

Chapter 1: General Provisions and Chapter 8: Records

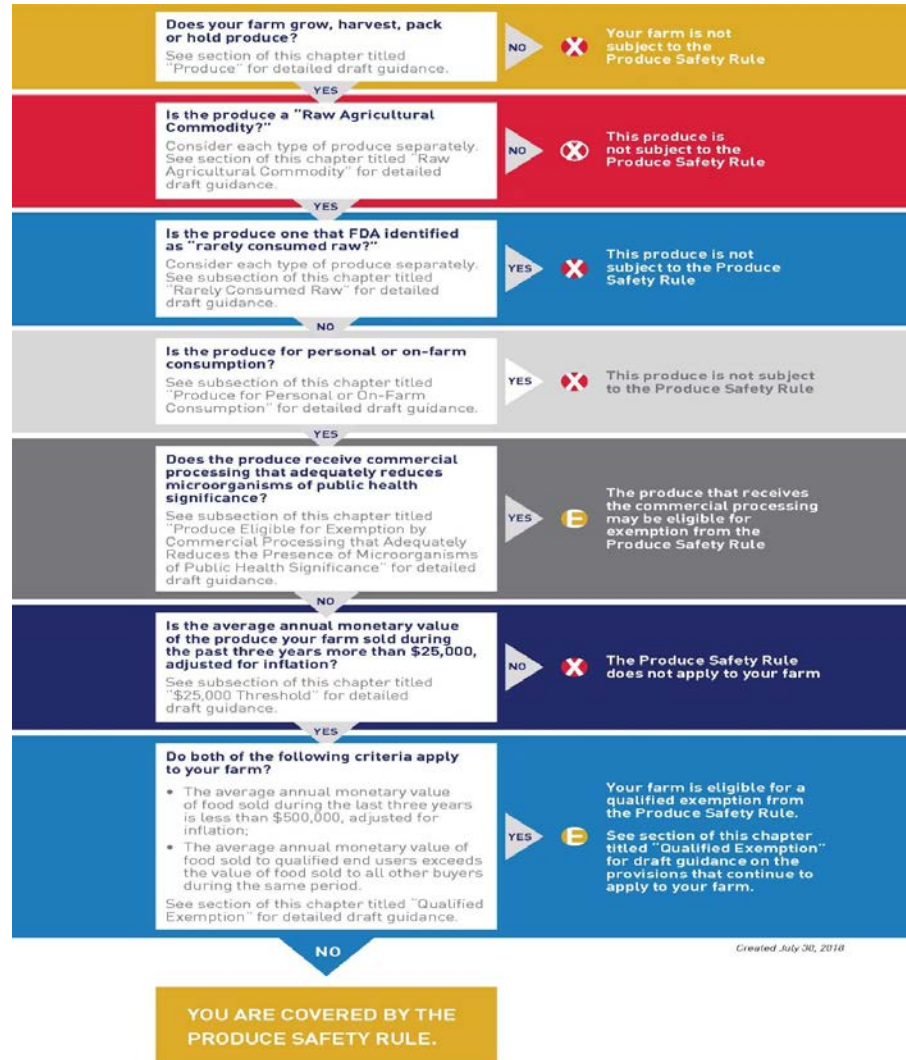
(Subparts A and O)

Chapter 1: General Provisions Overview



1. Produce
2. Raw Agricultural Commodity
3. Covered Produce
 - Rarely consumed raw
 - Personal consumption and on-farm consumption
 - Produce eligible for exemption by commercial processing that adequately reduces microorganisms of public health significance
4. Covered Farms
 - \$25,000 threshold
 - Qualified exemption
5. Covered Activities

Standards for Produce Safety: Coverage and Exemptions



Produce and Raw Agricultural Commodity



1. Produce

- Examples
 - Additional types of produce
 - Produce not subject to the rule
 - Harvestable or harvested part of the crop examples

2. Raw Agricultural Commodity (RAC)

- Changing a RAC into a processed food
- Examples of activities and products

Covered Produce



3. Covered Produce

- Rarely Consumed Raw
- Personal and On-Farm Consumption
- Produce Eligible for the Commercial Processing Exemption
 - Commercial processing
 - Disclosure accompanying the produce and affiliated records
 - Written assurances from your customers and affiliated records^{*}

^{*}On January 5, 2018, we published a notice of availability for guidance “Policy Regarding Certain Entities Subject to the Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs” stating our intent to exercise enforcement discretion until we can complete rulemaking to consider options for assurance requirements.

Covered Farms and Covered Activities



4. Covered Farms

- \$25,000 Threshold Calculation Examples
- Qualified Exemption Calculation Examples

5. Covered Activities

- Examples

Chapter 8: General Provisions Overview



1. General Requirements for All Records
2. Records Storage
3. Use of Existing Records
4. Records Retention
5. Records Format
6. Records Disclosure
7. Specific Records Requirements

General Requirements and Recommendations for All Records



1. General Requirements for all Records

- **Farm Name and Location**
- **Location of Growing or Activity Area**
- Adequate Description of Covered Produce
- **Actual Values and Observations**
- **Created when Activity is Performed or Observed**
- Date and Time
- Accurate, Legible and Indelible
- Dated and Signed or Initialed by the Person Who Performed the Activity
- **Review by a Supervisor or Responsible Party**

Recommendations for Review by a Supervisor or Responsible Party



- Supervisors or Responsible Parties should determine whether:
 - Records are complete
 - If any problems were recorded, were they addressed?
 - Any necessary corrective measures were taken in a timely manner
 - trends in recorded values or observations are present
- You should adopt procedures to ensure records are reviewed consistently within a reasonable timeframe
- Reviews should be performed at a time when personnel can focus on the review

Records Storage, Records Format and Use of Existing Records



2. Records Storage

- You should evaluate how frequently you need to access your records and develop a storage strategy that best fits your needs
 - All records must be readily available and accessible to FDA
 - Offsite storage is permitted if they can be provided within 24 hours of request for official review

5. Records Format

- Records can be maintained in several formats including original records, true copies or electronic records

3. Use of Existing Records

- You may use existing records if they contain all of the required information and satisfy the rule requirements

Recommendations for Specific Records and Personnel



- The draft guidance contains more information on recommendations for specific records in the relevant chapters:
 - Chapter 1: General Provisions
 - Produce eligible for the commercial processing exemption
 - Qualified exemption
 - Chapter 2: Personnel Qualifications and Training
 - Chapter 4: Biological Soil Amendments of Animal Origin (BSAAOs)
 - Chapter 7: Equipment, Tools, Buildings and Sanitation
- Personnel assigned to develop, create, complete or review records should understand your procedures

**Chapter 1: General Provisions
and
Chapter 8: Records
(Subparts A and O)**