

BEFORE THE DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES OF THE STATE OF MONTANA

In the matter of the adoption of New Rules I through XI and the amendment of ARM 37.110.238 pertaining to the production and sale of cottage food products) NOTICE OF ADOPTION AND AMENDMENT)))))

TO: All Concerned Persons

1. On July 30, 2015, the Department of Public Health and Human Services published MAR Notice No. 37-717 pertaining to the public hearing on the proposed adoption of the above-stated rules at page 1008 of the 2015 Montana Administrative Register, Issue Number 14. On August 27, 2015, the Department of Public Health and Human Services published MAR Notice No. 37-717 pertaining to the public hearing on the amended notice of proposed adoption and amendment of the above-stated rules at page 1241 of the 2015 Montana Administrative Register, Issue Number 16.

2. The department has adopted New Rule I (37.110.501), II (37.110.502), IV (37.110.504), V (37.110.506), VI (37.110.507), VII (37.110.508), X (37.110.513), and XI (37.110.514) as proposed.

3. The department has amended ARM 37.110.238 as proposed.

4. The department has adopted the following rules as proposed with the following changes from the original proposal. Matter to be added is underlined. Matter to be deleted is interlined.

NEW RULE III (37.110.503) APPROVED COTTAGE FOOD PRODUCTS

(1) Only those products approved by the department and listed in the registration may be produced by a cottage food operation. A cottage food operation is allowed to produce the following food items as long as they are a non-potentially hazardous food:

(a) ~~baked good~~ products that ~~are~~ may be cooked in an oven including:

(i) through (b)(v) remain as proposed.

(c) repackaged, commercially dried fruit or vegetables from an approved source as described in [New Rule VIII(2)], ~~except that cottage food operators may not dry or package fresh fruits or vegetables~~ or fresh fruits that;

(i) have a natural pH below 4.6, specifically: apples, apricots, grapefruit, lemons, limes, mangos, nectarines, oranges, peaches, plums, pomegranates, tangerines, blackberries, blueberries, cherries, cranberries, currants, gooseberries, grapes, raspberries, strawberries, and huckleberries; and

(ii) are dried by cottage food operators with the following methods:

(A) during the fruit drying process the fruit must reach 160° Fahrenheit within an hour of processing the fruit;

(B) the fruit must then maintain 140° Fahrenheit for the remainder of the drying process;

(C) dried fruit may not be packaged using any method of reduced oxygen packaging, including vacuum packaging.

(d) through (2) remain as proposed.

(3) Other products may be approved on a case-by-case basis by the department in consultation with the local health ~~department~~ authority of the county in which the cottage food operator is registered.

AUTH: 50-50-102, 50-50-103, MCA

IMP: 50-50-102, 50-50-116, 50-50-117, MCA

NEW RULE VIII (37.110.510) MANUFACTURE OF COTTAGE FOOD PRODUCTS (1) remains as proposed.

(2) Food must be obtained from approved sources, including:

(a) and (b) remain as proposed.

(c) In many cases local farm products are considered approved sources; consult with your local health authority to make determinations on a case-by-case basis.

(3) through (8) remain as proposed.

(9) Food must only contact surfaces of equipment and utensils that are cleaned and sanitized as specified:

(a) and (b) remain as proposed.

(c) To the extent practicable, cottage food manufacturers should either dip utensils, dishes, and equipment in a 100 ppm chlorine bleach solution (or other approved sanitizer) and allow to air dry, or use the sanitizing cycle of a dishwasher.

(10) Toxic chemicals such as ~~soap and~~ household cleaners, concentrated bleach, and pesticides must be stored in a way that will not contaminate food, food-preparation areas, and food-contact surfaces.

AUTH: 50-50-103, MCA

IMP: 50-50-103, 50-50-116, MCA

NEW RULE IX (37.110.511) REGISTRATION REQUIREMENTS

(1) through (5) remain as proposed.

(6) At the time of registration, the registrant must demonstrate that the water for the cottage food operation is either:

(a) and (b) remain as proposed.

(c) Water sampling may also be required by the state or local health authority when cottage food is suspected of being associated with an illness or outbreak.

(7) A registration fee of \$40.00 must be paid to the county in which the cottage food operation is registered. Once registered a cottage food operator may sell their registered products anywhere in the state of Montana. The cottage food operation must register again with the local ~~regulatory~~ health authority and pay the registration fee if it wishes to change the location of its cottage food operation or

produce new products. Recipe changes to an existing approved product that necessitate redetermination as to whether that product constitutes a non-potentially hazardous food or contains a major allergen are new products for the purposes of this rule. While not exhaustive, the following are examples of when a new fee must be paid:

(a) when a cottage food operator moves to a new house;

(b) when a cottage food operator changes a recipe in a way that may make the recipe potentially hazardous or adds an allergen, such as switching from a traditional frosting to one that contains cream cheese or adding walnuts to chocolate chip cookies; and

(c) when a cottage food operator wishes to make a completely new product, such as dried fruit when they had previously registered chocolate chip cookies.

(8) remains as proposed.

AUTH: 50-50-103, MCA

IMP: 50-50-103, 50-50-116, 50-50-117, MCA

5. The department has thoroughly considered the comments and testimony received. A summary of the comments received and the department's responses are as follows:

COMMENT #1: Two commenters requested that cottage food operators be allowed to dry their own fruit.

RESPONSE #1: The department agrees with the comment. The adopted rule has been revised to reflect this change providing that the fruit being dried has a natural pH below 4.6, specific drying methods are followed, and no reduced oxygen packaging is used.

COMMENT #2: Two commenters appreciated the department's use of language that allows products not listed in the rule to be reviewed on a case-by-case basis.

RESPONSE #2: The department agrees.

COMMENT #3: Two commenters liked the use of an example label and requested that more examples like this one be used throughout the rules.

RESPONSE #3: The department agrees and will try to use examples such as this whenever possible.

COMMENT #4: Two commenters requested that the language regarding an approved source be clarified to specify that local farm products may be used in the production of cottage food.

RESPONSE #4: The department agrees. The adopted rule has been revised to reflect this change.

COMMENT #5: Two commenters requested that the language regarding when water sampling must occur be clarified.

RESPONSE #5: The department agrees. The adopted rule has been revised to reflect this change.

COMMENT #6: Two commenters requested that examples be added to New Rule IX to clarify when a new registration fee must be paid.

RESPONSE #6: The department agrees. The adopted rule has been revised to reflect this change.

COMMENT #7: One commenter requested the rule be changed to explicitly state that once registered an operator may sell their registered products anywhere in Montana.

RESPONSE #7: The department agrees. The adopted rule has been revised to reflect this change.

COMMENT #8: One commenter requested the term "Domestic Residence Kitchen" be defined, and suggested the following definition: "Domestic Residence Kitchen" means the area of the domestic residence stated in law, designed and intended for use by a resident or residents for personal food preparation, or the processing, storage, or packaging of cottage food products. The domestic residence kitchen must only use food equipment designed for residential use, and must not use commercial types of food equipment typically used in larger retail or wholesale food establishments.

RESPONSE #8: The department disagrees. The statute is clear that cottage food operators must operate within their domestic residence. The distinction between commercial grade and residential grade equipment is not clear and review criteria for this distinction would be difficult, if not impossible, to enforce.

COMMENT #9: One commenter asked if advertisements for cottage food products are allowed under the cottage food rule.

RESPONSE #9: This comment does not necessitate any changes. The rules do not prevent advertising in local papers or on social media. All cottage food sales, however, are required to be direct (in-person) sales.

COMMENT #10: One commenter does not think that the line between cottage food operators and licensed wholesalers is clear, and requested that the rule make the distinction between cottage food operators and licensed wholesalers.

RESPONSE #10: The department disagrees. The statutory requirements limiting cottage food operators to direct sales make it clear that they are not wholesalers of food.

COMMENT #11: One commenter requested that all cottage food operators undergo regular inspections and be rated based on health and safety parameters related to their operation.

RESPONSE #11: The department disagrees. The statute clearly states when an inspection will be conducted. This cannot be changed in rule.

COMMENT #12: One commenter requested that the rule be consistent in its references to the entity with whom the cottage food operator registers and recommends using the term "local health authority" throughout.

RESPONSE #12: The department agrees. The adopted rule has been revised to reflect this change.

COMMENT #13: One commenter requested that the term "application for review" be changed to "registration for review" to clarify the rule.

RESPONSE #13: The department agrees. The adopted rule has been revised to reflect this change.

COMMENT #14: One commenter requested that the fees be structured in a tiered manner based on the number of recipes that are to be reviewed.

RESPONSE #14: The department disagrees. The proposed fee reflects the intent of both HB-478 and HB-630 (2013). During the development of these bills fees of between thirty and fifty dollars were discussed. Forty dollars was chosen as it is the average of the two.

COMMENT #15: One commenter requested that preparation methods and recipes not be required for submittal.

RESPONSE #15: The department disagrees. In order to protect public health the department must review preparation methods and recipes. As stated in the proposed rule, the ingredient list will be made public as is required by federal and state labeling laws while the preparation methods and recipes will be confidential.

COMMENT #16: One commenter requested that animal treats be included in the cottage food rule.

RESPONSE #16: The department disagrees. Licensing of pet and animal feed production is regulated through the Department of Livestock.

COMMENT #17: One commenter requested that diaper-age children be explicitly prohibited from the production and packaging area in a cottage food production area.

RESPONSE #17: The department disagrees. New rule sections specifically pertaining to cleaning food contact surfaces and personal cleanliness already cover contamination that may occur from the presence of diaper-age children.

COMMENT #18: One commenter requested that information regarding the sanitization of dishware be added, and suggested the following language: "Dishes, utensils and equipment can be sanitized in using the sanitizing cycle of a dishwasher OR by dipping them in 100 ppm chlorine bleach solution (or other approved sanitizer) and allowed to air dry."

RESPONSE #18: The department does not believe that sanitization should be required in all operations. However, to the extent practicable, a sanitizing dip and air drying or a sanitizing dishwasher should be used. The adopted rule has been changed to reflect this guidance.

COMMENT #19: One commenter requested that the term "household cleaners" be used instead of "soap," and that the term "pesticides" be added to the examples of toxic chemicals in New Rule VIII Manufacture of Cottage Food Products (10).

RESPONSE #19: The department agrees, and the adopted rule reflects the changes.

6. These rule amendments are effective September 25, 2015.

/s/ Nicholas Domitrovich
Nicholas Domitrovich, Attorney
Rule Reviewer

/s/ Richard H. Opper
Richard H. Opper, Director
Public Health and Human Services

Certified to the Secretary of State September 14, 2015.