# Ohio Farm Bureau Small-Scale Food Business Guide





A MEMBER BENEFIT for OHIO FARM BUREAU MEMBERS

# **Contents**

Introduction	Pesticides
Adulterated and Misbranded Food4	State Law
Relevant Federal & State Government Agencies 7	Package and Labe
-	Sale
Ohio Licensing and Registration9	Am I covered by
Retail Food Establishments 9	Contact
Retail Food Establishment License	
Ohio Department of Agriculture Licensing 10	Ciders and Juices
Farm Market and Farm Product Auction Registration 10	Regulation
Food Processing Establishment Registration 12	Packaging and La
Contacts & Resources	Label Example
	Checklist
Cottage Foods	Contact List & Re
Regulation	
What are Cottage Foods?	Eggs
Packaging	Regulations
Labeling	State
Sale	Package and labe
Label Example	Sale
Accepted Collective or Generic Name Table*	Checklist for Sma
Starting from Scratch	Contacts & Resor
Contacts for Cottage Foods	More Sources
Contacts for Cottage 1 cods	wiore sources
Home Bakery - Refrigerated Baked Goods	Selling Raw Meat
Regulation	General Informat
Products	Livestock Care St
Packaging	Animal Diseases.
Label	Ante-Mortem Ins
Label Example	Post-Mortem Ins
Home Bakery Contact Information	Harvesting and P
Starting from Scratch	Licensing an
	I Have Livestock;
Honey, Maple Syrup, and Sorghum	Selling Frozen Liv
Honey	Exemptions from
Maple Syrup	Marketing
Sorghum	Selling Raw Poul
Regulation for Honey, Maple Syrup, and Sorghum 28	Selling Frozen Po
Facilities and Equipment	Regulation
Packaging	Fully Inspected C
Labels	Exemptions from
Label Example: Honey	Poultry Specific F
Label Example: Syrup	Is it okay to slaug
Checklist for Exempt Maple Syrup, Honey,	my poultry o
and Sorghum Producers	Marketing/Label
Sale	Contacts and Res
Contacts & Resources	Contacts and Res
Contacts & Resources	Dairy
	Licensing
	Regulation

Fresh Unprocessed Fruits and Vegetables	33
FSMA Regulations	33
FSMA Exemptions	34
Pesticides	34
State Law	35
Package and Label	35
Sale	35
Am I covered by FMSA?	36
Contact	36
Ciders and Juices	37
Regulation	
Packaging and Label	38
Label Example	
Checklist	
Contact List & Resources	40
Eggs	41
Regulations	
State	
Package and labeling	
Sale	
Checklist for Small Egg Producers	
Contacts & Resources	
More Sources	
112010 0041000	
Selling Raw Meat	45
General Information	
Livestock Care Standards	
Animal Diseases.	
Ante-Mortem Inspection of Animal Health	
Post-Mortem Inspection of Carcass	
Harvesting and Processing Facility	1/
Licensing and Inspection	47
I Have Livestock; What are My Options?	
Selling Frozen Livestock/Red Meat	
Exemptions from Fully Inspected Facility Requirement	
Marketing	
Selling Raw Poultry	
Selling Frozen Poultry Meat	
Regulation	
Fully Inspected Operation	
Exemptions from Fully Inspected Facility Requirement	
Poultry Specific Exemptions	
Is it okay to slaughter and process	37
my poultry on the farm? Chart	57
Marketing/Label	
Contacts and Resources	
Contacts and resources	57
Dairy	61
Licensing	
Regulation	
Labeling	
Sale	
Contacts & Resources	
	_
Appendix	67

### Introduction

Farm-to-table type home-based products are an increasingly popular concept that hold a large window of opportunity for farm owners looking to expand their businesses. While the concept of selling home-based foods may be enticing, getting started can be a daunting task. The laws and rules surrounding the production and sale of food products come from many different sources, both state and federal, often creating a confusing and hard to navigate regulatory space. The purpose of this guide is to aid Ohio Farm Bureau members in identifying the food safety regulations that are relevant to their businesses.

Unless otherwise specified, this guide focuses on the small-scale home production of food items for sale within Ohio and the exemptions to the general licensing and registration that may apply.

Within each section, you will see footnotes citing the applicable code or rule section. The Ohio Revised Code and Ohio Administrative Code are both accessible at http://codes.ohio.gov. Federal regulations are available at http://fmcsa.dot.gov.

Please note this publication is a service to the members of the Ohio Farm Bureau Federation and should be used for informational purposes only. This publication is not intended to provide, nor should it be considered, legal advice. If you have a question regarding food marketing regulations, we hope this publication can assist you. However, this publication cannot serve as a substitute for legal advice from a competent attorney who can provide information based upon the specific facts of your situation. Food safety laws change frequently, both in substance and interpretation. There is no guarantee regarding the accuracy or reliability of the information contained within this publication.

This guide is not intended to be, nor should it be considered as, a substitution for the regulations cited. For specific text of regulations, visit http://fmcsa.dot.gov and http://codes.ohio.gov.



In this guide you will find an overview of the regulatory requirements involved in producing food for sale. While food safety regulations are a large part of operating a food production business, these are not the only legal requirements that new business owners should consider. Some additional questions those wanting to start a new market business should consider include:

## Have I considered what business structure might be best for me?

- There are several options for people to consider when it comes to structuring their business. Different business structures will have different characteristics, legal requirements, and tax implications.
- You can find information on starting, maintaining, or dissolving a business on the Ohio Secretary of State's website: ofb.ag/businessinformation.

#### Have I considered my liability?

 Businesses offering food they have produced on their own farm can encounter a number of different circumstances that can create liability. Risks from a market business can range from a product liability claim arising from a

- contaminated product, to a premise liability claim arising from a fall on the property.
- Individuals looking to sell food products should reach out to their insurance provider to ensure they are covered for all the risks they may encounter in their new food business venture. Ohio Farm Bureau Select Partners are independent insurance and financial service agencies endorsed by county Farm Bureaus and focused on serving the agricultural industry. You can find agency information for a Select Partner in your area at ofbf.org/membership/tools-and-resources/select-partners.

#### Have I researched my local zoning laws to make sure I do not violate them?

- To avoid zoning violations, it is important to make sure the use of a piece of land for the sale of your product is a permissible use under your local zoning code. Municipalities have a pretty broad authority to limit the use of land, including prohibiting the use of land for agricultural activities. County and township zoning officials generally do not have the authority to regulate agricultural activities, including a farm market where 50% or more of the gross income received from the market is derived from produce raised on farms owned or operated by the market operator in a normal crop year. However, local zoning officials may regulate farm market factors such as size of structures, parking areas, set back building lines, and egress or ingress where that regulation is necessary for public safety.
- You can find more information about zoning in the "Zoning and Land Use" portion of our Landowner Toolkit available on ofb.ag/landownertools.

#### Have I identified my tax requirements?

- Taxation requirements may vary based on factors such as your business structure, the items you are selling, how much revenue you are generating, if you have employees, and your location.
- For more information about federal tax requirements please visit IRS.gov, and for more information about Ohio tax requirements, please visit tax.ohio.gov.

#### Have I researched labor laws as they apply to my business?

- Businesses that choose to hire individuals as they grow should familiarize themselves with labor laws. Minimum wage, child labor laws, and employer liability are just some of the labor law topics employers should be aware of.
- When looking for introductory information about Ohio labor laws, ohio.gov can be a good place to start.

#### Are there any environmental, waste, or livestock permits that apply to my operation?

Especially when dealing with large numbers of livestock, producers may need to meet certain requirements to

- ensure the safety of the environment and the animals.
- For more information about managing environmental safety, please visit the Ohio Department of Agriculture's website at agri.ohio.gov and the Ohio Environmental Protection Agency's website at epa.ohio.gov.

#### **Adulterated and Misbranded Food**

State and federal law prohibits the manufacture, sale, holding or offering for sale any food product that is adulterated or misbranded.1 Violations of the prohibition against the introduction of adulterated or misbranded foods into commerce can lead to criminal charges, fines, and imprisonment.<sup>2</sup> Elements considered when determining whether or not a food product is adulterated or misbranded may vary by food item, so food producers need to ensure they are aware of the standards that apply to the specific food they would like to offer for sale.

#### State Law Definitions

Adulterated Food:<sup>3</sup> Food is adulterated if any of the following apply:

- It contains any poisonous or deleterious substance that may render it injurious to health; but in case the substance is not an added substance, the food shall not be considered adulterated if the quantity of the substance in the food does not ordinarily render it injurious to health.
- It contains an added poison or deleterious substance required to make the product, but the amount is beyond the acceptable limit.
- It consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.
- It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered diseased, unwholesome, or injurious to health.
- It is the product of a diseased animal or an animal that has died otherwise than by slaughter, or an animal that has been fed upon the uncooked offal from a slaughterhouse.
- Its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.
- Any valuable constituent has been, in whole or in part, omitted or abstracted from the food.
- Any substance has been substituted wholly or in part for the food.
- Damage or inferiority has been concealed in any manner.
- Any substance has been added to or mixed or packed with the food so as to increase its bulk or weight, reduce its quality or strength, or make it appear better or of greater value than it is.
- 21 USC 331, ORC 3715.52(A)
- 21 USC 333, ORC 3715.99
- ORC 3715.59

- It is confectionery and it bears or contains any alcohol or non nutritive article or substance other than harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of one percent, harmless natural wax not in excess of four-tenths of 1%, harmless natural gum, or pectin, except that this division shall not apply to any confectionery by reason of its containing less than one-half of 1% by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.
- It bears or contains an unacceptable coal-tar color other than one that has been certified under the authority of the Federal Food, Drug, and Cosmetic Act.
- It has been produced by a cottage food operation and is acidified, a low acid canned food, or a potentially hazardous food.

#### Misbranded Food: Food is misbranded when:

- Its labeling is false or misleading in any particular way.
- It is offered for sale under the name of another food.
- Its container is so made, formed, or filled as to be misleading
- It is an imitation of another food, unless its label bears in type of uniform size and prominence, the word "imitation," and immediately thereafter the name of the food imitated.
- When it is in packaged form, it does not have a label identifying:
  - The name and place of business for the producer.
  - An accurate statement of the contents in terms of quantity.
  - For cottage food if the label does not contain all of the required elements specified by the revised code (see cottage food section).
- Any word, statement, or other information required by law to appear on the package is not prominently placed in such a way that would make it easily read and understood by the consumer.
- It proports to be, or is represented as, a food for which a
  definition and standard of identity have been prescribed by
  statute or rule, unless:
  - It conforms with such definition and standard.
  - It bears the name of the food specified in the definition and standard as required by law, and the common names of optional ingredients other than spices, flavoring, and coloring present in the food.
  - (This provision does not apply unless it bears labeling clearly giving the common or usual name of the food or, in the case it is fabricated from two or more ingredients, the common or usual name of each ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings, without naming each.)

- It proports to be or is represented as:
  - A food for which a standard of quality has been prescribed by rule or law and its quality falls below the standard unless its label bears, in the manner and form that the rules specify, a statement that it falls below the standard.
  - A food for which standards of fill container has been prescribed by law and it falls below the standard unless its label bears, in the manner and form that the rules specify, a statement that it falls below the standard.
- It purports to be or is represented to be for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as provided by ODA rules.
- It bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact; provided, that to the extent that compliance with the requirements of this division is impracticable, exemptions will be established by ODA.

#### Federal Law Definitions

Adulterated Food:<sup>5</sup> A food shall be deemed to be adulterated if:

- It bears or contains any poisonous or deleterious substance which may render it injurious to health, but if the substance is not an added substance and is of a quantity that does ordinarily render it injurious to health then the food is not adulterated.
- It bears or contains any added poisonous or deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that has been deemed unsafe, or the quantity present goes beyond the acceptable safe limit.
- It bears or contains a pesticide chemical residue that is unsafe or in an amount beyond the tolerance level.
- It bears or contains any food additive or new animal drug that is unsafe or is present in a level that has been deemed unsafe.
- It consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.
- It has been prepared, packed, or held under insanitary conditions where it may have become contaminated with filth, or where it may have been rendered injurious to health.
- It is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter.
- The container is composed, in whole or in part, of any
  poisonous or deleterious substance which may render the
  contents injurious to health.
- It has been intentionally subjected to radiation, unless the
  use of the radiation was in conformity with a regulation or
  exemption found in the law.

ORC 3715.60 5 21 USC 342

- When any valuable constituent has been in whole or in part omitted or abstracted from the food.
- When any substance has been substituted wholly or in part.
- When a damage or inferiority has been concealed in any manner.
- When any substance has been added, mixed, or packed so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it
- It is, or it contains, a color additive deemed unsafe.
- It is a confectionery and
  - has partially or completely imbedded therein any nonnutritive object, unless such object is deemed to be of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;
  - bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts, unless allowable under state law;
  - bears or contains any non nutritive substance, unless it is a safe non nutritive substance present for some practical functional purpose.
- It is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.
- It is a dietary supplement or contains a dietary ingredient
  - presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.
  - is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.
  - has been declared as an imminent hazard to public health
  - is or contains a dietary ingredient that renders it adulterated.
- It is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations.
- It is an article of food imported or offered for import into the United States and the article of food has previously been refused admission

It is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with regulations.

**Misbranded Food:**<sup>6</sup> A food shall be deemed to be misbranded if:

- Its labeling is false or misleading in any way.
- Its advertising is false or misleading in a material respect or its labeling is in violation of the law.
- It is offered for sale under the name of another food.
- It is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.
- Its container is so made, formed, or filled as to be misleading.
- Its package does not contain a label with (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, unless exempt by law.
- Any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- It purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations and does not conform with that definition or standards.
- It purports to be or is represented as a food for which a standard of quality or standard of fill of container has been prescribed by regulations and it does not meet those standards.
- It purports to be a food that is pasteurized and it has not been properly pasteurized.
- The nutritional information is not present (when required) or not in compliance with the nutritional information requirements found in 21 USC 343(r).
- It does not disclose major allergens when required.

#### **Relevant Federal & State Government Agencies**

Food and Drug Administration (FDA)

The FDA is a federal agency in charge of protecting and promoting public health by ensuring the safety of the United States' food supply. This includes all domestic and imported foods sold across state lines, including eggs, but not including meat and poultry. Through the promulgation of rules, the FDA establishes production standards, inspection requirements, model guidelines, and food safety standards for states to use when implementing food safety regulations in their state.

Unless otherwise exempt, any owner, operator, or agent in charge of a domestic or foreign facility that is engaged in the manufacturing /processing, packing, or holding of food for consumption in the United States must register with the FDA, regardless of whether or not the food enters interstate commerce. Exemptions from this rule include farms, retail food establishments, restaurants, certain nonprofit food establishments, fishing vessels, and facilities that are regulated exclusively through the USDA under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act. The following definitions found in the Code of Federal Regulations are important to know for the purposes of this guide:

- Farm: A primary production farm that is an operation under one management in general and devoted to the growing of crops, the harvesting of crops, the raising of animals, or a combination thereof. This includes operations that hold/ pack agriculture commodities or hold/pack processed food consumed on the farm. This definition also includes farms that manufacture or process foods through drying/ dehydration, treatment to manipulate ripening, and packaging and labeling raw commodities.<sup>9</sup>
- Restaurant: A facility that prepares and sells food directly
  to consumers for immediate consumption. This does not
  include facilities that provide food to interstate conveyances,
  central kitchens, and other similar facilities that do not
  prepare and serve food directly to consumers.<sup>10</sup>
- Retail Food Establishment: An establishment that sells food
  products directly to consumers as its primary function.
  This includes facilities that manufacture, process, pack,
  or hold food if the establishment's primary function is
  to sell from that establishment food, including food that
  it manufactures, processes, packs, or holds, directly to
  consumers. A retail food establishment's primary function
  is to sell food directly to consumers if the annual monetary
  value of sales of food products directly to consumers
  exceeds the annual monetary value of sales of food products
  to all other buyers. It also includes certain farm-operated

businesses selling food directly to consumers as their primary function (i.e. roadside stands, farmers markets, and other direct-to-consumer sales platforms).<sup>11</sup>

Depending on the type of food a person would like to produce and sell, navigating when a food facility may or may not be exempt from FDA registration can be confusing. Registration with the FDA must occur prior to when any facility operations occur to create food for human consumption. A private residence, meaning a home without commercial facilities, is not a "facility" for the purposes of FDA Food Facility registration. If a home or buildings on a home property (i.e. a detached garage) have been modified to the extent that it no longer meets the customary expectations for use as a private home, the facility must then register.

Registration is free, can be done online and it must be renewed every other year and updated as needed. Failure to register or renew registration can result in criminal charges. Facilities are able to apply for a waiver by submitting a written request explaining why it is not reasonable for them to submit registration, registration renewal or updates, or registration cancellation.

For more information about the FDA, visit FDA.gov

#### U. S. Department of Agriculture (USDA)

The USDA Food Safety and Inspection Service is the agency responsible for monitoring the safe and wholesome production of all meat, poultry, and processed egg products that enter interstate commerce. This regulatory power comes from four federal acts 1) the Federal Meat Inspection Act, 2) the Poultry Products Inspection Act, 3) the Eggs Products Inspection Act, and the Humane Methods of Slaughter Act. USDA FSIS inspected facilities undergo consistent inspection to ensure the facilities and the products that they produce adhere to rules that meet U.S. food safety standards. To prevent foodborne illnesses, USDA FSIS rules require inspected facilities to implement approved Hazard Analysis Critical Point (HACCP) plans and sanitation programs.

USDA provides rules for and inspects the proper labeling of meat and poultry products, providing parameters for what must be present and what may not be present. Additionally, USDA provides voluntary grading, certification, and verification services to provide standards and guidelines to producers of agricultural commodities looking to "guarantee" the quality and wholesomeness of their product.

For more information about the USDA, visit USDA.gov.

<sup>11</sup> ld

<sup>12 21</sup> CFR 1.230

<sup>13</sup> See guidance https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-facility-registration-seventh-edition

<sup>14</sup> ld

<sup>15 21</sup> CFR 1.230, 1.231

<sup>16 21</sup> CFR 1.241

<sup>17 21</sup> CFR 1.245, see https://www.fda.gov/food/online-registration-food-facilities/food-facility-registration-user-guide-step-step-instructions-registration

<sup>8 21</sup> CFR 1.226 9 21 CFR 1.227

<sup>10</sup> lo

#### Ohio Department of Agriculture

ODA is responsible for ensuring the safety of the state's food supply and the health of Ohio's food animals and plant life, and to create economic opportunities for Ohio's farmers, food processors and agribusinesses. Within the ODA are various divisions that take charge of monitoring the regulation of the different aspects of agriculture. The divisions relevant to this guide include:

- The Division of Food Safety
- The Division of Dairy
- The Division of Meat Inspection
- The Division of Animal Health

As you will see in this guide, each division will have its own mission centered around ensuring the safety of Ohio's food supply.

For more information about ODA, please visit agri.ohio.gov.

#### Ohio Department of Health

Together with local health districts, the Ohio Department of health works to advance public health and safety. The ODH Food Safety Program provides assistance to the local health departments as they administer the rules found in Ohio's Uniform Food Safety Code. Local health districts/health departments are responsible for overseeing Ohio's Retail Food Establishments, which is every non-exempt facility that stores, processes, prepares, manufactures, or otherwise holds food for sale to consumers. ODH's Food Code Reference Guide provides helpful summaries for those looking to get an overview of the food safety code: ofb.ag/odhfoodcode. For more information about ODH, please visit odh.ohio.gov.

# Ohio Licensing and Registration

Selling homegrown or homemade products is a fun, hands-on way to generate more revenue from your farm. As exciting as it is to make that first sale, farmers need to first make sure they have met all of the appropriate licensing and registration requirements. These requirements will vary based on the product/products an individual would like to sell. This chapter will acquaint you with the various food processing related licensing or registration requirements found within this guide. For a more in-depth look at the specific regulations for the various food items, please proceed to the relevant chapters.

#### **Retail Food Establishments**

With the aid of 113 local health departments, the Ohio Department of Health and the Ohio Department of Agriculture work to protect and promote the health of Ohio communities. Local health departments maintain independent governance, so any person wishing to apply for a retail food establishment license will need to reach out to their local health department. While there are certain standards and requirements set by the state for retail food establishments, there may be some variation in rules between the local departments.

#### **Retail Food Establishment License**

Unless otherwise exempt, any entity that stores, processes, prepares, manufactures, or otherwise holds food for sale to consumers must obtain a retail food establishment license from their local health department. The following categories are the establishments relevant to this guide that are exempt from the retail food licensing requirement under specific circumstances:

- A person at a farmers market that offers for sale fresh unprocessed produce, products of a cottage food operation, tree syrup, sorghum, honey, commercially prepackaged foods, apple syrup, and/or apple butter;
- A person who offers for sale at a roadside stand only fresh fruits and fresh vegetables that are unprocessed;
- A cottage food production operation, on the condition that the operation offers its products directly to the consumer from the site where the products are produced;
- 1 ORC 3717.21, 3717.01(C)
- 2 ORC 3717.22(B)



- A tree syrup and sorghum processor, beekeeper, or apple syrup and apple butter processor that sells directly to the consumer from the site of production;
- A person who annually maintains 500 or fewer birds, on the condition that the person offers the eggs from those birds directly to the consumer from the location where the eggs are produced;
- A person who annually raises and slaughters 1,000 or fewer chickens, on the condition that the person offers dressed chickens directly to the consumer from the location where the chickens are raised and slaughtered;
- A person who raises, slaughters, and processes the meat
  of nonamenable species, on the condition that the person
  offers the meat directly to the consumer from the location
  where the meat is processed;
- A properly registered farm market or farm product auction. Retail food establishment applications are submitted to an entity's local health department for review and approval. An application for a license must be filed at least 10 days prior to an establishment opening for business and include information about the facility layout and equipment specifications.<sup>3</sup> In addition to asking for information about plumbing, lighting, and food surface materials, applications will also ask for information about the type of food a facility would like to offer.

There are several categories of Retail Food Establishment licenses, varying by the size, risk level, mobility, and permanence of the facility applying.<sup>4</sup> There are four risk levels an establishment may be categorized as, with the entire establishment risk level being based on the highest risk level food present.5

- Risk level I poses potential risk to the public in terms of sanitation, food labeling, sources of food, storage practices, or expiration dates.
  - Example: self service drinks, fresh unprocessed fruits and vegetables, pre-packaged refrigerated or frozen time/temp controlled for safety food, and food delivery operations.
- Risk level II poses a higher potential risk to the public than risk level I because of hand contact or employee health concerns but minimal possibility of pathogenic growth exists.
  - Example: handling, heat treating, or preparing non-time/ temperature controlled food for safety; or hand dipping of commercially manufactured ice cream.
- Risk level III poses a higher potential risk to the public than risk level II because of the following concerns: proper cooking temperatures, proper cooling procedures, proper holding temperatures, contamination issues or improper heat treatment in association with longer holding times before consumption, or processing a raw food product requiring bacterial load reduction procedures in order to sell the product as ready-to-eat.
  - Example: handling, cutting, or grinding raw meat; cutting or slicing ready-to-eat meats and cheeses; or operating soft serve ice cream machines.
- Risk level IV poses a higher potential risk to the public than risk level III because of concerns associated with: handling or preparing food using a procedure with several preparation steps that includes reheating of a product or ingredient of a product where multiple temperature controls are needed to preclude bacterial growth.
  - Example: operating a heat treatment dispensing freezer, catering, using a freezer for parasite destruction, or performing activities requiring a HACCP plan.
  - The categories a license may fall under include:6
- Retail food establishments, including micro markets, in which the interior premises is under 25,000 square feet for each risk level.
- Retail food establishments in which the interior premises is 25,000 square feet or more for each risk level.
- Temporary retail food establishments as a per event fee or as a per day fee.
- Mobile retail food establishments and low risk mobile retail food establishments.

A renewal application must be submitted every year between February and March,<sup>7</sup> and fees for the licensing process will vary by health district and specific facility licensing and inspection needs.8 Facility inspection frequency will depend on the risk level of the food establishment, though inspections will occur every 15 months at a minimum. In order to pass inspections, facilities must be constructed, equipped, and managed in a manner that complies with both Ohio's Uniform Food Safety Code and RFE regulations applicable to your operation.<sup>10</sup> Licensure denials, suspensions, or revocations may be appealed to the licensor, with a hearing conducted by a hearing officer.11

A mobile retail food establishment is a retail food establishment that operates from a movable vehicle or other portable structure that routinely changes location. 12 Mobile retail food establishments only need to receive their license from the local health district where they are headquartered and this license may be used to serve food anywhere in Ohio.<sup>13</sup> Mobile retail food establishments are subject to inspection by the licensing authority of any area they operate regardless of where they obtained their license.14 Establishments that operate from any one location for more than 40 consecutive days will no longer be eligible to be licensed as a mobile retail food establishment. Mobile retail food establishments are a popular option for those looking to sell frozen meat directly to consumers in locations such as a farmers' market.

Anyone interested in more information about retail food establishment licensing should reach out to their local health department, which can be found online here: ofb.ag/odhgateway.

#### Ohio Department of Agriculture Licensing

Division of Food Safety

Through the Division of Food Safety, the Ohio Department of Agriculture helps to protect consumers from unsafe, adulterated, or mislabeled foods. Farms that wish to produce, process, and sell food items should acquaint themselves with both the voluntary and required registrations available through ODA prior to selling food to consumers to ensure food quality and avoid penalties.

#### **Farm Market and Farm Product Auction Registration**

Farm markets and farm product auctions are a great way to directly market products to consumers. Individuals looking to sell farm and home sourced food from either their own facility or in a farmers market location should consider the rules and regulations specifically governing the operation of these markets to ensure they are compliant with the law. Elements

- ORC 3717.43, OAC 3701-21-02
  - 8 ORC 3717.25
  - 9 OAC 901:3-4-06
  - 10 ORC 3717.05, OAC 901:3-4-07, 3717-1
  - 11 OAC 901:3-4-08
  - 12 ORC 3717.01(O)
  - 13 ORC 3717.23 : 13 One 3. : 14 ORC 3717.26

- OAC 901:3-4-03
- OAC 901:3-4-05
- OAC 901:3-4-03

such as cleanliness and food safety must not be overlooked when selling food items to consumers.

A **Farm Market** is a producer operated facility where only the following are offered for sale:

- Fresh unprocessed fruits or vegetables;
- Products of a cottage food production operation;
- Maple syrup, sorghum, or honey that is produced by a maple syrup or sorghum producer or beekeeper;
- Commercially prepackaged food that is not potentially hazardous, on the condition that the food is contained in displays, the total space of which equals less than 100 cubic feet on the premises where the person conducts business at the farm market;
- Cider and other juices manufactured on site at the farm market;
- Raw eggs, raw poultry, and raw non-amenable meat on the condition that those products were produced by the farm market operator, and further conditioned that, with respect to the eggs offered from the location where the eggs are produced, the farm market operator annually maintains 500 or fewer poultry, and with respect to the dressed poultry offered from the location where the poultry is raised, the farm market operator annually raises and slaughters 1,000 or fewer poultry.<sup>15</sup>

A **Farm Product Auction** is a location where agricultural products, including food products, are offered for sale at auction. Farm product auctions may offer for sale:

- Raw eggs, raw poultry, or raw non-amenable meat species on the condition that, with respect to the eggs offered, the producer annually maintains 500 or fewer poultry, and with respect to the dressed poultry, the producer annually raises and slaughters 1,000 or fewer poultry.
- · Fresh unprocessed fruits or vegetables;

Separate from farm markets, farmers markets that sell only one or more of the following are exempt from RFE licensing:

- · Fresh unprocessed fruits or vegetables;
- Products of a cottage food production operation;
- Tree syrup, sorghum, honey, apple syrup, or apple butter that is
  produced by a tree syrup or sorghum producer, beekeeper, or apple
  syrup or apple butter processor;
- · Certain authorized wines; and
- Commercially prepackaged food that is not potentially hazardous, on the condition that the food is contained in displays, the total space of which equals less than one hundred cubic feet on the premises where the person conducts business at the farmers market.

Farmers markets that fall under this exemption are also not required to register with ODA. Farmers markets that would like to sell items outside of this scope will need to look into licensing requirements from their local health department and/or ODA Food safety.

- Products of a cottage food production operation;
- Maple syrup, sorghum, or honey that is produced by a maple syrup or sorghum producer or beekeeper.

In order to ensure consumer safety and avoid penalties, farm market and farm product auction operators must, at a minimum, abide by the rules set forth and enforced by ODA. Operators must grant ODA inspectors access to the premises to allow for inspection and supply records to inspectors when requested. If an inspector identifies a food product being sold outside of the scope of the allowable farm market or farm product auction exempt food, then the inspector will refer the facility to the local health department for an RFE license. RFE licensed facilities may still voluntarily register with ODA as a farm market or farm product auction. Compliant farm markets and farm product auctions will observe the following general practices (in addition to other item specific regulations that may be needed): 19

- Food is obtained from legally compliant sources;
- Food is properly labeled in an honest manner with no misleading information;
- All unsafe, adulterated, or mislabeled food is discarded;
- Food is protected from contamination;
- Food is not displayed or stored on the ground (unless it is a whole raw agricultural product);
- Eggs are sound, clean, and maintained at 45 degrees Fahrenheit;<sup>20</sup>
- Ice used as a cooling medium is made with either municipal water or water that is regularly inspected for coliform;<sup>21</sup>
- Poultry and non-amenable meats are maintained at a frozen or internal temperature of 41 degrees Fahrenheit or less;<sup>22</sup>
- Foods that require refrigeration are held in mechanical refrigeration at the proper temperature.<sup>23</sup>
- Facilities and equipment are maintained and clean.<sup>24</sup>
- Toilet facilities must be readily accessible to the farm market of farm product auction personnel.<sup>25</sup>
- Market personnel observe proper handwashing procedures and there must be access to municipal or an otherwise compliant source for hand washing.<sup>26</sup>

If a farm market or farm product auction offers raw poultry, non-amenable meats or both, the facility must properly sanitize utensils and food contact surfaces and equipment used in the preparation, display, and sale of the raw product.<sup>27</sup> Proper sanitation will include a two or three compartment sink or an

```
15 OAC 901:3-6-01
```

<sup>16</sup> ORC 3717.221(C)

OAC 901:3-6-07

<sup>18</sup> OAC 901:3-6-08

<sup>19</sup> OAC 901:3-6-02

<sup>20</sup> OAC 901:3-6-03

<sup>21</sup> OAC 901:3-6-06 22 OAC 901:3-6-03

<sup>23</sup> OAC 901:3-6-03

<sup>24</sup> OAC 901:3-6-03

<sup>25</sup> OAC 901:3-6-03

<sup>26</sup> OAC 901:3-6-05, 901:3-6-06

<sup>27</sup> OAC 901:3-6-04

ODA approved substitute, and a proper multi-step sanitization process must be followed.28

Farm markets and farm product auctions may register online with ODA's Division of Food Safety. Markets or auctions not registered with ODA must otherwise be licensed as an RFE with the district health department.29

#### **Food Processing Establishment Registration**

A "food processing establishment" is a place where food is processed, packaged, manufactured, held, or otherwise handled for distribution to another location or for sale at wholesale. This will include the activities of a bakery, confectionery, cannery, bottler, warehouse or distributor, and the activities of an entity that receives or salvages distressed food for sale or use as food. The following are not included within the definition of "food processing establishments" and are not required to register as such when the product is prepared and processed in accordance with the law:

- cottage food producers,
- processors of tree syrup,
- processors of sorghum,
- processors of apple syrup,
- processors of apple butter, and
- processors of honey.30

Food processing establishments must register annually with ODA, with the registration expiring every year on January 31. Renewal applications will be automatically sent to current establishments and must be submitted prior to the expiration of the registration. Before issuing a certificate of registration to a new establishment, ODA will first inspect the facility to ensure the establishment is in compliance with state regulations. Fees for registration of an establishment are based on the size of the establishment and can range from \$50 to \$300, with late fees ranging from \$25 to \$50.31 Registration certificates must be displayed in an area where customers of the establishment will see it. Food processing establishments not properly registered with ODA will be issued a warning from ODA, with 10 days to come into compliance. Failure to comply within the 10 day period can result in civil penalties ranging from \$500 to \$5,000.

ODA does have the authority to revoke or suspend the registration of a food processing establishment they find to be in violation of state law. In the event a violation is found, establishments will normally be provided an opportunity to appeal ODA's determination prior to the revocation or suspension taking effect. In the event ODA determines a food processing establishment presents an immediate danger to public health, they may issue an order immediately suspending an establishment's registration, with an appeal being available no later than 10 days after the suspension has taken effect.

#### Food Processing Establishment - Warehouse Registration

A person operating a warehouse facility to hold or store food may be required to register with ODA Division of Food Safety if they do not otherwise have a license with the Division of Food Safety. Warehouse registration is especially notable for anyone looking to store frozen meat on their farm or at their household for later sale. Warehouse registration comes with an annual fee of \$50 or more depending on the square footage of the facility, with the fee being due at the time of inspection. Typical inspections will check the location of the freezer or fridge (making sure it is not located inside a residence), the cleanliness of the location, and the accuracy of the thermometer being used in the storage equipment. Request for inspection forms can be found on ODA's Division of Food Safety webpage.

#### **Cold Storage Registration**

No person may operate a cold-storage facility for hire without registering as a warehouse.<sup>32</sup> The annual registration period runs from February 1 through January 1 with an initial fee of \$200 and a renewal fee of \$50 or more depending on the square footage of the facility. A cold-storage warehouse is a place artificially cooled by the employment of refrigerating machinery or ice or other means, in which articles of food are stored for 30 days or more at a temperature of 40 degrees Fahrenheit, or lower.<sup>33</sup> An inspector will evaluate the location of the warehouse and assess the sanitary conditions. Sanitary warehouses with the proper equipment for cold storage will be issued a license to operate a warehouse. Warehouses deemed to be unsanitary or not in compliance with applicable laws and administrative rules may be closed and/or have their license revoked.34

#### Cannery License<sup>35</sup>

Vegetable, fruit, and specialty product canneries must first obtain a cannery license from ODA prior to engaging in the business of operating a cannery (packaging products in hermetically sealed containers and thermally sterilizing them to be sold for human consumption) regardless of where the product will be sold. Canning foods that fall within Ohio's cottage food category is the one exception to the general licensing requirement.

Before issuing the initial license, ODA will first conduct an inspection to ensure the facility is compliant with all relevant rules and regulations, including federal Good Manufacturing Practices.<sup>36</sup> Requirements may vary based on the pH level of the food a facility would like to process.37 Those producing a

<sup>28</sup> Id

<sup>29</sup> OAC 901:3-6-01

ORC 3715.021

<sup>31</sup> OAC 901:3-21-01, Under ORC 3715.041(G), licensed bakeries, canneries, soft drink plants, cold-storage warehouses or lockers, and those with a flock less than 500 laying hens engaged in egg production are not required to pay food processing establishment processing fees

<sup>32</sup> ORC 915.02

<sup>33</sup> ORC 915.01

<sup>34</sup> ORC 915.10, 915.23

<sup>35</sup> ORC 913

<sup>36</sup> 21 CFR 117

ORC 913.04

naturally high acid canned food will need to have the product tested to determine the actual pH before reaching out to ODA. Further, individuals that wish to produce an acidified canned food or low acid canned food must attend "Better Process Control School," have the product evaluated by a process authority, register with the FDA as a cannery, and file the canning process with the FDA prior to contacting ODA, Division of Food Safety. A process authority is someone the FDA recognized as knowledgeable in food processing. According to ODA:

- A naturally high acid canned food is a food that has a natural (without the addition of acid) pH of 4.6 or below. Example: tomato-based products
- An acidified canned food is a low acid food to which an acid or acid food has been added. Example: pickles
- A low acid canned food is a food that has a pH greater than 4.6
   and a water activity greater than 0.85. Example: green beans
   Facilities not required to register with the FDA will need
   to be able to show the processes for each processing method
   utilized prior to processing food. Inspection will include
   the type of equipment used, the type of thermal processing
   equipment used, minimum initial temperatures, time and
   temperature of processing, sterilizing values, and critical
   control factors.

The cannery licensing period is July 1 through June 30, and canneries must renew prior to June 30 every year. The annual licensing fee is \$200 and is due at the time of the application submission or renewal. ODA may enter the premises of a licensed cannery during normal business hours for the purposes of inspection and investigation.<sup>39</sup>

FDA establishment registration & process filing for acidified and low-acid canned foods can be found online: ofb.ag/homebakery.

#### Home Bakery Registration<sup>40</sup>

Any person that owns or operates a Home Bakery must register with the ODA to receive a Home Bakery License. The licensing fee is \$10 and licenses must be renewed annually between October 1 and September 30. Those wishing to obtain a license must first submit to and pass ODA inspection. Producers can request a Home Bakery Inspection on ODA's website at the following location: ofb.ag/homebakerysafety.

For more information about home bakery registration, please see page 21.

The ODA Division of Meat Inspection works to protect consumers through regulatory oversight of meat processing facilities. Through regular inspections, the Division of Meat Inspection ensures that meat products that come from ODA inspected facilities are safe, wholesome, and properly labeled.

For information about the Fully Inspected Operator License, Custom Operator License, & Voluntary Inspection License offered by the ODA Division of Meat Inspection, please see page 45. Chapter 918 of the Ohio Revised Code contains Ohio's laws covering meat inspection with section 901:2 of the Ohio Administrative Code containing ODA's rules regarding meat inspection.

#### Fully Inspected Operator License<sup>41</sup>

Fully inspected facilities are monitored by the Ohio Department of Agriculture, Division of Meat inspection, with ODA inspectors being present at the facility each day it is processing a product intended for sale. Fully inspected operator licenses come with a fee of \$100 and must be renewed annually by March 31. Applications can be requested from and submitted to the Ohio Department of Agriculture Meat Inspection Division.

#### Custom Operator License<sup>42</sup>

Custom operator licenses are monitored by the Ohio Department of Agriculture, Division of Meat inspection. licenses come with a fee of \$100 and must be renewed annually by March 31. Applications can be requested from and submitted to the Ohio Department of Agriculture Meat Inspection Division.

#### **Voluntary Inspection License**<sup>43</sup>

The Voluntary Meat Inspection License is a voluntary licensing and inspection system that allows custom operators to harvest and/or process certain exotic animals under modified regulatory compliance standards with ODA oversight to ensure certain food safety standards are being met. Establishments that receive a voluntary state inspection must renew with ODA annually, with the licensing term expiring March 31. Renewals are sent each year by the ODA Division of Meat Inspection. In addition to a \$100 licensing fee, establishments will also be required to pay inspection fees at an hourly rate.

#### Division of Dairy

The ODA Division of Dairy is responsible for the oversight of dairy production in Ohio. Through inspection and sampling, the Division of Dairy works to ensure that Ohio's milk and milk products meet or exceed the FDA and USDA standards to provide safe and wholesome products to consumers.

Division of Meat Inspection

<sup>38 &</sup>quot;Better Process Control Schools" are often offered in an online format by universities such as The Ohio State University.

<sup>39</sup> ORC 913.03

<sup>40</sup> ORC 911.02

<sup>41</sup> ORC 918.28

<sup>42</sup> ORC 918.28

<sup>: 43</sup> ORC 918.12

For information about the Milk Dealer's License, Milk Hauler License, Milk Processor License, Milk producer License, and the Weigher, Sampler & Tester License offered by the ODA Division of Dairy, please see page 61.44 Chapter 917 of the Ohio Revised Code contains Ohio's laws covering Dairy inspection with section 901:11 of the Ohio Administrative Code containing ODA's rules regarding dairy inspection.

#### Milk Dealer's License<sup>45</sup>

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. 46 Applications can be submitted online with a \$15 fee.

#### Milk Hauler License<sup>47</sup>

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. 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. A license remains valid unless it is suspended, revoked, or canceled.

#### Milk Processor License<sup>48</sup>

In order to produce and sell milk products, producers must first obtain a milk processor license based on the product they would like to sell. 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.

#### Milk Producer License<sup>49</sup>

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, and evidence of a completed and acceptable inspection from the district sanitarian.

#### Weigher, Sampler & Tester License

Persons in charge of collecting and handling milk samples from a bulk tank on a farm, or the person collecting official regulatory samples in a milk plant must have a Weigher, Sampler, and Tester License. Applications must be submitted to ODA along with the \$15 licensing fee.<sup>50</sup> No one will be issued a license unless they have received a passing Weigher, Sampler, and Tester examination score.51

#### **Contacts and Resources**

#### **Ohio Department of Health**

Phone: (614) 466-3543 Web: odh.ohio.gov

Find local health districts: ofb.ag/localhealthdistricts

#### Ohio Department of Agriculture

Division of Food Safety Phone: (614) 728-6250

Email: foodsafety@agri.ohio.gov

Web: ofb.ag/foodsafety

#### Division of Meat Inspection

Phone: (614) 728-6260 Email: meat@agri.ohio.gov Web: ofb.ag/meatinspection

#### Division of Dairy

Phone: (614) 466-5550 Email: dairy@agri.ohio.gov Web: ofb.ag/dairydivision

#### **Additional Resources**

State of Ohio Uniform Food Safety Code:

ofb.ag/foodsafetycode

#### **Ohio Food Safety Rules:**

ofb.ag/foodsafetyrules

#### **Federal Good Manufacturing Practices:**

ofb.ag/manufacturingpractices

<sup>44</sup> ORC 917.09

<sup>45</sup> OAC 901:11-1-04(A)

<sup>46</sup> ORC 917.01(D)

<sup>47</sup> OAC 901:11-4-02 OAC 901:11-1-04(A)

<sup>50</sup> ORC 917.09; OAC 901:11-4-02

<sup>51</sup> ORC 917.08, OAC 901:11-4-02(D)

# **Cottage Foods**

Ohio law has distinguished a limited category of food producers, cottage food producers, who are not subject to the typical regulatory requirements that other food processing establishments will encounter. With very little oversight from food safety authorities, cottage food production and sales can be a very attractive opportunity for those wishing to start at-home production. Cottage food producers are those who produce non-potentially hazardous food items in their own home to sell to consumers within the state.

#### Regulation

Under Ohio's cottage food law, home producers are not required to abide by all of the normal licensing and registration requirements a food producer may encounter. A "home" is the primary residence occupied by the residence's owner, on the condition that the residence contains only one stove or oven used for cooking, which may be a double oven, designed for a common residence usage and not for commercial usage, and that the stove or oven be operated in an ordinary kitchen within the residence. When approved foods are made within a home meeting this definition and sold exclusively within Ohio, producers can be exempt from inspection and licensing by the Ohio Department of Agriculture and the retail food establishment license requirement.

Although cottage food producers are not subject to licensing and registration requirements, they will still be subject to certain regulatory requirements and controls. The Ohio Department of Agriculture is responsible for the monitoring of compliance with the law. In addition to labeling, packaging, and sales regulations, all cottage food products are subject to the ODA's food sampling authority. Sampling procedures will test for any misbranding or adulteration of food products (see definitions for misbranding and adulteration). Sampling of cottage food products can be done at random or under any of the following circumstances:

- When a food, food additive, or food packaging is subject to a consumer complaint;
- When requested by a consumer whose doctor has identified an organism from the consumer;
- 1 ORC 3715.021
- 2 ORC 3715.01(A)(19)
- 3 ORC 3715.01(A)(17)
- 4 ORC 3715.022, 3715.02, OAC 901:3-20-03



- When a food, food additive, or food packaging material is suspected of having caused an illness;
- When a food, food additive, or food packaging material is suspected of being adulterated or misbranded;
- When a food, food additive, or food packaging material is subject to verification of food labeling and standards of identity;
- At any other time the ODA director considers a sample analysis necessary.<sup>5</sup>

The purpose of ODA sampling is to help promote consumer health and assist producers in remaining compliant. Food sampling is not optional, and any food found to be in violation of cottage food laws will likely be contacted by ODA to conduct a more thorough investigation to identify the cause of the violation. Violations of food safety laws can result in anywhere from a minor misdemeanor to a first-degree misdemeanor.

#### What are cottage foods?

Cottage foods are non-potentially hazardous foods that carry a lower risk of improper preparation and handling. A potentially hazardous food item is one that:

- Has a pH level greater than 4.6 when measured at 75 degrees Fahrenheit or 24 degrees Celsius;
- 5 ORC 3715.02(B)
- 6 ORC 3715.52(A)(6)
- 7 ORC 3715.99

- Has a water activity value greater than 0.85;
- Requires temperature control because it is in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms, the growth and toxin production of clostridium botulinum, or in the case of raw shell eggs, the growth of salmonella enteritidis.8

The Ohio Department of Agriculture has identified foods that meet this low risk criteria through its rule-making procedures. The following food products have been identified as approved cottage food products:9

- Baked goods that do not require refrigeration (bread<sup>10</sup>, cookies, brownies, cake, fruit pie, and fruit cobbler)
- Candy<sup>11</sup>
- Fruit jams
- Fruit jellies
- Flavored honey produced by an exempt beekeeper
- Fruit chutneys
- Fruit butters
- Granola, granola bars dipped in candy
- Maple sugar produced by an exempt maple syrup producer
- Popcorn, flavored popcorn, kettle corn, popcorn balls, caramel corn
- Unfilled baked donuts
- Waffle cones and waffle cones dipped in candy
- Dry cereal and nut snack mixes with seasonings
- Roasted coffee, whole beans or ground, flavoring permitted
- Dry baking mixes in a jar (other pkg permitted)
- Dry herbs and herb blends
- Dry tea blends
- Dry soup mixes
- Dry seasoning blends

Cottage food production operations are not permitted to process acidified foods,12 low acid canned foods,13 potentially hazardous foods, or non-potentially hazardous foods that are not specifically identified as acceptable cottage foods.<sup>14</sup>

ODA has identified the following items as products the cannot be offered as cottage foods:

- Any item that requires refrigeration to keep from spoiling, including fresh fruit garnishes or fillings, raw or cooked animal products, cooked vegetables, and garlic in oil
- Candy covered fresh fruit
- Freezer jam
- Sugar-free jams/jellies/fruit butters
- ORC 3715.01(A)(18) OAC 901:3-20-04
- White bread for sale must be manufactured in compliance with ORC 911.33.
- No person shall manufacture for sale candy with an admixture of terra alba, barytes, talc, or other mineral substance, or with poisonous colors or flavors or other ingredients detrimental to health. ORC 3715.23
- Acidified foods are low acid foods to which acid or acid foods have been added.
- Low acid foods are foods with a finished equilibrium pH greater than 4.6 and water activity greater than 0.85.
- 14 OAC 901:3-20-05

- Fresh pasta
- Dehydrated fruits or herbs
- Cheesecake, cream pie, pumpkin pie
- Fry pies
- Popping corn
- Acidified foods (pickles, relishes)
- Hot pepper butter, pumpkin butter, nut butter
- Hummus
- Waffles or Belgian waffles
- Raw pizza dough, cookie dough
- Cream cheese frosting
- Beef jerky
- Meals
- Freeze-dried products

Partially Hydrogenated Oils (PHOs) are not Generally Recognized as Safe (GRAS) and therefore PHOs may not be used in cottage foods. 15 Also, keep in mind that adulterated food products are never acceptable for sale under any circumstance (see definition of adulterated food). Food products must be prepared and stored in a clean and safe manner with no ingredient substitutions or dangerous additions. 16 Adulterated or spoiled food should immediately be disposed of.

#### **Packaging**

Equally as important as ensuring the safe production of food products is the proper packaging and labeling of the items. Packaging must honestly present the items and must not conceal any product damages or inferiorities.<sup>17</sup> Food packaging must always be done in sanitary conditions away from filth or contaminated areas that could create unhealthy food products.<sup>18</sup> Cottage food producers will need to be just as mindful as licensed producers about their packaging to ensure there are no poisonous or dangerous elements within the packaging that could cause food items to become unhealthy for consumption.<sup>19</sup>

Additionally, cottage food products may not be packaged using reduced oxygen packaging.20 This means that packaging may not be done in a way that removes oxygen, displaces oxygen with another gas, or otherwise controls the oxygen level to a content below the level normally found in the surrounding atmosphere.21 Reduced oxygen packaging includes vacuum packaging and modified atmosphere packaging.<sup>22</sup>

<sup>15 21</sup> CFR 170.38

<sup>16</sup> ORC 3715.59

<sup>17</sup> ORC 3715.59

<sup>18</sup> ORC 3715.59

<sup>19</sup> ORC 3715.59 20 OAC 901:3-20-04

<sup>21</sup> OAC 901:3-20-01(B)(6)

<sup>22</sup> OAC 901:3-20-01(B)(6)

#### Labeling

In order to offer cottage food products for sale, product packaging must be labeled in compliance with state and, via state adoption, federal law.<sup>23</sup> The following information must be included:24

- Statement of Responsibility: The name and address of the business of the cottage food production operation. The address must include the street address, the city or town, the state, and zip code. Additional information such as telephone numbers, web addresses and email addresses are permitted but must not be placed between the ingredient list and the required information for the Statement of Responsibility and cannot be used in lieu of the Statement of Responsibility.25
- Statement of Identity: The common or usual name of the food product that accurately describes the nature of the food or its characterizing properties in bold type font on the principal panel of display. If the product is an imitation product, the label must bear the word "imitation" in uniform font immediately after the name of the food imitated.26
- **Ingredient List:** The ingredients of the food product, in descending order of predominance by weight (meaning heaviest ingredient is listed first). Ingredient names must be specific and not a collective or generic name unless specifically identified in the "Acceptable Ingredient Designations" list at the end of this chapter. Ingredients composed of two or more ingredients must list those sub-ingredients parenthetically following the name of the ingredient.<sup>27</sup> Any food item that contains a "major food allergen" in any amount, even trace amounts, must declare the presence of the allergen by either including it in the list of ingredients or placing the word "contains" followed immediately by the allergen or the name of the food source from where the allergen is derived after or adjacent to the ingredient list. The nine major food allergens are sesame, milk, eggs, tree nuts, peanuts, wheat, soybeans, fish, and Crustacean shellfish.
- Net Quantity of Contents: The net weight and volume of the food product in both the U.S. Customary System and the SI metric system in a prominent and distinct location on a principal display of the food package. The term "NET WT" or other appropriate abbreviation must be used immediately prior to stating the quantity of food contained within the package (Ex. NET WT 12 OZ (340.19g)).28 No qualifying phrases should be used in the net quality of contents statement to exaggerate the amount of food (e.g. Net Wt.

- = 1 Large oz. (5g) is not acceptable).<sup>29</sup> The net weight only includes the average quantity of food within the package and does not include the weight of the packing materials.<sup>30</sup>
- Cottage Food Declaration: The statement (in at least 10-point type) "This Product is Home Produced."31

Informational panel labeling should be printed in a type size that is prominent, conspicuous and easy to read. Letters should be at minimum 1/16 inch in height and must not be more than three times high as they are wide. Wording colors must contrast with the background and not be crowded with artwork or other non-required labeling.<sup>32</sup> Artwork on labels is permissible as long as it does not hide or detract from the prominence of the required label statements or misrepresent the food.<sup>33</sup>

Labels on cottage food products are not generally required to contain the food's nutrition facts; however, if the label makes a nutrient content claim (i.e. low fat, low sodium, etc,) or a health claim (i.e. may reduce cholesterol, healthy) then the label must include a complete nutrition facts panel.34 Cottage food producers who wish to include nutrient content claims should first research the minimum content levels required to make the claim as well as other labeling requirements related to the specific claim.

#### Sale

Items sold under the cottage food product licensing exemption may not be sold outside of Ohio.35 Within the state, producers have a wide array of options of venues for selling their products. Properly labeled cottage food products may be sold:

- Direct to consumer at the location of production,
- At a licensed farm market,<sup>36</sup>
- At a farmers market,37
- At licensed retail food establishments or food service operations such as restaurants and grocery stores, 38 and
- At festivals or celebrations that last no longer than seven consecutive days and have been organized by a political subdivision of the state.39



- 23 OAC 901:3-20-02
- ORC 3715.023(A)
- ORC 3715.023(A)(1), 21 CFR 101.5
- ORC 3715.023(A)(2), 21 CFR 101.3
- ORC 3715.023(A)(3), 21 CFR 101.4
- ORC 3715.023(A)(4), 21 CFR 101.7

- 21 CFR 101.105(o)
- 21 CFR 101.5(g)
- ORC 3715.023(A)(5)
- 21 CFR 101.2(c) & (f)
- 33 21 CFR 1.21(a)(1), 21 CFR 101.3(a), 21 CFR 101.105(h)
- 34 21 CFR 101.9(j)(3), 21 CFR 101.13
- 35 OAC 901:3-20-05
- 36 ORC 3717.22(B)(16)
- 37 ORC 3717.22(B)(2)
- 38 OAC 901:3-20-02
- ORC 3717.22(B)(15)

#### **Label example**

#### BASIC REQUIRED FOOD LABELING COMPONENTS LABEL EXAMPLE (COTTAGE FOOD PRODUCTION)

This label example is just one way to present the information required on a food product label. Information may be placed in different ways and may appear on more than one label. Labels must comply with all applicable regulations and all information must be accurate and not misleading. Foods cannot be made with partially hydrogenated oils. Additional information can be found at ofb.ag/foodlabelingexample.

Ingredient List – Ingredients shall be listed by common or usual name in descending order of predominance by weight. Meaning, the ingredient that weighs the most is listed first, followed by the next heaviest ingredient, with the ingredient that weighs the least listed last. Any ingredient that is composed of two or more ingredients (sub-ingredients) must list those sub-ingredients parenthetically following the name of the ingredient. The label of any food that contains an ingredient that is or contains a protein from a "major food allergen" shall declare the presence of the allergen by its common or usual name either in the list of ingredients or placing the word "Contains" followed by the name of the food source from which the allergen is derived immediately after or adjacent to the list of ingredients (e.g. Contains: wheat, soy, milk, eggs, almonds).

Statement of Identity - The Statement of Identity is the name of the food. The name shall be the common or usual name of the food and shall accurately identify or describe the basic nature of the food or its characterizing properties or ingredients.

Ref: ORC 3715.023

Ref: ORC 3715.023

#### **Chocolate Chip Cookies**

Ingredients: enriched flour (bleached wheat flour, malted barley flour, niacin, reduced iron, thiamine mononitrate, riboflavin, folic acid), brown sugar (molasses, sugar), semisweet chocolate chips (semi-sweet chocolate (sugar, chocolate liquor, cocoa butter), soy lecithin, vanilla), vegetable shortening (soybean and cottonseed oil, mono- and diglycerides, artificial butter flavor, beta carotene (pro vitamin a-added for color)), milk chocolate chunks (sugar, cocoa butter, milk, chocolate liquor, soy lecithin, vanillin), eggs, milk, baking powder (potassium bitartrate, corn starch, baking soda), natural flavor, salt, baking soda.

MURRAY LINCOLN COOKIE CO. 280 N. HIGH ST. FLOOR 6, **COLUMBUS, OHIO 43215** 

net wt 8 oz (227 g)

This product is home produced.

Statement of Responsibility -

Shall include the:

**Business Name** Street Address City, State, Zip Code

All information in the Statement of Responsibility shall be continuous.

Telephone numbers, website addresses, and e-mail addresses are permitted, but not required. This type of extra information shall not be placed between the Ingredient List and the Statement of Responsibility and cannot be used in lieu of listing the business name, street address, city, state, and/or zip code.

Ref: ORC 3715.023

Net Quantity of Contents -

The term "NET WEIGHT" - or an appropriate abbreviation - shall be used when stating the Net Quantity of Contents in terms of weight. The Net Quantity of Contents shal be declared in both the U.S. Customary System and the SI (metric system).

Ref: ORC 3715.023

Cottage Food Declaration - Food products that are manufactured in compliance with Ohio's Cottage Food Rules, must be properly labeled and bear the statement, "This product is home produced." In 10-point type font. The statement means that the food product was produced in a private home that is not subject to inspection by a food regulatory authority.

Ref: ORC 3715.023

ODA - Ohio Department of Agriculture ORC - Ohio Revised Code

The 9 major food allergens are sesame, milk, eggs, tree nuts (e.g., almonds, walnuts, pecans), peanuts, wheat, soybeans, fish (e.g., anchovies) and crustacean shellfish.

#### Accepted Collective or Generic Name Table 40\*

Accepted Declaration	Compound Elements	
Skim milk or nonfat milk	Skim milk, concentrated skim milk, reconstituted skim milk, nonfat dry milk	
Milk	Milk, concentrated milk, reconstituted milk, and dry whole milk	
Cultured (substrate)	Bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "Made from the cultured skim milk or cultured buttermilk"	
Buttermilk	Sweetcream buttermilk, concentrated sweetcream buttermilk, reconstituted sweetcream buttermilk, dried sweetcream buttermilk	
Whey	Whey, concentrated whey, reconstituted whey, dried whey	
Cream	Cream, reconstituted cream, dried cream, plastic cream (also known as concentrated milk fat)	
Butterfat	Butteroil and anhydrous butterfat	
Eggs	Dried whole eggs, frozen whole eggs, liquid whole eggs	
Egg whites	Dried egg whites, frozen egg whites, liquid egg whites	
Egg yolks	Dried egg yolks, frozen egg yolks, liquid egg yolks	
"(Vegetable, animal, or marine) (fat or oil) shortening" or "blend of (vegetable, animal, or marine) oils"	Blends of fats and/or oils may be designated in their order of predominance in the food as " shortening" or "blend of oils", the blank to be filled with the word "vegetable", "animal", or "marine", with or without the terms "fat" or "oils", if immediately following the term the common or usual name of each individual vegetable, animal, or marine fat or oil is given in parentheses. E.G. "Vegetable oil shortening (soybean and cottonseed oil)"	
Leavening (individual leavening agents)	Ingredients that act as leavening agents in food may be declared in the ingredient statement by stating the specific common or usual name of each individual leavening agent in parentheses following the collective name "leavening", e.g., "Leavening (baking soda, monocalcium phosphate, and calcium carbonate)". When applicable, individual leavening agents must be in descending order of predominance.	
Yeast nutrients (individual yeast nutrients)	Ingredients that act as yeast nutrients in foods may be declared in the ingredient statement by stating the specific common or usual name of each individual yeast nutrient in parentheses following the collective name "yeast nutrients", e.g., "yeast nutrients (calcium sulfate and ammonium phosphate)". When applicable, individual yeast nutrients must be in descending order of predominance.	

#### **Accepted Collective or Generic Name Table continued**

Accepted Declaration ough	Compound Elements	
Dough conditioner (individual dough conditioners)	Ingredients that act as dough conditioners may be declared in the ingredient statement by stating the specific common or usual name of each individual dough conditioner in parentheses following the collective name "dough conditioner", e.g., "dough conditioners (L-cysteine, ammonium sulfate)". When applicable, individual dough conditioner must be in descending order of predominance.	
(list of firming agents) Firming agents	Ingredients that act as firming agents in food (e.g., salts of calcium and other safe and suitable salts in canned vegetables) may be declared in the ingredient statement, in order of predominance appropriate for the total of all firming agents in the food, by stating the specific common or usual name of each individual firming agent in descending order of predominance in parentheses following the collective name "firming agents". Firming agents not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", "contains one or more of the following:"	
Sugar	Sucrose, sucrose sugar, cane sugar, or beet sugar	

\*Not including spices, flavorings, colorings, chemical preservatives and compound ingredients with common or usual name established pursuant to the Meat Inspection or Poultry Product Inspection Acts by USDA or standards of identity determined by FDA. The use of established common ingredients requires the listing of sub-ingredients parenthetically following the name of the ingredient.<sup>41</sup> Spices may be declared in an ingredient list by using their common or usual name or by using the declarations "spices," "flavor," "natural flavor," or "artificial flavor"; however, spice blends, flavors, or colors must list each ingredient by name. 42 This list is intended to only serve as an example of accepted abbreviated compound ingredients, this is not a complete list and items on this list are not necessarily ingredients appropriate for use in cottage food production.

#### **Contacts for Cottage Foods**

Ohio Department of Agriculture, Division of Food Safety

Phone: (614) 728-6250

Email: foodsafety@agri.ohio.gov Web: ofb.ag/cottagefoodsafety

## **Starting from Scratch**

- Know your regulations. While there may be no specific licensing requirements, cottage foods are still subject to ODA sampling.
- Select a food item that is among the approved non-potentially hazardous food items.
- Ensure that you have a compliant home kitchen within your residence where you can produce your chosen food item.
- Package the food item in a safe and sanitary manner and do not use reduced oxygen packaging.
- Create and properly place your label. Remember to include all required items and be sure to include nutritional facts if you make a nutrient content claim.
- Decide where you would like to sell your food item within Ohio.

# Home Bakery – Refrigerated Baked Goods

Those looking to produce and sell baked goods from their home beyond the nonpotentially hazardous options covered by cottage food laws have the option of registering their operation as a "Home Bakery." Although bakeries are included within the definition of a "food processing establishment," licensed home bakeries are distinct from other bakeries, and, in addition to lesser registration fees, they will not be required to register as food processing establishments in order to sell their product. Provided they meet certain safety requirements, any person who owns and operates a bakery with only one noncommercial oven in the primary kitchen of their own home may register to become a licensed home bakery.<sup>2</sup>

#### Regulation

#### Licensing

Ohio Department of Agriculture is responsible for the monitoring and licensing home bakeries. Prior to selling any potentially hazardous bakery items to consumers, home bakery owners must first obtain a Home Bakery License from ODA.<sup>3</sup> Anyone looking to own and operate a home bakery can go to ODA's website to find and submit a Request for Inspection form.<sup>4</sup> Applicants can expect to provide their contact information, the location of the home bakery, and a description of the product they would like to produce. There is an annual home bakery licensing fee of \$10, with renewals being due by September 30 every year.<sup>5</sup>

#### Inspection

Upon receiving a request for inspection and prior to issuing a license, the ODA Division of Food Safety will conduct an inspection of the residence where the food will be produced

- 1 ORC 3715.041(G)(1)
- 2 ORC 911.02
- 3 ORC 911.02
- 4 https://agri.ohio.gov/divisions/food-safety/resources/home-bakery
- ORC 911.02



to ensure the kitchen is meeting all legal requirements. Home bakeries may not use a secondary kitchen within the home or a commercial oven to prepare home bakery items for sale.

Those undergoing an inspection can expect the inspector to be

Those undergoing an inspection can expect the inspector to be looking for the following:<sup>6</sup>

- The kitchen has walls, ceilings, and floors that are in good repair, clean and easily cleanable.
- The kitchen does not have carpeted floors.
- The home is free of pests.
- The home does not have pets and no pets are permitted in the home.
- The kitchen is maintained in a sanitary condition.
- Equipment and utensils are maintained in a sanitary condition
- There is a mechanical refrigerator, equipped with a properly located thermometer, capable of maintaining 45 degrees Fahrenheit or less.
- Homes with well water are tested annually for coliform bacteria, with a negative test result within the past year.
- Adequate labels that are available for inspection.
- All other legal requirements have been met.

Ohio requires that bakery ingredients and products are stored, handled, or transported in a manner that protects them from spoilage, vermin, contamination, disease and unwholesomeness.7 Bakery facilities and equipment, including vehicles used to transport baked goods, must be maintained at all times in sanitary conditions free from dirt, dust, flies, insects and other contaminating matter.8 Containers used to store and transport bakery products must only be used for bakery products and be constructed and sanitized in such a way to prevent outside contamination.9 Any showcases or shelves used to display unwrapped bakery products must be well covered, properly ventilated, adequately protected from dust and flies and other contaminating matter and must be maintained in a "sweet, clean, and wholesome condition." 10

Table surfaces should remain free of clutter and no one should sit or lounge on any surface used in connection with any stage of food production.11

Any person handling the ingredients used in home bakery production must wash their hands before beginning their work,12 and any person affected with any contagious, infectious, or other disease or physical ailment should stay away from the bakery items.13

Like cottage foods, home bakery products are subject to the food sampling authority of the ODA.<sup>14</sup> Violations of home bakery laws, including selling home bakery items without a license, can result in a first-degree misdemeanor.15

- ORC 911.07
- ORC 911.10
- ORC 911.08
- 10 ORC 911.09
- ORC 911.14 12 ORC 911.13
- 13 ORC 911.12, 911.11
- 14 ORC 3715.022
- ORC 911.99

#### **Products**

A licensed home bakery may manufacture and sell not only non-potentially hazardous bakery products, but also potentially hazardous bakery products that require refrigeration to prevent the growth of infectious or toxic microorganisms. A potentially hazardous food is a food that to which the following apply:

- It has a pH level greater than 4.6 when measured at 75 degrees Fahrenheit or 24 degrees Celsius.
- It has a water activity value greater than 0.85.
- It requires temperature control because it is in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms, the growth and toxin production of clostridium botulinum, or in the case of raw shell eggs, the growth of salmonella enteritidis.16 Examples of potentially hazardous bakery products that a home bakery may produce for sale include:
- Cheesecake
- Cream pie
- Pumpkin pie
- Fry pie
- Filled donuts
- Waffles
- Belgian waffles
- Raw dough
- Egg noodles17
- Cream cheese frosting
- Pepperoni rolls

Home bakery products cannot be made with any ingredient that is likely to deceive the consumer or would lessen the nutritive value unless the product has been clearly marked to inform consumers of the actual ingredient. 18 Partially

16 ORC 3715.01(A)(18)

Additional licensing requirements may apply depending on the location

18 ORC 911.05



Hydrogenated Oils (PHOs) are not Generally Recognized as Safe (GRAS) and therefore PHOs may not be used in bakery foods.<sup>19</sup>

#### **Packaging**

Similar to cottage foods, home bakery items must be packaged in sanitary conditions away from filth or contaminated areas that could create unhealthy food products.<sup>20</sup> Producers need to be just as mindful about their packaging to ensure there are no poisonous or dangerous elements within the packaging that could cause food items to become unhealthy for consumption.<sup>21</sup> Packaging must honestly present the items and must not conceal any product damages or inferiorities.<sup>22</sup>

#### Label

The label requirements for home bakery items come from both state law and, via state adoption, federal law.<sup>23</sup> Honest and accurate labels should be placed on the principal display panel portion of a package so a consumer can easily find the necessary information at the time of purchase.

- Statement of Responsibility: The name and address of the business of the operation. The address must include the street address, the city or town, the state, and zip code. Additional information such as telephone numbers, web addresses and email addresses are permitted but must not be placed between the ingredient list and the required information for the Statement of Responsibility and cannot be used in lieu of the Statement of Responsibility.<sup>24</sup>
- **Statement of Identity:** The common or usual name of the food product that accurately describes the nature of the food or its characterizing properties in bold type font on the principal panel of display. If the product is an imitation product, the label must bear the word "imitation" in uniform font immediately after the name of the food imitated.25
- **Ingredient List:** The ingredients of the food product by their common or usual name, in descending order of predominance by weight (meaning heaviest ingredient is listed first). Ingredient names must be specific and not a collective or generic name unless specifically identified in the "Acceptable Ingredient Designations" list at the end of the Cottage Food chapter. Ingredients composed of two or more ingredients must list those sub-ingredients parenthetically following the name of the ingredient.26 Any food item that contains a "major food allergen" in any amount, even trace amounts, must declare the presence of the allergen by either including it in the list of ingredients or placing the word "contains" followed immediately by the allergen or the name

- of the food source from where the allergen is derived after or adjacent to the ingredient list. The nine *major* food allergens are sesame, milk, eggs, tree nuts, peanuts, wheat, soybeans, fish, and crustacean shellfish.
- Net Quantity of Contents: The net weight and volume of the food product in both the U.S. Customary System and the SI metric system in a prominent and distinct location on a principal display of the food package. The term "NET WT" or other appropriate abbreviation must be used immediately prior to stating the quantity of food contained within the package (Ex. NET WT 12 OZ (340.19g)).27 No qualifying phrases should be used in the net quality of contents statement to exaggerate the amount of food (e.g. Net Wt. = 1 Large oz. (5g) is not acceptable).<sup>28</sup> The net weight only includes the average quantity of food within the package and does not include the weight of the packing materials.<sup>29</sup>
- **Perishable Food Sale Date:** Bakery products with a quality assurance period of 30 days or less must be clearly marked with its sale date.<sup>30</sup> However, this is not required when the packaged food is sold at a place of business that has less than \$100,000 worth of all products sold during the previous year.31 Sell by dates must be legible and easily understood by the average consumer. "Best if Used By," "Best before," "Sell by," "Use by," and "Use before" conveys the date by which the producer of a product recommends that the food product be sold based on the food product's quality assurance period.<sup>32</sup> Words, numbers, abbreviations or a combination of the three such as "Dec. 27, 12-27, December 27, etc." are acceptable.<sup>33</sup> Bakery products with a sale date less than 7 days from the date of packaging may use the following abbreviations:34

DAY OF THE WEEK	ABBREVIATIONS	
Sunday	SU, SUN	
Monday	MO, MON	
Tuesday	TU, TUE	
Wednesday	WE, WED	
Thursday	TH, THU, THUR	
Friday	FR, FRI	
Saturday	SA, SAT	

27 21 CFR 101.7; FPLA, Title 15 - Chapter 39, 1453(a) (2)

28 21 CFR 101.105(o)

29 21 CFR 101.5(a)

31 ORC 3715.171(B).

30 ORC 3715.171

<sup>21</sup> CFR 170.38

ORC 3715.59

ORC 3715.59

<sup>22</sup> ORC 3715.59

<sup>21</sup> CFR 101.5

<sup>21</sup> CFR 101.3 21 CFR 101 4

OAC 3717-1-03.1

<sup>32 21</sup> CFR 107.20 33 OAC 901:3-57-04(D)

<sup>34</sup> OAC 901:3-57-04(E)

#### **Label Example**

#### BASIC REQUIRED FOOD LABELING COMPONENTS LABEL EXAMPLE

Labels must comply with all applicable state and federal regulations. Labeling regulations applied to a home bakery are the same as those applied to other food processors. All information on the label must be truthful and not misleading. This label example is just one way to present the required information. Foods cannot be made with partially hydrogenated oils.

Ingredient List - Ingredients shall be listed by common or usual name in descending order of predominance by weight. Meaning, the ingredient that weighs the most is listed first, followed by the next heaviest ingredient, with the ingredient that weighs the least listed last. Any ingredient that is composed of two or more ingredients (sub-ingredients) must list those sub-ingredients parenthetically following the name of the ingredient. The label of any food that contains an ingredient that is or contains a protein from a "major food allergen" shall declare the presence of the allergen by its common or usual name either in the list of ingredients or placing the word "Contains" followed by the name of the food source from which the allergen is derived immediately after or adjacent to the list of ingredients (e.g. Contains: milk, eggs, wheat, soy).

Ref: CFR 21, Part 101.4; FALCPA - Public Law 108-282, Title 2

Statement of Identity – The Statement of Identity is the name of the food. The name shall be the common or usual name of the food and shall accurately identify or describe the basic nature of the food or its characterizing properties or ingredients. Foods that have a Standard of Identity must conform to all requirements of the standard

Ref: CFR 21, Part 101.3

#### **Buttermilk Pie**

INGREDIENTS: FILLING: BUTTERMILK (CULTURED PASTEURIZED SKIM MILK AND MILK, SODIUM CITRATE AND SALT), SUGAR, BUTTER (CREAM (MILK)), MOLASSES, EGG, EGG YOLK, CORNMEAL, CORNSTARCH, SALT, NATURAL FLAVOR. CRUST: ENRICHED FLOUR (BLEACHED WHEAT FLOUR, MALTED BARLEY FLOUR, NIACIN, REDUCED IRON, THIAMINE MONONITRATE, RIBOFLAVIN, FOLIC ACID), SUGAR, SALT, SOYBEAN OIL, BUTTER (CREAM (MILK)), WATER.

MURRAY LINCOLN COOKIE CO. 280 N. HIGH ST. FLOOR 6, **COLUMBUS, OHIO 43215** 

**BEST BY APR 14 2026 ←** 

**Keep Refrigerated** 

#### **NET WT 8 OZ (227 g)**

Statement of Responsibility -

**Business Name** Street Address City, State, Zip Code

Shall include the:

All information in the Statement of Responsibility shall be continuous. If the business name is listed in the local telephone directory, the street address may be omitted. If the business name is listed in the local telephone directory, a Post Office Box may be used in place of the street address.

Telephone numbers, website addresses, and e-mail addresses are permitted, but not required. This type of extra information shall not be placed between the Ingredient List and the Statement of Responsibility.

Ref: CFR 21, Part 101.5

Net Quantity of Contents - The term "NET WEIGHT" - or an appropriate abbreviation shall be used when stating the Net Quantity of Contents in terms of weight. The Net Quantity of Contents shall be declared in both the U.S. Customary System and the SI (metric system). The second declaration shall be stated parenthetically.

The quantity of contents shall be placed on the principal display panel. It shall be within the bottom 30% of the area of the label panel in lines that are generally parallel to the bottom of the package as it is designed to be displayed.

Ref: CFR 21, Part 101.7 Ref: FPLA, Title 15 - Chapter 39, 1453(a) (2)

Perishable Food Sale and Date - Home Bakery products that begin to diminish in quality in 30 days or less must be marked with a sale date that is easily understood by the consumer. The date indicates the period of peak quality. The period of peak quality is determined by the manufacturer. ORC 3715.171

Keep Refrigerated – ODA recommends any product requiring refrigeration for food safety or to maintain quality bear the declaration "Keep Refrigerated" or a similar declaration to that effect.

ODA – Ohio Department of Agriculture CFR - Code of Federal Regulations ORC – Ohio Revised Code FPLA - Fair Packaging and Labeling Act FALCPA – Food Allergen Labeling and Consumer Protection Act

The principal display panel (PDP) is that portion of the package label that is most likely to be seen by the consumer at the time of purchase.

The 8 major food allergens are milk, eggs, tree nuts (e.g., almonds, walnuts, pecans), peanuts, wheat, soybeans, fish and Crustacean shellfish.



The manufacturer, processor, or packager is responsible for establishing the sale date of perishable food products.<sup>35</sup> ODA has the authority to establish a sale date for a product upon receiving a consumer complaint and conducting the proper investigation and hearing procedures.<sup>36</sup>

**Keep Refrigerated**: ODA recommends that any product requiring refrigeration for food safety or quality should be marked with the words "Keep Refrigerated" or something similar.

Informational panel labeling should be printed in a type size that is prominent, conspicuous and easy to read. Letters should be at minimum 1/16 inch in height and must not be more than three times high as they are wide. Wording colors must contrast with the background and not be crowded with artwork or other non-required labeling.<sup>37</sup> Artwork on labels is permissible as long as it does not hide or detract from the prominence of the required label statements or misrepresent the food.<sup>38</sup>

Bakery products that are sold directly to consumers or are manufactured by small businesses that have annual gross sales made or business done in sales to consumers that is not more than \$500,000 or has annual gross sales made or business done in sales of food to consumers of not more than \$50,000 are not required to include nutrition facts on the label.<sup>39</sup> However, if the label makes a nutrient content claim (i.e. low fat, low sodium, etc.) or a health claim (i.e. may reduce cholesterol, healthy) then the label must include a complete nutrition facts panel. Home bakery producers that wish to include nutrient

- 35 OAC 901:3-57-03
- 36 ORC 3715.171(A)
- 37 21 CFR 101.2(c) & (f)
- 38 21 CFR 1.21(a)(1), 21 CFR 101.3(a), 21 CFR 101.105(h)
- 39 21 CFR 101.9(j)(3), 21 CFR 101.9(j)(1)

content claims should first research the minimum content levels required to make the claim as well as other labeling requirements related to the specific claim.

You can find more information about food labeling in the FDA's food labeling guide online: ofb.ag/foodlabelingguide

#### Sale

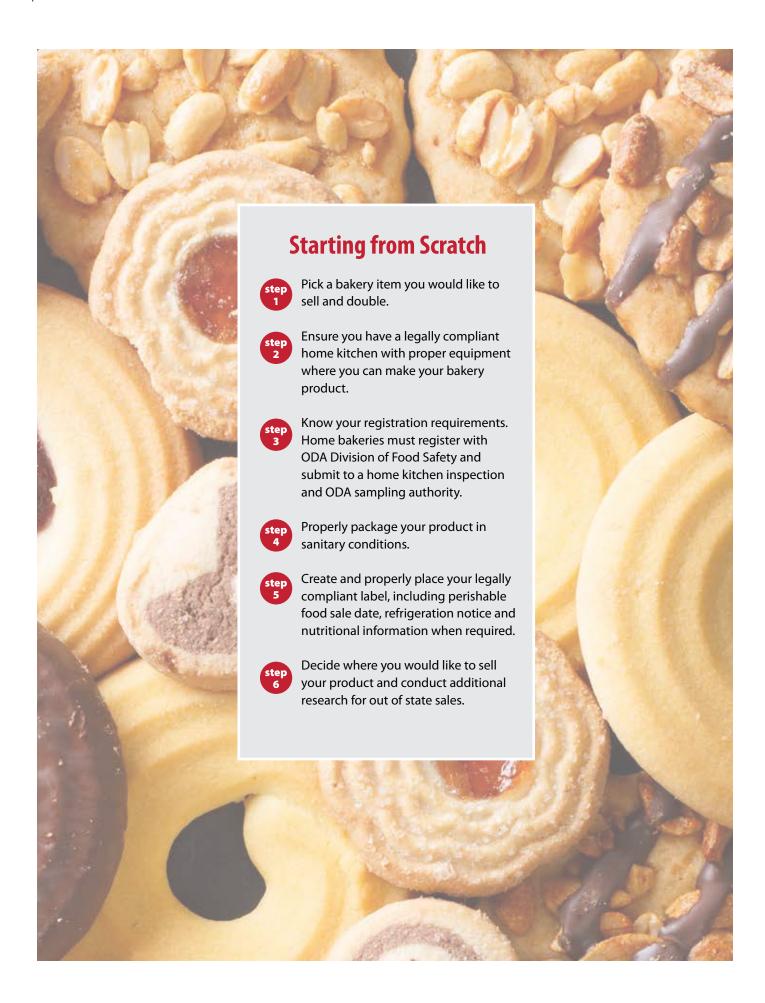
Home bakery items that are properly produced, packaged, and labeled may be sold from the bakery where the item was made. Bakery products may also be sold through grocery stores, convenience stores, farm markets, farmers markets, and other retail outlets such as grocery stores or restaurants. Keep in mind that retail outlets may be subject to additional regulations that they may require you to abide by in order to sell your bakery product in their establishment.

Home bakery items may be sold outside of the state of Ohio; however, items sold outside of Ohio will be subject to the licensing requirements and laws of the state in which it is sold. Anyone who wishes to sell their home bakery items in another state should first research that state's rules and regulations.

#### **Home Bakery Contact Information**

Ohio Department of Agriculture Division of Food Safety Phone: (614) 728-6250

Email: foodsafety@agri.ohio.gov Web: ofb.ag/homebakerysafety



# Honey, Maple Syrup, and Sorghum

#### Honey<sup>1</sup>

The revised code defines honey as the nectar and saccharine exudation of plants that has been gathered, modified, and stored in a honeycomb by honeybees.<sup>2</sup> Although unflavored honey (honey) is not considered to be a cottage food, beekeepers producing jars of honey that are composed of 75% of honey from their own hives at minimum will be exempt from the "food processing establishment" licensing, registration and mandatory inspection requirements.3 Producers who do not comply with the 75% minimum threshold will not be eligible for this exemption and will need to register as a food processing facility. Flavored honey is a cottage food and must comply with the cottage food rules and regulations (see the Cottage Food chapter, page 15).

The Ohio Department of Agriculture is the agency responsible for monitoring both the owners of bees and the sale of honey. Any person owning one or more colonies of bees in Ohio must register with ODA annually and display the designated registration number, regardless of whether they are owned for hobby or commercial processes.<sup>4</sup> In order to ensure hive health and prevent the spread of disease, ODA may enter any premises where hives or honey is stored to inspect and take samples to assess the condition of the hives, honey and the equipment.<sup>5</sup> Hives must be maintained in easily accessible locations with honeycombs available for easy removal.<sup>6</sup> Cross-comb hives or domiciles are prohibited and may be seized if not removed within a year of receiving notification to remove them.<sup>7</sup> Violation of Ohio's apiary laws can lead to license suspension, hive removal, and/or criminal misdemeanor charges.<sup>8</sup>



USDA has created a voluntary system to set uniform standards for grades of honey. The grading system ranges from U.S. Grade A to U.S. Grade C, with a Substandard grade being applied to honey that does not meet Grade C quality. Grading scores will take into account the type of honey, the preparation, the color, the style, the favor, the absence of defects, and other quality factors. Anyone interested in Honey grading should visit USDA's website for more information: ofb.ag/honey

#### Maple Syrup<sup>9</sup>

Maple syrup is the unadulterated liquid food derived by concentration and heat treatment of pure maple sap or by reconstituting maple sugar or maple concrete with water to a density of not less than 66 degrees on the brix scale at 68 degrees Fahrenheit. A maple syrup processor, who boils sap when a minimum of 75% of the sap used to produce the syrup is collected directly from trees by that processor, is exempt from the licensing, registration and mandatory inspection required of other food processing establishments. Note, maple sugar

- 1 7 CFR 1212.9
- 2 ORC 3715.01(A)(11), OAC 901:3-46-01(D)
- 3 ORC 3715.021(A)
- 4 ORC 909.02
- 5 ORC 909.05
- 6 ORC 909.12
- 7 ORC 909.12
- 8 ORC 909.13, 909.99

- 9 21 CFR 168.140, ORC 3715.24
- 10 OAC 901:3-46-01
- 11 ORC 3715.021(A)

that has been produced by an exempt maple syrup producer will also be exempt under the cottage food list.<sup>12</sup>

USDA has created a voluntary system to set uniform standards for grades of maple syrup.<sup>13</sup> To determine a product's quality, a maple syrup is assessed by looking at factors such as the percentage of solids, color, flavor, and odor. For example, a Grade A maple syrup will have the following qualities:

- No more than 68.9 % solids:
- Good uniform color;
- Good flavor and odor, and intensity of flavor normally associated with the class:
- Is free from off flavors and odors;
- Free from cloudiness, turbidity, sediment, and is clean;
- No deviants for damage.

Maple syrup that has been properly inspected for these qualities may show the USDA grade on the label. Anyone interested in USDA grading can find more information on USDA's website ofb.ag/maplesyrup.

#### Sorghum<sup>14</sup>

Sorghum is the unadulterated liquid food derived by concentration and heat treatment of the juice of pure sorghum cane. 15 A processor of sorghum who processes sorghum juice when a minimum of 75% of the sorghum juice used to produce the sorghum is extracted directly from sorghum plants by that processor, is exempt from licensing, registration and mandatory inspection.16

#### Regulation for Honey, Maple Syrup, and Sorghum

#### **Federal**

Anyone who wishes to sell honey or maple syrup should first determine if they are required to register with FDA as a Food Facility by evaluating their facilities, their intended mode of sale, and their activities. According to FDA guidance, the need to register will depend on the activities of the producer. When it comes to maple syrup, while the gathering/harvesting of sap is exempt from registration under the definition of farm, the making of the syrup by concentrating sugar maple sap is a form of processing that may be required to register.<sup>17</sup> For honey, while the activities associated with beekeeping will fall within the farm exemption to registration, if a producer would like to heat honey for pasteurization they may need to register with the FDA.18

- 80 FR 4853 page 4853-4855, document number 2015-01618 https://www.federalregister.gov/documents/2015/01/29/2015-01618/united-states-standards-for-gradesof-maple-sirup-syrup
- 14 21 CFR 168.160
- 15 OAC 901:3-46-01(G)
- ORC 3715.021(A)
- 21 CFR 1.227, also see FDA guidance B.1.13 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-facility-registration-seventh-edition. If over half is sold direct-to-consumer with no out of state sales then a producer likely does not need to register with the FDA.
- 18 See FDA quidance B.1.19, C.4.3

#### State

Exempt producers of honey, maple syrup, or sorghum are exempt from mandatory inspection of their processing facilities, however, producers may request that ODA conduct a voluntary inspection of the processing facilities. 19 Registration for voluntary inspection expires annually on May 1 and will need to be renewed.<sup>20</sup> Producers that wish to sell honey, maple syrup, or sorghum that do not fall within the exemptions described above will be subject to the registration and inspection requirements of food processing facilities. All packaged maple syrup, sorghum, and honey made to be sold to consumers are subject to the food sampling requirements conducted by ODA. Sampling procedures will test for misbranding or adulteration of the product. Sampling of food products can be done at random or under the following circumstances:

- When a food, food additive, or food packaging is subject to a consumer complaint;
- When requested by a consumer whose doctor has identified an organism from the consumer;
- When a food, food additive, or food packaging material is suspected of having caused an illness;
- When a food, food additive, or food packaging material is suspected of being adulterated or misbranded;
- When a food, food additive, or food packaging material is subject to verification of food labeling and standards of identity;
- At any other time the ODA director considers a sample analysis necessary.21

In adherence with the revised code, ODA has established tolerance levels for certain substances to be used when determining whether maple syrup, honey, or sorghum is acceptable for human consumption:<sup>22</sup>

- Lead tolerance levels range from 0 to 499 parts per billion.<sup>23</sup> A level of lead greater than 500 parts per billion will be considered adulterated.
- There is zero tolerance for the presence of any antibiotics in any sample of honey or the beeswax of honey. The detection of antibiotics will render the honey as adulterated.
- Coumaphos cannot exceed 100 parts per billion in any honey sample or 100 parts per million in any sample of the beeswax honey. Any presence of coumaphos exceeding these limits will render the honey as adulterated.

ODA sampling is not voluntary and failure to allow ODA to conduct its food sampling procedures can result in a criminal misdemeanor.24

- ORC 3715.024, OAC 901:3-46-02
- OAC 901:3-46-03
- ORC 3715.02(B) 21
- OAC 901:3-44-01
- ODA will issue a warning letter to any producer with food products containing levels between 250 and 500 ppb.
- 24 ORC 3715.52, 3715.70, 3715.99

Producers interested in ODA's voluntary inspection should contact ODA's Division of Food and Safety at 614-728-6250.

#### **Facilities and Equipment**

Producers not exempt from mandatory ODA inspection will be required to have facilities and equipment that pass ODA inspection for good manufacturing practices. Production and processing facilities must have walls and a roof that effectively protect processing areas from any weather or animals and vermin (except those involved in production). Floors must be made of concrete, wood or well-maintained gravel with a dirt floor only being acceptable in areas where insects are maintained for the production of the product. Light bulbs must be shielded and coated or otherwise shatter resistant when over processing or bottling equipment. Facilities are required to always have soap, disposable paper towels, and a method to adequately wash hands. Any surfaces that will come in contact with food must be maintained in good repair, be easily cleanable, and cleaned and sanitized prior to use and after any interruption of use. Gasoline, oil, pesticides, and other hazardous materials should never be in areas used to process food.<sup>25</sup> Facilities must have potable water available for handwashing and sanitizing food equipment, with any nonmunicipal water source being tested annually.<sup>26</sup>

Equipment used to collect and transport maple sap, sorghum juice, or honey must be made with food grade materials and may not be used for any other purpose.<sup>27</sup> Food grade materials are materials that, when in contact with food, will remain safe, durable, free of rust, non-absorbent; and, will not allow the migration of deleterious substances, impart color, odor, or taste to food under normal use.<sup>28</sup> Equipment should be thoroughly washed with a chemical sanitizer in accordance with US EPA's approved manufacturer's label and rinsed with potable water prior to use and air dried and properly stacked for storage.<sup>29</sup> All equipment that comes in contact with food, including hoses, may not be stored on the ground.<sup>30</sup>

Barrels, drums, or other bulk containers used to ship or store products must be made of food grade materials, be in good condition and easily cleanable, be cleaned and sanitized prior to each use, and must be free of water prior to use. No container that has rusted, has lead solder on the food-contact surface, or has previously contained a chemical or other hazardous material such as lead or paint may be used to store or ship maple syrup, honey, or sorghum.<sup>31</sup>



#### **Packaging**

Packaging for maple syrup, honey, and sorghum must be made of food grade materials, be clean and free of water prior to filling, free from rust or any other material that could damage the contents, constructed with an air tight closing mechanism, and filled with not less than 90% of the package's capacity.<sup>32</sup> Canning containers designed for reuse may be used more than once if they are washed and sanitized, but the closures for the containers may only be used once.<sup>33</sup> ODA also recommends the sanitation of new containers when the container has been loosely wrapped or the source of the container is questionable.

#### Labels

Exempt maple syrup, honey, and sorghum processors must include the following information on the label of each of their products:<sup>34</sup>

- Statement of Responsibility: The name and address of the business of the operation. The address must include the street address, the city or town, the state, and zip code. Additional information such as telephone numbers, web addresses and email addresses are permitted but must not be placed between the ingredient list and the required information for the Statement of Responsibility and cannot be used in lieu of the statement of responsibility.<sup>35</sup>
- Statement of Identity: The common or usual name of the food product that accurately describes the nature of the food or its characterizing properties in bold type font on the principal panel of display.<sup>36</sup> Foods containing only honey must be named honey and may include the source of the honey (i.e. "Clover Honey").<sup>37</sup>

<sup>25</sup> OAC 901:3-46-08

<sup>26</sup> OAC 901:3-46-09

<sup>27</sup> OAC 901:3-46-05

<sup>28</sup> OAC 901:3-46-01(C)

<sup>29</sup> OAC 901:3-46-05

<sup>30</sup> OAC 901:3-46-08(E)

<sup>31</sup> OAC 901:3-46-07

<sup>32</sup> OAC 901:3-46-06(A)

<sup>33</sup> OAC 901:3-46-06(B)

<sup>34</sup> ORC 3715.023

<sup>35</sup> ORC 3715.023, 21 CFR 101.5

<sup>36 21</sup> CFR 101.3

<sup>37 21</sup> CFR 101.3(b)

#### **Label Example: Honey**

#### EXAMPLE LABEL OF BASIC LABELING COMPONENTS

Labels must comply with all applicable state and federal regulations. Labeling regulations for a honey processor are the same as those applied to other food processors. All information on the label must be truthful and not misleading. The label example below is just one way to present the required information.

Ingredient List – Most food products are required to have an Ingredient List declaring all ingredients by common or usual name in descending order of predominance by weight. Honey is a single ingredient food; an Ingredient List is not required.

Ref: ORC 3715.023

Statement of Responsibility

Shall include the:

**Business Name** Street Address City, State, Zip Code

All information in the Statement of Responsibility shall be continuous. Telephone numbers, website addresses, and e-mail addresses are permitted, but not required. This type of extra information shall not be placed between the Ingredient List and the Statement of Responsibility and cannot be used in lieu of listing the business name, street address, city, state, and/or zip code.

Ref: ORC 3715.023

CFR - Code of Federal Regulations

ORC - Ohio Revised Code

FPLA – Fair Packaging and Labeling Act

The principal display panel (PDP) is that portion of the package label that is most likely to be seen by the consumer at the time of purchase.

**Statement of Identity** – The Statement of Identity is the name of the food. The name shall be the common or usual name of the food, and shall accurately identify or describe the basic nature of the food or its characterizing properties or ingredients. Foods that have a Standard of Identity must conform to all requirements of the standard. The common or usual name may also include the floral source of the honey, such as "Clover Honey," on the label.



Net Quantity of Contents – The term "NET WEIGHT" - or an appropriate abbreviation - shall be used when stating the Net Quantity of Contents in terms of weight. The Net Quantity of Contents shall be declared in both the U.S. Customary System and the SI (metric system). The second declaration shall be stated parenthetically. The quantity of contents shall be placed on the principal display panel. It shall be within the bottom 30 percent of the area of the label panel in lines that are generally parallel to the bottom of the package as it is designed to be displayed.

Ref: CFR 21, Part 101.7; FPLA, Title 15 - Chapter 39, 1453(a) (2) Ref: ORC 3715.023

#### **Label Example: Syrup**

#### **EXAMPLE LABEL OF BASIC LABELING COMPONENTS**

Labels must comply with all applicable state and federal regulations. Labeling regulations for a honey processor are the same as those applied to other food processors. All information on the label must be truthful and not misleading. The label example below is just one way to present the required information.

Ingredient List – Most food products are required to have an Ingredient List declaring all ingredients by common or usual name in descending order of predominance by weight. Maple Syrup is often a single ingredient food; an Ingredient List is not required except when using optional ingriedients.

Ref: ORC 3715.023

Statement of Responsibility -

Shall include the:

Business Name Street Address City, State, Zip Code

All information in the Statement of Responsibility shall be continuous. If the business name is listed in the local telephone directory, the street address may be omitted or a post office box may be used in it's place. Telephone numbers, website addresses, and e-mail addresses are permitted, but not required.

Ref: ORC 3715.023

CFR – Code of Federal Regulations

ORC - Ohio Revised Code

FPLA – Fair Packaging and Labeling Act

The principal display panel (PDP) is that portion of the package label that is most likely to be seen by the consumer at the time of purchase. **Statement of Identity** – The Statement of Identity is the name of the food. The name shall be the common or usual name of the food, and shall accurately identify or describe the basic nature of the food or its characterizing properties or ingredients. Foods that have a Standard of Identity must conform to all requirements of the standard.

Ref: ORC 3715.023



**Net Quantity of Contents** – The term "NET WEIGHT" - or an appropriate abbreviation - may be used when stating the Net Quantity of Contents in terms of weight. The Net Quantity of Contents shall be declared in both the U.S. Customary System and the SI (metric system). The second declaration shall be stated parenthetically. The quantity of contents shall be placed on the principal display panel. It shall be within the bottom 30 percent of the area of the label panel in lines that are generally parallel to the bottom of the package as it is designed to be displayed.

Ref: CFR 21, Part 101.7; FPLA, Title 15 - Chapter 39, 1453(a) (2) Ref: ORC 3715.023

#### **Checklist for Exempt Maple Syrup, Honey, and Sorghum Producers**



Consider voluntary ODA inspection of facilities and be aware of mandatory ODA food sampling authority. Double check the need for FDA Food Facility registration.



Make sure your product is made up of at least 75% of materials harvested from your own farm.



Adopt plans to ensure you have adequate and clean facilities and equipment to handle the products.



Check that all packaging products meet the minimum standards in quality and cleanliness.



Prepare and properly place on all products a label that meets all legal labeling requirements.

- **Ingredient List:** Normally, the ingredients of the food product by their common or usual name should be listed in descending order of predominance by weight (meaning heaviest ingredient is listed first). However, with single ingredient foods such as honey, maple syrup, and sorghum, an ingredient list will not be required.<sup>38</sup> If maple syrup is made with the optional ingredients of salt, or chemical preservatives, an ingredient list will then be required on the label.<sup>39</sup> Flavored honey should be labeled in accordance with the rules found in the cottage food section.
- **Net Quantity of Contents:** The net weight and volume of the food product in both the U.S. Customary System and the SI metric system should be placed in a prominent and distinct location on a principal display of the food package. When selling maple syrup or honey on site, the label must declare the net weight in the U.S. Customary System (ounces) but it does not need to have the weight in metric (grams). If maple syrup or honey is sold off site, the label will need to provide both ounces and grams. The term "NET WT" or other appropriate abbreviation must be used immediately prior to stating the quantity of food contained within the package (Ex. NET WT 12 OZ (340.19g)).40 No qualifying phrases should be used in the net quality of contents statement to exaggerate the amount of food (e.g. Net Wt. = 1 Large oz. (5g) is not acceptable).41 The net weight only includes the average quantity of food within the package and does not include the weight of the packing materials.<sup>42</sup>

Labels should be glued or secured to the packaging, however, in the event a package is so unusual that a label will not stick, a label may be attached as a card to the package. If the label makes a nutrient content or health claim, then the label must also contain all of the nutritional information in the form of a Nutritional Facts panel as prescribed by federal law.<sup>43</sup>

Exempt maple syrup, honey, and sorghum processors who have undergone voluntary inspection may also place the ODA seal of conformity and inspection on their product's label.44 Prior to incorporation of ODA seals of conformity and inspection, producers must first submit a sample of their proposed label to ODA for approval.<sup>45</sup> Products bearing the seal without inspection or approval by ODA will be considered misbranded and may be subject to penalties.46

Under Ohio law, it is illegal to label or represent a product that resembles honey as being honey when it is in fact not honey.<sup>47</sup> For products that combine honey with other ingredients, labels that include the word honey must indicate the existence of other ingredients by prominently displaying the word "blend" or something similar. 48 It is a misdemeanor to misbrand honey.49

Further, it is a misdemeanor to indicate that a product is "maple" when the product is not maple syrup, maple sugar, maple cream, or otherwise entirely derived from maple syrup without additional sweetener.<sup>50</sup> Maple syrup processors may add salt, chemical preservatives, or defoaming agents as a processing aid as long as it is listed on the ingredient list.<sup>51</sup> Producers whose standards conform with the USDA grading system may place the grade name on the package label as "U.S. Grade \_\_," and include the full grade name as listed.52

Grade A Color Classes	Taste	Light Transmittance (%Tc)
U.S. Grade A Golden	Delicate	>75.0
U.S. Grade A Amber	Rich	50.0-74.9
U.S. Grade A Dark	Robust	25.0-49.9
U.S. Grade A Very Dark	Strong	<25.0

#### Sale

Exempt syrup, sorghum, and honey producers may sell their qualifying products without being licensed as a retail food establishment when the product is sold direct-to-consumer at the following locations:

- Direct to consumers from the site of production,<sup>53</sup>
- at a farm market,54
- at a farm product auction,55
- at a festival,56 and/or
- at a farmers market.57

#### Contacts and Resources

Ohio Department of Agriculture Division of Food Safety

Phone: (614)-728-6250

Email: foodsafety@agri.ohio.gov

Web: ofb.ag/foodsafety

#### Additional Resources

Maple Syrup: ofb.ag/maplesyrupsafety

Honey: ofb.ag/honeysafety

Syrup and Extract License: ofb.ag/extractlicense

```
21 CFR 101.4
```

- 48 ORC 3715.38(C)
- 49 ORC 3715.99
- 50 ORC 3715.24, 3715.25, 3715.99
- 51 OAC 901:3-45-03, 901:3-45-02
- 52 OAC 901:3-45-03
- 53 ORC 3717.22(B)(7)
- 54 ORC 3717.22(B)(16)(c)
- 55 ORC 3717.22(B)(11)
- 56 ORC 3717.22(B)(15)
- : 57 ORC 3717.22(B)(2)(c)

OAC 901:3-45-02

<sup>40 21</sup> CFR 101.7; FPLA, Title 15 - Chapter 39, 1453(a) (2)

<sup>41 21</sup> CFR 101.105(o)

<sup>42 21</sup> CFR 101.5(a)

<sup>43 21</sup> CFR 101

<sup>44</sup> OAC 901:3-46-04

OAC 901:3-46-04(E)

OAC 901:3-46-04(F)

ORC 3715 38

# Fresh Unprocessed Fruits and Vegetables

The sale of fresh unprocessed fruits and vegetables can be a relatively accessible way for newcomers to get involved in farm-to-table markets. In Ohio, regulatory burdens for the production and sale of fresh unprocessed fruits and vegetables is very minimal. A fruit or vegetable is "unprocessed" when it is not processed beyond merely rough trimming and rinsing. To sell produce that has been processed (including washing) or on a larger scale, producers will need to determine what additional regulatory or licensing requirements may apply in order to sell their fruits and vegetables.

#### **FSMA Regulations**

The sale of fruit and vegetables is predominantly regulated by FDA through the Food Safety Modernization Act² with the ODA Division of Food Safety being the responsible agency for enforcement in Ohio. FSMA rules establish science-based minimum standards that covered farms and processors must adhere to ensure the safe growing and handling of fruits and vegetables produced for human consumption. The key requirements under FSMA address health and safety concerns with agricultural water quality, biological soil amendments, sprouts,³ domestic and wild animals, worker training and health, and equipment and buildings. FSMA rules/standards and guidance may be accessed on ODA's website at ofb.ag/foodsafety. Here are just some of the topics producers can expect to find

• Agricultural water that would be reasonably likely to transfer harmful microbes to produce through either direct or indirect contact cannot have any detectable amount of generic E. coli. Examples include water used for handwashing, to clean food-contact surfaces, or that would come in contact with produce during or after harvest (i.e. ice). If water is found to be above the general E.coli thresholds, corrective action must be taken as soon as practicable but no later than the following year.<sup>4</sup>

1 ORC 3717.01(R)

in the FSMA:

- 2 21 CFR 112, OAC 901:3-12-01
- 3 21 CFR 112.141 through 112.151
- 4 21 CFR 112.41 through 112.50. Water used to grow produce may have a geometric mean of 126 or less CFU of generic E. coli per 100mL of water with a statistical threshold of 410 CFU or less generic E. coli in 100mL of water.



- FSMA rules require that untreated biological soil
  amendments of animal origin must be applied in a manner
  that does not contact covered produce during application
  and minimizes the potential for contact with produce after
  application. Any compost used in produce production must
  meet the microbial standards that set limits on detectable
  amounts of bacteria.<sup>5</sup>
- Farmers are required to take all measures reasonably necessary to identify and not harvest produce that has been contaminated by wild or domestic animals. This requires, at minimum, visual examination of the growing areas and additional assessments during growing seasons if there is significant evidence of potential contamination by animals. Measures should be taken when there is significant evidence of the contamination to assist later during harvest (i.e. placing flags around the affected area).
- Workers should take all necessary measures to prevent contamination of produce and food-contact surfaces by sick individuals. Proper hygienic practices and available toilet and handwashing facilities for all visitors to the farm is imperative. Employees who come in contact with foodcontact surfaces need to be properly and regularly trained in the importance of health and hygiene.<sup>7</sup>
  - 21 CFR 112.51 through 112.60
- 5 21 CFR 112.81 through 112.140
- 7 21 CFR 112.21 through 112.33

Facilities must take measures to prevent contamination of produce through measures such as appropriate storage facilities, and proper maintenance and cleaning of all equipment and tools.8 The Produce Safety Rule requires that at least one responsible party from every farm covered by the rule be trained under the FDA curriculum. Training is offered by ODA at no cost to in-state producers throughout the state.

For more information about the federal standards for growing, harvesting, and holding produce for human consumption please see: ofb.ag/fsmafinalrule and ODA's website ofb.ag/divisionfoodsafety.

#### **FSMA Exemptions**

Certain small farms or producers are not covered by FSMA standards for produce safety and will be exempt from inspection for FSMA compliance. These exemptions include:

- Farms that have an average annual income of \$25,000 or less over the previous three-year period;9
- Farms that only produce fruits and vegetables for personal or on-farm consumption;10 and
- Produce that has been identified as rarely consumed raw.<sup>11</sup> This includes:
  - Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

Other farms may be eligible for qualified exemptions and modified FSMA requirements if they meet one of the following criteria:

- The on average income from food sales is less than \$500,000 and the majority of food is being sold to "qualified endusers" (the consumer of the food or a restaurant or retail food establishment located in the same state or not more than 275 miles from the farm);<sup>12</sup> or
- The produce is intended for commercial processing that adequately reduces pathogens.<sup>13</sup>

Farms with qualified exemptions will still need to meet modified requirements, including disclosing the name of the farm the produce was grown at the point of purchase and other record-keeping requirements.14

- 21 CFR 112.121 through 112.140
- 21 CFR 112.4(a)
- 21 CFR 112.2(a)(2)
- 11 21 CFR 112.2(a)(1)
- 12 21 CFR 112.3(c)
- 21 CFR 112.2(b) 21 CFR 112.2, 112.6, 112.7



voluntary inspection under the FSMA Produce Safety Rule.<sup>15</sup> Farms that request voluntary inspection must register annually with ODA between March 1 and February 28/29. Once a farm has voluntarily registered with ODA it may not withdraw its registration unless specifically permitted by ODA. Farms that choose to undergo voluntary inspection will receive documentation from ODA showing they have been inspected under the federal standards. Prior to requesting voluntary registration and inspection, farmers are able to receive a free consultation visit from ODA to help determine the specific requirements for their farm.

#### **Pesticides**

US EPA is the responsible agency for determining the appropriate use and tolerance levels of pesticides used in food production. Food with residue of any pesticide chemical beyond the tolerance or maximum levels set by EPA will be deemed unsafe for human consumption.16 Tolerances and exemptions for pesticide chemical residues can be found within the Code of Federal Regulations.17

Similar to federal regulations, Ohio law deems food to be unsafe and adulterated when any poisonous or deleterious substance is added during its production, except where such substance is required or cannot be avoided.<sup>18</sup> ODA is the responsible state agency for the regulation of pesticides and pesticide application in Ohio. Prior to the application of anypesticide or fertilizer, individuals should first contact the Pesticide & Fertilizer Section within ODA to ensure it is aware of any potential requirements, such as applicator licensing.

- 15 ORC 3717.221, OAC 901:3-12-06
- 21 USC 346a
- See 40 CFR 180. For information about how to search for tolerance levels, visit https://www.epa.gov/pesticide-tolerances.
- 18 ORC 3715.62, 3715.59

#### **State Law**

Ohio has, for the most part, adopted the federal standards for growing, harvesting, packing and holding produce for human consumption found in Title 21 of the Code of Federal Regulations.<sup>19</sup> The Ohio Department of Agriculture Division of Food Safety is responsible for overseeing produce safety enforcement. ODA has divided those who grow produce into four categories:

- Farms excluded from the FSMA rule.
- Farms that are eligible for a qualified exemption.
- Farms that are covered by the rule.
- Farms that request voluntary inspection under the rule. Farms that request voluntary inspection receive a free inspection and documentation to show they are inspected under the FSMA Produce Safety Rule. This can be a good way for small producers to show they are following produce safety standards that reduce the risk of microbial contamination during the growing, harvesting, packing, and holding of their product.

Ohio's uniform safety code specifically states that raw fruits and vegetables are to be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form. However, whole, raw fruits and vegetables that are intended for washing by the consumer before consumption need not be washed before they are sold.<sup>20</sup> Keep in mind, in order to sell fruits or vegetables without first needing to obtain a retail food establishment license, the produce must be unprocessed. This means that unless a farm has obtained proper licensing for food processing, the seller may only roughly trim and/or rinse their product before offering it for sale.

#### **Package and Label**

All statements made about fruit and vegetables, either written or verbal, must be true and honest with reference to quantity, grade, price, variety, minimum size, or the state of origin when offered for sale.<sup>21</sup>

Fruit or vegetables sold in containers used to hold or enclose a quantity of items need to be marked in a plain and legible manner with the following information:

- The full name and address of the farm.
- The contents of the package by net weight at the time of sale, numerical count, or dry measure.
- The grade in accordance with the standards adopted by the USDA if the container holds peaches, apples, potatoes, or dry onions.

- The minimum size and variety of apples or graded peaches held by the container. If the variety cannot be identified, the term "variety unknown" should be used.
- The identity of the fruit or vegetable if it is concealed.<sup>22</sup>
  Labels or stamps with the required information must use a font of adequate size<sup>23</sup> and be placed on the side, end, or cover of the container, the front or face of any bag, or on a tag attached to any bag.<sup>24</sup> Whenever fresh fruits or vegetables are packed or offered for sale in containers previously used by another person or in containers that were manufactured and labeled for a purpose other than the sale of the produce it contains, any old and/or inaccurate markings must be covered and new markings must be properly placed. If any type of bag is re-used, it should be turned inside out so that no previous markings are visible.<sup>25</sup>

When ODA has reason to believe that a container of any fruit or vegetable has been improperly labeled, it has the authority to mark the container with a notice that the container is being detained for being improperly marked.<sup>26</sup> Once a container has been marked as mislabeled, no person is able to remove or dispose of the container without the permission of ODA or a court of competent jurisdiction.<sup>27</sup>

USDA offers voluntary quality standards for fruits and vegetables and provides uniform language describing the quality and condition of the produce for sale. Information about USDA grades and standards can be found on their website: https://www.ams.usda.gov/grades-standards.

#### Sale

Fresh, unprocessed fruits and vegetables may be sold without a Retail Food Establishment License at the following locations:<sup>28</sup>

- 1. A roadside stand where only fresh fruits and vegetables are offered.<sup>29</sup>
- 2. A farmers market.<sup>30</sup>
- 3. A farm product auction.31
- 4. A festival or celebration organized by a political subdivision of the state, <sup>32</sup> and
- 5. A registered farm market.<sup>33</sup>

<sup>22</sup> ORC 925.22(A)

<sup>23</sup> ORC 925.22(B)

<sup>24</sup> ORC 925.22(C)

<sup>25</sup> ORC 925.24

<sup>26</sup> ORC 925.30

<sup>27</sup> Id

<sup>28</sup> ORC 3717.22

<sup>29</sup> ORC 3717.22(B)(3)

<sup>30</sup> ORC 3717.22(B)(2)(a)

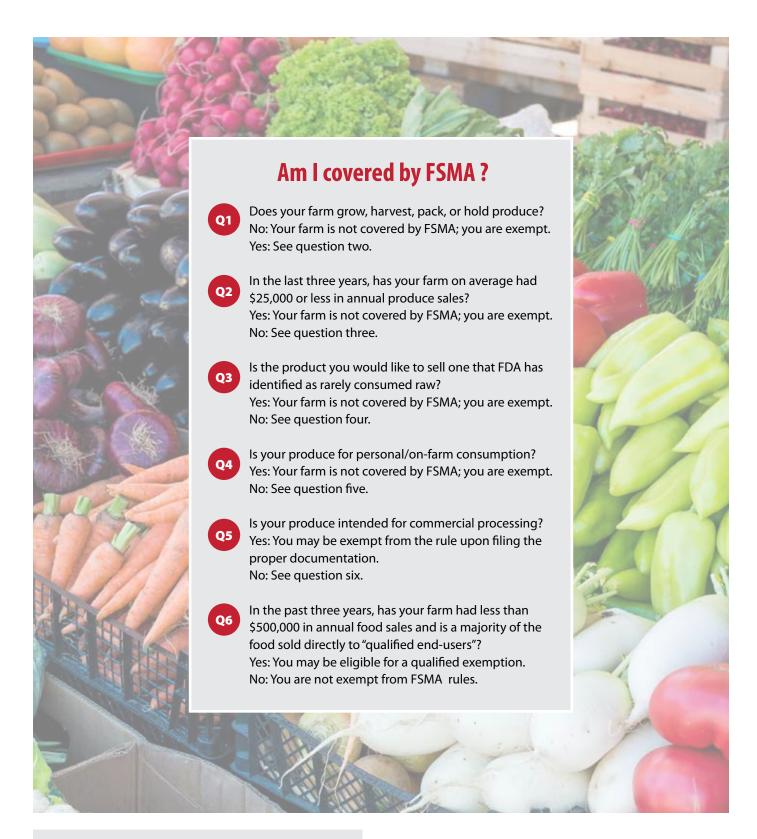
<sup>31</sup> ORC 3717.22(B)(11)(b) 32 ORC 3717.22(B)(15)(a)

<sup>33</sup> ORC 3717.22(B)(16)(a)

<sup>19</sup> OAC 901:3-12

<sup>20</sup> OAC 3717-1-03.2(G)

<sup>21</sup> ORC 925.29



#### **Contacts and Resources**

Ohio Department of Agriculture Division of Food Safety Produce Safety Manager

Phone: (614) 600-4272

Email: matthew.fout@agri.ohio.gov Web: ofb.ag/divisionfoodsafety

## Ciders and Juices

Although juices and ciders do not fall within the Ohio Food Safety Code's definition of "potentially hazardous food," the potential for juices and ciders to have illness causing infectious/toxic microorganisms or chemical/physical contaminants makes them a "high risk food." Because high risk foods can be especially dangerous for young children, older adults, and those with weakened immune systems, producers need to take extra care in the production and labeling of these products.<sup>2</sup>

To address the risk of food borne illnesses associated with ciders and juices, the FDA has established (and Ohio has largely adopted) a rule requiring processors to employ pasteurization or other similar process to achieve a 5-log reduction in the number of pathogens found within the product, and they must use Hazard Analysis and Critical Control Point (HACCP) principles for processing.<sup>3</sup> HACCP regulations apply to cider and juice products sold both in state and out of state, though there are some circumstances where a producer may be exempt from complete HACCP compliance.

## Regulation

#### **Hazard Analysis and Critical Control Point (HACCP)**

HACCP plans require juice producers to evaluate the hazards that are reasonably likely to occur for each juice they would like to produce and create individual plans to address the hazards that have been identified.<sup>4</sup> Requirements under the HACCP include good manufacturing practices, sanitation standard operation procedures, a written hazard analysis, and an HACCP plan that will consistently produce a minimum of a 5-log pathogen reduction.<sup>5</sup> 5-log pathogen reduction may be able to be achieved in several ways, with pasteurization being a common method. Plans must be written by certified individuals who have completed appropriate training in the application of HACCP principles to juice processing.<sup>6</sup> Failure to create and

- 1 OAC 3717-1-01(B)(101)
- 2 OAC 3717-1-03.7(A)
- 3 OAC 901:3-23
- 4 21 CFR 120
- $5\,$  OAC 901:3-23-07, 5-log reduction consists of pasteurization or other methods used to reduce 99.999% in microorganisms of concern.
- 6 21 CFR 120.8, 21 CFR 120.13, OAC 901:3-23-04, 901:3-23-08



implement a proper hazard analysis and critical control point plan may result in cider and juice products being declared as adulterated.<sup>7</sup>

Sanitation standard operating procedures should be regularly monitored and should include sanitation controls for:<sup>8</sup>

- water safety for water that comes in contact with food;
- condition and cleanliness of food contact surfaces, utensils, gloves, and outer garments;
- prevention of cross contamination from any insanitary objects to food;
- maintenance of hand sanitizing and toilet facilities;
- protection of food, food equipment, and food packaging material from contaminants;
- proper labeling, storage, and use of toxic compounds;
- control of employee health conditions that could result in contamination of food;
- exclusion of pests from food.

A hazard analysis determines whether there are food hazards reasonably likely to occur for the juice being processed and to identify control measures for those hazards. Hazards that are considered include microbiological contamination, parasite, chemicals, pesticides, decomposition of food, natural toxins, unapproved additives, presence of undeclared allergens,

- 7 OAC 901:3-23-10
- 3 21 CFR 120.6, OAC 901:3-23-02
- 9 21 CFR 120.7, OAC 901:3-23-03

and physical hazards. 10 A written hazard analysis will, at minimum, consist of:

- identification of food hazards;
- an evaluation of each food hazard to determine if it is reasonably likely to occur, thus requiring an HACCP plan;
- identification of control measures that can apply to control food hazards that are reasonably likely to occur;
- review of the current process to determine if any changes can be made;
- identification of critical control points.

Whenever a hazard analysis identifies one or more food hazards as reasonably likely to occur, an HACCP plan must be created, verified, validated and implemented.<sup>11</sup> At a minimum, a HACCP plan will list:

- an approved process to achieve a 5-log reduction in pertinent pathogenic microorganism hazards reasonably likely to occur;
- critical points for each of the identified hazards;
- critical limits that must be met at each of the critical points;
- procedures to monitor critical points;
- any corrective action plan that has been properly developed;
- a record-keeping system.

Corrective actions must occur whenever there is a deviation from the critical limits set in HACPP plans. 12 Corrective action can either be established in the HACCP, or can follow the following plan:

- segregate and hold affected product;
- perform a review to determine the acceptability of the product for sale;
- take action to ensure no product that is injurious to health enters commerce;
- take action to correct the cause of the deviation from the critical point;
- perform timely reassessment with an individual trained in HACCP principles.

All corrective actions must be properly recorded in compliance with the record keeping procedures.<sup>13</sup>

For more Juice HACCP guidance, please visit FDA's website: ofb.ag/juiceguidance.

### **HACCP Exemptions**

There are a couple of exemptions to HACCP compliance allotted by state and federal law; however, this does not mean there are no other regulatory requirements that will apply to production.

Raw cider and juice (juice and cider that has not undergone a 5-log reduction) may be sold at the site of production if the facility is licensed by the local health department as a retail food establishment, a licensed food establishment with ODA, or a registered farm market.<sup>14</sup> Registered farm markets or food processing facilities that would like to sell raw juice or cider will be inspected by ODA Division of Food Safety to make sure the facility is in compliance with good manufacturing practices.<sup>15</sup> Outside of the ODA licensing exemptions, a premise that produces, stores, prepares, manufactures, or otherwise handles juice is a retail food establishment that will need to apply for a license with their local health department in order to sell their product to consumers. 16 Please see the licensing section for more information.

Ohio law requires unfermented cider to be manufactured by using a mechanical washing and scrubbing device equipped with automatic scrubbing brushes and a means to add sanitizer to the water in order to remove orchard soil and dirt from the fruit prior to crushing the fruit.<sup>17</sup> "Cider" is the unfermented juice, obtained by mechanically expressing the juice from sound, mature, non-citrus fruit, from which is removed excess pulp and seeds, other than embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice.18

## Packaging and Label

Fresh juice packaged in a food service operation or retail food establishment must be honestly presented and contain the following information:19

- **Statement of Responsibility:** The name and address of the business of the operation. The address must include the street address, the city or town, the state, and zip code. Additional information such as telephone numbers, web addresses and email addresses are permitted but must not be placed between the ingredient list and the required information for the Statement of Responsibility and cannot be used in lieu of the Statement of Responsibility.<sup>20</sup>
- Statement of Identity: The common or usual name of the food product that accurately describes the nature of the food or its characterizing properties in bold type font on the principal panel of display. Juices made from concentrate must be labeled with terms such as "from concentrate," or "reconstituted" as part of the name. Beverages that contain juice must declare the % of juice on the information panel near the top. If there is no informational panel, the % of juice may be placed on the

<sup>14 21</sup> CFR 120.12, OAC 301:3-23-07

<sup>15</sup> ORC 3715.021, OAC 301:3-17, 21 CFR 117

<sup>16</sup> ORC 3717.22

<sup>17</sup> ORC 3715.27(B)

<sup>18</sup> ORC 3715.27(A) 19 OAC 3717-1-08

<sup>20 21</sup> CFR 101.5

<sup>10 21</sup> CFR 120.7(c)

<sup>11 21</sup> CFR 120.11, OAC 901:3-23-06

<sup>21</sup> CFR 120.10, OAC 901:3-23-05

<sup>13 21</sup> CFR 120.12, OAC 901:3-23-07

## **Label Example**

## BASIC REQUIRED JUICE LABELING COMPONENTS APPLE CIDER LABEL EXAMPLE

This label example is just one way to present the information required on a food product label. Information may be placed in different ways and may appear on more than one label. Labels must comply with all applicable regulations and all information must be accurate and not misleading.

Ingredient List – Ingredients shall be listed by common or usual name in descending order of predominance by weight. Meaning, the ingredient that weighs the most is listed first, followed by the next heaviest ingredient, with the ingredient that weighs the least listed last. Single ingredient food products are not required to have an ingredient statement.

Ref: CFR 21, Part 101.4

**Statement of Identity** – The Statement of Identity is the name of the food. The name shall be the common or usual name of the food and shall accurately identify or describe the basic nature of the food or its characterizing properties or ingredients. Juices made from concentrate must be labeled with terms such as "from concentrate," or "reconstituted" as part of the name.

Beverages that claim to contain fruit or vegetable juice must declare the percentage of juice in the beverage. The percent juice must be on the information panel near the top. If the package does not have an information panel, the percent juice must be placed on the principal display panel in a type size as large as the net quantity of contents.

Ref: CFR 21, Part 101.3 Ref: CFR 21, Part 102.33

## **100% APPLE CIDER**

INGREDIENTS: APPLES, POTASSIUM SORBATE (TO MAINTAIN FRESHNESS)

**Statement of Responsibility** – Shall include the:

Business Name Street Address City, State, Zip Code

All information in the Statement of Responsibility shall be continuous. If the business name is listed in the local telephone directory, the street address may be omitted. If the business name is listed in the local telephone directory, a Post Office Box may be used in place of the street address.

Telephone numbers, website addresses, and e-mail addresses are permitted, but not required. This type of extra information shall not be placed between the Ingredient List and the Statement of Responsibility.

Ref: CFR 21, Part 101.5

➤ OFBF JUICE CO. 280 N. HIGH ST. FLOOR 6 COLUMBUS, OHIO 43215



Net contents 1 gal (3.79 L)

PASTEURIZED
REFRIGERATE FOR QUALITY

**Net Quantity of Contents** – The Net Quantity of Contents shall be declared in both the U.S. Customary System and the SI (metric system). The second declaration shall be stated parenthetically. The term "Net Contents" is optional.

The quantity of contents shall be placed on the principal display panel. It shall be within the bottom 30% of the area of the label panel in lines that are generally parallel to the bottom of the package as it is designed to be displayed.

**Note:** Labeling requirements for Net Quantity of Contents is under the purview of the ODA Division of Weights and Measures. Local enforcement is provided by Weights and Measures programs administered by the county Auditors' throughout the state of Ohio

Ref: CFR 21, Part 101.7 Ref: FPLA, Title 15 – Chapter 39, 1453(a) (2) Keep Refrigerated – ODA recommends any product requiring refrigeration for food safety or to maintain quality bear the declaration "Keep Refrigerated" or a similar declaration to that effect.

#### Pasteurized -

Pasteurization is a heat treatment sufficient to destroy pathogens. Therefore, to be labeled as "pasteurized," a juice must be heat treated to destroy pathogens.

#### Warning Statement –

All juices that are not processed to kill harmful bacteria that can cause illness in those who consume it must have the following warning statement:

**WARNING:** This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.

ODA – Ohio Department of Agriculture FPLA – Fair Packaging and Labeling Act

CFR – Code of Federal Regulations

ORC – Ohio Revised Code

FALCPA – Food Allergen Labeling and Consumer Protection Act

The principal display panel (PDP) is that portion of the package label that is most likely to be seen by the consumer at the time of purchase.

The information panel is the label panel immediately to the right of the PDP, as seen by the consumer facing the product.

principal display panel in the same size as the net quantity of contents. The % of juice is calculated on a volume/volume basis.<sup>21</sup> Any beverage containing less than 100% juice must qualify the word "juice" with another term such as "beverage."22 For mixed fruit or vegetable juices, the name of the juices must be in descending order of predominance by volume or indicate that the juice is a "juice blend."23

- **Ingredient List**: The ingredients of the food product by their common or usual name, in descending order of predominance by weight (meaning heaviest ingredient is listed first). Single ingredient food products are not required to have an ingredient statement.24
- **Net Quantity of Contents:** The net weight and volume of the food product in both the U.S. Customary System and the SI metric system in a prominent and distinct location on a principal display of the food package. The term "NET WT" or other appropriate abbreviation must be used immediately prior to stating the quantity of food contained within the package (Ex. NET WT 1 GAL (3.79 L)).<sup>25</sup> No qualifying phrases should be used in the net quality of contents statement to exaggerate the amount of food (e.g. Net Wt. = 1 Large gal. (3.79 L) is not acceptable).<sup>26</sup> The net weight only includes the average quantity of food within the package and does not include the weight of the packing materials.<sup>27</sup> The quantity must be placed somewhere on the bottom 30% of the principal display panel.
- Warning Statement: Fresh juice or any beverage containing fresh juice must contain the following warning statement: WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.28
- **Keep Refrigerated:** ODA recommends any product requiring refrigeration for food safety or to maintain quality should display "keep refrigerated," "refrigerate for quality," or something similar.
- **Pasteurized:** Juice that has been properly heat treated/ pasteurized to destroy pathogens may be labeled as "pasteurized." Note, only juice or cider that has not undergone pasteurization or another form of acceptable treatment must include the above warning statement on the label.

the label must also contain all of the nutritional information in the form of a Nutritional Facts panel as prescribed by federal law.29



#### **Contact and Resources**

Ohio Department of Agriculture, Division of Food Safety

Phone: (614) 246-8256

Email: foodsafety@agri.ohio.gov

Web: ofb.ag/applecider

## **Additional Resources**

FDA HACCP Information Page: ofb.ag/haccp

If the label makes a nutrient content or health claim, then

- 21 21 CFR 101.3, 21 CFR 101.30, 21 CFR 102.33
- 22 21 CFR 102.33
- 23 21 CFR 102.33
- 24 21 CFR 101.4
- 25 21 CFR 101.7; FPLA, Title 15 Chapter 39, 1453(a) (2)
- 26 21 CFR 101.105(o)
- 21 CFR 101.5(a)
- 28 21 CFR 101.17(g), OAC 3717-1-08

# **Eggs**

Backyard flocks are not an uncommon occurrence in Ohio and can be an opportunity for chicken owners to create an additional source of income through the sale of eggs. Small egg operators enjoy certain exemptions that make the small-scale sale of farm fresh eggs possible without jumping through the regular regulatory hoops a larger scale operation is subject to. While there are less requirements imposed on small scale operators, this does not mean there are absolutely no regulatory requirements. Registration requirements will vary based on where a person would like to sell their eggs. The production and sale of eggs can be regulated and supervised by up to four government agencies: USDA, FDA, ODA, and/or a local health department. Anyone looking to sell eggs should first check what regulatory requirements they must meet.

## **Regulations**

#### **Federal**

Under the Egg Products Inspection Act,<sup>1</sup> it is unlawful to buy, sell, or transport in commerce any restricted eggs capable of use as human food unless specifically authorized by regulation.<sup>2</sup> USDA has the authority to inspect egg producers and egg processing establishments to ensure regulatory compliance and to prevent any restricted eggs or restricted egg products from entering the market for human consumption.<sup>3</sup>

A restricted egg means any check, dirty egg, incubator reject, inedible, leaker, or loss.<sup>4</sup>

- Check: An egg that has a broken shell or crack in the shell but has its shell membranes intact and contents not leaking.
- Dirty egg: An egg that has an unbroken shell with adhering dirt or foreign material.
- Incubator reject: An egg that has been subjected to incubation and has been removed from incubation during the hatching operations as infertile or otherwise unhatchable.



- Inedible: An egg that has one of the following descriptions: black rot, yellow rot, white rot, mixed rot, sour egg, egg with a green white, egg with a stuck yolk, moldy egg, musty egg, egg showing blood rings, and an egg containing embryo
- Leaker: An egg that has a crack or break in the shell and shell membranes to the extent that the egg contents are exposed or are exuding or free to exude through the shell.
- Loss: an egg is unfit for human food because it is smashed or broken so that its contents are leaking; or overheated, frozen, or contaminated; or an incubator reject; or because it contains a bloody white, large meat or blood spot, a large quantity of blood, or other foreign material.<sup>5</sup>

Restricted eggs must be properly disposed of by either shipping the egg directly to a processing plant for segregation and processing, destroying the egg, or by processing the egg for industrial use or animal food. To ensure compliance, USDA, through the Agricultural Marketing Service, will conduct periodic inspections of facilities, inventories, operations, transport vehicles, and records of egg handlers engaged in the transporting, shipping, or receiving of eggs.

<sup>1 21</sup> USC 15

<sup>2 21</sup> USC 15 1037

<sup>3 21</sup> USC 15 1034, Specifically the Agricultural Marketing Service and the Food and Safety Inspection Service

<sup>4 21</sup> USC 15 1033

<sup>5 7</sup> CFR 57.1, 9 CFR 590.5

<sup>6 7</sup> CFR 57.720

<sup>7 7</sup> CFR 57.28

Egg producers that sell the eggs from their own flocks at the site of production, on a door-to-door retail route, or at an established place of business away from the site of production owned by the producer are exempt from the AMS enforced regulations and inspections when they sell fewer than 30 dozen eggs that contain no more loss or leaker eggs allowed under the U.S. Consumer Grade B shell egg standards.8 Egg producers with a flock of 3,000 hens or less, or producers who sell directly to household consumers are also exempt from the AMS regulations.9

Egg processing plants are subject to continuous USDA Food Safety Inspection Service, inspections. 10 An egg product is any dried, frozen, or liquid egg, with or without added ingredients. 11 Cooked egg products are not included within the definition of egg products for purposes of the EPIA. Unless otherwise exempt, all egg products must be pasteurized prior to leaving a processing plant subject to USDA inspection.<sup>12</sup> Poultry producers who process and sell eggs from their own flock directly to household consumers for their exclusive use are exempt from continuous FSIS inspection.<sup>13</sup>

In addition to specifying the standards of identity for egg products, the FDA has the authority to regulate and inspect egg production establishments.14 Under the "Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation final rule, egg producers and processors must take measures to prevent human consumption of eggs contaminated with the bacterium Salmonella Enteritidis. Individualized written SE prevention plans must be made for every egg producing farm including, at minimum, the following prevention measures:15

- Pullets are raised under SE monitored conditions, or procured from a facility where they were SE monitored;
- A biosecurity program that limits visitors, protects against cross contamination via equipment or people, stray animal prevention, and no at home bird raising;



- 7 CFR 57.100(c)
- 7 CFR 57.100
- 10 21 USC 1034
- 9 CFR 590.5
- 21 USC 1036
- 9 CFR 590.100
- 21 CFR 118
- 21 CFR 118.4

- Rodent, fly, and pest monitoring and control;
- Disinfecting and cleaning poultry houses to, at a minimum, remove visible manure, dust, feathers, and old feed;
- Holding and transporting eggs at or below 45 degrees F beginning 36 hours after the egg was laid.

Producers with a flock of less than 3,000 hens and who sell all of their eggs directly to consumers are exempt from the FDA's SE prevention rule, but are not exempt from the safe handling instructions rule (see Package/Label section).16

USDA provides a voluntary egg grading service that egg producers may pay to participate in. Only shell eggs that participate in this program are eligible to bear the USDA grade mark. Eggs graded by the USDA service are categorized into one of the following categories:<sup>17</sup>

- USDA Grade AA The freshest and highest quality egg
- USDA Grade A Very high-quality eggs
- USDA Grade B Eggs are usually used for breaking stock (liquid eggs) and baking.

Certified inspectors will evaluate egg quality by observing the shell, the air cell, the white, and the yolk. AA quality eggs will have normal, clean and unbroken shells with 1/8 an inch or less of an air cell, a white that is clear and firm, and a yolk that is slightly defined and clear from defect.

For more information about USDA grading you can visit USDA's website: ofb.ag/eggstandards.

## State

Licensing or registration requirements for shell egg producers will vary depending on the producer and where they would like to sell their eggs. At a baseline, a place where food is stored, processed, prepared, or otherwise held for sale must register to obtain a Retail Food Establishment License unless otherwise exempt. 18 Additionally, ODA has the authority to enter and inspect any premises where eggs are produced, processed, stored, or sold as necessary to determine regulatory compliance.<sup>19</sup> Depending on where the eggs will be sold, RFE or ODA registration exemptions may apply.

Generally, egg producers and processors must maintain shell eggs in refrigeration at a temperature that does not exceed 45 degrees Fahrenheit.<sup>20</sup> Egg producers and processors are also required to keep records of the date of processing of the shell eggs distributed, sold, or offered for sale by them for six months.21 Small egg producers who maintain 500 birds or less and sell their eggs only from the place where the eggs at the place of production are exempt from the refrigeration and recording keeping requirements.<sup>22</sup>

- 16 21 CFR 118
- 17 ORC 925.02, 7 CFR 56
- 18 ORC 3717.22
- 19 ORC 925.07, 925.10
- 20 ORC 925.03
- 21 ORC 925.04
- 22 ORC 925.10

Small egg operators maintaining 500 or fewer birds who wish to only sell raw eggs from the premises where the eggs are produced may do so without obtaining a Retail Food Establishment license from their local health department or registering with ODA.<sup>23</sup> However, producers who sell eggs at the location of production may voluntarily register as a farm market with ODA to receive an inspection and certificate of registration.<sup>24</sup> ODA registration is free and inspections will include:

- a review of the label and packaging to ensure all legal requirements have been met,
- checking that the eggs are properly refrigerated at 45 degrees or less, and
- ensuring homes served by private wells have tested negative for coliform bacteria within the past year.

Those who pass inspection and receive a certificate of registration that shows they are in compliance with the law will be eligible to sell their eggs directly to retailers, hotels, restaurants, or institutions as an approved source.<sup>25</sup> Approved sources will also be eligible to sell their eggs directly to consumers offsite at a farmers' market if they obtain an RFE license from the health department.26

Eggs that are to be offered for sale outside of the premises where they were produced must be kept in refrigeration at an ambient temperature that does not exceed 45 degrees Fahrenheit from the time the egg is received to the time the egg is sold.<sup>27</sup> Refrigeration equipment must have in use at all times a thermometer, graduated in degrees Fahrenheit, that clearly indicates the temperature at which the eggs are being maintained.

Small egg operators who choose to sell eggs at an onsite registered farm market alongside other approved farm market items are also exempt from RFE licensing.<sup>28</sup> However, if a farm market would like to sell eggs alongside items that are not approved farm market items, an RFE license will be required in addition to the ODA farm market registration.<sup>29</sup> For more information about farm market licensing, please see page 9.

#### Package and Labeling

Egg cartons must be labeled in a prominent location with a conspicuous font providing the following information:30

- The name and address of the packer or distributor;
- An accurate statement of the quantity of the contents in terms of numerical count;
- The date the eggs were packed into the carton;
- 23 ORC 3717.22(B)(8)
- 24 ORC 3717.221
- OAC 3717-1-03.1(A) 25
- ORC 3717.21 & 3717.01 26
- 27 ORC 925.03, 925.10
- 28 ORC 3717.22(B)(16)
- ORC 3717.21
- ORC 925 021



- The identification of "ungraded" or "unclassified"31; and
- The phrase "mixed sized".

The package must also include a safe handling statement either on the outside of the carton or inside of the carton lid. The safe handling statement should read as follows: "SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly."32

Cartons may be reused if they are clean, free from debris, and in sound condition. When reusing a carton created by a processor other than the current user, all non-pertinent information such as the original processor's information, any graded information, dates, etc., must be defaced from the carton.

#### Sale

The necessary licensing/registration requirements for small scale egg producers will be determined by where the producer would like to sell their eggs.

- Direct to the consumer from the farm the birds were raised: no licensing/registration requirements.33
- At an on-site farm market with other approved farm market items: ODA Farm Market Registration required.34
- At a farmers market: RFE license from the local health department and small egg operator license.35
- At a farm product auction: no licensing/registration requirement, though voluntary registration is available with ODA.36
- To a restaurant, hotel, or retailer: Small egg operator registration.37

- 32 21 CFR 101.17(h)
- 33 ORC 3717.22(B)(8)

- 35 ORC 3717.21, 3717.01, 925, 3715.021, 3715.041(G)(6)
- 36 ORC 3717.22(B)(8)
- OAC 3717-1-03.1(A)

It is illegal to falsely advertise, label, or imply that ungraded eggs have been federally graded. See ORC 925.025.

Note, if items other than farm market products are sold then the producer will need to obtain an RFE license from the local health department. See ORC 3717.21 &



## **Contacts and Resources**

Ohio Department of Agriculture Division of Food Safety

Phone: (614) 728-6250

Email: foodsafety@agri.ohio.gov

Web: ofb.ag/eggsafety

## **Additional Resources**

Egg Products Inspection Act: ofb.ag/egginspection

USDA Shell Eggs From Farm to Table: ofb.ag/egghandling

# **Selling Raw Meat**

#### **General Information**

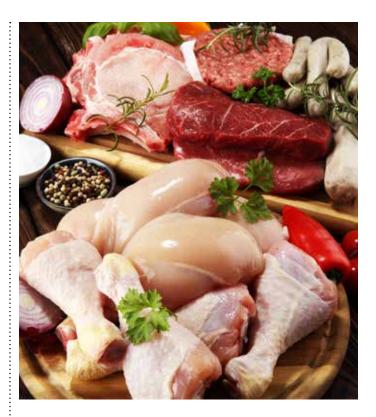
This guide covers rules and regulations those wishing to sell meat products should be aware of, but is not a complete guide. In this section you will find rules covering livestock care standards (p. 45), animal diseases (p. 46), and processing plant licensing (p. 47). Later in the section you will find rules and exemptions that are specific to the processing and sale of "red meat" such as beef, pork, or lamb (p. 52) as well as rules and exemptions that are specific to the processing and sale of poultry products (p. 55).

The purpose of this section is to provide you with an overview of the rules and regulations you may encounter as you look to process and sell the livestock raised on your farm. Anyone wishing to produce and sell their own meat products should seek guidance from the appropriate regulatory agencies for more information specific to their operation.

#### Livestock Care Standards<sup>1</sup>

Before addressing the legal requirements for processing and selling meat products, it is important to address the responsibilities associated with raising livestock. Ohio's Livestock Care Standards Board is responsible for adopting rules governing the well-being of livestock by considering factors such as best management practices, biosecurity, the prevention of disease, animal morbidity, food safety practices, affordable food supply, and generally accepted veterinarian practices (though the ODA director controls all of the processing standards).<sup>2</sup> General livestock care standards include:

- Regular access to food and water to allow normal body condition and growth.<sup>3</sup>
- Housing facilities must be designed in a manner meant to minimize injury and bruising.<sup>4</sup>
- Animals must be moved and sorted in a humane way, with the use of devices such as electric prods to be used only in the manner allowed by law.<sup>5</sup>
- 1 Note, this is a general overview of standards relevant to small scale operations. Operators reaching a higher number of animals will need to evaluate the need for permits under ORC 903.
- 2 ORC 904.03, 904.08
- 3 OAC 901:12-3-02
- 4 OAC 901:12-3-03(A)
- 5 OAC 901:12-3-03(D)



- Animals are not permitted to be maliciously or recklessly thrown, dropped, or dragged by their handlers and no handler shall pick up livestock by the ears or tail in a distressing manner.<sup>6</sup>
- Humane and approved euthanasia processes must always be used followed by proper carcass disposal.<sup>7</sup>
- Proper monitoring, health care and treatment of animals, including proper adherence to medication label instructions for administration, dosage, storage, and withdrawal times.<sup>8</sup>
- Humane transportation methods and equipment.<sup>9</sup>
- Proper care for disabled, non-ambulatory disabled or distressed livestock.<sup>10</sup>

Standards have also been created to address species and industry specific care for equine species, 11 veal, 12 alpacas and llamas, 13 dairy cattle, 14 beef cattle, 15 swine, 16 poultry layers, 17 poultry broilers and breeders, 18 turkeys and turkey breeders, 19 sheep, 20 and goats. 21

- OAC 901:12-3-03
- 7 OAC 901:12-3-04; 901:12-1. See also 7 USC 1901, 1902
- 8 OAC 901:12-3-05 9 OAC 901:12-3-06
- 10 OAC 901:12-4
- 11 OAC 901:12-15
- 12 OAC 901:12-5
- 13 OAC 901:12-14
- 14 OAC 901:12-6
- 14 OAC 901:12-6 15 OAC 901:12-7
- 16 OAC 901:12-8
- 17 OAC 901:12-8
- 18 OAC 901:12-10
- 19 OAC 901:12-11 20 OAC 901:12-12
- 21 OAC 901:12-13

Livestock care standards are independent from animal cruelty laws, with livestock care standards being enforced by ODA. Violations of Ohio livestock care standards can result in penalties ranging from \$500 to \$5,000 plus the cost incurred by ODA to investigate.<sup>22</sup> Livestock care rules can be found in OAC 901:12 or on ODA's website: ofb.ag/livestockcarestandards.

#### **Animal Diseases**

Monitoring livestock health and identifying diseased animals is not only an important practice to maintain animal welfare, but it is also vital to the industry as a whole. It is not legal to sell to another person an animal that a person knows, or has reason to know, is infected with any dangerously contagious or infectious disease or a disease of concern or is adulterated with a residue. Under Ohio law, if any person has reason to suspect the existence of a dangerously contagious or infectious disease, a disease of concern, or a residue, the person must immediately notify ODA or a licensed veterinarian.<sup>23</sup> A "dangerously contagious or infectious disease" is any disease, including any foreign animal disease, or vector, that the Ohio director of agriculture determines to be of harmful effect on the animal or poultry industry or the public health and to be capable of transmission by any means from a carrier animal to a human or to another animal.<sup>24</sup> A "disease of concern" means any disease, including any foreign animal disease, or vector, that the director determines may have an adverse impact on the animal or poultry industry or to the public health in this state, but that is not a disease that is reportable to the United States Department of Agriculture.<sup>25</sup>

ODA is responsible for protecting and promoting animal health and it does so through livestock and poultry testing and inspection, licensing, controlling animal diseases in Ohio, and providing veterinary diagnostic laboratory services. ODA has the authority to conduct investigations, including inspection of the animal owner's property or requiring the quarantine of animals. Investigations may be prompted by reports of suspected animal diseases or if ODA has reasonable suspicion that a dangerously infectious disease is present.<sup>26</sup> If a person refuses to allow ODA access to their property to inspect the premises, ODA may order the slaughter or impound of the animal suspected to be infected.<sup>27</sup>

Diseases currently listed as reportable are:28

- Anthrax
- Bluetongue
- Burcellosis (abortus, canis, melitensis, suis)
- Ceratomyxosis
- 22 OAC 901:12-2-01
- ORC 941.06 23
- ORC 941.01(A)
- 25 ORC 941.01(B)
- ORC 941.04 26
- ORC 941.043
- OAC 901:1-21-02

- Contagious equine metritis
- Eastern equine encephalomyelitis
- Equine herpes virus 1 (clinical or exposed neurological disease)
- Equine infectious anemia
- Equine piroplasmosis (babesia caballi, theileria equi)
- Foot and mouth disease
- Fowl typhoid
- Highly pathogenic avian influenza
- Hog cholera
- Infectious encephalomyelitis (poultry)
- Infectious hematopoietic necrosis
- Infectious laryngotracheitis
- Infectious pancreatic necrosis
- Infectious salmon anemia
- Lymphocytic choriomeningitis virus
- Monkeypox
- Mycoplasma gallisepticum (turkeys)
- Newcastle disease
- Poultry chlamydiosis-ornithosis
- Poultry paramyxovirus (other than Newcastle)
- Proliferative kidney disease
- **Pseudorabies**
- Psoroptic cattle scabies
- Psoroptic sheep scabies
- Rabies
- Salmonella pullorum
- Transmissible spongiform encephalopathies
- **Tuberculosis**
- Venezuelan equine encephalomyelitis
- Vesicular exanthema
- Viral hemorrhagic septicemia
- Whirling disease (myxobolus cerebralis)

## Ante-Mortem Inspection of Animal Health

Prior to slaughter, healthy animals must be properly transported to a processing facility. Livestock in transit to a facility must be provided with food, water, and rest every 28 hours.<sup>29</sup> The unloading of animals should be done in a manner that limits the excitement and discomfort of the animals, and livestock should not be forced to move faster than a walking speed.<sup>30</sup> Inspectors must perform an ante-mortem inspection prior to livestock being granted entry into any department of the establishment where they are to be slaughtered or where edible products are handled.<sup>31</sup> Animals found to be dead or dying, plainly showing symptoms of disease, or seriously crippled or non-ambulatory32 must be condemned and/or

- 29 49 U.S.C. 80502
- 30 9 CFR 313.2
- 9 CFR 309.1

32 Non-ambulatory disabled livestock are livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions. 9 CFR 309.2(b).

properly disposed of. Some examples of conditions that will lead to the condemnation of animals include:

- Plainly showing disease that would cause the disposal of the carcass upon the post-mortem inspection. This includes animals presenting with arthritis, abrasions, bruises, abscesses, mange, scabs, emaciation, anemia, and other diseases.
- Showing symptoms of certain metabolic, toxic, nervous, or circulatory disturbances, nutritional imbalances, or infectious or parasitic diseases.<sup>33</sup>
- Any swine having a temperature of 106 °F. or higher and any cattle, sheep, or goats having a temperature of 105 °F.
- · Comatose or semi-comatose condition
- Positive test for leptospirosis or anaplasmosis
- Reaction to the tuberculin test, unless labeled as an official "USDA Reactor"
- · Affected with epithelioma of the eye
- · Affected with anasarca\*
- · Hogs affected with swine erysipelas\*
- Affected with vesicular exanthema or vesicular stomatitis\* \*Animals presenting symptoms may be able to undergo supervised treatment or observation and be released for any purpose.

## **Post-Mortem Inspection of Carcass**

Post-mortem inspection of the carcass must also occur to ensure the safety and wholesomeness of the product. Inspectors will examine the carcass and organs to detect any abnormalities, diseases, or other conditions that may render the meat adulterated.<sup>34</sup> Federal law deems a carcass, part thereof, meat or meat food product to be adulterated under one or more of the following circumstances:

- It bears or contains any poisonous or deleterious substance which may render it injurious to health;
- It consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;
- It has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;
- It is, in whole or in part, the product of an animal which has died otherwise than by slaughter;
- Its container is composed, in whole or in part, of any
  poisonous or deleterious substance which may render the
  contents injurious to health;
- 33 Diseases can be found in 9 CFR 311. Notably, symptoms of anaplasmosis, ketosis, leptospirosis, listeriosis, parturient paresis, pseudorabies, rabies, scrapie, tetanus, grass tetany, transport tetany, strangles, purpura hemorrhagica, azoturia, infectious equine encephalomyelitis, toxic encephalomyelitis (forage poisoning), dourine, acute influenza, generalized osteoporosis, glanders (farcy), acute inflammatory lameness or extensive fistula should be identified as condemned and disposed of. See also 9 CFR 309.4.

- It has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption;
- If any valuable constituent has been in whole or in part
  omitted or abstracted therefrom; or if any substance has
  been substituted, wholly or in part therefore; or if damage
  or inferiority has been concealed in any manner; or if any
  substance has been added thereto or mixed or packed
  therewith so as to increase its bulk or weight, or reduce its
  quality or strength, or make it appear better or of greater
  value than it is; or
- It is margarine containing animal fat and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance.<sup>35</sup>

### Harvesting and Processing Facility Licensing and Inspection

Generally, in order for any cut of raw meat to be eligible for sale to consumers, the product must be processed by a licensed and inspected harvesting and processing facility. There are several different categories a facility may operate under: 1) ODA Fully Inspected Operator License, <sup>36</sup> 2) ODA Custom Exempt Operator License, 3) ODA Voluntary Inspection License, & 4) USDA Fully Inspected Facilities.

#### Federally Inspected Facility

USDA's Food Safety and Inspection Service is responsible for ensuring that meat and poultry products are safe, wholesome, and properly labeled. In order to be eligible to enter interstate commerce, a product must be processed at a USDA inspected facility or a facility that is a Cooperative Interstate Shipping Program participant.<sup>37</sup> Federal inspectors conduct day-to-day plant inspections to verify continued compliance with federal standards, observing the process from the ante-mortem inspection to the post-mortem inspection.

The Federal Meat Inspection Act and its accompanying regulations provide the standards, rules, and procedures that a facility slaughtering and/or processing meat must follow.<sup>38</sup> These mandatory guidelines cover topics including facility inspection,<sup>39</sup> sanitation,<sup>40</sup> pre and post-mortem inspections,<sup>41</sup> the humane handling and slaughter of livestock,<sup>42</sup> adulteration and misbranding standards,<sup>43</sup> disposal of diseased or otherwise adulterated carcasses and parts,<sup>44</sup> sales and recalls, <sup>45</sup> marking

<sup>35 21</sup> U.S.C. 601

ODA operated facilities may also be a participant in the Federal CIS Agreement.

<sup>37</sup> ODA holds a CIS agreement with USDA which allows facilities with less than 25 employees that have met certain minimum federal requirements to produce products for interstate commerce. For more information see https://www.fsis.usda.gov/inspection/state-inspection-programs/cooperative-interstate-shipping-program.

<sup>38 21</sup> U.S.C. 601-695, 9 CFR 300-599

<sup>39 9</sup> CFR 307, 318,

<sup>40 9</sup> CFR 416

<sup>41 21</sup> U.S.C. 603, 604; 9 CFR 309, 310

<sup>42 21</sup> U.S.C. 610, 9 CFR 313

<sup>43 9</sup> CFR 301

<sup>44 21</sup> U.S.C. 610, 9 CFR 311

<sup>45 21</sup> U.S.C. 610....

and labeling,46 record keeping,47 consumer protection standards, and other food safety standards.<sup>48</sup>

Major cuts of meat processed in a federally inspected facility that have passed inspection will receive a standard "inspected and passed" mark or stamp, while products that do not pass will receive a "inspected and condemned" mark or stamp. 49 USDA inspection stamps and USDA grading are two separate processes. While USDA inspection (or CIS inspection) is required for the interstate sale of products, USDA grading is an optional service that certifies meat is of a particular quality.<sup>50</sup> It is unlawful to place the official inspection legend or any other official mark on any product or product container except under the supervision of a federally approved program employee.<sup>51</sup>

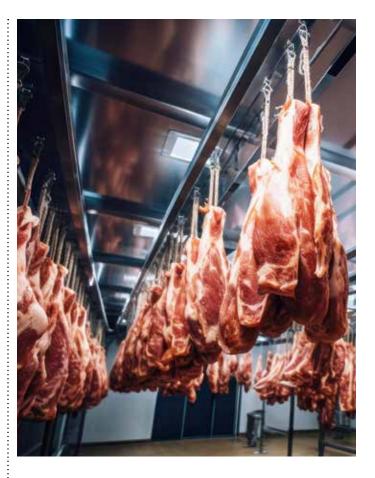
For more information about standards and inspections for federal facilities, please visit USDA's FSIS website: ofb.ag/federalmeatinspection.

## **ODA Fully Inspected Operators**

An establishment that has been licensed as a fully inspected operator with ODA is able to produce products eligible for sale to the general public only within the state of Ohio.<sup>52</sup> Fully inspected facilities are monitored by the Ohio Department of Agriculture, Division of Meat Inspection, with ODA inspectors being present at the facility each day it is processing a product intended for sale.53 Fully inspected operator licenses come with a fee of \$100 and must be renewed annually by March 31.54 Applications can be requested from and submitted to the Ohio Department of Agriculture Meat Inspection Division.<sup>55</sup>

On-site surveys for facility compliance will evaluate all relevant categories of requirements, marking them as 1) compliant with regulations, 2) a potential area of food safety concern, or 3) an area of critical concern. Categories surveyed include:

- Required documentation: Written sanitation SOP, written HACCP Plan, Water Potability Certificate, Sewage Certificate, other certificates, food defense plan, and recall
- Marks of inspection: labels, brands, and security for accountable items.
- Building construction: Building, structures, rooms, floors, walls, ceilings, doors, ventilation, separation of official & non-official spaces, and facilities for employees.
- Plumbing: water and supply distribution, and drains.
- Safety: hazards.
- Facilities and equipment: welfare, outside premise (pests),
- 21 U.S.C. 619, 9 CFR 316, 412
- 21 U.S.C. 642, 9 CFR 320 47
- 9 CFR 441
- 49 21 U.S.C. 606
- 7 CFR 53, 54
- 9 CFR 316.3, 317.1
- In order to sell products outside of Ohio, processing plants must be licensed by
- ORC 918.02
- ORC 918.08
- ORC 918 28



storage area, chilling systems, and other production areas.

- Ante-mortem: facilities & lighting, suspect facilities/lighting, and humane handling facilities.
- Post-mortem: facilities & equipment, lighting, retain products facilities, and condemned/inedible facilities.
- Processing: facilities, retained product facilities, and condemned/inedible facilities.

If, after inspection, ODA finds that an establishment is not in compliance with the relevant rules and laws, an application for a license will be denied.<sup>56</sup> If a violation is found at a facility that is already licensed, ODA will issue a notice of the violation and allow the facility 10 days to come into compliance before imposing progressive enforcement actions, or revoking or suspending the license.<sup>57</sup> Violations of certain meat inspection laws will allow for immediate enforcement actions by ODA.58

Ohio has adopted a large portion of the Federal Food Safety Inspection Act, making requirements such as written Standard Sanitation Operating Procedures (SSOP), written Hazard Analysis and Critical Control Point Plans (HACCP), and written blueprint narratives for processing and slaughter areas necessary requirements for inspected facilities.<sup>59</sup>

<sup>56</sup> ORC 918.28(A)

<sup>57</sup> ORC 918.28(B)

<sup>58</sup> ORC 918.28(C)

<sup>59</sup> OAC 901:2-1

An SSOP must be established and documented at every licensed facility and should consider the following requirements:<sup>60</sup>

- Sanitary Facilities: The regulation requires that processing establishments have facilities, including buildings, fixtures, and equipment, that are designed and maintained in a manner that prevents food contamination. This includes having adequate lighting, ventilation, plumbing, drainage systems, and employee facilities such as dressing rooms and lavatories to ensure cleanliness and prevent the growth of bacteria. Pest management in a manner that is safe and effective for a food processing facility is also imperative to prevent the harborage and breeding of pests. This may involve implementing preventive measures, such as proper waste management, sealing entry points, and using approved pesticides.<sup>61</sup>
- Equipment and Utensils: Processing establishments must have equipment and utensils that are clean, maintained in good repair, and sanitary. Equipment surfaces that come into contact with food must be made of materials that are corrosion-resistant and non-toxic. They must be cleaned and sanitized regularly to prevent cross-contamination.<sup>62</sup>
- Cleaning and Sanitizing: Processing establishments have effective procedures for cleaning and sanitizing all areas, equipment, and utensils to protect against adulteration during processing, handling, storage, loading, unloading and transport. This includes establishing protocols for the frequency of cleaning, the use of appropriate cleaning agents, and the verification of cleanliness.<sup>63</sup>
- Employee Hygiene: Employees involved in the processing of meat and poultry products maintain a high level of personal hygiene. This includes following proper handwashing practices, wearing clean and appropriate clothing, and taking necessary precautions to prevent contamination. Any person who has or appears to have an infectious disease, open lesions, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.<sup>64</sup>
- SSOP: Establishments must develop, implement, and maintain SOPs for sanitation that will be conducted daily in order to prevent direct contamination or adulteration of products.<sup>65</sup>
- Record Keeping: Establishments are required to maintain records that document their compliance with the sanitation requirements. These records should include details of

cleaning procedures, frequency, and results of testing or verification activities.<sup>66</sup>

Facilities must also create and implement a HACCP plan which identifies potential food safety hazards likely to occur in the production process and identifies measures to control these hazards.<sup>67</sup> HACCP plans should consider the following:

- Hazard Analysis: A thorough hazard analysis that identifies biological, chemical, and physical hazards that may be reasonably likely to occur. This analysis helps in determining critical control points (CCPs).<sup>68</sup>
- Critical Control Points (CCPs): Establishments must identify CCPs, which are specific steps in the process where control measures can be applied to prevent, eliminate, or reduce identified hazards to an acceptable level.<sup>69</sup>
- Establishing Critical Limits: Critical limits are established for each CCP, which are specific criteria or values that must be met to ensure food safety. These limits are based on scientific principles and are designed to prevent, reduce, or eliminate the identified hazards.<sup>70</sup>
- Monitoring: Establishments must monitor the CCPs to ensure they are within the established critical limits.
   Monitoring involves conducting measurements or observations and recording the results to ensure the process is under control.<sup>71</sup>
- Corrective Actions: If a deviation from a critical limit occurs, establishments must take appropriate corrective actions to address the deviation, restore control, and prevent the distribution of unsafe food.<sup>72</sup>
- Verification: Establishments are required to conduct verification activities to ensure the HACCP system is functioning effectively. Verification includes procedures such as reviewing records, conducting audits, and reassessing the HACCP plan.<sup>73</sup>
- Record Keeping: Establishments must maintain records documenting the implementation of the HACCP system, including the hazard analysis, CCPs, critical limits, monitoring activities, corrective actions, and verification procedures.<sup>74</sup>

Written blueprint narratives for slaughter and processing areas are also required in order to be a fully licensed facility. These written narratives will include descriptions of various aspects related to the business such as:

- · Location and contact information
- The flow of operation
- Lighting
- Ventilation

<sup>60</sup> USDA SSOP guideline https://www.fsis.usda.gov/guidelines/2020-0009

<sup>61 9</sup> CFR 416.2

<sup>62 9</sup> CFR 416.3

<sup>63 9</sup> CFR 416 4

<sup>64 9</sup> CFR 416.5

<sup>65 9</sup> CFR 416.11, 416.12, 416.13, 416.14

<sup>66 9</sup> CFR 416.16

<sup>67 9</sup> CFR 417

<sup>68 9</sup> CFR 417.2

<sup>69 9</sup> CFR 417.2(c)

<sup>70</sup> lo

<sup>71 9</sup> CFR 417.4

<sup>72 9</sup> CFR 417.3 73 9 CFR 417.4

<sup>74 9</sup> CFR 417.5

- Refrigeration
- Plumbing
- Sewage
- Dry Storage
- Welfare Facilities
- Slaughter
- Stunning
- Rails and Truck Ways
- Viscera Separation
- Carcass Washing
- **Retention Rooms or Compartments**
- Species Specific Plans

More information on what is required to be included in a blueprint narrative can be found on ODA's website: https://agri. ohio.gov/divisions/meat-inspection/licenses/meat-inspectionlicense-for-fully-inspected-operators.

#### Custom Exempt Operator License

Separate from a fully inspected operator license, ODA offers a custom exempt operator license for facilities looking to operate outside of the otherwise strict day-to-day inspection requirements. With less stringent requirements than a fully inspected processing facility, custom exempt operator licensed facilities may offer the service of harvesting and processing poultry and red meat products, but they may not produce products available for sale to consumers in the general market. Products produced under this license must be labeled "not for sale," kept separate from meat products eligible for sale, and may only be delivered to the owner of the animal. Facilities must keep a record of the animals they process under the custom exempt license. Records must include the date of processing, the name of the owner, the address of the owner, the number of animals processed, and the services performed (MI-93 Record).

Facilities operating under this license are required to comply with federal sanitation requirements designed to prevent the creation of insanitary conditions and prevent product adulteration through an SSOP (see above). Custom exempt facilities are <u>not</u> required to develop and implement an HACCP program. Further, unlike Fully Inspected Operators who are required to have a daily ODA inspector visit, Custom Exempt Operators will be covered on a random basis.

On-site surveys for facility compliance will evaluate all relevant categories of requirements, marking them as 1) compliant with regulations, 2) a potential area of food safety concern, or 3) an area of critical concern. Survey categories will generally include an inspection for:

- Required documents such as written sanitation SOPs, water potability certificates, sewage certificates and MI-93 records;
- Marks of inspection and proper labeling;
- Proper building construction and layout;
- Proper plumbing with adequate water supply, distribution, and drainage;

- Proper safety measures in place to address hazards;
- · Proper equipment and facilities, including upkeep and maintenance; and
- Proper processing procedures.

Licenses come with a fee of \$100 and must be renewed annually by March 31.75 Applications can be requested from and submitted to the Ohio Department of Agriculture Meat Inspection Division.<sup>76</sup> If, after inspection, ODA finds that an establishment is not in compliance with the relevant rules and laws, an application for a license will be denied.<sup>77</sup> If a violation is found at a facility that is already licensed, ODA will issue a notice of the violation and allow the facility 10 days to come into compliance before imposing progressive enforcement actions, or revoking or suspending the license.<sup>78</sup> Violations of certain meat inspection laws will allow for immediate enforcement actions by ODA.79

## Voluntary Meat Inspection License for Custom Operators<sup>80</sup>

The Voluntary Meat Inspection License is a voluntary licensing and inspection system that allows custom operators to harvest and/or process certain exotic animals under modified regulatory compliance standards with ODA oversight to ensure certain food safety standards are being met. Products produced under this license are eligible to be sold anywhere in the United States. The following food processing facilities may be eligible for a Voluntary Meat Inspection License:

- Cervidae, other bovidae, camelidae and hybrids thereof
- Ratites, domestic rabbits
- Monitored captive deer, captive deer with status, or captive deer with certified chronic wasting disease status
- Pheasant
- Quail
- Partridge
- Peafowl
- Grouse
- Captive raised wild turkey
- Captive raised waterfowl
- Other poultry

Voluntarily licensed facilities are required to comply with federal sanitation requirements, which are designed to prevent the creation of insanitary conditions and prevent product adulteration. Standard operating procedures must

<sup>75</sup> ORC 918.08

<sup>76</sup> ORC 918.28

<sup>77</sup> ORC 918.28(A)

<sup>78</sup> ORC 918.28(B)

ORC 918.28(C)

<sup>80</sup> ORC 918.12

be established and documented at every licensed facility and should consider the following requirements:

- Sanitary Facilities: The regulation requires that processing establishments have facilities, including buildings, fixtures, and equipment that are designed and maintained in a manner that prevents food contamination. This includes having adequate lighting, ventilation, plumbing, drainage systems, and employee facilities such as dressing rooms and lavatories to ensure cleanliness and prevent the growth of bacteria. Pest management in a manner that is safe and effective for a food processing facility is also imperative to prevent the harborage and breeding of pests. This may involve implementing preventive measures, such as proper waste management, sealing entry points, and using approved pesticides.81
- Equipment and Utensils: Processing establishments must have equipment and utensils that are clean, maintained in good repair, and sanitary. Equipment surfaces that come into contact with food must be made of materials that are corrosion-resistant and non-toxic. They must be cleaned and sanitized regularly to prevent cross-contamination.82
- Cleaning and Sanitizing: Processing establishments must have effective procedures for cleaning and sanitizing all areas, equipment, and utensils to protect against adulteration during processing, handling, storage, loading, unloading and transport. This includes establishing protocols for the frequency of cleaning, the use of appropriate cleaning agents, and the verification of cleanliness.83
- Employee Hygiene: Employees involved in the processing of meat and poultry products must maintain a high level of personal hygiene. This includes following proper handwashing practices, wearing clean and appropriate clothing, and taking necessary precautions to prevent contamination. Any person who has or appears to have an infectious disease, open lesions, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.84
- Sanitation Standard Operating Procedures (SOP): Establishments must develop, implement, and maintain SOPs for sanitation that will be conducted daily in order to prevent direct contamination or adulteration of products.85
- Record Keeping: Establishments are required to maintain records that document their compliance with the sanitation requirements. These records should include details of cleaning procedures, frequency, and results of testing or verification activities.86

Facilities must also create and implement a Hazard Analysis and Critical Control Point plan (HACCP) which identifies potential food safety hazards likely to occur in the production process and identifies measures to control these hazards.87 HACCP plans should consider the following:

- Hazard Analysis: A thorough hazard analysis that identifies biological, chemical, and physical hazards that may be reasonably likely to occur. This analysis helps in determining critical control points (CCPs).88
- Critical Control Points (CCPs): Establishments must identify CCPs, which are specific steps in the process where control measures can be applied to prevent, eliminate, or reduce identified hazards to an acceptable level.89
- Establishing Critical Limits: Critical limits are established for each CCP, which are specific criteria or values that must be met to ensure food safety. These limits are based on scientific principles and are designed to prevent, reduce, or eliminate the identified hazards.90
- Monitoring: Establishments must monitor the CCPs to ensure they are within the established critical limits. Monitoring involves conducting measurements or observations and recording the results to ensure the process is under control.91
- Corrective Actions: If a deviation from a critical limit occurs, establishments must take appropriate corrective actions to address the deviation, restore control, and prevent the distribution of unsafe food.92
- Verification: Establishments are required to conduct verification activities to ensure the HACCP system is functioning effectively. Verification includes procedures such as reviewing records, conducting audits, and reassessing the HACCP plan.93
- Record Keeping: Establishments must maintain records documenting the implementation of the HACCP system, including the hazard analysis, CCPs, critical limits, monitoring activities, corrective actions, and verification procedures.94

In addition to sanitary requirements, facilities will also need to comply with humane animal handling regulations, labeling requirements, and all relevant sections of chapter 918 of the Revised Code.

Establishments that receive a voluntary state inspection must renew with ODA annually, with the licensing term expiring March 31. Renewals are sent each year by the ODA Division of Meat Inspection. In addition to a \$100 licensing fee, establishments will also be required to pay inspection fees at an hourly rate.

<sup>9</sup> CFR 416.2

<sup>9</sup> CFR 416.3

<sup>9</sup> CFR 416.4

<sup>9</sup> CFR 416.5

<sup>9</sup> CFR 416.11, 416.12, 416.13, 416.14

<sup>9</sup> CFR 416.16

<sup>87 9</sup> CFR 417

<sup>88 9</sup> CFR 417.2

<sup>89 9</sup> CFR 417.2(c)

<sup>91 9</sup> CFR 417.4

<sup>92 9</sup> CFR 417.3 93 9 CFR 417.4

<sup>94 9</sup> CFR 417.5

## **Selling Frozen Livestock/Red Meat**

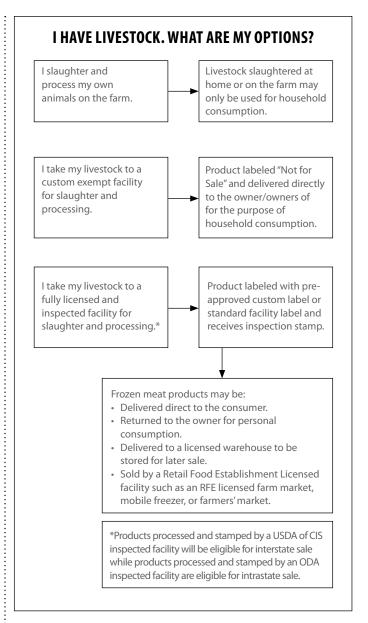
In order to sell typical domestically produced raw red meat such as beef, pork, or lamb in Ohio, the product will need to be harvested and processed by a licensed operator. While Ohio has largely adopted the requirements found in the Federal Meat Inspection Act for Ohio's fully inspected facilities, there are differences in regulations and enforcement.95 Only products produced in a USDA or CIS inspected facility may travel across state lines for sale. The sale of products from an ODA inspected facility must remain within the state. In addition to being aware of the inspection level of their processing facility, producers will also need to be aware of the licensing requirements specific to their desired method of sale.

## **Fully Inspected Operation**

In order for a raw meat product to be eligible for sale for human consumption it must be harvested and processed by a fully inspected and licensed operator. Products from USDA inspected facilities may be sold outside of Ohio while products from ODA inspected facilities may only be sold within the state of Ohio. ODA fully inspected facilities that participate in the Cooperative Interstate Shipping Program may operate as federally-inspected facilities to produce products eligible for interstate sale.96

Producers that utilize fully inspected facilities may then choose to have their product delivered directly to the consumer or returned to them. A producer that chooses to have the product returned to their farm or home must either store the meat for later sale in an ODA inspected storage facility or use the product for their personal household consumption. It is important to note that a storage area within the home will not be eligible to become a registered warehouse, though a barn or garage may be eligible. Storage areas must be free from chemicals and pests and the equipment must be suitable to maintain the product at the proper temperature. Processed cuts of meat meant for sale should never be stored with any unprocessed animal carcasses.97

In order to sell products that have not been delivered directly to consumers from the processing facility, producers may need to obtain a Retail Food Establishment License from their local health department. This includes selling frozen meat products at a farm market, from a mobile freezer, or at a farmers market. A retail food establishment license is not required in situations where frozen meat is pre-ordered and delivered directly to the individual who ordered it without intermediate storage. Individuals should reach out to their local health department to determine their licensing requirements.



## Exemptions from Fully Inspected Facility Requirement

While the general rule is that meat must be processed in a fully inspected facility in order to be used for human consumption, there are several exemptions that may apply.

## At home for personal use

Livestock products slaughtered on the farm for personal use may only be for the private use of the owner raising the livestock, members of their household, household non-paying guests, or household employees only.98 The slaughter and processing can only be performed by the owner of the livestock in order for the personal use exemption to apply.

Even though the licensing and inspection requirements do not apply to the personal use of livestock meat, it is still unlawful to serve any product that is unfit for human

<sup>95</sup> ORC 918, OAC 901:2-1

<sup>9</sup> CFR 332

ORC 915 09



consumption, misbranded products, or handle the product under any unsanitary conditions.<sup>99</sup> Additionally, personal exempt meat products may only be consumed for personal use and may not be sold or donated under any circumstance.

#### Custom Exempt License Operator

Custom Exempt License holders may provide slaughter and processing services to owners of livestock for their exclusive use in the household of the owner, by the owner, members of the owner's household, non-paying guests, and employees. <sup>100</sup> Exempt Operators must keep records documenting the numbers and amount of livestock slaughtered, the types of products prepared, and the names and addresses of the owners of the livestock and products. <sup>101</sup>

Operators may not slaughter any livestock that would result in food being unfit for human consumption. <sup>102</sup> This includes a prohibition against slaughtering any cattle that arrive in a non-ambulatory disabled state. <sup>103</sup> Field-dressed livestock may be brought to a Custom Exempt Operator for processing, though the operator may require a written statement confirming the animal was ambulatory at the time of slaughter. Further, operators may not produce any product that would be considered adulterated under the Federal Meat Inspection Act. <sup>104</sup> This means products cannot include specified risk materials such as the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord, dorsal root ganglia of cattle 30 months of age or older, and the distal ileum and tonsils from

cattle. 105 These materials and any other inedible material must be disposed of in a manner that would prevent them from entering human food channels. Custom Exempt Operators are also required to comply with the Humane Methods of Livestock Slaughter Act. 106

Facilities that operate as both a Custom Exempt Operation and a Fully Inspected Operation must keep the products separate either by time or by location. Any product created under the custom exemption must be labeled as "Not for Sale" and delivered to the owner. Meat produced under this exemption may only be returned to the owner of the livestock and cannot be sold or donated. Any product not delivered to the owner of the animal must be denatured and identified as not suitable for human consumption. Open to the owner of the animal must be denatured and identified as not suitable for human consumption.

Although the meat produced under this exemption may not be sold to consumers in the traditional sense; whole, half, and quarter cuts may be sold directly to consumers for their personal use. In Ohio, up to four owners may be listed as the owner of an animal when it is delivered for slaughter. This means that those wishing to receive meat slaughtered and processed will need to purchase an animal based on the live weight, price-perhead basis, or other quantity pertaining to the live animal with the Custom Exempt Operator only being able to charge a fee for their services. No individual cuts may be sold and no less than a quarter of an animal may be sold under this exemption. An individual licensed as a Custom Exempt Operator who owns livestock may sell a live animal to a buyer and also provide their slaughter and processing services separately.

Custom Exempt products must be delivered directly to the party/parties listed as the owner of the livestock.

## Marketing

Misbranded or adulterated products may not be sold. In order to enter into commerce, meat produced at a fully inspected facility must display a label that has been inspected and approved by the proper authority. For federally inspected facilities, no final label may be used on any product unless it has been approved by the FSIS Labeling and Program Delivery staff.<sup>111</sup> For state inspected facilities, no final label may be used unless it has been approved by ODA Labeling staff.<sup>112</sup> Official establishments, both state and federal, are authorized to use generically approved labels as long as all of the mandatory labeling features are present and no there are no special statements or claims such as logos, trademarks, or nutritional claims.<sup>113</sup> Livestock owners may choose to use the facility's

<sup>99 21</sup> U.S.C. 623(d)

<sup>100 9</sup> CFR 303.1(a)(2)

<sup>101</sup> OAC 901:2-1-04(C)(3)

<sup>102 9</sup> CFR 303.1(f)

<sup>103 9</sup> CFR 309.3(e)

<sup>104 9</sup> CFR 303.1(b)(1)

<sup>105</sup> Cite FSIS

<sup>106 7</sup> U.S.C. 1901-1907, 9 CFR 313

<sup>107</sup> OAC 901:2-1-04(C)(2)

<sup>108 9</sup> CFR 303.1(a)(iii), 9 CFR 316.16

<sup>109 9</sup> CFR 303.1(b)(4)

<sup>110</sup> OAC 901:2-1-04(C)(3)

<sup>111 9</sup> CFR 412.1

<sup>112</sup> OAC 901:2-1-04(N)

<sup>113 9</sup> CFR 412.2, OAC 901:2-1-04(N)(4)

generic label or they may choose to create their own and submit an application for label approval. Label approval guidelines for both FSIS inspected facilities and ODA inspected facilities can be found in the "Inspection Label Approval Guideline" available on ODA's website: https://agri.ohio.gov/divisions/ meat-inspection/inspection-labels.

#### Label Requirements:

Products must provide the following information on a label placed on the principal panel of display:114

- Product name: All products must be identified by their standard name and properly spelled. If no standard identity is established for a product, then the common or usual name must be used.115
- **Ingredient statement:** If the product is fabricated from two or more ingredients, the word "ingredients" followed by the list of ingredients by their common or usual name arranged in descending order of prominence with multiingredient components sublisted. The term "spice" means any aromatic vegetable substance in the whole, broken, or ground form, with the exceptions of onions, garlic and celery, whose primary function in food is seasoning rather than nutritional and from which no portion of any volatile oil or other flavoring principle has been removed. 116
- The name and place of business of the manufacturer, packer, or distributor for whom the product is prepared: The name or trade name of the person that prepared the product may appear as the name of the manufacturer or packer without qualification on the label. Otherwise the name of the distributor of the product shall be shown with a phrase such as "Prepared for \* \* \*" or "Distributed by \*\*\*".117
- An accurate statement of the net quantity of contents: On the lower 30% of the principal panel of display with proper size and spacing. This cannot include any term qualifying a unit of weight or measure. Except when dealing



with packages containing 1 pound or 1 pint and less than 4 pounds or 1 gallon when the statement shall be expressed in ounces or pounds, weight must be expressed in terms of avoirdupois weight or liquid measure. For example, a declaration of 34 pound of avoirdupois weight shall be expressed as "Net Wt. 12 oz." and a declaration of 1 1/2 pounds of avoirdupois weight shall be expressed as "Net Wt. 24 oz.," "Net Wt. 1 lb. 8 oz.," "Net Wt. 1 ½ lb.," or "Net wt.  $1.5 \ lbs.$ "  $^{118} \ USDA$  permits exceptions from this requirement for individually-wrapped, random-weight, consumer-size packages shipped in bulk containers and certain meat and poultry products subject to shrinkage.

- An official inspection legend and the number of the official establishment: An official inspection legend is any symbol prescribed by regulation showing that a carcass or parts of carcasses were inspected and passed by FSIS in an official establishment in accordance with federal regulations. Official establishment numbers are assigned to each establishment granted inspection service.119
- Any other label information in accordance with the special provisions associated with the standards of identity or composition as prescribed.120
- Safe Handling Statement: Packaged products that require special handling to maintain their wholesome condition must prominently display the applicable handling statement "Keep Refrigerated," "Keep Frozen," or "Perishable - Keep Refrigerated or Frozen."121
- Safe Handling Instructions: Raw or partially cooked meat destined for household consumers or institutional uses must include the following under the heading "Safe Handling Instructions":
  - "This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, please follow these safe handling instructions."

This statement then should be accompanied by the following statements:

- "Keep refrigerated or frozen. Thaw in refrigerator or microwave. [This statement must appear next to a graphic illustration of a refrigerator.
- Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry. [This statement must appear next to a graphic illustration of soapy hands under a faucet.]
- Cook thoroughly. [This statement must appear next to a graphic illustration of a skillet.]

<sup>121 9</sup> CFR 381.125

 Keep hot foods hot. Refrigerate leftovers immediately or discard. [This statement must appear next to a graphic illustration of a thermometer]."122

Nutrition labeling is not required for meat products that are single-ingredient, raw, produced by small businesses, 123 intended for further processing, not for sale to consumers, prepared and sold at a retailer, and products in small packages (total surface area of less than 12 square inches). However, if a label makes any sort of nutritional claim, such as "low sodium" or "no sugar added," then the mandatory nutritional labeling requirements will apply.<sup>124</sup> When required, nutritional panels must include the total calories, calories from fat, total fat, saturated fats, cholesterol, sodium, total carbohydrates, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron. Voluntary nutrient disclosures include calories from saturated fat, trans fat, stearic acid, polyunsaturated fat, monounsaturated fat, potassium, insoluble fiber, sugar alcohol, other carbohydrates, vitamins, and minerals. 125 Nutrient and food components must be declared based on a serving size, which is the amount of food customarily consumed per eating occasion. 126

Special logos, statements and claims, such as claims that a product is "natural," health claims, claims regarding the raising of animals, claims that a product is organic, ingredient and processing claims, allergen statements, negative claims (that something is not in the product), and claims of geographical significance must be approved by ODA or FSIS. Label claims must be supported by evidence that the claim is true in order to be approved for use.

122 9 CFR 317.2(I)

 $123\,$  A company employing 500 or fewer people, specific products produced a 100,000 products per year or less qualifies under this exemption.

124 9 CFR 317.400

125 9 CFR 317.309

126 9 CFR 317.300-317.400

127 9 CFR 412.1

## **Selling Frozen Poultry Meat**

Similar to other meat products, poultry producers who wish to sell their product must utilize the processing services of a licensed inspection plant. However, unlike other meat producers, the law affords some additional exemptions for certain small producers looking to market their poultry products. "Poultry" includes not only chicken, but it also includes pheasant, quail, partridge, peafowl, grouse, captive raised wild turkey, or captive raised waterfowl.128 The regulatory authority over the production and sale of raw poultry will vary based on several factors such as flock size or the desired consumer/place of sale. The ODA Division of Meat Inspection is responsible for enforcing Ohio's rules and regulations at processing facilities while the USDA Food and Safety Inspection Service oversees federally licensed facilities and monitors their regulatory compliance. Local food and safety departments will be responsible for overseeing the licensure of those required to obtain a Retail Food Establishment License in order to sell food within Ohio.

For more general information about the different processing facility licensing standards and requirements please see the "Selling Raw Meat General" or "Licensing" section of this guide.

## **Regulation**

#### Federal

In order to sell poultry products across state lines, poultry must be processed by a USDA inspected facility in compliance with the federal Poultry Production Inspection Act. 129

128 ORC 918.21, 918.12 129 21 USC 451-472; 9 CFR 381



Unless covered by an exemption, the PPIA covers every establishment where poultry is slaughtered for the purpose of human consumption. 130 Standards and requirements under this act regulate factors such as facility inspection,131 worker conditions, 132 operating procedures, 133 ante-mortem inspections, 134 post-mortem inspections and carcass disposition,135 labeling and containers,136 and record keeping.137

#### Ohio law

Ohio has largely adopted the rules and regulations found in the PPIA, removing or modifying certain provisions dealing with topics such as exemptions, official markings, imported products, and voluntary inspections. 138 Unless otherwise exempt, poultry products must be processed by a fully inspected and licensed facility in order to be eligible for sale to consumers.139

## **Fully Inspected Operation**

Similar to the processing and sale of other livestock type meats, poultry cuts processed at a fully inspected facility will be eligible for sale for human consumption. Products from USDA inspected facilities may be sold outside of Ohio while products from ODA inspected facilities may only be sold within the state of Ohio. ODA fully inspected facilities that participate in the Cooperative Interstate Shipping Program may operate as federally-inspected facilities to produce products eligible for interstate sale.140

Producers that utilize fully inspected facilities may then choose to have their product delivered directly to the consumer or returned to them. Upon receiving the product back from the processor, a producer may either use the product for personal consumption or they may store the product in a storage area registered as a warehouse with ODA Food Safety (see Licensing chapter for more information).<sup>141</sup> It is important to note that a storage area within the home will not be eligible to become a registered warehouse, though a barn or garage may be eligible. Storage areas must be free from chemicals and pests and the equipment must be suitable to maintain the product at the proper temperature. Processed cuts of poultry meant for human consumption should never be stored with any unprocessed animal carcasses.142

In order to sell products that have not been delivered directly to consumers from the processing facility, producers

130 9 CFR 381.6 131 9 CFR 381.16-381.22 132 9 CFR 381.30-381.46 133 9 CFR 381.65 134 9 CFR 381.70-381.75 135 9 CFR 381.76-381.94 136 9 CFR 381.115-381.144 137 9 CFR 381.175-381.182 138 OAC 901:2-3 139 ORC 918.26 140 9 CFR 332 141 ORC 915.02 142 ORC 915.09

may need to obtain a Retail Food Establishment License from their local health department. This includes selling frozen meat products at a farm market, from a mobile freezer, or at a farmers market. A retail food establishment license is not required in situations where frozen meat is pre-ordered and delivered directly to the individual who ordered it without intermediate storage. Individuals should reach out to their local health department to determine their licensing requirements.

## Exemptions from Fully Inspected Facility Requirement Personal consumption

Farms that slaughter and process healthy poultry that they have raised on their own premises for their personal or family use are not required to be licensed or inspected. 143 Poultry slaughtered for personal consumption should be processed and slaughtered under sanitary standards that result in products that are sound, clean, and fit for human consumption.

#### Custom Exempt Processing

Custom Exempt License holders may provide slaughter and processing services to owners of poultry for their exclusive use in the household of the owner, by the owner, members of the owner's household, non-paying guests, and employees. 144

Poultry processed under this exemption must be healthy at the time of slaughter and processed under sanitary practices that result in a product fit for human consumption. 145 Products must be labeled as "Not for Sale" and delivered only to the owner. If the product is delivered or stored in a shipping container, the container must bear the producer's name and address and the statement "ODA exempt #(4-digit plant number)."146

Although the poultry cuts produced under this exemption may not be sold to consumers in the traditional sense, whole, half, and quarter cuts may be sold directly to consumers for their personal use. This means that those wishing to receive poultry slaughtered and processed will need to purchase the animal based on the live weight, price-per-head basis, or other quantity pertaining to the live animal, with the Custom Exempt Operator only being able to charge a fee for their services. No individual cuts may be sold and no less than a quarter of an animal may be sold under this exemption. An individual licensed as a Custom Exempt Operator who owns poultry may sell a live animal to a buyer and also provide their slaughter and processing services separately.

Custom Exempt products must be delivered directly to the party/parties listed as the owner of the poultry without intermediate storage.

143 ORC 918.27(A)(1), 9 CFR 381.10(a), OAC 901:2-3-04(B)(1) 144 OAC 901:2-3-04(B)(2), 9 CFR 381.10(a) 145 OAC 901:2-3-04(B)(2) 146 ld

## **Poultry Specific Exemptions**

The legal compliance requirements for the processing and sale of poultry products will vary based on the exemption a producer falls under or wishes to operate under. Producers should study these exemptions carefully and note the specific legal requirements.

## Establishments that produce and sell less than 1,000 birds annually

Processors that grow and slaughter poultry on their own property may be exempt from licensing and inspection requirements when they meet the following requirements:<sup>147</sup>

- Less than 1,000 birds are grown and processed annually;
- The birds are hatched and raised on the premises;
- Birds are slaughtered and processed on the premises;
- Only sound and healthy birds are slaughtered for consumption;
- Poultry is sold directly to a hotel, institution, restaurant consumer, or other person for preparation in their own kitchen.<sup>148</sup>

Facilities producing poultry products for sale under this exemption may only sell their product within Ohio and must comply with facility sanitary standards and practices that result in food fit for human consumption. PRelevant safety practices can be found in 9 CFR 416, which covers conditions dealing with pest control, building construction, lighting, ventilation, plumbing, sewage disposal, water supply, restrooms, equipment, sanitary operations, employee hygiene, maintenance, corrective actions, and more. Producers must also comply with laws dealing with poultry adulteration, misbranding, and record-keeping requirements. Although these facilities may be exempt from licensing and inspection, no producer may deny access to an authorized inspector for the purposes of enforcing applicable meat inspection laws.

Producers eligible for this exemption may also sell raw dressed poultry alongside other items at a registered farm product auction or at a registered farm market (meaning the market is registered with ODA and/or has an RFE license) on the condition that the individual selling the poultry is also the operator of the farm market. Poultry sold at farm markets must be kept frozen or at an internal temperature of 41 degrees Fahrenheit or less, be properly labeled, be safe and unadulterated, and be honestly presented. Any equipment or utensil used at a farm market or farm product auction

147 ORC 918.27(A)(4), OAC 901:2-3-04(B), 9 CFR 381.10(a)(6), (c)

148 Note, although sales to hotels, restaurants and institutions are allowed under this exemption, these entities usually require that their products come from an "approved"/ licensed source. Anyone wishing to sell to these entities should consider reaching out to their local health department.

149 OAC 901:2-3-04(B)(3)

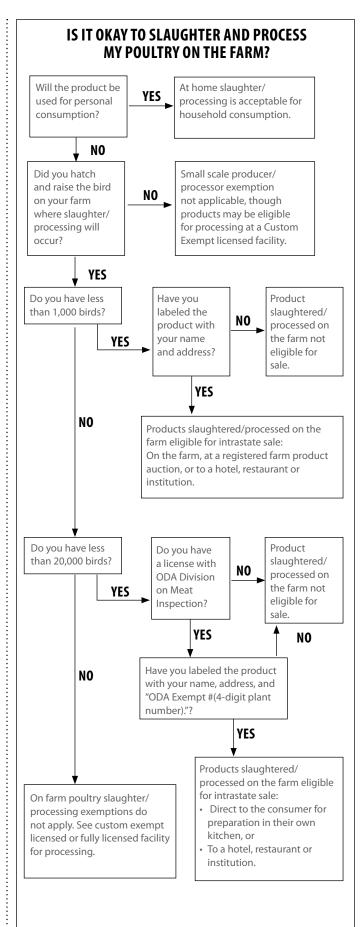
150 ORC 918.27(B), 918.26

151 ORC 918.26(B)

152 ORC 3717.22(B), OAC 901:3-6-01(B)

153 At a farm product auction, poultry may be chilled by submersion in crushed ice. OAC 901:3-6-03

154 OAC 901:3-6-02



offering raw poultry must be properly cleaned and sanitized in compliance with ODA's three step process, and market personnel must wash their hands before and after handling raw meat. 155

Producers that wish to sell poultry directly from the farm under this exemption need to first label their products with their name and address.

#### 1,000 to 20,000 birds produced and sold annually

Processors that produce between 1,000 to 20,000 birds a year may process and sell raw poultry products if/when they receive a license from ODA Division of Meat Inspection and meet the following requirements:156

- No more than 20,000 birds are grown and processed
- The birds are hatched or raised from chicks on the farm;
- No live birds are purchased to be processed for sale;
- Only sound and healthy birds are slaughtered for consumption;
- The birds are slaughtered and processed on the farm;
- Poultry is sold directly to a hotel, institution, restaurant consumer, or other person for preparation in their own kitchen.

Facilities producing poultry products for sale under this exemption may only sell their product within Ohio and must comply with facility sanitary standards and practices that result in food that is fit for human consumption. 157 Relevant safety practices can be found in 9 CFR 416, which covers conditions dealing with pest control, building construction, lighting, ventilation, plumbing, sewage disposal, water supply, restrooms, equipment, sanitary operations, employee hygiene, maintenance, corrective actions, and more. Producers operating within this exemption must also comply with laws dealing with poultry adulteration, misbranding, and record keeping requirements.<sup>158</sup>

Under this exemption, poultry products may be labeled with the producers name, address, and the statement "ODA exempt #(4 digit plant code)" in lieu of the normal labeling requirements.159

## **Marketing and Label**

Misbranded or adulterated products may not be transported into commerce for sale. 160 For federally inspected facilities, no final label may be used on any product unless it has been approved by the FSIS Labeling and Program Delivery staff.<sup>161</sup> For state inspected facilities, no final label may be used unless it has been approved by ODA Labeling staff. Official establishments, both state and federal, are authorized to use

generically approved labels as long as all of the mandatory labeling features are present and no there are no special statements or claims such as logos, trademarks, or nutritional claims. Poultry processed at a fully inspected facility and will be offered for sale must bear a label that provides the following information:162

- The product name: All products must be identified by their standard name and properly spelled.163
- An inspection legend and the number of the official establishment: Accurate inspection legend based on where the product was produced and inspected.<sup>164</sup>
- The net weight: Appears on the lower 30% of principal panel of display with proper size and spacing. This cannot include any term qualifying a unit of weight or measure. Except when dealing with packages containing 1 pound or 1 pint and less than 4 pounds or 1 gallon when the statement shall be expressed in ounces or pounds, weight must be expressed in terms of avoirdupois weight or liquid measure. For example, a declaration of 34 pound of avoirdupois weight shall be expressed as "Net Wt. 12 oz." and a declaration of 1 ½ pounds of avoirdupois weight shall be expressed as "Net Wt. 24 oz.," "Net Wt. 1 lb. 8 oz.," "Net Wt. 1 ½ lb.," or "Net wt. 1.5 lbs." 165
- The name and place of business of the manufacturer, packer, or distributor for whom the product is prepared: The name or trade name of the person that prepared the product may appear as the name of the manufacturer or packer without qualification on the label. Otherwise the name of the distributor of the product shall be shown with a phrase such as "Prepared for \* \* \*" or "Distributed by \*\*\*." 166
- Any other label information in accordance with the special provisions associated with the standards of identity or composition as prescribed.167
- Safe Handling Statement: Packaged products that require special handling to maintain their wholesome condition must prominently display the applicable handling statement "Keep Refrigerated," "Keep Frozen," or "Perishable – Keep Refrigerated or Frozen."168
- **Safe handling instructions:** 169 Raw or partially cooked meat destined for household consumers or institutional uses must include one the following under the heading "Safe Handling Instructions" depending on their place of processing:
  - "This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions." Or

<sup>155</sup> OAC 901:3-6-04, 05

<sup>156</sup> ORC 918.27, OAC 901:2-3-04(A)(5), 9 CFR 381.10(b)

<sup>157</sup> OAC 901:2-3-04(B)(3)

<sup>158</sup> ORC 918.27(B), 918.26

<sup>159</sup> OAC 901:2-3-04(B)

<sup>160 9</sup> CFR 381.181

<sup>161 9</sup> CFR 412.1, 383.131

<sup>162 9</sup> CFR 381.115 - 381.140

<sup>163 9</sup> CFR 381.117

<sup>164 9</sup> CFR 381.96, OAC 901:2-3-04(B)(18)-(20)

<sup>165 9</sup> CFR 381.121

<sup>166 9</sup> CFR 381.122

<sup>167 9</sup> CFR 319, https://www.fsis.usda.gov/guidelines/2005-0003

<sup>168 9</sup> CFR 381.125(a)

<sup>: 169 9</sup> CFR 381.125(b)

- "Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions."

These statements may then be required to be accompanied by the following language:

- Keep refrigerated or frozen. Thaw in refrigerator or microwave. (Any portion of this statement that is in conflict with the product's specific handling instructions may be omitted, e.g., instructions to cook without thawing.) (A graphic illustration of a refrigerator shall be displayed next to the statement.);
- Keep raw meat and poultry separate from other foods.
   Wash working surfaces (including cutting boards),
   utensils, and hands after touching raw meat or poultry. (A graphic illustration of soapy hands under a faucet shall be displayed next to the statement.);
- Cook thoroughly. (A graphic illustration of a skillet shall be displayed next to the statement.); and
- Keep hot foods hot. Refrigerate leftovers immediately or discard. (A graphic illustration of a thermometer shall be displayed next to the statement.)
- Ingredient statement: If the product is fabricated from two
  or more ingredients, the word "ingredients" followed by the
  list of ingredients by their common or usual name arranged
  in descending order of prominence with multi-ingredient
  components sub listed.<sup>170</sup>

Small businesses that offer single-ingredient, raw poultry major cuts that are not ground or chopped are not required to provide nutritional labeling.<sup>171</sup> However, if a label makes any sort of nutritional claim, such as "low sodium" or "no sugar added," then the mandatory nutritional labeling requirements will apply.<sup>172</sup> When required, nutritional panels must include the proper serving size, the total calories, calories from fat, total fat, saturated fats, cholesterol, sodium, total carbohydrates, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron. Voluntary nutrient disclosures include calories from saturated fat, trans fat, stearic acid, polyunsaturated fat, monounsaturated fat, potassium, insoluble fiber, sugar alcohol, other carbohydrates, vitamins, and minerals. Nutrient and food components must be declared based on a serving size, which is the amount of food customarily consumed per eating occasion.173

Special logos, statements and claims, such as claims that a product is "natural," health claims, claims regarding the raising of animals, claims that a product is organic, ingredient and processing claims, allergen statements, negative claims (that something is not in the product), and claims of geographical

significance must be approved by ODA or FSIS.<sup>174</sup> Label claims must be supported by evidence that the claim is true in order to be approved for use.

#### **Contacts and Resources**

Ohio Department of Agriculture Division of Meat Inspection

Phone: (614) 728-6260 Email: meat@agri.ohio.gov Web: ofb.ag/meatinspection

Ohio Department of Agriculture Division of Animal Health

Phone: (614) 728-6220

Email: OhioLivestockCare@agri.ohio.gov Web: ofb.ag/livestockcarestandards

#### **Additional Resources**

Ohio Revised Code Chapter 918, Meat Inspection: ofb.ag/chapter918orc

Ohio Administrative Code Section 901:2, Meat Inspection: ofb.ag/chapter9012orc

ODA Meat Inspection Labeling: ofb.ag/inspectionlabels

ODA List of Inspected Facilities in Ohio: ofb.ag/inspectioncoveragemap

**USDA Federal Meat Inspection Act:** ofb.ag/meatinspectionact

**USDA Poultry Products Inspection Act:** ofb.ag/poultryinspectionact

**USDA Cooperative Interstate Shipping Program:** ofb.ag/interstateshipping

USDA Basics of Labeling: ofb.ag/labelingbasics

USDA Small Plant Guidance: ofb.ag/smallplantguidance

SDA HACCP Guidebook: ofb.ag/haccpplans

# **Dairy**

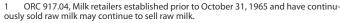
Milk and dairy products are one of the most highly regulated food products in commerce, with state and federal law combining to create extremely high standards for the handling of dairy at all stages of production. Ohio rules and regulations can be found in chapter 917 of the Ohio Revised code and section 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, and it is illegal to ship anything labeled as "milk" for human consumption across state lines if it has not been pasteurized. 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.

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.<sup>4</sup> 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.<sup>5</sup> Religious exempt registrants will still be subject to all



<sup>2 21</sup> USC 331



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

• Milk Dealer's License<sup>7</sup> - 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.<sup>8</sup>

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. Applications must also be submitted with a \$15 application fee.

 Milk Hauler License<sup>10</sup> – 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.

<sup>3</sup> ORC 917.05

<sup>4</sup> ORC 917.09, 917.02

<sup>5</sup> OAC 901:11-1-04(B)

<sup>5</sup> I

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

<sup>8</sup> ORC 917.01(D)

<sup>9</sup> OAC 901:11-1-04(F)

<sup>10</sup> ORC 917.09(A)(6); OAC 901:11-4-02

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 Tester<sup>12</sup> – 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.<sup>17</sup> 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 License<sup>18</sup> 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.
- OAC 901:11-4-02(I)
- 12 ORC 917.09, OAC 901:11-4
- 13 ORC 917.01(X)
- OAC 901:11-4-03 14
- 15 ORC 917.09(E)-(G), OAC 901:11-4-02
- ORC 917.08, OAC 901:11-4-02(D) 16
- 17 ORC 917.09(I)
- 18
- 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.<sup>20</sup> 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.<sup>21</sup> 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 Facilities*<sup>22</sup>

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:

- 20 OAC 901:11-1-04, ORC 917.031
- 21 OAC 901:11-1-04(L)
- : 22 OAC 901:11-2-09 901:11-2-44

- Producers must have a facility of a size and arrangement that promotes sanitary milking operations.<sup>23</sup> Conditions inside the barn must be clean, provide adequate light, have sufficient air circulation, and have concrete gutters in good repair.<sup>24</sup> Feed storage must be in a tightly covered bin, and no swine or fowl should be allowed in the milking facility.<sup>25</sup> If milk is exposed for any reason in the facility, it must be protected from contamination.<sup>26</sup> 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.<sup>27</sup>
- Manufactured milk milking procedures may only be done in the milking barn/parlor.<sup>28</sup> Animal teats must be clean, sanitized, and dried prior to milking.<sup>29</sup> 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.<sup>30</sup>
- 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.<sup>31</sup> Farm chemicals and drugs must be stored in a manner that will prevent them from coming in contact with milk.<sup>32</sup> 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.<sup>33</sup> 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.<sup>34</sup>

**Milk Processor License**<sup>35</sup> - 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
- 23 OAC 901:11-2-10(A) 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.
- 28 OAC 901:11-2-11(A)
- 29 ld
- 30 OAC 901:11-2-11(B)
- 31 OAC 901:11-2-13
- 32 OAC 901:11-2-14 33 OAC 901:11-2-16
- 34 OAC 901:11-2-16
- 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.
- 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.<sup>37</sup> The FMMO separates milk products into four categories based on the intended use of the milk in order to establish pricing.<sup>38</sup> 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).<sup>39</sup> 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.<sup>40</sup>
- **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.<sup>43</sup> 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

- 21 CFR 1240.61
- 7 CFR 1033.1, see also https://dairymarkets.org/pubPod/pubs/AMS-559.pdf
- 38 7 CFR 1000.4
- 39 7 CFR 1000.9
- 7 CFR 1030.10, 1032.10
- 41 7 USC 1637, 7 CFR 1170
- You can find more information about mandatory dairy reporting on USDA's website: https://www.ams.usda.gov/rules-regulations/mmr/dmr
- 7 CFR 58.122
- 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
72°C (161°F)	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°C (5°F). Grade A pasteurized milk must then be cooled and maintained at a temperature of 7°C (45°F).49

<sup>45</sup> ORC 917.03, 917.031

<sup>46</sup> OAC 901:11-1

<sup>47</sup> See https://agri.ohio.gov/divisions/dairy/new-producers-and-processors

<sup>21</sup> CFR 131.3(b), PMO Section 1, RR (PDF page 35), OAC 901:11-1-02(A)

<sup>49</sup> PMO section 7 table 1



- 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.<sup>51</sup> 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. This includes butter, natural or processed cheese, frozen desserts, and evaporated, condensed and dry products. This 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. 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

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.<sup>55</sup>
- Adequate and compliant water supply properly located, the ability to provide steam, and proper disposal of waste.<sup>56</sup>
- Properly designed and installed equipment specific to your operation that is able to be adequately cleaned and sanitized in a manner meeting rule standards.<sup>57</sup>

The pasteurization of Manufacture Milk products must comply with the applicable portions of item 16p of the PMO.<sup>58</sup> 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.<sup>59</sup> 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

<sup>50</sup> PMO Section 7 table 1

<sup>51</sup> ORC 917.01(L), see also the PMO

<sup>52</sup> ORC 917.01(M)

<sup>53</sup> lc

<sup>54 901:11-2-04(</sup>B); 901:11-2-21(A)(2),(C),&(F); 901:11-2-26(B)&(I)

<sup>55</sup> OAC 901:11-2-20

<sup>56</sup> OAC 901:11-2-21

<sup>57</sup> OAC 901:11-2

<sup>58</sup> OAC 901:11-2-26(B)

<sup>59</sup> 

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.<sup>60</sup>

- 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.<sup>63</sup>

#### Frozen Dessert:<sup>64</sup>

- 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.<sup>67</sup>
- 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.<sup>69</sup>
- 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,<sup>71</sup> Ohio's pure food and drug laws,<sup>72</sup> and the "Nutrition Labeling and Education Act of 1990,"73 as amended

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

and regulations adopted under it.74 Label requirements will vary

- prescribed standard of identity.76
- The net quantity of contents.<sup>77</sup>
- 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

```
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
    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
    ORC 3715
   21 USC 343
```

- 74 ORC 917.11
- 75 21 CFR 101
- 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

## **Appendix**

- Arnold, N., Hall, P. K., Marrison, E., & Ruff, G. (2023). Selling Meat and Poultry. *Starting a Food Business*. The Ohio State University.
- Barrett, E., Hall, P. K., & Bachelor, E. (2019, March). Sales Taxes and Vendor's Licenses for Ohio Farm Market Sales. Retrieved from CFAES Ohio State University Extenstion: https://farmoffice.osu.edu/sites/aglaw/files/site-library/LawBulletins/ SalesTaxVendorsLicenseMarkets.pdf
- Center for Food Safety and Applied Nutrition, Food and Drug Administration. (2021, December). *Juice HACCP and the FDA Food Safety Modernization Act: Guidance for Industry.* Retrieved from FDA.gov: http://www.fda.gov/FoodGuidances
- Daniels, C. (n.d.). Sampling Home-Based Food Products: Keeping You Responsible for a Safe Food Product. Retrieved from CFAES Farm Office Ohio State University Extension: https://farmoffice.osu.edu/blog-tags/food-sampling
- Endras, B., & Armstrong, R. (2013). *Ohio Direct Farm Business*. University of Illinois at Urbana-Champaign.
- Graham, D. G., & Milo, D. (2018). A Brief Summary of Regulations Governing Maple Syrup Production in Ohio. Ohio State University; Ohio Department of Agriculture.
- Hall, P. K. (2020, May 22). Thinking of direct food sales? Consider these legal issues. Retrieved from CFAES Farm Office Ohio State University Extension: https://farmoffice.osu.edu/blogtags/direct-marketing
- Hall, P. K. (2023, March). Selling Farm-based Foods at the Farm: Do You Need a License? Retrieved from farmoffice.osu.edu.
- Hall, P. K., Barrett, E., Adams, E., & Neikirk, H. (2017, August 3). *Selling Eggs in Ohio: Marketing and Regulations*. Retrieved from Ohioline: https://ohioline.osu.edu/factsheet/anr-59
- Office of Nutrition, Labeling, and Dietary Supplements. (2013, January). A Food Labeling Guide. Retrieved from Food and Drug Administration: www.fda.gov/FoodLabelingGuide
- Ohio Department of Agriculture Dairy Division. (2018, February 14).

  Dairy Processor Pre-Licensing Consultation Topics. Retrieved from agri.ohio.gov: https://agri.ohio.gov/divisions/dairy/resources/Dairy-Processing-Licensing-Discussion-Topics
- Ohio Department of Agriculture Division of Food Safety . (2019, March). *Home Bakery Printable Fact Sheet*. Retrieved from agri.ohio.gov: https://agri.ohio.gov/divisions/food-safety/resources/home-bakery
- Ohio Department of Agriculture Division of Food Safety. (2018, August). Apple Cider and Juices Fact Sheet. Retrieved from agri.ohio.gov: https://agri.ohio.gov/divisions/food-safety/resources/Apple-Cider-Juice
- Ohio Department of Agriculture Division of Food Safety. (2018, August). Small Egg Production Operation. Retrieved from Ohio Department of Agriculture: https://agri.ohio.gov/divisions/food-safety/resources/small-egg-production/

- Ohio Department of Agriculture Division of Food Safety. (2019, July).

  Maple Syrup Requirements and Printable Fact Sheet. Retrieved from agri.ohio.gov: https://agri.ohio.gov/divisions/food-safety/resources/Maple-Syrup
- Ohio Department of Agriculture Division of Food Safety. (2021, November). *Honey Printable Fact Sheet*. Retrieved from agri.ohio.gov: https://agri.ohio.gov/divisions/food-safety/ resources/Honey
- Ohio Department of Agriculture Division of Food Safety. (2024, February). *Cottage Food Printable Fact Sheet*. Retrieved from agri.ohio.gov: https://agri.ohio.gov/divisions/food-safety/resources/cottage-food
- Ohio Department of Agriculture Division of Food Safety. (n.d.). Labeling Requirements. Retrieved from agri.ohio.gov: https:// agri.ohio.gov/divisions/food-safety/resources/Labeling-Requirements
- Ohio Department of Agriculture Division of Meat Inspection. (2024, April). *Division of Meat Inspection Label Approval Guideline*. Retrieved from agri.ohio.gov: https://agri.ohio.gov/divisions/meat-inspection/inspection-labels
- Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Access to Areas Outside the Poultry House): Questions and Answers Regarding the Final Rule; Guidance for Industry. (2022, August). College Park, Maryland: U.S. Department of Health and Human Services .
- Richardson, J. J. (2012). Legal Liability in Agritourism and Direct Marketing Operations. College of Agriculture and Life Sciences, Virginia Polytechnic Institute and State University.
- U.S. Department of Health and Human Services, Public Health Services, Food and Drug Administration. (2019). *Grade "A" Pasteurized Milk Ordinance*. Retrieved from FDA.gov: https://www.fda.gov/media/140394/download
- USDA Office of Pest Management Policy Factsheet Pesticide Residues on Fruits and Vegetables. (2021, April 29). U.S. Department of Agriculture, Office of the Chief Economist.
- USDA-FSIS. (2018, May). FSIS guideline for Determining Whether a Livestock Slaughter or Processing Firm is Exempt from Inspection Requirements of Federal Meat Inspection Act.

  Retrieved from USDA Food Safety and Inspection Service: https://www.fsis.usda.gov/guidelines/2018-0007
- Whether a Poultry Slaughter or Processing Operation is Exempt from Inspection Requirements of Poultry Products Inspection Act. United States Department of Agriculture Food Safety and Inspection Service.

