



RHODE ISLAND
DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

DIVISION OF AGRICULTURE
235 Promenade Street, Room 370
Providence, Rhode Island 02908

To: Janet L. Coit, Director
From: Ananda Fraser
Date: February 22, 2019

RE: Response to oral and written public comments pertaining to proposed adoption of the ***Produce Safety Rule 250-RICR-40-00-2***.

Notice for proposed adoption of the Produce Safety Rule was posted on the Rhode Island Secretary of State's website on December 24, 2018. The comment period whereby the Department of Environmental Management (DEM) would receive written comments pertaining to the proposed rules and regulations ended at end of business on January 28, 2019; and the public hearing was held at 2:30 P.M. on January 23, 2019.

Written comments regarding the ***Produce Safety Rule*** were provided by Heidi Quinn, representing the Rhode Island Farm Bureau; Senator Joshua Miller, representing the Rhode Island Senate Committee on Environment and Agriculture; Senator Dawn Euer, representing the Rhode Island Senate Committee on Environment and Agriculture; Senator Louis P. DiPalma, representing the Rhode Island Senate Committee on Environment and Agriculture; Senator William J. Conley Jr., representing the Rhode Island Senate Committee on Environment and Agriculture; Senator Stephen R. Archambault, representing the Rhode Island Senate Committee on Environment and Agriculture; Senator Cynthia A. Coyne, representing the Rhode Island Senate Committee on Environment and Agriculture; Senator V. Susan Sosnowski, representing the Rhode Island Senate Committee on Environment and Agriculture. Comments from the Rhode Island Senate Committee on Environment and Agriculture were combined in a single submission. There were six non-departmental attendees at the public hearing Heidi Quinn, representing the Rhode Island Farm Bureau; Shelly Pezza, representing Pezza Farm; Bill Stamp, representing Stamp Farm; Tyler Young, representing Young Family Farm; Patricia Breslin, representing Senate Office of the President of the Senate.

COMMENT 1

COMMENTOR: Heidi Quinn, Director, Rhode Island Farm Bureau

SECTION: Overall

COMMENT: Commented on the support of the Rhode Island Farm Bureau for the adoption of the federal Produce Safety Rule by reference.

DEM RESPONSE: The Department appreciates the comment and support of the proposed regulation adoption. The Department will ensure that changes that may occur on the federal level will be reviewed by the State to allow for the best interests of Rhode Island farmers to be considered, prior to incorporation into State Law.

COMMENT 2

COMMENTOR: Shelly Pezza, Pezza Farms

SECTION: Overall

COMMENT: Commented on the amendment of Federal regulations for Rhode Island. Concern that domestic farms are being held to a more stringent standard than foreign farms.

DEM RESPONSE: The Department appreciates the comment; however, the comment was not within the scope of the proposed regulation.

COMMENT 3

COMMENTOR: Bill Stamp, Stamp Farm

SECTION: Overall

COMMENT: Commented on the concern of the burden of food safety risk being given to farmers. Expressed the desire to keep the implementation of this regulation within State Government.

DEM RESPONSE: The Department appreciates the comment; however, the comment was not within the scope of the proposed regulation. Furthermore, failure of the State of Rhode Island to enforce this law will result in Federal enforcement.

COMMENT 4

COMMENTOR: Tyler Young, Young Family Farm

SECTION: Overall

COMMENT: Commented on the possibility of Rhode Island Farm Bureau submitting additional comments prior to the close of the public comment period.

DEM RESPONSE: The Department appreciates the comment; and allowed for additional comments to be submitted.

COMMENT 5

COMMENTOR: Doreen Pezza, Pezza Farm

SECTION: Overall

COMMENT: Commented on the desire for exemptions for Rhode Island from federal regulations.

DEM RESPONSE: The Department appreciates the comment; however, the comment was not within the scope of the proposed regulation. Furthermore, failure of the State of Rhode Island to enforce this law will result in Federal enforcement.

COMMENT 6

COMMENTOR: The Rhode Island Senate Committee on Environment and Agriculture and Rhode Island Farm Bureau

SECTION: 2.1.1 Authority

COMMENT: Commented on changing of language within the Authority Section by substituting the word under with pursuant to.

DEM RESPONSE: The Department appreciates the comment and will amend the proposed section of the regulation.

COMMENT 7

COMMENTOR: The Rhode Island Senate Committee on Environment and Agriculture and Rhode Island Farm Bureau

SECTION: 2.1.2 Purpose

COMMENT: Commented on amending of language within Section 2.1.2 Purpose of this proposed regulation. Suggested amendments included the replacing of safety with science based and removal of certain text.

DEM RESPONSE: The Department appreciates the comment and will amend some parts of this section of the proposed regulation but will not include all requested amendments within this section. The Department will accept the change to remove “that are consistent with those” from the Purpose section of the proposed regulation. The Department will not include “science-based”, and “safety” nor remove the word “safety” in the first sentence of this section. The Department feels that the standards set forth in language of this regulation

is appropriate and are defensible since they are consistent with federal standards. The Department was given authority under Rhode Island General Law 2-1-9 and 2-1-10 to carry out this federal standard.

COMMENT 8

COMMENTOR: The Rhode Island Senate Committee on Environment and Agriculture and Rhode Island Farm Bureau

SECTION: 2.1.3 Applicability

COMMENT: Commented on changing of language within Section 2.1.3 Applicability of this proposed regulation. Suggested amendments included the removal “be liberally constructed to”, removal of “goals, and policies” and inclusion “federal and” within this Section.

DEM RESPONSE: The Department appreciates the comment and will amend some parts of this section of the proposed regulation but will not include all requested amendments within this section. The Department will remove “be liberally constructed to” and include “federal and” as requested within this section. The Department will not remove “goals, and policies” from this section. The Department feels that the standards set forth in the language of this section of proposed regulation is appropriate and defensible since it is consistent with agency standards.

COMMENT 9

COMMENTOR: The Rhode Island Senate Committee on Environment and Agriculture and Rhode Island Farm Bureau

SECTION: 2.1.4 Scope

COMMENT: Commented on changing of language within this Section and provided an alternative Scope Section for the proposed regulation.

DEM RESPONSE: The Department appreciates the comment and will amend some parts of this section of the proposed regulation but will not include all requested amendments within this section. The Department will accept the suggestion to include “for human consumption” within the first sentence of this Section. The Department will also amend the first sentence to read “These Regulations, in accordance with Rhode Island General Law 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”. The Department appreciates the additional comments on this section but will not amend this section further. The Department feels that the language set forth within this section is consistent to our obligation to set forth in Rhode Island General Laws 2-1-9 and 2-1-10. Section 2.3 Definitions, of this proposed regulation states “Person” means any individual, partnership, corporation, association or other legal entity. The Department believes this definition of person covers the scope of 21 C.F.R. §112 which may apply to non-farm entities that conduct activities covered under this rule.

COMMENT 10

COMMENTOR: The Rhode Island Senate Committee on Environment and Agriculture and Rhode Island Farm Bureau

SECTION: 2.2. Incorporated Materials

COMMENT: Commented on changing of language within Section 2.2 Incorporated Materials of this proposed regulation to cite Public Law 111-353 instead of 21 C.F.R. §112.

DEM RESPONSE: The Department appreciates the comment but will not amend the proposed regulation. The Department feels that the language set forth within this section is consistent with our obligation to adopt 21 C.F.R. §112. Public Law 111-353 (The Food Safety Modernization Act) encompasses the entire food system, both nationally and internationally, and is of a much broader scope than the authority given to The Department by Rhode Island General Law 2-1-9 and 2-1-10. The provision that was requested to be removed will remain within this Section to ensure that future federal changes to 21 C.F.R. §112 are not incorporated into Rhode Island Law without State review, as these changes may have adverse effects on Rhode Island agriculture.

COMMENT 11

COMMENTOR: The Rhode Island Senate Committee on Environment and Agriculture and Rhode Island Farm Bureau

SECTION: 2.3 Definitions

COMMENT: Commented on changing of language within this Section and the inclusion of all definitions within 21 C.F.R. §112.

DEM RESPONSE: The Department appreciates the comment and will amend the proposed regulation to include the federal definition for produce within the proposed regulation. The definition of produce is amended to “*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)”.

As this proposed regulation is incorporating the entirety of 21 C.F.R. §112 all definitions within 21 C.F.R. §112 will be also be incorporated into Rhode Island regulation. The definitions included within Section 2.3 only capture terms that are used with 250-RICR-40-00-2 which does not reference the list of covered and not covered produce.

COMMENT 12

COMMENTOR: The Rhode Island Senate Committee on Environment and Agriculture and Rhode Island Farm Bureau

SECTION: Overall

COMMENT: Commented on the referencing of 21 C.F.R. §112 which arguably exceed language outline in federal law, Pub. Law 111-353 which exempts certain farms.

DEM RESPONSE: The Department appreciates the comment but will not amend the proposed regulation. The Department feels that the language set forth within this section is consistent with our obligation to adopt 21 C.F.R. §112, by the authority given by Rhode Island General Law 2-1-9 and 2-1-10. Also, Public Law 111-353 which includes the Produce Safety Rule and six additional rules, is not a stand-alone law, but a law that amends the Food, Drug and Cosmetic Act, and other parts of Title 21. DEM does not have any authority as it pertains to the Food Drug and Cosmetic Act as a whole, rather only the authority given under RIGL 2-1-9 and 2-1-10. The Department does not have the authority to enforce Public Law 111-353 (Food Safety Modernization Act). The Department only has the authority to enforce the Produce Safety Rule, not the other six rules under FSMA (Preventive Controls for Human Foods, Preventive Controls for Animal Foods, Sanitary Transportation, Foreign Supplier Verification, etc.).

Qualified Exemption criteria as outlined in the Tester-Hagan Amendment under Public Law 111-353 is consistent with the Qualified Exemption criteria in 21 C.F.R. §112.5 and 112.6. Specifically, this Amendment states the criteria for Qualified Exemption are as follows; those farms with a three-year rolling average of all food sales is less than \$500,000 and with the majority of those sales going to Qualified End User may be eligible for modified requirements. These criteria and the associated modified requirements are consistent with 21 C.F.R. §112 Subpart A.

The only farms or entities that are excluded from this regulation are those that do not grow, harvest, pack or hold produce as outlined in 21 C.F.R. §112.1 and 112.2, and those whose previous three-year average of

annual produce sales is less than \$25,000 (21 C.F.R. §112.4). It is not the intent of the Department to include any farm or entity that should be excluded from this regulation. The adoption of these minimum food safety standards put forth in 21 C.F.R. §112 will allow for continued market access for Rhode Island farmers, ensure that Rhode Island farmers remain competitive within the region, protection of public health, protection for consumers of produce, and assure the continued track record of safe, quality produce grown in Rhode Island.