

AT A GLANCE: KEY POINTS IN THE PRODUCE SAFETY RULE DRAFT GUIDANCE

CHAPTER 8: RECORDS CHART

PRODUCE SAFETY RULE PROVISION IN PART 112 OF THE CODE OF FEDERAL REGULATIONS	HIGHLIGHTED REQUIREMENTS FOR RECORD-KEEPING IN THE PRODUCE SAFETY RULE	IS A SUPERVISOR/ RESPONSIBLE PARTY REQUIRED TO REVIEW, DATE AND SIGN?	SEE MORE DRAFT GUIDANCE IN THIS CHAPTER
112.161: Under Subpart O (Records), what general requirements apply?	This section describes the general requirements on how required records must be established and maintained. You may have to meet specific requirements for the sections of the rule that apply to your farm, such as those detailed below.	NO , unless required in specific sections that apply to your farm	8
112.2: What records are required for produce eligible for the commercial processing exemption?	<p>For produce that will receive commercial processing that adequately reduces the presence of microorganisms of public health significance:</p> <ul style="list-style-type: none"> • You must establish and maintain documentation of your compliance with the applicable requirements that you: <ul style="list-style-type: none"> ▪ disclose that the produce has not been so processed, and ▪ receive written assurances that a subsequent entity in the distribution chain, either the customer or another entity later in the chain, will perform the required commercial processing in accordance with the requirements in 112.2(b)(3)¹. 	NO	1, 8
112.7: What records must I establish and keep if my farm is eligible for a qualified exemption (in accordance with 21 CFR 112.5)?	<p>You must establish and keep records required for a qualified exemption according to the requirements found in Subpart O. However, the requirement in subpart O for a signature or initial of the person performing the activity is not required for sales receipts kept in the normal course of business. Such receipts must be dated.</p> <p>You must establish and keep adequate records necessary to demonstrate that your farm satisfies the criteria for a qualified exemption, including a written record reflecting that you have performed an annual review and verification of your farm's continued eligibility for the exemption.</p>	YES , for the records that demonstrate eligibility for a qualified exemption	1, 8



<p>112.30: Under Subpart C (Personnel Qualifications and Training), what records requirements apply?</p>	<p>You must establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the persons(s) trained.</p>	<p>YES</p>	<p>2, 8</p>
<p>112.60: Under Subpart F (Biological Soil Amendments of Animal Origin and Human Waste), what records requirements apply?</p>	<p>For any biological soil amendment of animal origin you use, you must establish and keep the following records:</p> <ul style="list-style-type: none"> • For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) at least annually that: <ul style="list-style-type: none"> ▪ The process used is a scientifically valid process that has been carried out with appropriate process monitoring; and ▪ The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in-process biological soil amendment of animal origin. • For a treated biological soil amendment of animal origin, you produce for your own covered farm(s), documentation that process controls (for example, time, temperature, and turnings) were achieved. 	<p>YES, for records pertaining to treated biological soil amendment you produce for use on your own farm.</p>	<p>4, 8</p>
<p>112.140: Under Subpart L (Equipment, Tools Buildings, and Sanitation), what records requirements apply?</p>	<p>You must establish and keep documentation of the date and method of cleaning and sanitizing of equipment subject to this subpart used in:</p> <ul style="list-style-type: none"> • Growing operations for sprouts; and • Covered harvesting, packing, or holding activities 	<p>YES</p>	<p>7, 8</p>

¹ FDA announced in January 2018 that it intends to exercise enforcement discretion regarding the written assurance requirements in the Produce Safety Rule while it reconsiders options for the assurance requirements. However, this does not affect the requirement for disclosure statements.