

## **DEPARTMENT OF AGRICULTURE**

### **Inspection and Consumer Services Division**

#### **RULES PERTAINING TO THE ADMINISTRATION AND ENFORCEMENT OF THE PRODUCE SAFETY ACT**

##### **8 CCR 1202-17**

Pursuant to the provisions and requirements of the Produce Safety Act, Title 35, Article 77, C.R.S., the following rules are hereby promulgated to enforce under Colorado law the federal Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption, 21 CFR § 112.

##### **Part 1 DEFINITIONS**

- 1.1 "Act" means the Produce Safety Act, Title 35, Article 77, C.R.S.
- 1.2 "Commissioner" means the Colorado Commissioner of Agriculture or any employee designated by the Commissioner.
- 1.3 "Covered Activity" has the same meaning as set forth in 21 CFR 112.3.
- 1.4 "Covered Farm" has the same meaning as set forth in 21 CFR 112.4
- 1.5 "Covered Produce" has the same meaning as set forth in 21 CFR 112.3.
- 1.6 "Department" means the Colorado Department of Agriculture.
- 1.7 "Farm" has the same meaning as set forth in 21 CFR 112.3 and includes all buildings or areas where covered activity occurs or covered produce is grown, stored, handled or kept. It includes farms incorporated into other businesses.
- 1.8 "Farm Records" means any record that identifies a farm's ownership, or contains trade secrets, privileged information, or confidential commercial, financial, geological, or geophysical data. Such records can be in written, printed, photographic, electronic or digital format and can include, but are not required to include: crop information, financial information, purchase and sale information, operational protocols, or account numbers or unique identifiers issued by government or private entities.
- 1.9 "FDA" means the United States Food and Drug Administration.
- 1.10 "Mixed-Type Facility" has the same meaning as set forth in 21 CFR 112.3.
- 1.11 "Produce" has the same meaning as set forth in 21 CFR 112.3.
- 1.12 "Produce Safety Act" means the Colorado Produce Safety Act, Title 35, Article 77, C.R.S.
- 1.13 "Program" means the Produce Safety Program within the Colorado Department of Agriculture.
- 1.14 "Registrant" means a covered farm that is required to register pursuant to the Act.
- 1.15 "Registration" means the annual submission of a registration form to the Commissioner identifying a covered farm and complying with the requirements of Title 35, Article 77, C.R.S.

- 1.16 "Registration Period" means the time when submission of required information to the Program occurs.
- 1.17 "Routine Regulatory Inspection" means an inspection of a Registrant's farm to monitor for compliance with these Produce Safety Rules.

## **Part 2 ADOPTION OF FEDERAL CODE**

- 2.1 The Department herein incorporates by reference 21 CFR § 112, "Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption", Subpart A, B, C, D, F, I, K, L, N, O, Q, and R published November 27, 2015, and Subpart E published March 18, 2019. Such incorporation excludes any later amendments or editions. Copies of 21 CFR § 112, and any other materials incorporated by reference, are available for public inspection and copy during regular business hours at the Department, 305 Interlocken Parkway, Broomfield Colorado 80021, or at the offices of the U.S. Food and Drug Administration, 10903 New Hampshire Avenue Silver Spring, MD 20993. This information may also be accessed online by visiting: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=112>

## **Part 3 REGISTRATION REQUIREMENT**

- 3.1 A farm or mixed type facility, that conducts Covered Activity of any Covered Produce at any primary production farm or secondary activities farm location, and which the average annual monetary value of produce sold during the previous three-year period is more than average monetary value determined in Part 3.5 of this Rule, must register and is subject to the General Provisions in Subpart A of 21 CFR § 112, "Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," published November 27, 2015.
- 3.2 A farm that is eligible for a qualified exemption, as defined in Subpart A of 21 CFR § 112.5, must register with the Department and is only subject to sections of Subpart A of 21 CFR § 112, "Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption", stated in 21 CFR § 112.6 and 112.7
- 3.3 Registration and the General Provisions of Subpart A of 21 CFR § 112 do not apply to a farm or mixed-type facility that has an annual monetary value of produce sold during the previous three year period that is less than the monetary value determined in Part 3.5 of this Rule, even if that farm or mixed-type facility conducts Covered Activity.
- 3.4 Each farm, or mixed type facility, required to register shall do so annually during the registration period of November 1 to December 31. Such registration shall be completed by the submission of a form in the manner required by the Commissioner. All such information shall be complete and accurate.
- 3.5 For the ~~2023~~2024 registration year of ~~January 1, 2023 to December 31, 2023~~January 1 2024 to December 31, 2024, a farm that sold an average monetary value of produce during ~~2019, 2020 and 2021-2020, 2021 and 2022~~ with more than ~~\$29,245~~\$30,509 must register with the Department.

## **Part 4 GENERAL PROVISIONS**

- 4.1 These Rules incorporate by reference the General Provisions in Subpart A of 21 CFR § 112, "Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption", published November 27, 2015. Such incorporation excludes any later amendments or editions.

## **Part 5 RESERVED**

## **Part 6 CONFIDENTIALITY OF RECORDS**

- 6.1 Farm records are confidential pursuant to §35-77-107, C.R.S. and §24-72-204, C.R.S.
- 6.2 Complaints of record, investigations, and inspection reports may, at the discretion of the Commissioner, be closed to public inspection except to the person of interest, as defined in §24-72-202, C.R.S., or as provided by court order.

## **Part 7 GENERAL REQUIREMENTS**

- 7.1 These Rules incorporate by reference the General Requirements in Subpart B of 21 CFR § 112, "Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption", published November 27, 2015. Such incorporation excludes any later amendments or editions.
- 7.2 Each farm must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated, as defined in section 402 of the Federal Food, Drug, and Cosmetic Act on account of such hazards.

## **Part 8 PERSONNEL QUALIFICATIONS AND TRAINING**

- 8.1 These Rules incorporate by reference all the Personnel Qualifications and Training requirements found in Subpart C of 21 CFR § 112, "Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," published November 27, 2015. Such incorporation excludes any later amendments or editions.

## **Part 9 HEALTH AND HYGIENE**

- 9.1 These Rules incorporate by reference all the Health and Hygiene requirements found in Subpart D of 21 CFR § 112, "Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," published November 27, 2015. Such incorporation excludes any later amendments or editions.

## **Part 10 AGRICULTURAL WATER**

- 10.1 These Rules incorporate by reference all the Agricultural Water requirements found in Subpart E of 21 CFR § 112, "Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," published March 18, 2019. Such incorporation excludes any later amendments or editions.

## **Part 11 BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN AND HUMAN WASTE**

- 11.1 These Rules incorporate by reference all the Biological Soil Amendments of Animal Origin and Human Waste requirements found in Subpart F of 21 CFR § 112, "Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," published November 27, 2015. Such incorporation excludes any later amendments or editions.

## **Part 12 RESERVED**

## **Part 13 RESERVED**

## **Part 14 DOMESTICATED AND WILD ANIMALS**

- 14.1 These Rules incorporate by reference all the Domesticated and Wild Animals requirements found in Subpart I of 21 CFR § 112, “Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” published November 27, 2015. Such incorporation excludes any later amendments or editions.

#### **Part 15 RESERVED**

#### **Part 16 GROWING, HARVESTING, PACKING and HOLDING ACTIVITIES**

- 16.1 These Rules incorporate by reference all the Growing, Harvesting, Packing and Holding Activity requirements found in Subpart K of 21 CFR § 112, “Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” published November 27, 2015. Such incorporation excludes any later amendments or editions.

#### **Part 17 EQUIPMENT, TOOLS, BUILDINGS, AND SANITATION**

- 17.1 These Rules incorporate by reference all the Equipment, Tools, Buildings and Sanitation requirements found in Subpart L of 21 CFR § 112, “Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” published November 27, 2015. Such incorporation excludes any later amendments or editions.

#### **Part 18 RESERVED**

#### **Part 19 ANALYTICAL METHODS**

- 19.1 These Rules incorporate by reference all the Analytical Methods requirements found in Subpart N of 21 CFR § 112, “Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” published November 27, 2015. Such incorporation excludes any later amendments or editions.

#### **Part 20 RECORDS**

- 20.1 These Rules incorporate by reference all the Records requirements found in Subpart O of 21 CFR § 112, “Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” published November 27, 2015. Such incorporation excludes any later amendments or editions.

#### **Part 21 RESERVED**

#### **Part 22 COMPLIANCE AND ENFORCEMENT**

- 22.1 These Rules incorporate by reference all the Compliance and Enforcement requirements found in Subpart Q of 21 CFR § 112, “Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” published November 27, 2015. Such incorporation excludes any later amendments or editions.

#### **Part 23 WITHDRAWAL OF QUALIFIED EXEMPTIONS**

- 23.1 These Rules incorporate by reference all the Withdrawal of Qualified Exemption requirements found in Subpart R of 21 CFR § 112, “Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” published November 27, 2015. Such incorporation excludes any later amendments or editions.

#### **Part 24 UNLAWFUL ACTS**

- 24.1 In addition to the Unlawful Acts in §35-77-109, C.R.S., the following acts and omissions shall constitute violations for which a civil penalty of up to \$2500 per violation may be imposed:
- 24.1.1 Failure to timely register with the Program;
  - 24.1.2 Providing false, inaccurate or misleading information to the Commissioner or Department of Agriculture; or
  - 24.1.3 Failure to comply with any of the requirements in Part 3, 4, 7, 8, 9, 10, 11, 14, 16, 17, 19, 20, 22, 23, or 24 of these Rules.

## **Part 25 RESERVED**

## **Part 26 INSPECTIONS**

- 26.1 For each registration period and prior to any Routine Regulatory Inspection, a Registrant, or authorized representative, must attest that they understand that they have specific rights regarding a Routine Regulatory Inspection. A registrant's attestation shall be completed in a form established by the Commissioner, referred to as the Notice of Inspection Rights. The form must include attestations that Registrant understands they have the right to:
- 26.1.1 Receive notification at least five (5) days in advance of a Routine Regulatory Inspection of their farm.
  - 26.1.2 Meet with the Commissioner prior to the start of a Routine Regulatory Inspection to explain ongoing operations and to ask questions about the inspection process.
  - 26.1.3 Escort the Commissioner at all times while observing the registrant's operations.
  - 26.1.4 Discuss any observations of these Produce Safety Rules with the Commissioner away from the production area of the Registrant's operations. The provisions of this section shall not limit the Commissioner's ability to issue a Cease and Desist Order, assess an administrative penalty, or otherwise enforce regulatory provisions at a later date pursuant to C.R.S. § 35-77-108 or C.R.S. § 35-77-110.
- 26.2 The Commissioner reserves the right to conduct an inspection without the notice specified in 25.1.1 under the following conditions:
- 26.2.1 The Registrant cannot be reached at the contact information provided at the time of Registration;
  - 26.2.2 The Commissioner wishes to ascertain whether corrections have been made to address a previous violation of these Produce Safety Rules;
  - 26.2.3 The Commissioner has a reasonable belief that the Registrant is in violation of these Produce Safety Rules resulting in a risk to public health.
- 26.3 Registrants who meet the criteria for a qualified exemption pursuant to Part 3.2 shall not be subject to Routine Regulatory Inspection, but may be subject to limited records inspections to confirm compliance.

## **Part 27 STATEMENT OF BASIS, SPECIFIC STATUTORY AUTHORITY AND PURPOSE**

- 27.1 Adopted September 9, 2020. Effective Oct 30, 2020**

### Statutory Authority

The Commissioner of Agriculture adopts these rules pursuant to §35-77-106(1), C.R.S.

### Purpose

The Purpose of this rulemaking is to define the administration and enforcement of the Colorado Produce Safety Act, §§35-77-101 through 111, C.R.S. These rules incorporate 21 CFR 112, “Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” define Colorado registration requirements and timelines, and establish confidentiality protections for farm records and registrants.

### Factual and Policy Basis

House Bill 19-1114, Colorado’s Produce Safety Act, was passed by the General Assembly and signed into law by Governor Polis in 2019. The Act, codified in §§35-77-101 through 111, C.R.S., authorized the creation of a program within the Department, in lieu of the FDA, to regulate the safe production, handling, packing and storage of produce as defined in 21 CFR Part 112. This rulemaking provides definitions, references and rules to assist in the administration and enforcement of Colorado’s Produce Safety Act.

## **27.2 Adopted September 8, 2021 - Effective October 30, 2021**

### Statutory Authority

The Commissioner of Agriculture adopts these rules pursuant to §35-77-106(1), C.R.S.

### Purpose

The purpose of this rule change is to increase the threshold limit for farms Exempt from the rule.

### Factual and Policy Basis

Increased limits allowed for Exempt status are consistent with FDA’s annual adjusted for inflation calculations.

## **27.3 Adopted October 12, 2022 – Effective December 15, 2022**

### Statutory Authority

The Commissioner of Agriculture adopts these rules pursuant to §35-77-106(1), C.R.S.

### Purpose

The purpose of this rule change is to increase the threshold limit for farms Exempt from the rule.

### Factual and Policy Basis

Increased limits allowed for Exempt status are consistent with FDA’s annual adjusted for inflation calculations.

## **27.4 Adopted July 12, 2023 – Effective October 30, 2023**

### Statutory Authority

Adoption authority for these rules pursuant to §35-77-106(1), C.R.S.

Purpose

The purpose of this rule change is to increase the threshold limit for farms Exempt from the rule.

Factual and Policy Basis

Increased limits allowed for Exempt status are consistent with FDA's annual adjusted for inflation calculations. \_\_\_\_\_