Summary of Requirements for Dairy Plant Construction and Operation in North Dakota

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Introduction

This booklet provides the background and summary of the North Dakota Department of Agriculture (NDDA) requirements for milk and milk product manufacturing facilities. North Dakota differentiates between manufacturing grade dairy products and grade A milk and dairy products. Each type of dairy product plant is inspected by NDDA, with some minor differences in inspection forms, product sampling procedures and enforcement actions.

The NDDA is responsible for licensing, inspecting and sampling dairy products. The laws are established in the ND Century Code 4.1-25 and the associate regulations are established in the Administrative Code Article 7-03.2.

All processors must obtain a license from the NDDA prior to producing products for sale. The first step is contacting NDDA at 701-328-2231. The Livestock Industries Division, Dairy Program will assist you throughout the planning process as you develop your dairy business. Working with your NDDA dairy inspector on planning your facility will help ensure that regulations are met, avoiding potentially costly construction changes.

Other considerations you should check into are the laws and regulations from the local government, state and federal labor regulations, safety regulations, environmental protection regulations, zoning and tax laws, and milk marketing order licensing. Depending on the type of product you intend to produce, you may need to meet further regulatory requirements to ship across state lines.

Grade A products cannot be shipped across state lines unless the plant passes a sanitary survey conducted by a certified sanitation rating officer. Passing the survey will qualify your plant to be listed as an Interstate Milk Shipper (IMS). To obtain IMS listing, all milk and ingredient suppliers must come from IMS listed dairy farms. If any Grade A product made in an IMS listed dairy plant is not made from milk from an IMS listed dairy farm, then the product is subject to recall and would need to be reprocessed as a manufacturing grade product or destroyed, regardless if the product is only distributed intrastate.

The NDDA development team may be able to assist with planning, including potential grant money for feasibility studies or market analysis, facilitating permitting or coordinating technical assistance. Contact the NDDA to discuss options, such as Agricultural Products Utilization Commission (APUC) grants.

Submission of Plans

Plans for dairy plants must be submitted prior to new construction or extensive alterations to existing dairy plants. Construction plans will require site mapping to establish safe setbacks from existing well locations or other areas of concerns. No construction may begin prior to written approval from the NDDA.

Complete plans must be legible and drawn to scale. Each room must be labeled, and the equipment location provided. All the applicable requirements for plant construction must be met prior to beginning operations.

License Requirements

A license is required for all businesses that buy, distribute, or manufacture Grade A or manufacturing grade milk and milk products. The cost of the license is $25.

A person may not sample, haul or test milk or milk products for the purposes of determining the value or grade without obtaining a license from the department. The sampler and/or tester license is $10 per individual.

Financial Disclosure and Security Bonding Requirements

North Dakota Century Code 4.1-25 requires that applicants that purchase milk must disclose financial information and may be required to file a surety bond acceptable to the NDDA. A purchaser of milk in North Dakota shall file a release authorizing the NDDA access to the applicant's financial records held by financial institutions, accountants and others with the license application. Anyone that purchases milk shall file an audited financial statement prepared by an independent certified or licensed public accountant. If it appears that financial condition of the applicant is not adequate, a bond may be required. All audited financial statements must be reviewed by the Bank of North Dakota and are kept confidential.

Grades of Dairy Products

Grade A Milk and Milk Products

Grade A milk and milk products are all dairy products that meet the definition established in the Pasteurized Milk Ordinance (PMO). This includes fluid milk products, cottage cheese, whey products, and milk or milk products that contain at least 2% milk proteins and a minimum of 65% milk/milk product by weight.

Grade A milk and dairy products must meet the minimum requirements for facility and production as provided in the Grade A Pasteurized Milk Ordinance.

Manufacturing Grade Dairy Products

Manufacturing grade products are other dairy products that do not fall under the definition for Grade A. Cheese, butter, and ice cream, etc. must meet the specific standard of identity, if

defined in the Code of Federal Regulations (CFR), and the producer must obtain a license to manufacture those products prior to sale.

Manufacturing grade products must meet the requirements as written in the General Specifications for Dairy Plants Approved USDA Inspection and Grading Service.

Grade A milk and milk products must be made from Grade A milk and if the Grade A product is produced with manufacturing grade milk, then the product would be subject to recall, to be reprocessed as a manufactured product or destroyed.

Plant Construction Guide

The plant must meet all the requirements for the respective products being produced (manufacturing grade or grade A dairy products). The PMO is the requirements for Grade A dairy plants, which pasteurize fluid type milk products. The requirements are similar for manufacturing type plants but the "General Specifications for Dairy Plants Approved USDA Inspection and Grading Service" does have specific requirements for some types of products, such as cheese, whey, cottage cheese or frozen desserts. In general, the majority of plants that meet the PMO will be very close to meeting the requirements for manufacturing grade products, so for brevity, this document will only provide a summary of the PMO.

Summary of PMO

The following is a breakdown of the minimum expectations for the construction and operation of a dairy plant, as given in the PMO. For exact specifics, please refer to the most recent revision of the PMO, which the NDDA adopts every two years. For facilities that plan to install advanced milk processing equipment (e.g. milk dryers, dry milk handling equipment, HHST, etc.), further evaluation and specific requirements may be involved.

If any of the following conditions are not met through inspection, the NDDA may delay operations or suspend permits until violations are corrected.

All references to milk products are intended to include milk and/or milk products. This may also include dry milk, or milk product ingredients. Please review the PMO for specific exceptions and clarification, if necessary.

ITEM 1p. Floors - Construction

All the floors in the milk plant in areas that could impact milk products, equipment, or packaging must be concrete, tile, metal or other appropriate material that is impervious and washable. Dry ingredient or packaging material storage floors may be tightly joined wood. All floors must be sloped to a drain to prevent any standing water and the drains shall be trapped to prevent sewer gas from backing up into the plant.

ITEM 2p. Walls and Ceilings - Construction

Walls and ceilings are finished with smooth, washable, light colored impervious materials. All of the finishes shall be kept in good repair.

ITEM 3p. Doors and Windows

All openings to the outside shall be properly screened. Outer doors must be tight and self-closing. Screen doors shall open outward. Effective rodent proofing is necessary.

ITEM 4p. Lighting and Ventilation

The milk plant shall have adequate light so sanitary conditions can be observed. The fixtures and bulbs need shielding to protect against glass breakage. The ventilation shall be sufficient to limit odors and condensation. If the ventilation is pressurized, the intake must be filtered.

ITEM 5p. Separate Rooms

Separate rooms shall be provided for:

1. Pasteurizing, processing, cooling, packaging, etc. of milk or milk products
2. Packaging of dry milk products
3. Cleaning of milk cans and containers, bottles, cases, and dry milk containers
4. Fabrication of containers and closure
5. Cleaning and sanitizing for milk tank trucks
6. Receiving of milk cans

The plant must also provide an area for returned product to be clearly separated and isolated from Grade A dairy operations.

Bulk milk storage tanks shall be vented into a room used for pasteurizing, processing, cooling or packaging, or into a storage tank gallery room. Proper air filtering is required.

Rooms where milk is handled, processed or stored; or in which containers, utensils, and/or equipment is stored or washed, shall not open directly into any stable or any room used for domestic purposes.

Every room shall be sufficiently sized for its intended purpose. Special considerations must be made for plants that incorporated specialized processes for manufactured products and Grade A products.

ITEM 6p. Toilet - Sewage Disposal Facilities

Every milk plant shall provide a toilet facility that meets local building and plumbing code.

- The toilet room may not open directly into any room in which milk products are processed, condensed or dried. The doors shall be tight fitting and self-closing.
- The dressing rooms and toilet rooms are to be kept in good repair with proper lighting and ventilation.
- The toilet facility shall have sufficient supplies and must use water to operate.

ITEM 7p - Water Supply

Every milk plant shall have a supply of hot and cold water, from an approved source. The supply shall be properly located, protected and operated and shall be easily accessible, adequate and of a safe, sanitary quality.

ITEM 8p. Handwashing Facilities

Handwashing is essential to personal cleanliness and reduces the likelihood of contamination of milk products.

- Handwash sinks must have hot and cold, or warm running water, soap and individual sanitary towels.
- Handwash sinks shall be in all rooms in which milk plant operations are conducted and convenient to all toilets and kept in good repair.

ITEM 9p. Milk Plant Cleanliness

The milk plant shall be kept clean, neat and free of evidence of insects and rodents.

- Only equipment directly related to milk plant operation may be stored in milk handling areas.
- Non-product contact surfaces must be kept clean (ceilings, tables, fans, floors, etc.).
- Trash cans must be covered when not in use.

ITEM 10p - Sanitary Piping

Piping, connections and fittings in milk plants must be made of approved inert, corrosion resistant, easily cleanable materials.

- The piping shall be in good repair, constructed without dead ends, and properly installed to allow for drainage and inspection.
- Pasteurized milk and milk products may only be conducted from one piece of equipment to another through sanitary milk piping.

Detailed plans for welded pipeline systems shall be submitted to NDDA for written approval prior to installation. No changes to welded pipelines shall be made without prior written approval from the NDDA.

ITEM 11p. Construction and Repair of Containers and Equipment

All milk product contact surfaces shall be made of smooth, impervious, corrosion resistant, and non-toxic materials.

- All joints in containers and equipment are flush and smooth.
- All covers of tanks, vats, etc. are protected with raised edges, overlapping aprons and other means to prevent any contaminates from dripping, draining or being drawn into milk products.
- All containers and equipment shall have rounded corners and kept in good repair.
- Milk cans shall have umbrella-type covers.
- Strainers must be perforated metal (unless functional reasons inherent to certain production practices make perforated metal impractical).
- Single-Service containers must come from an approved plant, that complies with Appendix J of the PMO.

Equipment that conforms to 3-A Sanitary Standards and Accepted Practices complies with the sanitary design and construction standard of the PMO. Inspection by the NDDA shall determine initial and ongoing compliance.

ITEM 12p. Cleaning and Sanitizing of Containers and Equipment

The product-contact surfaces of all multi-use containers, utensils and equipment that have been used shall be effectively cleaned after each day's use and sanitized before use.

- Pasteurized storage tanks shall be cleaned at intervals of less than 72 hours.
- Raw or heat-treated milk silos shall have temperature recording devices installed if milk is held longer than 24 hours.
- Milk tank trucks shall be washed and sanitized within 24 hours of use and must be re-sanitized within 96 hours if not used.
- CIP circuits shall have temperature monitoring devices that adequately record the cleaning and sanitizing schedule of all CIP cleaned circuits.
- Manually washed containers must be done in a three-compartment sink, if sanitizing is done with chemicals.

ITEM 13p. Storage of Cleaned Containers and Equipment

All containers, utensils and equipment shall be clean and stored off of the floor to protect them from contamination before use.

ITEM 14p. Storage of Single-Service Articles, Utensils and Materials

All films and plastics used for milk product containers and closures for single-service use must be kept in sanitary tubes, wrappings or cartons in clean, dry places. The cartons or boxes which have had contents partially removed are kept closed. Protect all single-service containers and closures from contamination.

ITEM 15p. Protection from Contamination

Equipment and operations are located within the milk plant to prevent overcrowding and contamination by splash, condensation or manual contact. Spilled milk products must be discarded. All product contact surfaces are covered or otherwise protected to prevent the access

of insects, dust, condensation or other contamination. All container openings shall be capped or otherwise protected. Pressurized air must be oil, dust, moisture, and odor free.

Only poisonous or toxic materials that are necessary for plant maintenance may be present in the milk plant. All chemicals shall be used according to label and in a manner to prevent contamination of milk products.

The pipeline and storage systems must be set up to appropriately separate Grade A milk from non-Grade A milk products, raw products from pasteurized products, and milk products from cleaning solutions.

Milk plants that handle nondairy food allergens shall implement a written food allergen control plan. Byproducts saved for use as animal food shall be labeled and handled appropriately to prevent contamination.

ITEM 16p. Pasteurization, Aseptic Processing and Packaging, and Retort Processed After Packaging

Every particle of milk or milk product is heated in properly designed and operated equipment to meet the requirements of Appendix H of the PMO. Every individual pasteurization system shall meet 3A sanitary design standards and practices. NDDA will inspect and test all pasteurization equipment is properly working and all public health controls are working. In order to assure pasteurization controls for timing, temperature and pressure cannot be altered, NDDA will seal those controls after testing. Whenever seals are broken, the processing plant must immediately notify NDDA. NDDA will test all equipment with broken seals before resealing equipment.

All milk and milk products and ingredients, i.e. milk solids, whey, nonfat dry milk, condensed milk, cream, skim milk, etc. eggs, egg products, cocoa, cocoa products, emulsifiers, stabilizers, vitamins and liquid sweeteners must be pasteurized. Only those ingredients that are safe and suitable for addition without pasteurization may be incorporated after pasteurization, which include:

a. Ingredients permitted by CFR standard of identity when considering standardized milk or milk products;
b. Fresh fruits and vegetables provided the final product is reduced to pH of 4.6 throughout shelf life of the product;
c. Ingredients subjected to prior heating or sufficiently treated to destroy pathogens;
d. Ingredients having a a_w of 0.85 or less;
e. Ingredients with high acid (pH of 4.6 or less) or high alkalinity (pH of 11.0 or greater);
f. Roasted nuts;
g. Dry sugars and salts;
h. Flavors with high alcohol content;
i. Safe and suitable bacterial cultures and enzymes;
j. Ingredients found safe and suitable by FDA.

All Grade A milk and milk products shall be pasteurized at the plant at which they are packaged.

Pasteurization Times and Temperatures for Every Particle of Milk or Milk Product:

Fluid Milk and Milk Products		145°F	30 min (vat)
		161°F	15 sec (HTST)
		191°F	1 sec (HTST)
Milk Products with	≥10% fat content, or ≥18% total solids, or Added sweetener	150°F	30 min (vat)
		166°F	15 sec (HTST)
		196°F	1 sect (HTST)
Eggnog and frozen Dessert Mixes		155°F	30 min (vat)
		175°F	25 sec (HTST)
		180°F	15 sec (HTST)
Cream for Butter Making		165°F	30 min (vat)
		185°F	15 sec (HTST)

Every pasteurization system must meet the minimum requirements and shall be operated as described in Item 16p. of the PMO.

ITEM 17p. Cooling of Milk and Milk Products

All raw milk and milk products shall be maintained at 45°F or less until processed, except for dry milk or high acid-type whey.

Pasteurized milk and milk products shall be cooled immediately in approved equipment prior to filling or packaging and stored at 45°F or less. Specific exemptions from the cooling parameters are specified in item 17p. of the PMO, which include cultured or acidified products.

All refrigerated rooms, where milk or milk products are stored, shall be equipped with a thermometer placed in the warmest zone of the refrigerated room. Storage tanks and silos shall be equipped with indicating thermometers.

Item 18p. Bottling, Packaging and Container Filling

All milk and milk products shall be bottled and packaged at the milk plant where final pasteurization is performed. The bottling or packaging must be done with approved mechanical equipment, in which the bottling and closures systems are integral within the same system.

Overhead shielding shall be designed and installed to protect the bottles and packages at all times from condensation, drips or splashes. Any milk foam or imperfectly bottle products shall be re-pasteurized prior to repackaging.

Item 19p. Capping, Container Closure and Sealing and Dry Milk Storage

Capping or sealing of milk product shall be done on approved mechanical equipment in a sanitary manner. Hand capping is prohibited, unless suitable mechanical equipment, for the capping of 3-gallon or more containers is not available.

All caps and closures must be designed to protect the pouring lid of the container and cannot be removed without detection. The first cap from each tube and the outermost layer from each roll of packaging film shall be discarded. Caps left in the chute after production must be discarded.

The packaging, cutting, molding, and other handling of frozen dessert mix shall be done in a sanitary manner. Dry milk products shall be stored in a sanitary manner.

Containers and Packaging - Multi-Use vs. Single Use for Grade A products

Multi-use containers and packaging:

- Containers must be made of suitable materials.
- Containers must be washed and sanitized.
    - Meet Specific Temperature, Time Exposure, and Causticity requirements for automatic bottle washers (Section 12p of PMO)
- Plastic containers - identified with plant of manufacture, date of manufacture and type and class of material used. Codes are acceptable if revealed to NDDA.
    - A device capable of detecting volatile organic contaminants, shall be installed on the filling line.
    - Closure caps shall be single-service. Screw caps shall not be used.
    - The phrase “Use only for food” shall be on all multi-use plastic containers.
- Residual Bacteria Counts sampled - 4 bottle set sampled monthly, if possible

Single Service containers and packaging:

- Containers, closures, and product contact films must be made in an IMS listed plant that conforms to Standards of Appendix J.
    - If final assembly of container is in the ND milk plant, samples for Residual Bacteria Counts of 4 containers set sampled monthly, if possible.
- Non-toxic materials, packed and shipped in a manner to protect them from contamination
- All containers shall be identified as to the plant of manufacture.
- Closures shall be single-service and designed to protect the pouring lip of the container.
- Inspected prior to filling
- Glass single service containers- must be washed and sanitized if they are not protected from contamination during shipping and storage.
- Every container must be labeled “single-service use only.”

A list of all certified manufacturers of single-service containers and/or closures for milk products is available at https://www.fda.gov/food/federalstate-food-programs/interstate-milk-shippers-list.

(specific exceptions may apply - review ITEM 12p of PMO for information)

Item 20p. Personnel - Cleanliness and Practices

No person with any communicable disease shall work in any capacity that could contaminate milk or milk products. Open lesions, sores and infections shall be adequately covered. Personnel with reportable diseases shall report their conditions to their supervisors and the appropriate health department.

Hands shall be washed prior to commencing milk plant functions and as often as necessary and immediately after using toilet facilities. No tobacco, chewing gum, eating, or drinking in processing areas is allowed. Hair nets, caps, beard covers, or other hair restraints are required while processing milk or milk products.

Item 21p. Vehicles

All vehicles used to transport milk or milk products shall be clean, capable of keeping products at 45°F or less and have appropriate enclosed bodies with well-fitted, solid doors. Milk tank cars, trucks or potable shipping bins shall not be used to transport any substance that may be toxic or harmful to humans.

Item 22p. Surroundings

The milk plant surroundings shall be kept neat, clean and free of conditions that might attract flies, rodents or that might otherwise constitute a nuisance.

Trash, garbage and waste shall be stored in suitable covered containers. The outdoor milk truck unloading areas shall have smooth concrete or other impervious material that is properly sloped to drain. Rooftops shall be kept clean of dry milk or milk products.

Drug Residue Testing

It is important that dairy plants assure consumers that no antibiotics (drug residues) are found in its milk or milk products. The dairy plant must test incoming raw milk supply for drug residues using an approved testing method. The testing facility must have a laboratory area and be an approved drug residue screening site that has been evaluated by a Laboratory Evaluation Office (LEO). The individuals testing the milk must have a testers license through NDDA, as well.

Every load of raw milk must be screened for Beta Lactam drugs, in accordance with Appendix N of the PMO. Records associated with the Appendix N screens must be maintained and available for inspection review. If any records are not available, the plant could automatically be removed from IMS listing during a rating or check rating.

All presumptive positive loads shall be reported to the NDDA. Trace-back procedures will identify the farm(s) with the antibiotic residues, and appropriate actions will be taken by the NDDA.

Requirements for drug residue testing can be found under Appendix N of the PMO.

Testing Requirements for Raw Milk and Finished Milk or Milk Products

During any consecutive six months, NDDA will pull least 4 samples of each milk or milk product produced at each milk plant. Typically, NDDA will collect every milk product from each facility monthly. The plant is responsible for ensuring that samples are available.

- Recirculated cooling water samples and glycol coolant samples are collected by NDDA at least every six months.
- Well water samples are collected at least every 3 years by NDDA.

Chemical, Bacteriological and Temperature Standards for Grade "A" products:

Grade A raw milk brought into and stored in the milk plant prior to pasteurization	Temperature	≤45°F and maintained
	Bacterial Limits	Individual producer milk not to exceed 100,000 per mL. Not to exceed 300,000 per mL as commingled milk prior pasteurization
	Drugs	No positive results
Grade A Pasteurized Milk and Milk Products	Temperature	Cooled to ≤45°F and maintained
	Bacterial Limits	20,000 per mL or gm**
	Coliform	Not to exceed 10 per mL. (bulk milk transport shipments shall not exceed 100 per mL)
	Phosphatase**	Less than 350 milliunits/L
	Drugs	No positive results

** Not applicable to acidified or cultured milk or milk products, eggnog, cottage cheese and products as identified in the latest revision of M-a-98.

++ not all tests are applicable to all milk products. Please review latest revision of M-a-98 for full list of approved testing methods, and required tests for each type of Grade A product.

Chemical, Physical, Bacteriological, and Temperature Standards for Manufacturing Dairy Products

Manufacturing Grade Raw Milk for Pasteurization	Temperature	≤45°F
	Bacterial Limits	Individual producer milk not to exceed 500,000 per mL. Not to exceed 1,000,000 per mL as commingled milk prior pasteurization
	Bacterial Limit (cream for frozen dessert only)	800,000 per mL
	Drugs	No positive results
	Freezing Point	0.530° Horvet minimum
Pasteurized Frozen Desserts and Mixes	Temperature	≤45°F for mixes Frozen solid for frozen desserts
	Bacterial Limits	20,000 per mL
	Coliforms	Plain Frozen Dessert- 10 per mL Flavored Frozen desserts-20 per mL
	Drug Residues	No positive results
	Butterfat	Per standards listed in 21 C.F.R 135.
Butter, Whipped Butter	% Butterfat	Not less than 80%
	Temperature	≤45°F
	Proteolytic count	Not more than 50 per gram
	Yeast and Mold	Not more than 10 per gram

Vitamin Fortification

Vitamin addition is optional for whole milk but required for low fat or reduced fat milk in order to replenish any reduction of essential nutrients caused by the removal of the fat. Vitamin fortification must be done prior final pasteurization and can be accomplished during different points in the processing, but preferably after separating. Vitamins can be added with metering pumps, in-line standardizing pumps or in batch additions.

The plant must maintain vitamin use records and shall also send in milk samples to a certified lab for vitamin analysis. The annual vitamin analysis records must be submitted to the NDDA. Whenever a vitamin analysis indicates that vitamin fortification is not in acceptable range, the product shall be resampled and the cause of the problem determined.

Acceptable Range for Vitamins A and D (International Units per Quart):

Vitamin A	2000 IU – 3000 IU
Vitamin D	400 IU – 840 IU

Overfortification with levels of vitamin A over 6000 IU per quart and vitamin D over 1500 IU per quart in fluid milk shall be referred to FDA for a health hazard review.

Product Labeling

Milk and milk products shall be labeled in accordance with the *FFD&CA,* the *Nutrition Labeling and Education Act* (NLEA) of 1990. Misleading labeling is prohibited as are super grade designations.

Also included on all bottles, containers, and packages, except milk truck tanks:

1. The identity of the milk plant where processed
2. The words "keep refrigerated after opening" for shelf-stable milk products
3. The common name of the hooved mammal producing the milk if other than cattle's milk
4. The words "Grade A" on the exterior surface

Dry milk, reconstituted, recombined milk or milk products, and milk tank trucks have additional labeling requirements as specified in Section 4 of the PMO.

Vehicles and milk tank trucks containing milk or milk products shall be legibly marked with the name and address of the milk plant or hauler in possession of the contents.

Food Safety Modernization Act (FSMA) and Appendix T

The FSMA requires dairy plants to develop food safety plans as required by 21 CFR 117.126. Each plant may qualify for an exemption from the food safety plans, but they must register with FDA and provide self-attestation that the plant qualifies for the exemption from the FSMA food safety plan requirements. Food facilities can register online through the FDA website (https://www.fda.gov/food/online-registration-food-facilities/food-facility-registration-user-guide-step-step-instructions).

Milk Plants Food Safety Plans include:

1. The written Recall Plan;
2. The written Hazard Analysis;
3. The written Preventive Controls, as appropriate, for hazards not addressed by this *Ordinance*;
4. The written Supply-Chain Program, as appropriate, for hazards not addressed by this *Ordinance*;
5. The written Procedures for Monitoring the Implementation of the Preventive Controls, as appropriate, for hazards not addressed by this *Ordinance*;
6. The written Corrective Action Procedures, as appropriate, for hazards not addressed by this *Ordinance*; and
7. The written Verification Procedures, as appropriate, for hazards not addressed by this *Ordinance*.

The development, implementation and maintenance of the food safety plans shall be performed by a Preventive Control Qualified Individual (PQCI). The food safety plans of IMS listed milk plants that are not exempt will be evaluated during FDA check ratings. If during the Appendix T audit by FDA, the food safety plans are found to be inadequate, the milk plant may fail the check rating and be withdrawn from the IMS listing. Specifics of the food safety plan for milk plants are covered by Appendix T of the PMO.