

250-RICR-40-00-2

## **TITLE 250 – DEPARTMENT OF ENVIRONMENTAL MANAGEMENT**

### **CHAPTER 40 – AGRICULTURE AND RESOURCE MARKETING**

#### **SUBCHAPTER 00 – MARKETING AND FOOD SAFETY**

##### **PART 2 – Produce Safety Rule**

### **2.1 Authority and Purpose**

#### **2.1.1 Authority**

These regulations are promulgated under the authority conferred by R.I. Gen. Laws §§ 2-1-9 and 2-1-10, and are established to implement and enforce the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule) under the FDA Food Safety Modernization Act, Pub. Laws 111-353, as it pertains to commercial growers of fruits and vegetables.

#### **2.1.2 Purpose**

The purpose of these regulations is to adopt minimum safety standards for the growing, harvesting, packing and holding of produce for human consumption with those established by the FDA pursuant to 21 C.F.R. Part 112 (2016).

#### **2.1.3 Applicability**

The terms and provisions of these regulations shall permit the Rhode Island Department of Environmental Management (DEM) to effectuate the purposes of federal and state law, goals, and policies.

#### **2.1.4 Scope**

These regulations, in accordance with R.I. Gen. Laws § 2-1-10, apply to every person who grows, harvests, packages and/or holds produce for human consumption on-farm, whether or not for profit. Inspections apply to any field, building, storehouse, warehouse, cold-storage plant, packing house, stockyard, or any other building or place on-farm where farm products are produced, kept, stored or offered for sale.

## 2.2 Incorporated Materials

These regulations hereby adopt and incorporate the FDA Food Safety Modernization Act Final Rule on Produce Safety 21 C.F.R. Part 112 (2016) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

## 2.3 Definitions

- A. For the purposes of these regulations, the following terms shall have the following meaning:
1. "Act" means the FDA Food Safety Modernization Act Final Rule on Produce Safety, incorporated above at § 2.2 of this Part.
  2. "Adulterated" means as prescribed in the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 342, and the Act, incorporated above at § 2.2 of this Part.
  3. "C.F.R." means the Code of Federal Regulations.
  4. "Covered farm" means as prescribed in the Act, incorporated above at § 2.2 of this Part.
  5. "Covered produce" means as prescribed in the Act, incorporated above at § 2.2 of this Part.
  6. "Department" means the Rhode Island Department of Environmental Management.
  7. "Director" means the Director of the Department of Environmental Management.
  8. "Egregious condition" means a practice, condition, or situation on a farm or in a packing house that is reasonably likely to lead to:
    - a. Serious adverse health consequences or death from the consumption of or exposure to Covered Produce; or
    - b. An imminent public health hazard if corrective action is not taken immediately.
  9. "FDA" means the U.S. Food and Drug Administration.

10. "Follow-up inspection" means a subsequent inspection that occurs to allow the review of an issue or concern that was identified and documented on a previous inspection.
11. "For-cause inspection" means an inspection that occurs in response to a specific issue or produce safety concern, such as an outbreak, reported complaint, or recall.
12. "Initial inspection" means an inspection that is the first regulatory inspection activity conducted at a farm or facility covered under R.I. Gen Laws §§ 2-1-9 and 2-1-10 and these regulations.
13. "Law" means any applicable federal, state or local statute, ordinances and regulations.
14. "Misbranded" means as prescribed in the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 342, and the Act, incorporated above at § 2.2 of this Part.
15. "Person" means any individual, partnership, corporation, association or other legal entity.
16. "Processing exemption" means as outlined in 21 C.F.R. § 112.2(b), incorporated above at § 2.2 of this Part.—
17. "Produce" means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent or flint-corn, sorghum, oats, rice, rye, wheat, amaranth,

quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

18. "Qualified exemption" means as outlined in 21 C.F.R. § 112.5, incorporated above at § 2.2 of this Part.
19. "R.I. Gen. Laws" means the General Laws of Rhode Island, as amended.
20. "Routine inspection" means regularly scheduled inspections carried out under R.I. Gen. Laws §§ 2-1-9 and 2-1-10 and these regulations.
21. "These regulations" means all parts of the Produce Safety Rule codified as 250-RICR-40-00-2.

## **2.4 Standards for Growing, Harvesting, Labeling, Packing, and Holding Produce**

- A. The standards for growing, harvesting, labeling, packing, and holding produce shall be identical to the FDA Food Safety Modernization Act Final Rule on Produce Safety, incorporated above at § 2.2 of this Part.
- B. The standards for off-farm packing, labeling and holding of produce by a Covered Farm shall be identical to the FDA Food Safety Modernization Act Final Rule on Produce Safety, incorporated above at § 2.2 of this Part.
- C. All Covered Farms shall use a record keeping and coding system for regulated produce that identifies all produce placed into the distribution chain or delivered directly to retail markets.
- D. All Covered Farms shall have a written traceability program that, at a minimum, allows a traceback investigation to follow the produce both forward and backward at least to the next level in the marketing chain. Records for the traceability program may be in paper or electronic form and must be made available within twenty-four (24) hours after request during any inspection or investigation.

## **2.5 Registration of Produce Farms, Voluntary Inspections**

- A. The owner of a produce farm shall be required to register annually with the Department and provide the following information on a form prescribed by the Department:
  1. Name;
  2. Address;

3. Name and address of the produce farm that the applicant seeks to register;
  4. Description of all produce to be grown at the produce farm; and
  5. Address of actual location where produce will be grown and acreage; and
  6. Address of actual location where produce will be grown and type of indoor growing facility (greenhouse, hoop house, etc.), if applicable.
  7. Address of actual location where produce will be packaged, held or stored.
  8. Such other information as the Department may reasonably require to protect public health and safety.
- B. All registrations shall expire on February 28 of the year after the date of issuance and shall be eligible for renewal annually. Renewal applications shall be filed not later than thirty (30) days prior to expiration of existing registration.
- C. If not renewed within sixty (60) days of expiration, a registration shall be deemed surrendered and a new application shall be required.
- D. All Covered Farms shall be subject to a routine inspection as part of the annual registration renewal process for compliance with the Act, incorporated above at § 2.2 of this Part, and these regulations for all Covered Produce. The Department shall conduct inspections in accordance with these regulations. If the inspection does not reveal any violations that are found to be significant or to pose a concern to public health, then the Department shall issue the registration and a certificate to the owner or operator of the Covered Farm.
- E. The owner or operator of a produce farm that is not a Covered Farm or a Farm eligible for modified requirements through an exemption (either Qualified Exemption or Processing Exemption) may submit an affidavit and supporting documents to the Department that it is not a Covered Farm by reason of exclusion or exempt by reason of Qualified Exemption or Processing Exemption on a form to be provided by the Department. This affidavit is valid until February 28 of the year after submission. The affidavit is not binding on the Department for any determination that such farm is not a Covered Farm or meets the criteria for modified requirements through an exemption. Not covered farms, Processing Exempt and Qualified Exempt farms are subject to further document review to verify the farm's coverage status. The Department will issue an approval for not covered, Processing Exempt and Qualified Exempt Farms. The owner or operator of a produce farm that is not a Covered Farm may register and request an inspection of such produce farm for compliance with the Act, incorporated above at § 2.2 of this Part, and these regulations. The Department shall conduct

inspections in accordance with these regulations. If the inspection does not reveal any violations that are found to be significant or to pose a concern to public health, then the Division shall issue a registration and certificate to the owner or operator of the produce farm.

- F. Any person who receives a registration pursuant to these regulations shall notify the Department of any changes to the information supplied on the application for such registration no later than ten (10) business days after such change.
- G. After registration, farms shall be inspected periodically, as determined by the Department.
- H. Registrations are not transferrable or assignable.
- I. Qualified Exemptions may be withdrawn at any time if the Department identifies through any report, document, or findings provided to the Department that an Egregious Condition or imminent threat to public health or safety exists or has existed.

## **2.6 Inspections**

- A. The Department may inspect for compliance with R.I. Gen. Laws §§ 2-1-9 and 2-1-10 and these regulations, and investigate complaints. Such inspection may include but is not limited to, any farm, field, lot, area, building or vehicle under the control of a registrant or any person, firm or corporation where produce is grown, harvested, packed, stored, or held, including vehicles used to transport and hold produce. Inspections may be random systematic inspections or in response to a specific complaint or request. An inspection initiated from a specific complaint or request is not limited to that complaint or request. At the time of the inspection, the inspector may record all violations. Such inspections may include obtaining samples and specimens for laboratory analysis.
- B. Inspectors for the Department, after identifying themselves, may enter all relevant areas of a Covered Farm, at any time, for the purpose of making an inspection to ascertain whether the entity is in compliance with R.I. Gen. Laws §§ 2-1-9 and 2-1-10 and these regulations. Individuals engaged in regulated activities shall provide access to Department inspectors at all times for inspection of the Covered Farm.
- C. Initial and Routine Inspections shall be coordinated with the registrant and shall take place during the normal business hours of the entity receiving inspection, on an annual basis. Additionally, the Department shall be given access to and the right to review and copy any and all records pertaining to 21 C.F.R. Part 112,

incorporated above at § 2.2 of this Part, R.I. Gen. Laws §§ 2-1-9 and 2-1-10 and these regulations when requested, or within twenty-four (24) hours of request.

- D. Upon the completion of an inspection the Department shall issue a Produce Inspection Observation Form to the registrant being inspected that covers all produce, facilities, acreage and other areas identified in the registration, as well as any other areas that the Department deems inherent to the conduct of an inspection under its authority.
- E. Follow-up Inspections/re-inspections shall be conducted to ensure that identified corrective actions and prior non-conformances, R.I. Gen. Laws §§ 2-1-9 and 2-1-10 and these regulations, have been corrected and documented.
- F. Follow-up Inspections/re-inspections may take place during the normal business hours of the entity receiving inspection and will take into account the priority of the corrective action as indicated in the Produce Inspection Observation Form and Summary Report of inspection, or through any other report, document or finding supplied by the Department upon the completion of an inspection activity.
- G. For-Cause Inspections shall take place when the Department is made aware, through report or information, that a specific issue related to a public health risk or produce safety concern, such as an outbreak, reported complaint, or recall has taken place or is imminent. For-Cause Inspections will follow all inspectional protocols and procedures identified in this section.
- H. Covered Farms registered pursuant to these regulations or produce farms who voluntarily request inspection pursuant to these regulations, may be subject to unannounced inspections, as determined by the Department to protect public health and safety.
- I. In accordance with 21 C.F.R. Part 112, incorporated above at § 2.2 of this Part, and R.I. Gen. Laws §§ 2-1-9 and 2-1-10, the Department shall have the right to enter and inspect any facility, building or structure used to store, cool, pack and/or hold produce covered under 21 C.F.R. Part 112, incorporated above at § 2.2 of this Part.
- J. If the person in charge at the time of the inspection refuses entry to an inspector for the Department, refuses to permit an authorized inspection, refuses access to records, or interferes with the Department, or any agent thereof, in the performance of its duties, the Department may:
  - 1. Seek an administrative search warrant to search/inspect the premises, in accordance with the provisions of R.I. Gen. Laws § 42-17.1-2(20); and/or

2. Take steps to refuse to issue certificates, inspection documentation or to impose administrative penalties or fines, in accordance with R.I. Gen. Laws § 42-17.1-2(22) and/or
  3. Issue an order to cease and desist operations.
- K. The completed Produce Inspection Observation Form and Summary Report of Inspection, and other related inspectional and enforcement documents, shall be public records as defined in R.I. Gen. Laws Chapter 38-2, unless a specific exemption applies in a particular case.

## **2.7 Adulterated and Misbranded Produce**

- A. The sale or offering for sale of Adulterated or Misbranded produce shall be prohibited.
- B. The Department may investigate any allegation of adulteration, misbranding, illness or injury alleged to have been caused by produce grown and offered for sale by a Covered Farm, or a farm that has requested voluntary inspection, or any other farm in the State. Such investigation may include any area, building or vehicle under the respondent's control where produce is grown, harvested, packed, stored, held, or transported. Such investigation may include obtaining samples and specimens for laboratory analysis.
- C. Whenever a complaint is investigated the Department shall inform the respondent of the nature of the complaint and of their right to provide a written response to the complaint and to obtain a copy of the complaint and any reports, results of laboratory analysis and other documentation in the custody of the Department upon completion of the investigation and subject to the provisions of R.I. Gen. Laws Chapter 38-2.
- D. A certificate of analysis from a laboratory of the Rhode Island Department of Health, the United States Food and Drug Administration, the United States Department of Agriculture or other accredited laboratory acceptable to the Department, shall be considered *prima facie* evidence of the ingredients and constituents of any sample or specimen submitted for analysis by the Department.
- E. Violations of this section shall be subject to the enforcement provisions set out in §§ 2.9 through 2.11 of this Part.

## **2.8 Required Records**

- A. Records shall be kept in compliance with 21 C.F.R. Part 112 subpart O, incorporated above at § 2.2 of this Part, as well as with documents and records



identified in these regulations and shall be available for inspection, or made available for inspection or copying, within twenty-four (24) hours of request.

- B. All produce farms in the State shall use a record keeping/product coding system to trace-back produce they grow, harvest, pack, store and introduce into commerce to facilitate the effective recall of produce when such action is necessary to protect public health. Records shall be capable to trace produce entered into wholesale or retail distribution back to the producing farm and/or related acreage. Such records shall be maintained for a period of time that exceeds the expected shelf life of the produce or one (1) year, whichever is longer. Trace-back records shall be made available to the Department immediately upon request.

## **2.9 Enforcement and Compliance**

- A. Whenever an inspection or investigation reveals any violation of the Act, incorporated above at § 2.2 of this Part or these regulations which does not rise to the level of an Egregious Violation, the registrant, applicant or respondent shall be notified in writing of such violations(s) and of any corrective actions necessary to cure the violation and specifying the time period within which such corrective action(s) shall be implemented. After notification, if such registrant, applicant or respondent fails to correct a violation within the specified time period, the Department may suspend, revoke, deny or refuse to renew any registration or certificate issued pursuant to the Act, incorporated above at § 2.2 of this Part, and these regulations. The Department may also issue orders for recall, embargo, destruction, or stop sale in the event that registrant, applicant, or respondent fails to correct a violation within a specified time frame.
- B. Whenever an inspection or investigation reveals a violation of the Act, incorporated above at § 2.2 of this Part, or these regulations that constitutes an Egregious Condition warranting immediate action, the Department shall have the authority to issue recall, embargo, destruction or stop sale orders immediately as necessary to ensure adequate mitigation and correction of conditions. Such orders shall become effective upon issuance. Following issuance of any such order, subsequent proceedings shall proceed in accordance with R.I. Gen. Laws § 42-17.1-2(21)(ii).
- C. The Department may place an embargo on produce with probable cause to believe is Adulterated or has been associated with an Egregious Condition or presents an immediate public health risk, provided that:
  - 1. A written notice is issued to the registrant or the person in charge at the facility, or if no one is present at the facility, conspicuously posted at the facility; and

2. The notice specifies the reason(s) for the embargo order.
- D. The Department shall affix a tag, label, or shall otherwise identify any produce subject to the embargo order. The tag or label shall state that the product:
1. Is believed to be Adulterated or is associated with an Egregious Condition or presents an immediate public health risk;
  2. Has been embargoed for ten (10) days; and
  3. Cannot be removed, used, sold, or disposed of without permission of the Director or his or her agent.
- E. The Department shall permit storage of the produce under conditions specified in the embargo order, unless storage is not possible without imminent threat to the public health, in which case immediate destruction or isolation of the produce may be ordered and accomplished. If the produce subject to embargo is found to be Adulterated or Misbranded, the Department shall take such steps as they shall deem necessary, to affect the condemnation and disposal or reconditioning of the produce.
- F. If the produce subject to embargo is found not to be Adulterated or associated with an Egregious Condition or an immediate public health risk, it shall be released.
- G. The farm owner/operator is responsible for the storage of embargoed produce. If storage facilities are not available, the farm owner/operator is responsible for any cost incurred to store embargoed produce. The farm owner/operator is responsible for any additional fees associated with the embargoed produce.
- H. Nothing in this section shall be construed to limit the Department's authority to issue a cease and desist order, stop sale, or destruction order, in order to respond to a condition that may present a public health hazard, or to issue orders necessary to effectuate the purposes of the Act, incorporated above at § 2.2 of this Part, and these regulations, including, but not limited to, orders for the embargo, destruction, and release of produce. Any orders described herein shall become effective upon service by the Department.
- I. The reasonable period of time for correction of violations shall be within the discretion of the Department to establish in each instance and shall be based on an evaluation of the type and the severity of each violation, corrective action or deficiency.

## 2.10 Hearings and Dispute Resolution

- A. The following shall apply an order for the recall, embargo, destruction, or stop sale order and an appeal therefrom:
1. No person shall donate, remove, dispose of, sell or offer for sale such produce subject to an embargo, destruction or quarantine order without the permission of the Department. Any person aggrieved by an embargo, destruction or quarantine order may request a hearing before the Department not more than five (5) business days after the issuance of such order. The hearing shall be conducted not later than five (5) business days after the receipt of the appeal. If no appeal is made pursuant to this subsection the order shall be deemed agreed to and shall be enforced.
  2. Following any hearing, the Department shall make a determination as to whether such produce complies with the provisions of the Act, incorporated above at § 2.2 of this Part, and these regulations and is safe for use as a food. If the Department determines the produce is unsafe or unfit for use as food, the Department may order the owner or custodian to destroy, denature or dispose of such produce. The Department shall supervise the destruction or other disposition of such produce. If the Department finds the produce is safe for use as food and is not detrimental to public health, or finds such produce can be properly packaged, marked or otherwise brought into compliance with the provisions of the Act, incorporated above at § 2.2 of this Part, or these regulations, the Department may order such produce to be so packaged, marked or otherwise brought into compliance and may thereafter authorize the release produce. The owner of such produce shall pay all of the costs of storage, handling, destruction and other related expenses.
  3. If the embargo, destruction or quarantine order is removed by the Director, an Administrative Hearing Officer, or by a court, neither the Department, any employee of the Department, nor the State shall be held liable for damages unless the court finds that there was no probable cause for the embargo, destruction or quarantine order.
- B. Any person aggrieved by an order issued pursuant to this section may appeal therefrom pursuant to R.I. Gen. Laws §§ 42-17.1-2(21) and 42-17.7-1 *et seq.* Nothing in this section shall be construed to prevent the Department from entering into a stipulated agreement or any other remedy with an aggrieved party which resolves the dispute.

## **2.11 Penalties**

- A. If the Department finds that that the owner or operator of a Covered Farm has failed to register pursuant to the Act, incorporated above at § 2.2 of this Part, and these regulations, the Department may assess a civil penalty not to exceed one thousand dollars (\$1,000).
- B. If the Department finds that the owner or operator of a farm subject to the Act, incorporated above at § 2.2 of this Part, or these regulations cultivates, grows, harvests, handles, or stores produce in this State in violation of the requirements of the Act, incorporated above at § 2.2 of this Part, and these regulations, the Department may assess a civil penalty not to exceed five thousand dollars (\$5,000) per day. Each day that the violation continues to exist shall be deemed a new violation.
- C. In addition to a civil penalty, the Department may suspend, revoke, deny or refuse to renew any registration required, or certificate issued pursuant to the Act, incorporated above at § 2.2 of this Part, and these regulations.

## **2.12 Coordination with Other Agencies**

The Department may enter into agreements and MOUs with applicable state and federal partners to coordinate and enhance inspections, investigations, embargos and the recall of produce already in commerce within the State as well as outside of its jurisdiction. The Director shall establish and maintain these agreements and will review their effectiveness on an annual basis.

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**PART 2 - PRODUCE SAFETY RULE**

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