

Title	Number of respondents	Number of responses/ respondent	Burden per response (in hrs.)	Total burden (hrs.)
Total				67,289

Dated: June 12, 2003.

Thomas A. Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Food and Drug Administration

RIN 0920-AA03

Control of Communicable Diseases

AGENCIES: Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Department of Health and Human Services (HHS).

ACTION: Notice of embargo and prohibition on transportation or offering for transportation in interstate commerce, or sale, offering for sale, or offering for any other type of commercial or public distribution, including release into the environment, of certain rodents and Prairie dogs.

SUMMARY: Shipments of rodents (order *Rodentia*) from Africa capable of transmitting monkeypox virus in humans are being imported into the United States and further distributed. In the United States, Prairie dogs (*Cynomys sp.*) and certain rodents from Africa may further transmit the monkeypox virus in humans.

Because of the public health threat posed by the importation of rodents from Africa, CDC is implementing an immediate embargo on the importation of all rodents (order *Rodentia*) from Africa until further notice. In addition, as a public health measure, CDC and FDA are prohibiting, until further notice, the transportation or offering for transportation in interstate commerce, or the sale or offering for sale, or offering for any other type of commercial or public distribution, including release into the environment, of Prairie dogs and the following rodents from Africa: Tree squirrels (*Heliosciurus sp.*); Rope squirrels (*Funisciurus sp.*); Dormices (*Graphiurus sp.*); Gambian Giant Pouched Rats (*Cricetomys sp.*); Brush-tailed

porcupines (*Atherurus sp.*), Striped mice (*Hybomys sp.*).

This prohibition does not apply to individuals who transport listed animals to veterinarians or animal control officials or other entities pursuant to guidance or instructions issued by Federal, State, or local government authorities.

This action is being taken because at least six different species of potentially infected rodents have been implicated in the current outbreak of monkeypox virus in humans. Monkeypox virus was also subsequently transmitted from infected rodents to native Prairie dogs. Based on epidemiologic and scientific knowledge gathered to date, specific interstate restrictions on the species within these genera are required to contain further movement of implicated animals. A ban on the intrastate sale or offering for sale or offering for any other type of commercial or public distribution of the species within these genera is also necessary because of the potential impact on interstate disease spread. Furthermore, a ban on the importation of shipments of all rodents from Africa is necessary to mitigate the harm of further introductions of monkeypox virus into the United States.

DATES: This embargo and prohibition is effective on June 11, 2003, and will remain in effect until further notice.

FOR FURTHER INFORMATION CONTACT:

Thomas A. Demarcus, National Center for Infectious Diseases (E03), Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Atlanta, GA 30333, 770-488-7100, or Gloria Dunnavan, Division of Compliance, Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place (HFV-230), Rockville, MD 20855, 301-827-1168.

SUPPLEMENTARY INFORMATION:

I. Background

As of June 10, a total of 50 persons with suspected monkeypox had been reported from Wisconsin, Illinois, Indiana, and New Jersey. Monkeypox had been confirmed by laboratory tests in four persons. Seven of the people with suspected monkeypox had been hospitalized for their illness; there have been no deaths related to the outbreak. The number of cases and States

involved in the outbreak will likely change as the investigation continues.

Onset of illness among patients began in early May. All patients reported direct or close contact with Prairie dogs, most of which were sick. In May, the Prairie dogs were sold by a Milwaukee animal distributor to two pet shops in the Milwaukee area and during a pet "swap meet" (pets for sale or exchange) in northern Wisconsin. The Milwaukee animal distributor had obtained Prairie dogs and a Gambian giant rat that was ill at the time from a northern Illinois animal distributor. On the basis of preliminary findings from the trace-back investigation of the Prairie dogs and the Gambian giant rat, it appears that the source of the infection was a shipment of rodents from Africa, which included six distinct species of rodents. It appears that the primary route of transmission may be from infected rodents from Africa to native Prairie dogs and then to humans as a result of close contact.

II. Public Health Risks

Monkeypox is a rare zoonotic viral disease that occurs primarily in the rain forest countries of central and west Africa. Studies have shown that rodents from Africa are capable of transmitting monkeypox virus in humans. In humans, the illness produces a vesicular and pustular rash similar to that of smallpox. Limited person-to-person spread of infection has been reported in disease-endemic areas in Africa; the incubation period is about 12 days. Case-fatality ratios in Africa have ranged from 1 percent to 10 percent. It is likely the virus entered the United States via imported rodent species from Africa. Further transmission of the virus likely occurred in the storage and handling of these imported rodents during sale and distribution within the United States. This resulted in secondary transmission to domestic Prairie dogs housed in the same animal-holding facility or pet shop.

III. Immediate Action

Introduction of exotic species, such as rodents from Africa, poses a serious public health threat because of the potential of human monkeypox virus infection. Transportation in interstate commerce or sale or any other type of commercial or public distribution, including release into the environment, of species of rodents linked to the initial

infected shipment and Prairie dogs poses a serious public health threat because of the potential for further spread of the monkeypox virus to other species and humans.

The scope of this communicable disease problem is inherently and necessarily an interstate problem that cannot be controlled by individual state health authorities. Thus, the appropriate measures taken by the health authorities of any state or possession are insufficient to prevent the interstate spread of human monkeypox virus infection. Accordingly, CDC and FDA, pursuant to 42 CFR 70.2 and 21 CFR 1240.30, are prohibiting, until further notice, the transportation or offering for transportation in interstate commerce, or the sale, offering for sale, or offering for any other type of commercial or public distribution, including release into the environment, of Prairie dogs and the following rodents from Africa: Tree squirrels (*Heliosciurus sp.*); Rope squirrels (*Funisciurus sp.*); Dormice (*Graphiurus sp.*); Gambian Giant Pouched Rats (*Cricetomys sp.*); Brush-tailed porcupines (*Atherurus sp.*); Striped mice (*Hybomys sp.*).

This prohibition does not apply to individuals who transport listed animals to veterinarians or animal control officials or other entities pursuant to guidance or instructions issued by Federal, State, or local government authorities. In addition, pursuant to 42 CFR 71.32(b), CDC is implementing an immediate embargo on the importation of all rodents from Africa (order *Rodentia*).

Dated: June 12, 2003.

Julie Louise Gerberding,

Director, Centers for Disease Control and Prevention.

Dated: June 12, 2003.

Mark B. McClellan,

Commissioner of Food and Drugs.

[FR Doc. 03-15423 Filed 6-13-03; 5:07 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0234]

Canned Asparagus Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing

that a temporary permit has been issued to Chiquita Processed Foods, LLC, and Crown Cork & Seal Co., to market test a product designated as "VERI-GREEN Cut Asparagus Spears" that deviates from the U.S. standard of identity for canned asparagus. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the food.

DATES: This permit is effective for 15 months, beginning on the date the test product is introduced or caused to be introduced into interstate commerce, but no later than September 16, 2003.

FOR FURTHER INFORMATION CONTACT: Catalina Ferre-Hockensmith, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2371.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Chiquita Processed Foods, LLC, P.O. Box 458, Walla Walla, WA 99362, and to Crown Cork & Seal Co., 11535 South Central Ave., Alsip, IL 60803.

The permit covers limited interstate marketing tests of a product designated as "VERI-GREEN Cut Asparagus Spears" that deviates from the U.S. standard of identity for canned asparagus (21 CFR 155.200) in that the test product will contain added zinc chloride and stannous chloride at a maximum level of 75 parts per million (ppm) of zinc and 35 ppm of stannous chloride in the finished food. The test product meets all requirements of the standard with the exception of the variation. The purpose of the variance is to test the use of added zinc chloride and stannous chloride to retain the green color of the food and fresh taste.

The permit provides for the temporary marketing of 387,192 pounds (lb) of the test product (175,200 kilograms (kg)) (10,000 cases, each containing 6 lb, 7 ounce (2.92 kg) cans). The product will be manufactured at Chiquita Processed Foods, LLC, 516 West Rose, Walla Walla, WA 99362. The product will be distributed in the United States.

For the purpose of the permit, the name of the product is "VERI-GREEN Cut Asparagus Spears." Each of the ingredients used in the food must be declared on the label as required by the applicable sections of 21 CFR parts 101

and 130. The permit is effective for 15 months, beginning on the date the test product is introduced or caused to be introduced into interstate commerce, but not later than September 16, 2003.

Dated: June 10, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Physicians' Experience of Ethical Dilemmas and Resource Allocation

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Dental and Craniofacial Research (NIDCR), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Physicians' Experience of Ethical Dilemmas and Resource Allocation. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* Health care costs are rising ceaselessly and there are currently no generally accepted way of controlling them. This study will access the experience of physicians regarding resource allocation in clinical practice, and how allocation decisions made at other levels shapes this experience. The primary objectives of the study are to determine if physicians make decisions to withhold interventions on the basis of cost, how often they report doing so, what types of care are withheld, and what criteria are used in making such decisions. The findings will provide valuable information concerning: (1) The practice of resource allocation in clinical practice, (2) the possible effects of perceived constraints on this practice, and (3) international comparisons on these two aspects. *Frequency of Response:* Once. *Affected Public:* Individuals or households; businesses or other for-profit; not-for-profit institutions. *Type of Respondents:* Physicians. The annual reporting burden is as follows: *Estimated number of Respondents:* 250; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:*