Dear Senators RICE, Den Hartog, Jordan, and Representatives BOYLE, Dayley, Erpelding:

The Legislative Services Office, Research and Legislation, has received the enclosed rules of the Department of Agriculture:

IDAPA 02.05.01 - Rules Governing Produce Safety (New Chapter) - Proposed Rule (Docket No. 02-0501-1801).

Pursuant to Section 67-454, Idaho Code, a meeting on the enclosed rules may be called by the cochairmen or by two (2) or more members of the subcommittee giving oral or written notice to Research and Legislation no later than fourteen (14) days after receipt of the rules' analysis from Legislative Services. The final date to call a meeting on the enclosed rules is no later than 07/31/2018. If a meeting is called, the subcommittee must hold the meeting within forty-two (42) days of receipt of the rules' analysis from Legislative Services. The final date to hold a meeting on the enclosed rules is 08/28/2018.

The germane joint subcommittee may request a statement of economic impact with respect to a proposed rule by notifying Research and Legislation. There is no time limit on requesting this statement, and it may be requested whether or not a meeting on the proposed rule is called or after a meeting has been held.

To notify Research and Legislation, call 334-4834, or send a written request to the address on the memorandum attached below.



Legislative Services Office Idaho State Legislature

Eric Milstead Director Serving klaho's Citizen Legislature

MEMORANDUM

- **TO:** Rules Review Subcommittee of the Senate Agricultural Affairs Committee and the House Agricultural Affairs Committee
- FROM: Deputy Division Manager Katharine Gerrity
- **DATE:** July 11, 2018
- SUBJECT: Department of Agriculture
- IDAPA 02.05.01 Rules Governing Produce Safety (New Chapter) Proposed Rule (Docket No. 02-0501-1801)

Summary and Stated Reasons for the Rule

The Idaho State Department of Agriculture submits notice of proposed rule at IDAPA 02.05.01 - Rules Governing Produce Safety. This is a new chapter. According to the department, the Produce Safety Rule is part of the new FDA Food Safety Modernization Act and establishes science-based minimum standards for the safe growing, harvesting, packing and holding of fruits and vegetables grown for human consumption. The department notes that farms that meet the criteria may be subject to on-farm inspections. The department states that it was given statutory authority to conduct on-farm inspections subject to the FDA Produce Safety Rule by the 2018 Legislature in House Bill 537.

Negotiated Rulemaking / Fiscal Impact

Negotiated rulemaking was conducted. There is no negative fiscal impact.

Statutory Authority

The rulemaking appears to be authorized pursuant to sections 22-101, 22-113 and 22-5404, Idaho Code.

cc: Department of Agriculture Brian J. Oakey

*** PLEASE NOTE ***

Per the Idaho Constitution, all administrative rules must be reviewed by the Legislature during the next legislative session. The Legislature has 3 options with this rulemaking docket: 1) Approve the docket in its entirety; 2) Reject the docket in its entirety; or 3) Reject the docket in part.

Kristin Ford, Manager	Paul Headlee, Manager	April Renfro, Manager	Glenn Harris, Manager
Research & Legislation	Budget & Policy Analysis	Legislative Audits	Information Technology
			T.I. 200 224 2475

Tel: 208–334–2475 www.legislature.idaho.gov

IDAPA 02 – DEPARTMENT OF AGRICULTURE 02.05.01 – RULES GOVERNING PRODUCE SAFETY DOCKET NO. 02-0501-1801 (NEW CHAPTER) 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 Sections 22-101(3), 22-113, and 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 July 18, 2018. 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:

The Produce Safety Rule is part of the new FDA Food Safety Modernization Act (FSMA) and establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. These minimum standards were developed to ensure the safe production and harvesting of produce by domestic and foreign farms. Farms that meet the criteria may be subject to on-farm inspections. ISDA was given statutory authority to conduct on-farm inspections of farms subject to the FDA Produce Safety Rule by the 2018 Legislature in House Bill No. 537.

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

No fee or charge is imposed or increased for this rule.

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:

No negative fiscal impact on the state general fund greater than ten thousand dollars (\$10,000) during the fiscal year results from this rulemaking.

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 May 2, 2018 Idaho Administrative Bulletin, **Volume 18-5**, pages 38-39.

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: ISDA was given statutory authority to conduct on-farm inspections of farms subject to the FDA Produce Safety Rule by the 2018 Legislature in House Bill No. 537.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Pamm Juker, Chief of Staff at (208) 332-8502. 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 July 25, 2018.

DATED this 6th day of June, 2018.

Brian Oakey Deputy Director Idaho Department of Agriculture 2270 Old Penitentiary Road P.O. Box 790, Boise, Idaho 83701 Phone: (208) 332-8550 / Fax: (208) 334-2710

Idaho Administrative Bulletin

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. ()

001. TITLE AND SCOPE.

01. Title. The title of this chapter is "Rules Governing Produce Safety."

()

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. ()

03. Citation to Rule. The official citation of this chapter is IDAPA 02.05.01.000 et seq. For example, this Section's citation is IDAPA 02.05.01.001.

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. ()

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.

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.

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&gramediv5.

005. OFFICE – OFFICE HOURS – MAILING ADDRESS – STREET ADDRESS – WEB ADDRESS.

01. Physical Address. The central office of the agency is in Boise, Idaho. The address is the Idaho State Department of Agriculture, 2270 Old Penitentiary Road, Boise, Idaho 83712-0790. ()

02. Mailing Address. The mailing address for the central office is P.O. Box 790, Boise, Idaho 83701.

- **03.** Telephone Number. The telephone number of the central office is (208) 332-8500. ()
- 04. Fax Number. The fax number of the central office is (208) 334-2170. ()
- 05. Office Hours. Office hours of the central office are 8 a.m. to 5 p.m., Mountain Time, Monday

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through Friday, except holidays designated by the state of Idaho.

06. Internet Website. The web address is www.agri.idaho.gov. ()

006. PUBLIC RECORDS ACT COMPLIANCE.

These rules are public records and are available for inspection and copying at the Idaho State Department of Agriculture.

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:

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.

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.

011. ABBREVIATIONS.

01. FDA. The U.S. Food and Drug Administration.

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:

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. ()

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. ()

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. ()

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. ()

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 submit the petition still does not meet the requirements of Subpart P of the Produce Safety Rule and 21 CFR 10.30, the Department will

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follow the procedure in Subparagraph 012.01.b.ii. (

02. Support and Withdrawal of Petitions.

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.

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. ()

013. – 999. (RESERVED)

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