Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. 95–002–1]

Khapra Beetle; Brassware and Wooden Screens From India

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to remove brassware and wooden screens from Bombay, India, from the list of articles whose importation into the United States is restricted because of possible infestation with the khapra beetle. This action would allow the importation of these articles without fumigation and other restrictions. We believe this action is warranted because brassware and wooden screens from Bombay, India, no longer present a significant risk of introducing the khapra beetle into the United States.

DATES: Consideration will be given only to comments received on or before August 10, 1995.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 95–002–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Ms. Jane Levy, Staff Officer, Port Operations Permit Unit , PPQ, APHIS, Suite 4A03, 4700 River Road Unit 136, Riverdale, MD 20737–1236; (301) 734–8295.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR part 319.75 through 319.75–9 (referred to below as the regulations), specify required procedures for importing certain articles into the United States. The purpose of the regulations is to protect against the introduction of khapra beetle into the United States.

The khapra beetle (*Trogoderma granarium* Everts) is a plant pest that damages grain and cereal products, seeds, cottonseed meal, nut meats, dried fruits, and other products. This pest can cause serious damage to stored products. When infested products are left undisturbed in storage for long periods of time, total loss can be expected.

The regulations impose restrictions on those articles that present a significant risk of carrying the khapra beetle at the time of importation into the United States. The articles subject to restrictions are designated as restricted articles. Restricted articles may be imported into the United States only when treated by fumigation as required in § 319.75–4 of the regulations, and when specified permit, marking, identification, and notification requirements are met.

The list of restricted articles in § 319.75–2 of the current regulations includes brassware and wooden screens from Bombay, India. We are proposing to remove brassware and wooden screens from Bombay, India, from the list of restricted articles. Numerous requests from importers have encouraged the Animal and Plant Health Inspection Service (APHIS) to revise the current restrictions. APHIS has determined that wooden screens and brassware no longer present a significant risk of introducing the khapra beetle into the United States. These articles are no longer stored in khapra beetle infested warehouses in Bombay, India, and are now packed in paper and plastic rather than in jute bagging and straw, which are materials that the khapra beetle live in.

Therefore, we are proposing to remove brassware and wooden screens from Bombay, India, from the list of restricted articles in § 319.75–2. We are also proposing to remove references to brassware and wooden screens from § 319.75–4, which sets out fumigation requirements.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

The major economic impact of this proposed rule will be on methyl bromide producers and fumigators, and on domestic importers of brassware products. Ten percent of methyl bromide fumigation in the United States in FY 1993 was used on brassware products from India. The economic effect on the fumigators will be important only in the next few years because under provisions of a final rule published by the Environmental Protection Agency in the **Federal Register** on December 10, 1993 (58 FR 65018–65082), domestic use of methyl bromide must be phased out by the year 2001.

Fumigation using methyl bromide is done mainly by private contractors at the ports of entry, under the supervision of APHIS inspectors. Brassware is fumigated by approximately 17 private contractors at the following ports of entry: Los Angeles, San Francisco, and San Pedro, CA; Miami, FL; Savannah, GA; Chicago, IL; New Orleans, LA; Detroit, MI; Wilmington, NC; Elizabeth, NJ; Brooklyn, NY; Cleveland, OH; Charleston, SC; Houston, TX; Norfolk, VA; and Seattle, WA.

Methyl bromide is produced by two chemical manufacturers in the United States who, in turn, sell to distributors who may or may not be end users. Small Business Administration (SBA) standards consider agricultural chemical manufacturers and retailers small businesses if they employ 500 people or less. Methyl bromide manufacturers would not be considered small by these standards. The number of distributors of methyl bromide is not known. However, out of the 12 commercial suppliers listed in APHIS' Plant Protection and Quarantine Treatment Manual, which was revised in 1993, only one other company besides the primary manufacturer remains in business as a supplier/distributor of methyl bromide in the United States. APHIS estimates that over 90 percent of methyl bromide

fumigators would be considered small by SBA standards.

In FY 1993, approximately 37,800 pounds of methyl bromide was used to fumigate brassware products from India. Based on this figure, exempting Indian brassware products from fumigation, which costs approximately $1.50 a pound, would result in fumigators as a group losing about $56,700 a year in sales of methyl bromide. The contractor charges for methyl bromide and labor are approximately $275 per fumigation. In addition, those fumigators would also lose the unloading and loading charges of approximately $500 per fumigation. At the Long Beach, CA, port of entry the approximate annual revenue of methyl bromide fumigators for brassware fumigations was $337,400. Long Beach comprises 37.7 percent of the national brassware fumigations. Using the Long Beach estimate as a base, methyl bromide fumigators may lose approximately $894,960 on brassware fumigations nationwide.

Information on the number of importers of brassware from Bombay, India, is unavailable. Domestic importers would save on the treatment costs. The treatment costs include the charges of methyl bromide fumigators and overtime costs for APHIS inspectors during fumigations. In Long Beach, CA, the annual overtime charges are approximately $37,400. Using the Long Beach estimate as a base, overtime charges nationwide would be approximately $100,000 annually. As a group, importers would save about $1 million a year in overtime and contractor charges.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 319

Bees, Coffee, Cotton, Fruits, Honey, Imports, Incorporation by reference, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, 7 CFR part 319 would be amended as follows:

PART 319—FOREIGN QUARANTINE NOTICES

1. The authority citation for part 319 would continue to read as follows:

Authority: 7 U.S.C. 150dd, 150ee, 150ff, 151–167, and 450; 21 U.S.C. 136 and 136a; 7 CFR 2.17, 2.51, and 371.2(c).

§ 319.75–2 [Amended]

2. Section 319.75–2 would be amended by removing paragraph (a)(2) and by redesignating paragraphs (a)(3) through (a)(8) as (a)(2) through (a)(7), respectively.

§ 319.75–4 [Amended]

3. In § 319.75–4, paragraph (a) introductory text would be amended by removing the words ''Brassware; wooden screens; goatskins;'' and by adding the word ''Goatskins;'' in their place.

Done in Washington, DC, this 30th day of June 1995.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–16886 Filed 7–10–95; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 95N–0034]

Dental Devices; Effective Date of Requirement for Premarket Approval of Over-the-Counter (OTC) Denture Cushions or Pads and OTC Denture Repair Kits

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of product development protocol (PDP) for OTC denture cushions or pads and OTC denture repair kits. The agency is also summarizing its findings regarding the benefits to the public from use of the device, as well as, the degree of risk of illness or injury intended to be eliminated or reduced by requiring that the devices have an approved PMA or a completed PDP. In addition, FDA is announcing the opportunity for interested persons to request the agency to change the classification of the device based on new information.

DATES: Submit written comments by October 10, 1995; requests for a change in classification by July 26, 1995. FDA intends that if a final rule based on this proposed rule is issued, PMA's or notices of completion of PDP's will be required to be submitted within 90 days of the effective date of the final rule.

ADDRESSES: Submit written comments or requests for a change in classification to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Louis Hlavinka, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. For the sake of convenience, this preamble refers to the devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date as ''preamendments devices.''

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or notice of completion of a PDP until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the act, whichever is later. Also, such a device is exempt from