

32. Cramp, John A., P. M. Griffin, and F. J. Angulo, "Bacterial Contamination of Animal Feeds and its Relationship to Human Foodborne Illness," *Clinical Infectious Diseases*, 35:859–865, 2002.

## List of Subjects

### 21 CFR Part 1

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

### 21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 1 and 11 be amended as follows:

## PART 1—GENERAL ENFORCEMENT REGULATIONS

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

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 304, 321, 331, 334, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Subpart J is added to part 1 to read as follows:

### Subpart J—Establishment, Maintenance, and Availability of Records

#### General Provisions

Sec.

- 1.326 Who is subject to this subpart?
- 1.327 Who is excluded from all or part of the regulations in this subpart?
- 1.328 What definitions apply to this subpart?
- 1.329 Do other statutory provisions and regulations apply?
- 1.330 Can existing records satisfy the requirements of this subpart?

#### Requirements to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Previous Source of All Food

- 1.337 What information is required in the records you must establish and maintain to identify the nontransporter and transporter immediate previous source?

#### Requirements to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipient of All Food

- 1.345 What information is required in the records you must establish and maintain to identify the nontransporter and transporter immediate subsequent recipient?

#### Requirements to Establish and Maintain Records to Trace the Transportation of All Food

- 1.351 Who is required to establish and maintain records for tracing the transportation of all food?
- 1.352 What information is required in the transportation records?

#### General Requirements

- 1.360 What are the record retention requirements?
- 1.361 What are the record availability requirements?
- 1.362 What records are excluded from this subpart?
- 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA?

#### Effective Dates

- 1.368 What are the compliance dates for this subpart?

### Subpart J—Establishment, Maintenance, and Availability of Records

#### General Provisions

##### § 1.326 Who is subject to this subpart?

(a) Domestic persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for consumption in the United States are subject to the regulations in this subpart, unless you qualify for one of the exclusions in § 1.327. In addition, foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States are subject to these regulations, unless you qualify for one of the exclusions in § 1.327. If you conduct more than one type of activity at a location, you are required to keep records with respect to those activities covered by this subpart, but are not required by this subpart to keep records with respect to activities that fall within one of the exclusions in § 1.327.

(b) Persons subject to the regulations in this subpart must keep records whether or not the food enters interstate commerce.

##### § 1.327 Who is excluded from all or part of the regulations in this subpart?

- (a) Farms are excluded from all of the regulations in this subpart;
- (b) Restaurants are excluded from all of the regulations in this subpart;
- (c) Fishing vessels including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel are excluded from all of the regulations in this subpart, except § 1.361 and § 1.363. However, those fishing vessels otherwise engaged in processing fish,

which for purposes of this subsection means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding, are subject to all of the regulations in this subpart;

(d)(1) All retail facilities are excluded from § 1.345 of this subpart;

(2) Retail facilities that employ 10 or fewer full-time equivalent employees that:

- (i) Are located in the same general physical location as a farm; and
- (ii) Sell unprocessed food grown or raised on that farm or on another farm located in the same general physical location are excluded from all of the regulations in this subpart, except § 1.361 and § 1.363, with respect to that unprocessed food.

(e) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food that is within the exclusive jurisdiction of the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) are excluded from all of the regulations in this subpart with respect to that food.

(f) Foreign facilities are excluded from all the regulations in this subpart, if food from such facilities undergoes further manufacturing/processing (including packaging) by another foreign facility outside the United States. This exclusion does not apply to a foreign facility if the further manufacturing/processing (including packaging) conducted by the subsequent facility consists of adding labeling or any similar activity of a de minimis nature.

(g) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import pet food who are not subject to the recordkeeping provisions of the animal proteins prohibited in ruminant feed regulation (§ 589.2000 of this chapter) are, with respect to pet food records, excluded from all the regulations in this subpart except for § 1.361 and § 1.363.

##### § 1.328 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this subpart.

In addition, for the purposes of this subpart:

*Act* means the Federal Food, Drug, and Cosmetic Act.

*Domestic person* means any person located in any State or Territory of the