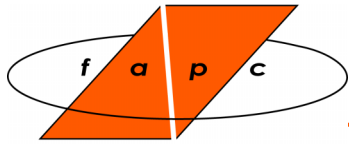


Food and Agricultural Products Center



FLASH!!

May 6, 2003

Registration to Protect U.S. Food Supply

STILLWATER, Okla. – Domestic and foreign facilities involved with food production must register with the Food and Drug Administration by Dec. 12, 2003, as a result of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

The Act takes steps toward providing safer food supplies, said Jason Young, Food and Agricultural Products Research and Technology Center quality management specialist.

“With the increasing possibility of biological terrorism in the world today, it is important for the United States to take appropriate measures to secure the food supply,” he said. “This registration process is a necessary step to prevent the possibility of contamination from terrorism.”

Registration is one of several tools that will enable FDA to act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply by giving FDA information about all facilities that manufacture, process, pack or hold food for consumption in the United States, Young said.

In the event of an outbreak of food-borne illness, such information will help FDA and other authorities determine the source and cause of the event. In addition, the registration information will enable FDA to notify quickly the facilities that might be impacted by the outbreak.

Improving the FDA’s food safety inspection, detection and monitoring capabilities is and has been a top priority of the Department of Health and Human

Services even before the events of Sept. 11, Young said.

According to the Department of Health and Human Services, the Act calls for facilities responsible for the manufacturing, processing, packing or holding of food for human or animal consumption in the United States to register. This also includes dietary supplements; infant formula; beverages, such as alcoholic beverages; and food additives.

States also must register with the FDA, as well as domestic facilities, regardless of whether or not food produced enters interstate commerce.

Foreign facilities performing the same activities as domestic operations fall under the regulation guidelines listed above, unless further processing or packaging by another facility is performed.

Operations exempt from registering include farms; retail food operations; restaurants; non-profit operations preparing food for, or serving food directly to consumers; fishing vessels not engaged in processing; and facilities regulated exclusively throughout the entire facility by the USDA.

Those who fail to comply with the Bioterrorism Act are guilty of performing a prohibited act, and the FDA may bring a civil or criminal action against that operation or individual, Young said.

“If foreign facilities attempt to import food into the United States, the food must be held at the port of entry unless the FDA decides it should be moved to

another secure location,” Young said. “The manufacturers also will be responsible for any costs associated with movement or detainment of the shipments.”

Registration for the Bioterrorism Act is free, and the FDA is proposing it be completed electronically, via the Internet or, mailed to the administration.

The proposed regulation would require the owner, operator or agent in charge of a domestic or foreign facility to submit a registration to FDA, including the name and address of each facility, the trade names of which the registrant conducts business and the categories of food the facility handles. The proposal also would require facilities to update any changes to the information previously submitted within 30 days of the change.

A registration number and confirmation will be sent to each facility once registration is complete. The final date for the FDA to publish the rules and establish the

means of registration in the *Federal Register* is Oct. 12, 2003, and forms should not be sent in before that time.

The FDA estimates approximately 202,000 domestic and 205,000 foreign facilities will meet guidelines and be required to register.

The FDA Web site, www.fda.gov/oc/bioterrorism/bioact, regularly updates information concerning this topic. Single copies of the Bioterrorism Act proposals may be obtained from the Web site or by writing to Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, Md., 20852.

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Issued in furtherance of Cooperative Extension work, acts of May 8 and June 30, 1914, in cooperation with the U.S. Department of Agriculture, Sam E. Curl, Director of Oklahoma Cooperative Extension Service, Oklahoma State University, Stillwater, Oklahoma. This publication is printed and issued by Oklahoma State University as authorized by the Dean of the Division of Agricultural Sciences and Natural Resources and has been prepared and distributed at a cost of \$433.50 for 850 copies. 0503 RLJ.