

Best Practices For Raw Ground Products

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

**Facilitated by:
Beef Industry Food Safety Council
Executive Committee**

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BEST PRACTICES FOR RAW GROUND BEEF DOCUMENT TABLE OF CONTENTS

- I. Best Practices for Raw Ground Products
 - A. Introduction
 - B. The Grinding Process
 - C. Lotting
 - D. Reprocessed Product (Rework)
 - 1. Intra-batch Materials
 - 2. Product Over Run
 - 3. Returned and Re-inspected Finished Products
 - 4. Inter-lot Reprocessing
 - II. Best Practices
 - A. Raw Material Source
 - 1. Process Interventions and/or Controls for Food Safety
 - 2. Foreign Material Contamination
 - 3. Testing/Pre-screening Requirements
 - B. Supplier Evaluations
 - 1. New Supplier Approval
 - 2. Ongoing Supplier Evaluations
 - C. Pre-receipt of Raw Material Verification
 - 1. Negative Pre-Screen for E. coli
 - 2. Trailer Seal Integrity (Security)
 - D. Receipt of Raw Materials
 - 1. Receiving Meat
 - III. Non-Meat Items and Allergens
 - IV. Storage of Raw Materials
 - V. Raw Material Processing
 - A. Tempering / Thawing of Frozen Materials
 - B. Grinding / Processing
 - C. Interventions / Inhibitors
 - D. Packaging / Labeling
 - E. Allergen Control Program
 - F. Storage of Finished Products
 - G. Pre-shipment Requirements
 - H. Lot Minimization of Finished Products
 - I. Loading / Shipping
 - VI. System Challenges to Measure Effectiveness
-
-

- A. Recall Program and Mock Stock Recoveries
- B. Plant Security
- VII. Product Handling for Microbial Testing of Finished Products
 - A. Conducted by the Establishment
 - B. Conducted by the Food Safety and Inspection Service
- VIII. HACCP in a Grinding Operation

IX. Appendices

Appendix A. Title 21: Food and Drugs, Part 110 – Current Good Manufacturing Practices in Manufacturing, Packing or Holding of Human Food

Appendix B. Raw Ground Beef Process Flow Charts

- Modified Atmosphere
- Frozen 100% Beef Patties and Bulk IQF

Appendix C. Ground Beef Lotting

Appendix D. Raw Material Inspection Report

Appendix E. Recall Records

Appendix F. Formulation Records

Appendix G. Safe and Suitable Ingredients for Meat and Poultry Products

Appendix H. Guide to E. coli O157:H7 Testing of Raw Ground Beef and Raw Ground Beef Components

Appendix I. Loading Plan Checklist

Appendix J. USDA FSIS Beef Slaughter Guide; Data on Validated Interventions

I. Best Practices for Raw Ground Products

A. INTRODUCTION

Producers of raw ground products, including ground beef, recognize that these products have inherent food safety risks due to the nature of the process and the lack of a sufficient “kill” step for biological hazards within 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 and in sourcing safe raw materials.

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 (reworking) of raw 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 (Appendix 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.

B. 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, e.g., the addition of non-meat ingredients and incorporation of other process steps. (Appendix B).

C. LOTTING

The concept of lotting systems in ground beef operations is a complex and detailed issue. The USDA definition for a lot, when there is a positive result for *E. coli O157:H7*, is “from full sanitation to full sanitation.” In most commercial grinding operations this definition affects an entire day’s production. However, the USDA has changed its’ definition for a lot (MICROBIOLOGICAL TESTING PROGRAM AND OTHER VERIFICATION ACTIVITIES FOR *Escherichia coli O157:H7* IN RAW GROUND BEEF PRODUCTS AND RAW GROUND BEEF COMPONENTS AND BEEF PATTY COMPONENTS; FSIS Directive 10,010.1, 3/31/04) and now considers the source raw materials used and finished product testing programs being widely used in the Industry, to determine the potentially affected product(s) when there are positive test results for *E. coli O157:H7*. This new definition can potentially expand the amount of product(s) affected when there is a positive result for *E. coli O157:H7* to include any raw ground beef produced with “common source” raw materials. Therefore it is even more critical that proper documentation and controls, including finished product testing, be used to provide sub-lotting under this new definition and minimize the amount of affected product(s). For example, sampling finished product at set intervals and testing specifically for *E. coli O157:H7* may allow the day’s production to be broken into sub-lots regardless of the raw materials used. If a company is testing finished ground products for *E. coli O157:H7*, then it should require all of the product(s) 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.

While not necessarily a “best practice”, the concept of lotting or sub-lotting may be used in conjunction with the Best Practices for Raw Ground Beef to reduce the liability of a processor in the event of an undesirable situation. The purpose of lotting and sub-lotting is to separate sections of the production day so that the implications of a positive test result affect only a portion of the day, rather than the entire day and also limit exposure to only one production day. The use of lotting and sub-lotting may result in one or more sub-lots being implicated, while allowing many more sub-lots to be released. A sub-lot of the day may be a set period of time (such as the sampling frequency for the pathogen), a batch, or a raw material source change. The lot and sub-lot are to be defined by the processor, as long as the criteria for the lot and sub-lot are well defined.

Considering the complexity and implications of the USDAs’ new definition we have attached a Guidance document that attempts to clarify this further. It is titled “**Guide to *E. coli O157:H7* Testing of Raw Ground Beef and Raw Ground Beef Components**” (Appendix G), and was provided for use by National and Southwest Meat Associations.

All grinding operations must have a lotting mechanism for coding and recording finished products to allow for tracing the product back through the system to the raw material(s) used and for tracing the product forward through the supply 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 defined by some time factor (i.e., hour, shift, day, etc.) which is reflected in specific lot identification codes applied to each finished product package.

In addition, when regulatory samples (e.g., FSIS verification samples for *E.coli O157:H7*) are taken, lotting allows establishments to place the finished product represented by the regulatory sample on hold. 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 or prevent the need a recall entirely.

The lotting is dependent upon a record keeping system, and it is recommended that the following items be documented for each identified lot.

- Raw material source(s):
 - By vendor, including vendor establishment number pack dates (or bone dates), receive dates, raw material type, time used, quantity used, and any other plant-specific identification information provided (e.g., shift vat number, serial number)
- Rework: if used, should be treated as a raw material source. Be sure you consider the USDA common source raw material rules when considering use of rework at any time.
- Data collected during process:
 - (Temperatures, microbial data, etc.)

As a best practice, carry-over (rework) from one day's production must not be reintroduced into later production dates because this can increase the amount of product implicated if there is a problem. Rework carried from one day to the next can be used only if you have a validated sub-lotting program in place and are testing all finished products specifically for *E. coli O157:H7*.

Sub-lotting requires the following additional types of documentation:

- Batching records – These records must identify the types of raw materials used by their 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 must be coded with the actual times they are packed and sealed and pallets of product should contain consecutive products off the line. Equipment 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. Packaged product information tracking should be able to be used to track back to the actual raw materials used in the process.
- Microbiological testing and tracking — If a company is performing microbial testing, then the results must be recorded and traceable to the sub-lot(s) tested.

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 that sufficient controls were in place to minimize the amount of product affected. An example of a lotting system that could be used for ground beef is provided in Appendix C.

D: REPROCESSED PRODUCT (Rework):

Reintroducing broken/misshapen patties, ground product, over-run at the end of the day, rework, etc... back into the processing flow are procedures that should be fully addressed by grinders. For the purpose of this document, a lot was defined as the finished product manufactured during one single days' production 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. Intra-batch 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 must 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 fat/lean analysis must remain within the same batch. The equipment used for taking these samples must be cleaned and sanitized between samples.

2. Product Over-run:

These are excess raw materials and ground products 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, that is not always a realistic option. Therefore, the following recommendations are being provided to address product over-run:

- Direct the product to further processing, a cooking process, and identify or specify as product for cooking only. You must have this written into your HACCP program and you must have a program in place to show that these materials were sold and transferred to a facility having a validated intervention step.
- Utilize the materials to produce a designated batch/lot — Combine the raw materials and other intra-batch 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 risks 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.). The use of this option must be limited to “break” the re-work cycle, and reduce the risk of an expanded recall. Re-work

should be discarded within a set time period, to avoid the carry-over from being continuous. Some operations may choose a few days to a week between cycle breaks. The decision of how long to maintain the rework cycle must consider the length of time finished product is in commerce, and may be involved in a recall of product that tests positive on a subsequent date.

- Destroy the raw materials or finished products.

It is also noted that raw material(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 rework.

3. Returned and Re-inspected Finished Product:

The optimal situation is to eliminate the need for finished 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 re-inspected products:

- Direct the finished product to further processing, a cooking process, and identify or specify as product for cooking only. You must have this written into your HACCP program and you must have a program in place to show that these materials were sold and transferred to a facility having a validated intervention step.
- Destroy the finished product
- Utilize the finished product to produce a designated batch/lot — Combine the finished products 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 risks 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. The economic impact of an increased recall based upon this option may negate cost savings avoided by not selecting the first two options.)

4. Inter-lot Reprocessing:

This allows the establishment to reprocess a formulated batch of ground beef over a designated time period (i.e. – shift) to allow an out-of-spec batch to be used on the same day's production. If ground beef is added from an out-of-spec batch into other batches/lots during the day, then all finished products produced that contain the out-of-spec ground beef 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 and the batches/lots that it is used in, and clear breaks in the process (i.e., clean-ups) are maintained. The practice of inter-lot reprocessing may negate the sub-lotting of product, due to the dispersal of the out-of-spec batch throughout the entire day.

The recommendations provided above should help an establishment make decisions relating to the reprocessing of raw materials and finished 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.

II. 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.

A. RAW MATERIAL SOURCE

Grinders should encourage and support further actions at all sectors of the industry (from animal production to consumer) to reduce microbial contamination and food-borne illness. This is especially important for beef and the control of *E. coli* O157:H7 and other pathogens. 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 of raw materials for ground product(s).

1. Process Interventions and/or Controls for Food Safety:

- a. 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.
- b. For beef, the following items are specific to *E. coli* O157:H7:
 - Raw material suppliers must 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** must be plant specific using indicator organisms, and it should be specific to the process(es) being applied at the establishment. This requirement can be incorporated into the grinder's Raw Material Purchase Specifications or other plant programs to ensure that all raw materials are produced using **validated** CCPs and **process interventions**. This is true for both domestic and imported suppliers of raw beef to be used in ground product(s).

- In addition to the requirements for **validated** processes, the raw material suppliers must also conduct routine **verification testing** as a part of the CCPs within the HACCP plan. Grinders should be aware of the **verification** testing being done by suppliers, and should be assured that **verification** testing is appropriate for the CCPs.
- c. *E. coli* O157:H7 Testing - It is also important for beef grinders to have specific data on *E. coli* O157:H7 in raw ground beef components to support the position taken during the hazard analysis. If the grinding establishment has determined that it is a hazard that is “not reasonably likely to occur” then there must be evidence/data to support this position.

****Validate** = authenticate, verify, prove. As used in the context of this document **validation** is the act of **verifying** that the process is achieving the results identified in the HACCP Program.

2. 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 the Grinders Raw Material Specifications to the supplier outlining items that are not acceptable in the raw materials.

See Appendix D – Raw Material Inspection Report. By tracking the results for individual loads or lots from Suppliers, processors can determine who is achieving the best results and what their processes are capable of producing on a regular basis. Data can be graphed, compared and trended over time to insure ongoing compliance with your specifications or standards and insure Suppliers are actually controlling their process.

3. Testing / Prescreening Requirements:

- a. Sampling and testing for *E. coli* O157:H7 - There must 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, 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 raw material is being transported to the customer while the test is pending to ensure that all positive raw materials are handled according to the plant’s written protocol.
- b. 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.

- c. Laboratory services used for testing samples must be **reputable** and **accredited**. Furthermore, the **testing method must be accredited (AOAC, FDA BAM)**, and it is incumbent upon the grinder to ensure the proper method is being followed. In house laboratories must be audited by reputable and qualified auditors. Competence of the laboratory testing methods must be established in order to accept testing results.
- d. In-plant microbiological testing - If a grinder elects to conduct his/her own testing of raw materials and/or finished product for *E. coli* O157:H7, then he/she should notify the supplier in advance, because the results will impact the supplier's production and distribution of product. The best practice is to cooperate with the raw material supplier for **verification** sample testing.

**Verification = the process of examination, testing, etc., required to prove or establish validity; evidence that establishes or confirms the accuracy or truth of something.

B. SUPPLIER EVALUATIONS

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

1. New Supplier Approval:

- a. Each new supplier should provide written acknowledgement of the grinder's Raw Material Purchase Specifications and their willingness to comply.
- b. Each supplier must meet the guidelines outlined in the Raw Material Purchase Specifications for microbial testing and profiles. For **new suppliers**, a grinder may want to establish an **intensified sampling program** to determine if the supplier can consistently meet the specifications.
- c. Each supplier must have a plant audit conducted on a specified frequency to ensure compliance with the Purchase Specifications and other programs outlined in the Purchase Specifications. The supplier 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.
- d. Grinders must conduct quality (AQL) inspections of incoming raw 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.

See Appendix D – Raw Material Inspection Report. By tracking the results for individual loads or lots from Suppliers, processors can determine who is achieving the best results and what their processes are capable of producing on a regular basis. Data can be graphed, compared and trended over time to insure ongoing compliance with your specifications or standards and insure Suppliers are actually controlling their process.

Microbiological Testing Example – Intensified testing may consist of collecting samples from all combo bins (20) contained in a single load from one supplier. Samples should

be collected using an n=25 (n = number of samples) or greater protocol and analyzed for a complete microbiological profile; (Aerobic Plate Counts, Coliform, E. coli, Staphylococcus aureus, Salmonella sp., and Listeria.) This kind of sampling and testing regimen provides a way to accumulate accelerated data on an individual supplier's ability to meet identified microbiological standards or specifications. Semi-Intensified testing may consist of collecting samples from all sub-lots contained in a single load from one supplier (4 sub-lots per load). Routine testing may consist of collecting samples from a representative sample from the entire load and performing one microbiological profile for the entire load.

By tracking the microbiological results for individual loads or lots from Suppliers, processors can determine who is achieving the best results and what their processes are capable of producing on a regular basis. Data can be graphed, compared and trended over time to insure ongoing compliance with your specifications or standards and insure Suppliers are actually controlling their process.

2. Ongoing Supplier Evaluations:

a. Grinding operations must periodically provide an update of the Raw Material Purchase Specifications to each supplier and request on updated acknowledgement of receipt of the specifications and their willingness to comply.

b. **Data must be collected and tracked on the following items to identify supplier trends and help make purchasing decisions:**

- Microbial profile data — may include, but is not limited to: *Salmonella*, *E. coli* O157:H7, generic *E. coli*, Total Plate Count (TPC), Aerobic Plant Count (APC), coliforms, *Listeria* and coagulase positive *Staph.*
- Foreign object contamination
- Defect(s) (unacceptable indigenous inclusions)
- Plant audit results
- Age of raw material at receipt
- Temperature of raw material at receipt
- On-time delivery
- Other plant-specific requirements

By tracking the results for the information outlined above processors can determine who is achieving the best results and what their processes are capable of producing on a regular basis. Data can be graphed, compared and trended over time to insure ongoing compliance with your specifications or standards and insure Suppliers are actually controlling their process.

C. 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.

1. 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 must 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 raw material 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 raw material to ensure that it is not used prior to receiving the negative test result for *E. coli* O157:H7. This will require good tracking and documentation procedures and sufficient training of all employees involved in both receiving and production to prevent the use of the raw material. The establishment must also have a procedure for handling the raw material if the test result is positive.

2. Trailer 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 must be a procedure for re-sealing the load and a tracking system for each seal placed on the truck. This process will help maintain raw material integrity and security.

D. RECEIPT OF RAW MATERIALS

1. Receiving Meat:

Incoming meat must be **evaluated** to ensure that it meets the plant-established purchase specifications. Trucks, containers and carriers of raw materials **must be evaluated upon receipt** to ensure that the conditions meet plant requirements for transporting meat. All containers/cartons should be intact. All incoming meat must be coded/identified for plant use and for the in-plant tracking system. Product tracking is essential to **verify** intended use of raw material to ensure that the raw material on the truck matches the raw material identified on the invoice and on the microbiological test results, if applicable. Specific items to consider:

- a. Designated employee must **verify** that the raw material is from a company approved supplier. Each plant must set supplier requirements and maintain a list of approved suppliers.
- b. Designated employee must **evaluate** and **document** on a raw material receiving log the condition of the trailer, shipping container(s), and carriers of raw materials upon arrival, and must **document** the time the inspection was conducted. Items for evaluation may include:
 - Cleanliness of trailer — no foreign materials, no dirt, free of debris, free of off odors
 - Temperature of trailer — temperature of the trailer must be acceptable to maintain raw material temperature. Plant may set a specific temperature for the raw material and/or the trailer as part of the purchasing specifications. If specific temperatures

- are set, then there must be a written procedure that defines the action(s) that will be taken if the temperature does not meet the specification. It is recommended that all raw material loads utilize mechanical or electronic temperature monitoring devices that track the temperature of the trailer during the entire transportation segment.
- General trailer condition — void of cracks, insulation in good condition, trailer door is sealed properly, paper on floors for carcass carriers, etc. No signs of rodent or pest activity.
- c. If the truck condition is acceptable, the designated employee must **verify** that the incoming raw 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 or pack date
 - No foreign objects
 - **Verification** of intended use — **verify** raw material and combo identification matches the raw material ordered and the bill of lading, including the proper match for raw material and microbiological test results.
 - Supplier microbiological testing results, if required. If the supplier is required to test for *E. coli* O157:H7, then the raw material must 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 raw material 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 raw material must 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 <5days from fabrication or bone date; and frozen meat no more than 6 months from fabrication.
- d. If the raw material meets the purchase specifications, then the designated employee must **evaluate** the actual condition of the raw materials. The following items are recommended for **evaluation**:
- Temperature of raw materials (i.e., frozen <10°F; fresh <40°F). Each operation must have a separate procedure for taking the temperature of incoming raw material and calibrating thermometers. It's recommended that both core and surface temperatures of the raw material are taken and **evaluated**.
 - Organoleptic **evaluation** of raw material for off odor, discoloration, improper appearance.
 - Raw material must have supplier code information and proper lot/load identification on materials.
- e. If incoming raw materials pass the receiving inspection, then all raw materials must receive plant specific tracking/coding information prior to entering the storage or production facility.

III. Non-Meat Items and Allergens

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 must be stored, handled and used in a manner that will maintain the integrity of the items. Purchase Specification and acknowledgement for packaging materials and non-meat ingredients may include a continuing letter of guarantee to document compliance with the Food, Drug and Cosmetic Act.

Based on CDC estimates food allergies are linked to 29,000 emergency room visits and 150 to 200 deaths a year. The meat industry's implementation of best practices and strategies for control of *E. coli* O157:H7 are important, but so too are controls for allergens to address these startling statistics. There are eight specific categories of food allergens; milk, eggs, peanuts, tree nuts, soy, fish, shellfish and wheat.

There are several ways to eliminate the possibility of unintentional contamination and maintain strict guidelines for separation and isolation of these ingredients from other products. Facilities that use allergen ingredients need to consider these process steps when developing their Allergen Control Programs; sourcing, scheduling, separation, staging, line clearance, verification and sanitation. Outlined below is an overview of each step and some suggestions on items to consider:

Sourcing: All allergen raw materials received must have a Letter of Guarantee on file or with the shipment when received showing that they have been processed and verified to be free of unintentional contamination by other sources of allergens.

Scheduling: All products containing allergens must be processed on dedicated equipment and the equipment should be labeled when other non-allergen products are running at the same time in the same plant area. Every attempt must be made to process products containing allergens exclusively in a separate processing area when possible.

Separation: Allergen ingredients must be stored separately and identified during storage from other dry goods and non-allergen ingredients to prevent unintentional contamination.

Staging: Allergen ingredients must be staged and segregated from other raw materials to prevent unintentional contamination.

Line Clearance: This step is simply removing all ingredients for all other products from the weighing and production areas before beginning production of products which contain allergens.

Verification: Constant **verification** of all of the steps outlined in the control program will help insure that there is no inadvertent or unintentional contamination of other products. End product testing must only be completed when there is sufficient reason to suspect that there has been contamination with allergens in products which do not contain allergens. **Verification** of labeling prior to and after production of products containing allergens must be completed prior to product shipments.

Sanitation: All product lines, equipment, containers and the facility must be fully disassembled and cleaned prior to production of non-allergen products after production of a

product that contains allergens. Sanitation must be completed and **verified** during pre-operational sanitation.

The summary above is only a guideline and is not to be considered comprehensive. Each facility must conduct their own process assessment and **evaluate** controls necessary for production of products containing allergens. Production of allergen free products requires a solid food safety program which must include supplier controls, ingredient specifications, employee education programs, product and ingredient identification, traceability and recall procedures and well defined good manufacturing practices and sanitation standard operating procedures.

IV. Storage of Raw Materials

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 must be stored at temperatures that maintain proper condition – temperature, integrity, etc. Frozen raw materials must 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 must allow for a proper in-plant tracking system. Specific items to consider:

1. For shelf-life purposes place fresh, raw material into cold storage (i.e., <40°F) and frozen raw materials into freezers (i.e., <10°F).
2. Complete plant specific storage records or raw material identification, so raw materials will be used on a FIFO basis or according to plant raw material rotation/inventory control schedule.
3. Utilize all fresh raw materials preferably within 5 days but definitely not more than 7 days from fabrication or bone date. Utilize all frozen raw materials within 6 months of fabrication.
4. Store raw materials 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 must be maintained according to pre-requisite and allergen program requirements to ensure raw material integrity during storage
6. Plant security must address raw material and finished product storage areas.

V. Raw Material Processing

A. TEMPERING/THAWING OF FROZEN RAW MATERIALS

If tempering or thawing is required prior to use, then it must be done in a time/temperature controlled manner which is adequately **monitored, documented and verified**. The raw material package integrity is important during this process. The raw material's traceability must 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 raw material in a tempering room that is <40°F and allow raw material to reach desired level of tempering or thawed state; actual time will vary depending on amount of raw material 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 raw material.) Air temperature and velocity are important variables affecting proper thawing.
2. The raw material must be **monitored** on a scheduled basis to prevent degradation of the package integrity and minimize raw material drip.
3. The raw material temperature must be **monitored** on a scheduled basis to ensure that the desired end temperature is not exceeded.
4. All of the raw materials must maintain the plant-specific tracking/coding information to ensure proper traceability of raw material from receiving through to final end products.

B. GRINDING / PROCESSING

This document includes weighing, mixing, blending, coarse and final grinds, forming, packaging, and labeling and other plant specific aspects of the process. Throughout all of the steps the temperature of the ground product must be maintained and documented. The use of aged trim for the finished product to be produced must be considered. In producing ground beef, the highest risk products are often made utilizing the most at risk ingredients. Age of trim, cold chain management, and historical information on raw material supplier(s) should be used when formulating a product for specific customers Food Safety Objectives.

Steps must be taken to prevent species cross-contamination and proper labeling to maintain end-product identity. An organoleptic **evaluation** of the raw material ingredients must be completed during pre-grind and prior to adding the meat to the batch. The ingredients must be **evaluated** for chemical composition (%fat and lean) to formulate finished product to desired endpoint. Procedures for ensuring proper finished product characteristics (i.e., weights, size, shape, quantity, etc.) must be in place. The in-plant tracking mechanism must allow for batch identification and time of batch production. Specific items to consider for grinding:

1. Prior to entering the production process, grinders must ensure that a negative *E. coli* O157:H7 result has been received, if the raw material was subjected to testing. It is recommended that all raw materials used for raw ground products be sampled, tested and found negative for *E. coli* O157:H7 prior to use.
2. Inspection of raw materials prior to grinding - Use an AQL program or some process for **evaluating** the raw materials. (See example program in Appendix D).
3. Formulation of the finished product - Utilize a batch sheet to document batch identification to include raw materials used, specific weights and amounts, fat percent, etc. The formulation documentation must address quality characteristics, product specifications, and traceability both forward and backward in the production system.
4. Temperature monitoring of room and ground product to ensure integrity - The room temperature must be controlled and the actual time of processing should be as fast as possible to maintain ground product integrity during production. A target

of <50°F for the processing room is most often used and records of actual room temperatures should be maintained.

5. Defect inspection and elimination systems must be used when possible for bones, metal, etc.
6. Rework, reprocessing of intra-batch or finished product over-runs must at all times have appropriate identification and tracking for traceability purpose. When reused in formulation these products must be tracked on the batch records.
7. Target finished product temperatures commonly used for ground products are: <32°F for forming fresh products; <35°F for spiral/tunnel freezing chubs, and <10°F for IQF patties. During processing, these temperatures may be exceeded for brief time periods, but each establishment must carefully **evaluate** and control time and temperature.
8. Production employees must complete an **evaluation** of the equipment including a breakdown of the equipment (grinders – plate 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 documented, 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 finished 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.

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 must identify the types of raw materials used by its tracking codes, the amount used in each batch of formulated product, the specific grinding system, the time the batch was formulated, the in-process cleaning and inspections of the entire process system by authorized representatives.
- **In-process Control Records** - These records must identify the types of **control checks** performed on metal detectors and other control instruments, the time **checks** were performed and the line and/or finished product code information.
- 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 finished product be segregated, that cleaning and sanitizing of the processing line be completed prior to restarting production, and that a new lot/sub-lot be started when production begins. This information must be documented on a plant specific SSOP or HACCP document so it can be used for sub-lotting products produced during the same period.

Finished ground products must be designed and engineered to perform optimally under the designated conditions. The final customer must be considered when designing products;

this includes cooking methods, storage conditions, handling of product, and type of customer. Examples to consider include:

- Excess denatured protein “skin” can result in inconsistent cooking. This can be caused by overworking the meat block or the direct application of cryogenic compounds for freezing products; N2 or CO2.
- Cold chain integrity is critical to the performance of the finished product. Thawing and refreezing of products can denature surface proteins that results in inconsistent cooking.
- Fat content of product can affect cooking consistency and time required for doneness.
- Structure of product (shape, size, forming) may affect cooking consistency and time required to reach proper temperature.
- Cooking method of customer (if known) may dictate changes to product to ensure cooking consistency.
- Cooking instructions included on finished product packaging must be precise and consider all of the various platforms products may be cooked on. It is recommended to include in these cooking instructions that end point temperatures **must** be verified with a thermometer or other device.

C. INTERVENTIONS / INHIBITORS

Appendix G provides a list of possible interventions. Those approved by USDA are listed in FSIS Directive 7120.1. Grinding operators should explore the use of new technologies as they become available.

www.fsis.usda.gov/oppde/rdad/fsisdirectives/7120.1_amend3.pdf

D. PACKAGING / LABELING

It is important that the finished product is properly packaged and labeled to protect the integrity of the finished 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 finished product identification/tracking mechanism must identify specific processing lines used to produce this finished product. This may help narrow the finished 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 finished products with product identity and code dates that include an expiration date, sell-by-date, use-by-date and production date, 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 finished product’s requirements, as well as specific cooking instructions.

6. Bar coding is an option that can be used to help with the finished product identification and tracking.
7. If finished products contain allergens, they must be appropriately labeled. Additional information on Allergen Control Programs is contained in the next section.
8. It is recommended that tamper-evident packaging be applied to all finished product.

Cooking instructions appearing on packaging must be accurate. Retail ground beef and ground beef products (i.e. frozen hamburger patties) may not achieve the desired doneness across all cooking methods and under all conditions. However, it is important to list proper end point temperatures. Additionally, it is important that if cook times and cooking methods are recommended, the combination of those times and temperatures will yield fully cooked product.

During 2007, there were a number of recalls and illnesses associated with retail ground beef products; specifically with frozen ground beef patties. Processors of these types of retail products must be cognizant of the customer they are servicing with their products and must consider this in relation to their HACCP and Microbiological Testing programs. They may want to utilize as many microbiological verification steps as possible, including testing finished products specifically for *E. coli* O157:H7 in their programs. These types of finished product testing programs have proven to be very effective at mitigating risks to consumers when applied properly.

E. ALLERGEN CONTROL PROGRAM:

See Raw Material receiving section for details.

F. STORAGE OF FINISHED PRODUCT

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

Specific items to consider:

1. For shelf-life purposes, place fresh finished product into cold storage (i.e., <40°F) and frozen finished product into freezers (i.e., <10°F).
2. Utilize finished products in a plant specified time-period to maintain shelf-life requirements. Shelf-life of the finished product is dependent upon the type of product, type of package, temperature of storage, condition of incoming raw materials, etc. Therefore, each establishment must have specific guidelines for storing and utilizing finished products.
3. Store finished products to maintain package/pallet and lot integrity to help minimize customer risk.

4. Storage conditions must be maintained according to pre-requisite program requirements to ensure product integrity during storage.
5. Plant security must address raw material and finished product storage areas. Lock and/or secure areas during periods when the plant is not operating, if possible.

G. PRE-SHIPMENT REQUIREMENTS

1. Ensure that the HACCP pre-shipment review has been completed prior to transferring ownership of the finished product to the customer. USDA considers transfer of finished 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’s risk.
3. Make sure that there are no hold tags prior to releasing finished 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 for handling test results and notifying customer of results, if necessary.

H. LOT MINIMIZATION OF FINISHED PRODUCTS

When possible, grinders may want to consider shipping the same finished product 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.

I. LOADING / SHIPPING

Finished products must 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 must be evaluated prior to loading and shipping to ensure that the condition meets plant requirements for transporting raw ground meat. All trailers and carriers must 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 must be coded or identified for intended use and for recall or market withdrawal purposes. Specific items to consider:

1. Designated employee must **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, no signs of pests or rodents.
 - Temperature of trailer — temperature of the trailer must be acceptable to maintain finished product temperatures.
 - Trailer door seals must be intact to control temperature.
 - General trailer condition — void of cracks, insulation in good condition, etc.

2. All finished products must be handled properly to maintain the condition of the finished products. Therefore, the time the finished products remain on the loading and receiving docks must be controlled based on the temperature of the docks.
3. The loading/shipping employees must be aware of the finished products being transported and the proper handling techniques for these products.
4. All trailers must be pre-chilled prior to loading finished products and the trailers must at least reach the same temperature as the temperature of the product being shipped and should be lower if possible. This may not always be possible, especially for frozen finished product. Hold and **verify** prior to release and delivery of load documents. It is recommended that temperature monitoring devices be used on all loads. These devices must be **verified** to insure that temperatures were maintained during the transport segment to the customer.
5. Package integrity must be maintained during loading/shipping and delivery to customer.
6. Product identification must be maintained through loading and shipping to ensure that the finished products can be traced if needed for recall and/or market withdrawal purposes.
7. Trucks must be sealed for load security and security of trailer.
8. Plant security may address driver identity – including copies of driver’s license, tractor trailer identification for each driver to minimize risk to customer and grinding operators.
9. Just as standards are being elevated within processing facilities, the same criteria needs to be applied to distribution centers used to hold and ship product. Cleanliness, cold chain management, control of product and security are vital at distribution centers, just as they are in processing facilities. It is recommended that there be a verification system in place to insure the handling and distribution of products through the distribution chain.

VI. System Challenges to Measure Effectiveness

A. RECALL PROGRAM AND MOCK STOCK RECOVERY DRILLS

All grinding operations must develop a recall program. The program must include mock recalls conducted on a periodic basis to ensure that the program works as planned. The recall program must include identification and tracking of raw materials, packaging, and finished products. The program must cover all raw materials (meat, non-meat ingredients), packaging materials to the finished product. The program must identify all suppliers, customers, distributors and everyone involved in the process and must include their contact information. There must be a primary and secondary contact available at all times, especially for after hours and weekends and include contact phone numbers, fax numbers and emails. 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 E**.

B. PLANT SECURITY

Plant security systems must 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 must 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. Visitor Security is an important factor and must be enforced at all levels of the establishment's operation.

The following web link can be used to access the USDA Model Food Security Program for Meat and Poultry Processing:

http://www.fsis.usda.gov/PDF/Model_FoodSec_Plan_Processing.pdf

On the same web site there is a Self Assessment Checklist that can be used to verify that you have addressed all of the aspects of the Food Security Model. The following web link can be used to access the Self Assessment Checklist:

http://www.fsis.usda.gov/PDF/Self_Assessment_Checklist_Food_Security.pdf

Other Food Security Models are also available from USDA FSIS and through the Food and Drug Administration; FDA's web link is: <http://www.cfsan.fda.gov/~dms/secguid6.html>

VII. Product Handling For Microbial Testing of Finished Products

A. 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 finished product testing to establish a lot minimization system. The process for implementing this type of testing program will vary with the finished product(s) being produced and the amount of risks that plants are trying to minimize through the testing program.

B. 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 must 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 lot or sub-lot.

- The plant should have a written procedure for regulatory sampling to ensure that the finished 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 finished 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 finished product as if it is positive and diverting it to 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 finished 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 (Office of Public Health and Science) to be added to the system.

VIII. HACCP in a Grinding Operation

HACCP is a process control system designed to prevent, eliminate or reduce to an acceptable level food safety hazards. The establishment must consider biological, physical, and chemical food safety hazards. This is a raw product 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 must 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. Those establishments that have determined through their hazard analysis that *E. coli* O157:H7 is not reasonably likely to occur may need specific data on prevalence rates of *E. coli* O157:H7 in raw beef ingredients along with some knowledge of the interventions used to achieve appropriate level of control. Some plants using a hold/test/release program for *E. coli* O157:H7 have determined through their hazard analysis that this hazard is reasonably likely to occur. In this case, the establishment may choose to adopt a “product disposition” CCP whereby product disposition is made based on testing results. Product that has tested positive for *E. coli* O157:H7 is sold for cooking only.

These Best Practices were developed with input from technical personnel at firms that produce raw ground beef. As additional intervention technologies, changes in Regulatory Standards or new information becomes available, these documents will be reviewed and updated. Questions or suggestions are welcome and should be addressed to: Timothy P. Biela, 817-271-9146 or timbiela3@gmail.com or Mark Andersen, 651-366-6569 or mandersen@rancherslegacy.com.

APPENDICES

Appendix A –

Title 21: Food and Drugs

PART 110—CURRENT GOOD MANUFACTURING
PRACTICE IN MANUFACTURING, PACKING, OR
HOLDING HUMAN FOOD

Title 21: Food and Drugs
PART 110—CURRENT GOOD MANUFACTURING PRACTICE IN
MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

§ 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.

§ 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 harborage 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.

§ 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.

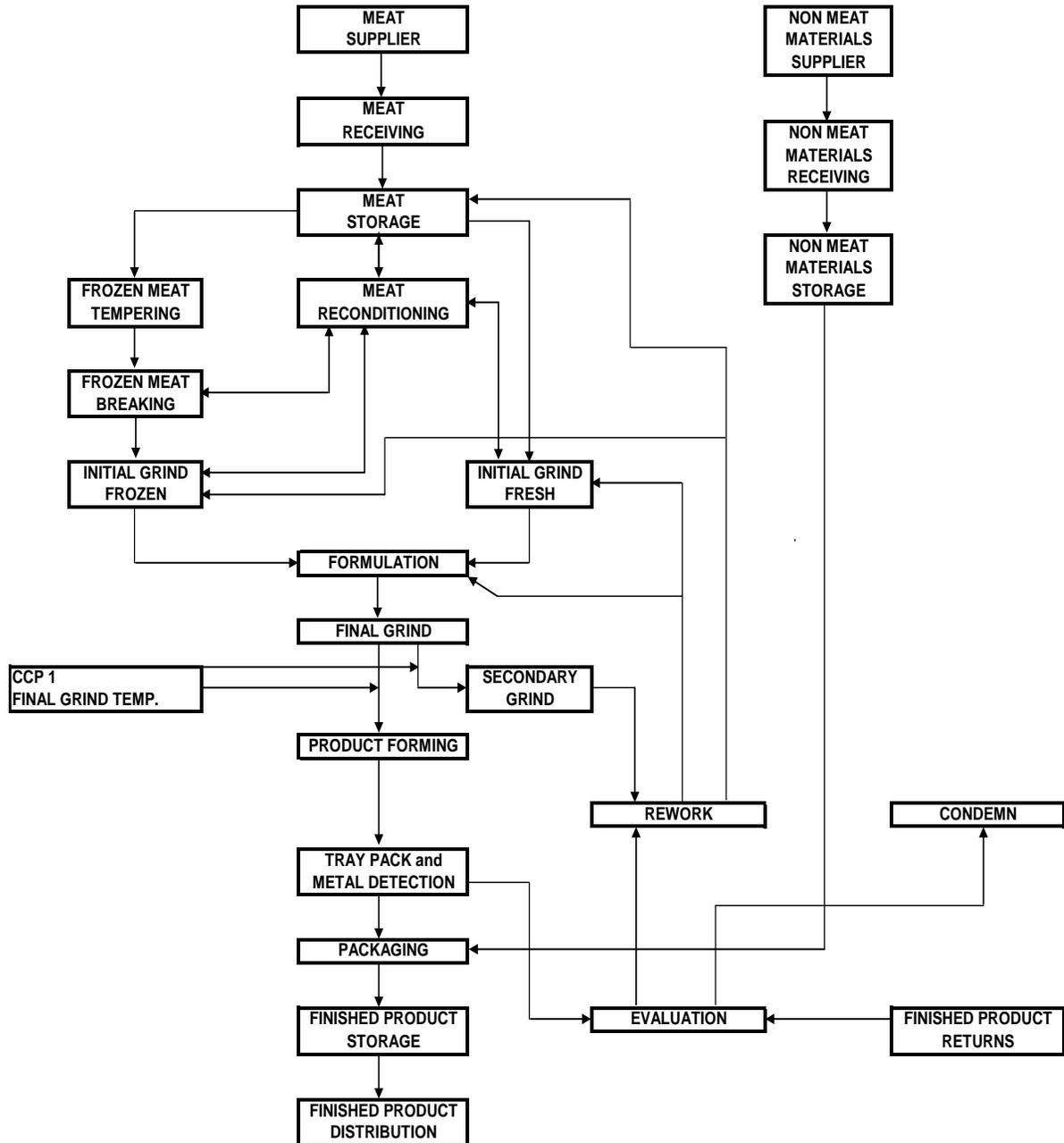
APPENDICES

Appendix B – Process Flow Charts

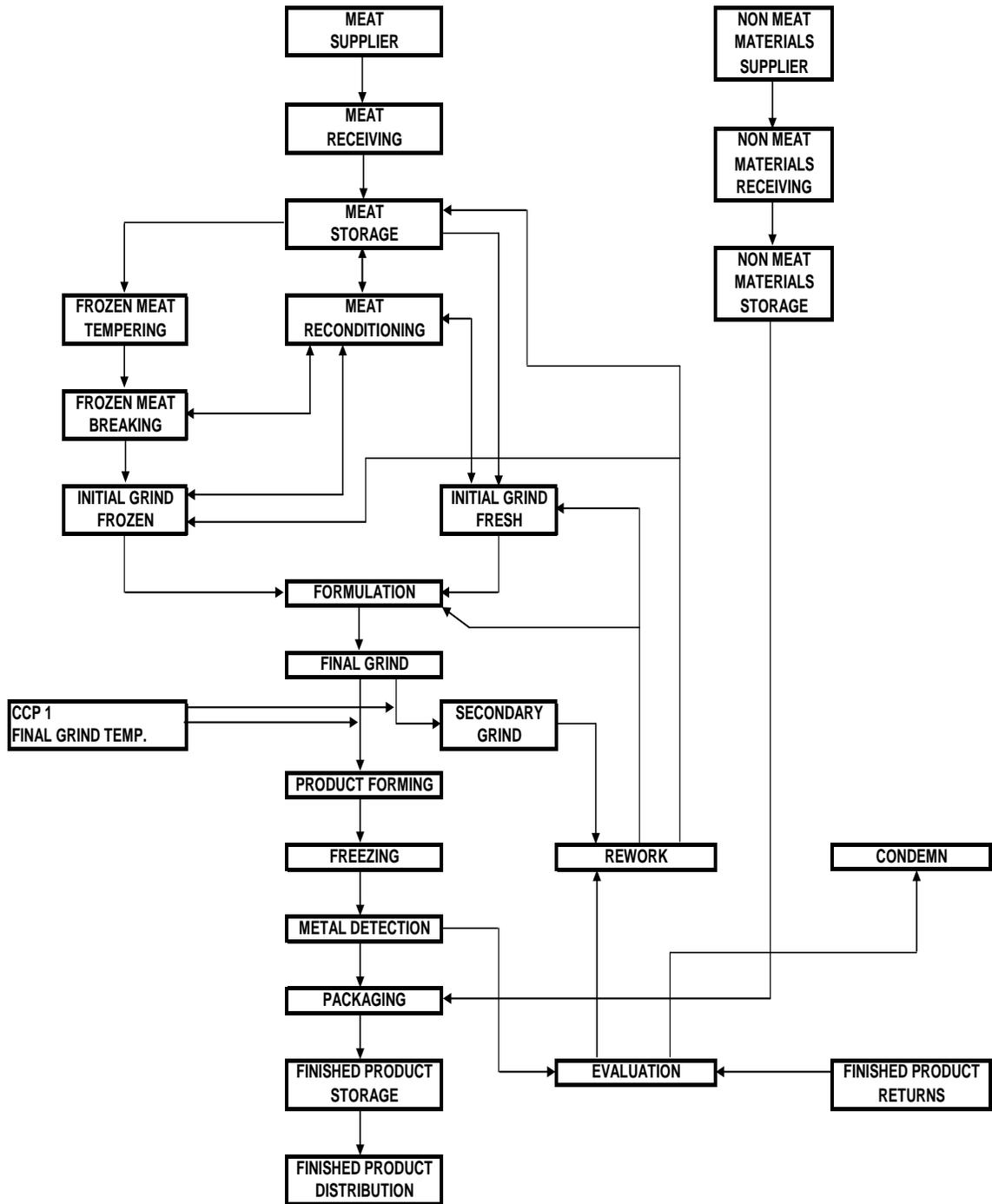
FLOW CHART - RAW GROUND FRESH - MAP

**FLOW CHART – RAW GROUND – FROZEN 100%
BEEF PATTIES**

FLOW CHART - 100% GROUND BEEF FRESH : MAP



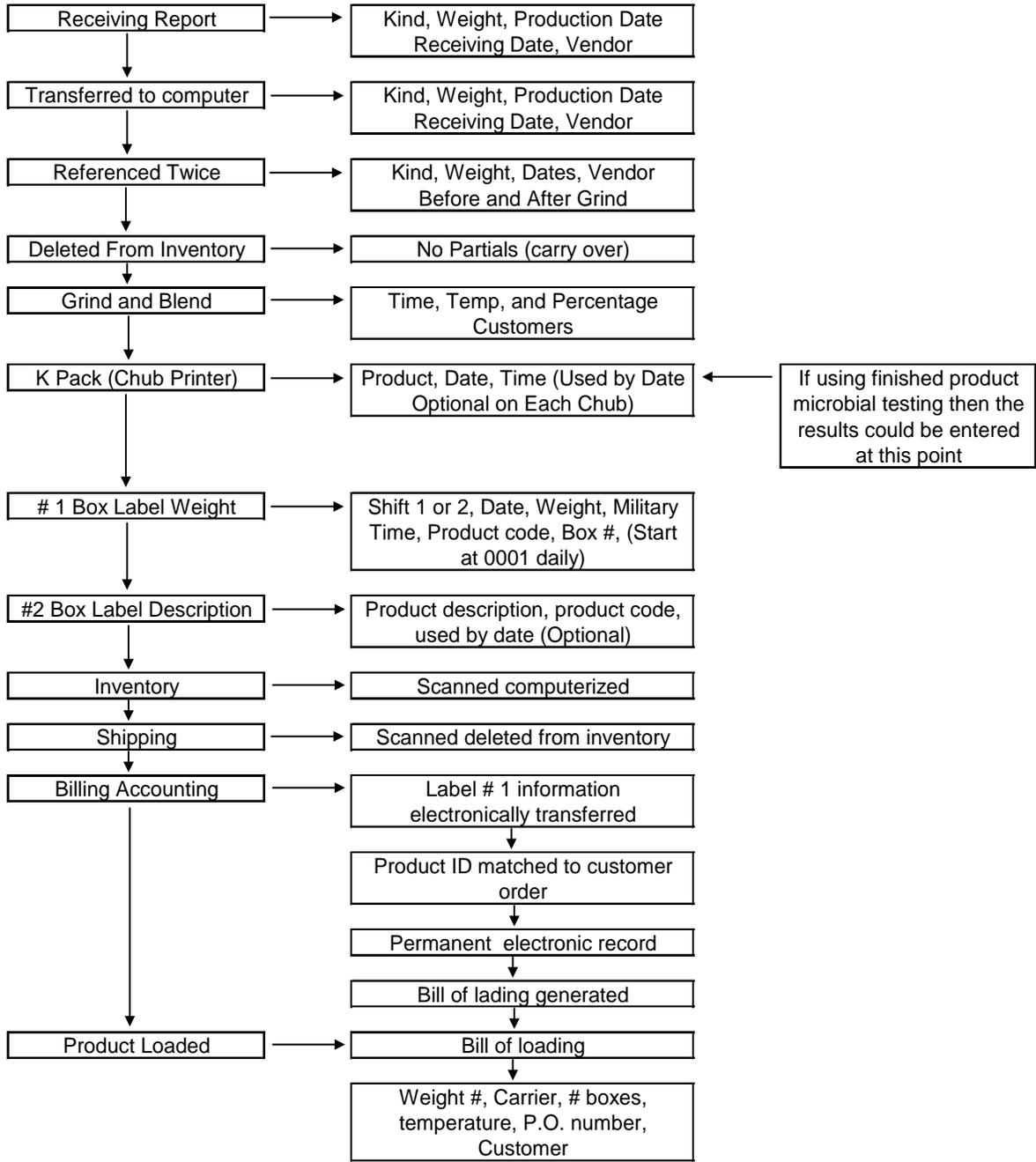
FLOW CHART - 100% GROUND BEEF FROZEN BEEF PATTIES & BULK IQF



APPENDICES

Appendix C – Ground Beef Lotting

GROUND BEEF LOTTING



APPENDICES

Appendix D – Raw Material Inspection Report

**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: _____

APPENDICES

Appendix E – Recall Records

PRODUCT RECALL DIARY OF EVENTS

And

SUMMARY OF DOCUMENTS – MOCK RECALL

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: _____

Summary of Documents - Product Mock Recall

Product(s) Recalled:

Record(s) Collected and Reviewed:

Daily Yield Report

Production Records:

Batching Records

Attribute & In-Process Records

Rework Batch Records

HACCP & SSOP Records

Dry Goods Packaging Information

Detail Contact Information

Crisis Team Contacts:

Local Media Contacts

External Contacts

Customer Contacts

Distribution Center Contacts

Product and tracking Information

Microbiological Reports

Raw Material Screening

Raw Material Profiles

Rework Profiles

Laboratory Sample Manifests

Shipping and Inventory Control Records

Bills of Lading and Load Plans

Summary

Mock Recall Closed

APPENDICES

Appendix F – Formulation Record

FOR EXAMPLE ONLY

Formulation Sheet

Product:

Date:

Shift: 0

Sheet: 1

Floor: 0

Batch Number	1	2	3	4	5	6	23	24	25
Grinder Number									
Batch Time									
Frozen									
L. F. T. B.									
Fresh Lean									
Fresh Trim									
Frozen Trim									
Fresh Rework									
Frozen Rework									
Finegrind Rework									
Lean Adjustment									
Trim Adjustment									
Reject For Fat									
Batch Weight									
Fat Percentage									
Adjusted Fat									
Running Fat									
Batch Temperature									
Grinder Heads Cleaned									
Anyl Ray Checks									
Frozen Supply							#REF!	#REF!	#REF!
2nd Frozen Supply							#REF!	#REF!	#REF!
L. F. T. B. Supply							#REF!	#REF!	#REF!
Fresh Lean Supply							#REF!	#REF!	#REF!
Fresh Trim Supply							#REF!	#REF!	#REF!
Frozen Trim Supply							#REF!	#REF!	#REF!
Percentage Frozen									
Percentage L. F. T. B.									
Percentage Trim									
Percentage Fresh Lean									
Percentage Rework									
Percentage Finegrind									

QC Tech:

Grind Plates:

Scale Calibrated:

Total Frozen Lean:

Total L. F. T. B.:

Total Fresh Lean:

Total Fresh Trim:

Total Frozen Trim:

Total Formulated:

Fresh Rework:

Frozen Rework:

Finegrind Rework:

Total Rework:

Total % Frozen:

Total % L. F. T. B.:

Total % Fresh Lean:

Total % Trim:

Mix Times

Lean Blender:

Trim Blender:

M/G # 1:

M/G # 2:

M/G # 3:

* Same Raw Material Used

All Grind Heads Cleaned

@ Finegrind Head Cleaned

APPENDICES

Appendix G –

Safe and Suitable Ingredients for Meat and Poultry Products

www.fsis.usda.gov/oppde/rdad/fsisdirectives/7120.1_amend3.pdf

APPENDICES

Appendix H–

Guide to *E. coli* O157:H7 Testing of Raw Ground Beef and Raw Ground Beef Components

Introduction

Since 1994, when *E. coli* O157:H7 was declared an adulterant in raw comminuted beef products, the Food Safety and Inspection Service (FSIS) has been testing raw ground beef for this pathogen. The general rule as to what product would be implicated by a positive finding *had* remained unchanged prior to 2002.

Under the general rule, all products that ran over the same contact surfaces as the positive sample from clean-up to clean-up were implicated. This would include any “rework” initially produced on the sample day where it might have become contaminated and then used on subsequent days. This “rework” would implicate all raw products run over the same contact surfaces on these subsequent days, clean-up to clean-up.¹

In 1997 a second rule was added: the “point source” rule. Under this rule, if a unit of raw materials – a single combo or a box – was broken up and used on different days and one of those days tested positive, any other days in which the remainder of the combo/box were used were also implicated – clean-up to clean-up.

In 2002, the agency’s approach to this pathogen began to change – it was paying more attention to the raw materials used in ground beef. That year there was an 18 million pound recall of trim which had not been tested for *E. coli* O157:H7, but had been produced on a day when other combos had tested positive.² Also that year at least one recall (involving illnesses) was conducted based on the grinder’s

¹ Obviously, without some break, “rework” could technically contaminate subsequent products *ad infinitum*.

² Trim which had been tested and found negative was not included in the recall

use of the same load of raw materials on different production days, even though the grinder followed the clean-up to clean-up and point source rules.

Changed Inquiry from Clean-Up to Clean-Up/Point Source to “Same Source Materials”

In 2004, FSIS issued its second set of Questions and Answers involving testing for *E. coli* O157:H7.³ In the second question, FSIS rejected clean-up to clean-up as the means of identifying product implicated by a positive sample. Given its importance, the entire Q & A is reprinted in its entirety:

2. Question: Can “clean-up to clean-up” be used as a method of distinguishing one portion of production of raw ground beef from another portion of production?

Response: No. The establishment should support its basis for distinguishing one portion of production from another, and clean-up to clean-up is not an adequate basis for distinguishing one portion of production from another. If an establishment finds product positive or presumptive positive (and does not confirm it negative) for *E. coli* O157:H7, it is important that the establishment conduct complete cleaning and sanitizing procedures to prevent possible *E. coli* O157:H7 cross contamination in product produced after the positive or presumptive positive finding. In this situation, the establishment would need to have a basis other than the clean-up to determine that the ground product produced after the clean-up from the *same source materials* as the product found positive or presumptive positive is not implicated by the test results. (Emphasis added.)

Following this Q & A, clean-up to clean-up still remains relevant to the issue of possible cross-contamination of equipment, but it is no longer determinative. FSIS’ focus is now the raw material; the “Same Source Materials” rule.

From a logical perspective, the agency’s focus on same source materials makes sense, since the *E. coli* O157:H7 enters the ground beef through the raw materials (now called “raw ground beef components” by FSIS). Unfortunately, the change removes the certainty grinders previously had as to what product is implicated by an agency or establishment sample so that all implicated products could be held. This summer, a recall was initiated because the grinder did not take into account the same source materials when its own test of ground beef yielded a positive *E. coli* O157:H7; that establishment only relied on clean-up to clean-up/point source to determine the implicated product.

To assist both grinders and raw material suppliers, this Guide will explain the new “same source materials” rule. It will provide suggestions on how to minimize the amount of product implicated and how to avoid preventable recalls. Finally, it will summarize the rules applicable to the new FSIS National Trim Baseline, which includes testing of trim for *E. coli* O157:H7.

General Considerations Under the “Same Source Materials” Rule

As noted in the recent Q & A 2, the establishment needs to distinguish between “same source materials” to limit the amount of finished product implicated by a positive sample result. The agency does not specify precisely how to distinguish “same source materials;” rather that is left to the grinder.

The only currently acceptable way to distinguish same source materials is to test. So, there are three basic possibilities:

- The grinder lacks any test results – in which case the entire shipment of the particular raw beef component from the supplier will be deemed to be same source material.

³ http://www.fsis.usda.gov/OPPDE/rdad/fsisdirectives/10010_1/Directives_Q&A.pdf

- The supplier has tested the raw ground beef component and divided the shipment into “lots” or “sub-lots” – in which case, each individual lot or sub-lot would stand on its own, *provided*, the supplier has a sound basis for its testing program.
- The grinder itself has conducted extensive finished product testing – in which case, the establishment could segment the production day, *provided*, the grinder has a sound basis for its testing program.

Establishment Testing

For an establishment to limit the amount of “same source materials,” all the raw material or the finished product must be tested. However, not all testing is created equal.

Raw Ground Beef Components

For raw beef components, three types of sampling regimes have been recognized by FSIS as providing a “sound basis” for separating tested product. Two involve excision sampling – the taking of surface samples from the trim or other raw components; the other involves core sampling.

On excision sampling, the establishment must take a significant number of surface samples. FSIS has recognized 30 and 60 samples per combo lot (generally referred to as N=30 and N=60 respectively). Indeed, as discussed in the section below on the FSIS National Trim Baseline, FSIS itself uses the N=60 method.

The core sampling is based on the requirements of a quick service restaurant. Under this approach, a “core gun” removes a column of meat from each combo (five cores per combo). The sample so collected is then composited with the samples from the other combos comprising the lot and analyzed for *E. coli* O157:H7.

Under all the methods, the “lot” is generally restricted to five combos or less, though some companies will include up to six combos per lot – to go further could dilute the sample rigor. This lotting and testing of combos provides the “sound basis” to distinguish one lot of combos from the other lots.

Most raw ground beef component suppliers use one of the sampling methods above for the beef trim. However, other raw materials used for comminuted beef products may not be tested. Although FSIS expects suppliers to test any component that is to be used in raw comminuted products, the producing establishment may not test a particular raw material if it does not have a reason to believe that the materials will be used in raw ground beef production. These materials could include heart, cheek meat, or fatty trimmings. Should a grinder intend to use such materials and is uncertain as to whether the material has been tested, the grinder is strongly advised to contact the producing establishment to ensure that these components are tested. Virtually all raw ground beef component suppliers will test these materials upon request. Since these raw materials are often used over several days of production, failure to obtain tested materials could end up implicating multiple production days if there is a positive *E. coli* O157:H7.

There is one other potential raw ground beef component which may not be tested by the supplier and needs to be addressed separately – boxes of vacuum packaged boneless beef (primarily sub-primals).⁴ The vast majority of these products are used for a variety of purposes, but not for raw ground beef. Moreover, much of this product is routinely sold through distributors. So, the supplier generally will not anticipate the vacuum package beef will be used for raw ground products. Absent a direct contact with the supplier, it is unlikely a grinder will obtain tested boxed beef. If the grinder is currently using vacuum packaged boneless beef which is not tested, it should consider contacting the supplier to ensure

⁴ We do note that most imported frozen boneless beef, domestic boneless beef in combo bins, and beef trim in boxes are routinely tested for *E. coli* O157:H7 as a matter of course. The above discussion relates to boneless beef in vacuum packages.

the product the grinder is purchasing is tested. We anticipate that the boneless beef so tested would not be provided in vacuum packaging, but would be sent in the same manner as trim.

For completeness, we do wish to note that some grinders purchase coarse ground beef for fine grinding. In that case, the question becomes what testing the supplier is conducting. Some suppliers test the raw ground beef components used in the coarse grind. The rules above would apply to these products. Other suppliers conduct intensive testing of their coarse ground products. The rules applicable to these products are discussed below.

Finished Raw Ground Beef Testing

To clarify one point up front on finished raw ground beef testing – neither the periodic verification sampling a company conducts, nor is FSIS sampling sufficient to “lot” finished product. The magnitude of sampling must be much greater.

To date, FSIS has recognized only one finished product sampling system to limit the amount of product implicated by a positive finding. The system, initially adopted as a requirement by a quick service restaurant, requires intensive sampling of finished product daily (either every 15 or 30 minutes of production). Four samples are composited (for every one hour or two hour period) and analyzed for *E. coli* O157:H7. If a single composite is positive, that “lot” is retained as well as the lots before and after the positive period. If there are multiple positive periods, the same rule applies (positive lot plus the lot on either side), though numerous positives could call into question whether the negative lots from that day are truly negative. Testing programs of this type must be validated in each facility that considers their use. Validation testing requires very extensive sampling and testing across an entire days production to show how and when the organism enters the system and how the grinding system “cleans” itself over time. Consideration must be given to how “internal product failure” or rework is handled and reintroduced into the system as this will have a definite impact on how you bracket around a positive period.

It is important to note that when an establishment conducts this intensive finished product sampling, FSIS does not impose the clean-up to clean-up requirement. The basis of this policy are studies and establishment data showing that *E. coli* O157:H7 is not an environmental contaminant; rather, it is introduced by the raw material and subsequent raw material will “clean the system out” in approximately one hour. See, ICMF book, [Microorganisms in Food 7](#) (the contaminated raw materials cause a “comet-like” effect so that the contamination decreases over time to zero as the system cleans itself out). It should be emphasized that, as a general matter, FSIS will recognize this “comet effect” *only* if the establishment has been conducting sound, intensive testing.

FSIS Testing

The amount and nature of FSIS testing will likely change over the next few years. The agency has increased the amount of testing for *E. coli* O157:H7 in finished ground beef. It will also soon start testing trimmings for the pathogen. We anticipate that FSIS will maintain a level of approximately 10,000 tests per year, but that, as time passes, a larger percentage of those tests may be on trim and other raw ground beef components in lieu of finished product testing.

National Trim Baseline

FSIS has recently initiated its National Trim Baseline study.⁵ The agency has already started drawing trim samples and beginning on November 28, 2005, it will begin analyzing those samples for *E. coli* O157:H7. If the trim tests positive, FSIS will ensure no trim product implicated by the sample is used for raw ground beef production.

⁵ At present, the baseline will be limited to trim. FSIS anticipates expanding the Baseline to include heart, cheek and variety meats, perhaps as early as next year.

As mentioned above, FSIS is using the N=60 sampling method whereby it will take 60 surface excision samples from a combo lot of approximately 15 grams each. From these 900 grams sampled, FSIS will select 375 grams (the same sample weight as currently used for regulatory ground beef samples).

Under Notice 73-05, FSIS will take its sample regardless of whether the establishment has already cleared the product (*i.e.* has tested the trim and found it negative). This is being done to minimize the delay of waiting for the establishment and agency tests to be conducted sequentially, thereby preserving the value of the fresh trim.

If the establishment normally tests trim, the Notice provides that the agency expects the establishment to follow its procedures on the lot sampled by the agency. Indeed, the agency is very serious in its expectation that the plant will follow its normal procedures. Should the establishment sample test positive, the establishment must notify FSIS of the finding so that the agency's test result can be excluded from the baseline data. This is because such trim would never have entered commerce for raw ground beef production.

It is important to note that FSIS recognizes that there will be times when a company test is negative and the agency's is positive (and *visa-versa*). In and of itself, this will not invalidate or otherwise call into question the company's testing methodology.

In terms of what product is implicated by a positive, the basic rule is that the combos tested by FSIS will be the only trim implicated, *provided*, the establishment can demonstrate that no other combos from that production day are implicated. The only basis currently recognized by FSIS to distinguish the other combos intended for raw ground beef is that the combos have been tested (and any combos testing positive have beef diverted to non-raw use). The policy adopted in 2002 by FSIS – “the agency will respect your negatives” – is still valid. Admittedly, it is uncertain what degree of rigor the establishment's sampling program must achieve to overcome any agency positive.⁶ The apparent safe harbor would be one of the three sampling programs already recognized by FSIS: N=30, N=60, or core.

FSIS Finished Ground Beef Sampling

In 2005, FSIS increased the number of samples taken for *E. coli* O157:H7. In the first eight months of 2005, FSIS conducted approximately the same number of samples it drew in all of 2004 (coincidentally, the number of positive findings are the same for both years).

As discussed above, in absence of any contrary information, a positive FSIS *E. coli* O157:H7 finding will implicate: all product manufactured from the shipment of “same source materials” and any other product manufactured over the same food contact surfaces as the same source materials, clean-up to clean-up. This can implicate multiple days, especially when the raw material shipment was of a component that is used over time, such as hearts, cheek meat or frozen boxed beef.

The first step in limiting exposure is to further differentiate the load of incoming raw materials. This is done by having the raw materials “lotted” or sub-lotted based on test results. That way, the shipment can be divided into smaller units.

The second step is to minimize the number of different lots or sub-lots used when a sample is being taken for *E. coli* O157:H7. This would also include holding any unused combos/boxes from the “lot” or sub-lot until the sample results are reported. In addition, an establishment should also look to see if combos/boxes from the lot were used in previous production. If so, and the finished product was shipped, the establishment should let the inspector know that the sample could implicate shipped product. Under agency policy, a sample is not to be taken if the establishment did not have an opportunity to hold all product implicated by the sample.

⁶ As regards analytical method, the method must be recognized and equivalent to the FSIS method, such as the PCR based-BAX® System.

The third step is to address the issue of what products could potentially have become cross contaminated through common food contact surfaces. Even though clean-up to clean-up is no longer determinative as to all products potentially implicated, the establishment must consider potential cross contamination in determining what production is implicated by a sample.

There is another way an establishment can minimize the amount of product potentially implicated by a positive agency finding. As part of the sample procedure, the FSIS inspector randomly selects a time to draw a sample. If the time selected is late in the day, the entire production before the sample could be implicated given common contact surfaces and common lots. However, FSIS has officially indicated that if: (a) there is a sound basis for the lotting of raw materials and (b) the establishment has previously explained its lotting/production practices to the in-plant inspector -- when the inspector randomly selects a time, the establishment can demonstrate to the inspector what raw materials would be used at a time randomly selected. By so doing, the establishment can run the selected product at the start of operations and follow with a pre-op cleaning/sanitizing. Provided the relevant raw materials and sampled finished product is held, the remainder of the day would be free to ship.

One final note on FSIS testing. If the establishment is conducting routine intensive product testing (multiple samples/analyses per day), FSIS will treat its positive the same as an establishment's positive. This means the positive period plus a period to either side (the "window or bracket") will be implicated. Barring an establishment positive the same day in a different period, the remainder of the day outside the window or bracket is free to ship.

Some Helpful Hints

Based on the above, there is some general guidance that can be given for trim and ground beef producers

For trim producers:

- Test (using a recognized methodology) **all** raw materials intended for raw ground use with a scientifically sound sampling program – that way if an FSIS sample tests positive for *E. coli* O157:H7, the only product implicated will be the combos from which FSIS sampled. If the establishment does not conduct any testing, the entire day is suspect.
- Work with the FSIS IIC now, so that there is no confusion as to what product is implicated when FSIS begins its regulatory sampling and analyses.
- Obviously, if FSIS' sample tests positive, the agency will expect the establishment to conduct a review of its total food safety system for all slaughter dates and fabrication dates involved, just as if the establishment's sampling yielded a positive.

For grinders:

- Purchase raw ground beef components which have been tested for *E. coli* O157:H7 using a scientifically "sound" sampling program.
- Understand the suppliers' lotting or sub-lotting procedure so combos/boxes within the same lot can be identified and kept separate when necessary.
- When ground beef is to be sampled for *E. coli* O157:H7, identify the lots of raw materials in the blend at the time the sample is drawn and hold any unused combos/boxes from these lots and any finished product previously made from the lots until the test results are back. If finished product has shipped, let inspector know before the sample is sent to the FSIS laboratory.
- Manage raw material inventory so that partial lots are not held any longer than necessary.
- Work with the inspector to ensure he/she understands the establishment's lotting/scheduling procedures so that the product selected to be sampled by FSIS at a random time can nonetheless be run at the beginning of the shift.

APPENDICES

Appendix I–

Loading Plan Checklist

APPENDICES

Appendix J–

Beef Slaughter Guide; Data on Validated Interventions