

NOTICE OF INTENT TO ADOPT ADMINISTRATIVE RULES

TAKE NOTICE that the North Dakota Department of Health will hold three public hearings to address proposed new rules to N.D. Administrative Code chapter 33-33-10 at the following:

March 22, 2018 (9 am to 11 am CST)  
ND Dept. of Health  
J-wing Room 212  
600 E. Blvd. Ave.  
Bismarck, ND 58505-0200

March 22, 2018 (1 pm – 3 pm MST)  
Southwestern District Health Unit  
Training Room  
227 - 16th Street West  
Dickinson, ND 58601

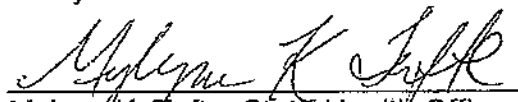
March 23, 2018 (10:00 am to 12:00 pm CST)  
Fargo Cass Public Health  
Oak Room  
1240 - 25th Street South  
Fargo, ND 58103-2367

The purpose of the proposed rules concern preparation of cottage food products for sale. The rules will not impact the regulated community in excess of \$50,000.

The proposed rules may be reviewed at the Division of Food & Lodging, 600 East Boulevard Avenue, Bismarck, ND 58505-0200. A copy of the proposed rules may be requested by writing the above address or calling 701-328-1291. Written or oral comments on the proposed rules sent to the above address or phone number and received by April 4, 2018 will be fully considered.

If you plan to attend a public hearing and will need specific facilities or assistance relating to a disability, please contact the Health Department at the above phone number or address at least three days prior to the public hearing.

DATED this 15<sup>th</sup> day of February 2018.

  
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Mylynn K. Aulte, State Health Officer  
North Dakota Department of Health

**Chapter 33-33-10**  
**Preparation of Cottage Food Products for Sale**

The following Sections are created as follows:

33-33-10-01	Definitions
33-33-10-02	Cottage Food Products Approved for Sale
33-33-10-03	Standards of Home-Canned Products – Verification
33-33-10-04	Safe Handling Instructions and Product Disclosure
33-33-10-05	Illness or Environment Health Complaint Investigation
33-33-10-06	Infectious Disease

**33-33-10-01. Definitions.** For purposes of this chapter:

1. "Acid foods or acidified foods" means high-acid food to which acid or acid food is added to reduce the pH to 4.6 or below. Foods commonly called "pickles" or "pickled" are examples of acidified food. Foods that are low in acid (pH greater than 4.6) or stored, distributed, and retailed under refrigeration are not included in this definition.
2. "Adulterated" means the condition of a food or drink if it:
  - a. bears or contains any poisonous or deleterious substance in a quantity which may render it injurious to health;
  - b. bears or contains any added poisonous or deleterious substance for which no safe tolerance has been established by rule, or in excess of such tolerance if one has been established;
  - c. consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for human consumption;
  - d. has been processed, prepared, packed, or held under unsanitary conditions, whereby it may have become contaminated with filth, stagnant or contaminated water, or whereby it may have been rendered injurious to health; or
  - e. packaging container is composed in whole or in part of any poisonous or deleterious substance which may render the contents injurious to health.
3. "Cottage food production area" means the portion of a private home or home kitchen where the preparation, packaging, storage, or handling of cottage food products occurs.
4. "Department" means the state department of health.
5. "Environmental health hazard" means a chemical agent, physical object, a source of filth, cause of illness or injury, or condition that is a hazard to the public or to the environment.
6. "Farm" means an operation in one general physical location devoted to the growing of crops, the harvesting of crops, the packing and holding of raw agricultural commodities, the raising of animals or any combination of these activities.
7. "Fermented" means low-acid foods subjected to the action of certain microorganisms, which produce acid during their growth and reduce the pH of the food to 4.6 or below.

8. "Frozen" means maintaining frozen foods in a frozen state at 0 degrees Fahrenheit or less.
9. "Inspection" means any activity done by a representative of the department or local regulating authority at a cottage food production area, farmers market, or other venue serving as a point of sale or point of purchase of cottage food products.
10. "Investigation" means entering, inspecting, evaluating, photographing, and securing any samples, photographs or other evidence from any producer or cottage food production area or component thereof.
11. "Homemade" means home-canned product, home-processed, home-baked, and home-packaged cottage food products prepared in a cottage food operator's home kitchen.
12. "Home-baked good" means a food produced in North Dakota from dough or batter that is baked before consuming.
13. "Home-canned products" means fruits or vegetables processed in North Dakota using a boiling water canner where the product does not require temperature control for safety. Homemade canned products do not include products containing dairy, meat, wild game, poultry products, fish, or seafood.
14. "Home kitchen" means a kitchen in a private home intended for use by the cottage food operator in the production of cottage food products and may include equipment such as a refrigerator, freezer, grinder, ice maker, mixer, oven, scale, sink, slicer, stove, hood, table, countertop, temperature measuring device, pH meter, or dishwashing machine.
15. "Home-packaging or -packaged" means food placed into a container (bottled, boxed, cartoned, canned, securely bagged, or securely wrapped) that directly contacts the food by which the cottage food products are received by the consumer safe and protected. Packing of harvested, raw agricultural commodities such as whole, intact fruits and vegetables, is not included in this definition.
16. "Home-processing or -processed" means additional handling or preparation of foods, beverages, or ingredients such as sorting, repackaging, grinding, mixing, peeling, cutting, slicing, or chopping.
17. "Misbranded" means the presence of any written, printed, or graphic matter, upon or accompanying food or containers of food, including signs or placards displayed in relation to such products, which is false or misleading.
18. "Other food and drink products" means a food or beverage approved as a cottage food product.
19. "Point of Sale or Point of Purchase" means the place where a cottage food operator completes a direct sale or transaction face-to-face with an informed end-consumer.
20. "Potential for hydrogen or pH" means a measure of acidity or alkalinity of a solution alkalinity using a numerical scale between 1 and 14. A pH value of 1 is most acidic, a pH value of 7 is neutral and values above 7 are referred to as basic or alkaline.

21. "Poultry products" means:
  - a. Whole, frozen raw poultry slaughtered by the producer on the farm located in North Dakota where the poultry is raised, or
  - b. In-shell farm, flock eggs from poultry raised by the producer on the farm located in North Dakota.
22. "Private home or residence" means a single-family dwelling or an area within a rental unit where a single person or family actually resides; but does not include any group or communal residential setting within any type of structure; or outbuilding, shed, barn, or other similar structure.
23. "Producer" in the context of this chapter is a cottage food operator according to definition stated in North Dakota Century Code section 23-09.5-01.
24. "Product disclosure statement" means a statement indicating the product was transported and maintained frozen.
25. "Ready-to-eat" means food that is ready to eat for which further baking or cooking is not required for food safety.
26. "Safe handling instructions" means specific requirements included on a label for certain products that informs the ultimate end consumer proper handling instructions where it has been established with reasonable certainty illness from bacteria can be prevented.
27. "Standards" are processes, practices, or recipes used by a cottage food operator as practical for use under the conditions of cottage food production that adequately reduces the presence of microorganisms of public health significance and to eliminate spore-forming microorganisms that cause botulism.
28. "Subject matter expert" means a competent person or organization having expert knowledge of home-canning practices and who also has access to a testing facility for making such determinations.
29. "Temperature control for safety" means any perishable food which consists in whole or in part of milk or milk products, eggs, meat, poultry, fish, shellfish, or other ingredients capable of supporting rapid and progressive growth of infectious or toxigenic micro-organisms unless maintained at a safe holding temperature of forty-one degrees Fahrenheit [7.22 degrees Celsius] or below.
30. "Undesirable microorganisms" means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.
31. "Water activity" means a measure of the free moisture in a product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature. At 0.85 or less, the level of moisture in food is low enough to prevent the growth of undesirable microorganisms.

32. "Venue" means any venue not otherwise prohibited by law of requiring a food license by the department. Examples include farmers markets, roadside stands, craft shows, county fairs and community-spirited fund raising events.

History:

General Authority: North Dakota Century Code 23-01-03

Law Implemented: North Dakota Century Code 23-09.5

**33-33-10-02. Cottage Food Products Approved for Sale.** Homemade cottage food products approved for sale in accordance with North Dakota Century Code section 23-09.5-02 are as follows:

1. Home-canned products, such as jams, jellies, or pickles, shall meet one or more of the following standards:
  - a. A high acid food that has a natural pH of 4.6 or less;
  - b. Naturally fermented or acidified foods which have acid or acid food added where the final pH of the food has been reduced to 4.6 or less; or
  - c. Water activity is 0.85 or less.
2. Home-baked goods :
  - a. Home-baked goods requiring temperature control for safety, such as kuchen, cheesecake, or pumpkin pie, shall be maintained frozen. Items shall be fully baked and not partially baked and are ready-to-eat once thawed;
  - b. Dry mixes used as ingredients for baking baked goods;
  - c. Raw home-baked goods, such as cookie dough or bread dough, requiring temperature control for safety, shall be maintained frozen.
  - d. Ready-to-eat home-baked goods that do not require temperature control for safety, such as bread, cookies, or biscuits, shall be fully-baked.
3. Home-processed or home-packaged dry goods and other food and drink products produced in North Dakota that do not contain dairy, meat, wild game, poultry products, fish, seafood, or seed sprouts of any variety, and do not require temperature control for safety such as hulled or un-hulled seeds, grains, flour, candy, popcorn, and dry roasted coffee.
4. Dehydrated or dried foods, such as herbs, fruit, or fruit leather, produced in North Dakota where water activity has been reduced to 0.85 or less and do not contain dairy, meat, wild game, poultry products, fish, or seafood;
5. Honey produced in North Dakota by the cottage food operator's own hives located on the farm, property, or at the private home where the cottage food operator resides;
6. Non-alcoholic beverages and other drink products, such as dry-mix lemonade, black coffee, or brewed tea, produced in North Dakota that do not require temperature-control for safety.
7. Poultry products in accordance with these rules and North Dakota Century Code section 23-09.5-02 part 3 subdivision d.

History:

General Authority: North Dakota Century Code 23-01-03

Law Implemented: North Dakota Century Code 23-09.5

**33-33-10-03. Standards of Home-Canned Products – Verification.** Home-canned product standards required in accordance with these rules shall be verified by one of the following methods:

1. Use of a standard recipe and process for approved, home-canned products from:
  - a. Ball® Blue Book™ 37<sup>th</sup> edition;

- b. United States Department of Agriculture Complete Guide to Home Canning published August 19, 2011, revised 2015;
  - c. National Center for Home Food Preservation; or
  - d. A university extension service.
2. Use of a custom recipe and process approved by a subject matter expert who also has access to a testing facility or where the final product from the custom recipe has been home-tested using a calibrated pH meter.

History:

General Authority: North Dakota Century Code 23-01-03

Law Implemented: North Dakota Century Code 23-09.5

**33-33-10-04. Safe Handling Instructions and Product Disclosure.**

1. Home-baked goods requiring refrigeration and temperature control for safety shall be labeled with safe handling instructions and a product disclosure statement in accordance with North Dakota Century Code section 23-09.5-02(7).
2. Safe handling instructions and a product disclosure statement shall appear:
  - a. On the label prominently, conspicuously, and in a type size no smaller than one-sixteenth of one inch; and
  - b. In a hairline box and the words "safe handling instructions" must appear in bold capital letters.

History:

General Authority: North Dakota Century Code 23-01-03

Law Implemented: North Dakota Century Code 23-09.5

**33-33-10-05. Illness or Environment Health Complaint Investigation.**

1. Authorized representatives of the department or local regulating authority may request access to a cottage food production area of a home kitchen under the authority of North Dakota Century Code section 23-09.5-02. The cottage food operator may request to see the representatives' credentials.
2. An investigation conducted by the department or local regulating authority in accordance with North Dakota Century Code section 23-09.5-02 may include inspection of the following:
  - a. Cottage food product;
  - b. Cottage food production area and any equipment used in the production or delivery of the cottage food product;
  - c. Location or venue serving as the point of sale or point of purchase; and
  - d. Cottage food product testing records, if applicable.
3. A cottage food operator shall provide the department or local regulating authority access to the items identified in subsection 2 of this section, which are required by the department or local regulatory authority as part of an investigation conducted in accordance with North Dakota Century Code section 23-09.5-02:
4. If the department or local regulatory authority determines, as part of an investigation conducted in accordance with North Dakota Century Code 23-09.5-02 the source of an environmental health hazard or an illness complaint is associated with preparation, processing, packaging, or point of sale of a cottage food product, or otherwise associated with the cottage food operation, and poses a threat to public health or safety, where all reasonable measures have not been taken to ensure a cottage food product is not adulterated, contaminated by undesirable microorganisms, or that cottage food product is misbranded or misrepresented to the informed end consumer, the cottage

food operator will be notified and provided guidance regarding a recall of implicated products.

5. The cottage food operator shall prepare and submit to the department a plan of correction in accordance with the minimum standards of these rules and North Dakota Century Code chapter 23-09.5. The plan shall contain adequate information to enable the department to determine whether the proposed corrective action measures will abate or prevent ongoing threat to public health.

History:

General Authority: North Dakota Century Code 23-01-03

Law Implemented: North Dakota Century Code 23-09.5

**33-33-10-06. Infectious Disease.** A cottage food operator afflicted with a contagious or infectious disease or skin condition shall not knowingly:

1. Handle or prepare cottage food products, or
2. Work in a cottage food production area.

History:

General Authority: North Dakota Century Code 23-01-03

Law Implemented: North Dakota Century Code 23-09.5