

BEFORE THE DEPARTMENT OF LIVESTOCK
OF THE STATE OF MONTANA

In the matter of the adoption of NEW) NOTICE OF PROPOSED
RULE I pertaining to recalls) ADOPTION
)
) NO PUBLIC HEARING
) CONTEMPLATED

TO: All Concerned Persons

1. The Department of Livestock proposes to adopt the above-stated new rule.

2. The Department of Livestock will make reasonable accommodations for persons with disabilities who wish to participate in the rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Livestock no later than 5:00 p.m. on August 28, 2020, to advise us of the nature of the accommodation that you need. Please contact the Department of Livestock, 301 N. Roberts St., Room 308, P.O. Box 202001, Helena, MT 59620-2001; telephone: (406) 444-9321; TTD number: (800) 253-4091; fax: (406) 444-1929; e-mail: MDOLcomments@mt.gov.

3. The rule as proposed to be adopted provides as follows:

NEW RULE I RECALLS (1) A recall is an establishment's voluntary action to remove product from commerce to protect the public from consuming adulterated or misbranded products.

(2) Each establishment inspected by the department must have a recall plan that will be implemented whenever the establishment suspects that it has produced and put into commerce adulterated or misbranded product.

(3) Recalls are initiated by the manufacturer or distributor of the meat or poultry. These establishments must notify the department within 24 hours of the establishment's decision to conduct a recall.

(4) The department will coordinate with the establishment initiating the recall to ensure the product has been properly identified and removed from commerce.

(5) If the department has reason to believe adulterated or misbranded product has entered commerce and no recall has been initiated, or if an establishment requests assistance determining whether a recall is necessary, the department will:

(a) conduct a preliminary investigation, which may include some or all of the following steps:

(i) contacting the manufacturer of the food for more information;

(ii) interviewing consumers who allegedly became ill or injured from eating the suspect food;

(iii) collecting and analyzing food samples;

(iv) collecting and verifying information about the suspected food;

(v) discussing the situation with departmental field inspection and compliance personnel;

(vi) contacting State and local health departments; and

(vii) documenting a chronology of events; and

(b) convene a recall committee using the following process:

(i) the recall committee will review available information and make a consensus recommendation about the need for a recall; and

(ii) the recall committee will consist of five to seven members representing the following types of individuals:

(A) meat science specialist, who may be retained from an appropriate entity outside of the department;

(B) microbiologist, who may be retained from an appropriate entity outside of the department;

(C) Board of Livestock member or the department's executive officer;

(D) The department's Animal Health and Food Safety Division administrator or chief meat inspector; and

(E) Meat and Poultry Inspection Bureau enforcement, investigations, and analysis officer or equivalent; and

(iii) if the recall committee recommends a product recall, the committee will prepare a report to be sent to the establishment confirming the evaluation of the hazard, the scope of the recall, the area of distribution, and the department's understanding of the establishment's recall strategy.

(6) After the committee recommends a recall, the establishment has 48 hours to declare its intent to accept or deny the recommendation in writing to the department's chief meat inspector.

(7) If an establishment refuses to recall a product following the recommendation of the committee, the department may notify the public of the refusal to conduct a recall and may detain or retain affected products.

(8) The department will notify the public of any recall or detention of state inspected meat and poultry food products and conduct effectiveness checks.

(9) If a recall is not recommended because no affected products remain in commerce but a potential health risk to consumers exists from products that may still be in the consumers' possession, or from products which are unaccounted for, the department may notify the public of that risk through a public health alert.

(10) All public notifications from the department concerning recalled products, products that an establishment chooses not to recall, and products that are not subject to recall but that may pose a potential health risk will include the name of the producing establishment, the official establishment number, the name of the product, and any other available identifying information such as lot numbers, production dates, or use-by dates.

AUTH: 81-2-102, 81-9-220, MCA

IMP: 81-9-220, 81-9-226, 81-9-234, MCA

REASON: The Department of Livestock is proposing this new rule to formalize the recall process that was drafted and adopted by the department following a series of public meetings with the meat and poultry industry. The industry encouraged the

department to implement a more formal and transparent recall process, and this rule is the outcome of that recommendation. This rule does not create a new recall process; it puts into administrative rule an existing process that has been published and followed by the department for the last two years.

4. Concerned persons may submit their data, views, or arguments either orally or in writing concerning the proposed action to the Executive Officer, Department of Livestock, 301 N. Roberts St., Room 308, P.O. Box 202001, Helena, MT 59620-2001, by faxing to (406) 444-1929, or by e-mailing to MDOLcomments@mt.gov to be received no later than 5:00 p.m., September 4, 2020.

5. If persons who are directly affected by the proposed action wish to express their data, views, or arguments orally or in writing at a public hearing, they must make a written request for a hearing and submit this request along with any written comments to the above address no later than 5:00 p.m., September 4, 2020.

6. If the department receives requests for a public hearing on the proposed action from either 10 percent or 25, whichever is less, of the businesses directly affected by the proposed action; from the appropriate administrative rule review committee of the Legislature; from a governmental subdivision or agency; or from an association having not less than 25 members who will be directly affected, a public hearing will be held at a later date. Notice of the public hearing will be published in the Montana Administrative Register. Ten percent of those directly affected has been determined to be 4 persons based on there being currently 37 businesses that will be impacted by this rule.

7. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 4 above or may be made by completing a request form at any rules hearing held by the department.

8. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

9. With regard to the requirements of 2-4-111, MCA, the department has determined that the adoption of the above-referenced rule will not significantly and directly impact small businesses.

BY: /s/ Michael S. Honeycutt
Michael S. Honeycutt
Executive Director
Board of Livestock
Department of Livestock

BY: /s/ Cinda Young-Eichenfels
Cinda Young-Eichenfels
Rule Reviewer

Certified to the Secretary of State July 28, 2020.