Dairy

Milk and dairy products are one of the most highly regulated food products in commerce, with state and federal law combining to create extremely high standards for the handling of dairy at all stages of production. Ohio rules and regulations can be found in chapter 917 of the Ohio Revised code and section 901:11 of the Ohio Administrative Code. Ohio has largely adopted the standards set forth by FDA in its Grade "A" Pasteurized Milk Ordinance for Grade A milk products, though Ohio has not adopted the same PMO standards for manufactured milk products.

It is illegal in Ohio to offer raw milk for sale directly to consumers,¹ and it is illegal to ship anything labeled as "milk" for human consumption across state lines if it has not been pasteurized.² Further, Ohio law does not allow for the use of goat's milk, sheep's milk, or any other animal's milk for human consumption unless it is used in the manufacturing of certain approved dairy products or recognized as nonstandardized traditional product normally manufactured from the animal's milk.³

This chapter provides only a high-level overview of the rules and regulations that new dairy producers and processors should be aware of. Anyone who wishes to pursue the production and sale of dairy products should contact the ODA Dairy Division for more information.

Licensing

ODA is the licensing and enforcement agency of Ohio's dairy regulations. ODA may issue, renew, suspend, or revoke all of the five different available Ohio licenses that relate specifically to the dairy industry.⁴ Operators who wish to produce, process, and sell their own dairy products will need to determine every license they will need in order to be legally compliant. Anyone not able to obtain a license due to their religion is able to submit a religious exemption certificate for each registration type.⁵ Religious exempt registrants will still be subject to all

1 $\,$ ORC 917.04, Milk retailers established prior to October 31, 1965 and have continuously sold raw milk may continue to sell raw milk.

- 2 21 USC 331
- 3 ORC 917.05

⁴ ORC 917.09, 917.02





provisions governing licenses such as testing, sampling, and inspection.⁶

Milk Dealer's License⁷ - A milk dealer is a person who purchases or receives milk from a producer for the purpose of bottling, packaging, selling, processing, jobbing, brokering, or distributing the milk except where the milk is disposed of in the same container in which it is received, without removal from the container and without processing in any way except by necessary refrigeration. Any person who buys or distributes milk in containers under their own label is a dealer.⁸

Milk dealer applicants are required to submit evidence of financial responsibility through either a surety bond to the state, depositing cash or negotiable securities with a trustee, or filing a sworn financial statement showing all assets and liabilities with any necessary supporting data.⁹ Applications must also be submitted with a \$15 application fee.

Milk Hauler License¹⁰ – This license is for any individual that *owns* tankers or conveyances that are used to move milk from farms to processing locations, or between processing locations.

Id

6

- 7 ORC 917.09(3);8 ORC 917.01(D)
- 9 OAC 901:11-1-04(F)
- 10 ORC 917.09(A)(6); OAC 901:11-4-02

ORC 917.09(3); OAC 901:11-1-04(A)

There are four categories of milk hauler licenses 1) Grade A Bulk Milk Hauler, 2) Grade A Can Milk Hauler, 3) Manufacture Bulk Milk Hauler, and 4) Manufacture Can Milk Hauler. Applications for the four categories must be submitted with the \$15 licensing fee and may be subject to additional inspection fees.¹¹ A license will remain valid unless it is suspended, revoked, or canceled. Licensed milk haulers must provide ODA with a list identifying all transport tanks or conveyances used to transport raw milk, amended annually as needed. Listed transport tanks and conveyances will receive an identification number from ODA, which must be placed on the tank or conveyance.

Weigher, Sampler, and Tester¹² – Individuals in charge of weighing, testing, or sampling milk at a farm or dealer for the purpose of official regulatory samples or determining price must have a Weigher, Sampler, and Tester License.¹³
Milk haulers that pick-up milk from a dairy farm must have a Weigher, Sampler, and Tester License and be well versed in the legally acceptable milk standards.¹⁴

License applications must be submitted to ODA along with the \$15 licensing fee.¹⁵ No one will be issued a license unless they have received a passing Weigher, Sampler, and Tester examination score.¹⁶ Exams are composed of a minimum of 20 questions that cover sanitation and personal cleanliness; sampling and weighing procedures; milk or cream testing procedures; proper use, care and cleaning of equipment; and record keeping. Licensed individuals must meet annual continuing education requirements in order to remain licensed.¹⁷ For more information please see The Ohio Bulk Haulers Manual and the Milk Hauler and Weigher, Sampler, and Tester Video, which can be found on ODA's website: ofb.ag/bulkmilkhaulers and agri.ohio.gov/divisions/dairy/ resources/Milker-Hauler-Video.

- Milk Producer License¹⁸ Anyone wishing to ship milk from their facility must first obtain approval from ODA. In addition to submitting the general application to ODA with the \$15 application fee, producers should be prepared to submit acceptable water samples from the EPA, a facility plan submittal form that includes drawings of the facility,¹⁹ and evidence of a completed and acceptable inspection from the district sanitarian.
- 11 OAC 901:11-4-02(I)

- 13 ORC 917.01(X)
- 14 OAC 901:11-4-03
- 15 ORC 917.09(E)-(G), OAC 901:11-4-02
- 16 ORC 917.08, OAC 901:11-4-02(D)
- 17 ORC 917.09(I)
- 18 ORC 917.09(A)(1)
- 19 Plan submittal forms are not required for proposed can milk manufacturer farms.

Grade A Facilities

A Grade A milk facilities are those that produce milk intended to be used as Grade A fluid milk or to be used in Grade A milk products. Grade A facilities must comply with Appendix D of the PMO's water source standards. These standards cover aspects such as the distance water sources must be from sources of contamination, construction or development of water sources, disinfection of water sources, and the reclaiming of water from milk sources and its uses. District sanitarians will evaluate water sources and their compliance during their inspection.

District sanitarians will also assess the milking methods and procedures, the milking areas construction and cleanliness, the cowyard/housing, the milk house construction and cleanliness, the equipment construction, storage and cleanliness, the cow cleanliness, the milk and equipment protection, the drug and chemical control, the handwashing facilities and personnel cleanliness, the milk cooling and the pest control around the entire facility. Appendix C of the PMO provides guidelines that help producers know what they can and cannot do when designing a production facility.

Grade A milk producers are responsible for paying the milk inspection fees that are prescribed by the milk sanitation board.²⁰ If ODA determines that a Grade A milk producer sold or offered for sale raw milk containing drug residues greater than the allowable levels, their milk producer license will be immediately suspended. For the first occurrence in a 12-month period, the license will be suspended for a minimum of two days; for the second occurrence, the license will be suspended for a minimum of four days; and for the third occurrence, the license will be suspended for a minimum of four days and ODA will begin the administrative procedures necessary to revoke the license.²¹ Suspended licenses will not be reinstated until the producer's milk is no longer positive for drug residues, the producer has displayed and submitted to ODA a validation form signed by the producer and a licensed veterinarian stating that they have reviewed the "Milk and Dairy Beef Residue Prevention" manual and that a veterinarian client/ patient relationship exists.

Manufacture Milk Facilities²²

Manufacture milk facilities are those that produce milk intended for use in manufacture milk products. In order to receive a Manufacture Milk License, a producer must be in compliance with the applicable rules found in OAC 901:11-2-01 to 901:11-2-44. Licensed farms will be inspected for compliance annually, and ODA may issue, deny, suspend, or revoke licenses as necessary when a farm is not in compliance. Some of the qualifications include:

- 21 OAC 901:11-1-04(L)
- 22 OAC 901:11-2-09 901:11-2-44

¹² ORC 917.09, OAC 901:11-4

²⁰ OAC 901:11-1-04, ORC 917.031

- Producers must have a facility of a size and arrangement that promotes sanitary milking operations.²³ Conditions inside the barn must be clean, provide adequate light, have sufficient air circulation, and have concrete gutters in good repair.²⁴ Feed storage must be in a tightly covered bin, and no swine or fowl should be allowed in the milking facility.²⁵ If milk is exposed for any reason in the facility, it must be protected from contamination.26 Manufactured milk stored on the property must be stored in cans at a temperature of 61 degrees Fahrenheit or in a bulk tank at a temperature of 55 degrees Fahrenheit.27
- Manufactured milk milking procedures may only be done in the milking barn/parlor.28 Animal teats must be clean, sanitized, and dried prior to milking.²⁹ Anyone milking an animal should be clean and dry themselves before performing milk house duties, and they should not perform milking on any animal if they have an open wound.³⁰
- A clean, separate, properly constructed milk house or milk room must be provided for handling and cooling milk and for washing, handling, and storing the utensils and equipment.³¹ Farm chemicals and drugs must be stored in a manner that will prevent them from coming in contact with milk.32 All equipment on the farm used in milk production must be maintained in good condition.
- Dairy farm water supply must be from an approved source and properly located, protected, and operated, and must be easily accessible, ample, and of safe, sanitary quality for the cleaning of dairy utensils and equipment.³³ House, milk house, milkroom, and toilet wastes must be disposed of in a manner that will not pollute the soil surface, contaminate any water supply, or be exposed to insects.³⁴

Milk Processor License³⁵ - In order to operate as a provider of any of the following products, facilities must first obtain a Milk Processor License.

- Grade A Fluid Milk Processor
- Grade A Cultured Milk Producer
- Grade A Milk Receiving and Transfer Stations
- Grade A Condensed Milk Products Processor
- Grade A Dry Milk Products Processor
- Grade A Cottage Cheese
- Grade A Transport Vehicle Washing
- Manufacture Milk Receiving and Transfer Stations
- OAC 901:11-2-10(A) 23
- 24 Id
- 25 Id 26
- OAC 901:11-2-10(B)
- ORC 917.23, OAC 901:11-2-12. Note: Milk that is stored in cans may only be used in in the manufacture of cheese. 27 28 OAC 901:11-2-11(A)
- 29 ld
- 30
- OAC 901:11-2-11(B) OAC 901:11-2-13 31
- OAC 901:11-2-14 32
- 33 OAC 901:11-2-16
- 34 OAC 901:11-2-17
- 35 ORC 917.09; OAC 901:11-1-04(A)

- Butter Manufacturer
- Frozen Desserts Manufacturer
- Natural and Processed Cheese Manufacturer
- Condensed Milk Products Manufacturer
- Dry Milk Products Manufacturer •
- . Dairy Products Blender Manufacturer
- Non-standardized Dairy Product Manufacturer •

Complete applications must be submitted with the \$15 licensing fee. ODA will conduct an inspection to ensure all applicable standards have been met by the facility. ODA recommends that new processors consider the following before applying for a Milk Processor License:

- Building and equipment plans.
- Products to be processed.
- Application and submittal process (including categories to be applied for).
- Other licenses that may be needed.
- IMS program participation.
- Product labeling. •
- Drug residue testing and reporting.
- Fee structure and monthly usage reporting.
- Inspection procedures and policies.
- Equipment testing procedures and policies.
- Product sampling requirements.
- Other agency requirements (EPA, Local Building Codes, FDA, USDA).
- Questions from you, the prospective processor.

The processing of dairy products needs to be done in a separate room or structure from a processor's home and cannot be done in a home kitchen.

Regulation

Federal

- Pasteurized Milk Ordinance: Developed by the United States Public Health Services and the FDA, the PMO sets the federal regulations and standards for the sanitary production and handling of milk. Adoptable in part or in whole by states, the PMO covers various aspects of milk safety and quality such as pasteurization, facility and equipment standards, storage, animal disease control, milk sampling and transportation, water source standards, cleaning and sanitation, chemical and bacterial tests, packaging and labeling, drug residue testing, and other aspects involved in milk safety.
- Interstate Milk Shippers: The Interstate Milk Shippers is a program managed by FDA to ensure the quality of milk and milk products in interstate commerce. Dairy producers and processors that are enrolled in the IMS program will be subject to routine supervision to ensure compliance with federal regulations and standards found in the PMO. The IMS is a voluntary program that producers and processors may enroll in in order to obtain a permit to ship their milk across state lines. Milk or milk products may not enter interstate commerce

without undergoing pasteurization (unless there is a specific exemption provided in federal law).³⁶

- Federal Milk Marketing Orders: The Federal Milk Marketing Orders establish minimum uniform prices within marketing areas for milk throughout the United States in order to encourage market stabilization. There are 11 FMMO areas, with most of Ohio falling in the Mideast order.³⁷ The FMMO separates milk products into four categories based on the intended use of the milk in order to establish pricing.38 Milk prices are established based on economic conditions, adequate supply, farm income assurance, and the public interest. The FMMO does not regulate the retail price of milk. Milk handlers are the ones subject to FMMO regulation and milk handlers operating under the order must abide by the minimum pricing, accurate test, accurate weight, and proper use of milk requirements. A "handler" is anyone who operates a pool plant or a non-pool plant, a processor of raw milk, or anyone brokering milk for processing (basically the first buyer of milk from the producer).³⁹ Dairy producer-handlers are not controlled by FMMOs unless they are considered to be a large-scale producer-handler. Producer-handlers are producers who distribute their own milk, manage and care for their own dairy animals and have complete ownership and control of the enterprise while bearing the sole risk.⁴⁰
- **Reporting Requirements:** The storage and pricing of dairy products comes with very stringent, mandatory reporting requirements.⁴¹ Facilities that produce or hold dairy products should verify their reporting requirements based on their specific product and the quantity of the product they sell. Reports are sent to the National Agricultural Statistics Service (NASS), and can be required on a weekly or monthly basis.⁴²
- USDA Grading: USDA has created a uniform scale for the quality of dairy products that qualified dairy plants may participate in on a uniform basis.⁴³ Anyone interested in USDA grading can find more information on USDA's website: ofb.ag/dairystandards.

State

ODA has the authority to adopt rules regulating the sanitary production, storage, transportation, manufacturing, handling, processing, sampling, testing, examination, and sale of dairy products within Ohio.⁴⁴ The Milk Sanitation Board is an advisory board made up of various industry specialists who

- 37 7 CFR 1033.1, see also https://dairymarkets.org/pubPod/pubs/AMS-559.pdf
- 38 7 CFR 1000.4
- 39 7 CFR 1000.9
- 40 7 CFR 1030.10, 1032.10
- 41 7 USC 1637, 7 CFR 1170
- 42 You can find more information about mandatory dairy reporting on USDA's website: https://www.ams.usda.gov/rules-regulations/mmr/dmr
- 43 7 CFR 58.122
- 44 ORC 917.02(1)(a)

may advise and make recommendations to ODA and approve or disapprove agreements between ODA and any public or private entity.⁴⁵

Ohio has largely adopted the PMO which covers every aspect of the Grade A dairy industry, including animal health, dairy farm and plant construction and inspections, standards for milk and milk products, pasteurization, drug residue testing, equipment specifications, transportation, product labeling, and more. Ohio has adopted most, but not all of the PMO, omitting or amending sections or parts of sections dealing with topics such as adulterated or misbranded products, permits, drug residue testing and surveillance, sanitation, equipment, inspection guidelines, animal health, and compliance enforcement procedures.⁴⁶ Anyone looking to produce, process, and sell Grade A dairy products should acquaint themselves with the PMO and these exclusions or amendments as applied to the product they would like to produce or sell.

ODA recommends that anyone looking to process dairy products on the farm begin by considering the following topics:⁴⁷

- Separate rooms: Milk and milk products must be handled in separate rooms. A milk house or a private residence may not be used as a separate room for these purposes.
- **Pasteurization:** Dairy products, including fluid milk, must be properly pasteurized prior to being offered for sale to consumers. Pasteurization is the process of heating every particle of milk or milk product, in properly designed and operated equipment, to the appropriate temperature for a minimum of the specified time.⁴⁸ For example, when using Batch (Vat) Pasteurization, Grade A milk must be heated to 63°C (145°F) for at least 30 minutes, and when using Continuous Flow Pasteurization:

TEMPERATURE	TIME
72ºC (161ºF)	15 seconds
89°C (191°F)	1.0 seconds
90°C (194°F)	0.5 seconds
94°C (201°F)	0.1 seconds
96°C (204°F)	0.05 seconds
100°C (212°F)	0.01 seconds

Note, if the fat content of the milk is 10% or greater, a totalsolids of 18% or greater, or contains added sweeteners, the temperature must be increased by $3^{\circ}C$ ($5^{\circ}F$). Grade A pasteurized milk must then be cooled and maintained at a temperature of 7°C ($45^{\circ}F$).⁴⁹

- 46 OAC 901:11-1
- 47 See https://agri.ohio.gov/divisions/dairy/new-producers-and-processors
- 48 21 CFR 131.3(b), PMO Section 1, RR (PDF page 35), OAC 901:11-1-02(A)
- 49 PMO section 7 table 1

^{36 21} CFR 1240.61

⁴⁵ ORC 917.03, 917.031



- **Drug residue testing:** Dairy processors are required to test for drug residue as well as certain bacteria. Grade A Milk samples submitted for testing must not exceed the bacterial limit of 20,000 per mL, the coliform limit of 10 per mL, the phosphate limit of 350 milliunits/L, and a drug residue limit of 0.⁵⁰
- Filling and capping of containers: All dairy product containers must be mechanically filled and capped. No hand capping is allowed.
- Source of the milk: Licensed dairy processors must receive their milk from a licensed and inspected dairy.⁵¹ If a producer would like to make and sell Grade A products, then they must also be licensed as a Grade A producer.

Manufactured Milk Products

A manufactured milk product is any milk product, other than raw milk, for sale to the ultimate consumer and Grade A milk products that are derived from milk and are for human consumption.⁵² This includes butter, natural or processed cheese, frozen desserts, and evaporated, condensed and dry products.⁵³ Ohio Manufacture Milk Rules are separate from the Grade A milk requirements that rely heavily on the PMO, adopting only a select few provisions of the PMO standards.⁵⁴ Although manufacture milk product production is not required to adhere to quite as stringent standards as those found in the PMO, this does not mean manufacture milk producers are not required to meet any standards in those areas. The Ohio Administrative Code addresses the standards for animal health, facility construction, water, sewage, equipment, cleanliness, sanitization, storage, hygiene, somatic cell counts, drug residue

52 ORC 917.01(M)

53 Id

level and pasteurization that are not covered by state or federal law.

Anyone looking to process Manufacture Milk products under a Manufacture Milk License must obtain their milk from a Manufacture Milk licensed production facility and comply with the applicable Manufacture Milk rules found in OAC 901:11-2-01 through 901:11-2-44. Some processing facility rules dealing with facility requirements to be aware of:

- Proper building construction, considering things like the floors, lighting, ventilation, temperature and climate control, separate room requirements, storage and the ability to sanitize surfaces.⁵⁵
- Adequate and compliant water supply properly located, the ability to provide steam, and proper disposal of waste.⁵⁶
- Properly designed and installed equipment specific to your operation that is able to be adequately cleaned and sanitized in a manner meeting rule standards.⁵⁷

The pasteurization of Manufacture Milk products must comply with the applicable portions of item 16p of the PMO.⁵⁸ The required timing, location, and/or method of heat treatment or pasteurization may differ based on the intended final product the milk will be used for.⁵⁹ In addition to specific pasteurization requirements, Manufacture Milk rules also provide additional or substitute product specific requirements for processors. Examples of these item specific regulations include rules regulating cheese production and rules regulating frozen dessert production. Examples of these specific rules include:

• Cheese:

 Cooking: Each batch of cheese must be cooked in suitable equipment and must be thoroughly comingled and

⁵⁰ PMO Section 7 table 1

⁵¹ ORC 917.01(L), see also the PMO

^{54 901:11-2-04(}B); 901:11-2-21(A)(2),(C),&(F); 901:11-2-26(B)&(I)

⁵⁵ OAC 901:11-2-20

⁵⁶ OAC 901:11-2-21

⁵⁷ OAC 901:11-258 OAC 901:11-2-26(B)

⁵⁹ ld

cooked at a temperature of at least 158 degrees Fahrenheit for at least 30 seconds. No ingredients can be added to the cheese after the batch has reached the final temperature, and the cheese must be emptied as soon as possible once heating is complete.⁶⁰

- Packaging: Different room specifications may apply based on the type of cheese being produced. Requirements may include adequate room sizing, separate packaging areas, temperature controls, cooling/curing room cleanliness, and higher sanitary standards.61
- Equipment: In addition to general equipment requirements, specific construction and sanitation standards apply to equipment specific to cheese production (i.e. cheese vats, mechanical agitators, cheese press, and so on).62
- Operating Procedures: In addition to the general requirements, specific sanitation requirements, construction standards and filling procedures for containers to be used in cheese processing may apply.63

• Frozen Dessert:⁶⁴

- Pasteurization: Separate temperature and time requirements apply to the pasteurization of frozen desserts.65 Unless product is being transported in an acceptable "tote" as defined by ODA, pasteurization must occur at the milk plant where the retail packaging occurs.66 Milk, egg, cocoa, emulsifiers, stabilizers, vitamins, and liquid sweeteners should be added prior to pasteurization unless otherwise approved by ODA.67
- Equipment: Frozen dessert processing requires quick freezer rooms for rapid and complete freezing within 24 hours.68
- HACCP: Frozen dessert manufacturers must have a hazard analysis and critical control point plan.69
- SSOP: Frozen dessert manufacturers must have a written sanitation standard operating procedure that is specific to the facility.70

Labeling

All dairy products must be identified during processing, and packaged products must be labeled in accordance with Ohio's dairy product laws,⁷¹ Ohio's pure food and drug laws,⁷² and the "Nutrition Labeling and Education Act of 1990,"73 as amended

- 60 OAC 901:11-2-26
- 61 OAC 901:11-2-28(O)-(T)
- 62 OAC 901:11-2-36 63 OAC 901:11-2-38
- 64 OAC 901:11-3 65 OAC 901:11-3-05
- 66 ORC 917.10, OAC 901:11-2-26(H), 901:11-3-05(D) 67 OAC 901:11-3-05(B)
- OAC 901:11-2-29(D) 68
- 69 OAC 901:11-3-06
- 70 OAC 901:11-3-10
- 71 ORC 917
- 72 ORC 3715
- 21 USC 343 73

and regulations adopted under it.74 Label requirements will vary based on the final product, though producers should generally be prepared to provide information such as:75

- The name of the product in compliance with the relevant prescribed standard of identity.76
- The net quantity of contents.⁷⁷ •
- The name and address of the packer, manufacturer, or distributor.78
- A list of ingredients in descending order if the packaged food consists of more than two ingredients, including identification of any major food allergens.79

Small businesses are generally exempt from nutritional labeling; however, producers should be mindful of the fact that this exemption will no longer apply if a nutrient claim is made.80

Sale

In order to sell dairy products directly to consumers, a producer must first obtain a Retail Food Establishment License. This means that a farm market that would like to offer milk or cheese for sale must be licensed with their local health department. For more information about the RFE license, please see page 9.

Contacts and Resources

Ohio Department of Agriculture Dairy Division Phone: (614) 466-5550 Email: dairy@agri.ohio.gov Web: ofb.ag/odadairy

Additional Resources

Pasteurized Milk Ordinance: ofb.ag/pasteurizedmilk

Ohio Revised Code Chapter 917 (Dairy Law): ofb.ag/chapter917orc

Ohio Administrative Code Section 901:11 (Dairy Rules): ofb.ag/chapter90111orc

74 ORC 917.11

- 76 21 CFR 101.3. Standards of identity can be found in OAC 901:11-5; 21 CFR 130, 131,
- 133 & 135; PMO Appendix L 77 21 CFR 101.7. See also 21 CFR 1.24, 21 CFR 101.100 for exemptions.
- 78 21 CFR 101.5
- 79 21 CFR 101.4
- : 80 21 CFR 101.9

^{75 21} CFR 101