

**Minnesota Department of Agriculture
Food and Feed Safety Division**

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Title: Field Compliance Actions SOP	

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1. PURPOSE

The purpose of this document is to describe the procedures for implementing field-based compliance actions during food inspections as provided for in MN Statute in 34A.06 Administrative Actions, 34A.11 Embargo, Seizure, and Condemnation, MN Statute 31.09 Commissioner to Render Certain Food Unsalable, and MN Rule 4626.1805 Embargo and 4626.1810 Condemnation.

2. SCOPE

This procedure applies to inspections conducted by the Retail Food and Manufactured Food Programs of the Minnesota Department of Agriculture (MDA), Food and Feed Safety Division (FFSD). The procedures are applicable to inspections or investigations of any industry, transportation vehicles or products under the regulatory authority of the Retail Food or Manufactured Food Programs whether or not the person holds a license with MDA.

This procedure does not apply to inspections conducted by the Commercial Feed Program of the MDA -FFSD.

3. BACKGROUND

Minnesota Statutes 31, 31A and 34A (and any other applicable laws and regulations) provide the legal authority for Department staff to take appropriate action to control food products when they may be adulterated or misbranded in order to determine compliance with the Minnesota laws including, but not limited to, MN Chapters 17, 28, 28A, 29, 30, 31, 31A, 32 and 34A and Agency rules promulgated there under including MN Rule 4626 which provides additional authorities in Retail Food Establishments.

Minnesota Statute 31.09 describes the over-arching authorities as:

The commissioner and the commissioner's assistants, inspectors, agents, and employees, shall also have power and authority, in their discretion, to render unsalable for use as food, any food the sale or use of which is now or hereafter prohibited by law, or which is manufactured, sold, used, transported, offered for sale or transportation, or had in possession with intent to use, sell, or transport in violation of any provision thereof, or in violation of any provision of any rule, definition, standard, or ruling made, adopted, and published thereunder, and the commissioner and assistants, inspectors, agents, and employees shall be exempt from liability for any such action.

Minnesota Statute 31.161 provides authority for issuance of a Sanitary Notice with MS 31.165 requires a firm to place the establishment in a clean and sanitary condition.

This document was created based upon previous policies and current authorities granted in MN Statute and Rules.

4. RESPONSIBILITY

Food Program Manager – The Manufactured Food or Retail Food Program Manager will assist in determining appropriate field compliance actions as needed including evidence collection.

Supervisor (Food Inspection, Rapid Response Team, Compliance) – The Supervisor will provide guidance and feedback to inspectors as requested regarding issuance of field compliance actions including evidence collection.

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Compliance Officer – The Compliance Officer will assist in the determination of evidence collection related to field compliance actions.

Food Inspector – The Food Inspector will determine appropriate field compliance actions in consultation with the Supervisor and Program Manager as needed; determine probable cause related to field compliance actions; collect evidence and document field compliance actions per the applicable procedures.

5. DEFINITIONS

Several of the words and phrases defined below are expressly defined in Minnesota law and include the legal reference. For definitions where there is no legal definition, a dictionary definition is used; the legal basis for doing so is in MN Statute 645.

Adulterated/Adulteration: Represents a specific violation as identified in MN Statute 34A.02 clauses (1-15).

Cease and Desist: an official order to stop doing something immediately.

Condemnation: a determination by the Commissioner, Commissioner’s Agent, or the courts that food or an animal or other product is found to be adulterated or misbranded or otherwise in violation of Chapter 34A, and must be remedied as in 34A.11 Subd 4. MDA must petition the Courts for an order and decree to condemn food, however 34A.11 Subd 5 allows the Commissioner to condemn Perishable Food. MN Rule 4626.1810 allows for Condemnation of food, equipment, clothing or utensils in a Retail Food Establishment.

Consumer Commodity: as defined in MN Statute 31.01 is Food (as defined below) or by the Federal act but does not include tobacco or tobacco product, any drug subject to the provisions of sections [151.34](#) to [151.40](#), any beverage subject to the provisions of chapter 340A or any commodity subject to the provisions of chapter 21.

Embargo: a restriction on trade by government order detaining, restricting or prohibiting commerce, especially trade, of a given commodity such as food or equipment. An embargo, as described in MN Statute 34A.11, can be issued when the food or commodity is, or is suspected of being, adulterated, misbranded, or distributed in violation of MN Statute 34A. This means that an embargo can be issued when the condition of the product is not known or has yet to be determined to stop its movement in commerce. MN Rule 4626.1805 allows for Embargo of food, equipment, or utensils in a Retail Food Establishment. It is unlawful for the firm or person to whom the embargo is issued to remove or dispose of an embargoed article without permission of MDA or the court.

Field Compliance Actions: Field compliance actions are actions performed during an inspection to achieve compliance with regulations. These actions include, but are not limited to, reinspections, cease and desist orders, and embargos. These actions are initiated by a firm’s non-compliance with regulatory requirements as evidenced by an inspection report, violative sample results, or other collected documentation of conditions.

Food: as defined in MN Statute 34A.01 is every ingredient used for, entering into the consumption of, or used or intended for use in the preparation of food, drink, confectionery, or condiment for humans or other animals, whether simple, mixed, or compound; and articles used as components of these ingredients.

Frozen Food: as defined in 34A.01 is food that is processed and preserved by freezing and which is intended to be sold in the frozen state.

Misbranded: represents a specific violation as identified in MN Statute 34A.03 clauses (1-13)

Most Responsible Person (MRP): the owner, operator, or agent who is present at a manufacturing firm and is responsible for the operation at the time of inspection or an owner, operator, or agent who is otherwise responsible for an operation, including food in transit.

Non-perishable Food: food with a shelf life of more than 90 days and that is not perishable food, readily perishable food, or frozen food, as defined in as defined in MN Statute 34A.01.

Owner/agent: individual with physical custody of identified food during an event AND representing the legal ownership. This may be the legal owner of the facility/food, the MRP or PIC as applicable.

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Perishable Food: food including, but not limited to, fresh fruits, fresh vegetables, and other products that need protection from extremes of temperatures in order to avoid decomposition by microbial growth or otherwise, as defined in as defined in MN Statute 34A.01. Includes Readily Perishable Food but does not include packaged pickles, jellies, jams, and condiments in sealed containers, bakery products such as bread, rolls, buns, donuts, fruit-filled pies, and pastries, dehydrated packaged food; dry or packaged food with a water activity that precludes development of microorganisms; and food in unopened hermetically sealed containers that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution.

Person: any individual, firm, partnership, cooperative, society, joint stock association, association, company, or corporation and includes any officer, employee, agent, trustee, receiver, assignee, or other similar business entity or representative of one of those entities as defined in MN Statute 34A.01.

Person in Charge (PIC): the individual present at a retail food establishment who is responsible for the operation at the time of the inspection as defined in MN Rule 4626.0020.

Probable cause: sufficient reason based upon known facts to believe a violation has been committed or that certain property is connected with a violation. Probable cause must exist to seize property in the belief the items are evidence of a violation. Technically, probable cause has to exist prior to embargo, search or seizure.

Readily Perishable Food: food or a food ingredient consisting in whole or in part of milk, milk products, eggs, meat, fish, poultry, or other food or food ingredient that is capable of supporting growth of infectious or toxigenic microorganisms. Readily perishable food requires time and temperature control to limit pathogenic microorganism growth or toxin formation, as defined in as defined in MN Statute 34A.01.

Sanitary Notice: a regulatory action that may be applied when a food establishment is in a filthy, unclean or unsanitary condition. MN Statue 31.161 states that no person, firm or corporation shall operate a food facility (or vehicle) if the same is in or is permitted to be in a filthy, unclean or insanitary condition. MN Statute 31.165 requires that the facility to be placed in a clean and sanitary condition within a reasonable time, but in no case less than 2 days.

Seizure: acting on a court order, the forcible taking of property by a government official of a given commodity. The State takes possession of the product; however the firm/person still technically owns the product. Per the authority in MN Statute 34A.11 Subd. 2, products that can be seized are a carcass; part of a carcass; meat or meat food product of an animal; or dead, dying, disabled, or diseased animal that is being transported in interstate commerce or is held for sale in Minnesota after transportation in intrastate commerce.

Sell/sale: keeping, offering, or exposing for sale, use, transporting, transferring, negotiating, soliciting, or exchanging food; having in possession with intent to sell, use, transport, negotiate, solicit, or exchange food; storing, manufacturing, producing, processing, packing, and holding of food for sale; dispensing or giving food; or supplying or applying food in the conduct of any food operation or carrying food in aid of traffic in food whether done or permitted in person or through others, as defined in MN Statute 34A.01.

USAFS: USA Food Safety is the electronic inspection reporting system used by the FFSD Food Inspection Program. It is the required system for generating inspection reports and must be used whenever possible. In the rare instance when USAFS cannot be used and a hand-written inspection report is necessary, the appropriate standard order language is required following the report writing SOP.

6. PROCEDURE

6.1. Embargo

6.1.1. Determine if there is probable cause to issue an embargo on product that meets any of the following criteria:

6.1.1.1. Food known or suspected to be adulterated due to the presence of biological, chemical or physical contaminants, or

6.1.1.2. Equipment or facilities that are known to be or suspected of causing the adulteration of food,
or

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- 6.1.1.3. Known or suspected to be misbranded as to be dangerous or fraudulent, or
- 6.1.1.4. Otherwise being distributed in violation of MN Statute 34A.
- 6.1.2. Situations that may represent probable cause may include, but are not limited to:
 - 6.1.2.1. Fire in a building (or an adjacent building) where food was stored or manufactured
 - 6.1.2.2. Flooding in a building and food was affected, either submerged or in a building that contained flood water
 - 6.1.2.3. Rodents or rodent droppings found in food production areas, food storage areas
 - 6.1.2.4. Source of food is in question (i.e. does it meet regulatory requirements based on production location and where the product was sold/used)
 - 6.1.2.5. Insects (live or dead), casts, webbing is found in food production areas, food storage areas
 - 6.1.2.6. Extended power outages where potentially hazardous food was not held at proper temperatures.
 - 6.1.2.7. Production processes out of control where critical limits are not met or significant deviations from a firm's filed process (LACF, AF)
 - 6.1.2.8. Product produced without a filed process when one is required (LACF, AF)
 - 6.1.2.9. Gross insanitary conditions such as food contact surfaces with old food residue or mold where ingredients, raw materials, or finished products are affected
 - 6.1.2.10. Laboratory results confirm pathogen contamination in the processing environment potentially resulting in adulteration of food
 - 6.1.2.11. Laboratory results confirm pathogens in food
 - 6.1.2.12. Pesticide drift onto a food crop for which the pesticide was not approved or had an inappropriate withdrawal period
 - 6.1.2.13. Probable allergen cross contact during processing
 - 6.1.2.14. One species of fish being represented as another
 - 6.1.2.15. Processing equipment believed to be contributing to adulteration of food (poor design, materials, long-term sanitation), in particular when there appears no means for correction.
 - 6.1.2.16. Facilities believed to be contributing to adulteration of food (leaking roof, floors/walls in poor condition resulting in harborage areas for pathogens)
- 6.1.3. Embargo of a geographic area may be necessary when the governor declares an emergency and there is probable cause to believe that all livestock, food or a consumer commodity within a specific area is likely to be adulterated because of the emergency or misbranded as to be dangerous or fraudulent.
 - 6.1.3.1. In such cases, the MDA Communications staff, in consultation with the RRT Supervisor, Food Program Manager, and/or the appointed Incident Commander will issue a notice to the public (see *RESP.50.06 - Communication with the Public SOP*) and to those with custody of the product in as thorough a manner as is possible.
- 6.1.4. Use professional discretion in the decision to issue an embargo. Violations must be taken in context of impact to the adulteration or misbranding of food. Determine if the observation potentially results in a violation of 34A.02 or 34A.03.
- 6.1.5. Consult with a Supervisor (primary contact), Compliance Officer or FFSD Management by phone or email to verify that probable cause has been established prior to an embargo being issued.

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- 6.1.5.1. The content of the notification should include all relevant data including name of the firm, probable cause, type and quantity of products involved, etc.
- 6.1.6. Issue an Embargo on any food, animal, equipment, facility, or consumer commodity according to authorities in MN Statute 34A.11 when probable cause has been established.
- 6.1.6.1. Additionally, embargo equipment and utensils in a Retail Food Establishment that do not meet the requirements of MN Rule 4626 according to authorities in MN Rule 4626.1805.
- 6.1.7. Identify or otherwise mark products placed under embargo using MDA supplied embargo tape, tags, stickers, or truck seals.
- 6.1.7.1. Circumstances may dictate that all food products in an entire facility are embargoed, or that include any future product that is produced or brought into the facility in which case not all products would be marked. Ensure this is clearly described in the observation statement when this situation occurs.
- 6.1.7.2. A field of a food crop may be embargoed based on a description of the field. A geographic land designation should be obtained when at all possible to specify the land/area to which the embargo applies.
- 6.1.8. Direct the firm owner/agent to segregate and otherwise identify as necessary the embargoed products so that products are not moved, sold, shipped, or otherwise disposed of until permission for removal or disposal is given by the commissioner or the court.
- 6.1.9. Collect evidence as documentation of the probable cause, to make a determination as to whether the product is adulterated or misbranded, and/or to show the products that are covered under the embargo. Such evidence may include:
- 6.1.9.1. Photographs or Video
- 6.1.9.1.1. Collect photos or videos to demonstrate/support probable cause, such as rodent droppings, insect presence, insanitary conditions, extent of contamination, etc. Refer to *FOOD.WI.30.59 – Documenting Digital Photographs-Video Evidence-Manufactured Foods WI* or *FOOD.WI.30.62 – Documenting Digital Photographs-Video Evidence-Retail Food WI* as applicable.
- 6.1.9.1.2. Collect photos or videos close up to show the product that is embargoed and further back to show the location of where the embargoed product is stored to identify that it is located within a particular facility or crops in a particular field
- 6.1.9.2. Records to support your probable cause; i.e. production records, filed processes, laboratory reports, receipts of purchases, bills of lading, crop production records/field tickets, formulation sheets
- 6.1.9.3. Samples to confirm probable cause, potentially including food, environmental swabs, environmental materials such nesting material, packaging materials, rodent evidence, insects or their evidence, or water. Refer to *FOOD.30.23 – Investigation Sampling-Inspector Initiated SOP* and related documents.
- 6.1.9.4. Food labels that would demonstrate misbranding. Refer to *FOOD.30.23 – Investigation Sampling-Inspector Initiated SOP* and related documents.
- 6.1.9.5. Reports from other agencies (i.e. a report from a fire department that shows the type of material that burned or was used to extinguish the fire)
- 6.1.9.6. Statements from employees, managers about conditions that were observed or described
- 6.1.10. Evaluate whether the items meet the criteria for being considered adulterated or misbranded based on language in MN Statutes 31.02 Prohibited Acts, 34A.02 Adulteration, and 34A.03 Misbranding.

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6.2. Release of Embargo

6.2.1. Release the Embargo within five (5) days when the Supervisor, FFSD Management, or Compliance Officer has evaluated sample results and other evidence and made one of the following determinations:

6.2.1.1. The firm determines that they will voluntarily discard the embargoed products. Refer to *FOOD.30.05 – Inspection Report SOP*.

6.2.1.2. Embargoed products are not found to be adulterated, misbranded or otherwise in violation of 34A. Products will be released for normal use. (See 6.2.3)

6.2.1.3. Embargoed products are found to be adulterated, misbranded or otherwise in violation of 34A and are to be Condemned (See 6.7, 6.8, or 6.9)

6.2.1.4. Embargoed products are found to be adulterated, misbranded or otherwise in violation of 34A and can be corrected by proper labeling or processing of the food or animal, either by the owner/agent or by a licensed Salvor (See 6.10)

6.2.1.5. Equipment and utensils Embargoed under Food Code authorities have been modified to meet requirements of MN Rule 4626 and are approved by the inspector.

6.2.2. Release an Embargo placed by another regulatory agency at their request, when that product is physically located in Minnesota and product meets one of the criteria noted in 6.2.1.1. through 6.2.1.4.

6.2.3. When embargoed products are released for normal use complete the following:

6.2.3.1. Remove any identifying marks, embargo tape, stickers, and seals from products.

6.2.3.2. Inform the firm owner/agent that the products no longer need to be segregated and may be moved, sold, shipped, in normal channels of commerce or used as an ingredient, as appropriate.

6.3. Seizure

6.3.1. Collect evidence to support a court petition to Seize and Condemn products when directed by a Supervisor, FFSD Management or Compliance Officer who will provide further information regarding the documents, photographs, samples, etc. to be collected in these circumstances.

6.3.2. When the court has determined that a Seizure and Condemnation is appropriate and as directed by FFSD Management, issue the seizure order to the owner/agent.

6.3.2.1. Identify/mark seized products using tape, tags, stickers, truck seals as appropriate.

6.3.2.2. Collect photos or videos, in close proximity, to show the product that is being seized and collect wide range view photos or videos to show the location of where the seized product is stored in order to identify that it is located within a particular facility or crop in a particular field.

6.3.3. Evaluate whether the items meet the criteria for being considered adulterated or misbranded based on language in MN Statutes 31.02 Prohibited Acts, 34A.02 Adulteration, and 34A.03 Misbranding.

6.4. Release of Seizure

6.4.1. Release the Seizure within five(5) days, after the Courts, Supervisor, FFSD Management, or Compliance Officer has evaluated the evidence as to whether the products are adulterated, misbranded or otherwise in violation of MN Statute 34A and made one of the following determinations:

6.4.1.1. Seized products were not found to be adulterated, misbranded or otherwise in violation of 34A. Products will be released for normal use. OR

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6.4.1.2. Seized products are found to be adulterated misbranded, or otherwise in violation of 34A

6.4.2. When seized products are released for normal use, complete the following:

6.4.2.1. Remove any identifying marks, tape, stickers, seals from products

6.4.2.2. Inform the firm owner/agent the products no longer need to be segregated and may be moved, sold, shipped, in normal channels of commerce or used as an ingredient, as appropriate.

6.4.3. When seized products are found to be adulterated and condemned complete the following:

6.4.3.1. Apply/enforce the remedy as determined by the Courts, FFSD Management, Supervisor, or Compliance Officer which may include Condemnation (see 6.7, 6.8, or 6.9), Voluntary Destruction (see 6.2.1.1), or correction of misbranding (6.10).

6.4.3.2. Provide oversight of the destruction process.

6.4.3.3. Collect photos or videos to show the product that is being destroyed.

6.4.3.4. Remove any identifying marks such as tape, tags, stickers, truck seals at the time of disposition or correction.

6.5. Cease and Desist

6.5.1. Determine if there is probable cause to issue a Cease and Desist order to notify a person/firm to discontinue doing an activity when public health is jeopardized or the firm is otherwise in significant violation of the law. Acting in violation of a statute, regulation or other law does not necessarily constitute reason to require a firm to discontinue.

6.5.2. Examples of situations that may require a Cease and Desist order include:

6.5.2.1. A firm is found operating without a food handlers license and:

6.5.2.1.1. The firm does not meet the criteria to become licensed at that time due to inadequate equipment, facilities, or other regulatory requirements

6.5.2.1.2. Another legal reason exists to not issue a license.

6.5.2.2. Using a process/method of production that may be contributing to the adulteration of a food product or is otherwise in violation of the law.

6.5.2.2.1. Example: The firm is using a processing method or equipment that does not allow the food to reach a required critical limit, for example a pasteurizer is not set up properly to ensure that apple cider has received a 5 log reduction as required

6.5.2.2.2. Example: The firm is using a production method without critical limit records when a HACCP plan is required, for example no batch records indicating amount of cure, time-temperature for cooling, etc. for an ROP cooked meat product.

6.5.2.3. Using a piece of equipment, or a specific processing room or area of a facility that may be contributing to the adulteration of a food product or is otherwise in violation of the law.

6.5.2.3.1. Example: The firm is using processing equipment that is believed to be contributing to the adulteration of food, for example environmental swabs taken from a food contact surface show the presence of *Listeria monocytogenes*.

6.5.2.3.2. Example: The firm is using production or holding equipment that has not been certified (i.e., NSF, UL, ETL, CSA, NAMA) to an appropriate equipment standard or is otherwise not approved for use by the regulatory authority per the MN Food code.

6.5.2.4. A firm is found to be using, moving/has moved product held under embargo

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6.5.3. Evaluate whether the items meet the criteria for being considered adulterated or misbranded based on language in MN Statutes 31.02 Prohibited Acts, 34A.02 Adulteration, and 34A.03 Misbranding.

6.5.4. Conduct reinspections or follow-up inspections as applicable or as directed to verify compliance with Cease and Desist orders. (Refer to *FOOD.30.02 - Reinspection and Follow-Up Inspection SOP*).

6.5.5. Lift the Cease and Desist order when the owner has met or corrected the issue for which the Cease and Desist order was initially issued. Examples may include:

6.5.5.1. Issuing a license when the firm meets the requirements

6.5.5.2. Releasing a piece of equipment when it has been repaired or cleaned to a satisfactory condition

6.5.5.3. A process/method of production has been properly evaluated and it has been determined that it allows for the safe production of food

6.6. Condemnation – Perishable Foods

6.6.1. Condemn Perishable Food when:

6.6.1.1. They are found to be unsound, or contain any filthy, decomposed, or putrid substance, or that may be poisonous or deleterious to health or otherwise unsafe, AND

6.6.1.2. They are under conditions that require immediate action.

6.6.2. Conditions that require immediate actions include but are not limited to a vehicle/truck accident, fire, natural disaster, loss of power for extended periods of time, or other timely conditions with approval from FFSD Management. However when storage of a product is an option until a determination can be made, this alternative must be used.

6.6.3. Evaluate whether the items meet the criteria for being considered adulterated or misbranded based on language in MN Statutes 31.02 Prohibited Acts, 34A.02 Adulteration, and 34A.03 Misbranding.

6.6.4. Notify the owner/agent of their responsibility to arrange the method of destruction, transportation of product, etc. for condemned food items to ensure product is destroyed or rendered unsalable as human food. Options for destruction include:

6.6.4.1. Placement in a compacting garbage truck or dumpster

6.6.4.2. Placement in an open dumpster followed by application of a denaturing agent such as bleach, dye, or other appropriate chemical

6.6.4.3. Disposal in an approved landfill

6.6.4.4. Other methods when approved by a Supervisor, FFSD Management or Compliance Officer

6.6.5. Witness the destruction of the product to the extent possible and as necessary.

6.7. Condemnation – Non Perishable Foods, Equipment or Seized Articles

6.7.1. Condemn Non-perishable Food, Equipment or Seized Articles(s) when directed by a Supervisor, FFSD Management or Compliance Officer because the Court has found the item to be adulterated, misbranded (with no means for correction), or otherwise in violation of MN Statute 34A.

6.7.2. Evaluate whether the items meet the criteria for being considered adulterated or misbranded based on language in MN Statutes 31.02 Prohibited Acts, 34A.02 Adulteration, and 34A.03 Misbranding.

6.7.3. Notify the owner/agent of their responsibility to arrange the method of destruction, transportation of product, etc. for condemned food items to ensure product is destroyed or rendered unsalable as human food. These actions are at the expense of the owner/agent. Options for destruction include:

6.7.3.1. Placement in a compacting garbage truck or dumpster

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6.7.3.2. Placement in an open dumpster followed by application of a denaturing agent such as bleach, dye, or other appropriate chemical

6.7.3.3. Disposal in an approved landfill

6.7.3.4. Other methods when approved by a Supervisor, FFSD Management or Compliance Officer

6.7.4. Witness the destruction of the product to the extent possible and as necessary to ensure compliance.

6.8. Condemnation – Retail Food, Equipment, Utensils

6.8.1. Condemn products in a Retail Food Establishment (per MN Rule 4626.1810) that meets any of the following criteria:

6.8.1.1. Food, equipment, clothing or utensils the use of which does not comply with the Code or that is being used in violation of the Code,

6.8.1.2. Equipment, clothing or utensils that because of dirt, filth, extraneous matter, insects, corrosion, open seams, or chipped or cracked surfaces is unfit for use.

6.8.1.3. Examples of appropriate use of this retail authority include the following:

6.8.1.3.1. Date Marking 4626.0400 and .0405 – applicable food products were not date marked and the appropriate date cannot be determined or products were held past the date required in the code

6.8.1.3.2. Hot and Cold Holding 4626.0395 – applicable foods were found at a temperature significantly deviating from the required food code temperatures

6.8.1.3.3. Utensils –Condition 4626.0820 – food contact surfaces of preparation or serving utensils were pitted or scored resulting in a not easily cleanable surface

6.8.2. Consult with a Supervisor, Food Compliance Officer or FFSD Management by phone or email to confirm that a Condemnation is appropriate when the value of the product exceeds \$300.

6.8.2.1. The content of the notification should include all relevant data including name of the firm, cause, type and quantity of products involved, etc.

6.8.3. Evaluate whether the items meet the criteria for being considered adulterated or misbranded based on language in MN Statutes 31.02 Prohibited Acts, 34A.02 Adulteration, and 34A.03 Misbranding.

6.9. Sanitary Notice

6.9.1. Determine whether there is probable cause to issue the Sanitary Notice when violations meet any of the following criteria

6.9.1.1. Conditions or an event that represents an imminent health hazard.

6.9.1.2. Gross insanitary conditions.

6.9.1.3. Conditions that are or would allow for a food product to be contaminated or adulterated.

6.9.1.3.1. Food may be directly contaminated (e.g. rodent droppings on/in food).

6.9.1.3.2. Food may become contaminated due to contact with affected facilities, equipment.

6.9.2. Violations that may represent probable cause may include one or more the following:

6.9.2.1. Rodents, insects, birds or other vermin (dead or live) present in processing/food preparation areas, warehouse areas, retail sales/display areas.

6.9.2.2. Droppings/frass, urine, casts, or feathers of rodents, insects, birds, or other vermin.

6.9.2.3. Traps holding pests (indicating a possible infestation).

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- 6.9.2.4. Harborage conditions outdoors or in the facility.
- 6.9.2.5. Nesting material.
- 6.9.2.6. Pest access points into a facility (holes in walls, gaps under doorways, torn/missing screens).
- 6.9.2.7. Insanitary conditions (soiled food contact surfaces, non-food contact surfaces).
- 6.9.2.8. Filthy, equipment and/or facility.
- 6.9.2.9. Product abuse during production or storage that could lead to contamination from employees or environment.
- 6.9.2.10. Environmental neglect- inadequate maintenance, poor repair or inadequate sanitation.
- 6.9.2.11. Filthy, un-cleanable equipment and/or facility.
- 6.9.2.12. Product abuse during production or storage that could lead to contamination from employees or environment.
- 6.9.2.13. Waste water back-up in processing/prep areas, storage areas, or rest rooms.
- 6.9.3. When initial conditions are identified that may indicate the need to issue a sanitary notice, conduct a focused inspection of the facilities, equipment, etc. to ensure a complete evaluation of the situation has been determined.
- 6.9.4. Use professional discretion when considering the issuance of a sanitary notice. Consider the following questions when assessing the violations:
 - 6.9.4.1. Are conditions such that alone or in combination they create an environment that may adulterate the product?
 - 6.9.4.2. What is the proximity of the issue to the food, food equipment, and/or packaging material. Is the issue in a production/prep area vs a back storage area or break room?
 - 6.9.4.3. Has the operator taken care to maintain their facility through proper repair and cleaning?
 - 6.9.4.4. Are the employees acting in ways that are insanitary and could contaminate the product?
 - 6.9.4.5. The number/amount of pests, droppings, etc.
 - 6.9.4.6. Is there an active rodent or insect infestation or do conditions indicate it occurred in the past?
 - 6.9.4.7. Is it an isolated incident or pattern?
 - 6.9.4.8. Is the operator being proactive?
 - 6.9.4.9. The availability of the issuing inspector to conduct the reinspection should NOT be a determining factor.
- 6.9.5. Consult with a Supervisor (primary contact), Compliance Officer or FFSD Management by phone or email to verify that probable cause has been established prior to a sanitary notice being issued.
 - 6.9.5.1. The content of the notification should include all relevant data including name of the firm, probable cause, conditions found, products affected, etc.
- 6.9.6. Collect evidence as documentation of the probable cause. Such evidence may include:
 - 6.9.6.1. Photographs or videos (refer to *FOOD.WI.30.59 - Documenting Digital Photographs-Video Evidence-Manufactured Foods WI* or *FOOD.WI.30.62 - Documenting Digital Photographs-Video Evidence-Retail Food WI*)

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6.9.6.1.1. Conditions that supported the probable cause, such as droppings, dead or live pests (rodents, insects, birds), gnawing on packaging or facility, insanitary equipment/facilities.

6.9.6.1.2. Food products that are or could potentially be affected.

6.9.6.1.3. Photographs are to be taken to clearly indicate the pest or other insanitary condition but also to provide an indication of the facility and location within the facility.

6.9.6.2. Samples that support your observations.

6.9.6.2.1. Dead Rodents (dead rodents need not be collected when a photograph clearly depicts a rodent)

6.9.6.2.2. Insects (insects are not to be shipped/delivered in a live condition to the lab)

6.9.6.2.3. Packaging material (gnawed, urine stained)

6.9.6.2.4. Rodent droppings

6.9.6.2.5. Insect frass or eggs

6.9.6.2.6. Nesting material

6.9.7. Evaluate whether the items meet the criteria for being considered adulterated or misbranded based on language in MN Statutes 31.02 Prohibited Acts, 34A.02 Adulteration, and 34A.03 Misbranding.

6.10. Sanitary Notice Reinspection

6.10.1. Conduct the reinspection no sooner than 2 days (48 hours) from the day and time of issuance to day and time the reinspection begins.

6.10.2. Evaluate compliance with each order for which the compliance date has passed to determine if you are able to clear the orders associated with the sanitary notice. If yes, the sanitary notice is cleared/considered in compliance.

6.10.2.1. Document on the inspection report in the comment section that the sanitary notice was complied with and the date.

6.10.2.2. Describe details as to the actions the firm took to come into compliance (cleaning, daily pest inspection, hiring a pest control professional, etc.).

6.10.2.3. Photographs may be taken of same areas that showed violations previously to depict how the firm complied with orders issued.

6.10.3. If the any of the orders associated with the sanitary notice are not in compliance, then the sanitary notice is not cleared/complied with.

6.10.3.1. Take photographs to document current conditions, with preference for conditions/locations that were noted on the initial inspection.

6.10.3.2. Evaluate if further field compliances actions need to be taken.

6.10.3.3. Contact your supervisor or compliance officer to inform of the non-compliance and discuss options to obtain compliance, possible additional field compliance actions and/or further enforcement actions.

6.10.3.4. Reissue orders not in compliance including the Sanitary Notice order. Refer to section 6.12.3.5.

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6.10.3.4.1. Write observation statements that document current conditions and actions taken by the firm.

6.10.3.4.2. If previously issued, do not reissue Cease and Desist order(s) – state in the published comments that the Cease and Desist order is still in place.

6.10.4. Reissuance of a Sanitary Notice requires another Reinspection. Follow the applicable USAFS Guidance/WI for documenting further actions.

6.10.5. Additional reinspections are conducted until compliance is confirmed. Additional field compliance actions and/or enforcement actions must be considered to ensure public health and utilize progressive enforcement. Refer to *FOOD.60.10 – Enforcement Trigger and Assessment SOP* for referral to compliance information.

6.11. Other Remedies

6.11.1. Witness the firm making appropriate corrective actions when directed by the Supervisor, FFSD Management, or Compliance Officer because the adulteration or misbranding can be corrected. Remove any identify marks such as embargo tape, tags, or stickers.

6.11.2. If the product is in such condition that it could be salvaged or be used as an animal food/feed, contact a Supervisor, for further instructions.

6.11.3. When the firm determines that they will voluntarily destroy products, follow documentation requirements in *FOOD.30.05 – Inspection Report SOP*.

6.12. Reporting

6.12.1. Complete an inspection report in USAFS following applicable USAFS Guidance/WI and *FOOD.30.05 Inspection Report SOP*.

6.12.2. Issue orders that reflect the proper regulatory authority for the action being exercised.

6.12.3. Document observations for the issued order(s). Additional action specific guidance for observation statements is as follows:

6.12.3.1. Embargo or Seizure

6.12.3.1.1. Include the probable cause, a description of any evidence that supports the order. the specific location where product is being held , truck seal numbers, etc.

6.12.3.1.2. When a field of a food crop, an entire facility, or geographic area are embargoed, include a detailed description of the product, field, facility, or area.

6.12.3.2. Release of Embargo

6.12.3.2.1. Include the outcome or reason for the release of the embargo. Any evidence that supported the determination must be referenced or described.

6.12.3.2.2. When products are not found to be adulterated or misbranded, include a statement that they are released for normal use

6.12.3.2.3. When products are found to be adulterated or misbranded include statements regarding disposition of the product.

6.12.3.3. Cease and Desist

6.12.3.3.1. Include the justification or probable cause for the order including a description of any evidence that supports the order.

6.12.3.3.2. When the Cease and Desist is lifted, document orders complied with or other evidence of correction observed or collected from additional inspections.

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6.12.3.4. Condemnation

- 6.12.3.4.1. Describe the conditions or incident that occurred that led to the product becoming adulterated, the method of destruction, landfill location, waste disposal company, and statements regarding witness of the destruction/disposal.

6.12.3.5. Sanitary Notice

- 6.12.3.5.1. Issue applicable orders using the proper regulatory authority (MN Food Code or GMPs). Examples by program area may include:

GMP Citations

- 110.35(a) Sanitation of physical facilities
- 110.35(c) Exclude all pests from the establishment
- 110.35 (d) Sanitation of food contact surfaces
- 110.35 (d)(3) Sanitation of non food contact surfaces

MN Food Code Citations

- 4626.0840 Equipment, Food-Contact Surfaces, Non-Food-Contact Surfaces and Utensils
- 4626.1520 Maintain physical facilities in a clean condition
- 4626.1565 Eliminate all pest harborage conditions
- 4626.1570 Remove dead or trapped animals and pests from the premises
- 4626.1580 – Maintaining Premises; Unnecessary Items and Litter

- 6.12.3.5.2. In the observation statement for each order, describe the findings that are relevant to the sanitary notice. Examples may include:

- a. Approximate numbers/quantify observed. Example: 50-100 suspect rodent droppings, “flies too numerous to count”
- b. General description of what was observed, i.e., Suspect rodent droppings, what appear to be gnawed packages, dried on food residue, food contaminating insects
- c. Specific locations where the violations were observed. Example: on the sheeter belt, in stored clean equipment, in, on, and adjacent to food contact surfaces, floor in the NW corner of the rear storage room
- d. Make reference to whether it appears that there is an “active pest infestation” if live insects, rodents or fresh droppings are found

- 6.12.3.5.3. Issue the Sanitary Notice order (under Item 57 MS 31.161, 31.165 in USA FS). In the observation statement, reference the violations cited that are associated with issuance of the Sanitary Notice see 6.12.3.5.1 above

Example: Under the authority of Minnesota Statutes sections 31.161 and 31.165, you are notified that filthy, unclean, insanitary conditions exist in the premises and are issued a Sanitary Notice. You are required to place the premises in a clean and sanitary condition by complying with the sanitation orders cited as follows: 21 Code of Federal Regulations (CFR) 110.35(a)- Physical facility cleaning; 21 CFR 110.35(c)-Removal of pests; and 21 CFR 110.35(d)(3)- Non-food contact cleaning, and referenced in this report. (Observed the following:

A. Suspect rodent/mice droppings were observed under the taproom bar prep area. Sample #3 was collected on 11/2/16.

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B. Suspect rodent/mice droppings were observed on bags of packaged organic sugar and pure sugar in the warehouse. See Voluntary disposal MS 31.09, 34A citation and product disposal section.

C. Suspect rodent gnawing of two partial bags of malted grain/barley in the maintenance area.

D. Suspect rodent/mice droppings were observed on the floor under the fermentation tanks; behind the stills and distillery equipment; and on wheeled racks for stainless steel product barrels; and under and amongst a grain mill for display in the production room.)

6.12.3.5.4. When a Sanitary Notice is not complied with,

- a. Re-write applicable violations that were not corrected, including GMP, MN Food Code and the Sanitary Notice order.
- b. Indicate as a repeat order, do not issue a new compliance date

6.12.4. Document any evidence collected in the observation statement or published comments section, e.g. records, labels, samples or photographs taken, that will support the probable cause or assist in making a determination as to whether the product is adulterated or misbranded.

6.12.4.1. Include any statements from other agencies or statements from employees or managers about conditions that were observed.

6.12.4.2. Include statements made to owners when embargoed products are released for normal use (Refer to 6.2.3)

6.12.5. Attach any evidence related to the field compliance action to the inspection report using the following guidance:

6.12.5.1. Photographs or videos must be collected, saved and documented per *FOOD.WI.30.59 - Documenting Digital Photographs-Video Evidence-Manufactured Foods WI* or *FOOD.WI.30.62 - Documenting Digital Photographs-Video Evidence-Retail Food WI*.

6.12.5.2. Documents collected at the firm are to be scanned and uploaded as an attachment e.g. invoices, production or sanitation records, bills of lading, filed processes, procedures, HACCP plans, sample reports, etc.

6.13. Communication

6.13.1. The Supervisor will provide further notification to Retail Food or Manufactured Food Program area, or FFSD Management based on the quantity of product, reason for the embargo or condemnation, or sensitivity of the issue.

6.13.2. The Supervisor, Compliance Supervisor, Retail or Manufactured Food Program Manager, or other member of FFSD Management is responsible for notification to Department Counsel, Commissioners Office and/or other agencies, such as FDA, USDA, MDH, local health agencies, DPS/Homeland Security, FBI, etc. dependent on the situation.

7. RELATED DOCUMENTS (includes References, Attachments):

USAFS Guidance/WI

FOOD.30.01 – Inspection Protocol – Food Manufacturing

FOOD.30.02 - Reinspection and Follow-Up Inspection SOP

FOOD.30.05 - Inspection Report SOP

FOOD.WI.30.59 – Documenting Digital Photographs-Video Evidence-Manufactured Foods WI

FOOD.WI.30.62 – Documenting Digital Photographs-Video Evidence-Retail Food WI

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FOOD.30.23 – Investigation Sampling-Inspector Initiated SOP

FOOD.30.32 – Response, Complaint, and Enforcement Sampling SOP

RESP.50.06 - Communication with the Public SOP

FOOD.60.10 – Enforcement Trigger and Assessment SOP

8. EQUIPMENT/MATERIALS NEEDED

Embargo tape, tags, truck seals

Sampling supplies

Digital Camera or iPhone

USAFS electronic inspection system

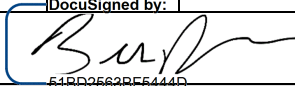
9. SAFETY

All MDA employees must follow the personal protective equipment requirements and field safety guidelines outlined in the initial and annual Food Inspector safety training. Never enter an area or perform any job task that you think will result in injury or illness. If you do identify any unsafe conditions – STOP the inspection immediately and consult with the facility management or your supervisor regarding a corrective action for the hazard(s). Lastly, stick to the specific focus of your position and as always – THINK SAFETY!

10. CIRCULATION

This document is circulated to the following: food inspection staff, food inspection supervisors, compliance officers, compliance supervisor, food program manager, compliance program manager, and RRT staff. The current version will be stored electronically on the FFSD document control site.

11. APPROVAL/DOCUMENT HISTORY

Document History		
Version #	Status (I, R)	Change History
1	I	Initial Policy Drafting.
2	R	Addition of Sanitary Notice to the procedure; addition of field compliance actions definition; removal of Voluntary Destruction; added reference to applicable Food Program photograph collection work instructions; added language to each field compliance action section regarding determination of adulteration or misbranding or product; added equipment to section 6.7-Condensation; removal of Attachment A from the document.
DocuSigned by:  <small>548D2563BF6444D...</small>		1/3/2017
Approved By:		Date
Approved By:		Date

I = Initial document; R = Revised document