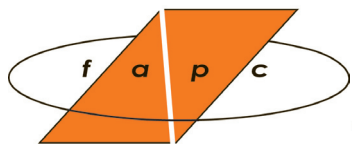


Food & Agricultural Products Center



FLASH!!

OKLAHOMA STATE UNIVERSITY™

July 18, 2005

FDA Provides Guidelines for the Establishment and Maintenance of Records

STILLWATER, Okla. – Protecting the U.S. food supply is of utmost concern for the U.S. Food and Drug Administration. In a combined effort with the U.S. Department of Health and Human Services, new guidelines have been put in place for the establishment and maintenance of records.

The new guidelines, published in a FDA booklet, “What You Need to Know about Establishment and Maintenance of Records,” restate the current legal requirements for the establishment and maintenance of records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, also known as the Bioterrorism Act, said Jason Young, Food & Agricultural Products Center quality management specialist.

“Final regulations were issued that created requirements regarding the establishment and maintenance of records who manufacture, process, pack, transport, distribute, receive, hold or import food,” Young said.

The FDA is specifying the information that businesses must keep to maintain the records, but not the form in which the records must be maintained.

“According to the FDA, the records can be kept in any system, paper or electronic, as long as they contain all the required information,” Young said. “If the current records containing the required information exists, there is no need for duplicate information.”

Businesses excluded from the record requirements include restaurants and retail food establishments that employ 10 or fewer full time employees, farms, those producing for personal consumption, non-profit food establishments and FSIS-inspected facilities.

The records and subsequent recipients that must be established and maintained for non-transporters include:

- 1) The name and information of the previous sources.
- 2) The type of food, including the brand name and specific variety.
- 3) The date received and quantity and type of packaging.

For those that manufacture, process or pack food, a lot or code number needs to be included and the specific source of each ingredient that was used to make every lot of finished product.

The records that must be established and maintained for transporters must include:

- 1) Names of the transporter’s immediate previous source and immediate subsequent recipient.
- 2) Origin and destination points.
- 3) Date shipment received and date shipment released.
- 4) Number of packages.
- 5) Description of freight.

- 6) Route of movement during the time that the food was transported.
- 7) Transfer point(s) through which the shipment was moved.

According to the FDA booklet, these records must be created when the food is received, released or transported, and the period for which the records must be retained depends on how perishable the food. The record can be retained at the establishment where the activities covered in the records occurred or at a reasonably accessible location.

The records that are excluded from record access requirements are recipes, financial data, pricing data, personal data, research data and sales data. Recipes are excluded only if they have the formula and instructions needed to create a food product. If the ingredients to the food product are the only things listed, it is not excluded.

All businesses, except small and very small businesses, covered by this rule must meet the terms by Dec. 9, 2005.

Small businesses (11 to 499 full-time equivalent employees) must comply by June 9, 2006, and very small businesses (10 or fewer full-time equivalent employees) have to comply by Dec. 11, 2006.

For more information on establishment and maintenance of records, visit the FDA Web site at www.fda.gov/oc/bioterrorism/bioact.html.

###

Jason Young is a quality management specialist for the FAPC. He may be contacted at (405) 744-6071 or jason.young@okstate.edu .
--

Oklahoma State University, in compliance with Title VI and VII of the Civil Rights Act of 1964, Executive Order 11246 as amended, Title IX of the Education Amendments of 1972, Americans with Disabilities Act of 1990, and other federal laws and regulations, does not discriminate on the basis of race, color, national origin, sex, age, religion, disability, or status as a veteran in any of its policies, practices or procedures. This includes but is not limited to admissions, employment, financial aid, and educational services.

Issued in furtherance of Cooperative Extension work, acts of May 8 and June 30, 1914, in cooperation with the U.S. Department of Agriculture, Robert E. Whitson, Dean and 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 \$84 for 600 copies. 0705 MHG.

Food & Agricultural Products Center
Oklahoma State University
Room 148
Stillwater, OK 74078-6055