

Starting a Minnesota Custom Exempt Meat Plant



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1. INTRODUCTION



This manual provides basic information and general guidance for individuals interested in starting a custom exempt 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 to succeed.

Terms

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\(a\)\(2\)](#); [Minnesota Statutes Chapter 31A.02, Subdivision 5](#); [31A.10](#); [31A.15, Subdivision 1](#))

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. ([Minnesota Statutes Chapter 28A](#))

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. ([Minnesota Statutes Chapter 28A.04, Subdivision 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. ([Minnesota Statutes Chapter 28A.04, Subdivision 2](#))

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 custom exempt plants must meet. ([9 C.F.R. Part 416](#))

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 has an ante-mortem and post-mortem inspection. Animals that pass inspection can be processed for wholesale and retail sale, but only within Minnesota. ([Minnesota Statutes Chapter 31A](#))

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. ([Minnesota Statutes Chapter 34A.01, Subdivision 12](#))

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.

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 conducted for plants and food facilities with retail operations.

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.

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. ([Minnesota Statutes Chapter 31A.02, Subdivision 24](#))

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 products which contain meat or poultry only in a relatively small proportion or products that traditionally have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product or poultry food product by the commissioner. ([Minnesota Statutes Chapter 31A.02, Subdivision 10](#))

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.

Carcass

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

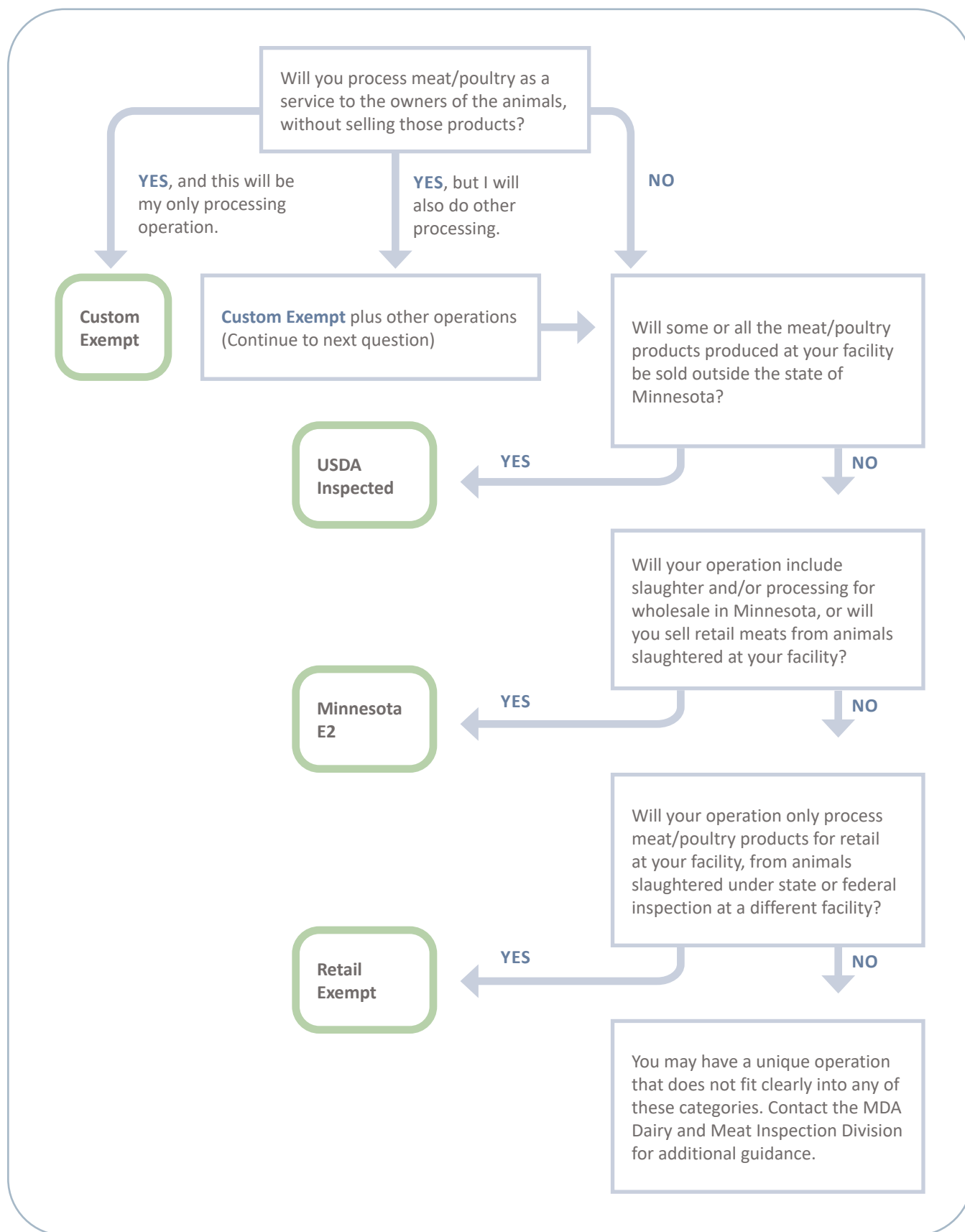
Options for Meat & Poultry Processing in Minnesota

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

Options for Meat & Poultry Processing in Minnesota	
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.

If you're not sure whether your plans fit within custom exempt or some other type of processing operation, use the decision tree below to verify. Follow the arrows that correspond with your answers to each question.



As a custom exempt processor, you will be able to slaughter and process meat, poultry, and wild game as a service for the owners of those animals; however, these products cannot be sold. Processors who wish to sell their products or process meat or poultry to allow the owners to sell those products will need a grant of inspection from either the MDA (for E2 status, to sell within Minnesota) or the USDA (to sell across state lines). Processors can also have retail exempt operations, which involves the sale of Minnesota E2 or USDA inspected meat from a retail storefront.

Custom exempt operations can vary widely by scale and activity. Some processors produce only raw cuts and ground product, while others further season, cure, or smoke products. Some custom exempt facilities are set up for receiving and holding livestock on site, while others conduct on-farm slaughter at the premises of the owner of the animal and bring the carcass back to the plant for additional processing. Live animal markets are another form of custom exempt model. In these operations, customers can purchase a live animal at the market and then have their animal processed on site. Some facilities choose to process wild game, either solely or in addition to other meat or poultry products.

As you plan your custom exempt operation, consider both your start-up and long-term business goals and market opportunities. General sanitation, facility, equipment, and documentation standards are similar for all meat and poultry licensed and permitted operations, but there may be additional considerations for E2 or USDA processors that do not apply to custom exempt processors. Retail exempt operations come with additional requirements based on the Minnesota Food Code. If your goal is to someday sell products, you will want to keep this in mind.

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/

2. 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 custom exempt 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 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. Custom exempt 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.

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 require substantial upgrades which may or may not be feasible. 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 More than One Type of Operation

Some custom exempt 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 the retail rules and requirements and how they are applied in conjunction with a 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 Minnesota E2 inspection or USDA inspection to your operation, you should also consult the appropriate inspection staff prior to purchasing an existing facility. For Minnesota E2 operations, this inspector will be the same inspector you consult for your custom exempt operations. If you desire to become a USDA-inspected processor, you must work directly with the USDA's regional office. 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 separation of products.

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 more 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 Minnesota Pollution Control Agency (MPCA) rules. Typically, any business would be required to have an approved septic system separate from any home on the same property and built to commercial standards.

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

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 your project. These include the USDA [Business and Industry Loan Guarantee Program](#) through the office of [Minnesota USDA Rural Development](#) and the MDA [Agricultural Growth, Research, and Innovation \(AGRI\) Program](#). For more information on the AGRI Program, contact the MDA Agricultural Marketing and Development Division at 651-201-6500.

Additional Considerations

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 needed for any employees you plan to hire.

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.

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

3. FACILITIES, EQUIPMENT, AND SANITATION



Custom exempt 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 custom exempt plants can meet the requirements.

Each processing environment is unique, and while the information presented in this section should be generally applicable to all processing 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 C.F.R. Part 416.1](#)

Each plant is responsible for providing a clean and sanitary environment to produce safe food. This applies even in situations not specifically addressed by the requirements described below.

Establishment Grounds and Facilities, [9 C.F.R. Part 416.2](#)

Grounds and pest control, Part 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 and storing them in a manner that does not contaminate product
- 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, Part 416.2(b)

The requirements for construction of buildings and rooms are general, 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.

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



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.



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 custom exempt activities, you may use any materials that are durable and impervious to moisture as long as 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, Part 416.2(c)

Lighting in the facility must be of good quality and of sufficient intensity to ensure that sanitary conditions can be maintained. This applies in areas such as:

- Where food is processed, handled, stored, or examined
- Where equipment and utensils are cleaned
- Handwashing stations, dressing and locker rooms, and toilets

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.



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

Ventilation, Part 416.2(d)

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.

Plumbing, Part 416.2(e)

Plumbing systems must be installed and maintained to:

- Carry enough water to required locations throughout the plant
- Properly remove sewage and liquid disposable waste from the establishment
- Prevent adulteration of product, water supplies, equipment, or utensils
- Provide adequate floor drainage in all areas
- Prevent back flow and cross-connections between piping systems that discharge wastewater or sewage and other water sources
- Prevent the back up of sewer gases

The custom exempt meat 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, 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.

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.

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.

Sewage disposal, Part 416.2(f)

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

- Sewage must be disposed into a sewage 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

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 supply and water reuse, Part 416.2(g)

Custom exempt processors must have a readily available supply of water that complies with [National Primary Drinking Water Regulations](#). This is often termed “potable water” and means that the water supply is safe to drink according to our national water standards. In addition to product records, plants must maintain certain water records. A water report issued under the authority of the state or local health agency which certifies that the water supply is potable must be made available upon request. Private wells must be tested at least semi-annually. The water supply must also be:

- At a suitable temperature (hot enough when hot water is required)
- Under sufficient pressure to complete cleaning and other necessary tasks
- Available in all areas where water is necessary, such as slaughter or processing rooms, cleaning areas, employee sanitary facilities or other locations
- Of adequate supply to accomplish the necessary tasks

Some meat processors reuse water, ice, and solutions. While this is generally allowed, this water must meet all safety requirements and special care should be taken to ensure water, ice, and solutions are only reused for their same purpose (e.g., raw product to raw product, ice to pack whole birds and parts for multiple batches). Processors must ensure the water, ice, or solutions are free of pathogens and do not contaminate products. More information on specific requirements can be found in the USDA Food Safety and Inspection Service (FSIS) [Guidance for Water, Ice, and Solution Reuse](#).

Equipment and Utensils, [9 C.F.R. Part 416.3](#)

Materials and construction

Maintaining and cleaning the equipment and utensils used in a meat processing plant is an important part of maintaining a clean and sanitary processing environment. The requirements for meat processing equipment and utensils do not specify the use of certain materials. However, this equipment must be made of materials and constructed in a way that allows for it to be cleaned to ensure that its use will not cause the adulteration of product during processing, handling, and storage. It is also important to ensure materials are durable and well-constructed for frequent use in a meat processing environment which can be harsh and have extreme temperatures.

Equipment and utensils must also be constructed and located in a place where inspection can be done; this is most often an issue for equipment that has compartments or closed off areas for motors. These areas can easily become contaminated with bits of meat and food and become a harborage for food safety pathogens.

Inedible receptacles

Containers for storing inedible materials must be of sound construction, sufficient to ensure that their use will not result in any adulteration of edible products or create insanitary conditions in the plant. These containers must also:

- Be used **only** for storing inedibles
- Have conspicuous and distinctive markings to clearly identify their purpose

Management of inedible containers is an important part of keeping a meat plant sanitary and clean. Containers must be well managed so that they don’t contaminate the environment.

For example, an inedible barrel cannot have a leak that causes blood and other fluids to run out the bottom and contaminate the floor, especially in an area where edible product is handled.

Sanitary Operations, [9 C.F.R. Part 416.4](#)

Proper cleaning and sanitation of your facilities and equipment is a critical part of producing safe products. Sanitation includes cleaning of both food contact and non-food contact surfaces as frequently as necessary to keep your facility and equipment clean. Sometimes this can be difficult to determine during operations; however, all surfaces must be cleaned prior to operations and maintained at an acceptable level of cleanliness during operations.

Cleaning compounds, sanitizing agents, processing aids, and other chemicals must be used, handled, and stored in such a manner that will not cause product adulteration. Critical to this process is maintaining documentation on the safety of the chemical's use in a processing environment and ensuring chemicals are in their original labeled containers (or are linked to containers with labels).

Most importantly, all products must be protected from adulteration or contamination during all phases of processing, handling, storage, loading and unloading, and during transportation while in the plant's control. This requirement is very broad and must be considered in many aspects of a plant's operations.

Employee Hygiene, [9 C.F.R. Part 416.5](#)

People can also become a point of contamination; hygiene and cleanliness practices are therefore key to ensuring products are produced safely. Similar to other requirements, these standards are broad and can apply to many parts of an operation. Key components include:

- All persons working with product, product packaging materials, and food-contact surfaces must adhere to hygienic practices (including proper handwashing).
- Aprons, frocks, and other outer clothing must be clean at the start of the day and changed throughout the day as often as necessary to prevent contamination or adulteration of product.
- Any person who has an infectious disease, open lesion, or harbors another source of microbial contamination cannot handle products or participate in any activities that may result in product contamination until their condition is resolved.

Maintaining employee illness logs is a common practice for meat and food processors. Plant management should ensure practices adjust for times when employees cannot handle products due to illnesses or other hygiene issues. More information on employee illness protocols can be found in Section 7: Handling Adverse Events.

Resources and References

- 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: <https://www.fsis.usda.gov/guidelines/2005-0005>

4. OTHER REGULATORY REQUIREMENTS



In addition to facility and sanitation requirements, custom exempt operators must meet other requirements related to the following areas:

- Recordkeeping
- Product Labeling
- Product Separation
- Product Storage and Distribution
- Inedibles Handling

These requirements are important parts of ensuring the products you handle are safe, traceable to their owners, and separated from other types of operations that you may conduct.

Recordkeeping

Slaughter records

Custom exempt operators must maintain certain records according to [9 C.F.R. Part 303.1\(b\)\(3\)](#). These records must include:

- The numbers and kinds of livestock slaughtered on a custom basis
- The quantity and types of products prepared (processed) on a custom basis
- The names and addresses of the owners of the livestock and products.

Records may be kept in hard copy or digital form as long as they can be accessed by inspection personnel for routine reviews. Such records must be maintained onsite, generally for a period of 2 years after December 31 of the year in which the record was made ([9 C.F.R. Part 320.2](#)). To assist you in keeping complete slaughter records, use the MDA Custom Slaughter Record Booklet to document all the necessary components. This record booklet is free and available upon request.

Record of Livestock Slaughtered or Processed								
B = Bull, S = Steer, Sx = Steer Calf, C = Cow, H = Heifer, Hx = Heifer Calf								
Date Slaughtered			If this animal was sold live by direct mkting, list farmer's name/address/phone	FARM SLTR	PLANT SLTR	BEEF AGE	SEX	AMBU- LATORY
MON	DAY	YEAR						

Species	Owner	Date Processed		
Hog, Beef, Sheep, Etc.	Name, Address, Phone	MON	DAY	YEAR

Cooking records

Cooking records must also be maintained for any custom exempt products that are smoked/cooked at the facility to ensure all products are cooked to the temperatures necessary to kill bacteria (lethality temperature) that can cause foodborne illness. These records should include, but are not limited to:

- Product type (e.g. summer sausage)
- Date cooked/smoked
- Internal temperature the product reached
- Holding times at the peak temperature, if using a time/temperature hold time for lethality

The [USDA FSIS Appendix A/Salmonella Compliance Guideline](#) provides guidance on appropriate cooking temperatures and holding times for a given product.

Cooking & Smoking Log					
Critical Limit: Minimum internal product temperature of 158°F for fully cooked products or time temperature combination as cited in FSIS Appendix A Guidelines: 145°F for 4 minutes/150°F for 72 seconds/155°F for 23 seconds					
Date	Product/Batch ID	Total lot weight (lbs)	CCP 1B		
			Cook Temp	Time	Monitor's initials

Water records

For information on water records, refer to Water Supply and Reuse in Section 3: Facilities, Equipment, and Sanitation.

Product Labeling

All custom exempt products must be labeled “NOT FOR SALE” throughout all stages of processing, up to and including delivery to the owner of the product. Each package or container must be labeled.

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 ready-to-eat products
- Separating custom exempt products from other types of products, such as 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.

Products may be separated by time and/or space. Custom exempt slaughter and processing operational times must be separate from those times you are handling other types of product, such as retail or E2, 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, and 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

Custom exempt slaughter and processing occurs on Mondays and Tuesdays. E2 slaughter and processing occurs on Wednesdays and Thursdays. On Fridays, E2 or other fully inspected products are processed in the first part of the day while custom exempt products are only processed after E2 processing is complete.



Packaged venison sausages are clearly labeled “NOT FOR SALE,” in accordance with labeling requirements for custom exempt processed products.

Separation by Space



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

Ideally, plants should have adequate storage capacity to be able to accommodate physical separation of custom exempt and retail 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 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

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

- When receiving farm slaughtered livestock carcasses or parts (such as hams, bellies, etc.), processors notify customers of the expectation that carcasses are clean and free from visible contamination (feces, ingesta, dirt, etc.).
- 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/compartment 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.

Storage and handling temperatures

Bacteria grow most rapidly at temperatures of 41-135 degrees Fahrenheit (F); therefore, coolers should be maintained below 41 degrees F. Targeting 35 degrees F or less can increase shelf life and product quality. [Meat starts to freeze at 26-28 degrees F](#) but is traditionally considered to be frozen when the core temperature reaches 0 degrees F. Thus, freezers should be kept below 0 degrees F. This provides the best barrier against pathogen growth and maximizes shelf life.

Maintaining product temperatures below pathogen growth levels (<41 degrees F) during transport and distribution is also important. Ideally, this is done with mechanical refrigeration, but it can also be achieved by using coolers to transport products from the plant. Shipping frozen meat versus refrigerated meat can provide better protection. Limiting the exposure to ambient temperatures during storage will increase shelf life and limit pathogen growth.

Handling Inedibles

Inedibles are meat products or biproducts that are not fit or suitable for human consumption. This typically includes bones, hides, heads, viscera/guts, or other offal from slaughter, as well as fatty trim or parts thrown away and not wanted by the owner of the animal. Products that are adulterated or unwholesome may also end up in inedible barrels/containers. Receptacles used for storing inedible materials must be maintained in a clean and sanitary manner when used in a plant and can never be used for the storage of edible products. Inedible containers must be labeled conspicuously and distinctively.

Inedible materials must be denatured (or rendered distinguishable from human food) by use of approved methods.

Acceptable denaturants include:

- The synthetic dyes FD&C green No. 3 coloring, FD&C blue No. 1 coloring, and FD&C blue No. 2 coloring
- Finely powdered charcoal
- Bleach or soap
- Sawdust or ashes from smokehouses
- Other material that will give a distinct color, odor, or smell to distinguish from human food

There are several options for disposal of inedibles. Approved options for disposal of inedibles may vary by your location and the species of animal you are handling. These may include:

- Rendering
- Composting
- Landfill
- Burial
- Incineration

Rendering is most commonly used by meat processors as there are multiple companies within the state that provide this type of service to meat processing facilities. The Minnesota Board of Animal Health (BOAH) regulates animal disposal in the state. Refer to the [Overview of Carcass Disposal Options](#) for resources on disposal of carcasses (and parts) as well as a list of licensed rendering companies.

Resources and References

- Code of Federal Regulations Title 9, Part 303.1 – Exemptions: www.ecfr.gov/cgi-bin/text-idx?SID=060039b7486bc6813fd931f58a0c4c64&mc=true&node=se9.2.303_11&rqn=div8
- Code of Federal Regulations Title 9, Part 320.2 – Place and Maintenance of Records: www.ecfr.gov/cgi-bin/text-idx?SID=060039b7486bc6813fd931f58a0c4c64&mc=true&node=pt9.2.320&rqn=div5#se9.2.320_12
- USDA FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A, June 2017: www.fsis.usda.gov/wps/wcm/connect/bf3f01a1-a0b7-4902-a2df-a87c73d1b633/Salmonella-Compliance-Guideline-SVSP-RTE-Appendix-A.pdf?MOD=AJPERES#:~:text=For%20dried%2C%20salt%2Dcured%20and,and%20acidification%20in%20these%20products
- Storage conditions and frozen meat quality: www.provisioneronline.com/articles/101438-storage-conditions-can-impact-frozen-meat-quality#:~:text=Meat%20starts%20to%20freeze%20at,may%20need%20to%20be%20reassess
- Minnesota Board of Animal Health (BOAH) Overview of Carcass Disposal Options: www.bah.state.mn.us/emergency-carcass-resources/#overview-of-carcass-disposal-options

5. LICENSING AND PERMITTING



Preparing for your License and Permit

Prior to receiving any licenses or permits, a supervisor will need to conduct an in-person establishment review at your facility. This review is used to verify that all facility requirements are met. Once the establishment review is complete and the supervisor has determined that the establishment meets the requirements, you may apply for a license (if currently unlicensed) and a custom processing permit.

License Types

The [Minnesota Consolidated Food Licensing Law](#) establishes that any food handler, including any person involved in the production, processing, packaging, labeling, handling, distribution, and sale of food must obtain a license, unless that person qualifies for a licensing exemption or exclusion. All food handlers, whether subject to licensing or not, must comply with all applicable rules adopted by the commissioner. Practically speaking, the term “food” is inclusive of all types of food for human consumption, including meat and poultry products.

The licensing category for custom exempt operators will vary based on the types of other operations that they have. The following diagram provides general guidance on the categories of licenses that would be issued in certain situations.

Possible License Categories for Custom Exempt Processors			
Custom Exempt ONLY	Custom Exempt PLUS		
Provide service for “Not for Sale” products	Custom + Retail	Custom + Wholesale	Custom + Retail + Wholesale
↓	↓	↓	↓
Custom Exempt Processor License	Retail Food Handler License	Wholesale Processor/Manufacturer License	Depends Upon Predominance of Retail or Wholesale

Your inspector and their supervisor will help determine the specific license type needed for your operation. Other license types may apply if you have mobile operations or other types of products such as animal food. License fees are based on a sliding scale according to your gross sales or service income.

Permit Requirements

In addition to a food handler's license, custom exempt establishments need a custom processing permit. The permit is separate from the license and requires a separate application; establishments with other operations, such as retail or E2, need a custom processing permit in addition to their license. This permit has no fee and will be issued when your license is issued.

Other Considerations

Once a business is licensed and permitted as a custom exempt processor, they will be routinely inspected by the MDA up to 4 times per year to ensure that construction, sanitation, and other requirements are being met. The inspection process is described in the next section.

Licensing and Permitting Contacts

- Dairy and Meat Inspection Division: 651-201-6300
 - Food and Feed Safety Division: 651-201-6027
 - Food and Feed Safety Division Licensing and Registration (for questions regarding current license status, fees, etc.): 651-201-6062
-

References

- Minnesota Statutes Chapter 28A. Licensing Food Handlers: www.revisor.mn.gov/statutes/cite/28A

6. THE INSPECTION PROCESS



Purpose of Inspections

Routine custom exempt inspections are performed by the MDA Minnesota Meat and Poultry Inspection Program (MN MPIP) at establishments in Minnesota claiming the custom exemption under the [Federal Meat Inspection Act \(FMIA\)](#) and the [Poultry Products Inspection Act \(PPIA\)](#). These inspections are performed to ensure that products produced in these facilities are produced in a sanitary environment and are not adulterated, as required by the FMIA and the PPIA.

Inspections focus on sanitation of facilities and product control and segregation; these requirements are found in the regulations listed below:

- [9 C.F.R. Part 303.1, 309.3, 310.22, 313, 316.6, 316.16, 381.10, 381.13, 381.14, 416.1-416.5](#)
- [Minnesota Statutes Chapter 31](#)
- [Minnesota Statutes Chapter 31A](#)
- [Minnesota Rules Chapter 1540](#)
- [Minnesota Rules Chapter 1545](#)

Frequency

The frequency of routine inspections in custom exempt establishments varies and is based upon several factors, including:

- The type of the custom exempt operations and products handled
- The establishment's history and compliance with regulations
- Previous observations of adulterated or misbranded product
- Other inspection activities at the establishment (e.g., E2 inspection)
- Other relevant information, such as verified consumer complaints or other facility issues
- Operations schedule for the facility (i.e., seasonal vs. year-round operation)

Custom exempt plants are usually inspected one to four times each year, with fewer inspections occurring at establishments with a demonstrated history of having clean, sanitary facilities with few food safety issues. Seasonal operations will only be inspected during operational months. Inspections are normally unannounced so that the operational conditions can be accurately assessed. However, inspections may be scheduled for some establishments, particularly if operational times are varied or unpredictable. Inspections can be performed in response to complaints, or as a follow up to outstanding orders, licensing, or other special investigations.

Inspection Procedures

When an inspection is conducted, the inspector will introduce themselves, provide credentials (identification), and notify plant management of the purpose of their inspection. The inspector will also provide a written “Notice of Inspection” to each establishment.

What is a notice of inspection?

This is a written notice of intent to inspect a site in order to evaluate compliance with regulatory requirements. The notice describes the legal authority of the MDA to inspect and investigate. It also discloses that data collected is protected until made public once an inspection or investigation is complete.

Inspections are performed in accordance with Minnesota law providing inspectors with the legal authority to enter and inspect a facility, copy records, take photographs, and collect samples in order to determine compliance with Minnesota Statutes and Rules (Minnesota Statutes Chapter [17.984](#), [31.04](#), [31.08](#), [31A.25](#), and [34A.04](#)). Refusing or impeding an inspection could subject you to an enforcement action including civil, administrative, or criminal penalties. In all interactions with your inspector, knowingly providing false information could put your business in jeopardy or subject you to enforcement action.

During your inspections, the inspector may ask questions or request information from you to help evaluate compliance with Minnesota Statutes and Rules. The information collected will be protected and cannot be publicly shared while the inspection is open and ongoing. For routine inspections, the case consists of the inspection and its results (on the report). Unless major compliance violations are noted, the case is usually closed after the inspection is completed. After a case is closed, inspections become public data unless they contain other data that is private or confidential.

Inspection Focus Areas

During routine inspections, the following areas will be assessed for compliance:

- Humane handling of livestock
- Establishment grounds and pest management
- Establishment construction
- Lighting
- Ventilation
- Sewage disposal
- Water, ice, and solution reuse
- Dressing rooms, lavatories, and toilets
- Food contact surface cleaning and sanitation
- Non-food contact surface cleaning and sanitation
- Cleaning compounds and sanitizers
- Operational sanitation (product protection)
- Carcass hygiene
- Employee hygiene
- Employee clothing
- Bovine spongiform encephalopathy/specified risk material handling procedures and records (for cattle only)
- Employee illness/disease control
- Labels (custom product identification)
- Cold storage temperature controls (coolers and freezers)

Inspections typically include a walk-through to view all production and storage areas of the facility, including the exterior of the buildings, as well as a review of records. Records reviewed during routine inspections may include:

- Custom slaughter and processing records
- Water quality reports (municipal or private well)
- Municipal sewer or private septic approval documentation
- Letters of guarantee from suppliers for additives, seasonings, and packaging materials
- Pest control records
- Cook/smoke records
- Safety data sheets (formerly known as MSDS) for chemicals

The Inspection Report

During the inspection, the inspector will document their findings, observations, comments, and orders for corrections (description of expectations for correcting violations), with comply-by dates (dates by which corrections need to be made) on the custom exempt inspection report. An excerpt of that form is shown below. See Appendix A for a copy of the full custom exempt inspection form.

Custom Exempt Inspection Form							
AC = Acceptable; UN = Unacceptable; CR = Critical; MJ = Major; MN = Minor							
Subject		AC	UN	CR	MJ	MN	Finding of Fact: Describe nature/magnitude of non-compliance. Identify location by department; stipulate a compliance date.
Employee hygiene	§416.5(a)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Employee clothing	§416.5(b)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
BSE/SRM handling procedures & records	§310.22	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Employee illness/ Disease control	§416.5(c)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Labels (custom product identification)	§316.16; 316.5; 317.16; 303.1(a) (2) (ii-iii)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Label carcasses "not for sale." Comply today. Identify all products retail or custom exempt through all stages of production (unlabeled luggars of product in cooler). Comply today

At the conclusion of the inspection, the report will be discussed with plant management to make sure they understand all orders and compliance expectations. Both the inspector and the plant-designated person in charge (PIC) will sign the inspection report. A copy of the signed report will be provided to the establishment before the inspector leaves.

Enforcement

The MDA Minnesota Meat and Poultry Inspection Program (MN MPIP) works with businesses to achieve compliance with regulatory requirements by using the action most appropriate for the level of food safety risk associated with the error or violation. Inspection staff will work to educate operators and employees while still making sure urgent food safety issues are immediately addressed. Orders written during inspections will be accompanied by specific compliance dates to give the business time to correct the violations. The length of time provided will vary by the severity of the findings. You are responsible for complying with these orders unless you submit a written appeal of the written orders.

If violations are not corrected within the specified timelines or if a critical food safety issue is identified, additional enforcement actions may be necessary. Intentional violations or refusal to correct may also result in penalties or other civil or criminal actions. While these are rare, these tools can be used if violations are severe and willful.

Types of enforcement actions

Reinspection

A non-routine inspection conducted specifically to follow up on violations identified during a routine or initial inspection of an establishment.

Reject/Retain Tag

The application of a regulatory tag to equipment that is unsanitary (reject tag) or product that is potentially adulterated or misbranded (retain tag). Affected product or equipment may be cleaned but cannot be used until the tag is removed by an MDA employee. In severe situations, an entire room or building may be tagged to effectively suspend operations. If product was retained, its safety will be assessed before determining if it can be used for human food or must be discarded.

Administrative Enforcement Action

The retention of product, rejection of equipment or facilities, or refusal to allow processing are all steps that can be taken by inspection personnel to control or prevent product adulteration or misbranding.

Warning Letter

A written notice sent to an establishment for the same violations or uncorrected violations that were identified on 2 or more routine inspections in a row. The letter identifies the violation(s) of concern, reiterates potential enforcement action that may occur, outlines expectations for correction, and describes the reinspection process.

Reinspection Fee

A fee assessed to an establishment when a reinspection occurs during which items cited during the initial inspection were not corrected or significant food safety issues were identified.

Administrative Meeting

A meeting between the MN MPIP staff and the establishment representatives during which violations or potential violations are discussed prior to the MDA determining whether more severe enforcement actions or criminal penalties are warranted.

Administrative Penalty

Penalties may be applied when violations are identified and subsequently not corrected. An administrative penalty of up to \$1,500 for each violation can be assessed. Each day a violation continues is a separate violation. This type of penalty is only used in certain situations when previous administrative enforcement was unsuccessful.

The image shows two green regulatory tags from the Minnesota Department of Agriculture. Both tags have a white circle at the top for a hole punch. The left tag has a red rectangular section with two white squares and the text 'MINN. REJECTED' and 'MINN. RETAINED'. Below this, there are fields for 'ITEM TAGGED AND LOCATION:', 'REASON FOR TAGGING:', 'TAGS APPLIED BY:', 'DATE:', 'REMARKS:', and 'PLANT OR EST. EMPLOYEE NOTIFIED:'. The right tag has a red rectangular section with two white squares and the text 'MINN. REJECTED' and 'MINN. RETAINED'. Below this, there is a 'NOTICE' section with the text 'This tag may be detached only by an authorized employee of the Minnesota Department of Agriculture.' and a 'No ####' field. At the bottom of the right tag, there is a '(see reverse)' note.

Resources and References

- Federal Meat Inspection Act (FMIA): www.fsis.usda.gov/wps/portal/fsis/topics/rulemaking/federal-meat-inspection-act
- Poultry Products Inspection Act (PPIA): www.fsis.usda.gov/wps/portal/fsis/topics/rulemaking/poultry-products-inspection-acts
- 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/

7. HANDLING ADVERSE EVENTS



In any business, operations won't always go as planned, despite our best efforts. It is important to be prepared for adverse events and have a plan in place to deal with them. This section will discuss examples of adverse events you may encounter and resources or ideas to help you plan for these at your establishment.

Employee Illness Response

Having an ill employee can be disruptive to your business, especially in terms of production and scheduling, but it will likely occur, so you must have procedures in place for dealing with employee illness. Maintaining food safety should be a top priority. **As a food business owner, you are responsible for protecting yourself, your employees, and your customers from foodborne illnesses.**

If workers are experiencing illness, such as diarrhea and/or vomiting, and are handling or preparing food, they may contaminate the food and cause others who consume that food to become ill. Therefore, excluding ill employees from the workplace is critical. Any employee who has diarrhea and/or vomiting must not come in to work and should only return when at least 24 hours have passed since their last symptoms. In other words, employees should stay home for a full 24 hours after they have begun to feel better and have stopped experiencing vomiting or diarrhea. Your employees must also report to you if they have been diagnosed with specific types of infection, such as Norovirus, Salmonella, Shigella, Hepatitis A virus, Shiga toxin-producing E. coli, or other bacterial, viral, or parasitic stomach or intestinal infections.

Maintaining an employee illness log will help you manage these events. This log can be used to track and report employee illnesses and may be consulted if a foodborne illness is ever linked to your products or processing plant. The Minnesota Department of Health (MDH) [employee illness log](#) template is shown below.

Employee Illness Log										
Report date	Employee name	Vomiting	Diarrhea	Jaundice	Fever	Respiratory (cough, sore throat, runny nose)	Comments or additional symptoms	Date returned to work	Diagnosed with a pathogen?	If diagnosed, 1-877-FOOD-ILL or local health agency contacted?
6/12/2019	John Doe	X	X				Sent home	6/15/2019	Yes norovirus	Yes

The MDH has many other resources available to assist you in managing employee illnesses, including decision-making tools that can be used to determine when an employee needs to be excluded from the workplace. While many of these tools are designed for retail food production businesses, the same concepts and approach apply to custom exempt processing and other food processing businesses. You can find additional resources from the MDH at [Foodworker Illness Awareness](#).

Emergency Response and Food Defense

Responding to emergencies and managing security at your plant are also important aspects of maintaining business operations when accidents, weather-related events, public health emergencies, or other incidents occur. As a general resource, refer to [USDA FSIS Emergencies and Food Safety](#).

Weather-related events

Floods, tornadoes, high winds, and other weather-related events can have a big impact on your business, particularly when electricity and sewer/water are necessary for daily operations. Consider the following scenarios as common examples of emergencies that could impact your business:

- Your cooler compressor malfunctions due to a disruption in electricity
- Flooding in the area contaminates your water supply
- Storms cause a tree to fall onto your building, leaving roof damage and water leakage into the facility

How do you respond in these situations? Your inspector is available to help you manage through these incidents and to ensure food safety is maintained. You may need to discard all products in an affected cooler or provide proof that adequate temperatures have been maintained in order to demonstrate safety and keep the products. If your water source is affected, you may need to identify a temporary water source or demonstrate the safety of the source you are using. In all cases, having a plan will help you cover all bases. Keep emergency contact information readily available for your inspector, local law enforcement office, insurance company or utility company, and others to help you respond more quickly.

Public health emergencies

In cases of large-scale disease outbreaks, radiological emergencies, or other situations that warrant a government-declared public health emergency, new procedures or restrictions may be put in place by executive order or other means. You may find yourself needing to rapidly adapt under new and unpredictable circumstances. Your inspector can help you navigate these situations. Depending on the nature of the emergency, you may also be contacted by state or local public health officials or other agencies working to contain or mitigate a public health emergency.

COVID-19

The COVID-19 pandemic is an example of a public health emergency that significantly impacted food processors of all types. Processing facilities had to adopt new employee illness protocols, health screening, and social distancing, among other measures, to slow the spread of the disease. Some processors were able to implement the needed changes better than others; one key to success is staying in communication with your inspector and keeping up to date on the latest public health announcements and recommendations.

Intentional product contamination or adulteration

Establishments often focus their preparation efforts on emergencies associated with natural events or accidents, but in food processing facilities, the risks posed by intentional product contamination or adulteration should also be considered. Be thorough in establishing security in your plant, managing visitors, and controlling access to internal areas of the plant to reduce the risk of intentional contamination.

Having a good food defense plan will also help prevent these risks to the extent possible. You can use the [FSIS Food Defense Risk Mitigation Tool](#) to help make your own food defense plan.

Recalls and Product Traceability

As a custom exempt processor, you are providing a service to the customer and do not own the products that you handle for these operations. As such, you may think that recalls and product traceability are less important than they would be at a facility that processes products for sale. Though custom exempt products are rarely recalled, maintaining traceability of products through product labeling and recordkeeping is still necessary to address issues when they do occur.

As described in Section 4: Other Regulatory Requirements, you are required to maintain records about the owner of the animal or products being processed and meet minimum labeling requirements. For every product that comes through your facility, document how much you process, what methods you use, and for whom you are processing. This will help you trace products if someone does become ill or questions are raised about a product's safety, quality, or quantity. This can also help protect your business in cases when adverse events do occur. Review the example provided here to learn more about how the quality of your recordkeeping can impact your business.

Case study on traceability and recordkeeping

John Jett's custom exempt slaughter plant has been very busy in recent months and he's found that he has had several new customers lately. In the past, John kept minimum records, often only using the individual's first name on the slaughter log because he was so familiar with his customers.

Last week, John was contacted by his meat inspector, who let him know that someone reported becoming ill with *Listeria monocytogenes* and that the person had mentioned consuming beef sticks processed at his plant. The inspector asked to examine his custom slaughter books and other records so that he could determine whether any other products were affected by the contamination.

After reviewing John's records, the inspector noted that he was unable to say which products were produced at the same time as the affected product. As a result, John was asked to contact all his customers who had product produced during that time to let them know that their products may be contaminated and should not consume them.

Managing Disruptions to Your Water Supply

Water is a key part of any meat processing business. Whether you are using it to clean equipment or as an ingredient in products, you must ensure your source is safe. Doing so requires routine testing of your water source(s). If you obtain results that indicate your supply may be contaminated with bacteria, you will need to discontinue using the source until you have resolved the issue.

If you are located within city limits or use a rural water source, your municipality will conduct regular testing for safety. If unsafe or potentially unsafe conditions are identified, a "Boil Water Notice" or other warning may be issued. If this occurs, you should follow the instructions in the notice; your inspector can be a resource to help you ensure potentially contaminated products are dealt with appropriately. The MDH has resources for managing well water failures. Visit [Well Disinfection - Well Management Program](#) for more information.

Resources

- Minnesota Department of Health (MDH) Employee Illness Log:
www.health.state.mn.us/people/foodsafety/dwi/empillog.html
- MDH Foodworker Illness Awareness:
www.health.state.mn.us/people/foodsafety/dwi/index.html
- USDA FSIS Emergencies and Food Safety:
www.fsis.usda.gov/food-safety/safe-food-handling-and-preparation/emergency-preparedness
- USDA FSIS Food Defense Risk Mitigation Tool:
www.fsis.usda.gov/food-safety/food-defense-and-emergency-response/food-defense/risk-mitigation-tool
- MDH Well Disinfection – Well Management Program:
www.health.state.mn.us/communities/environment/water/wells/waterquality/disinfection.html

APPENDIX A: Custom Exempt Inspection Report



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

DAIRY AND MEAT INSPECTION DIVISION Phone: 651-201-6300 Fax: 651-201-6116

CUSTOM EXEMPT INSPECTION FORM

NOTICE OF INSPECTION

Notice of Inspection is hereby served in accordance with Minnesota Statutes 17.984, 31.04, 31.08, 34A.04 or any other applicable legal authority of the Minnesota Department of Agriculture (MDA), to enter, inspect, copy records, take photographs and sample, in order to determine compliance with the Minnesota statutes and rules promulgated thereunder. Find statutes and rules at www.revisor.mn.gov.

Refusal, hindering, impeding, or preventing an inspection could subject you to an enforcement action including civil, administrative, or criminal penalties.

The MDA will provide an inspection report at the conclusion of the inspection or investigation. You are responsible for complying with all orders issued in the timeframe specified unless you submit a written appeal. You have 20 days from the close of the inspection to appeal any issued orders. Compliance with orders does not preclude the MDA from taking an enforcement action. Knowingly violating a statute, rule, or order or violating a statute, rule, or order that endangers humans or animals is a gross misdemeanor.

The MDA may charge reinspection fees under Minn. Stat. 28A.085 for additional inspections necessary to verify compliance with issued orders and/or insanitary conditions.

During this inspection or investigation, the MDA may ask an individual to supply private or confidential data about themselves or others, for the purpose of evaluating compliance with Minnesota Statutes and Rules. Individuals are not legally required to supply personal, private, or confidential data; however, such data may be subpoenaed. An individual supplying personal, private, or confidential data may reasonably expect the MDA to use the data in enforcement actions. In accordance with the Government Data Practices Act, the MDA will consider the data as protected non-public or confidential data. It is available only to those provided access by law; department employees whose job reasonably requires access, the Legislative Auditor, or by court order. Unless otherwise protected by law, any data collected will become public when the MDA determines not to take an enforcement action, the inspection or investigation becomes inactive or closed, the statutes of limitation expires, or all legal rights have expired.

Under Chapter 34A, a person must not knowingly make or offer a false statement on an application for registration, license, or permit; during an investigation of a violation; or on a record or report. A person may lose their license if they use fraudulent and deceptive practices to avoid following Minnesota food laws.

Date of Inspection _____

Report Number _____ Inspector Number _____ Custom Permit Number _____

Firm Name _____ Owner Name _____

Street Address _____ City _____ Zip Code _____ County _____

Phone Number _____ Email Address _____

CUSTOM EXEMPT INSPECTION FORM

Firm Name _____

License Number (record number as posted) _____ Expiration Date _____

Establishment Type (check all that apply)

☐ Custom Exempt Slaughter ☐ On Farm Slaughter ☐ Custom Processing ☐ Retail Exempt Meat

Inspection Purpose
☐ Routine ☐ Reinspection ☐ Complaint ☐ Special Investigation

Ritual Slaughter Performed ☐ Yes ☐ No

If yes, is the appropriate paperwork on file and current ☐ Yes ☐ No

Guidelines to determine Violation Severity: Critical / Major / Minor:

- Will the "deficiency" result in adulterated or misbranded/mislabeled product?
- Will the adulterated or misbranded product reach consumers?
- Will the product have a detrimental effect upon the consumers?

Certain
Likely
Potential
AC – Acceptable
UN – Unacceptable
CR – Critical
MJ – Major
MN – Minor

Subject		AC	UN	CR	MJ	MN	Findings of Fact: Describe nature/magnitude of non-compliance. Identify location by department; stipulate a compliance date.
Humane handling of livestock	\$313	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Establishment grounds and pest management	\$416.2(a)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Establishment construction	\$416.2(b)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Light	\$416.2(c)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Ventilation	\$416.2(d)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

CUSTOM EXEMPT INSPECTION FORM

Subject		AC	UN	CR	MJ	MN	Findings of Fact: Describe nature/magnitude of non-compliance. Identify location by department; stipulate a compliance date.
Plumbing	§416.2(e)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Sewage disposal	§416.2(f)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Water, ice, and solution reuse	§416.2(g)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Dressing rooms, lavatories, and toilets	§416.2(h)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Equipment and utensils	§416.3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Food-contact surface cleaning and sanitation	§416.4(a)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Non-food contact surface cleaning and sanitation	§416.4(b)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Cleaning compounds and sanitizers	§416.4(c)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Operational sanitation (product protection)	§416.4(d)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Carcass hygiene (Fecal contamination is critical)	§310.18 fsis dir 6420.1 & 6150.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

CUSTOM EXEMPT INSPECTION FORM

Subject		AC	UN	CR	MJ	MN	Findings of Fact: Describe nature/magnitude of non-compliance. Identify location by department; stipulate a compliance date.
Employee hygiene	\$416.5(a)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Employee clothing	\$416.5(b)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
BSE/SRM handling procedures & records	\$310.22	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Employee illness/ Disease control	\$416.5(c)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Labels (custom product identification)	\$316.16; 316.5; 317.16 303.1(a)(2) (ii-iii)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Custom records (slaughter & processing)	\$303.1(b)(3)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Trichinae Treatment/cooked Product Temperatures/ custom Product preparation	\$303.1(b)(1) 318.5; 318.6; 318.10; 318.300-311	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Inedible materials Handling/control	\$325.13	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Sewer certificate	\$416.2(f)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Water quality report	\$416.2(g)(1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Municipal <input type="checkbox"/> Well

CUSTOM EXEMPT INSPECTION FORM

Subject		AC	UN	CR	MJ	MN	Findings of Fact: Describe nature/magnitude of non-compliance. Identify location by department; stipulate a compliance date.
Letters of guaranty for additives & package materials	§317.24 §381.144 Dir. 7410.1 & 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Cooler temp		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Freezer temp		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Assign Risk (check one) 1 ☐ 2 ☐ 3 ☐ 4 ☐ Any equipment or rooms tagged? Yes ☐ No ☐

If **Yes**, list tag numbers _____

All previous first notice orders are in compliance: Yes ☐ No ☐ NA ☐

All previous repeat orders are in compliance: Yes ☐ No ☐ NA ☐

If **No** for either question, list the violation as a repeat notice in this report.

Comments/or Additional Orders

Copy of this report received and explained to: _____

Name of Establishment Representative (print)	Signature of Establishment Representative	Date	
Name of Inspector (print)	Signature of Inspector	Date	

APPENDIX B: 9 C.F.R. Animals and Animal Products, Part 416 – Sanitation

The following is found online at www.ecfr.gov/cgi-bin/text-idx?node=pt9.2.416&rgn=div5

§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.

[64 FR 56417, Oct. 20, 1999]

§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.

[64 FR 56417, Oct. 20, 1999]

§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.

[64 FR 56417, Oct. 20, 1999]

§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.

[64 FR 56417, Oct. 20, 1999]

§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.

[64 FR 56417, Oct. 20, 1999]

§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.

[64 FR 56417, Oct. 20, 1999]

§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.

[61 FR 38868, July 25, 1996, as amended at 62 FR 26219, May 13, 1997]

§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.