IDAPA 02 – IDAHO STATE DEPARTMENT OF AGRICULTURE

02.05.01 – RULES GOVERNING PRODUCE SAFETY

DOCKET NO. 02-0501-2401 (ZBR CHAPTER REWRITE)

NOTICE OF RULEMAKING – PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 22-5404, Idaho Code.

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 16, 2024.

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking.

This rule is being presented for authorization as part of the ISDA's plan to review each rule every 5 years. Redundant language that is verbatim in statue has been removed, consistent with the Governor's Zero-Based Regulation Executive Order.

The rule was reviewed over the course of two negotiated rulemaking meetings, and that review benefited from the participation of program stakeholders. No negative comments were submitted as part of this rulemaking process.

This rule clarifies the procedure for administering the Food Safety Modernization Act and remedies of the Department for non-compliance.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased:

There is no change in fee or charge.

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state General Fund greater than ten thousand dollars ($10,000) during the fiscal year resulting from this rulemaking:
There is no fiscal impact on the state General Fund greater than ten thousand dollars ($10,000).

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published in the July 3, 2024 Idaho Administrative Bulletin, Volume 24-7, Pages 47 and 48.

INCORPORATION BY REFERENCE: Pursuant to Section 67-5229(2)(a), Idaho Code, the following is a brief synopsis of why the materials cited are being incorporated by reference into this rule:

The federal Food and Drug Administration made several edits to the CFR. This included deleting redundant language and clarifying pre-harvest water requirements.

IDAHO CODE SECTION 22-101A STATEMENT: Pursuant to 22-101A(1), for any rule promulgated or adopted by the director which is broader in scope or more stringent than federal law or regulations, or which regulates an activity not regulated by the federal government, the director shall identify the portions of the adopted rule that are broader in scope or more stringent than federal law or rules, or which regulate an activity not regulated by the federal government. The following sections of the rule are broader in scope, more stringent than federal law or regulations, or regulate an activity not regulated by the federal government:

The federal government does regulate the Food Safety Modernization Act (FSMA). Per Title 22, Chapter 54, Idaho Code, the agency is authorized to administer and enforce FSMA through this rule, and are not to exceed the standards required by federal law.

The detailed 22-101A analysis can be found on the agency's website at www.agri.idaho.gov.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Lloyd Knight at lloyd.knight@isda.idaho.gov.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 23, 2024.

DATED this 2nd day of October, 2024.

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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 02-0501-2401
(ZBR Chapter Rewrite)

02.05.01 – RULES GOVERNING PRODUCE SAFETY

000. LEGAL AUTHORITY.
~~This chapter is adopted under the legal authority of~~ Section 22-5404, Idaho Code. ~~(3-31-22)~~( )

001. ~~TITLE AND~~ SCOPE.

~~01.~~ ~~Title~~. ~~The title of this chapter is "Rules Governing Produce Safety."~~ ~~(3-31-22)~~

~~02.~~ ~~Scope~~. ~~The~~ The purpose of these rules is to establish standards for growing, harvesting, packing, and holding of safe and unadulterated produce for human consumption. ~~(3-31-22)~~( )

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.~~ ~~(3-31-22)~~

01. Code of Federal Regulations, Title 21, Part 112, ~~January 1, 2018~~ July 5, 2024. 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=7f8ab876ff3e20e6edd06e9de9141296&mc=true&node=pt21.2.112&rgn=div5~~ https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-pre-harvest-agricultural-water. ~~(3-31-22)~~( )

003. – 0~~09~~11. (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:~~ ~~(3-31-22)~~

~~**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. (3-31-22)~~

~~**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. (3-31-22)~~

~~**011. ABBREVIATIONS.**~~

~~**01. FDA**. The U.S. Food and Drug Administration. (3-31-22)~~

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: (3-31-22)~~

~~a~~**01. Submission of Variance**.~~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~~ 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 or hand delivered to the Department. ~~(3-31-22)~~( )

~~b~~**a.** 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~~. If the Department determines the petition meets all relevant requirements, the Department will submit the petition to the FDA within ten (10) days of that determination. ~~(3-31-22)~~( )

~~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. (3-31-22)~~

~~ii~~**b.** ~~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~~If the Department determines that the initial petition or any subsequent version is deficient, 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 for evaluation pursuant to subsection 2 of this section. ~~(3-31-22)~~( )

~~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. (3-31-22)~~

02. Support and Withdrawal of Petitions. (3-31-22)

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. (3-31-22)

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. (3-31-22)

013. – 999. (RESERVED)