

Starting a Minnesota 'Equal To' Meat Establishment

mn DEPARTMENT OF
AGRICULTURE



CONTENTS



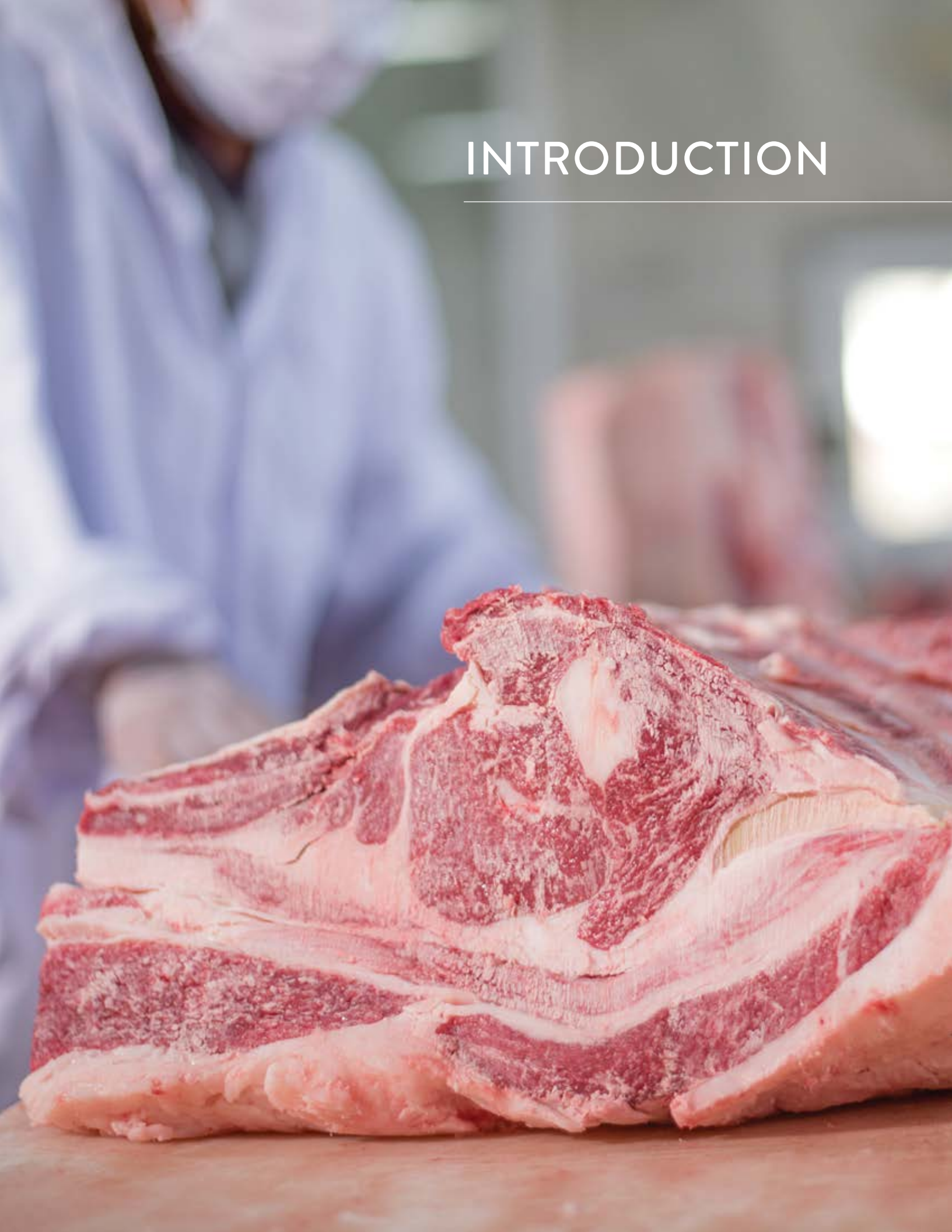



Introduction	2
Getting Started	8
Building or Buying	9
Location and Site	9
Considerations for Buying an Existing Business	9
Considerations for Shared Kitchens	10
Considerations for More Than One Type of Operation	10
Building and Plumbing Plans	10
Septic and Well	11
Financing Your Project	12
Additional Considerations	12
Resources and References	13
Facilities, Equipment, and Sanitation Requirements 9 CFR 416.2	14
Grounds and Pest Control, 9 CFR 416.2(a)	15
Construction, 9 CFR 416.2(b)	16
Lighting, 9 CFR 416.2(c)	17
Ventilation, 9 CFR 416.2(d)	17
Plumbing, 9 CFR 416.2(e)	18
Sewage and Waste Disposal, 9 CFR 416.2(f)	18
Water Source: Municipal/Well Water	19
Dressing Rooms and Lavatories, 9 CFR 416.2(h)	19
Equipment and Utensils, 9 CFR 416.3	19
Sanitary Operations, 9 CFR 416.4	20
Employee Hygiene, 9 CFR 416.5	21
Resources and References	21
Overview of the Requirements and Program	22
Equal To Inspection	23
Licensing / Permitting and Fees	25
Forms	27
Inspections	28
Auditing Process	30
Additional Requirements	30
Resources and References	33
Commonly Asked Questions	34
Appendices	36

In accordance with the Americans with Disabilities Act, this information is available in alternative forms of communication upon request by calling 651-201-6000. TTY users can call the Minnesota Relay Service at 711. The MDA is an equal opportunity employer and provider.

February 2025

INTRODUCTION





This manual provides basic information and general guidance for individuals interested in starting an Equal To (E2) slaughter and/or processing operation in Minnesota. It covers key factors to consider before starting your business, the regulatory requirements and inspection process, and other topics relevant to prospective processors.

Use this guidance document as a starting point for planning. You will need to consult other resources for specific questions on certain aspects of your operation. Your local Minnesota Department of Agriculture (MDA) meat inspector and other Minnesota Meat and Poultry Inspection Program (MN MPIP) personnel are also good resources. Working closely with them throughout the planning process can help you be confident that you've completed the necessary steps for success.

Terms

Carcass: The carcass is all parts, including viscera, of a slaughtered animal that could be used for human food.

Continuous Inspection: Continuous inspection means that the business's process is inspected every day during operations to ensure they are producing safe food. Continuous inspection is required for any business that wishes to sell their products to other retail outlets such as grocery stores, restaurants, or other food service institutions. In a slaughter processing facility, every animal is inspected to determine that the meat comes from an animal free from signs of disease.

Custom Exempt Processing: Custom exempt processing is the slaughter and/or processing of meat, poultry, or wild game products for the owner of the animal. Minnesota custom exempt processing facilities are inspected periodically by the MDA for sanitation compliance. Custom exempt processed products cannot be sold or donated and can only be consumed by the owner of the animal, the owner's household, and the owner's non-paying guests. ([9 C.F.R. Part 303.1\(a\)\(2\)](#); [MINN. STAT. 31A.02, Subd. 5](#); [31A.10](#); [31A.15, Subd. 1](#))

Custom Exempt Food Handler's License: This license is issued for a food handling business that only conducts custom exempt processing and labels all products "NOT FOR SALE". It must be renewed annually, and a fee must be paid when the license is renewed. There are other license categories for different types of food handling businesses in Minnesota. ([MINN. STAT. 28A.04, Subd. 1](#))

Custom Processing Permit: This permit is required for custom exempt processors in addition to their food handler's license. The permit functions as an exemption from continuous inspection. It is only issued once and does not come with a fee. ([MINN. STAT. 28A.04, Subd. 2](#))

Food Handler: A food handler is anyone who manufactures, processes, sells, stores, or otherwise handles food for human consumption. Meat and poultry processors are food handlers. Food handlers must be licensed to operate. ([MINN. STAT. 28A](#))

Hazard Analysis Critical Control Point (HACCP): HACCP stands for Hazard Analysis Critical Control Point. A HACCP plan is the written food safety plan for the establishment. This plan covers biological, chemical, and physical food safety hazards that may arise during the production process. The HACCP system is implemented to control these hazards in products and ensure the production of safe products.

Meat: Meat is the edible part of the skeletal muscle of cattle, sheep, swine, Cervidae (elk, red deer, etc.), bison, or goats, with or without the accompanying and overlaying fat and the portions of bone, skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue, and which are not separated from it in the process of dressing. Meat can also include parts of the tongue, diaphragm, heart, or esophagus but not muscle found in the lips, snout, or ears.

Meat food product; Poultry food product: Meat food product or poultry food product is a product usable as human food and made wholly or in part from meat or poultry or a portion of the carcass of cattle, sheep, swine, poultry, wild game or fowl, farmed Cervidae (elk, red deer, etc.), llamas, Ratitae (ostrich, emu, etc.), or goats. This does not include food products containing less than 2% cooked meat or poultry or 3% raw meat or poultry which are exempted from definition as a meat food product or poultry food product by the commissioner. An example could be a salad with bacon bits. ([MINN. STAT. 31A.02, Subd. 10](#))

Minnesota Equal To (E2): Minnesota E2 plants operate under regulations that meet or exceed the standards for federally inspected meat plants. Unlike custom exempt operations, these plants are under continuous inspection, where each animal slaughtered under inspection has an ante-mortem and post-mortem inspection. Animals that pass inspection can be processed for wholesale and retail sale, but only within Minnesota. ([MINN. STAT. 31A](#))

Potable water: water which is or may be used as a source of supply for human consumption including drinking, culinary use, food processing, and other similar purposes, and which is suitable for such uses in its untreated state or when treated using generally recognized treatment methods. ([MINN. STAT. 115.01, Subd. 14](#))

Plan Review (retail): This review process is conducted by retail inspection staff to ensure that a processing facility and equipment meets the minimum requirements of the [Minnesota Food Code](#) or other applicable rules before construction or remodeling begins. This type of review is required for plants and food facilities with retail operations.

Poultry: Poultry is any domesticated bird, captive-raised for production of eggs or for processing to be eaten as human food. This includes but is not limited to, chickens, turkeys, ducks, geese, and guineas. ([MINN. STAT. 31A.02, Subd. 24](#))

Prerequisite Programs: Prerequisite programs are written procedures that describe activities that an establishment can use to support decisions made within the hazard analysis. Examples include Standard Operating Procedures (SOP's), listeria control programs, and allergen control programs.

Retail Exempt: Retail establishments, such as grocery stores and markets, are exempt from federal inspection during processing of meat and poultry, provided the meat or poultry came from animals slaughtered under state or federal inspection. Under this exemption from federal inspection, a retail facility cannot slaughter animals, do thermal processing or canning of meat, sell to other retail markets, or sell to wholesalers or distributors.

Sale; Sell: In Minnesota, any time food changes hands or is transferred from one business or individual to another with the intent to sell, it is considered a sale. This includes everything from selling food in a store, to distributing, serving, retailing, wholesaling, and even donating food. ([MINN. STAT. 34A.01, Subd. 12](#))

Sanitation Performance Standards: The Sanitation Performance Standards (SPS) are adopted by Minnesota from the Federal Meat and Poultry Inspection Regulations. They describe requirements for facility, equipment, and sanitation which official Equal To and custom exempt plants must meet. ([9 C.F.R. Part 416](#))

Viscera: Viscera are the internal organs of the body, such as the heart, liver, or intestine. These parts may also be referred to by other terms such as innards, guts, inedibles, or offal.

Wholesale: Wholesaling is selling products to other retail outlets such as grocery stores, restaurants, or other food service institutions that will resell them to the end consumer. This type of sale requires continuous inspection through the USDA, or the Minnesota state Equal To inspection program.

Options for Meat & Poultry Processing in Minnesota

In Minnesota, meat and poultry processors conduct several different kinds of operations, sometimes all in one business. These include:

- Custom Exempt
- United States Department of Agriculture (USDA) or Minnesota “Equal To” (E2) Inspected
- Retail Exempt

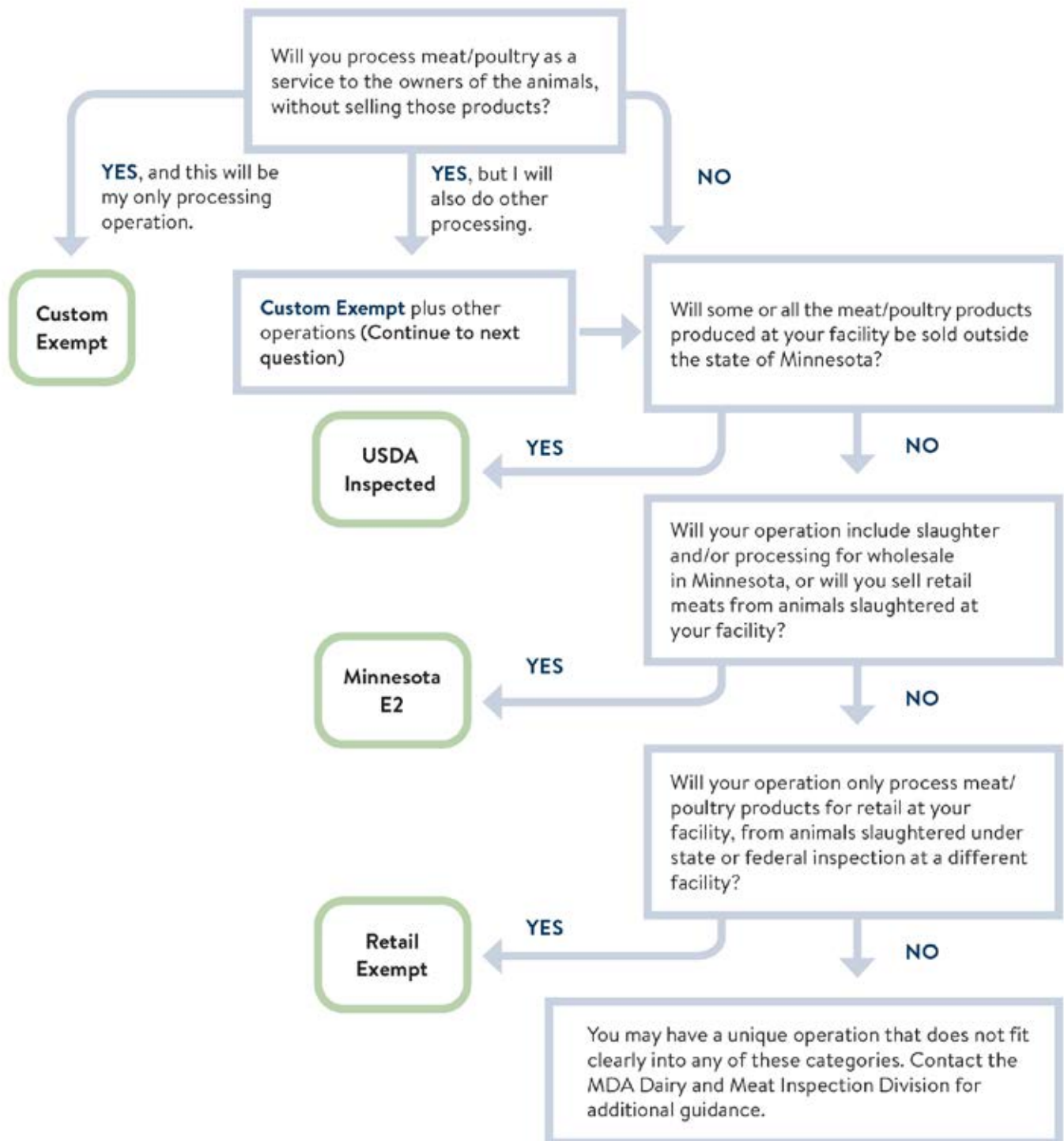
The following table gives a brief description of each type of meat and poultry processing operation.

Types of Meat Processing Operations

Type of Operation	Description
Custom Exempt	An operation that provides slaughter and/or processing services to the owner of the animal and returns the products to the owner of the animal. These products are labeled “Not for Sale” and cannot be sold or donated.
Minnesota “Equal To” (E2) Inspected	These plants operate under regulations that meet or exceed the standards for federally inspected meat plants. Unlike custom exempt operations, these plants are under continuous inspection, and each animal has an ante-mortem and post-mortem inspection. Animals that pass inspection can be processed for wholesale and retail, but only within Minnesota.
USDA Inspected	These plants operate under continuous inspection by federal meat inspectors. Each animal has an ante-mortem and post-mortem inspection. Animals that pass inspection can be processed for wholesale and retail, both within Minnesota and nationally.
Retail Exempt	Retail establishments, such as grocery stores and markets, are exempt from federal inspection during processing, provided the meat was derived from animals slaughtered under either state or federal inspection. Under this exemption from federal inspection, a retail facility cannot slaughter animals, do thermal processing or canning of meat, sell to other retail markets, or sell to wholesalers or distributors.

As an Equal To (E2) processor, you will be able to slaughter and process meat and poultry and sell meat and poultry products within the state of Minnesota. Processors wishing to cross state lines to sell products will need a grant of inspection from the USDA. E2 processors may also have retail exempt operations, which involves the sale of Minnesota E2 or USDA inspected meat from a retail storefront. Retail exempt operations come with additional requirements based on the Minnesota Food Code. You may want to keep this in mind if your goal is to sell retail products. As you plan your Equal To operation, consider both your start-up and long-term business goals and market opportunities.

If you're not sure what type of inspection your operation requires, use the decision tree below to determine the type of inspection needed. Follow the arrows that correspond with your answers to each question.




References

- Code of Federal Regulations Title 9 – Animals and Animal Products:
www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title09/9cfrv1_02.tpl
- Minnesota Revisor of Statutes: www.revisor.mn.gov/statutes
- Minnesota Administrative Rules: www.revisor.mn.gov/rules



GETTING STARTED





Actively seeking out answers to questions as you work on your business plan is key to successfully getting started. Each business is unique, not only by type of operation, but by other factors such as location and size. While many of the requirements for meat and poultry processing are state or federally based, local authorities also have regulations which impact new processors, such as zoning, water sources, plumbing, and septic or waste disposal systems. **These local regulations are often the first that need to be addressed.**

The following section provides basic guidance for planning your Equal To facility. Additional steps may be required depending on your local city, township, or county ordinances. As you work through these initial considerations, contact your local agencies to ensure a smooth transition into business. Once you've met local requirements, the MDA will work with you through the next steps in the process.

Building or Buying

Determining whether you should build a new facility or buy an existing facility may be one of the first major decisions you make. While buying an existing facility can come with added benefits and sometimes lower start-up costs, you'll need to make sure the facility meets the requirements and that you've fully assessed the necessary permitting and costs for any major renovations needed. Some specific things to consider when deciding whether to build or buy include:

- ▶ Location and site
- ▶ Changes needed to meet regulatory requirements in an existing facility
- ▶ Existing business operations, and whether other regulatory programs will need to be involved
- ▶ Building codes and changes needed in the plumbing, septic, and water systems

Location and Site

When considering purchasing an existing building or starting with new construction, review zoning and building code requirements with your local authorities (township/city/county/state) first. Equal To facilities are typically classified as commercial businesses and may require special permitting and/or be required to follow a conditional use approval process (CUP). Some localities may not allow meat processing businesses to operate in general agricultural-zoned areas, such as on farms. Historically, some municipalities have needed additional information to move forward and approve slaughter facilities.

Keep in mind, factors such as these fall outside the scope of regulation by the Minnesota Meat and Poultry Inspection Program (MN MPIP). You will need to do your own research to find answers to questions on these topics. Contact your local authorities for more information on requirements related to site suitability and other requirements that may be specific to your area, such as signage or advertising rules.

Considerations for Buying an Existing Business

Buying an existing building or business may significantly reduce costs and time needed to get your new business operational. However, some meat processing facilities are old and may require substantial upgrades, which may or may not be

financially feasible. It's important to not assume that every aspect of an existing facility will be up to date with current regulatory requirements. You may need to make facility or equipment upgrades to be in compliance when you start your operation. Assess the current condition of any existing facilities, including sanitation and construction, as well as size and flexibility of current operations.

Most importantly, you will want to research the site and the facility's history with inspection and its general compliance with regulations. For any business already regulated by the MDA, you can make a data request to obtain copies of the facility's inspection results to understand its degree of compliance with food safety regulatory requirements. Instructions on how to request data from the MDA can be found at [Data Access Procedures: Public Data](#). Other regulatory authorities and entities also have a similar process for requesting government data. For more information, visit [How to Request Data from a Minnesota Government Entity](#). If you decide to purchase an existing facility, you may also arrange a joint pre-purchase inspection with the existing owner(s) and the local inspector(s).

Considerations for Shared Kitchens

Shared commercial kitchens (also commonly referred to as shared-use, community, or incubator kitchens) rent space to food producers. These spaces allow individuals and businesses to use commercial kitchen equipment and be licensed there to produce food for the public (subject to regulatory approval). A shared kitchen is not a suitable space for meat or poultry slaughter; however, it may still be possible to produce Equal To meat or poultry products for sale out of a shared kitchen space. Your inspector can help you determine whether a particular shared kitchen facility will meet your needs. Additional information can be found in the supplemental document, [Starting & Operating a Food Business Out of a Shared Kitchen](#).

Considerations for More Than One Type of Operation

Some Equal To processors will want to include additional types of meat or food processing operations, such as a retail store. In this case, the business would also be a retail exempt operation. Whenever retail sales are part of a business plan, [Minnesota Food Code](#) rules will apply. In many cases, the area retail inspector and supervisor can work cooperatively with the area meat inspector to answer questions about retail rules and requirements and how they are applied in conjunction with a Minnesota E2 or custom exempt operation. For example, an official [Plan Review](#) is usually required if any changes are made to the retail portion of the facility, and some retail products are required to have HACCP plans (considered [Specialized Processes](#)) or other documentation and testing.

If you plan to add Custom Exempt Inspection to your operation, you should also consult the appropriate inspection staff prior to purchasing an existing facility. For custom exempt operations, this inspector will be the same inspector you consult for your Minnesota E2 operations. Facility requirements for custom exempt operations and E2 operations are very similar; however, you may need to make additional arrangements to accommodate greater product volumes and provide additional separation of products in your facility.

Building and Plumbing Plans

The Minnesota Department of Labor and Industry (DLI) regulates and enforces building codes, plumbing, and other infrastructure requirements. Understanding these requirements is an important part of the building or remodeling process. Take note of the following:

- New plumbing installations, changes, additions, and improvements must be done by a licensed plumber or registered apprentice.
- The Minnesota Plumbing Code requires plumbing plans to be submitted for review and approval **prior to** installation of plumbing.

For information on submitting plumbing plans and fees, visit [DLI Plumbing](#). For information about plumbing requirements, contact Plumbing Plan Review at 651-284-5063 or ims.bldplb.dli@state.mn.us



Septic and Well

Start-up Requirements

Businesses located in a city or municipality are often connected to city water and sewer services. These businesses can rely on documentation from the city or public water source to show that they meet the requirements. However, a processing plant on private, rural property typically has a private well and septic system. If you are building or buying a plant on private and/or rural property, you will need to provide written documentation showing the existing well and septic meet applicable requirements and codes.

Septic systems that are installed on rural, private properties are regulated and approved through the county and must meet [9 CFR 416.2\(f\)](#). Businesses may be required to have a septic system separate from any home on the same property and built to commercial standards. State or local health authorities typically work with the Minnesota Pollution Control Agency (MPCA). The establishment must furnish the MDA with a letter of approval from that authority upon request. [https://www.ecfr.gov/current/title-9/part-416#p-416.2\(f\)](https://www.ecfr.gov/current/title-9/part-416#p-416.2(f))

Well construction and code information, and information on well maintenance can be found by visiting the [Minnesota Department of Health Well Management](#) website.

Ongoing Requirements

Businesses connected to a municipal water supply are required to provide annual documentation for potability which can be obtained from your city or municipality. Potable water is water that is safe to drink. Businesses with private wells must have their water sampled at least semi-annually through an accredited laboratory; business owners are responsible for ensuring these samples are taken.

Financing Your Project

There are grant and loan opportunities to help offset the costs of certain projects. You may be able to benefit from the USDA Business and Industry [Loan Guarantee Program](#) through the office of [Minnesota USDA Rural Agriculture Development](#). Additionally, the USDA offers technical assistance for navigating federal grants through the [Meat and Poultry Processing Technical Assistance Program](#). At the state level, the MDA [Agricultural Growth, Research, and Innovation \(AGRI\) Program](#) supports a variety of agricultural endeavors, including meat processing. The annual Meat, Poultry, Egg, and Milk Processing AGRI grant can be used to facilitate the startup, modernization, or expansion of meat, poultry, egg, and milk processing businesses in Minnesota. For more information on the AGRI Program, contact the MDA Agricultural Marketing and Development Division at 651-201-6500.

Additional Considerations

As with any new business, the process of getting started and meeting all the legal requirements to operate can be overwhelming. The Minnesota Department of Employment and Economic Development (DEED) has a great [Resource Guide](#) to help new business owners, and the MDA [Starting a Food Business Roadmap](#) may also be a useful tool.

Almost all businesses in Minnesota must register with the Office of the Minnesota Secretary of State (SOS). Before registering your business, you will need to decide on the structure of your business (e.g., Corporation, LLC, Sole Proprietorship). For more information about business structures, see [Types of Minnesota Businesses](#). When registering your business with the SOS or obtaining a license with the MDA, you may be asked to provide personal information and other details about your business. Be prepared to provide your Minnesota Tax ID number or Social Security Number. Additionally, you will need to determine if workers' compensation insurance is required for any employees you plan to hire.

Resources and References

MDA Data Access Procedures: Public Data: www.mda.state.mn.us/home/data-access-procedures-public-data

How to Request Data from a Minnesota Government Entity:
mn.gov/admin/assets/howtorequest_tcm36-309309.pdf

Minnesota Food Code: www.revisor.mn.gov/rules/4626

MDA Plan Review – Retail Food Establishments: www.mda.state.mn.us/planreview

Specialized Processes – Hazard Analysis Critical Control Point and Variances:
www.mda.state.mn.us/food-feed/specialized-processes-hazard-analysis-critical-control-point-variances

Minnesota Department of Labor and Industry (DLI) Plumbing:
www.dli.mn.gov/business/get-licenses-and-permits/plumbing

Minnesota Department of Health (MDH) Well Management:
www.health.state.mn.us/communities/environment/water/wells/waterquality/test.html

USDA Business and Industry Loan Guarantee Program:
www.rd.usda.gov/programs-services/business-industry-loan-guarantees/mn

Minnesota USDA Rural Development Office: www.rd.usda.gov/mn

MDA Agricultural Growth, Research, and Innovation Program: www.mda.state.mn.us/grants/agri

Types of Minnesota businesses:
www.sos.state.mn.us/business-liens/start-a-business/types-of-minnesota-businesses

Minnesota Department of Employment and Economic Development (DEED) resource guide for starting a new business: mn.gov/deed/business/starting-business

Niche Meat Processors Assistance Network: www.nichemeatprocessing.org

Business Planning Guidebook:
www.nichemeatprocessing.org/wp-content/uploads/2024/03/NMPAN2023-BusinessGuide-3.6.24-PAGES.pdf

MDA Starting a Food Business Roadmap:
www.mda.state.mn.us/business-dev-loans-grants/starting-food-business-roadmap

A large, industrial-grade stainless steel mixing bowl is shown with its lid open. The lid is hinged and has several circular ports. Inside the bowl, there are several mixing blades or scrapers. The bowl is mounted on a base, and there are various pipes and mechanical components visible in the background.

FACILITIES, EQUIPMENT, AND SANITATION REQUIREMENTS 9 CFR 416.2



Equal To plants must meet certain facility, equipment, and sanitation requirements called the Sanitation Performance Standards (SPS) adopted by Minnesota from the federal meat and poultry inspection regulations. This section will provide an overview of those standards with examples of how Equal To plants can meet the requirements.

Each production environment is unique, and while the information presented in this section should be generally applicable to all production environments, it may not address the differences of every situation. Additionally, many of the standards described here allow for multiple ways of satisfying the regulatory requirement.

General Rules, 9 CFR Part 416.1

Each plant is responsible for providing a clean and sanitary environment to produce safe food. This includes but is not limited to the following regulations.



Grounds and Pest Control, 9 CFR 416.2(a)

The grounds around the plant must be maintained in a sanitary manner so that products do not become contaminated with filth or other food safety hazards. This includes the following requirements:

- Maintaining a pest control program that adequately prevents the entry of pests, such as rodents, flies, or other insects.
- Using safe and effective pest control substances meant for food production and storing them in a manner that does not contaminate products.
- Ensuring the grounds and facilities are kept clean and are well-drained, including the removal of trash and/or other items that could promote the breeding or harborage of pests.

Is a plant required to have a pest control business provide pest control services?

No, the plant may conduct pest control using any method available to them that is safe and effective for a food production environment. Effectiveness is usually measured by the presence or absence of pests. For example, the sighting of a mouse during an inspection would be a strong indicator that the pest control program is not adequate.

Do pest control substances need to be approved?

Any substance used for pest control within the establishment must be labeled as safe for use in food processing establishments and used in a manner that does not cause food to become contaminated. It is also important that these substances are kept in their original containers so that the safety labels and application instructions are readily available.

Construction, 9 CFR 416.2(b)

The requirements for construction of buildings and rooms are generalized, and many methods can be used to satisfy them:

- Buildings, including their structures, rooms, or compartments, must be of sound construction, kept in good repair, and of sufficient size to allow for processing, handling, and storage of product in a sanitary manner.
- Walls, floors, and ceilings must be built of durable materials that do not absorb moisture.
- Walls, floors, ceilings, doors, windows, and other openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.
- Rooms or areas where edible products are handled or stored must be kept separate from places that inedible product is stored.



This room in a processing facility has adequate lighting and acceptable floor, wall, and ceiling materials.



In the left photo, the door does not close tightly, leaving a gap between the door and the floor that is unacceptable in a meat processing facility as it could permit the entry of vermin; in the right photo, a hole in the ceiling needs to be repaired.

These requirements are ongoing; if materials become damaged or are in ill repair due to age and use, they will need to be fixed.

For example, some items that would need to be corrected include:

- Doors not closing tightly or with gaps as these could allow the entrance of vermin.
- Holes in the ceiling or windows that could allow entrance of vermin and/or dust.
- Scaling rust or scaling paint in the ceilings and walls of edible processing areas of the plant.
- Mold growth on the walls in production areas.

Are there specific material requirements for certain kinds of processing activities, such as slaughter?

For Equal To activities, you may use any materials that are durable and impervious to moisture if they do not pose a risk to the safety of the food. Specific kinds of materials, such as glass board or tiling, are not required but are often recommended as they have been used effectively in meat processing areas and are easy to clean. Keep in mind that other processing activities, such as retail exempt, have more specific requirements you may need to consider if you are building new, remodeling, or expanding your activities.

Lighting, 9 CFR 416.2(c)

Adequate lighting is essential to maintain a sanitary environment for slaughter and processing operations. Without adequate lighting, insanitary conditions are difficult to see and correct. Similarly, contaminants cannot be easily avoided or removed if they cannot be seen.

Lighting is a key part of maintaining good sanitation – if you cannot see well, you will not be able to identify cleanliness issues in your establishment. While this regulation does not provide a specific measurement standard for lighting, inspections will be based on the available lighting and your inspector will determine if lighting levels are appropriate.

Ventilation, 9 CFR 416.2(d)

A good ventilation system is important to the production of wholesome meat and poultry products. Unless the quality of air entering the establishment is controlled and the quality of the air in the establishment is maintained, products may become contaminated by dust, odors, smoke, fumes, and condensate. A poor ventilation system can serve as a vehicle for disseminating microorganisms.

Ventilation must be adequate to control odors, vapors, and condensation to the extent necessary to prevent contamination or adulteration of product and to maintain clean and sanitary operations. Condensation is a normal part of many meat processing activities; however, in some cases it also indicates that ventilation is not adequate. Condensation can be of major concern if it is located above a food processing area.

Your inspector will take action or write orders if condensation is dripping onto products, creating insanitary conditions, or interfering with inspection. For example:

- Heavily beaded condensation forms on a ceiling or wall of a processing area that is not regularly cleaned and sanitized.
- Condensate from a cooler ceiling drips onto carcasses.
- Condensate from a loading dock ceiling or wall drips onto boxes of product.

Most of these issues involve condensate dripping on exposed product or forming on a surface that has not been cleaned. Other kinds of condensate, such as over an ice or chill vat, may be acceptable so long as the surfaces are cleaned regularly.



Condensate on the ceiling of a cooler can drip onto contents below, creating a food safety risk.

Plumbing, 9 CFR 416.2(e)

Plumbing is a particularly important consideration in food establishments. Because plumbing systems transport water to and from establishments, problems with the plumbing system can easily lead to product contamination or adulteration. Plumbing impacts the establishment's water supply, drainage, and sewage disposal systems.

These regulations do not require that your meat inspector approve your plumbing system. However, the MDA will look for approved plumbing plans from your plumber, the Department of Labor and Industry (DLI), or local environmental health agency, especially for new builds or remodeling. When you are operational, compliance is evaluated by how well your systems are performing.

For more information:

- Contact the DLI for current procedures and requirements.
- Website www.dli.mn.gov/ or call 651-284-5067.
- The plumbing plan must be submitted by a licensed plumber
- Plan approval must be granted **prior to installation** by DLI

Drains are important systems in a meat plant and can harbor dangerous food safety pathogens, such as *Listeria monocytogenes*. Careful attention to your water supply and disposal can help ensure your products are safe and your plant is clean and sanitary.

Examples of issues that could be considered out of compliance include:

- Water pressure is too low to adequately wash and clean your equipment.
- Slaughter floor is flooded due to drain backing up during or after operations.
- Sewer gas smell permeates the establishment.

Sewage and Waste Disposal, 9 CFR 416.2(f)

Sewage and waste disposal systems must properly remove sewage and waste materials – manure, feces, feathers, paunch, trash, garbage, and paper – from the establishment. Systems must be approved prior to operation by local authorities.

Because sewage can contain harmful bacteria, adequate disposal systems are very important to maintaining a clean, sanitary plant. Minnesota E2 establishments must meet the following requirements:

- Sewage must be disposed into a system that is separate from all other drainage lines or disposed of through other means sufficient to prevent sewage backup into areas where product is processed, handled, or stored.
- Private disposal systems must have a letter of approval from the regulatory authority (this may be local or state).

It is a good idea to consult with your local regulatory authorities on the requirements for sewage disposal systems in your area, especially when you are building or remodeling. The requirements vary depending upon the location of your plant (city/rural) and the part of the state where you are located.

Some examples of situations that would be considered out of compliance include:

- A backup of sewage into the plant through drains or other means
- Sewage that is disposed of into other drainage lines or directly onto the ground

Other situations can occur once a plant is operational, and these can be much more difficult to correct. Building a compliant system from the start of the project will help to avoid problems occurring down the road.

Water Source: Municipal/Well Water

- Municipal water report must be made available upon request.
- Private well water must be sampled twice a year for coliform bacteria.
- Submit samples to an approved/accredited laboratory for testing and provide results to DMID.
- Potable water must be sourced from an approved municipal supply or private well.
- Hot and cold running water at adequate pressure is required.

Water Supply and Water Reuse, 9 CFR 416.2(g)

Water is used to clean facilities and equipment in meat and poultry establishments. In many operations, water is used as an ingredient in product formulations. Water, unless it comes from a safe supply, may serve as a source of contamination of product, equipment, utensils, and hands.

Potable water must be used in areas where animals are slaughtered, eviscerated, and dressed, and where edible products are processed, handled, and stored. The distribution system within the establishment must prevent contamination of the water supply.

Whenever ice is used in the processing or production of edible meat or poultry products, it must be sourced from potable water. If ice is sourced from outside the establishment, it must come from an approved source where a water potability certificate is provided upon request.

Dressing Rooms and Lavatories, 9 CFR 416.2(h)

A potential source of product contamination is cross-contamination from human feces, urine, and foreign materials from employee welfare facilities (break rooms and bathrooms). Employees can introduce pathogens into product by handling it with contaminated hands and street clothing. Personal belongings carry foreign materials that can indirectly contaminate product or food contact surfaces, therefore, areas designated to accommodate employees' personal needs must be designed to prevent overcrowding and congestion and be conveniently located within the establishment.

Hand sinks are required to have running hot and cold water; soap and towels, must be placed in or near restrooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.

Equipment and Utensils, 9 CFR 416.3

Equipment used in meat and poultry establishments range from utensils (simple hand tools) to highly complex electronically operated machinery. Since product contacts a variety of equipment surfaces, there is a potential for it to be contaminated. Equipment design and construction can have significant impact on sanitation in the plant and the goal of preventing product contamination. It is important to consider the design, installation, and maintenance of equipment to ensure that all surfaces and parts are capable of being cleaned and maintained in a sanitary manner.

Inedible materials must be stored in clearly and distinctively marked containers and can never be used for storing any edible product.

To assist with effective cleaning and sanitation, separate sinks based on use is recommended:

- 3-compartment sink – for washing equipment and utensils (wash, rinse, and sanitize);
- Hand wash sink – in each processing or slaughter room for hand washing only; Product sinks for product rework and washing-not to be used for handwashing or other sanitation purposes.



Sanitary Operations, 9 CFR 416.4

Sanitation procedures and maintenance of facilities during slaughtering and processing must be accomplished in a manner to ensure the production of wholesome, unadulterated product. Frequent and effective cleaning of certain areas of the establishment is necessary to prevent accumulation of buildup resulting from meat and poultry residue on equipment and utensils. The method, frequency, and areas to be cleaned can vary depending on the establishment's operations.

Below are some points to consider as part of sanitary operations:

- All carcasses must be visibly free of fecal contamination.
- All product contact surfaces must be constructed of smooth, easily cleanable, non-porous, non-absorbent materials.
- Walls and ceiling would have to be finished with approved materials. (Glass board/FRP enameled metal, ceramic tile, etc.) No exposed wood is permissible.
- Floors must be maintained in good repair and easily cleanable. Concrete is an option, but it must be sealed. Paint is not recommended.
- The slaughter and processing facility must be divided into at least two rooms.
 - The first room would be dedicated for killing and dressing. A hand wash sink must be provided for food handlers in this room.
 - The second room would be dedicated for processing the carcasses and meat products that are manufactured. A hand wash sink must be provided for food handlers in this room also.

Employee Hygiene, 9 CFR 416.5

Employees can be disease carriers and bring contaminants from the outside such as dirt, debris, and other foreign materials that can both directly and indirectly contaminate food. Foodborne illness outbreaks have been linked to poor personal hygiene of workers involved in food processing and handling. Therefore, personal hygienic practices for employees are essential to the production of safe and wholesome meat and poultry products.

Resources and References

FSIS Directive 5,000.1 Verifying An Establishment's Food Safety System:

www.fsis.usda.gov/sites/default/files/media_file/documents/5000.1.pdf

Code of Federal Regulations Title 9, Part 416 – Sanitation:

www.ecfr.gov/cgi-bin/text-idx?node=pt9.2.416&rgn=div5 (full text also copied in Appendix B)

Code of Federal Regulations Title 40, Part 141 – National Primary Drinking Water Regulations:

www.ecfr.gov/cgi-bin/text-idx?SID=b88fa8cc9dc7a43b188c32b76e126bbb&mc=true&node=pt40.25.141&rgn=div5

USDA FSIS Guidance for Water, Ice, and Solution Reuse:

www.fsis.usda.gov/wps/wcm/connect/6be974fc-f605-4065-9301-ffebe963916e/san_update1.pdf?MOD=AJPERES

OVERVIEW OF THE REQUIREMENTS AND PROGRAM



Equal To Inspection

SSOP Requirements, 9CFR 416.12 -416.16

Requirements

SSOP stands for Sanitation Standard Operating Procedures. These are written procedures that describe the processor's cleaning program and the records they use to monitor it. The program needs to describe sanitary personnel practices and operations that are used to keep the environment and plant facilities in a clean condition.

- SSOPs must describe the activities the processor performs before they start to process food each day (preoperational SSOPs). It also describes steps taken during operations (Operational SSOPs) that the processor uses to prevent direct product contamination. These written procedures need to be specific and must contain many details of a processor's sanitation program.
- Provide the Dairy and Meat Inspection Division (DMID) with a written SSOP (Sanitation Standard Operating Procedures). 9CFR 416.11-17
- Procedures must include both Pre-operation and Operation Sanitation Procedures
- Provide DMID with a written outline of your facility/equipment cleaning program/schedule.

HACCP Requirements

HACCP is a technical term that stands for Hazard Analysis & Critical Control Points. This is a system that processors use to put a business's food safety practices into action. The system focuses on preventing food safety problems and ensures the production of safe food products. HACCP applies scientific-based and technical information to practical situations in the meat and poultry production process.

- Flowchart of process
- Hazard Analysis to identify potential Hazards
- HACCP Plan
- Determine Critical Control Points
- Supporting Documentation for the decisions
- Record Keeping Documentation to support the monitoring of Critical Control Points

Note: A HACCP plan is required for each inspected product category.

Labels

Labels should include product name, ingredient statement, handling/perishability statement, net weight statement, the inspection legend, name, and address. Learn more about labeling E2 meat and poultry products from the labeling manual, [Labeling your "Equal To" Meat and Poultry Products](#).

- If custom exempt or retail exempt operations are conducted, all products must be marked and kept separate from the state inspected product.
 - ▶ Refer to [Starting a Minnesota Custom Exempt Meat Plant](#) for labeling custom exempt products.
- State Inspected carcasses, parts or product must be marked with the inspection legend.

Product Separation

Product separation is an important part of preventing cross contamination or adulteration and for maintaining traceability to the owners of the products. At a minimum, adequate product separation must address the following:

- Separating raw products from fully cooked, ready-to-eat products
- Separating Equal To inspected products from other types of products, such as custom exempt and retail exempt

Ensuring adequate separation is maintained between custom exempt products and retail exempt products in facilities where both types of operations are conducted is critical to avoiding cross contamination or adulteration.

Products may be separated by time and/or space. Equal To slaughter and processing operational times must be separate from those times you are handling other types of products, such as retail or custom, unless you can separate them by location in the plant. Products must also be separated by space, including the areas where they are stored or handled, unless you can completely separate the times that they are processed, handled, and stored. The degree of each of these depends upon your operation; it's unique to each business.

For Example:

Separation by Time

Plant Processing Schedule							
Time	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
AM	X	Custom	Custom	E2	E2	E2	X
PM	X	Custom	X	E2	X	Custom	X

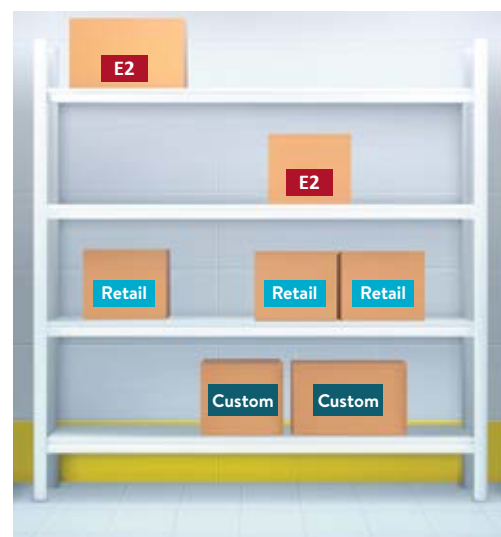
Equal To (E2) slaughter and processing occurs on Wednesdays. All other days of the week, E2 inspected products are processed in the first part of the day and retail or custom are processed after E2 processing is complete.

Separation by Space

Ideally, plants should have adequate storage capacity to be able to accommodate physical separation of Equal To inspected product, custom exempt, and retail exempt products and whenever possible; use one set of coolers for raw products and livestock carcass storage and a different set of coolers for smoked/cooked products. When spaces must be shared, such as in a freezer, product separation must still be maintained in some way. This could be by shelf or by wall/side of the freezer. Keep in mind, raw product should never be stored above fully cooked ready-to-eat product. Keeping these areas organized and not over-filled will help you maintain proper separation.

Product Storage and Distribution

Regulatory standards require plants to ensure product is protected from adulteration or contamination during processing, handling, storage, transportation, loading, and unloading. Basically, this addresses all stages of product handling. This can be done by implementing good manufacturing practices (GMPs) or Standard Operating Procedures (SOPs) for receiving, storage, production/processing, and loading/transport of custom carcasses or products.



Different product categories are separated by shelf in a walk-in cooler. The bottom shelf is reserved for custom exempt products, the middle shelf is for retail exempt products, and the top two shelves are for Equal To (E2).

The following are examples of common operational SOPs or GMPs used to address product contamination in Equal To operations:

- Food grade packaging, bags, or other coverings are used to protect products from adulteration or contamination.
- While in storage, products are covered to prevent contamination from other products being stored in the same room/compartments as well as from other sources of contamination (condensation, etc.).
- Coolers and freezers are maintained at temperatures necessary to prevent pathogen growth and maintain product shelf life.
- Prevent cross contamination of allergens through various control measures.

Recalls

A recall involves removing distributed products (i.e., products that have already left your establishment and are no longer under your control) from commerce when there is reason to believe the products are adulterated or misbranded.

All Equal To establishments must prepare and maintain written recall plans ([9 CFR 418](#)). Recall plans describe how you decide whether to recall a product and the procedures you will follow in the event of a recall to ensure that the unsafe or unsuitable product is contained and either destroyed or rendered safe. For information on building a recall plan, along with templates, refer to the [USDA Recall Plan Booklet](#).

Licensing / Permitting and Fees

Licensing

A license is required for any entity handling food or meat products. Depending on what type of operation you have will determine which license is required.

Retail Food Handler's license – Issued by MDA if your operation is selling products directly to the end consumer from your place of business. – The fee is dependent upon the gross annual sales expected for the year. The license runs for 1 year starting on July 1, through June 30, for each calendar year license fees are not prorated if you start your business mid-year.

Wholesale food processor/manufacture license- Issued by MDA if your operation is wholesaling products to other entities or manufacturing products and not selling the products retail from your place of business. The fee is dependent upon the gross annual sales expected for the year. The license runs for 1 year starting on January 1, through December 31, each calendar year, license fees are not prorated if you start your business mid-year.

Custom Exempt Food Handler's license – Issued by MDA if your operation is exclusively providing a service of slaughter and/or processing of meat, poultry, or wild game products for the owner of the animal. The fee is dependent upon the gross annual sales/service expected for the year. The license runs for 1 year starting on July 1, through June 30, each calendar year, license fees are not prorated if you start your business mid-year.

This license is only applicable if you are exclusively operating as a custom exempt establishment. If you are conducting retail, wholesale, or manufacturing of products you must obtain either retail or wholesale/manufacturing food handler's license.

Note: If you currently have a license from a different Minnesota state agency, county, or local authority you may be able to keep that license and still come under MN Equal To inspection.



Permits

Issued by MDA in addition to one of the two licenses above. Permits do not have a fee associated with them. Permits allow your operation to add a specific or unique operation to your business. The most common permit issued to meat processing establishments is the Custom Exempt Processing permit.

Custom Exempt Processing Permit – Issued by MDA and doesn't have a fee. A Custom Exempt Processing Permit allows the operation to provide a service of slaughter and/or processing of meat, poultry, or wild game products for the owner of the animal.

The MDA must inspect your facility before a license or permit can be issued. When your facility meets the requirements of this department as outlined above, this department will accept your application for the appropriate license and will process it forthwith.

Grant of Inspection

Very similar to a permit, a grant of inspection is issued by Meat Program Management to a licensed establishment to include details on their specific operation for wholesaling meat or poultry products. There is no fee for the grant of inspection. To obtain a Grant of Inspection from the MDA, you need at a minimum the following:

1. **A HACCP Plan.** HACCP is an acronym for hazard analysis critical control point. Such a food safety “process control program” must be developed by someone formally trained in HACCP.
2. **A Sanitation Standard Operating Procedure (Sanitation SOP).**
3. **A suitable facility** where the walls, floors, and ceilings are cleanable, impervious to moisture, insects, vermin and meet other sanitary requirements.
4. **Proper labels** identifying inspected product.
5. **A recall plan** describing what procedures the establishment will take if unsafe food enters commerce.
6. **An effective pest control plan.**

How to Apply

The first step to applying for a grant of inspection is to contact Meat, Poultry and Egg Inspection at 651-201-6300 or email MDA.MeatPoultryEgg@state.mn.us. To provide you with the best guidance, it is important to provide all the information about your operation during initial discussions with program staff.

Before inspection is granted, each person shall submit a letter of intent, HACCP and SSOP plans including the associated prerequisite programs, proper labels, a recall plan, and an effective pest control plan to the St. Paul office for review. An onsite review of the facility will be scheduled with program staff prior to issuing a provisional grant of inspection. Letter of Intent and single or multi-ingredient label forms will be provided by a program employee. To request more information on how to acquire an Equal To grant of inspection contact Meat, Poultry and Egg Inspection at 651-201-6300 or email MDA.MeatPoultryEgg@state.mn.us.

Fees

License	Fee
Retail Food Handlers	Fee is based on gross sales or service: www.revisor.mn.gov/statutes/cite/28A.08
Wholesale food processor/manufacture	Fee is based on gross sales or service: www.revisor.mn.gov/statutes/cite/28A.08
Permits	
Custom Exempt permit	No fee – Issued by MDA
Grant of Inspection	No fee – Issued by MDA

Forms

Letter of Intent

The “letter of intent” is completed and submitted as a sort of cover letter along with the other documentation required prior to opening your meat processing facility. Other documentation includes HACCP plans, SSOPs, product formulations and labels, and more. The letter signifies your formal request/application for a grant of inspection, which you must have before you will be able to operate as an Equal To establishment. You will receive the Letter of Intent form from program staff before submitting any documentation.

Application for Inspection

MINNESOTA DEPARTMENT OF AGRICULTURE
420 Robert Street North, St. Paul, MN 55103-2538
www.mda.state.mn.us

Dairy and Meat Inspection Division Phone: 651-201-6300

APPLICATION FOR STATE MEAT, POULTRY INSPECTION

Date of Application _____ Type of Product: ☐ Meat ☐ Poultry ☐ Both

Type of Grant/Types of Animals

☐ Slaughterhouse ☐ Cattle ☐ Sheep ☐ Goats ☐ Processing ☐ Swine ☐ Birds ☐ Other (specify) _____

☐ Slaughter ☐ Chickens ☐ Turkeys ☐ Waterfowl ☐ Slaughter ☐ Chickens ☐ Turkeys ☐ Waterfowl ☐ Other (specify) _____

Type of Application (Check all that apply)

☐ New ☐ Change of Location ☐ Change of Ownership ☐ Other, Specify _____

Current Establishment Number _____

Form of Organization

☐ Individual ☐ Cooperative Association ☐ Partnership ☐ Corporation ☐ Educational Institution

☐ Limited Liability Corp (LLC) ☐ Other _____

If a Corporation Name of State or Territory where incorporated _____ date incorporated _____

Name of Applicant _____

Business Name and Plant Location (Full address) _____ Mailing Address if Different from Location Address _____

Establishment Phone _____ Establishment Fax _____ Establishment Email _____

Other Name – SDA _____

Describe the Scope of the Operation

Exemptions ☐ Custom Processing ☐ Fully Cooked – Not Shelf Stable ☐ Slaughter/Cutting ☐ Smoking ☐ Mechanical Delivering ☐ Slaughterhouse ☐ Meat Treating – Shelf Stable ☐ Slaughterhouse ☐ Meat Treating – Shelf Stable ☐ Slaughterhouse ☐ Meat Treating – Shelf Stable ☐ Slaughterhouse ☐ Meat Treating – Shelf Stable

HACCP Categories ☐ Fully Cooked – Not Shelf Stable ☐ Slaughter/Cutting ☐ Smoking ☐ Mechanical Delivering ☐ Slaughterhouse ☐ Meat Treating – Shelf Stable ☐ Slaughterhouse ☐ Meat Treating – Shelf Stable ☐ Slaughterhouse ☐ Meat Treating – Shelf Stable

Types of Product ☐ Meat ☐ Poultry ☐ Both

Days/Hours of Operation (Set hours by corresponding days)

Days	Processing	Slaughter
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		

The application for inspection is provided by the designated Meat Supervisor once all your documents have been reviewed and approved and is filled out in coordination with that supervisor. The application goes into more detail about your operational plans, such as HACCP categories, types of products produced or manufactured, contact information, and business hours. Once this application has been reviewed and signed by Meat Program Management, a provisional grant of inspection letter is sent to the establishment outlining their approved start of operations date, business days and hours of slaughter and/or processing. It also details program expectations. See Appendix B.

Checklist for Equal To Inspection

This checklist is a guide for your own planning purposes to ensure you have met all requirements necessary to obtaining a grant of inspection. The checklist does not need to be submitted for approval. See Appendix A.

"EQUAL TO" OR STATE CONTINUOUS INSPECTION REQUIREMENTS CHECKLIST

MINNESOTA DEPARTMENT OF AGRICULTURE

There are many steps to take prior to opening for business as a "Equal To" inspected facility. Below we have outlined most of the steps that must be taken prior to applying for a license with the Minnesota Department of Agriculture (MDA) – Dairy & Meat Inspection Division (DMID). This list is not all inclusive; there may be additional steps that are required by local city or county ordinances. Please review this information and contact all agencies involved to ensure a smooth transition into business. Our meat inspectors will work with you throughout the process.

OVERALL REQUIREMENTS

Building Permit / Zoning

☐ Check with city/county or other local authority for all applicable permits and zoning requirements before you start construction or buy a facility.

Other Codes to Consider

☐ Fire
☐ Electrical
☐ Occupancy

Plan Review

☐ Building plans are reviewed by the MDA for Custom Processing, "Equal To" and Retail Exempt operations.

☐ Prior to construction, all plans should be submitted to DMID to ensure any comments or "revisions" can be incorporated into your plan.

☐ Any facilities that will also operate as a retail establishment must complete an official plan review for the retail portion of the facility as required by the MN Food Code.

☐ Retail Plan Review Construction Guide
• New Plan Review - Retail Food Establishment - (Plan Review Application)
• Call 651-264-5563

☐ Also review the following documents found at the MN Department of Agriculture website:
[Starting a Food Business in Minnesota](#)

Water Supply

☐ Municipal report must be made available upon request.
☐ Private well water is tested twice a year for coliform bacteria.

☐ Submit samples to an approved accredited laboratory for testing and provide results to DMID.
☐ May be required to be separate from home well water source.

☐ Potable water must be used in areas where animals are slaughtered, eviscerated, and dressed, and where edible products are processed, handled, and stored. The distribution system within the establishment must preclude contamination of the water supply.
☐ Hot and cold running water is required.

Septic System or Sewer Hook-Up

☐ Approved by county, township, or city health department.
• May be required to be separate from home.

Plumbing System

☐ Contact the Department of Labor and Industry (DOLI) for current procedures and requirements.
• Department of Labor and Industry website, or
• Department of Labor and Industry Plumbing
• Call 651-264-5563

☐ The plumbing plan must be submitted by a licensed plumber.
☐ Plan approval must be granted prior to installation by Department of Labor & Industry.
☐ Sewer out to DMID for support for floor drains in coolers.

"Equal To" or State Continuous Inspection Requirements Checklist 1



Inspections

Continuous inspection under the Minnesota Equal To Inspection program means that your establishment is inspected every day during Equal To operations to ensure you are producing safe food. For slaughter establishments, this would include the inspector performing antemortem (before death) inspection of all livestock (or poultry) presented for slaughter prior to the start of operations, along with a preoperational sanitation inspection. The inspector remains at the establishment conducting various inspection tasks as part of their postmortem (after death) inspection activities.

During Equal To processing operations, the assigned inspector will visit each of their assigned establishments to verify food safety standards are met for SSOP, labeling, SPS, HACCP, and other regulatory requirements. Inspectors will vary the time of day in which they conduct their inspections to focus on various verification activities such as preoperational sanitation and monitoring by plant personnel, formulation and labeling of products, production and packaging of various meat/poultry products, and end of day cleaning. During all these activities, there is a focus on the review of establishment records to ensure ongoing SSOP and HACCP requirements compliance.

Scheduling

The scheduling of slaughter and processing inspections will be determined by Meat Program Management based on staffing resources and the establishment's grant of inspection which details their approved days and hours for slaughter and processing operations. Meat Program Supervisors work with the data coordinator to create the inspection schedule, which is assigned to inspection personnel on a weekly basis. Any changes to the schedule must be requested in advance and approved by Meat Program Management. This may include requests for additional production days, changes to approved days or hours of operation, closures due to holidays, or seasonal suspensions from inspection.

Frequency of Inspections

Most Equal To slaughter operations conduct inspected slaughter one day per week. Additional days may be granted based on current staffing on a case-by-case basis. Slaughter will be scheduled weekly and assigned to the Inspector In Charge (IIC) or the assigned relief inspector. Slaughter operations cannot start until the assigned inspector has arrived at the facility and conducted their antemortem and preoperational inspections. If an establishment's routine assigned day falls on a holiday, an alternate day for slaughter can be requested in advance.

Processing inspections will also be assigned weekly for each day of the week an establishment is approved for manufacturing meat or poultry products. The establishment must ensure they are operating within their designated days and hours as detailed on their Grant of Inspection. If an establishment wishes to add production days or not operate on certain days, they are to communicate this to their IIC in advance.

How Inspections Work

Below are explanations and examples of what types of actions a MN Equal To inspector may take while inspecting your establishment.

In Compliance means that the establishment's processes are working properly in accordance with the laws and regulations. Inspection includes all actions the Agency may take to examine the establishment and its processes, products, and systems. Enforcement actions are those the Agency takes when an inspector determines that the establishment's plans and systems are not in compliance with laws and regulations. There is a range of enforcement actions that MDA uses. Some examples of enforcement actions are regulatory control actions such as slowing or stopping the slaughter line, rejecting equipment or processing locations, or retaining product; withholding actions; or the suspension of inspection. We will discuss these actions in more detail later in this section. We have adopted the Rules of Practice, [9 CFR 500](#), which are FSIS's enforcement regulations.

Establishments have the right to do business and are guaranteed due process of law. The Constitution guarantees that the government cannot take away a person's basic rights to 'life, liberty or property, without due process of law.' "Due process rights" means that a fair "process" or proceeding, must take place before the government interferes with an individual's property or actions. This process might include notifications, hearings, or other activities. By following the Rules of Practice regulations, [9 CFR 500](#), FSIS and MDA assures that appropriate due process takes place.

Regulatory control action is commonly used by in-plant inspection personnel. This term refers to any action that inspection personnel take to control product or processes. Inspection personnel use regulatory control actions to identify regulatory noncompliance and prevent the movement of the product or use of the equipment or facility until the noncompliance has been corrected. A common example is the application of the MDA reject/retain tag on equipment, carcasses, or product.

Withholding actions withhold the marks of inspection. Such actions may be taken against product produced by a particular process or all products in the establishment. Withholding is a more severe enforcement action than a regulatory control action, because it can affect a larger part of an establishment or establishment processes. The decision to take an immediate withholding action can be made by whomever is in charge for MDA at the establishment (for example, the IIC or designee), the compliance officer, or the assigned supervisor).

Suspension refers to the interruption in the assignment of inspection personnel to the establishment. A suspension of inspection also has a severe impact on an establishment. A suspension is usually in effect for a much longer duration of time than a withholding action. Because a state inspected establishment cannot legally apply marks of inspection to product without an assigned inspector, this action stops all production, or it can be applied to a specific production process. For example, MDA may suspend all inspection at a beef slaughter and processing establishment. The decision to suspend inspection is made by the assigned supervisor, or higher level of authority.

Auditing Process

Food Safety Assessment

Food Safety Assessments (FSAs) are conducted at all MN Equal To establishments. These audits are done by a MN Enforcement Investigations and Analysis Officer (EIAO) and are completed by visiting the establishment during operations, assessing the establishment in action, and reviewing the food safety documents (HACCP, SSOPs, etc.) in detail. FSAs are completed to make sure the food safety procedures are effective.

After an establishment receives a provisional grant of inspection from the MN Meat Inspection Program, they are given 90 days to validate their HACCP and food safety systems. After 90 days, an FSA will be scheduled and once successfully completed a permanent grant is issued. FSAs are then scheduled at a frequency of at least once every 4 years or if there are other regulatory concerns raised. Upon conclusion of the FSA audit, a final report is issued to the establishment.

Humane Handling Audits

Humane animal handling is important to the welfare of animals. Also, proper animal handling helps prevent product adulteration. A more intense audit/inspection that focuses on humane handling provides an opportunity to educate establishment personnel and identify and correct handling issues. These audits are called humane handling audits for livestock establishments and good commercial practice audits at poultry establishments.

These audits are scheduled in advance and occur every 18 months. The reviewer should assess whether humane handling practices ([9 CFR 313](#)) or good commercial practices ([9 CFR 381.65\(b\)](#)) of the establishment meet regulatory requirements. The reviewer is expected to work collaboratively with the establishment personnel and inspection personnel. This includes, providing training materials to the establishment and inspection personnel as appropriate and answer questions regarding appropriate humane handling practices. Upon conclusion of the audit, a final report is issued to the establishment.

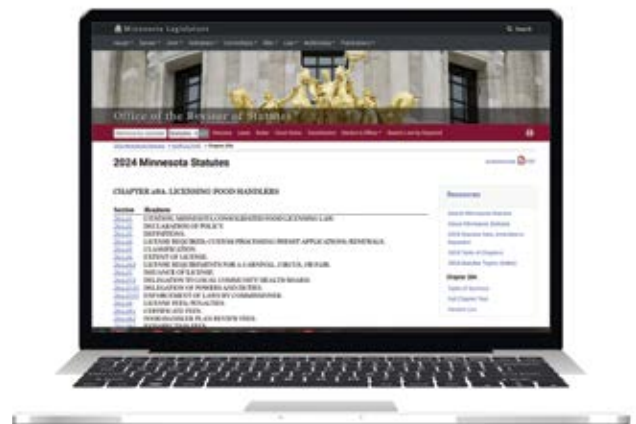
Additional Requirements

Testing and Sampling

Product testing by the establishment and MDA play a large part in verifying the written procedures are being implemented and sanitation is being maintained. Product testing is a required part of the inspection process for many different products produced. Products that will require testing by the establishment and/or MDA include the following:

- Poultry slaughter - testing for *Campylobacter* and/or *Salmonella*
- Red Meat Slaughter - testing for Generic *E.coli*.
- Ground Beef - testing for *E.coli* O157:H7 and *E.coli* STECs.
- Ready-to-Eat products - testing for *Listeria* and *Salmonella* and environmental sampling for *Listeria* species.

There may be required sampling outside of this list. The sampling will depend on the products you are producing, the volume of product produced, and written programs you develop.





HACCP Training

As required by [9 CFR 417.7](#), only an individual who has successfully completed HACCP training in the application of the seven HACCP principles of meat, poultry, or egg products processing, can develop the HACCP plan, conduct reassessments, and make modifications within the plan. For this reason, completing HACCP training prior to applying for the grant of inspection is best. There are online and in person training options to choose from. When selecting a HACCP training, ensure that the course includes red meat and poultry processing. Budget, topics covered, and learning style are items to take into consideration when determining what training method fit your needs.

Development of a HACCP plan can be very challenging. Some establishments may choose to hire a HACCP consultant to develop and reassess their HACCP plans. Budget, service responsiveness, and employee training should be taken into consideration when determining if a consultant will be hired. It is important to keep in mind that ongoing reassessment and/or modifications to the HACCP system would require someone who is trained in the 7 principles of HACCP, if a consultant has been hired, they may need to complete those tasks.

HACCP Validation and Reassessment

Validation is the collection or evaluation of scientific information or literature to determine if a HACCP plan is controlling the identified hazards, with specific emphasis on CCPs and associated critical limits.

Validation is usually conducted after initial development of the HACCP plan and on a periodic basis after development of the HACCP plan. Initial validation will be collected during the first few months of processing under the HACCP plan. Ongoing validation needs to occur annually, or more frequently, depending on needs and changes in the processing operation.

Validation must include: 1) hazard analysis justification, 2) support for hazard identification and CCP location, and 3) support of critical limits and monitoring activities.

Initial Validation

Initial validation of the HACCP plan will determine that 1) the plan is scientifically and technically sound, 2) all hazards have been identified, and 3) identified hazards will be effectively controlled if the HACCP plan is properly implemented. Simply put, validation of the HACCP plan will assure that the plan will prevent, eliminate, or reduce the level of hazards identified by the hazard analysis. A HACCP team may rely on expert advice, scientific studies,

scientifically based regulatory requirements or in plant measurements or studies for the initial validation of the HACCP plan. For example, processors that prepare cooked sausages will be able to refer to the FSIS Cooking Guidelines For Meat and Poultry Products for control of Salmonella as verification of their cooking process.

Ongoing Validation

In addition to initial validation, the HACCP team will need to conduct periodic validation (or testing) of the HACCP plan as needed. USDA regulations for meat and poultry products (9 CFR 417.4(a)(3)) require an annual reassessment or validation of the HACCP plan. In addition, validation should be conducted when there is an unforeseen failure. For example, an establishment may have collected initial validation to support a predetermined critical limit (CL) for cooling or stabilization as outlined in the FSIS Stabilization Guidelines and then modify their CL due to repeated failures during initial validation. Another example may be the initial collection of temperatures for receipt of incoming meat and storage to support a Standard Operating Procedure (SOP) or other prerequisite program and then conduct quarterly temperatures thereafter.

The HACCP team should record all verification and validation activities. In addition to documentation of the verification activity, a reassessment or change page for the HACCP document should be included. This can be included with the HACCP signature page to indicate annual and ongoing reassessment and what has been changed (or indicate when no changes are made). Regulatory requirements 9 CFR 417.4(a)(3) for meat and poultry plants indicate that “The responsible establishment official has signed and dated the HACCP plan at least annually thereafter upon required plan reassessment.”

Inspectional Space and Equipment

For establishments that include inspected slaughter operations, a file equipped with locked hasp (see image to the right) is required in the inspector office location (or other designated area of the facility for storage of inspection related equipment). MDA provides a universal padlock so that any inspection personnel assigned can access the locked file. These establishments will also need space in a cooler for storage of sampling supplies and a protected area for storage of an incubator for residue screening.



Slaughter establishments will also be required to provide the following equipment needed for inspection and evaluation during postmortem verification activities by inspection staff: beef head examination cradle or mounted hook station, viscera table/cart, and a table/cart for examination of the pluck (heart/lungs/trachea).

Ordering Carcass Stamp

When slaughtering animals under MN Equal To inspection, carcasses from those animals are stamped with the MN inspected and passed, mark of inspection. This ensures and supports that the carcass is wholesome and safe for human consumption and it passed inspection.

The stamp that is used for marking carcasses must be purchased by the establishment. Even though the establishment purchases the stamp; the inspector maintains control of the stamp during slaughter and then locks the stamp in the inspectors file when slaughter concludes.

There is a lengthy process to order and manufacture the stamp. Stamps are milled out of brass and are specific to the establishment, with MN Inspected and passed and the establishment number milled into the brass. The cost can be several hundred dollars with shipping. Typically, it takes 6-8 weeks to receive the stamp once it is ordered. Plan ahead with the assigned supervisor and your inspector to ensure the stamp is ordered and received by your intended first day of slaughter.

Resources and References

MINN. STAT. 28A: www.revisor.mn.gov/statutes/cite/28A

MINN. STAT. 31A: www.revisor.mn.gov/statutes/cite/31A

FSIS Directive 5,000.1 Verifying An Establishment's Food Safety System:
www.fsis.usda.gov/sites/default/files/media_file/documents/5000.1.pdf

9 CFR 417 Hazard Analysis and Critical Control Point (HACCP) Systems:
www.ecfr.gov/current/title-9/chapter-III/subchapter-E/part-417



COMMONLY ASKED QUESTIONS





Q: What is the difference between Equal To inspection and USDA?

A: Minnesota's "Equal To" (E2) program allows establishments to slaughter animals and process products for wholesale to any entity within the state of Minnesota. Businesses that want to produce and sell their products in other states and/or for export to other countries must be inspected by the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS).

Q: How long do routine inspections take?

A: Any time product is being produced that will have the marks of inspection on the label, inspection is required. The amount of time inspection staff spend at an establishment will be dependent on each operation and what assigned tasks inspectors are to verify that day (e.g., verifying that a sanitation program is being followed by reviewing records). In slaughter processing facilities, every animal is inspected to ensure they are handled humanely, and that the meat is wholesome and free from signs of disease. An inspector is required at the establishment the entire time slaughter is being conducted to provide this inspection. For facilities that do processing an inspector will be at the establishment during some point of the operation, but not the whole day. This allows the inspector to observe a snapshot of the operation and determine if the operation is following regulations and is implementing their plans as written.

Q: How long does the process take to get a grant of inspection?

A: Your level of experience and facility's readiness, among other factors, will affect the timeline for receiving a grant of inspection. The process may take anywhere from a few months for an applicant who is well-prepared, to years in some cases. Many applicants find HACCP development to be one of the most challenging parts of the process. Taking the time to understand HACCP principles and develop plans that can be implemented at your facility is very important and will pave a successful path forward. All required parts must be submitted for review before you will be issued a provisional grant of inspection.

Q: How many HACCP plans do I need?

A: A HACCP plan is needed for each product/processing category you intend to have in your facility. Common categories include Raw Non-Intact, Raw Intact, Heat Treated Not Shelf Stable, Fully Cooked Not Shelf Stable, and Slaughter. A single HACCP plan may cover multiple products if the hazards, critical control points, critical limits, and procedures within the plan are essentially the same.

Q: Is there funding available to help me get my business started?

A: There may be grants or loans available. For more information visit the [Business Development, Loans, and Grant Topics on the MDA website.](#)

Q: How much will a grant of inspection cost?

A: A grant of inspection is free of cost. However, there will be costs associated with the license type required, and other operating costs associated with getting started (example: ordering a carcass stamp, labels, HACCP training, etc.).

APPENDIX A: Equal To Facility Checklist

“EQUAL TO” OR STATE CONTINUOUS INSPECTION REQUIREMENTS CHECKLIST



There are many steps to take prior to opening for business as a State “Equal To” Inspected Facility. Below we have outlined most of the steps that must be taken prior to applying for a license with the Minnesota Department of Agriculture (MDA) – Dairy & Meat Inspection Division (DMID). This list is not all inclusive; there may be additional steps that are required by local city or county ordinances. Please review this information and contact all agencies involved to ensure a smooth transition into business. Our meat inspectors will work with you throughout the process.

OVERALL REQUIREMENTS

Building Permit / Zoning

- ☐ Check with city/county or other local authority for all applicable permits and zoning requirements before you start construction or buy a facility.

Other Codes to Consider

- ☐ Fire
- ☐ Electrical
- ☐ Occupancy

Plan Review

- ☐ Building plans are reviewed by the MDA for Custom Processing, “Equal To” and Retail Exempt operations.
- ☐ Prior to construction, all plans should be submitted to DMID to ensure any comments or suggestions can be incorporated into your plan.
- ☐ Any facilities that will also operate as a retail establishment must complete an official plan review for the retail portion of the facility as required by the MN Food Code.
 - Retail Plan Review Construction Guide
 - New Plan Review - Retail Food Establishment ; Plan Review Application
- ☐ Also review the following documents found at the MN Department of Agriculture website:
[Starting a Food Business in Minnesota](#)

Water Supply

- ☐ Municipal report must be made available upon request.
- ☐ Private well water is tested twice a year for coliform bacteria.

- ☐ Submit samples to an approved/accredited laboratory for testing and provide results to DMID.
- ☐ May be required to be separate from home well/water source.
- ☐ Potable water must be used in areas where animals are slaughtered, eviscerated, and dressed, and where edible products are processed, handled, and stored. The distribution system within the establishment must preclude contamination of the water supply.
- ☐ Hot and cold running water is required.

Septic System or Sewer Hook-Up

- ☐ Approved by county, township, or city health department
 - May be required to be separate from home.
- ☐ A letter from the applicable authority must be provided to MDA verifying that an adequate wastewater handling system is installed.

Plumbing System

- ☐ Contact the Department of Labor and Industry (DOLI) for current procedures and requirements:
 - Department of Labor and Industry website; or
 - [Department of Labor and Industry-Plumbing](#); or
 - Call 651-284-5063
- ☐ The plumbing plan must be submitted by a licensed plumber.
- ☐ Plan approval must be granted prior to installation by Department of Labor & Industry.
- ☐ Reach out to DMID for support for floor drains in coolers.

Facility Requirements

All surfaces must be constructed of a smooth, easily cleanable, nonporous, nonabsorbent material.

- ☐ Walls and ceiling must be finished with approved materials (glass board, enameled metal, ceramic tile, etc.). No exposed wood is permissible.
- ☐ Floors must be maintained in good repair and easily cleanable. Concrete is an option, but it must be sealed – paint is not recommended.
- ☐ A slaughter and processing facility would have to be divided into at least two rooms.
 - The first room would be dedicated for killing and dressing. A hand wash sink must be provided for food handlers in this room.
 - The second room would be dedicated for processing the carcasses and meat products that are manufactured. A hand wash sink must be provided for food handlers in this room also.

License/Grant of Inspection

- ☐ A Food Handler's license – Issued by MDA, if your operation is selling products directly to the end consumer from your place of business. The fee is dependent upon the gross annual sales expected for the year. The license must be renewed annually prior to its expiration. License fees are not prorated if you start your business mid-year.
- ☐ The MDA must inspect your facility before a license can be issued. If, at that time, your facility meets the requirements of this department as outlined above, this department will accept your application for the appropriate license.
- ☐ Grant of Inspection must be issued prior to wholesale distribution of any meat or poultry products.

Sink Requirements

- ☐ Must have separate sinks:
 - 3-compartment sink – for washing equipment and utensils.
 - Hand wash sink – in each processing or slaughter room for hand washing only.
 - Mop/service sink – for cleaning floors (required in Retail Food establishments).

BASIC REQUIREMENTS FOR OPERATING UNDER THE STATE “EQUAL TO” PROGRAM

Sanitation

- ☐ Refer to [Basic Facts about SSOP's and HACCP Plans for Meat Processors](#).
- ☐ Sanitation procedures and maintenance of facilities during slaughtering and processing must be accomplished in a manner to ensure the production of wholesome, unadulterated product. [9CFR416.1 – 6](#).
- ☐ Provide DMID with a written Sanitation Standard Operating Procedures Plan (SSOP's). [9CFR416.11- 17](#).

Procedures must include both Pre-operation and Operation Sanitation Procedures, monitoring frequencies, and recordkeeping forms.

HACCP Plan (Hazard Analysis of Critical Control Points)

- ☐ Refer to [Basic Facts about SSOP's and HACCP Plans for Meat Processors](#).
- ☐ Hazard Analysis to identify potential hazards.
- ☐ Flowchart of process.
- ☐ HACCP Plan.

- ☐ Determine Critical Control Points.
- ☐ Supporting Documentation for the decisions.
- ☐ Record Keeping Documents for monitoring of Critical Control Points.
- ☐ An individual at the establishment must successfully complete training in Meat HACCP ([9 CFR 417.7](#)).

Other SOP's Referenced in HACCP Plan or SSOP's

- ☐ Receiving procedures.
- ☐ Product handling procedures.
- ☐ Allergen control procedures where applicable when producing multi-ingredient products.

Listeria Control Plan: (required for all firms preparing Ready-To-Eat products)

- ☐ Written plan as described in [9 CFR 430.4](#) Control of Listeria.

Recall Plan

- ☐ Written plan as described in [9 CFR 418.3](#).

Traffic Control Procedures / Protocol

- ☐ Map the traffic patterns of the facility to look for cross contamination potential.

Thermometer Calibration procedures

- ☐ Written plan as described in 9CFR [417.2](#) and [417.4](#).

Marking and Labeling

- ☐ Review accuracy of labels and ingredient statements. Labels must be approved prior to use by MN DMID.
- ☐ Provide copies of all sub-ingredient labels when submitting multi-ingredient labels for review.
Product labels must include:
 - Name of product
 - Net weight
 - Ingredient statement
 - Manufacturer's name and address
 - Safe handling statement (if applicable)
 - Keep refrigerated or keep frozen statement.
- ☐ State Inspected carcasses and product must be marked with the inspection legend.

Sewage and Waste Disposal

- ☐ Sewage and waste disposal systems must properly remove sewage and waste materials – manure, feces, feathers, paunch, trash, garbage, and paper – from the establishment.
- ☐ Systems must be approved prior to operation by local authorities.

Pest Control

- ☐ The establishment's pest control operation must be capable of preventing product adulteration. Establishment management must make every effort to prevent entry of rodents, insects, or animals into areas where products are handled, processed, or stored. Openings (doors and windows) leading to outside or to inedible areas must have effective closures and completely fill the opening. Areas inside and outside the establishment must be maintained to prevent harborage of rodents and insects.

Inedible Material Control

- ☐ The inedible material control program must prevent the diversion of inedible animal products into human food channels.
- ☐ Containers supplied by a rendering company may not be relabeled and used as edible food handling containers.

PROCEDURES REQUIRED FOR SLAUGHTER FACILITIES

Generic E coli Testing (State E2 inspected facilities only)

- ☐ Written plan as described in [9 CFR 310.25](#) or [381.94](#).

Control of SRM's / BSE in Cattle > 30 Months of Age

- ☐ Written plan as described in [9 CFR 310.22](#).
- ☐ Recordkeeping forms to document ages of cattle and removal/disposal of SRMs.

REQUIREMENTS FOR STATE CONTINUOUS INSPECTION "EQUAL TO" FACILITIES

All requirements previously listed are also necessary for the "Equal To" facilities, in addition there are some specific requirements mandatory to the program.

- ☐ Slaughter facilities – inspection equipment for postmortem inspection – this equipment is determined on a case-by-case basis but may include:
 - Gut buggy
 - Inspection table
 - Head rack

- ☐ Office space for the inspector – at minimum one drawer of a file cabinet that a state provided lock will be added. Program information will be stored on site.
- ☐ Maintain up-to-date knowledge of new and existing regulations.
- ☐ An initial facility inspection will be conducted to determine if the facility meets basic requirements. A written report will be issued with deficiencies that need to be corrected.

"Equal To" or State Continuous Inspection Requirements Checklist 3

FOR ADDITIONAL INFORMATION CONTACT THE MDA

- Contact DMID at 651-201-6300
- For a Retail Exempt Only facility contact Food and Feed Safety Division at 651-201-6027
- Email: MDA.MeatPoultryEgg@state.mn.us
- Address: 625 Robert Street North, Saint Paul, MN 55155-2538

In accordance with the Americans with Disabilities Act, this information is available in alternative forms of communication upon request by calling 651-201-6000. TTY users can call the Minnesota Relay Service at 711. The MDA is an equal opportunity employer and provider.

"Equal To" or State Continuous Inspection Requirements Checklist 4

APPENDIX B: Application for State Meat, Poultry Inspection



625 Robert Street North, St. Paul, MN 55155-2538
www.mda.state.mn.us

Dairy and Meat Inspection Division Phone: 651-201-6300

APPLICATION FOR STATE MEAT, POULTRY INSPECTION

Date of Application _____ Type of Product: ☐ Meat ☐ Poultry ☐ Both

Type of Grant/Types of Animals

- ☐ Slaughtering
☐ Cattle ☐ Calves ☐ Sheep ☐ Goats
☐ Swine ☐ Chickens ☐ Turkeys ☐ Waterfowl
☐ Voluntary: _____ (include species)

Type of Grant/Types of Animals

- ☐ Processing
☐ Cattle ☐ Calves ☐ Sheep ☐ Goats
☐ Swine ☐ Chickens ☐ Turkeys ☐ Waterfowl
☐ Voluntary: _____ (include species)

Type of Application (Check all that apply)

- ☐ New ☐ Change of Location ☐ Change of Ownership ☐ Other, Specify _____

Current Establishment Number _____

Form of Organization

- ☐ Individual ☐ Cooperative Association ☐ Partnership ☐ Corporation ☐ Educational Institution
☐ Limited Liability Corp (LLC) ☐ Other

If a Corporation Name of State or Territory Where Incorporated _____ Date Incorporated _____

Name of Applicant _____

Business Name and Plant Location (full address) _____

Mailing Address if Different from Location Address _____

Establishment Phone _____ Establishment Fax _____ Establishment Email _____

Other Names – DBA _____

Describe the Scope of the Operation

Exemptions

- ☐ Custom Processing
☐ Custom Slaughter
☐ Retail Activities
☐ Halal Slaughter
☐ Kosher Slaughter

Voluntary Operations

- ☐ Slaughter
☐ Processing

HACCP Categories

- ☐ Fully Cooked – Not Shelf Stable
☐ Heat Treated Not Fully Cooked – Not Shelf Stable
☐ Heat Treated – Shelf Stable
☐ Not Heat Treated – Shelf Stable
☐ Product with Secondary Inhibitors – Not Shelf Stable
☐ Raw – Intact Products
☐ Raw – Non Intact Products
☐ Thermally Processed Commercially Sterile
☐ Slaughter

Types of Product

- ☐ Breaking/Cutting
☐ Boning
☐ Mechanical Deboning
☐ Fabricating
☐ Grinding
☐ Formulating
☐ Curing
☐ Smoking
☐ Cooking
☐ Canning
☐ Drying
☐ Slicing
☐ Convenience Items
☐ Other _____

Days/Hours of Operation

(list hours by corresponding days of operation)

Days	Processing	Slaughter
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		

In accordance with the Americans with Disabilities Act, this information is available in alternative forms of communication upon request by calling 651-201-6000. TTY users can call the Minnesota Relay Service at 711. The MDA is an equal opportunity employer and provider.

AG01341
2/23 Page 1 of 3

APPENDIX B: Application for State Meat, Poultry Inspection *(continued)*

Establishment Layout

If requested by MDA, please provide a diagram, schematic or copy of the blue print for the establishment premises that is requesting Minnesota E2 Inspection, specify type of document: _____

List all persons responsibly connected with the applicant. Include all owners, partners, officers, directors, holders or owners of 10 per centum or more of voting stock, and employees in a managerial or executive capacity in the business. Notify the Area Supervisor of any changes in the listings given.

Name/ Title	Date of Birth	Email Address	Cell Phone Number	Present Home Address (Number, Street, City, State, Zip)	Holder of 10% or More of Voting Stock (if Corp.)

In the box below enter the name of each person listed above who has been convicted in any Federal or State court of:

- any felony.
- more than one violation of any law (other than a felony) based upon the acquiring, handling, or distribution of unwholesome, mislabeled, or deceptively packaged food or upon fraud in connection with transactions in food.

Include the nature of the crime, the date of the conviction and the court in which convicted. If none have been convicted, write "None".

AGREEMENT AND CERTIFICATION: If inspection is granted under the application I (we) expressly agree to conform strictly to the Federal Meat Inspection Act 21 U.S.C. 601 et seq.), the Regulations Governing the Meat Inspection of the United States Department of Agriculture (9CFR Part 301 et seq.) or the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Poultry Products Inspection Regulations (9 CFR 381 et seq.), or both. I CERTIFY that all statements made herein are true to the best of my knowledge and belief. WARNING: Persons willfully making false, fictitious or fraudulent statements or entries are subject to \$10,000 fine or imprisoned not more than five years or both as prescribed by Title 18 U.S. Code 1001.

Signature and Title of Owner, Partner, or Authorized Officer Making this Application

Signature _____ Title _____

Print Name of Person Signing Application _____

In accordance with the Americans with Disabilities Act, this information is available in alternative forms of communication upon request by calling 651-201-6000. TTY users can call the Minnesota Relay Service at 711. The MDA is an equal opportunity employer and provider.

AG01341
2/23 Page 2 of 3

APPENDIX B: Application for State Meat, Poultry Inspection *(continued)*

For Office Use Only – To be Completed by the Minnesota Department of Agriculture (MDA)

Date Establishment will be ready to start service _____ Inspector Assigned _____

Establishment Number Assigned _____

	Yes	No	NA	Initials/Date
HACCP Plan meets basic requirements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Written SSOP meets basic requirements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Facility and SPS meets basic requirements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Written Recall Plan meets basic requirements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Written Food Defense meets basic requirements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
E. coli Testing Procedures meet basic requirements (slaughter only)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Listeria Control Plan meets basic requirements (RTE only)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Labels meet basic requirements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Religious slaughter exemption and supporting letters on file	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Date Received _____	Date Reviewed _____	Signature of Supervisor _____
This plant to be under Talmadge-Aiken Act: Yes <input type="checkbox"/> No <input type="checkbox"/>		Signature of Director _____ Date _____

In accordance with the Americans with Disabilities Act, this information is available in alternative forms of communication upon request by calling 651-201-6000. TTY users can call the Minnesota Relay Service at 711. The MDA is an equal opportunity employer and provider.

AG01341
2/23 Page 3 of 3

APPENDIX C

The following is found online at www.ecfr.gov/current/title-9

§ 416—Sanitation

§ 416.1 *General rules.*

Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.

§ 416.2 *Establishment grounds and facilities.*

- (a) Grounds and pest control. The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.
- (b) Construction. (1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.
- (2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.
- (3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.
- (4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.
- (c) Light. Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained, and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.
- (d) Ventilation. Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.
- (e) Plumbing. Plumbing systems must be installed and maintained to:
- (1) Carry sufficient quantities of water to required locations throughout the establishment;
- (2) Properly convey sewage and liquid disposable waste from the establishment;
- (3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;
- (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor;
- (5) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing; and
- (6) Prevent the backup of sewer gases.
- (f) Sewage disposal. Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.

(g) Water supply and water, ice, and solution reuse. (1) A supply of running water that complies with the National Primary Drinking Water regulations ([40 CFR part 141](#)), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.

(2) Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.

(3) Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on ready-to-eat product.

(4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in [paragraph \(g\)\(1\)](#) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in [paragraph \(g\)\(1\)](#) of this section.

(5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.

(6) Water that does not meet the use conditions of [paragraphs \(g\)\(1\)](#) through [\(g\)\(5\)](#) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.

(h) Dressing rooms, lavatories, and toilets. (1) Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.

(2) Lavatories with running hot and cold water, soap, and towels, must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.

(3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

§ 416.3 Equipment and utensils.

(a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.

(b) Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.

(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

§ 416.4 Sanitary operations.

- (a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.
- (b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.
- (c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review.
- (d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

§ 416.5 Employee hygiene.

- (a) Cleanliness. All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.
- (b) Clothing. Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.
- (c) Disease control. Any person who has or appears to have an infectious disease, open lesion, 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.

§ 416.6 Tagging insanitary equipment, utensils, rooms or compartments.

When an FSIS program employee finds that any equipment, utensil, room, or compartment at an official establishment is insanitary or that its use could cause the adulteration of product, he will attach to it a "U.S. Rejected" tag. Equipment, utensils, rooms, or compartments so tagged cannot be used until made acceptable. Only an FSIS program employee may remove a "U.S. Rejected" tag.

§ 416.11 General rules.

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

§ 416.12 Development of Sanitation SOP's.

- (a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).
- (b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.
- (c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.
- (d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

§ 416.13 Implementation of SOP's.

- (a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.

(b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.

(c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's.

§ 416.14 Maintenance of Sanitation SOP's.

Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

§ 416.15 Corrective Actions.

(a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s).

(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

§ 416.16 Recordkeeping requirements.

(a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

§ 416.17 Agency verification.

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

(a) Reviewing the Sanitation SOP's;

(b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;

(c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and

(d) Direct observation or testing to assess the sanitary conditions in the establishment.

§ 417—Hazard Analysis and Critical Control Point (HACCP) Systems

§ 417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System. The HACCP plan in operation, including the HACCP plan itself.

Hazard. SEE Food Safety Hazard.

Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official. The individual with overall authority on-site or a higher level official of the establishment.

§ 417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis.

(1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

(3) Food safety hazards might be expected to arise from the following:

- (i) Natural toxins;
- (ii) Microbiological contamination;
- (iii) Chemical contamination;
- (iv) Pesticides;
- (v) Drug residues;
- (vi) Zoonotic diseases;
- (vii) Decomposition;
- (viii) Parasites;
- (ix) Unapproved use of direct or indirect food or color additives; and
- (x) Physical hazards.

(b) The HACCP plan.

(1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with [paragraph \(a\)](#) of this section, including products in the following processing categories:

- (i) Slaughter—all species.
- (ii) Raw product—ground.
- (iii) Raw product—not ground.
- (iv) Thermally processed—commercially sterile.
- (v) Not heat treated—shelf stable.
- (vi) Heat treated—shelf stable.

- (vii) Fully cooked—not shelf stable.
- (viii) Heat treated but not fully cooked—not shelf stable.
- (ix) Product with secondary inhibitors—not shelf stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in [paragraph \(c\)](#) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of [part 431 of this chapter](#).

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

- (1) List the food safety hazards identified in accordance with [paragraph \(a\)](#) of this section, which must be controlled for each process.
- (2) List the critical control points for each of the identified food safety hazards, including, as appropriate:
 - (i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and
 - (ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;
- (3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;
- (4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;
- (5) Include all corrective actions that have been developed in accordance with [§ 417.3\(a\) of this part](#), to be followed in response to any deviation from a critical limit at a critical control point; and
- (6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.
- (7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with [§ 417.4 of this part](#).

(d) Signing and dating the HACCP plan.

- (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.
- (2) The HACCP plan shall be dated and signed:
 - (i) Upon initial acceptance;
 - (ii) Upon any modification; and
 - (iii) At least annually, upon reassessment, as required under [§ 417.4\(a\)\(3\) of this part](#).

(e) Pursuant to [21 U.S.C. 456](#), [463](#), [608](#), and [621](#), the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

[§ 417.3 Corrective Actions.](#)

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

- (1) The cause of the deviation is identified and eliminated;

- (2) The CCP will be under control after the corrective action is taken;
 - (3) Measures to prevent recurrence are established; and
 - (4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.
- (b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:
- (1) Segregate and hold the affected product, at least until the requirements of [paragraphs \(b\)\(2\) and \(b\)\(3\)](#) of this section are met;
 - (2) Perform a review to determine the acceptability of the affected product for distribution;
 - (3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;
 - (4) Perform or obtain reassessment by an individual trained in accordance with [§ 417.7 of this part](#), to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.
- (c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with [§ 417.4\(a\)\(2\)\(iii\)](#) and the recordkeeping requirements of [§ 417.5 of this part](#).

[§ 417.4 Validation, Verification, Reassessment.](#)

- (a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.
- (1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.
 - (2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:
 - (i) The calibration of process-monitoring instruments;
 - (ii) Direct observations of monitoring activities and corrective actions; and
 - (iii) The review of records generated and maintained in accordance with [§ 417.5\(a\)\(3\)](#) of this part.
 - (3) (i) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with [§ 417.7 of this part](#). The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of [§ 417.2\(c\) of this part](#).
 - (ii) Each establishment must make a record of each reassessment required by [paragraph \(a\)\(3\)\(i\)](#) of this section and must document the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment. For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination.
- (b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

§ 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

- (1) The written hazard analysis prescribed in [§ 417.2\(a\) of this part](#), including all supporting documentation;
- (2) The written HACCP plan, including decision making documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.
- (3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.
- (b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.
- (c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.
- (d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) Record retention.

- (1) Establishments shall retain all records required by [paragraph \(a\)\(3\)](#) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.
- (2) Off-site storage of records required by [paragraph \(a\)\(3\)](#) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.
- (f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

§ 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

- (a) The HACCP plan in operation does not meet the requirements set forth in this part;
- (b) Establishment personnel are not performing tasks specified in the HACCP plan;
- (c) The establishment fails to take corrective actions, as required by [§ 417.3 of this part](#);
- (d) HACCP records are not being maintained as required in [§ 417.5 of this part](#); or
- (e) Adulterated product is produced or shipped.

§ 417.7 Training.

(a) Only an individual who has met the requirements of [paragraph \(b\)](#) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

- (1) Development of the HACCP plan, in accordance with [§ 417.2\(b\) of this part](#), which could include adapting a generic model that is appropriate for the specific product; and
- (2) Reassessment and modification of the HACCP plan, in accordance with [§ 417.3 of this part](#).

(b) The individual performing the functions listed in [paragraph \(a\)](#) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat, poultry, or egg products processing, including a segment on the development of a HACCP plan for a specific product and on record review.

§ 417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

- (a) Reviewing the HACCP plan;
- (b) Reviewing the CCP records;
- (c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;
- (d) Reviewing the critical limits;
- (e) Reviewing other records pertaining to the HACCP plan or system;
- (f) Direct observation or measurement at a CCP;
- (g) Sample collection and analysis to determine the product meets all safety standards; and
- (h) On-site observations and record review.

§ 418 Recalls

§ 418.2 Notification.

Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or originating from the official establishment has entered commerce, if the official establishment believes or has reason to believe that this has happened. The official establishment must inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product.

§ 418.3 Preparation and maintenance of written recall procedures.

Each official establishment must prepare and maintain written procedures for the recall of any meat, meat food, poultry, or poultry product produced and shipped by the official establishment. These written procedures must specify how the official establishment will decide whether to conduct a product recall, and how the establishment will affect the recall, should it decide that one is necessary.

§ 418.4 Records.

All records, including records documenting procedures required by this part, must be available for official review and copying.

§430—Requirements for specific classes of product

§ 430.1 Definitions.

Antimicrobial agent. A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial process. An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes*, in the product throughout the shelf life of the product.

Deli product. A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.

Hotdog product. A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in [9 CFR 319.180](#) and [319.181](#).

Lethality treatment. A process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples

of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Post-lethality exposed product. Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

Post-lethality processing environment. The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment. A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Prerequisite program. A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called “prerequisite” because it is considered by scientific experts to be prerequisite to a HACCP plan.

Ready-to-eat (RTE) product. A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by [9 CFR 317.2\(i\)](#) and [381.125\(b\)](#)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

§ 430.4 Control of *Listeria monocytogenes* in post-lethality exposed ready-to-eat products.

(a) *Listeria monocytogenes* can contaminate RTE products that are exposed to the environment after they have undergone a lethality treatment. *L. monocytogenes* is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. RTE product is adulterated if it contains *L. monocytogenes*, or if it comes into direct contact with a food contact surface that is contaminated with *L. monocytogenes*. Establishments must not release into commerce product that contains *L. monocytogenes* or that has been in contact with a food contact surface contaminated with *L. monocytogenes* without first reworking the product using a process that is destructive of *L. monocytogenes*.

(b) In order to maintain the sanitary conditions necessary to meet this requirement, an establishment producing post-lethality exposed RTE product must comply with the requirements included in one of the three following alternatives:

(1) Alternative 1. Use of a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product and an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*. If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment’s HACCP plan. The antimicrobial agent or process used to suppress or limit the growth of the pathogen must be included in either the establishment’s HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of the post-lethality treatment incorporated in its HACCP plan in accordance with [§ 417.4](#). The establishment must document, either in its HACCP plan or in its Sanitation SOP or other prerequisite program, that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*.

(2) Alternative 2. Use of either a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product or an antimicrobial agent or process that suppresses or limits growth of *L. monocytogenes*. If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment’s HACCP plan. The antimicrobial agent or process used to suppress or limit growth of the pathogen must be included in either the establishment’s HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of a post-lethality treatment incorporated in its HACCP plan in accordance with [§ 417.4](#). The establishment must document in its HACCP plan or in its Sanitation SOP or other prerequisite

program that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*.

(iii) If an establishment chooses this alternative and chooses to use only an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(iv) An establishment that chooses this alternative and uses a post-lethality treatment of product will likely be subject to more frequent verification testing by FSIS than if it had chosen Alternative 1. An establishment that chooses this alternative and uses an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes* will likely be subject to more frequent FSIS verification testing than if it uses a post-lethality treatment.

(3) Alternative 3. Use of sanitation measures only.

(i) If an establishment chooses this alternative, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(ii) An establishment producing a deli product or a hotdog product, in addition to meeting the requirements of [paragraph \(b\)\(3\)\(i\)](#) of this section, must meet the following requirements:

(A) The establishment must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for *L. monocytogenes* or an indicator organism on a food contact surface in the post-lethality processing environment are effective by conducting follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and such additional tests in the surrounding food contact surface area as are necessary to ensure the effectiveness of the corrective actions.

(B) During this follow-up testing, if the establishment obtains a second positive test for an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result.

(C) In order to release into commerce product held under this section, the establishment must sample and test the lots for *L. monocytogenes* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes*. The establishment must document the results of this testing. Alternatively, the establishment may rework the held product using a process that is destructive of *L. monocytogenes* or the indicator organism.

(iii) An establishment that chooses Alternative 3 is likely to be subject to more frequent verification testing by FSIS than an establishment that has chosen Alternative 1 or 2. An establishment that chooses Alternative 3 and that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products.

(c) For all three alternatives in paragraph (b):

(1) Establishments may use verification testing that includes tests for *L. monocytogenes* or an indicator organism, such as *Listeria* species, to verify the effectiveness of their sanitation procedures in the post-lethality processing environment.

(2) Sanitation measures for controlling *L. monocytogenes* and procedures for antimicrobial agents or processes that suppress or limit the growth of the pathogen may be incorporated either in the establishment's HACCP plan or in its Sanitation SOP or other prerequisite program. When these control procedures are incorporated into the Sanitation SOP or prerequisite program, and not as a CCP in the HACCP plan, the establishment must have documentation that supports the decision in its hazard analysis that *L. monocytogenes* is not a hazard that is reasonably likely to occur.

(3) The establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416.

(4) If *L. monocytogenes* control measures are included in the HACCP plan, the establishment must validate and verify the effectiveness of measures for controlling *L. monocytogenes* included in its HACCP plan in accordance with [§ 417.4](#).

(5) If *L. monocytogenes* control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with [§ 416.14](#).

(6) If the measures for addressing *L. monocytogenes* are addressed in a prerequisite program other than the Sanitation SOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under [9 CFR 417.5](#).

(7) The establishment must make the verification results that demonstrate the effectiveness of the measures it employs, whether under its HACCP plan or its Sanitation SOP or other prerequisite program, available upon request to FSIS inspection personnel.

(d) [Reserved]

(e) An establishment that controls *L. monocytogenes* by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.

Starting a Minnesota 'Equal To' Meat Establishment

