IDAPA – 02 IDAHO DEPARTMENT OF AGRICULTURE

Administration Division

02.05.01 – Rules Governing Produce Safety

Who does this rule apply to?
Growers, handlers and packers of fruits and vegetables grown for human consumption.

What is the purpose of this rule?
The Food Safety Modernization Act (FSMA) gives the U.S. Food and Drug Administration (FDA) authority to regulate food from farm to fork, which enables the FDA to better protect the public by strengthening the food safety system. FSMA was signed into law on January 4, 2011, and represents the nation's largest overhaul of the federal food safety laws since 1938. The goal is to prevent foodborne outbreaks before they occur by taking proactive measures and shifting from a reactionary approach to a proactive approach. FSMA has created seven (7) new federal rules that address produce, human food, animal food, transportation, and imported food.

Under a grant provided by the FDA, the Idaho State Department of Agriculture, in conjunction with the University of Idaho Extension, will be providing educational opportunities for producers who may be covered by the FSMA Produce Safety Rule. The Produce Safety Rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. Compliance dates for the largest farms began in January 2018. The Produce Safety Rule includes six key requirements: (1) Agricultural Water; (2) Biological Soil Amendments; (3) Sprouts; (4) Domesticated and Wild Animals; (5) Worker Training and Health and Hygiene; and (6) Equipment, Tools and Buildings.

What is the legal authority for the agency to promulgate this rule?
This rule implements the following statute passed by the Idaho Legislature:

- 22-5404, Idaho Code – Idaho Produce Safety: Administration – Enforcement – Rules and Cooperation

Who do I contact for more information on this rule?

Idaho State Department of Agriculture
2270 Old Penitentiary Rd.
Boise, ID 83712
P.O. Box 7249
Boise, ID 83707
Phone: (208) 332-8500
Fax: (208) 334-2170
Email: rulesinfo@isda.idaho.gov
Webpage: https://agri.idaho.gov/main/

Table of Contents

02.05.01 – Rules Governing Produce Safety

000. Legal Authority. 3
001. Title And Scope. 3
002. Incorporation By Reference. 3
003. – 009. (Reserved) 3
010. Definitions. 3
011. Abbreviations. 3
012. Variance. 3
013. – 999. (Reserved) 4

000. LEGAL AUTHORITY.
This chapter is adopted under the legal authority of Section 22-5404, Idaho Code. (4-11-19)

001. TITLE AND SCOPE.

01. Title. The title of this chapter is "Rules Governing Produce Safety." (4-11-19)

02. Scope. The purpose of these rules is to establish standards for growing, harvesting, packing, and holding of safe and unadulterated produce for human consumption. (4-11-19)

002. INCORPORATION BY REFERENCE.
The following document is incorporated by reference pursuant to Idaho Code Section 67-5229. Copies of this document may be obtained from the Idaho State Department of Agriculture central office. (4-11-19)

01. Code of Federal Regulations, Title 21, Part 112, January 1, 2018. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. This document can be viewed online at https://www.ecfr.gov/cgi-bin/text-idx?SID=7f8ab876ff3e20c6cdd06c9de9141296&mc=true&node=pt21.2.112&rgn=div5. (4-11-19)

003. – 009. (RESERVED)

010. DEFINITIONS.
The Idaho State Department of Agriculture adopts the definitions set forth in Section 22-5403, Idaho Code. In addition as used in this chapter: (4-11-19)

01. Petition. A petition for submission to the U.S. Food and Drug Administration requesting a variance from the requirements of 21 CFR Part 112. (4-11-19)

02. Petitioner. An individual, business, group, association, or entity who submits a petition to the Department for submission to the U.S. Food and Drug Administration requesting a variance from the requirements of 21 CFR Part 112. (4-11-19)

011. ABBREVIATIONS.

01. FDA. The U.S. Food and Drug Administration. (4-11-19)

012. VARIANCE.

01. Procedure for Seeking a Variance. Under the Produce Safety Rule, only a State, tribe, or a foreign country may request a variance from the Produce Safety Rule's requirements by submitting a petition to the FDA in accordance with Subpart P of the Produce Safety Rule and with 21 CFR 10.30. Pursuant to 22-5404, Idaho Code, the Idaho Legislature designated the Department to administer the Produce Safety Rule, which includes the authority to decide whether to submit petitions to the FDA. The Department will submit a petition to the FDA if the following procedures are followed: (4-11-19)

a. The petitioner must prepare the petition in accordance with the requirements of Subpart P of the Produce Safety Rule and 21 CFR 10.30. Additionally, the petitioner must attach all required documentation and any other supporting documentation. The petitioner must submit the petition and all attached documents to the Department via the Department's food safety email at fsma@isda.idaho.gov or mailed to the Department at the mailing address above or hand delivered to the Department at the physical address above. (4-11-19)

b. Within thirty (30) days of receiving a petition, the Department will complete a review of a petition to determine whether it meets the requirements of Subpart P of the Produce Safety Rule and 21 CFR 10.30. (4-11-19)

i. If, after reviewing the petition, the Department determines that the petition meets the requirements of Subpart P of the Produce Safety Rule and 21 CFR 10.30, the Department will submit the petition to the FDA within ten (10) days of that determination. (4-11-19)

ii. If, after reviewing the petition, the Department determines that the petition does not meet the requirements of Subpart P of the Produce Safety Rule and 21 CFR 10.30, the Department will notify the petitioner

and return the petition for correction. After correcting the deficiencies, the petitioner must resubmit the petition to the Department. Within thirty (30) days, the Department will complete an additional review of the petition to determine if the petition meets the requirements of Subpart P of the Produce Safety Rule and 21 CFR 10.30. (4-11-19)

iii. If, after reviewing the petition, the Department determines that the petition meets the requirements of Subpart P of the Produce Safety Rule and 21 CFR 10.30, the Department will submit the petition to the FDA within ten (10) days of that determination. If, after reviewing the petition, the Department determines that the petition still does not meet the requirements of Subpart P of the Produce Safety Rule and 21 CFR 10.30, the Department will follow the procedure in Subparagraph 012.01.b.ii. (4-11-19)

02. Support and Withdrawal of Petitions. (4-11-19)

a. When the Department submits a petition to the FDA, the petitioner who prepared the petition, or an individual, business, group, association, or entity that supports the petition, shall assist the Department in responding to inquiries or directions from the FDA regarding the petition. If neither the petitioner nor an individual, business, group, association, or entity that supports the petition provides this assistance to the Department within thirty (30) days, the Department may withdraw the petition. (4-11-19)

b. If the FDA takes action to modify or revoke a variance previously granted to the Department, the Department may waive the opportunity for a hearing unless a petitioner or an interested person adequately supports the Department in defending the variance in whole or in part from modification or revocation by FDA. (4-11-19)

013. – 999. (RESERVED)

Subject Index

A

Abbreviations 3
- FDA 3

D

Definitions, IDAPA 02.05.01 3
- Petition 3
- Petitioner 3

I

Incorporation By Reference 3

L

Legal Authority 3

T

Title And Scope 3

V

Variance 3
- Procedure for Seeking a Variance 3
- Support & Withdrawal of Petitions 4