in food: Oral emergency	Sharp pain in mouth, face, neck, bleeding, plus possible metastatic or local infection.	4.27	$2,687	$3,540	$6,227
Objects in food: Tracheo-esophageal obstruction	Choking, difficulty breathing, cyanosis, hypertension	0.48	$304	$0	$304
Objects in food: Esophageal perforation	Pain in chest, bleeding aspiration pneumonia, requires surgery.	13.93	$8,776	$14,160	$22,936
Canning processes: Botulism	Nausea, diplopia, blurred vision, lack of coordination, Can include loss of muscle strength, paralysis, death.	667.94	$420,801	$29,526	$450,327
Filth: Salmonella	Vomiting, nausea, possible arthritis, low probability of death.	24.37	$15,357	$2,289	$17,646
Filth: E. coli	Vomiting, nausea, bloody stools, possible kidney damage, low probability of death.	10.79	$6,797	$4,829	$11,626

[1] Sources: *E. coli* and *Salmonella* costs were taken from ''Flexibility Analysis of the Proposed Rules to Ensure the Safety of Juice and Juice Products,'' 963 FR 24254 at 24259-24267, (May 1, 1998).

[2] Objects in food, allergens, and botulism costs were taken from Research Triangle Institute. Estimating the Value of Consumers' Loss from Foods Violating the Federal Food, Drug, and Cosmetic Act.

b. Other consumer benefits. While problems such as insects or filth in food may not always represent a direct health threat, they show that the food was not held in sanitary conditions. Moreover, consumers who purchase food expect it to be clean and sanitary. Consumer research shows cleanliness is important to consumers. For example, the Food Marketing Institute found 89 percent of consumers surveyed ranked a clean, neat store as a very important factor in selecting their primary supermarket. If consumers pay a premium believing their food is sanitary and the food is not, this payment represents a social loss. However, FDA cannot quantify this economic loss because FDA does not know what percentage of the price of food is a ''cleanliness premium.''

4. Costs of the Rule

Costs include both materials and time and would be incurred by both FDA and importers or consignees. The importers and consignees would bear the responsibility for marking; FDA would verify that the mark is affixed to the refused food. It is not clear which method importers and consignees will use to mark refused food imports, so FDA has, for purposes of this analysis, used labeling, an inexpensive and time efficient method, to estimate costs.

a. Materials. Placing labels on all the packages would require the use of a label gun and printed labels. Label guns cost approximately $100, and FDA assumes that three label guns would be needed at each of the 132 ports. Labels reading ''UNITED STATES REFUSED ENTRY'' would also have to be printed

[1] Currently FDA is considering a policy that would recommend the destruction of hazardous food imports. Because dangerous foods may be re-exported without this policy there is the potential for these foods to be port shopped. This proposed rule, if finalized, would then also discourage the re-importation of foods that present a direct hazard to the public health, as well as foods representing an indirect threat, and the rule's benefits would be higher.

at an approximate cost of $0.025 per label.

b. Time—i. Importer's time. The number of hours spent applying labels is a function of the number of rejected shipments and their size. FDA assumes the average shipment consists of 500 cartons and will take approximately 3 hours to mark. FDA also assumes the importer or consignee will hire labor at the average hourly cost for transportation and moving occupations published by the Bureau of Labor Statistics (BLS), $17.64 (BLS, ''Employer Costs for Employee Compensation Summary,'' 1999). Under these assumptions, it will cost approximately $53 in labor (3 hours x $17.64 per hour) to mark each shipment. It is not clear how many shipments will need to be marked. As a baseline, FDA estimates that 7,338 shipments would be marked. However, FDA expects more importers and consignees will decide to recondition after rejection (percent correctable in table 2 of this document), or will not attempt to import previously refused or unsafe food (expected avoidance in table 2 of this document), due to the higher cost of shipments being rejected. The ''static annual cost'' is the cost assuming more of the shipments found violative are corrected at the port. The ''dynamic annual cost'' is the ''static annual cost'' reduced by the percentage decrease (expected avoidance) we expect in initial importation attempts. Based on FDA's experience, the agency can estimate the number of shipments that can be reconditioned rather than re-exported. The percentage of shipments that can be reconditioned is a function of the reason for refusal. Also, the reduction in the number of attempted imports of violative shipments, ''expected avoidance,'' is a function of the ease of correcting the violation before shipment. Again, FDA bases its estimates on the agency's experience. For example, in fiscal year 1999, FDA refused admission to 2,260 shipments because the manufacturer was not registered or the process was not filed. Approximately 80 percent of these shipments can be corrected before importation or at the port by filing for process approval or by registering the manufacturer. This would reduce the number of shipments that could be marked from 2,260 to 452. The cost of marking these shipments would then be $23,925 in labor costs and $5,651 for labels for importers. It would cost FDA $33,229 to confirm the marks had been made. The sum of these costs is $62,805. However, because FDA expects importers and consignees will be less likely to attempt to import unsafe food initially (expected avoidance), FDA then reduces this cost by 50 percent, which is then $31,402. Added to this cost is a fraction of the cost of the label guns. Label guns are durable goods and so the value of a label gun should not be added to the cost of marking each shipment.

ii. FDA inspector's time. The proposed rule would require FDA to confirm that the importer or consignee marks the refused food import. FDA estimates that this process would require approximately 60 minutes in travel time and 30 minutes to confirm marking per shipment. FDA estimates the value of a FDA inspector's time based on a GS-10, step 5 rate, plus 100 percent in overhead. At this hourly rate, FDA's labor costs for each shipment would be $74.

TABLE 2.—ANNUAL LABELING COST ESTIMATES

	Reason for Refusal				
	Manufacturer Not Registered/Process Not Filed	Illegal Food/ Color Additives	Pesticide Contamination	Sanitation	Total Annual Refusals
Estimated refusals	2,260	1,530	873	2,675	7,338
Percent correctable	80%	0%	0%	50%	
Number of refusals to be marked	452	1,530	873	1,337	4,192
FDA Costs.					
FDA hours per refusal	1.5	1.5	1.5	1.5	
FDA hourly rate	$49	$49	$49	$49	
Total FDA cost	$33,229	$112,445	$64,160	$98,297	$308,131
Importer Costs.					
Importer hours per refusal	3	3	3	3	
Importer hourly rate	$17.64	$17.64	$17.64	$17.64	
Label costs	$5,651	$19,123	$10,912	$16,717	
Total importer cost	$29,576	$100,083	$57,106	$87,491	$274,257
Static annual cost	$62,805	$212,528	$121,266	$185,789	$582,388
Expected avoidance	50%	50%	15%	15%	
Dynamic annual cost	$31,402	$106,264	$103,076	$157,921	$398,663

TABLE 3.—FIXED LABELING COSTS

Labeling Guns for Importers	
Number of ports	132
Label guns needed per port of entry	3
Cost per label gun	$100
TOTAL LABEL GUN COSTS = NUMBER OF PARTS X LABEL GUNS NEEDED PER PORT OF ENTRIES X COST PER LABEL GUN	$39,600

TABLE 4.—TOTAL COSTS

Labeling Guns for Importers	
Annual costs	$398,663

TABLE 4.—TOTAL COSTS—Continued

Labeling Guns for Importers	
Other costs	$39,600
TOTAL FIRST-YEAR COSTS	$438,263

c. Diminished value of shipments. Cargo marked ''UNITED STATES REFUSED ENTRY'' will lose value due to diminished value in foreign ports, in addition to the loss of the U.S. market for the product. The importer or consignee suffers an initial loss of value due to rejection of its cargo, regardless of the mark. However, there is an additional loss of value attributable to the marking that is a cost of this rule. This loss of value is a cost of the rule that is borne directly by the importer or consignee, but may be passed on to consumers in the form of higher food prices. This loss ofvalue is difficult to quantify. How the mark decreases the value of the cargo would be a function of the initial value of the cargo, type of product, reason for refusal, and the reluctance of the new buyer to purchase previously refused merchandise.

5. Summary of Benefits and Costs

The uncertain nature of the number of illnesses prevented and the difficulty in quantifying the benefits to consumer of having clean foods, regardless of the danger, prevents a definitive statement about benefits and costs. Because FDA expects the costs to be approximately $438,263, this sets a threshold value for the benefits. If the benefits due to reduced illness and consumer valuation of clean food exceed $438,263, the rule's benefits will exceed its costs.

E. Initial Regulatory Flexibility Analysis

1. Introduction

FDA has examined the economic implication of these proposed rules as required by the Regulatory Flexibility Act (5 U.S.C. 601-612). If a rule would have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities.

2. Economic Effects on Small Entities

The proposed rule, if finalized, would affect many small entities, primarily food importers or consignees. More than 95 percent (1,690 of 1,725 importers identified through a search in Dialog Classic) of food importers are small (Ref. 3) as defined by the Small Business Administration (establishments with less than 100 employees). These small importers or consignees will face a cost of approximately $75 per unsafe food shipment in time and materials. In addition, the value of their unsafe food shipment will fall. This cost is difficult to quantify, but can be bounded by the cost of repackaging the merchandise. FDA does not expect this cost for any one small importer or consignee to be significant, so the agency concludes that this proposed rule does not place a disproportionate burden on small businesses. Furthermore, this cost is borne only by small businesses that attempt to re-import unsafe, and previously refused, foods.

3. Regulatory Options

Exempting small businesses from the proposed rule would lift the burden on small entities. However, since most entities affected by the rule are small, this would effectively negate the rule's purpose. For reasons already discussed in section VII.C of this document, other regulatory options, such as destroying all refused food imports, taking no action, marking some but not all refused food imports, and marking based on geographic origin, are not feasible in light of the proposed rule's purposes. FDA also notes that the proposal contains options (with respect to the method used to affix the mark) for importers and consignees, and importers and consignees whose shipments are refused admission for safety reasons may decide to re-condition, destroy, or re-export an unsafe food import. Given these options available to small entities, FDA did not consider additional options.

4. Relevant Federal Rules Which May Duplicate, Overlap, or Conflict With the Proposed Rule

FDA is not aware of any relevant Federal rule which may duplicate or conflict with the proposed rule. The exportation of refused food products must also comply with Customs rules for exportation of refused imports at 19 CFR 12.4, 18.25, 18.26, and 158.45. In addition, Customs routinely orders redelivery of refused merchandise under to the conditions contained in the basic importation and entry bond. Therefore, importers of refused food imports must comply with the bond conditions contained in 19 CFR 113.62, as required by 19 CFR 12.3.

VIII. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by April 9, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Bureau of Labor Statistics, Employer Costs for Employee Compensation Summary, http://stats.bls.gov/news.release/ecec.nws.htm (1999).

2. Congressional Hearing, The Safety of Food Imports: Fraud and Deception in the Food Import Process; Hearing Before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations, September 10, 1998.

3. Dialog Classic. Search of wholesalers who import with SIC codes between 5141 to 5149 that are importers, February 29, 2000.

4. Food and Drug Administration, ''Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rules to Ensure the Safety of Juice and Juice Products,'' (63 FR 24254, May 1, 1998).

5. Food and Drug Administration, ''Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rule to Require Refrigeration of Shell Eggs at Retail and Safe Handling Labels,'' (64 FR 36516, July 6, 1999).

6. Food Marketing Institute, 1999. Consumer Attitudes and the Supermarket. Research International USA.

7. GAO Report, ''Food Safety: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable'' (GAO/RCED–98–103).

8. Kaplan, R. M., J. P. Anderson, and T. G. Ganiats, ''The Quality of Well-

Being Scale: Rationale for a Single Quality of Life Index,'' edited by Walker, S. R. and Rosser, R. M., *Quality of Life Assessment: Key Issues in the 1990s*; The Netherlands: Kluwer Academic Publishers, 1993.

9. Mauskopf, J.A., Mt French, A. S. Ross, D. M. Maguire, R. W. Leukrith, Jr., and K. D. Fisher, ''Estimating the Value of Consumers' Loss from Foods Violating the Federal Food, Drug, and Cosmetic Act,'' Research Triangle Report to the Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, September 1988.

10. Viscusi, W. K., ''The Value of Risks to Life and Health.'' *Journal of Economic Literature,* Volume 31, pp. 1912-1946, December 1993.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 343, 352, 355, 360b, 362, 371, 374, 381; 42 U.S.C. 216, 264.

2. Add section 1.98 to subpart E to read as follows:

§ 1.98 Marking of food imports refused entry into the United States.

(a) If you are an importer or consignee and your imported food has been refused admission into the United States for safety reasons and you want to reexport the food, you must mark the refused food, before you reexport it, with the following mark:

Illustration 2

UNITED STATES REFUSED ENTRY

(b) You must make the mark at least 2.5 cm. or 1 inch high in capital or uppercase letters. The mark must be clear, conspicuous, and permanently affixed. You also must:

(1) Affix the mark to the packing container of the food, if possible, and to an invoice, bill of lading, and any other shipping document accompanying the food when it is exported. For purposes of this rule, a packing container is any contaner used to pack one or more immediate containers of the refused food, and an immediate container is any container which holds an imported food for sale to the ultimate consumer. the term ''packing container'' excludes trailers, railroad cars and similar transportation-related items, and

(2) Affix the mark, under the supervision of a FDA employee or individual designated by FDA, before the food is exported.

(c) You must not:

(1) Import or offer to import any food that has been previously refused admission into the United States and marked as ''UNITED STATES REFUSED ENTRY;'' or

(2) Alter, remove, tamper with, or conceal a ''UNITED STATES REFUSED ENTRY'' mark.

Dated: November 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

January 9, 2001,

Timothy E. Skud,

Acting Deputy Assistant Secretary. Department of the Treasury.

[FR Doc. 01–1607 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 870

RIN 1029–AB95

Abandoned Mine Land (AML) Fee Collection and Coal Production Reporting on the OSM–1 Form

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; reopening and extension of the comment period.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM) are reopening and extending the comment period on a proposal to amend our regulations governing Abandoned Mine Land (AML) reclamation fee reporting to allow for the electronic filing of the information required on the OSM–1 Form.

DATES: *Written comments:* We will accept written comments on the proposed rule until 5 p.m., Eastern time, on February 21, 2001.

ADDRESSES: If you wish to comment, you may submit your comments by any one of the following methods. You may mail or hand-deliver comments to the Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 101, 1951 Constitution Avenue, NW, Washington, DC 20240. You may also submit comments to OSM via the Internet at: osmrules@osmre.gov.

FOR FURTHER INFORMATION CONTACT: Mr. Sean Spillane, Office of Surface Mining Reclamation and Enforcement, Denver Federal Center, Building 20k, Room B–2005, Denver, Colorado 80225; Telephone 303–236–0330, Ext. 278. E-mail: sspkillan@osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background Information
II. How Would the Electronic Submission Process Work?
III. How Do I Submit Comments on the Proposed Rule?

I. Background Information

On February 15, 2000 (65 FR 7706), we published a proposed rule which would revise our regulations to allow a coal operator (or the entity reporting for the operator) the option of filing the OSM–1 Form electronically. Because of the notary requirement in section 402(c) of the Surface Mining Control and Reclamation Act of 1977 (SMCRA), the