

## **FDA Produce Rule Record Keeping Requirements**

*Document created 11.21.15 by Atina Diffley and Jo Ann Baumgartner on the just released Produce Rule*

---

### **SUBPART O - GENERAL RECORDKEEPING REQUIREMENTS**

*Apply to all record keeping requirements, with exceptions for Qualified Exemptions*

The general record keeping standards require records to include:

- Name and location of the farm
- Actual values and observations collected during monitoring activities
- An adequate description of the produce applicable to the record (e.g., commodity name, specific variety, or other identifier, such as a lot number)
- Location of the growing area or other area applicable to the record
- Date and time that an activity was performed or observed.

The records must be:

- Taken at the time an activity is performed or observed
- Must be accurate and legible
- Must be dated and signed by the person doing the activity

Record requirements below marked with an asterisk (\*) must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

Records must be immediately available to the FDA (or within 24 hours if stored off-site)

Records must be kept for 2 years (3 if for qualified exemption)

---

### **§ 112.7 RECORDS FOR A QUALIFIED EXEMPTION**

#### **What Records Must Your Keep**

You must establish and keep adequate records necessary to:

- Demonstrate that your farm satisfies the criteria for a qualified exemption (1/27/16)
- A written record reflecting that you have performed an annual review and verification of your farm's continued eligibility for the qualified exemption. \* (Compliance date based on size of farm)
- Packaging, label, placard indicating farm name and complete address (1/1/20)

#### **How Records Are Kept**

You must establish and keep records required with the requirements of subpart O of this part, except that the requirement for a signature or initial is not required for sales receipts kept in the normal course of business. Such receipts must be dated

---

### **SUBPART C: PERSONNEL QUALIFICATIONS AND TRAINING**

\* Document training of personnel, including:

- The date of training
- The topics covered
- The persons(s) trained

---

## **SUBPART E: AGRICULTURAL WATER**

### **For all agricultural water keeps records of:**

- Inspection of agricultural water sources and systems, and pooling of water
- Generic *E. coli* test results
- Water treatment monitoring
- Public water (annual) documentation
- Scientific data or information you rely on to support the adequacy of a method used to treat water

### **Irrigation water that directly contacts harvestable portion:**

- Microbial die-off or removal rates, and scientific documentation of method
- Scientific data or information you rely on to support a microbial die-off or removal rate
- Documentation of actions that support a microbial die-off or removal rate

---

## **SUBPART F: BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN AND HUMAN WASTE**

### **For a treated biological soil amendment of animal origin you receive from a third party (e.g. compost from a compost maker):**

- Annual documentation (such as a Certificate of Conformance):
  - The process used is scientifically valid and has been carried out with appropriate monitoring; and
  - It is handled, conveyed and stored in a manner and location to minimize the risk of contamination

### **For a treated biological soil amendment of animal origin (e.g. compost) you make yourself for your farm:**

- Documentation that process controls (for example, time, temperature, and turnings) were achieved. \*

---

## **SUBPART L: EQUIPMENT, TOOLS, BUILDINGS, AND SANITATION**

Record the date and method of cleaning and sanitizing equipment used for harvesting, packing, and holding activities. \* This includes:

- Toilet and hand washing facilities
- Produce contact surfaces
- Harvest tools and equipment
- Harvest and transport vehicles
- Harvest containers
- Coolers, ice machines
- Packing shed
- Storage areas, food and equipment
- Measuring instruments