

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 pertaining to the)
production and sale of cottage food)
products)

NOTICE OF PUBLIC HEARING ON
PROPOSED ADOPTION

TO: All Concerned Persons

1. On August 20, 2015, at 1:30 p.m., the Department of Public Health and Human Services will hold a public hearing in Room 107 of the Department of Public Health and Human Services Building, 111 North Sanders, at Helena, Montana, to consider the proposed adoption of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Public Health and Human Services no later than 5:00 p.m. on August 13, 2015, to advise us of the nature of the accommodation that you need. Please contact Kenneth Mordan, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; telephone (406) 444-4094; fax (406) 444-9744; or e-mail dphhslegal@mt.gov.

3. The rules as proposed to be adopted provide as follows:

NEW RULE I PURPOSE (1) The purpose of this subchapter is to provide rules in addition to the provisions stated in 50-50-102, 50-50-116, 50-50-117, and 50-50-121, MCA, so that cottage food products may be safely produced for the public in approved home kitchens.

AUTH: 50-50-103, MCA

IMP: 50-50-102, 50-50-103, 50-50-116, 50-50-117, 50-50-121, MCA

NEW RULE II DEFINITIONS In addition to the definitions contained in 50-50-102, MCA, the following definitions apply to this subchapter:

(1) "Baked goods" means breads, candies, cookies, pastries, and pies that are non-potentially hazardous because they are non-time temperature controlled for safety.

(2) "Cottage food operator" means a person registered with the regulatory authority to operate a cottage food operation.

(3) "Approved" means acceptable to the regulatory authority based on their determination of conformity with principles, practices, and generally recognized standards that protect public health.

AUTH: 50-50-103, MCA

IMP: 50-50-102, 50-50-103, 50-50-116, 50-50-117, 50-50-215, MCA

NEW RULE III 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 cooked in an oven including:
 - (i) loaf breads, rolls, biscuits, quick breads, and muffins;
 - (ii) cakes including celebration cakes such as birthday, anniversary, and wedding cakes;
 - (iii) pastries and scones;
 - (iv) cookies and bars;
 - (v) crackers;
 - (vi) cereals, trail mixes, and granola;
 - (vii) pies, except that custard style pies, pies with fresh fruit that is unbaked, or pies that require refrigeration after baking are not approved;
 - (viii) nuts and nut mixes; and
 - (ix) snack mixes;
- (b) standardized jams, jellies, preserves, and fruit butters as identified under 21 CFR, Part 150, subject to the following:
 - (i) fresh picked or harvested fruits from noncommercial sources are allowed for use;
 - (ii) fresh fruits may be frozen in a household freezer and used at a later time;
 - (iii) all recipes must have a cook step included such as a hot fill or hot water bath, and freezer or refrigerator-style products are not approved;
 - (iv) all jams, jellies, preserves and fruit butters must be sealed in containers that are sterilized prior to filling; and
 - (v) paraffin wax is not allowed for sealing;
 - (c) repackaged, commercially dried fruit 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;
 - (d) dry herb combining and packaging, and seasoning and mixture combining; examples of which are dry bean soup mixes, dry teas and coffees, and spice seasonings;
 - (e) popcorn, popcorn balls, cotton candy;
 - (f) fudge, candies, and confections that require a cook step;
 - (g) molded chocolate using commercial chocolate melts; and
 - (h) honey.
- (2) The following provisions apply to the production of cottage food products:
 - (a) fresh picked or harvested fruits from noncommercial sources are allowed in baked good products;
 - (b) fresh fruits can be frozen and used at a later time as long as there is a cook step in the recipe; and
 - (c) all frostings or glazes must have a cook step or be made with ingredients (such as a large amount of sugar) that when combined are stable at room temperature.

(3) Other products may be approved on a case-by-case basis by the department in consultation with the local health department 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 IV LABELING (1) Cottage food operations must adhere to the labeling requirements outlined in 50-50-116, MCA.

(2) The following is representative of a label meeting the requirements of (1):

<p>MADE IN A HOME KITCHEN THAT IS NOT SUBJECT TO RETAIL FOOD ESTABLISHMENT REGULATIONS OR INSPECTIONS</p> <p>Chocolate Chip Cookies</p> <p>Net Wt. 8oz (227g)</p> <p>Ingredients: Enriched flour (Wheat flour, niacin, reduced iron, thiamine, mononitrate, riboflavin and folic acid), butter (milk, salt), chocolate chips (sugar, chocolate liquor, cocoa butter, butterfat (milk), soy lecithin as an emulsifier), walnuts, sugar, eggs, salt, artificial vanilla extract, baking soda. Contains: Wheat, eggs, milk, soy, walnuts.</p> <p>Ashley Bryant 2550 Helena Lane Helena, MT 59620</p>

(3) The department may allow large cakes or a container of bulk products to be handled and labeled in the following manner:

- (a) be protected from contamination during transportation to the consumer;
- and
- (b) have a product label sheet with all the required information as listed in (1) that is provided to the consumer.

AUTH: 50-50-103, 50-50-116, MCA
IMP: 50-31-103, 50-50-116, 50-50-117, MCA

NEW RULE V COTTAGE FOOD OPERATOR HEALTH (1) Cottage food operators must not manufacture cottage food products (for example, working with exposed food; working with cleaning equipment, utensils, and linens; or working with unwrapped single-service or single-use articles) while experiencing the following symptoms:

- (a) vomiting;
- (b) diarrhea;
- (c) jaundice;

- (d) sore throat with fever;
 - (e) a lesion containing pus such as a boil or infected wound that is open or draining and is:
 - (i) on the hands or wrists, unless an impermeable cover such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover;
 - (ii) on exposed portions of the arms, unless the lesion is protected by an impermeable cover; or
 - (iii) on other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage;
 - (f) symptoms of any of the following illnesses as diagnosed by a health practitioner:
 - (i) norovirus;
 - (ii) hepatitis A virus;
 - (iii) shigella spp.;
 - (iv) shiga toxin-producing escherichia coli;
 - (v) salmonella typhi; or
 - (vi) nontyphoidal salmonella.
- (2) A cottage food operator experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth must not work with exposed food; clean equipment, utensils, and linens; or unwrapped single-service or single-use articles.

AUTH: 50-50-103, 50-50-116, MCA

IMP: 50-50-103, 50-50-105, 50-50-116, MCA

NEW RULE VI PERSONAL CLEANLINESS (1) Cottage food operators must keep their hands and exposed portions of their arms clean.

(2) Cottage food operators must use the following procedure in order to keep their hands and exposed portions of their arms clean:

- (a) rinse under clean, running warm water;
- (b) apply an amount of soap;
- (c) rub together vigorously for at least 10 to 15 seconds while:
 - (i) paying particular attention to removing soil from underneath the fingernails during the cleaning procedure; and
 - (ii) creating friction on the surfaces of the hands and arms or surrogate prosthetic devices for hands and arms, finger tips, and areas between the fingers;
- (d) thoroughly rinse under clean, running warm water; and
- (e) immediately follow the cleaning procedure with thorough drying using a single use towel.

(3) Cottage food operators must clean their hands and exposed portions of their arms immediately before engaging in food preparation, which includes working with exposed food, clean equipment and utensils, and unwrapped single-service and single-use articles, and:

- (a) after touching bare human body parts other than clean hands and clean, exposed portions of arms;
- (b) after using the toilet room;

- (c) after caring for or handling service animals, household pets, or aquatic animals;
 - (d) after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;
 - (e) after handling soiled equipment or utensils;
 - (f) during food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks;
 - (g) when switching between working with raw food and working with ready-to-eat food;
 - (h) before donning gloves to initiate a task that involves working with food; or
 - (i) after engaging in other activities that contaminate the hands.
- (4) Cottage food operators must keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough. Unless wearing intact gloves in good repair, a cottage food operator may not wear fingernail polish or artificial fingernails when working with unpackaged food.
- (5) Except for a plain ring such as a wedding band, cottage food operators may not wear jewelry on their arms and hands while preparing food, including medical information jewelry.
- (6) Cottage food operators must wear clean outer clothing to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles.

AUTH: 50-50-103, MCA

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

NEW RULE VII HYGIENIC PRACTICES (1) A cottage food operator must not eat, drink, or use any form of tobacco in the registered area of the domestic residence while preparing a cottage food, or where the contamination of exposed food, clean equipment, utensils, and linens, unwrapped single-service and single-use articles, or other items needing protection can result.

(2) Cottage food operators must provide a barrier between the registered area of their domestic residence and all pets while preparing and packaging cottage food items.

AUTH: 50-50-103, MCA

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

NEW RULE VIII MANUFACTURE OF COTTAGE FOOD PRODUCTS

(1) Cottage food products must be safe, unadulterated, honestly presented, and:

(a) must be offered for human consumption in a way that does not mislead or misinform the consumer;

(b) food or color additives and colored overwraps may not be used to misrepresent the true quality of a cottage food product, although dying cookies or other similar products and/or wrapping them for a theme such as a green cookie for St. Patrick's Day or a popcorn ball wrapped in red plastic for Christmas is allowed.

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

- (a) retail and wholesale establishments licensed by the state of Montana;
- (b) fluid and dry milk products must:
 - (i) be obtained pasteurized; and
 - (ii) comply with grade A standards.
- (3) Eggs and dairy ingredients must be stored under refrigeration.
- (4) Upon receiving food packages from an approved source, food packages must be maintained in good condition and protect the integrity of the contents so the food is not exposed to adulteration or potential contaminants.
- (5) Cottage food operators must minimize bare hand and arm contact with exposed food that is not in a ready-to-eat form.
- (6) Cottage food operators may not contact exposed, ready-to-eat food with their bare hands, and must use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment.
- (7) A cottage food operator may not use a utensil more than once to taste cottage food products or ingredients that are to be sold or served.
- (8) Food contact surfaces must be easily cleanable.
- (9) Food must only contact surfaces of equipment and utensils that are cleaned and sanitized as specified:
 - (a) equipment food-contact surfaces and utensils must be clean to sight and touch;
 - (b) food-contact surfaces of cooking equipment and pans must be kept free of encrusted grease deposits and other soil accumulations.
- (10) Toxic chemicals such as soap and concentrated bleach 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 REGISTRATION REQUIREMENTS (1) Registration must follow the requirements provided in 50-50-117, MCA.

- (2) The registrant must provide their name, mailing address, phone number, and e-mail address.
- (3) The registrant must provide a detailed description of cottage food product manufacturing process including equipment and utensils to be used.
- (4) The registrant must dispose of sewage through an approved facility that is:
 - (a) a public sewage treatment plant; or
 - (b) an individual sewage disposal system that is operated according to law.
- (5) The recipe for each product must be submitted with the application for review and kept on file at the cottage food operation location. Ingredient lists are subject to public disclosure, but recipes are proprietary and are not subject to public disclosure.
- (6) The registrant must demonstrate that the water for the cottage food operation is either:
 - (a) from an approved public water system; or

(b) meets minimum drinking water standards from a certified laboratory by providing results for total coliform and nitrates from the private well serving the domestic residence that is being registered for the cottage food operation;

- (i) nitrates must be below 10 mg/L from a sample within the last 12 months;
- (ii) total coliforms must be absent from a sample within the last 6 months;
- (iii) failure to meet minimum drinking water standards will result in registration being withheld until samples are provided that meet the minimum nitrate and total coliform standards in this rule.

(7) A registration fee of \$40.00 must be paid to the county in which the cottage food operation is registered. The cottage food operation must register again with the local regulatory 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.

(8) A department-approved certificate of registration will be provided to each new registrant. A certificate of registration must be made available to a local health authority upon request when a cottage food operator is vending to the public.

AUTH: 50-50-103, MCA

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

NEW RULE X ENFORCEMENT AND INSPECTIONS (1) Cottage food operations will be inspected according to the requirements of 50-50-301(3), MCA.

(2) Cottage food operators in violation of this subchapter are subject to enforcement action in accordance with Title 50, chapter 50, part 1, MCA.

AUTH: 50-50-103, MCA

IMP: 50-50-103, 50-50-301, 50-50-302, MCA

NEW RULE XI SAMPLES (1) A cottage food operator must furnish cottage food product or ingredient samples for analysis upon request of the regulatory authority when the food is suspected of being associated with an illness or outbreak.

AUTH: 50-50-103, MCA

IMP: 50-50-302, 50-50-303, MCA

4. STATEMENT OF REASONABLE NECESSITY

Summary of Proposed Rules

The Department of Public Health and Human Services (the department) is proposing new rules to regulate the cottage food industry. The proposed cottage food rules are intended to create a safe environment for the production and sales of food produced in a home kitchen. The rules limit the types of food that can be produced to specific non-potentially hazardous foods while leaving open the opportunity for cottage food operators to propose other types of foods that can be reviewed on a case-by-case

basis by the department in consultation with local regulatory authorities. The rules also specify parameters for labeling that include a sample label. Lastly a registration fee is established along with registration requirements. The proposed fee is \$40.00 for the initial registration and an additional \$40.00 fee for any significant changes arising from proposed production of new products, substantially altering existing approved products, or changing the location of a cottage food operation.

Proposed New Rules

The proposed new rules consist of eleven new rules, having the following proposed titles:

- 1) Purpose – this rule provides purpose and context for the rest of the subchapter along with core statutory citations, as they are very specific and will be used in conjunction with statute.
- 2) Definitions – this rule defines important terms that are not defined in statute.
- 3) Approved Cottage Food Products – this rule describes which cottage food products foods will be allowed in cottage food production in addition to what is provided in statute.
- 4) Labeling – this rule primarily cites the statute which gives specifics as to what needs to be on a cottage food label, and it provides a sample label.
- 5) Cottage Food Operator Health – this rule details those circumstances when a cottage food operator must not work with food; specifically, when they are contagious with a communicable disease.
- 6) Personal Cleanliness – this rule specifies how a cottage food operator should wash and maintain personal cleanliness in order to limit diseases that are generally spread through the oral-fecal route.
- 7) Hygienic Practices – this rule details specific practices that are prohibited such as pets in the kitchen while preparing food and smoking and drinking while packaging food.
- 8) Manufacture of Cottage Food Products – this rule details how cottage food items should be prepared and where they, or the food elements comprising the cottage food items, should be stored and from where items must be obtained.
- 9) Registration Requirements – this rule describes the information an individual must provide in order to be approved by the local regulatory authority to operate a cottage food operation.
- 10) Enforcement and Inspections – this rule cites the enforcement and inspection sections provided in statute.
- 11) Samples – this rule details how and when cottage food product or ingredient samples must be provided to the local regulatory authority.

Rule Necessity

The 64th Montana Legislature passed House Bill 478 which grants a person the ability to make food in their home kitchens and then sell this food directly to consumers if registered and approved by the regulatory authority as a cottage food operation. House Bill 478 also extends the department's rulemaking authority

regarding cottage food operations and directs the department to adopt administrative rules consistent with the legislative intent of the bill. The above-described eleven rules are necessary to ensure that the cottage food industry in Montana is administered in a way that is safe to the public and so consumers in Montana do not suffer adverse health effects from consuming food made by the cottage food industry.

Approach Taken to Writing Rules

HB 478 specifically states that whenever possible the cottage food rules should reflect the 2013 FDA Food Code (Food Code). The Food Code identifies five areas that are commonly implicated in disease: improper holding temperatures, inadequate cooking, contaminated equipment, food from unsafe sources, and poor personal hygiene. The department conducted an extensive review of the Food Code and determined which of those rules in the Food Code applied best to Montana home kitchens and would prevent outbreaks of disease from the above-listed sources.

Fiscal Impact

These rules are intended to provide basic health and safety standards for a newly recognized industry in Montana. The fiscal impact of these rules on cottage food operations should be the minor costs associated with conducting a small business, such as the inclusion of a one-time cottage food operator registration fee of \$40.00, the purchase of a barrier to human contact (such as deli tissues, tongs, or gloves) for ready to eat foods, and the purchase of single-use paper towels for drying hands after washing. NEW RULE IX does provide for an additional registration fee to be paid by a cottage food operator if that operator significantly changes the nature of their operation from what has been previously approved by the regulatory authority or if the operator changes location of the cottage food operation.

The cost to local health departments will include the time needed to review new cottage food operator's registration materials. This review time will vary based on the operator's proposed recipes and the number of proposed foods that the cottage food operator plans to make. Hourly cost of an employee's time will vary by county and the department estimates each review will take 1-2 hours to complete.

5. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Kenneth Mordan, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; fax (406) 444-9744; or e-mail dphhslegal@mt.gov, and must be received no later than 5:00 p.m., August 27, 2015.

6. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

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 5 above or may be made by completing a request form at any rules hearing held by the department.

8. An electronic copy of this proposal notice is available through the Secretary of State's web site at <http://sos.mt.gov/ARM/Register>. The Secretary of State strives to make the electronic copy of the notice conform to the official version of the notice, as printed in the Montana Administrative Register, but advises all concerned persons that in the event of a discrepancy between the official printed text of the notice and the electronic version of the notice, only the official printed text will be considered. In addition, although the Secretary of State works to keep its web site accessible at all times, concerned persons should be aware that the web site may be unavailable during some periods, due to system maintenance or technical problems.

9. The bill sponsor contact requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor was notified by mail on July 30, 2015.

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

/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 July 20, 2015.