

CHAPTER 8: RECORDS (SUBPART 0)

What is the goal of this chapter?

To explain the general requirements and recommendations for creating and maintaining all records required under the Produce Safety Rule. Records are needed to keep track of measures taken to reduce the risks of potential hazards, to identify a pattern of problems that increases risks, and to facilitate verification and compliance with regulatory standards.

This chapter describes the general requirements and recommendations that apply to all records under the Produce Safety Rule. However, the specific records that your farm is required to keep depend on the requirements of the rule that apply to your farm. Information on how to meet those record requirements for specific records in subparts A, C, F and L can be found in the corresponding chapters of the draft guidance (chapters 1, 2, 4 and 7, respectively). For example, Chapter 4 (subpart F) is about the use of biological soil amendments of animal origin (BSAAOs) and it contains information about the records related to BSAAOs.

For an overview of records discussed in the draft guidance, see the chart entitled “Chapter 8: Records Chart.”

References to “you” in this document (as well as in the Produce Safety Rule and draft guidance) mean the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of the rule. In addition, unless otherwise specified, we’re only talking about produce covered by the rule.

Who does this most affect?

Farms that must comply with the records requirements of the Produce Safety Rule, and the employees assigned to develop, create, complete or review records.

What information must all records include and what are some recommendations to meet these requirements?

Generally, for every required record, the information in bold must be included, as applicable. Some additional information and recommendations are also provided:

- **The name and location of your farm.** You should use, for example, a postal address or physical location, such as latitude and longitude.



- **The location of growing or other area relevant to the record.** Each record is linked to a specific area on the farm (for example, individual fields, lots, buildings, etc.) and you should have a system to use unique identifiers—such as numbers, names or specific map coordinates.
- **An adequate description of covered produce.** This could be the commodity, variety or brand name, and, when available, the lot number or code that identifies the covered produce.
- **Actual values and observations obtained during monitoring.** Specific measurement values or readings should be accurate, not vague or subject to interpretation. For example, the specific temperature value is the actual reading (96.2°F) rather than a rounded value or a classification of “satisfactory.”
- **The date and time.** Records must include the date and time of the activity documented. The time should be recorded without rounding or generalization.

Records are also required to be the following:

- **Created when the activity is performed or observed.** Creating the record at the time of activity helps to reduce the errors that can happen when people rely on their memory.
- **Accurate, legible, and indelible.** Make sure that handwritten records are not erasable (written in pen or permanent marker) and can be read easily. Corrected errors should allow both the original content and the correction to be viewed, such as by drawing a single line through the mistake and writing the corrected information next to it. Corrected errors also should show the date and identify the person who recorded the corrected value. Errors should not be erased or covered with whiteout and written over.
- **Dated, and signed or initialed by person who performed the activity.** If you have personnel with the same initials, you should have them use their full names or middle initial, or add some other unique identifier (e.g. “JW2”) so there is no question of who recorded the information.
- **Reviewed by a supervisor.** For some records, a supervisor or responsible party must review, date and sign. This requirement includes:
 - records that demonstrate eligibility for a qualified exemption;
 - records that document the process controls for a treated biological soil amendment of animal origin produced on your farm;
 - records that document cleaning and sanitizing of equipment.

There are templates that you can access from sources that include academia, extension services, and industry associations to assist you in creating a consistent approach for records.

What should my supervisors look for when reviewing records?

For records that must have supervisory review, supervisors or other responsible parties should determine whether the records are complete and legible, that activities were completed appropriately, identified problems were resolved, and that any corrective

measures taken were done in a timely manner. They should also look for trends in recorded values and for any unexpected results that may indicate follow-up is needed. For most required records, supervisors should review them in a timely manner (such as on a weekly basis or thereabouts). The timeframe for record review should allow for any necessary follow-up, such as to confirm that any necessary corrective measures were performed.

What are the requirements for storing and retaining records?

For storing records, the requirement is that they are readily available and accessible. This includes records kept onsite at the farm, at a main centralized office, or at storage facilities. Electronic records are considered onsite at your farm if they are accessible from an onsite location at your farm. For records that are stored offsite, you must be able to retrieve them and make them available within 24 hours of a request for official review.

For most required records, you must keep them for at least two years from the date the record was created. For records that relate to your eligibility for a qualified exemption, you may need to retain them for four years—three years for determining eligibility and the current year supporting your farm's exemption status.

Can I use existing records to satisfy the Produce Safety Rule records requirements?

Yes, you may use existing records and information if they meet the criteria required by the Produce Safety Rule. These can include documents maintained on your farm as part of the normal course of business or as part of a requirement for other federal, state, or local regulations. If existing records contain some but not all the information required, you can add the needed information, together on the existing record or separately.

What format do the records need to be in?

Records can be originals, copies, or electronic. If they are copies, they must be true copies, such as photocopies, pictures or scanned copies, and should clearly show any changes made to the original. Electronic records are subject to the same requirements as paper records under the rule.

For further explanation of the underlined words, see the [Key Terms Glossary](#).

The [draft guidance](#) contains more details and examples of FDA's recommendations and current thinking. It is recommended that you review the draft guidance for complete information.