

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 label review) 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 3, 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 LABEL REVIEW (1) The label for a single ingredient product produced in an establishment under state inspection may be used on that product without prior review from the department.

(2) The label for a multiple ingredient product produced in an establishment under state inspection may not be used on that product unless the establishment has submitted the label for review and the label has been accepted by the department.

(3) Requests for label review must be submitted on an approved label application form containing all required information.

(4) Establishments must maintain a copy of all labels used on products that bear the state mark of inspection.

(5) The department's acceptance of a label is valid for two years from the date the acceptance was issued unless the department provides a shorter time period in its acceptance. Establishments must resubmit labels for renewal after the acceptance period has expired.

(6) During the acceptance period, the establishment producing the label must ensure that the label is updated to meet all regulatory requirements following changes to the product formulation, processing procedures, regulation, or other events that may render the label noncompliant with applicable regulations.

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

IMP: 81-9-220, 81-9-226, 81-9-228, 81-9-234, MCA

REASON: The Department of Livestock is proposing this new rule to formalize longstanding department practices. The department has required and provided label approval for many years. This rule does not change the existing requirement that the establishment provide labels that fulfill its obligation to ensure meat and poultry products are properly marked, labeled, packaged, and not misbranded. The proposed rule would add a new component in (5) that provides a two-year acceptance period for labels, unless either the department provides a shorter acceptance period, or the manufacturing process or components are changed during the acceptance period. Previously, there was ongoing departmental review of approved labels.

The department provides label review to assist establishments in producing labels that meet the federal regulations required for labeling of meat and poultry products. The department provides expert guidance to establishments about the labeling requirements that exist in federal regulations and policy documents. This guidance assists establishments that have limited resources to devote to the regulatory requirements of labeling.

Requiring label review for state inspected establishments is a departure from the labeling process used by the United States Department of Agriculture's Food Safety Inspection Service (FSIS). FSIS allows federally inspected establishments to produce and apply labels under a process known as "generic labeling." Generic labeling for federal establishments means that for most products the plant creates labels without any oversight from FSIS; FSIS only audits labels for accuracy and regulatory compliance after the label has been used. Many large, federally inspected establishments employ staff with regulatory expertise who work full-time on labels for the establishment. State inspected establishments may not have access to similar resources. Under generic labeling, if FSIS finds noncompliance on the label of a product in commerce, a recall committee would be convened to make a recommendation regarding the need for a recall. Recall recommendations can be costly to the establishment that produced the recalled product in time expended, production lost, and potential damage to relationships with customers.

The department expects that this proposed rule would protect public health, reduce the likelihood of recalls, and formalize the department's practices for labeling review.

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., August 7, 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., August 7, 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 37 current 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 paragraph 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 June 30, 2020.