# **Rulemaking Summary**

# IDAPA 02.04.13 - Rules Governing Raw Milk

## Where is the rulemaking authority?

Authority for this rulemaking resides in the Title 37 Chapter 1101 Idaho Code

# What does this rule do?

These rules govern the production, processing, distribution, and sale of raw milk for human consumption, but not intended for pasteurization.

# What is the agency proposing to change?

The agency has performed Zero Based Regulation to simplify, clarify or remove outdated, unnecessary or irrelevant language in sections highlighted blue in the attached strawman. The amended language in these sections does not change the regulatory impact, scope, intent or authority in the current rule.

The agency has conducted an internal audit of this rule and identified multiple sections that may require amendments due to inaccurate or confusing language, recommendations to improve the efficiency of the program or changes that must be made to coincide with recent statutory amendments. The changes listed below, and highlighted in <a href="yellow">yellow</a> in the attached strawman, do result in a change to the regulatory impact, scope, intent or authority in the current rule.

- Updating incorporations by reference to current version (Section 004, 013 and 020)
- Require raw milk label fonts be of equal size (Section 14)

Section 000 Page 1 JPERRY\_10012020

#### 02.04.13 - RULES GOVERNING RAW MILK

#### 000. LEGAL AUTHORITY.

This chapter is adopted under the legal authority of Section 37-1101(5), Idaho Code.

(4-7-11)

#### 001. TITLE AND SCOPE.

**01. Title.** The title of this chapter is "Rules Governing Raw Milk."

(3-29-10)

**92. Scope**. These rules govern the production, processing, distribution, and sale of raw milk for human consumption, but not intended for pasteurization. (4-7-11)

#### 002. -- 003. (RESERVED)

## 004. INCORPORATION BY REFERENCE.

The following document is incorporated by reference: The Grade A Pasteurized Milk Ordinance 2017 2019 Revision, U.S. Department of Health and Human Services Public Health Service Food and Drug Administration ("2017 Pasteurized Milk Ordinance"), except those provisions establishing raw milk standards for raw milk for pasteurization. This document is available online at <a href="https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/UCM612027.pdf">https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/UCM612027.pdf</a>. (3-20-20)

## 005. -- 009. (RESERVED)

#### 010. DEFINITIONS.

The following definitions apply in the interpretation and the enforcement of this chapter:

(3-29-10)

- **01. Adulterated**. The meaning of adulterated includes the following:
- **a.** The addition or inclusion of unclean, unwholesome, inferior, impure or foreign material into a food product; or (4-7-11)
- **b.** The production, distribution, or sale of raw milk or raw milk products from a facility that does not possess a valid permit from the Department or is not registered with the Department as a Herd Share program; or (4-7-11)
  - c. Any raw milk product or facility that fails to meet any of the requirements of these rules. (4-7-11)
- **O2. Dairy Farm.** Any place or premises where one (1) or more cows, goats or sheep are milked and where a part or all of the raw milk or raw milk products are produced that are not intended for pasteurization, or are intended for human consumption without pasteurization, and are distributed, sold or offered for sale to persons other than members of the dairy farm's immediate household. (4-7-11)
- **03. Denatured**. To change the usual or normal nature of a material or substance by either chemical or physical means. (3-29-10)
- **104.** Herd Share. The undivided ownership interest in no more than seven (7) cows, fifteen (15) goats, or fifteen (15) sheep resulting from an investment of monetary value through a written contractual agreement between an owner and a farmer in exchange for raw milk or raw milk products. (4-7-11)
- **05. Official Laboratory**. A biological, chemical, or physical laboratory that is approved by the Department. (4-7-11)
  - **Owner.** A person who has made an investment of monetary value in the ownership or care of cows,

Commented [DSL1]: Mandated in statute. 37-1101c

Section 000 Page 2 JPERRY\_10012020

goats, or sheep and participates in a Herd Share program pursuant to a written contractual agreement. (4-7-11)

- **07. Raw Milk.** The lacteal secretion, practically free from colostrum, obtained by the complete milking of one (1) or more healthy cows, goats, or sheep, and that has not been pasteurized and is intended for human consumption. (4-7-11)
- 08. Raw Milk Permit. Written Aauthorization from the Department allowing raw milk and raw milk products to be sold for human consumption by a dairy farm or raw milk plant that complies with the requirements of these rules.

(4-7-11)

a. Small Herd Exemption Raw Milk Permit. Sale of raw milk and raw milk products as

- b. Unlimited Raw Milk Permit. Sale of an unlimited volume of raw milk and raw milk products as provided in Section 020 of these rules.
- 09. Raw Milk Plant. Any place, premises, or establishment where raw milk is collected, handled, stored, bottled, or processed into raw milk or raw milk products for sale or offered for sale for human consumption.
- 10. Raw Milk Products. Raw milk products include any milk product processed from raw milk that has not been pasteurized and is intended for human consumption by persons other than members of the dairy farm's immediate household. Cheese made from raw milk that has been processed and aged for a minimum of sixty (60) days at a temperature greater than thirty-five degrees Fahrenheit (35°F) in a licensed dairy processing plant is exempt from these rules. (4-7-11)
- 11. Registration. A requirement by the Department for the authorization of a Herd Share to provide raw milk and raw milk products for human consumption to owners of that Herd Share as provided in Section 040 of these rules. (4-7-11)
- 12. Sanitization. The application of any effective method or substance to a clean surface for the destruction of pathogens, and of other organisms as far as is practicable. Such treatment may not adversely affect the equipment, the raw milk or raw milk products or the health of consumers, and be acceptable to the Department.
- 13. Small Herd. The production of raw milk or raw milk products for human consumption, for use by people other than members of their immediate household or non-paying guests, in a facility with no more than three (3) lactating cows, seven (7) lactating goats, or seven (7) lactating sheep. The dairy farm herd may include other cows, goats, or sheep that are dry or are producing milk for purposes other than human consumption. (4-7-11)
- 14. Small Herd Raw Milk Permit. Written authorization from the Department to a small herd dairy farm allowing raw milk and raw milk products to be sold for human consumption as provided in Section 030 of these rules. (4-7-11)
- 15. Sterilized. The condition achieved by application of heat, chemical sterilant or other appropriate treatment that renders the piping, equipment and containers used for raw milk and raw milk products free of viable microorganisms. (3-29-10)

# 011. (RESERVED)

## 012. ADULTERATED OR MISBRANDED RAW MILK OR RAW MILK PRODUCTS.

**01. Prohibited Acts.** No person shall produce, provide, sell, offer, or expose for sale, or possess with intent to sell, within the State or its jurisdiction, any adulterated or misbranded raw milk or raw milk products for human consumption. (4-7-11)

Section 000 Page 3 JPERRY\_10012020

**Restriction on Sale**. Raw milk or raw milk products may not be sold or offered for sale through restaurants or other food service establishments. Grocery stores and similar establishments where raw milk or raw milk products are sold at retail, but not processed there, are exempt from the requirements of these rules, provided those stores and establishments receive raw milk or raw milk products from Department-authorized facilities. The sale of raw milk products, produced under the authority of this Rule, shall be limited to locations within the state of Idaho. The sale of raw milk and raw milk products outside the state of Idaho is prohibited.

(4-7-11)

**03. Disposition of Adulterated or Misbranded Product**. Any adulterated or misbranded raw milk or raw milk product may be impounded and disposed of as directed by the Department. The Department may issue a hold order when it is deemed necessary to protect human health. (4-7-11)

# 013. STANDARDS FOR RAW MILK AND RAW MILK PRODUCTS.

01. Requirements. All raw milk and raw milk products shall be produced and processed to conform with the standards listed in Subsection 013.02 of this rule. Unlimited Raw Milk Permit dairy farms must meet the sanitation requirements of the 2019 Pasteurized Milk Ordinance. Permitted dairy farms and raw milk plants must meet the sanitation requirements of the 2017 Pasteurized Milk Ordinance, unless the dairy farm has a Small Herd Raw Milk Permit or has registered a herd share arrangement with the Department. (4-11-19)

02. Chemical, Bacteriological, and Temperature Standards.

RAW MILK		
Temperature	Cooled to forty degrees Fahrenheit (40F or 5C) or less within two (2) hour after milking provided that the blend temperature after the first and subsequent milking does not exceed forty-five degrees Fahrenheit (45F or 7C).	
Bacterial Limits	Raw milk and raw milk products except cultured raw milk products shall not exceed fifteen thousand (15,000) per ml.	
Coliform Limits	Raw milk and raw milk products may not exceed twenty-five (25) per ml.	
Drugs	Raw milk must test negative by a test method approved by the Department.	
Somatic Cell Counts	Raw milk must not exceed five hundred thousand (500,000) per ml. Goat or sheep raw milk must not exceed seven hundred and fifty thousand (750,000) per ml.	
Brucellosis Test	Raw milk obtained from sheep or goats must be from animals that have tested negative on an annual-brucellosis test performed by an official laboratory within the last twelve <a href="12">(12) months</a> . Raw milk obtained from bovines must be from animals that have tested negative on the Brucellosis Ring Test performed by an official laboratory.	
Tuberculosis Test	All raw milk must be from animals that have been accredited as tuberculosis free or must have passed an annual tuberculosis test within the last twelve (12) months.	

(4-7-11)

**03.** Commingled Milk. Milk from commingled species must meet the somatic cell count of the most restrictive species. (4-7-11)

## 014. LABELING.

01. Applicability. Section 014 applies to holders of <u>Unlimited</u> Raw Milk Permits and holders of Small

**Commented [DSL2]:** These standards are mandated in statute for herdshares (37-1101c).

Section 000 Page 4 JPERRY\_10012020

#### Herd Exemption Raw Milk Permits. (4-7-11)Requirements. All raw milk and raw milk products must have Department-approved labeling. All bottles, containers, and packages enclosing raw milk or raw milk products must be conspicuously marked with the following: The words "not pasteurized," or "unpasteurized" in addition to "raw" must precede the name of the product, in equal size font; (4-7-11) (4-7-11)b. The quantity of contents; c. The name and address or permit number of the permit holder; and (4-7-11)d. When applicable, the word "goat" or "sheep" must precede the name of the raw milk or raw milk products. 03. Commingled Milk Label. The label of raw milk or raw milk products containing milk from commingled species must conspicuously identify the species from which the raw milk was obtained. (4-7-11)Small Herds. Department-approved labels are not required for the holders of Small Herd Exemption Raw Milk Permits if the raw milk or raw milk products are sold at the point of production. (4-7-11)Misleading Labels. It is a violation of these rules to use any misleading marks, words, or endorsements on the label. Registered trade designs or similar terms on the bottle cap or label may be used if the Department determines that the designs or terms are not misleading and do not obscure the labeling required by these rules. Any misleading labeling on the final container will cause the product to be considered misbranded. (3-29-10)015. -- 019. (RESERVED) 020. UNLIMITED RAW MILK PERMITS. Requirements Legal Sale. It is unlawful for any person who does not possess an Unlimited Raw Milk Permit from the Department to produce, process, sell or offer for sale raw milk or raw milk products for human consumption to persons other than members of the dairy farm's immediate household. Obtaining a Raw Milk Permit Requirements. Only a person who comp ceive and retain a Raw Milk Permit. Raw Milk Permits are not transferable with respect to persons or locations Prior to the issuance of an unlimited raw milk permit, each dairy farm whose raw milk or raw milk products are mption within the state of Idaho must comply with the following requirements (4-7-11)Submit to and pass a qualifying inspection conducted by the Department; (4-7-11)

Commented [DSL3]: Penalty for unlawful production?

Section 000 Page 5 JPERRY\_10012020

Meet the tuberculosis and brucellosis standards in Section 013 of these rules; and

Produce and process all raw milk and raw milk products

**b.** Meet the a Pasteurized Milk Ordinance; (4-11-19)

> c. d.

e. Proc on the same premises.

Meet the applicable sanitation, construction, and procedural requirements of the 2017-2019

Meet the raw milk and raw milk products quality standards in Section 013 of these rules; (4-7-11)

(4-7-11)

(4-7-11)

- **03. Inspection Frequency**. Following the issuance of a permit, the Department will inspect each Unlimited Raw Milk Permit holder operation at least once every three (3) months. (4-7-11)
- 04. Sanitation Requirements. All <u>unlimited</u> raw milk <u>permitted</u> dairy farms and raw milk <u>plants that</u> process raw milk or raw milk products into final containers for human consumption must meet the requirements of the 2017-2019 Pasteurized Milk Ordinance\_and Section 013 of these rules if the raw milk or raw milk products are for use by persons other than the dairy farm's immediate household.

  (4-11-19)
- 05. Transfer of Permits. Unlimited Raw Milk Permits are not transferable to another person or location

021. -- 029. (RESERVED)

# 030. SMALL HERD <u>EXEMPTION</u> RAW MILK PERMITS.

01. Legal Sale. It is unlawful for any person who does not possess a with a small herd exemption permit from the Department produce, process, sell or offer for sale raw milk or raw milk products for human consumption to persons other than members of the dairy farm's immediate household, to sell raw milk and raw milk products for human consumption without a Small Herd Raw Milk Permit issued by the Department. The Small Herd Raw Milk Permit applies to raw milk and raw milk products intended for human consumption for persons other than members of the dairy farm's immediate household.

(4-7-11)

0102. Obtaining a Small Herd Raw Milk Permit Requirements. Only a person who complies with these rules may receive and retain a Small Herd Raw Milk Permit. Prior to the issuance of a small herd exempt raw milk permit, each dairy farm must comply with the following requirements: The Small Herd Raw Milk Permit will indicate the physical location of the small herd and the mailing address of the owner or operator in charge of the herd's care and milk quality. Small Herd Raw Milk Permits are not transferable to another person or location. Applications for a Small Herd Raw Milk Permit may be upon a form provided by the Department. All holders of Small Herd Raw Milk Permits issued by the Department must meet the following conditions:

(4-7-11)

a. Submit an application to the Department indicating the physical location of the small herd and the mailing address of the responsible party.

- b. Meet the raw milk and raw milk products quality standards as set forth in Section 013 of these rules;
  (4-7-11)
  - **bc.** Meet the tuberculosis and brucellosis standards as set forth in Section 013 of these rules; (4-7-11)
- ed. Meet the applicable drug testing requirements as determined by the Department based on dairy farm drug therapy and milk quality history; and (4-7-11)
  - de. All raw milk and raw milk products must be produced and processed on the same premises.

    (4-7-11)
  - f. The dairy farm is not concurrently operating a herdshare or unlimited raw milk permit.

**0203. Testing Frequency**. Raw milk or and raw milk products must be tested at a frequency of at least four (4) times in separate months during any consecutive six-month period. (4-7-11)

**9304. Product Quality.** Whenever three (3) out of five (5) consecutive bacteria, coliform, or somatic cell counts exceed milk quality standards, the milk may not be offered for human consumption until subsequent product testing shows that the raw milk or raw milk products comply with Section 013 of these rules. (4-7-11)

0405. Test Results Made Available. A Small Herd Raw Milk Permit holder must provide raw milk and raw milk product quality tests results if requested by individuals who purchase raw milk and raw milk products.

(4-7-11)

Commented [DSL4]: Penalty?

Section 000 Page 6 JPERRY\_10012020

a Small Herd Rav	Exemption from Pasteurized Milk Ordinance. A small herd operation that is in compliance with w Milk Permit requirements is exempt from the sanitary, construction, inspection, and operation to 2017 Pasteurized Milk Ordinance. (4-11-19)	
07. person or location	Transfer of Permits. Small Herd Exemption Raw Milk Permits are not transferable to another	
031 039.	(RESERVED)	
040. HERD S	SHARE PROGRAMS.	
must register the <u>Code.</u> - <del>Registrat</del>	Registration. The dairy farm or farmer responsible for a herd participating in a herd share program farm or dairy with the Department and is subject to all the provisions of Section 37-1101, Idaho tion may be upon a form provided by the Department or may be a written statement containing, at a subject is in the provided by the Department or may be a written statement containing, at a subject is subject to all the provisions of Section 37-1101, Idaho tion may be upon a form provided by the Department or may be a written statement containing, at a	Commented [DSL5]: All redundant language. 37-1101(1c)
•	lowing information: (4.7-11)  The name of the farmer, farm, or dairy; (4.7-11)	
	A valid, current address for the farmer, farm, or dairy; and  (4-7-11)  A statement that raw milk or raw milk products are being produced at the farm or dairy. (4-7-11)	
02.	Proof of Ownership Interest. The farmer and each owner of the herd share must enter into a written ng the herd share arrangement. The contractual documents must include, at a minimum, the (4.7-11)	Commented [DSL6]: All redundant language. 37-1101(1c)
	A bill of sale, stock certificate, or other written evidence satisfactory to the Department; (4.7-11)	
	A boarding and care plan for the livestock; (4.7-11)  A conspicuous notice that the milk or milk products received under the contract will be raw; and (4.7-11)	
	Proof that written information regarding the herd health and production standards used by the dairy provided to each herd share owner.  (4.7-11)	
orth in Section 3'	Testing and Results. The farm or dairy must comply with the testing frequency and standards set 7-1101, Idaho Code. A copy of all test results, the name of the tests performed, and an explanation t results must be provided to each owner. Proof that the information has been provided to the owners	Commented [DSL7]: Redundant. 37-1101(1d)
nust be sent to the		
ounts exceed mil	Product Quality. Whenever three (3) out of five (5) consecutive bacteria, coliform, or somatic cell lk quality standards, the milk may not be offered for human consumption until subsequent product the raw milk or raw milk products comply with Section 013 of these rules.  (4.7-11)	Commented [DSL8]: Redundant. 37-1101(1f)
rrangement may	Restriction on Sale. No person who obtains raw milk or raw milk products under a herd share sell, offer for sale, advertise for sale, or distribute such raw milk or raw milk products to any person, stablishment, grocery store, or farmers' market.  (4.7-11)	Commented [DSL9]: Redundant. 37-1101(3)
eceived directly	Procurement of Raw Milk or Raw Milk Products Raw milk or raw milk products may only be from the dairy farm by the owners of a herd share or by an owner on behalf of another herd share or in the same herd share program.  (4.7-11)	Commented [DSL10]: Redundant. 37-1101(1b)
041 049.	(RESERVED)	
Section 000	Page 7 JPERRY_10012020	

## 050. PERMIT ENFORCEMENT.

Section 050 applies to the enforcement of <u>Unlimited Raw Milk Permits</u> and Small Herd <u>Exempt Raw Milk Permits</u>. (4-7-11)

- **01. Permit Suspension**. The Department may suspend a permit whenever it has reason to believe that a public health hazard exists, whenever the permit holder has violated any of the requirements of these rules, or whenever the permit holder has interfered with the Department in the performance of its duties. (4-7-11)
- a. Prior to suspending a permit, the Department will serve a written notice of intent to suspend the permit on the permit holder. The notice willthat specifiesy the alleged violation(s), and afford the permit holder a reasonable opportunity to correct such violation(s) in a manner agreed to by the parties. In the absence of such agreement, the corrective actions may be designated by the Department. The reasonable opportunity to correct the violation(s) will be given before the permit suspension order becomes effective. A permit suspension will remain in effect until the violation has been corrected to the satisfaction of the Department. (4-7-11)
- **b.** Whenever the raw milk or raw milk products create or appear to create an imminent hazard to the public health, or in the event of a willful refusal to permit an authorized inspection, the Department may immediately suspend the permit without the prior notice procedure set forth in these rules. The Department will provide notice and opportunity for hearing after the suspension, in accordance with Title 67, Chapter 52, Idaho Code.

  (4.7-11)
- **c.** Upon written request by any person whose permit has been suspended, or by any person who has been served with a notice of intent to suspend, the Department will proceed to a hearing and, upon evidence presented at such hearing, may affirm, modify, or rescind the suspension or intention to suspend. (4-7-11)
- **d.** The Department may forego permit suspension provided the raw milk or raw milk products in violation are not sold, offered for sale, or distributed for human consumption. (4-7-11)
- **02. Permit Revocation.** If repeated violations occur, the Department may revoke a permit after reasonable notice and an opportunity for a hearing have been given to the permit holder. This section is not intended to preclude the institution of court action. (4-7-11)
- **03. Permit Reinstatement**. Any raw milk producer whose permit has been suspended or revoked may make written application for the reinstatement of the permit. (4-7-11)
- **a.** When the permit has been suspended due to a violation of any of the bacterial, somatic cell, coliform, drug, or cooling-temperature standards, the Department may re-issue a temporary-the permit after raw milk samples show that the conditions responsible for the violation have been corrected. (4-7-11)
- **b.** Whenever the permit has been suspended due to a violation of a requirement other than bacteriological, coliform, somatic cell count, or cooling-temperature standards, the application for reinstatement must show that the violation has been corrected. Within one (1) week of the receipt of such application, the Department will make an inspection of the applicant's establishment inspections as deemed necessary. If the inspection shows that the raw milk or raw milk products meet the applicable standards and are in compliance with these rules, the permit will be reinstated. (4-7-11)

051. -- 999. (RESERVED)

**Commented [DSL11]:** Are these standards still appropriate?

Section 000 Page 8 JPERRY\_10012020