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02.05.01 – Rules Governing Produce Safety

IDAPA 02
TITLE 05
CHAPTER 01

02.05.01 – RULES GOVERNING PRODUCE SAFETY

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. WRITTEN INTERPRETATIONS.
In accordance with Section 67-5201(19)(b)(iv), Idaho Code, this agency may have written statements that pertain to the interpretations of rules of this chapter, or to the documentation of compliance with the rules of this chapter. Any such documentation is available for public inspection and copying at cost in the central office of this agency. (4-11-19)

003. ADMINISTRATIVE APPEAL.
Persons may be entitled to appeal agency actions authorized under these rules pursuant to Title 67, Chapter 52, Idaho Code and IDAPA 02.01.01, Rules of Procedure. (4-11-19)

004. 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)

005. ADDRESS, OFFICE HOURS, TELEPHONE, FAX NUMBERS, WEB ADDRESS.
The Idaho State Department of Agriculture central office is located at 2270 Old Penitentiary Road, Boise, ID 83712-8298. The office is open from 8 a.m. to 5 p.m., except Saturday, Sunday, and legal holidays. The mailing address is PO Box 7249, Boise, Idaho 83707. The phone number is (208) 332-8500 and the fax number is (208) 334-2170. The Department web address is https://agri.idaho.gov/. (6-30-19)T

006. PUBLIC RECORDS ACT COMPLIANCE.
These rules are public records and are available for inspection and copying at the Idaho State Department of Agriculture. (4-11-19)

007. – 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)

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