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 Idaho State Department of Agriculture:


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 09/24/2018. 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 10/23/2018.

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.
MEMORANDUM

TO: Rules Review Subcommittee of the Senate Agricultural Affairs Committee and the House Agricultural Affairs Committee

FROM: Deputy Division Manager - Katharine Gerrity

DATE: September 06, 2018

SUBJECT: Idaho State Department of Agriculture

IDAPA 02.04.09 - Rules Governing Milk and Cream Procurement and Testing - Proposed Rule (Docket No. 02-0409-1801)

Summary and Stated Reasons for the Rule

The Idaho State Department of Agriculture submits notice of proposed rule at IDAPA 02.04.09 - Rules Governing Milk and Cream Procurement and Testing. According to the department, the rule change is a result of a joint petition received from the Milk Producers of Idaho, Idaho Dairymen's Association and the Idaho Milk Processors Association to clarify language in the rule regarding the definition of terms, sample tolerance standards, enforcement protocols and the recertification process for labs that fail to meet performance standards.

Negotiated Rulemaking / Fiscal Impact

The department states that negotiated rulemaking was conducted. The department indicates that it does not anticipate any fiscal impact as a result of the rulemaking.

Statutory Authority

The rulemaking appears to be authorized pursuant to Section 37-516, 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.
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 37-506 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 September 19, 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:

This rule change is a result of a joint petition received from the Milk Producers of Idaho, Idaho Dairymen’s Association and the Idaho Milk Processors Association to clarify language in the rule regarding the definition of terms, sample tolerance standards, enforcement protocols and the recertification process for labs that fail to meet performance standards.

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

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:

The agency does not anticipate any fiscal impact as a result of 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 June 6, 2018 Idaho Administrative Bulletin, Vol. 18-6, page 21-22. Negotiated rulemaking meeting was held at the Idaho State Department of Agriculture on June 18, 2018. There were extensive comments received from the meeting attendees as well as written comments entered into the record that were taken into consideration when drafting this proposed rule.

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: N/A

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Dr. Scott Leibsle, Deputy Administrator – Division of Animal Industries at (208) 332-8540. 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 September 26, 2018.

Dated this 2nd day of August, 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
THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 02-0409-1801
(Only Those Sections With Amendments Are Shown.)

008. DEFINITIONS.
The following definitions shall apply in the interpretation and the enforcement of this chapter:

01. Abnormal Test. A test result from a producer sample that is dissimilar from recent producer milk
component or quality parameter testing results; an anomaly.

02. Accuracy Check. A test made at the beginning of each testing session and once per hour thereafter
to determine the continued accuracy of the testing device.

03. Approved Testing Methods. Methods approved by the director for testing milk or cream
components and quality parameters when those components and parameters are used as a basis of payment.

04. Calibration. The settings established on a testing device that will result in an average number of
results that are within tolerance.

05. Clearance Test. A sample set issued to an official laboratory, by the Department, to maintain a
probationary testing license or reinstate a suspended testing license.

06. Control Samples. Milk samples used to determine or set the calibration of the testing device.

07. Component Testing. An analysis of milk or cream constituents including milkfat, protein, lactose
or solids-nonfat, which is used as a basis of payment.

08. Department. The Idaho State Department of Agriculture.

09. Director. The Director of the Idaho State Department of Agriculture or his designee.

10. Detailed Pricing Description. The method used by the purchaser of milk or cream as the criteria
for determining the price paid.

11. Milk Component or Component. A unique compound within milk whose relative mass within the
milk may be used to determine the payment to producers. Component parts of milk include milkfat, protein, lactose,
solids-nonfat, other solids, and total solids.

12. Official Laboratory. A facility, licensed by the department, that tests milk or cream components
or quality parameters for the purpose of determining the value of the product when sold or purchased by producers or
processors.

13. Outlier. A regulatory sample result that appears to deviate markedly from other members of the
sample set in which it occurs.

14. Pay Records. Signed written or printed records, which itemize milk volume, milk component and
quality parameters used as payment to a producer or other processor.

15. Performance Error. The difference between the known percentage content of each milk
component in the control sample, as determined by the sample provider, and the percentage content as measured by
the testing device.
156. Person. An individual, association, partnership, firm, joint stock company, private company, or legal entity, which is recognized by law as the subject of rights and duties. (3-21-12)

157. Producer. A dairy farm permitted by the department to sell milk for human consumption. (3-21-12)

158. Processor. A creamery, milk plant, shipping or cream buying station, milk condensing plant, cheese factory, mix making plant, ice cream factory, reprocessing plant, cheese factory, mix making plant, ice cream factory, reprocessing plant, casein plant, powdered milk plant, or factory of milk products, or other person receiving or purchasing milk or cream in bulk other than a retail vendor of milk on the basis of volume, milk components, or milk quality. (3-21-12)

159. Quality Parameter. The quality of milk or cream as determined by the bacteria/plate count method, somatic cell count, temperature, drug residues or other parameters as approved by the department. (3-21-12)

20. Rolling Group of Thirteen (13). A series of thirteen (13) consecutive sample testing dates where the lab performance error of each biweekly component test is averaged together to represent the long term accuracy of the lab. To be considered a valid testing date, a lab must evaluate and provide results on no less than nine (9) component samples from each round of testing. (____) (3-21-12)

219. Testing Device. The equipment used to determine the percentage of milk or cream components. (3-21-12)

22. Sample Set. A group of not less than nine (9) milk samples issued by the Department to each official laboratory to evaluate component testing accuracy. (____) (3-21-12)

243. Tolerance. The allowable plus and allowable minus variances from zero (0) when conducting component testing. For purposes of this rule, the variances shall be within plus or minus forty-four one-thousandths percent (.044%) for milkfat or protein and within plus or minus eighty-four one-thousandths percent (.084%) for total solids or solids-nonfat, except that regulatory sample tolerances are those set forth in Section 302 of this rule. The acceptable performance error from the control values of each sample set as determined by the sample provider. (3-21-12) (____)

(BREAK IN CONTINUITY OF SECTIONS)

120. SAMPLE INTEGRITY. Milk or cream samples must be handled, stored, and shipped in a manner that maintains the integrity of the samples. Samples must be maintained in a temperature range of thirty-three degrees (33°) to forty-five degrees (45°) Fahrenheit (zero point fifty-five hundredths degrees (0.55°) to seven point twenty-two hundredths degrees (7.22°) Celsius). (3-21-12)

121. DAILY PERFORMANCE CHECKS. All testing devices must be subjected to a daily performance check before each day’s testing, in accordance with the standards set by the testing device manufacturer, or as set forth in this section. (3-21-12)

01. Daily Performance Check Samples. (3-21-12)

a. Source. A set of daily performance check samples must be obtained from a sample provider approved by the department, or may be made by the official laboratory. (3-21-12)

b. Number. Unless otherwise specified by the manufacturer of the testing device, a minimum of two (2) control milk samples must be analyzed before daily component testing begins. (3-21-12)

c. Requirements. The control samples must comply with the requirements set forth in Sections 102 and 104 of this rule and fall within the component ranges typically found in the samples to be tested. (3-21-12) (____)
02. **Procedure.** To conduct a daily performance check, the official laboratory must test a set of daily performance check samples. Based on the daily performance check, the official laboratory must do the following:

(a) Determine the performance error of the testing device with respect to each daily performance check sample. The performance error is the difference between the known percentage content of each milk component in that sample, as determined by the sample provider, and the percentage content as measured by the testing device; and

(b) Calculate the mean difference for the set of daily performance check samples. The mean difference is the sum of the performance errors for the individual samples, divided by the number of samples in the set.

03. **Calibration Based On Daily Performance Check.** If the mean difference calculated on a daily performance check exceeds plus or minus forty-four thousandths percent (.044%) for milkfat or protein, or eighty-four thousandths percent (.084%) for total solids or solids-nonfat, the testing device shall not be used until it is recalibrated in accordance with Section 111.

**BRAK IN CONTINUITY OF SECTIONS**

302. **REGULATORY SAMPLES.**

01. **Samples Set.**

(a) The department will provide a minimum of nine (9) sample sets to an official laboratory, on a bi-weekly basis or at a frequency determined by the department to be necessary to ensure accurate component testing results.

(b) The samples will be obtained from the company or entity that provides calibration samples to the official laboratory, if available. The department may provide regulatory samples from other sources if necessary.

(c) The official laboratory must immediately process the samples, while being observed by a department employee or agent, for those components used by the processor or procurer as a basis of payment.

(d) The official laboratory must evaluate the sample set using identical control standards and device settings which are used to routinely evaluate Idaho producer milk components for basis of payment.

If the official laboratory is unable to process the samples due to maintenance or mechanical issues, the department employee or agent who is delivering the samples may wait for the testing device to become operable. If the integrity of the regulatory samples is compromised due to the delay, the department may obtain and deliver an additional set of regulatory samples.

02. **Regulatory Sample Results.** The regulatory sample results will be compiled by the department and evaluated by the department in rolling groups of thirteen (13) test results.

03. **Outliers.** Sample results that have been identified as outliers will not be used in the calculation of tolerance for regulatory test results.

04. **Regulatory Sample Tolerances.** Each group of rolling thirteen (13) test results average shall be within the following tolerances for those components used as a basis of payment by the processor or procurer.
303. LICENSE SUSPENSION AND REVOCATION BASED ON REGULATORY SAMPLES.

01. Regulatory Sample Test Result Averages Two (2) Out of Four (4) Violation. Whenever the average performance error of two (2) of the last four (4) regulatory sample results rolling groups of thirteen (13) exceed the tolerance for milkfat, protein, or solids as set forth in Subsection 302.04 of this rule, the Department may suspend the official laboratory’s license. This notice shall be in effect as long as two (2) of the last four (4) rolling groups of thirteen (13) exceed the allowable tolerance for component testing.

02. Cumulative Regulatory Sample Results. When the department has accumulated a minimum of one thousand (1,000) regulatory sample results from an official laboratory, and the average of those regulatory sample results exceeds zero (0) by more than plus or minus two hundredths percent (.02%) for milkfat or protein, the department may suspend the official laboratory’s license.

03. Review of Records Prior to License Suspension. If two (2) out of four (4) of an official laboratory’s regulatory sample results rolling groups of thirteen (13) average are out of tolerance pursuant to Subsection 302.04 of this rule, the Department may review the records kept by the official laboratory pursuant to Section 350 of this rule. If the official laboratory is able to demonstrate through those records that it has performed all calibration and checks required under these rules, and that the results of those calibrations and checks show that the testing device is operating within the tolerances set forth in Sections 110, 111 and 130, the official laboratory may, at the department’s discretion, be placed on probation for a period of two (2) weeks. The department will review the most recent thirteen (13) week average following the next regulatory samples, and if that average remains out of tolerance pursuant to Subsection 302.04 of this rule, the department may suspend the official laboratory’s license.

a. Records Review. The Department shall review records kept by the official laboratory pursuant to Section 350 of this rule.

b. Clearance Test. The average performance error of the official laboratory must be within plus or minus thirty-one thousandths percent (.031%) protein, thirty-three thousandths percent (.033%) milkfat and sixty-five thousandths percent (.065%) other solids on all scheduled sample sets, until the official laboratory no longer exceeds the performance tolerance on two (2) out of four (4) rolling groups of thirteen (13) average. If an official laboratory does not meet these performance requirements on each component of the clearance test, the testing license shall be suspended.

c. Probation. The Department may place an official laboratory on probation for two (2) weeks if:

i. The records demonstrate all calibration and performance checks of all testing devices were performed, as required under these rules, and are operating within the tolerances set forth in Sections 110, 111, and 130 of this rule; and

ii. The average performance error in the clearance test sample set was within plus or minus thirty-one thousandths percent (.031%) protein, thirty-three thousandths percent (.033%) milkfat, and sixty-five thousandths percent (.065%) other solids. Clearance test results from laboratories on probationary status shall be included in the calculation of the rolling group of thirteen (13) average.

043. License Reinstatement. An official laboratory may seek reinstatement of a suspended license when the official laboratory provides the department written documentation detailing the procedural corrections that
have been made to the testing device. The documentation must include a minimum of two (2) weeks of component testing results demonstrating that the testing device has been and will remain in tolerance. Upon receipt of that information, the department may reinstate the official laboratory’s license by completing the following:

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b. Written Request. The official laboratory shall provide the Department a written request for reinstatement of their testing license. The request shall include documentation detailing the procedural corrections that have been made to the testing device(s), as well as a minimum of two (2) weeks of component testing results demonstrating that the testing device(s) have been and will remain in tolerance.

License Revocation for Repeated Out of Tolerance Test Results. If the regulatory sample results are repeatedly out of tolerance, the department may initiate steps to revoke the official laboratory’s license to conduct component testing for three (3) months or more.

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