

**Best Practices
For
Raw Ground Products**

**For
National Meat Association
Southwest Meat Association
American Meat Institute
National Cattlemen's Beef Association**

**Facilitated by:
Department of Animal Science
Texas A&M University
College Station, Texas**

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National Meat Association is pleased to be joined by the Southwest Meat Association, the American Meat Institute and the National Cattlemen's Beef Association in the development of these Best Practices for Raw Ground Beef Products. Leading manufacturers of ground beef met in April in Texas and under the guidance of Dr. Kerri Harris of the Department of Animal Science at Texas A&M University developed the information for these Best Practices, using Guidelines developed by National Meat Association in March 1998 as a starting point.

The operating practices at every company may vary slightly from these Best Practices, depending on differing operating situations. Producers of ground beef are urged to consider these Best Practices as guidelines for their own internal practices and documentation.

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Best Practices for Raw Ground Products

Introduction:

Producers of raw ground, including ground beef, products recognize that these products have an inherent food safety risk due to the nature of the process and the lack of a sufficient “kill” step for biological hazards in the process. Therefore, it is extremely important that grinders implement Best Practices to produce the safest products possible by increasing total process control throughout the grinding operation.

This document provides guidelines for grinding operations and can be used by establishments to develop plant specific programs. The guidelines are designed to provide a recommended set of practices and procedures that processors may want to adopt in their entirety or in part to ensure optimal quality and food safety. It also addresses the issues of designing an effective lotting system and reprocessing ground products. These recommendations focus solely on the grinding operation. It should be noted that the following items are not addressed in this document, but they should be covered by existing Sanitation Standard Operating Procedures (SSOPs) and/or other plant-specific processing programs.

- Personnel — disease control, hygiene, clothing, training, etc.
- Plant and grounds — construction and design, product flow, drainage, etc.
- Sanitary operations — general maintenance, cleaning and sanitizing, pest control, etc.
- Sanitary facilities and controls — water supply, plumbing, sewage disposal, rubbish and offal disposal, etc.
- Freezer and coolers — monitored and maintained to ensure temperature control, recording devices, alarms, etc.
- Equipment maintenance and calibration — adequate frequency for thermometers, recording devices, compressed air equipment, etc.

Many of the items listed above are also addressed in 21 CFR Part 110 – Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Human Food (Attachment A) – which was developed by the Food and Drug Administration and can be used as a resource if more information on any of these areas is needed.

The Grinding Process:

Although the grinding process will vary from establishment to establishment, this document includes a variety of flow charts. These flow charts are for examples only and should be modified as needed to match the establishment’s actual process flow. (Attachment B)

LOTTING

All grinding operations should have a lotting mechanism for coding and recording finished products to allow for tracing the product back through the system and for tracing the product forward through the chain. Some establishments may develop computerized bar codes or tracking systems that are very elaborate and detailed, and others may have simple handwritten documentation and box/package codes. Lotting is driven by some time factor (i.e., hour, shift, day, etc.) and is given a specific identification code. Creating smaller lots or utilizing a sub-lotting system for tracking information may help demonstrate/document process control and could possibly help minimize the economic impact of recalls.

Regardless of the mechanism each operation should have a record keeping system, and it is recommended that the following items be documented for each identified lot/sub-lot.

- Raw material source(s) by vendor, including vendor lot identification, time used
- Data collected during process (temperatures, microbial data, etc.)
- Metal detector records, if used
- Equipment evaluation records (i.e., grinder checks)
- Bone collection records
- Other items as specified by individual customers

If any abnormal indicator is found during the process then it is recommended that the product be segregated, that cleaning and sanitizing of the processing line be completed prior to reinitiating production, and that a new lot /sub-lot be started when product begins.

The concept of lotting systems in ground beef operations is a complex and detailed issue. The existing USDA definition for a lot, when there is a positive result for *E. coli* O157:H7, is “from full sanitation to full sanitation.” As a best practice, carry-over from one day’s production should not be reintroduced into later production dates because this can increase the amount of product implicated if there is a problem. In most commercial grinding operations this definition affects a full day’s production. However, proper documentation and controls (including product testing) may allow products to be sub-lotted under this definition to minimize the amount of affected products. For example, sampling product every 15 minutes and testing specifically for *E. coli* O157:H7 may allow the day’s production to be broken into sublots.

Sub-lotting under the context of the definition described above, as a result of microbial testing, requires the following types of documentation:

- Batching records — These records should identify the types of raw materials used by its tracking codes; the amount used in each batch of formulated product, the time it was used and the locations of equipment/lines it was used on.
- Packaged product tracking systems — The finished products should be coded with the actual times they are packed and sealed and pallets of product should contain consecutive products off the line. Packaging systems with multiple lines should have a consistent flow of raw materials to each packaging line and the ability to code and identify products from a specific line. Downtime tracking sheets can be used to

- identify lines that were not packaging products at the time of suspect incidents and therefore create a break in the flow of products through the system.
- Microbiological testing and tracking — If a company is sampling and testing finished formulated raw materials from each batch for potential microbial adulterants, then it should include the batch number samples, the time of the sample and a protocol tracking form for submission to the laboratory used for analysis. It is extremely important that an establishment clearly identifies and understands what lots/sub-lots are represented by the sample being tested.
 - Finished Product “Test and Hold” Programs — If a company is testing finished ground products for potential microbial adulterants, then it should require all of the product to be held until laboratory testing is completed and the results are available. Records for operations should include the total amount of products produced as well as their locations.

Utilizing the guidelines provided above will allow companies to better identify and document the amount of suspect or affected product. For example, if one composite sample for formulated products tested positive for *E. coli* O157:H7 during a day’s production where all other composites tested negative, then the information discussed above may provide added assurance to USDA Inspectors that sufficient controls were in place to minimize the amount of product affected.

Sub-lotting can also be used for other potential contamination such as a physical contaminant. Sub-lotting for physical contamination will require the following:

Batching records — These records should identify the types of raw materials used by its tracking codes, the amount used in each batch of formulated product, grinder head, the time the batch was formulated, the cleaning and inspections by authorized representatives.

In-process Control Records — These records should identify the types of control checks performed on metal detectors and other control instruments, the time checks were performed and the line and/or product code information.

An example of a lotting system that could be used for ground beef is provided in Attachment C.

REPROCESSED PRODUCT

During the development of these guidelines, the issue of reintroducing broken/misshapen patties or ground product, over-run at the end of the day, rework, etc. back into the processing flow was identified as an area that should be fully addressed by grinders. For the purpose of this document, a lot was defined as the finished product and a batch was defined as material that is in-process. The following categories are recommended to help distinguish between the types of raw materials being reintroduced and the points of entry into the grinding operation.

1. Intrabatch materials — These are raw materials that are maintained within the same batch. It should be covered by the actual flow diagram and a specific SOP should be written to document the procedure(s) for these activities. For example, the formulation of ground beef requires that raw materials be analyzed for chemical composition (%fat-lean). This is a part of the actual process of making the ground beef; therefore, the raw materials used for the analysis should remain within the same batch.
2. Product over-run — These are excess raw materials at the end of a production period that are not in the final product form. The optimal situation is to eliminate product over-run by controlling the amount of raw materials needed to meet the desired production levels. Unfortunately, this is not always a realistic option. Therefore, the following recommendations are being provided to address product over-run:
 - Direct the product to further processing — cooking process, identify/specify product for cook only.
 - Utilize the product to produce a designated batch/lot — Combine the raw materials and other intrabatch or over-run ground product for a specified time-period and process at the end of a shift or on a specified day as a designated batch/lot. (If this option is utilized, then one must accept the risk that if a problem is found in the designated batch/lot then all of the batches/lots that contributed to the designated batch/lot are subject to review. It will be imperative that a very detailed and accurate record keeping system is developed to document amounts and identify all of the batches/lots that were used in the designated batch/lot.)
 - Destroy the product.

It is also noted that product(s) remaining at the end of a day or due to line failure during the day that cannot be processed on the same day should be treated as above.

3. Returned and reinspected product — The optimal situation is to eliminate the need for products being returned after they leave the establishment. Unfortunately, this is not always a realistic option. For example, a shipment of frozen patties may be returned because the patties have stuck together. The product is still safe for consumption but

it does not meet the customer specifications and is returned. Therefore, the following recommendations are being provided to address returned and reinspected products:

- Direct the product to further processing — cooking process, identified/specified product only.
 - Identify a customer and sell the product to them for further processing.
 - Destroy the product.
 - Utilize the product to produce a designated batch/lot — Combine the raw materials for a specified time-period and process at the end of a shift or on a specified day as a designated batch/lot. (If this option is utilized, then one must accept the risk that if a problem is found in the designated batch/lot then all of the batches/lots that contributed to the designated batch/lot are subject to review. It will be imperative that a very detailed and accurate record keeping system is developed to document amounts and identify all of the batches/lots that were used in the designated batch/lot.)
4. Interlot reprocessing. This allows the establishment to reprocess a batch over a designated time period (i.e. – shift) to allow an out-of-spec batch or other ground product to be used on the same day’s production. If product is added from an out-of-spec batch into other batches/lots during the day, then all products produced that contain the out-of-spec product are subject to review if a problem is found with any of the final batches because it may be impossible to distinguish if the problem is from the out-of-spec batch or from the batch that it was added to. Therefore, it will be imperative that detailed and accurate records documenting the amount of out-of-spec product used, the batches/lots that it is used in, and clear breaks in the process (i.e., clean-ups) are maintained.

The recommendations provided above should help an establishment make decisions relating to the reprocessing of products. Each establishment will need to carefully consider the options and determine which one works best within their operation based on amount of production, opportunities for further processing, etc. Each establishment is encouraged to develop written procedures for how it will handle these issues.

BEST PRACTICES

The following guidelines for developing best practices for grinding operations are recommended for voluntary consideration and use in developing plant-specific procedures. These are not designed to control specific food safety hazards, but are intended to provide useful information to help grinders produce safe and wholesome products.

Raw Material Source:

Grinders should encourage/support further actions at all sectors of the industry (from animal production to consumer) to reduce microbial contamination and foodborne illness. This is especially important for ground beef and the control of *E. coli* O157:H7. The responsibility for safe food depends upon all sectors working together to produce the safest food possible for consumers. Grinders are responsible for outlining the requirements for raw material suppliers and for establishing a procedure for verifying that all of the requirements are implemented and working as designed. From a grinder's perspective, there are three points that should be considered in selecting suppliers for raw materials for ground product(s).

A. Process Interventions and/or Controls for Food Safety

1. HACCP

Grinders should ensure that the supplier has a HACCP program that meets all regulatory requirements and has been validated to control the food safety hazards identified as reasonably likely to occur. Grinders should verify that these programs are in place and implemented appropriately.

2. For Beef, the following items are specific to *E. coli* O157:H7

a. Raw material suppliers should have validated process interventions and/or validated Critical Control Points (CCPs) in place to prevent, eliminate or reduce *E. coli* O157:H7 to a non-detectable level. Validation may include scientific literature and/or plant specific validation using indicator organisms, and it should be specific to the process(es) being applied at the establishment. This can be incorporated into the grinder's purchase specifications or other plant programs to ensure that all raw materials are produced using validated CCPs or process interventions. This is true for both domestic and imported suppliers of raw beef to be used in ground product(s).

b. It is also important for beef grinders to have specific data on *E. coli* O157:H7 to support the position taken during the hazard analysis as "not reasonably likely to occur." These data must relate to the raw materials and/or finished product(s).

B. Foreign Material Contamination:

Grinders should track unacceptable inclusions, indigenous and foreign materials, found in raw materials to help identify trends in suppliers. These findings should be shared with the supplier to help them improve their process, and may be a factor in supplier selection for future orders. This should be included in

specifications to the supplier outlining items that are not acceptable in the raw materials.

C. Testing / Prescreening Requirements:

1. Sampling and testing for *E. coli* O157:H7
There should be a written protocol for sample collection, lab analysis and proficiency testing, as well as the procedures for reporting the results. It is very important that the supplier and the customer fully understand, with back-up documentation, what the sample represents (i.e., a single combo, a composite of 5 combos, an entire trailer load, etc.), and the steps to be taken in the event of a positive. Communication is extremely important for reporting the test results if the product is being transported to the customer while the test is pending to ensure that all positive product is handled according to the plant's written protocol.
2. Other microbiological Testing (*Salmonella*, APC, TPC, coliforms, etc.)
As above, there should be a written protocol for sample collection, lab analysis and proficiency testing, as well as the procedures for reporting the results. It is important to establish how the results will be used before data are collected. Most of these microbiological tests are used for tracking supplier trends over time; however, each establishment must clearly define how they are going to use the information and the consequences of failing to meet the testing requirements.
3. In-plant microbiological testing
If a grinder elects to conduct his/her own testing of raw materials and/or finished product, then he/she should notify the supplier because the results may impact the supplier's production and distribution of product.

Supplier Evaluations:

Raw material suppliers are critical to both food safety and quality aspects of producing ground products. Therefore, it is important that each new supplier is approved prior to using their products, and that there is a procedure for evaluating on-going suppliers. The following guidelines can be utilized to help design a system for evaluating suppliers.

A. New Supplier Approval:

1. Each new supplier should provide written acknowledgement of the grinder's purchase specifications and willingness to comply.
2. Each supplier should meet the guidelines outlined in the purchase specifications for microbial testing and profiling. For new suppliers a grinder may want to establish an intensified sampling program to determine if the supplier can consistently meet the specifications.
3. Each supplier should have a plant audit conducted on a specified frequency to ensure compliance with the purchase specifications and other programs. The audits may be conducted by the grinder or by a third-party auditor. The audit requirements should be provided to the supplier as part of the purchase specifications.

4. Grinders should conduct quality inspections of incoming materials to ensure that they are acceptable. For new suppliers a grinder may want to intensify the sampling frequency to ensure consistency in meeting the requirements.
- B. Ongoing Suppliers:
1. Grinding operations should periodically provide an update of the purchase specifications to each supplier and request on updated acknowledgement of receipt of the specifications and a willingness to comply.
 2. Data should be collected and tracked on the following items to identify supplier trends and help make purchasing decisions:
 - a. Microbial profile data — may include, but not limited to: *Salmonella*, *E. coli* O157:H7, generic *E. coli*, Total Plate Count (TPC), Aerobic Plant Count (APC), and coliforms.
 - b. Foreign object contamination
 - c. Defect(s) (unacceptable indigenous inclusions)
 - d. Plant Audits Results
 - e. Age of Product at receipt
 - f. Temperature of Product at receipt
 - g. On-time Delivery
 - h. Other plant-specific requirements

Pre-Receipt of Raw Material(s) Verification:

Based on all of the purchase requirements and plant specifications, it is important that a system of checks and balances are put in place to verify that the supplier is conducting their program as planned. This verification process will help minimize problems and increase the integrity of the entire supplier purchasing program.

A. Negative Pre-Screen for *E. coli* O157:H7

The best practice is to have a negative *E. coli* O157:H7 test result from the laboratory or the supplier prior to opening the trailer. This should include all documents related to product identification, written notification of the test results, bill of lading, seal number on load, if applicable, and other identification and tracking information.

If the product must be removed from the trailer prior to receiving the written negative test result, the plant must have written and documented procedures for off-loading, tagging and holding all of the product to ensure that it is not used prior to receiving the negative test result for *E. coli* O157:H7. This will require good tracking documentation procedures and sufficient training of all employees involved in both receiving and production to prevent the use of the product. The establishment should also have a procedure for handling the product if the test result is positive.

B. Seal integrity (security)

The optimal process is to seal the truck and have one delivery stop; however, this is not always possible. If the delivery will include multiple stops, then there should be a procedure for re-sealing the load and a tracking system for each seal

placed on the truck. This process will help maintain product integrity and security.

Receipt of Raw Material(s):

Receiving Meat

Incoming raw meat materials should be evaluated to ensure that they meet the plant-established purchase specifications. Trucks, containers and carriers of raw materials should be evaluated upon receipt to ensure that the conditions meet plant requirements for transporting meat. All containers/cartons should be intact. All incoming meat should be coded/identified for plant use and for the in-plant tracking system. Product tracking for fully cooked, non-intact products, etc. to verify intended use of product to ensure that product on truck matches product identified on invoice and product identified on microbiological test results, if applicable.

Specific items to consider:

1. Designated employees should verify that the raw material is from a company-approved supplier. Each plant should set supplier requirements and maintain a list of approved suppliers.
2. Designated employee should evaluate and document on a product receiving log the condition of the trailer, shipping container(s), and carriers of raw materials upon arrival, and should document the time the inspection was conducted. Items for evaluation may include:
 - Cleanliness of trailer — no foreign materials, dirt, free of debris, free of off odors
 - Temperature of trailer —temperature of the trailer must be acceptable to maintain product temperature. Plant may set a specific temperature for the product and/or the trailer as part of the purchasing specifications. If specific temperatures are set, then there should be a written procedure that defines the action(s) that will be taken if the temperature does not meet the specification.
 - General trailer condition — void of cracks, insulation in good condition, trailer door is sealed properly, paper on floors for carcass carriers, etc.
3. If the truck condition is acceptable, the designated employee should verify that the incoming material matches the plant purchase specifications and/or required documentation is provided with the load. The following items may be included:
 - Species identity and/or origin (bull, cow, etc.)
 - Domestic vs. foreign supply source
 - Institutional Meat Purchase Specifications (IMPS) or other product identity
 - Boning date/ slaughter date
 - No foreign objects
 - Verification of intended use — verify product and combo identification matches the product ordered and the bill of lading, including the proper match for product and test results.

- Supplier microbiological testing results, if required. If the supplier is required to test for *E. coli* O157:H7, then the material should not be used until the test results are received. If the supplier is testing for generic *E. coli*, coliforms, TPC or other microorganisms that can be used to establish supplier trend data, then the product does not have to be held until the results are received. However, if specific accept/reject levels are set for any specific microorganism then the product should not be accepted or it can be placed on hold until the test results are received.
 - Packaging/pallet requirements — i.e., no metal fasteners or bands, pallets in good usable condition, slip sheets, covers on combos, plastic pallets, etc. It is important that package integrity is maintained and documented.
 - Age of raw material — recommend fresh products ≤ 5 days from fabrication; and frozen meat no more than 6 months from fabrication.
4. If the product meets the purchase specifications, then the designated employee should evaluate the actual condition of the raw materials. The following items are recommended for evaluation:
- Temperature of raw materials (i.e., frozen $<10^{\circ}\text{F}$; fresh $<40^{\circ}\text{F}$). Each operation should have a separate procedure for taking the temperature of incoming product and calibrating thermometers. Recommend both core and surface temperatures of the product.
 - Organoleptic evaluation of raw material for off odor, discoloration, improper appearance.
 - Material must have supplier code information and proper lot/load identification on materials.
5. If incoming raw materials pass the receiving inspection, then all raw materials should receive plant specific tracking/coding information prior to entering the storage or product facility.

Non-meat Items

Grinding operators will need to make sure that all non-meat items, such as packaging materials, seasonings/spices, etc. meet the plant-established specifications. USDA currently requires companies to have a Letter of Guarantee (LOG) from suppliers of non-meat ingredients relating to the use of food grade substances, foreign materials, pest control programs, etc. After the company accepts the non-meat items, then these items should be stored, handled and used in a manner that will maintain the integrity of the items.

Purchase specification and acknowledgement for non-meat and non-meat ingredients may included: 1) continuing letter of guarantee to document compliance with the Food, Drug and Cosmetic Act and specific CFR standards; 2) feed ban compliance; 3) humane handling; etc.

Storage of Raw Material(s):

Raw materials should be used on a First-In/First Out (FIFO) basis or according to a plant specified product rotation/inventory control schedule. Raw materials should be stored at temperatures that maintain proper product condition – temperature, integrity, etc. Frozen materials should be kept frozen, unless tempering or thawing is required prior to use. The packaging/pallet integrity must be maintained throughout the storage period to maintain the condition of the raw materials. Product identity in storage should allow for proper in-plant tracking system.

Specific items to consider:

1. For shelf-life purposes place fresh product into cold storage (i.e., $\leq 40^{\circ}\text{F}$) and frozen product into freezers (i.e., $\leq 10^{\circ}\text{F}$).
2. Complete plant specific storage records or product identification, so product will be used on a FIFO basis or according to plant product rotation/inventory control schedule.
3. Utilize all fresh product within 7 days of fabrication. Utilize all frozen product within 6 months of fabrication.
4. Store products to maintain package/pallet integrity. It is recommended that combo bins have a protective covering (second cover) if they are being stored in racks and that the protective covering should be removed prior to entering the processing area where the primary covering is removed.
5. Storage conditions should be maintained according to pre-requisite program requirements to ensure product integrity during storage.
6. Plant security should address raw material and finished product storage areas. Lock and/or secure areas during periods when the plant is not operating, if possible.

Raw Material Processing:

Tempering/Thawing of Frozen Materials

If tempering or thawing is required prior to use, then it should be done in a time/temperature controlled manner which is adequately monitored and documented and verified. The product package integrity is important during this process. The product's traceability should be maintained throughout the tempering/thawing process. It is advisable to have a written program that outlines specific guidelines or procedures.

Specific items to consider:

1. Place frozen product in a tempering room that is $\leq 40^{\circ}\text{F}$ and allow product to reach desired level of tempering or thawed state; actual time will vary depending on amount of product and type of packaging. (If the room temperature is higher than 40°F then one must evaluate the time/temperature relationship to reduce the risk of potential

- microbial growth on the surface of the product.) You may want to consider air temperature and velocity to ensure proper thawing.
2. The product should be monitored on a scheduled basis to prevent degradation of the package integrity and minimize product drip.
 3. The product temperature should be monitored on a scheduled basis to ensure that the desired end temperature is not exceeded.
 4. All of the products should maintain the plant-specific tracking/coding information to ensure proper traceability of product from receiving through to final end products.

Grinding/Processing Records

These documents includes weighing, mixing, blending, coarse and final grinds, forming, packaging, and labeling and other plant specific aspects of the process. Throughout all of these steps the temperature of the product should be maintained and documented. Steps should be taken to prevent species cross-contamination and proper labeling to maintain end-product identity. An organoleptic evaluation of the raw material ingredients should be completed during pre-grind and prior to adding the ground meat to the batch. The ingredients should be evaluated for chemical composition (%fat and lean) to formulate product to desired endpoint. Procedures for ensuring proper endproduct characteristics (i.e., weights, size, shape, quantity, etc.) should be in place. The in-plant tracking mechanism should allow for batch identification and time of batch production.

Specific items to consider for grinding:

1. Prior to entering the production process, grinders should ensure that negative *E. coli* O157:H7 results have been received, if the raw material was subjected to testing.
2. Inspection of raw materials prior to grinding use an AQL program or some process for evaluating the raw materials. (See example program in Attachment D).
3. Formulation of the product should utilize a batch sheet to document batch identification and includes raw materials used, specific weights and amounts, fat percent, etc. The formulation documentation should address quality characteristics, product specifications, and traceability both forward and backward in the production system.
4. Temperature monitoring of the room and ground product to ensure integrity. The room temperature should be controlled and the actual time of processing should be as fast a possible to maintain product integrity during production. A target of $\leq 50^{\circ}\text{F}$ for the processing room is most often used and records of actual room temperatures should be maintained.
5. Defect inspection and elimination systems should be used when possible for bones, metal, etc.

6. Rework, reprocessing of intra-batch or product over-runs must at all times have appropriate identification and tracking for traceability purposes.
7. Target end-product temperatures commonly used for ground products are: $\leq 32^{\circ}\text{F}$ for forming fresh products; $\leq 35^{\circ}\text{F}$ for spiral/tunnel freezing chubs, and $\leq 10\text{F}$ for IQF patties. During processing, these temperatures may be exceeded for brief time periods, but each establishment should carefully evaluate and control time and temperature.
8. Production employees should complete an evaluation of the equipment, including a breakdown of the equipment (grinders – plates and blades, defect eliminators, metal detectors, etc.) on a scheduled basis and the time of each evaluation should be recorded. It is important that this is performed throughout the shift, and that this information is reviewed prior to releasing the finished product. This will help minimize the risks associated with equipment malfunctions that can impact the product. An establishment may want to include a review of the records associated with the equipment breakdown as part of their pre-shipment review to ensure that everything was working properly and there were no problems.

Interventions/Inhibitors:

There are some technologies currently available that can be applied on raw materials and utilized in a grinding operation. Research is currently being conducted to identify scientific technologies that may be useful for the treatment of trimmings prior to grinding, as well as the use of ingredients to inhibit microbial contamination and oxidation. Other available options and those currently being explored involve the treatment of the finished product. Grinding operators should explore the use of new technologies as they become available. Appendix E provides a list of approved interventions as of the date this document was published.

Packaging/Labeling:

It is important that the finished product is properly packaged and labeled to protect the integrity of the product and to provide appropriate handling and cooking instructions to the consumer.

Specific items to consider:

1. Package material must be approved for use with food.
2. Package material must protect the finished product.
3. The product identification/tracking mechanism should identify specific processing lines used to produce this finished product. This may help narrow the product impacted if there is a problem with a particular processing line that does not impact the other lines.
4. Packaging and labeling employees are responsible for properly labeling end-products with product identity and code dates that include an expiration date, sell-by-date, use-

- by-date, production date and time, using a dating system according to company procedures.
5. Packaging and labeling employees are responsible for including all safe handling and storage information according to each product's requirements, as well as specific cooking instructions.
 6. Bar coding is an option that can be used to help with the product identification and tracking.

Storage of Finished Product:

Finished products should be stored at plant designated time/temperatures to maintain product shelf-life. Frozen product should be kept frozen. A FIFO or a plant specified product rotation/inventory control schedule should be maintained for finished products. The package/pallet integrity should be maintained throughout the storage period to protect the condition of the finished product. Product identity in storage should allow for the in-plant tracking system to be used for recall and/or market withdrawal purposes.

Specific items to consider:

1. For shelf-life purposes place fresh product into cold storage (i.e., $\leq 35^{\circ}\text{F}$) and frozen product into freezers (i.e., $\leq 10^{\circ}\text{F}$).
2. Utilize products in a plant specified time-period to maintain shelf-life requirements. Shelf-life of the product is dependent upon the type of product, type of package, temperature of storage, condition of incoming materials, etc. Therefore, each establishment should have specific guidelines for storing and utilizing finished products.
3. Store products to maintain package/pallet and lot integrity to help minimize customer risk.
4. Storage conditions should be maintained according to pre-requisite program requirements to ensure product integrity during storage.
5. Plant security should address raw material and finished product storage areas. Lock and/or secure areas during periods when the plant is not operating, if possible.

Pre-shipment Requirements:

1. Ensure that the HACCP pre-shipment has been completed prior to transferring ownership of the product to the customer. USDA considers transfer of product ownership when a bill of lading is transferred to the customer.
2. Conduct review of quality checks – grinders, metal detectors, etc. to minimize customer risk.
3. Make sure that there are no hold tags prior to releasing product into inventory.

4. If microbiological testing is being conducted on the finished product, ensure that all test results have been received or that there is a written procedure of handling test results and notifying customer of results, if necessary.

Lot Minimization of Product:

When possible, grinders may want to consider shipping the same lot(s) to an individual customer rather than splitting lots between customers. This will minimize the number of lots going to a single customer and will make the tracking process much easier than having lots split among multiple customers. However, it is noted that this is not always possible due to production and customer orders.

Loading/Shipping:

Finished products should be handled properly on the loading docks and during transport to prevent product deterioration by temperature abuse or improper handling practices. Trailers, containers and carriers of finished products should be evaluated prior to loading and shipping to ensure that the condition meets plant requirements for transporting raw ground meat. All trailers and carriers should be suitable for transporting food products; therefore, it may be important to consider what items were hauled in prior loads. All of the finished products should be coded/identified for intended use and for recall or market withdrawal purposes.

Specific items to consider:

1. Designated employee should evaluate and document the condition of trailer, container and carriers of finished products prior to loading products.
 - Cleanliness of trailer — no foreign materials, dirt, free of debris, free of off odors
 - Temperature of trailer — temperature of the trailer should be acceptable to maintain product temperatures.
 - Trailer door seals should be intact to control temperature.
 - General trailer condition — void of cracks, insulation in good condition, etc.
2. All finished products should be handled properly to maintain the condition of the products. Therefore, the time the products remain on the loading and receiving docks should be controlled based on the temperature of the docks.
3. The loading/shipping employees should be aware of the products being transported and the proper handling techniques for these products.
4. All trailers should be pre-chilled prior to loading finished products and the trailers should at least reach the same temperature as the temperature of the product being shipped and lower if possible. This may not always be possible, especially for frozen product. Hold and verify prior to release and delivery of load documents.
5. Package integrity should be maintained during loading/shipping and delivery to customer.

6. Product identification should be maintained through loading and shipping to ensure that the products can be traced if needed for recall and/or market withdrawal purposes.
7. Trucks should be sealed for load security and security of trailer.
8. Plant security may address driver identity – including copies of drivers license, tractor trailer identification or license for each driver to minimize risk to customer and grinding operators.

SYSTEM CHALLENGES TO MEASURE EFFECTIVENESS:

Recall Program and Mock stock recovery drills:

All grinding operations should develop a recall program. The program should include mock recalls conducted on a periodic basis to ensure that the program works as planned. The recall program should include identification and tracking of raw materials, packaging, and finished products. The program must be able to cover all raw materials (meat, non-meat ingredients), packaging materials to the finished product. The program should identify all suppliers, customers, distributors and everyone involved in the process. The more details that are put in place prior to having a problem, the easier the recall or withdrawal will be when there is a problem. An example program is provided in Appendix F.

Plant Security:

Plant security systems should address the security of the raw materials and finished product, as well as the security of the trailers used to ship finished products. Access to the establishment should be controlled as part of the security program. Some of the items to consider include fencing the perimeter of the facility, employee screening procedures, establishing a security check-point for all employees and visitors entering and/or exiting the plant. Utilizing visitor Security is an important factor and should be enforced at all levels of the establishment's operation.

PRODUCT HANDLING FOR MICROBIAL TESTING OF FINISHED PRODUCTS:

Conducted by the Establishment:

1. Grinding operations may use finished product testing to document process control for the grinding operation or to conduct microbial mapping of the entire process. This may begin with raw materials and continue through the finished product to prove control of the process and product during the process. Periodic testing throughout the system will verify that the plant procedures for Sanitation, cold chain management, product integrity, etc. are being maintained.
2. Grinders can also use product testing to establish a lot minimization system. The process for implementing this type of testing program will vary with the product(s)

being produced and the amount of risks that plants are trying to minimize through the testing program.

Conducted by the Food Safety and Inspection Service:

1. *E. coli* O157:H7 testing. The agency will continue to test for *E. coli* O157:H7. All plants should participate in the LEARN program so they can receive the laboratory results in a timely fashion. The following items should be considered when FSIS is pulling a sample for testing.
 - FSIS personnel are required to notify the plant prior to pulling the sample to allow the plant to hold the product.
 - The plant should have a written procedure for when a regulatory sample is pulled to ensure that the product is held and controlled while waiting for the test result, or that the finished product is sent to a fully cooked operation or rendered.
 - The plant should define the scope of the product that is impacted by the sample (clean up to clean up; raw materials in the lot, rework, reprocessed product included in the sample, etc.).

Establishments should have a procedure for addressing a presumptive positive for *E. coli* O157:H7. This procedure may include treating the product as if it is positive and diverting it to a cook operation or holding the product until confirmation is received before making a determination on product disposition. Establishments should be prepared to handle a presumptive positive and should understand the impact that this may have on the products being tested.

2. *Salmonella*

As stated above, plants are encouraged to participate in the LEARN program to be able to receive individual test results. By receiving individual results a grinding operation can evaluate the process based on the results rather than waiting until the set is complete (i.e., evaluate supplier trends; raw materials and finished product trends, etc.).

To participate in LEARN an establishment should contact OPHS to be added to the system.

HACCP IN A GRINDING OPERATION

As we all know, HACCP is a process control system designed to prevent, eliminate or reduce to an acceptable level food safety hazards. The establishment should consider biological, physical, and chemical food safety hazards. This a raw process that has no scientific CCP for preventing, eliminating or reducing to an acceptable level microbial food safety hazards, such as *E. coli* O157:H7. (It is noted that irradiation of the finished product will reduce, but not eliminate, microbial contamination, but it is not widely used in grinding facilities at this time.) Therefore, grinders must focus on what can realistically be applied during the process to minimize the potential for growth of pathogens, if present on the raw material. These steps often involve time and temperature

controls (i.e., raw material and finished product temperature during processing cold storage or other steps) to minimize the potential for growth. While the control of growth does not truly meet the definition of a CCP because one microorganism in the raw material may be too many, it is a best practice that can be applied in a grinding operation.

All grinders should be able to support the decisions that are made in the HACCP program and to use the documentation generated from the program to demonstrate product safety.

APPENDIX A

**FOOD AND DRUG
ADMINISTRATION,
DEPARTMENT OF
HEALTH AND HUMAN
SERVICES**

**21 CFR PART 110 -
CURRENT GOOD
MANUFACTURING
PRACTICE IN
MANUFACTURING,
PACKING, OR
HOLDING HUMAN
FOOD**

**Subpart A - General
Provisions**

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Sec. 110.5 Current good
manufacturing practice.
Sec. 110.10 Personnel.
Sec. 110.19 Exclusions.

**Subpart B - Buildings and
Facilities**

Sec. 110.20 Plant and grounds.
Sec. 110.35 Sanitary
operations.
Sec. 110.37 Sanitary facilities
and controls.

Subpart C - Equipment

Sec. 110.40 Equipment and
utensils.

Subpart D - [Reserved]

**Subpart E - Production and
Process Controls**

Sec. 110.80 Processes and
controls.
Sec. 110.93 Warehousing and
distribution.

Subpart F - [Reserved]

**Subpart G - Defect Action
Levels**

Sec. 110.110 Natural or
unavoidable defects in

food for human use that
present no health hazard.

**SUBPART A - GENERAL
PROVISIONS**

110.3 Definitions.

The definitions and
interpretations of terms in
section 201 of the Federal
Food, Drug, and Cosmetic
Act (the act) are applicable
to such terms when used in
this part. The following
definitions shall also apply:

(a) "Acid foods or
acidified foods" means
foods that have an
equilibrium pH of 4.6 or
below.

(b) "Adequate" means that
which is needed to
accomplish the intended
purpose in keeping with
good public health practice.

(c) "Batter" means a
semifluid substance, usually
composed of flour and other
ingredients, into which
principal components of
food are dipped or with
which they are coated, or
which may be used directly
to form bakery foods.

(d) "Blanching," except
for tree nuts and peanuts,
means a prepackaging heat
treatment of foodstuffs for a
sufficient time and at a
sufficient temperature to
partially or completely
inactivate the naturally
occurring enzymes and to
effect other physical or
biochemical changes in the
food.

(e) "Critical control point"
means a point in a food
process where there is a
high probability that
improper control may cause,
allow, or contribute to a
hazard or to filth in the final
food or decomposition of
the final food.

(f) "Food" means food as
defined in section 201(f) of
the act and includes raw
materials and ingredients.

(g) "Food-contact
surfaces" are those surfaces
that contact human food and
those surfaces from which
drainage onto the food or
onto surfaces that contact
the food ordinarily occurs
during the normal course of
operations. 'Food-contact
surfaces' includes utensils
and food-contact surfaces of
equipment.

(h) "Lot" means the food
produced during a period of
time indicated by a specific
code.

(i) "Microorganisms"
means yeasts, molds,
bacteria, and viruses and
includes, but is not limited
to, species having public
health significance. The
term 'undesirable
microorganisms' includes
those microorganisms that
are of public health
significance, that subject
food to decomposition, that
indicate that food is
contaminated with filth, or
that otherwise may cause
food to be adulterated
within the meaning of the
act. Occasionally in these

regulations, FDA used the adjective 'microbial' instead of using an adjectival phrase containing the word microorganism.

(j) "Pest" refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

(k) "Plant" means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

(l) "Quality control operation" means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m) "Rework" means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(n) "Safe-moisture level" is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a (INFERIOR w)). An a (INFERIOR w) will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a

(INFERIOR w) will not support the growth of undesirable microorganisms.

(o) "Sanitize" means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(p) "Shall" is used to state mandatory requirements.

(q) "Should" is used to state recommended or advisory procedures or identify recommended equipment.

(r) "Water activity" (a (INFERIOR w)) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

110.5 Current good manufacturing practice.

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that

the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such

health conditions to their supervisors.

(b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary

condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education

or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d) *Supervision.* Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

110.19 Exclusions.

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more 'raw agricultural commodities,' as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

SUBPART B - BUILDING AND FACILITIES

110.20 Plant and grounds.

(a) *Grounds.* The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) *Plant construction and design.* Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and

locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

110.35 Sanitary operations.

(a) *General maintenance.* Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(b) *Substances used in cleaning and sanitizing; storage of toxic materials.*

(1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for

contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

(c) *Pest control.* No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted

only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) *Sanitation of food-contact surfaces.* All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

110.37 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) *Water supply.* The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that

contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) *Plumbing.* Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(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) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) *Sewage disposal.* Sewage disposal shall be made into an adequate

sewerage system or disposed of through other adequate means.

(d) *Toilet facilities.* Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(3) Providing self-closing doors.

(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).

(e) *Hand-washing facilities.* Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

(2) Effective hand-cleaning and sanitizing preparations.

(3) Sanitary towel service or suitable drying devices.

(4) Devices or fixtures, such as water control

valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

(5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.

(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(f) *Rubbish and offal disposal.* Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

SUBPART C - EQUIPMENT

110.40 Equipment and utensils.

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed

that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that

food is not contaminated with unlawful indirect food additives.

**SUBPART D -
[RESERVED]**

**SUBPART E -
PRODUCTION AND
PROCESS CONTROLS**

**110.80 Processes and
controls.**

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become

contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(a) *Raw materials and other ingredients.* (1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated

within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the

materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) *Manufacturing operations.* (1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall

be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, a (INFERIOR w), pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act.

Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45 (degree)F (7.2 (degree)C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140 (degree)F (60 (degree)C) or above.

(iv) Heat treating acid or acidified foods to destroy

mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a (INFERIOR w) that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that

protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food.

Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food.

Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.

(ii) Employing adequate heat processes where applicable.

(iii) Using adequate time and temperature controls.

(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(v) Cooling to an adequate temperature during manufacturing.

(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(iii) Using materials for food containers and food-packaging materials that are safe and suitable, as defined in Sec. 130.3(d) of this chapter.

(iv) Providing physical protection from contamination, particularly airborne contamination.

(v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a (INFERIOR w) for preventing the growth of

undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

- (i) Monitoring the a (INFERIOR w) of food.
- (ii) Controlling the soluble solids-water ratio in finished food.
- (iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a (INFERIOR w) of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

- (i) Monitoring the pH of raw materials, food in process, and finished food.
- (ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good

manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

SUBPART F - [RESERVED]

SUBPART G - DEFECT ACTION LEVELS

110.110 Natural or unavoidable defects in food for human use that present no health hazard.

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current

good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated

within the meaning of the act, regardless of the defect level of the final food.

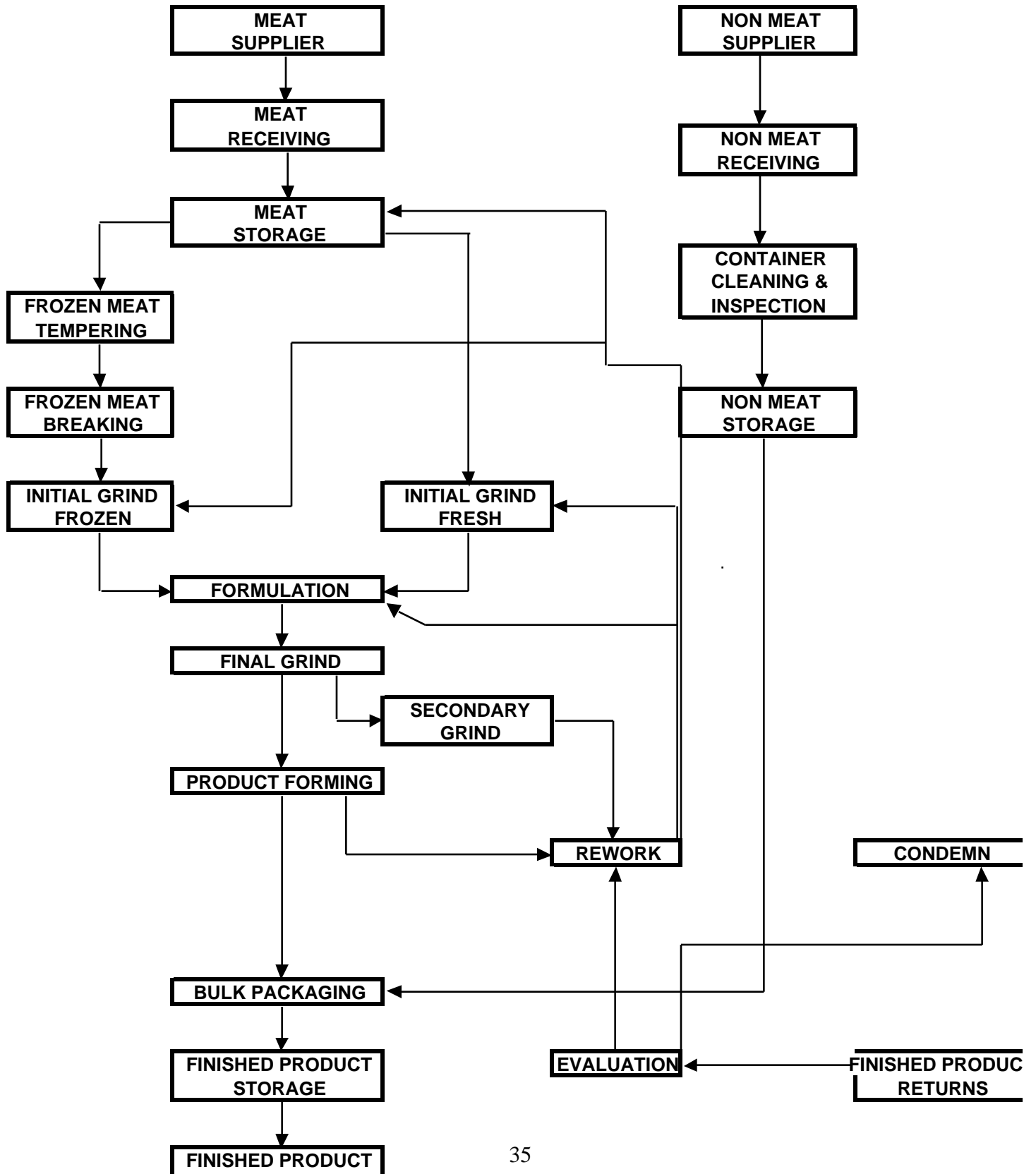
(e) A compilation of the current defect action levels for natural or unavoidable

defects in food for human use that present no health hazard may be obtained upon request from the Industry Programs Branch (HFF-326), Center for Food

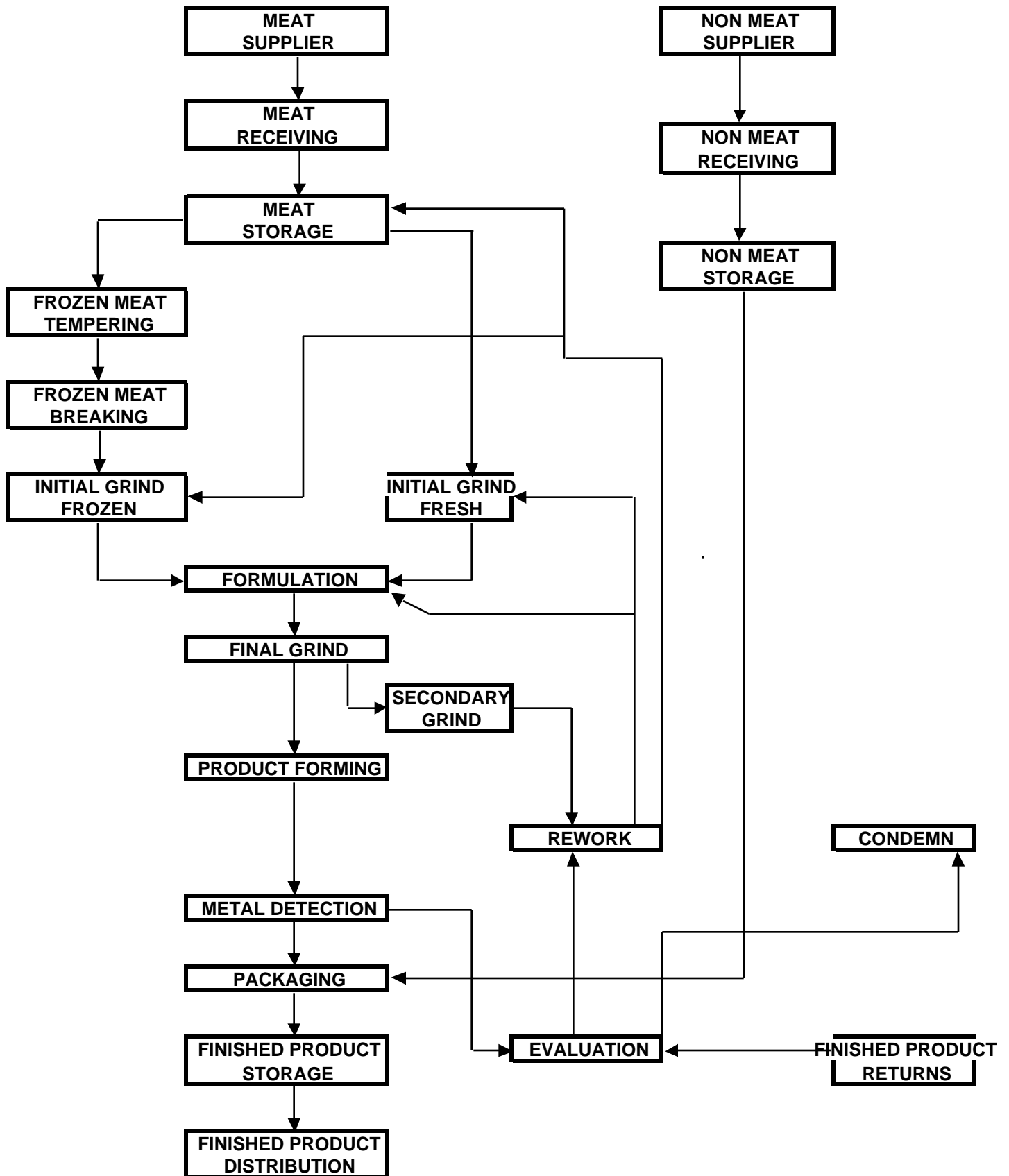
Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

APPENDIX B

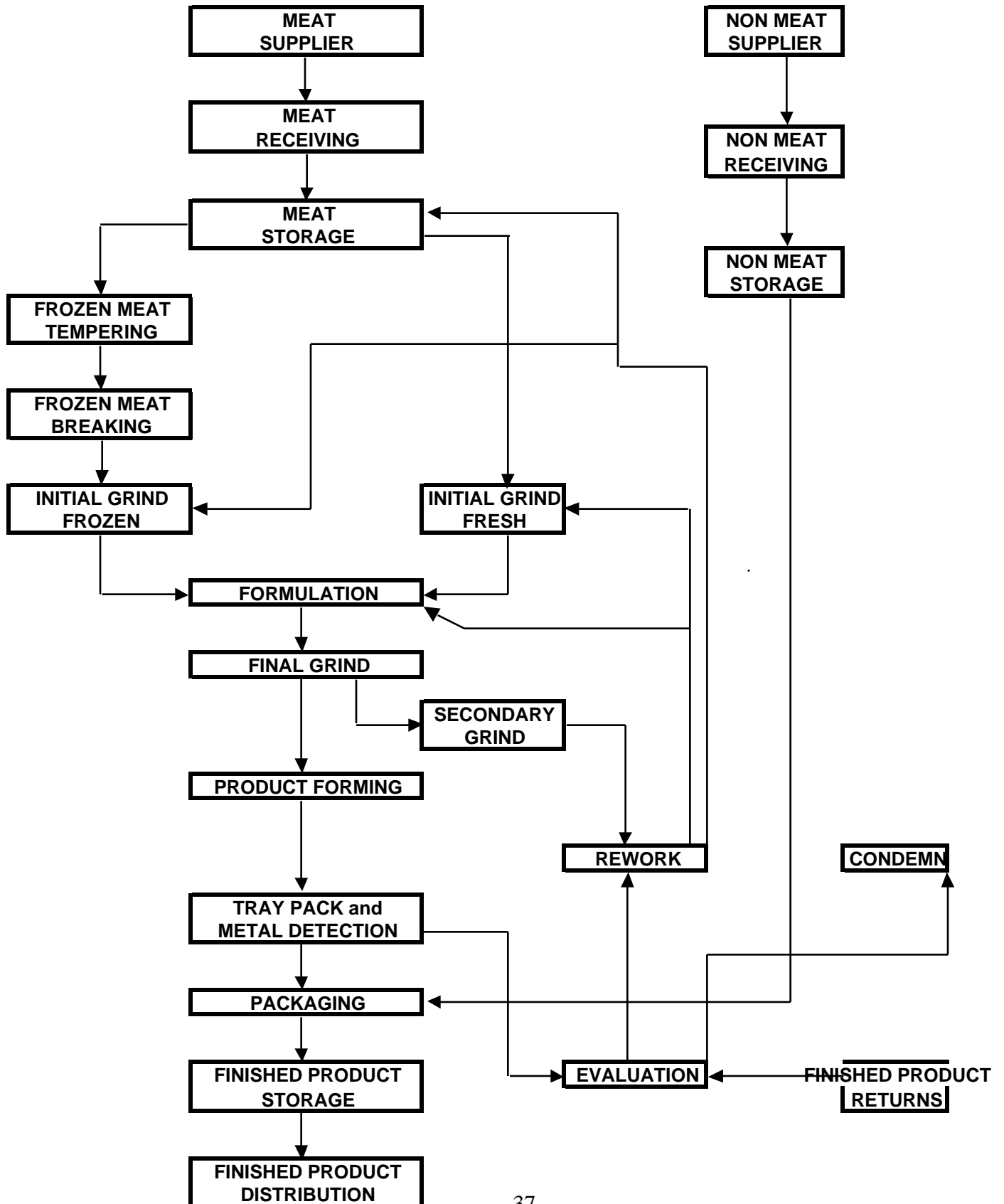
FLOW CHART - FRESH 100% GROUND BEEF BULK & 100% GROUND PORK BULK



FLOW CHART - 100% GROUND BEEF FRESH CHUB PACK

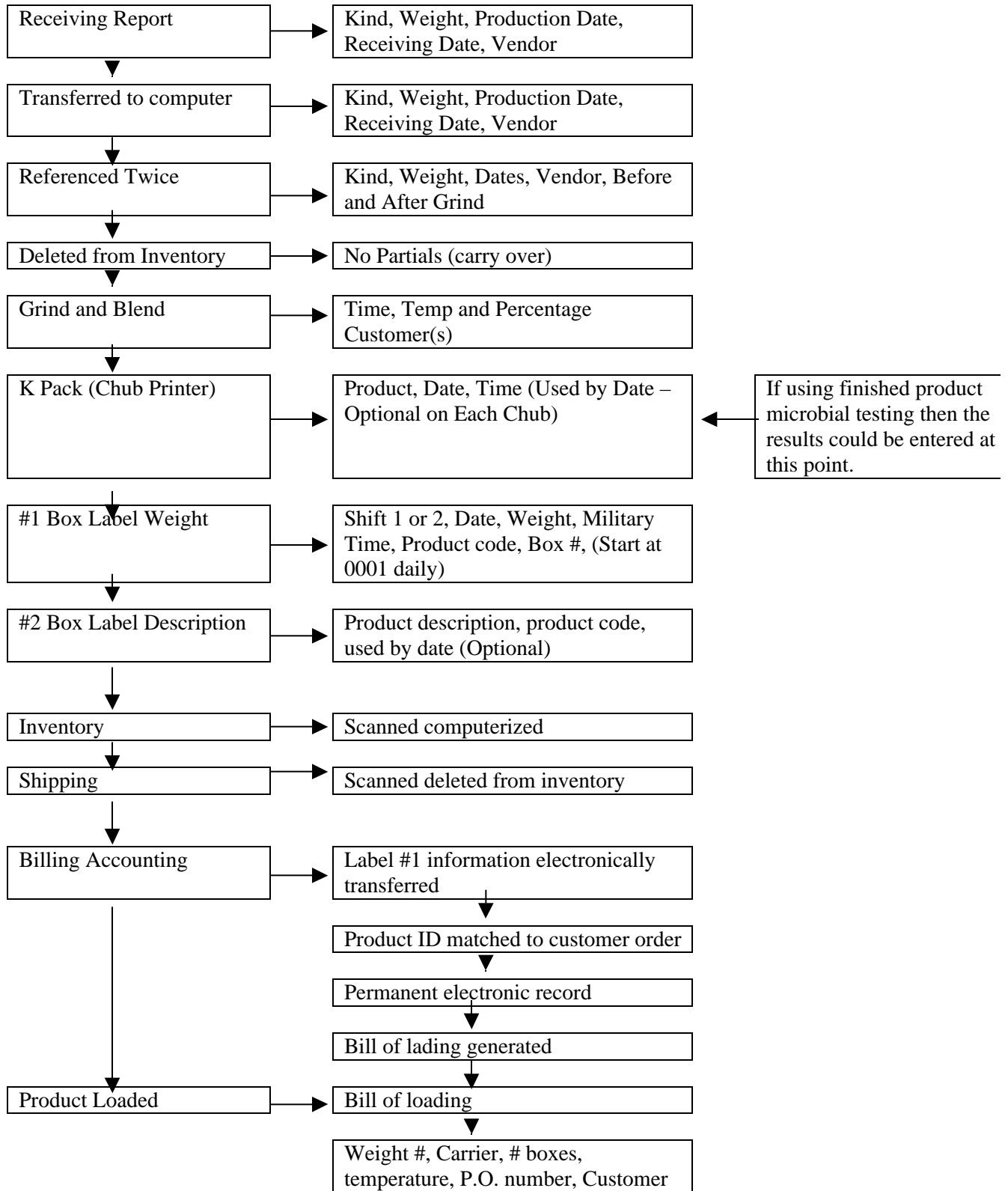


FLOW CHART - 100% GROUND BEEF FRESH : MAP



APPENDIX C

GROUND BEEF LOTTING



APPENDIX D

**ACCEPTABLE QUALITY LEVEL (AQL)
INSPECTION REPORT for RAW MATERIAL SUPPLIERS**

Quality Control Technician: _____ Date: _____
 Supplier: _____ Est. # _____ R/D : _____
 Product : _____ P/D : _____
 Temperature: _____ (degrees F) Bacterial Sample Taken : YES NO
 COLOR Excellent Good Fair Poor Bad
 ODOR Excellent Good Fair Poor Bad
 MOISTURE: _____ FAT: _____

ACCEPTABLE QUALITY INSPECTION (AQL): Results will be reported on a per thousand pound basis, unless otherwise noted. Record your results and the weights for each item. Calculate the weight on a per thousand pound basis and record in the appropriate block.

TENDONS: yes _____ no _____ weight _____ Per 1000 #'s _____
 GLANDS: yes _____ no _____ weight _____ Per 1000 #'s _____
 BONES/CHIPS: yes _____ no _____ weight _____ Per 1000 #'s _____
 BLOOD CLOTS: yes _____ no _____ weight _____ Per 1000 #'s _____
 BRUISES: yes _____ no _____ weight _____ Per 1000 #'s _____
 CARTIALGE: yes _____ no _____ weight _____ Per 1000 #'s _____
 ARTERIES & VEINS: yes _____ no _____ weight _____ Per 1000 #'s _____
 BACKSTRAP: yes _____ no _____ weight _____ Per 1000 #'s _____
 HIDE/HAIR: yes _____ no _____ weight _____ Per 1000 #'s _____
 PERITONEUM: yes _____ no _____ weight _____ Per 1000 #'s _____
 BENCH TRIM: yes _____ no _____ weight _____ Per 1000 #'s _____
 WIZZARD TRIM: yes _____ no _____ weight _____ Per 1000 #'s _____
 FOREIGN OBJECTS: yes _____ no _____ weight _____ Per 1000 #'s _____

INSPECTION COMMENTS:

Reviewed:

Date:

APPENDIX E

NEED AMI INTERVENTION LIST

APPENDIX F

PRODUCT RECALL DIARY OF EVENTS

DISCOVERY OF QUESTIONABLE PRODUCT:

Product Description: _____ Pack Date(s) _____

Complaint or Problem Description: _____

Total Number of Cases Involved: _____
(Attach copy of Daily Yield Report, Batch Records and Pallet Tally and Inventory Location Record)

INVESTIGATION OF SITUATION:

List Meeting Participants: _____

Discussion of Situation: (Brief) _____

Classification of Recall: _____

CHRONOLOGY OF EVENTS:

CONCLUSION OF RECALL: (Attach all documents collected during the recall)

Product Recalled: _____ Pack Date: _____

Complaint or Problem: _____

Source of Complaint: _____

Amount of Product Returned: _____

Disposition of Returned Product: _____

Effectiveness and Prevention Review: _____

