BEEF INDUSTRY BIFSCO FOOD SAFETY COUNCIL

Best Practices for Raw Ground Products

March 2020

**This document is intended for the production of raw ground product. See Best Practices: Pathogen Control During Tenderizing/Enhancing of Whole-Muscle Cuts and Guidance for Purchasers of Raw Beef for Non-Intact Use for information related to other non-intact products.*

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This is not a regulatory document. This Best Practices document represents the current thinking of Beef Industry Food Safety Council (BIFSCo) members based on available shared knowledge and experiences. However, this Best Practices document does not create or confer any rights or obligations for or on any person and does not bind NCBA, BIFSCo, its members, or the public. BIFSCo Best Practices documents are not universal in scope or application and do not establish legally enforceable responsibilities. (Section added June 1, 2020)

I. 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:

1. Personnel — disease control, hygiene, clothing, training, etc.
2. Plant and grounds — construction and design, product flow, drainage, etc.
3. Sanitary operations — general maintenance, cleaning and sanitizing, pest control, etc.
4. Sanitary facilities and controls — water supply, plumbing, sewage disposal, rubbish and offal disposal, etc.
5. Freezer and coolers — monitored and maintained to ensure temperature control, recording devices, alarms, etc.
6. 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.

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.

Throughout this document, best practices for *E. coli* O157:H7 are given. This document will only refer to O157:H7 but FSIS considers a system in control for O157:H7 in control for all non-O157:H7 STECs.

A. 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 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).

B. LOTTING

The concept of lotting systems in ground beef operations is a complex and detailed issue. The previous USDA definition for a lot, when there is a positive result for *E. coli* O157:H7, was "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 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 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 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.

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 a 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 for a recall entirely.

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

1. 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)
2. 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.
3. Data collected during process: temperatures, microbial data, etc.

Sub-lotting requires the following additional types of documentation:

1. 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 the raw material(s) was used and the locations of equipment/lines where the raw material(s) was used.
2. Packaged-product tracking systems: The finished products must be coded with the actual times they were packed and sealed, and pallets of product should contain consecutive products off the line. Equipment downtime tracking sheets can identify lines not in use to package 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 trace back to the actual raw materials used in the process.
3. 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.

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.

Utilizing the guidelines provided above allows 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.

C. REPROCESSED PRODUCT

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 production day, 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 maintained within the same batch and should be covered by the actual flow diagram. 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:

a) Direct the product to further processing and identify or specify as product for cooking only. You must have this written into your HACCP (Hazard Analysis and Critical Control Points) 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.

b) 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. The use of this option must be limited to "break" the rework cycle and reduce the risk of an expanded recall. Rework 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.

c) Destroy the raw materials or finished products.

If the second option is utilized, then one must accept the risks that if a problem is found in the designated batch/lot then all batches/lots that contributed to the designated batch/lot are subject to review. It is imperative that a very detailed and accurate recordkeeping system is developed to document amounts and identify all batches/lots used in the designated batch/lot.

Note 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:

a) Direct the finished product to further processing 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.

b) Destroy the finished product.

c) Utilize the finished product to produce a designated batch/lot. Combine the finished products for a specified time period and process them at the end of a shift or on a specified day as a designated batch/lot.

If the last option is utilized, then one must accept the risks that if a problem is found in the designated batch/lot then all the batches/lots that contributed to the designated batch/lot are subject to review. It is imperative that a very detailed and accurate recordkeeping system is developed to document amounts and identify all the batches/lots used in the designated batch/lot. The economic impact of an increased recall based upon this option may negate cost savings realized by choosing this option.

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 to which it was added. Therefore, it is imperative that detailed and accurate records are maintained documenting the amount of out-of-spec product used, the batches/lots where the product is used, and clear breaks in the process (i.e., clean-ups). 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 needs 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 to handle these issues.

II. BEST PRACTICES FOR RAW GROUND 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 foodborne 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 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).

It is important to understand the difference in the processes of validation and verification for the remainder of this document. Validation is actions taken by the establishment designed to determine that the HACCP plan (and parts thereof) are functioning as intended and achieving the results identified in the HACCP Program. Verification involves the use of methods, procedures or test in addition to those used for monitoring to determine if the Food Safety Systems are in compliance with the written HACCP plan

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

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.

For beef, 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. Intervention validation must be plant-specific using either appropriate indicator organism testing or by measuring critical operational parameters, such as pH, pressure, contact time, temperature, relative humidity, or other parameters critical to achieving the results of supporting science. It should also 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 for use 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.

It is also important for beef grinders to have specific data on *E. coli* O157:H7 and top 6 non-O157:H7 STEC's 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.

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 can produce on a regular basis. Data can be graphed, compared and trended over time to ensure ongoing compliance with your specifications or standards and ensure suppliers are controlling their process.

3. *Testing/Prescreening Requirements*

For sampling and testing for *E. coli* O157:H7, there must be a written protocol for sample collection (N60 or equivalent), lab analysis (equivalent to FSIS method or better) 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.

Laboratory services used for testing samples must be reputable and accredited. Furthermore, the testing method (enrichment and detection 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. 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. There should be ongoing verification testing (1x/month Apr – Sept; 1x/3 months Oct – Mar) occurring for *E. coli* O157:H7 and top 6 non-O157 serotypes.

Facilities should have a High Event Period (HEP) program in place. It should address localized events and systemic events. A positive rate statistically significantly greater than 5% in a given period signals a HEP. The program should evaluate the data that results in negative tested trimming and primals and address appropriately.

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 a procedure is in place for on-going evaluation of suppliers. The following guidelines can be utilized to help design a system for evaluating suppliers.

See Appendix D – Raw Material Inspection.

1. *New Supplier Approval*

Each new supplier should provide written acknowledgement of the grinder's Raw Material Purchase Specifications and their willingness to comply. These suppliers must

also 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. Suppliers 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. (GFSI certification and additional 3rd party or supplier O157 addendum annually).

Grinders must conduct quality (Acceptable Quality Level [AQL]) inspections of incoming raw materials to ensure they are acceptable. For new suppliers, a grinder may want to intensify the sampling frequency to ensure consistency in meeting the requirements. By tracking the results for individual loads or lots from Suppliers, processors can determine who is achieving the best results and what their processes produce on a regular basis.

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.

2. *Ongoing Supplier Evaluations*

Grinding operations must periodically provide an update of the Raw Material Purchase Specifications to each supplier and request an updated acknowledgement of receipt of the specifications and their willingness to comply. Data must be collected and tracked on the following items to identify supplier trends and help make purchasing decisions:

a) 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.*

b) Foreign object contamination

c) Defect(s) (unacceptable indigenous inclusions)

d) Plant audit results

e) Age of raw material at receipt

f) Temperature of raw material at receipt

g) On-time delivery

h) Other plant-specific requirements

C. PRE-RECEIPT OF RAW MATERIAL(S) VERIFICATION

Based on 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 its 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 result, 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 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 materials 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 must be considered when receiving raw material. 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. The designated employee must evaluate and document on a raw material receiving log the condition of the trailer and the shipping container(s) and carriers of raw materials upon arrival and must document the time the inspection was conducted. Items for evaluation may include:

a) Cleanliness of trailer — no foreign materials, dirt, debris, or off odors.

b) Temperature of trailer — Temperature of the trailer must be acceptable to maintain raw material temperature. The 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, a written procedure must be in place that defines the action(s) to take 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.

c) General trailer condition — void of cracks, insulation in good condition, trailer door sealed properly, paper on floors for carcass carriers, etc. No signs of rodent or pest activity.

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:

a) Species identity and/or origin (bull, cow, etc.)

b) Domestic vs. foreign supply source

c) Institutional Meat Purchase Specifications (IMPS) or other product identity

d) Boning date/slaughter date or pack date

e) No foreign objects

f) 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.

g) 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.

h) If the supplier is testing for generic *E. coli*, coliforms, TPC or other microorganisms, the results 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, the raw material must not be accepted, or it can be placed on hold until the test results are received.

i) Packaging/pallet requirements — e.g., 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.

j) Age of raw material — recommend fresh products <5 days from fabrication or bone date; and frozen meat no more than 6 months from fabrication.

If the raw material meets the purchase specifications, the designated employee must evaluate the actual condition of the raw material. The following items are

recommended for evaluation:

a) Temperature of the raw material (i.e., frozen <10°F; fresh <40°F). Each operation must have a 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 be taken and evaluated.

b) Organoleptic evaluation of the raw material for off odor, discoloration, improper appearance.

c) Supplier code information and proper lot/load identification on the raw material.

If the incoming raw material passes 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 grinding operation accepts the non-meat items, they 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 LOG to document compliance with the Food, Drug and Cosmetic Act.

Based on CDC estimates food allergies are linked to approximately 30,000 emergency room visits and 150 to 200 deaths a year (https://www.cdc.gov/mmwr/volumes/66/wr/mm6615a2.htm). 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:

A. SOURCING

All allergen raw materials received must have a LOG 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.

B. SCHEDULING

All products containing allergens must be processed on dedicated equipment that is 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 in a separate processing area, when possible.

C. SEPARATION

Allergen ingredients must be labeled and stored separately from other dry goods and non-allergen ingredients to prevent unintentional contamination.

D. STAGING

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

E. LINE CLEARANCE

Before beginning production of products which contain allergens, remove all ingredients for all other products from the weighing and production areas.

F. VERIFICATION

Constant verification of all the steps outlined in the control program will help ensure against inadvertent or unintentional contamination of other products. End-product testing must be conducted only when sufficient reason exists to suspect 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.

G. SANITATION

The facility must be cleaned, and all product lines, equipment, containers 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 before beginning new operations.

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, 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 conditions – 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 a plant raw material rotation/inventory control schedule.
3. Utilize all fresh raw materials preferably within 5 days but 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 prerequisite 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 it is necessary to 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 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 section includes guidelines on weighing, mixing and blending coarse and final grinds, forming, packaging, labeling and other plant-specific aspects of the process. Throughout all steps the temperature of the ground product must be maintained and documented. The use of aged trim in the finished product being produced must meet guidelines. In producing ground beef, the use of at-risk ingredients often results in the highest-risk products. Age of trim, cold-chain management, and historical information on raw material supplier(s) should be taken into account when formulating a product

for a specific customer's Food Safety Objectives.

Steps must be taken to prevent species cross-contamination and to ensure 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 the finished product to the 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 include batch identification and time of batch production. Specific items to consider for grinding:

1. Negative *E. coli* O157:H7 result - 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 the room and the 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. Inspection for defects - Defect inspection and elimination systems must be used when possible for bones, metal, etc.
6. Traceability for rework – Rework and 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:
    a) <32°F for forming fresh products
    b) <35°F for spiral/tunnel freezing chubs
    c) <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. The time of each evaluation should be recorded. It is important that this evaluation 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. Prior to shipping a product, an establishment may want to include a review of the evaluation records associated with equipment breakdowns to ensure that everything was working properly and there were no problems during the product's production.

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

1. Batching record - This record must identify the type of raw material used by its tracking code, the amount used in the 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.
2. In-process Control Record - This record 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.
3. Metal detector record, if used
4. Equipment evaluation records (i.e., grinder checks)
5. Bone collection record
6. Other records as specified by individual customers

If any abnormal indicator is found during the process, 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 a product; this includes the cooking method, storage condition, handling of the product, and the type of customer. Examples to consider include:

1. 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; N^2 or CO^2.
2. Cold-chain integrity is critical to the performance of the finished product. Thawing and refreezing of products can denature surface proteins that result in inconsistent cooking.
3. Fat content of product can affect cooking consistency and time required for doneness.
4. Structure of product (shape, size, forming) may affect cooking consistency and time required to reach proper temperature.
5. Cooking method of customer (if known) may dictate changes to product to ensure cooking consistency.
6. Cooking instructions included on finished-product packaging must be precise and consider all various cooking platforms possible. It is recommended to include in the 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.
https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/7000-series.

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 a problem occurs with only one particular processing line.
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 code-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 requirement, as well as specific cooking instructions.
6. Bar-coding is an option that can 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 (e.g. 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, a number of recalls and illnesses associated with retail ground beef products occurred, specifically, with frozen ground beef patties. Processors of these types of retail products must be cognizant of their customers and must consider them 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 prerequisite 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 the finished product does not have any "no-hold tags" prior to releasing it into inventory.
4. If microbiological testing is being conducted on the finished product, ensure that all test results have been received or a written procedure is in place for handling test results and notifying the 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 customers receiving partial lots and will make the tracking process much easier than it would be if lots were 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 the finished products must be coded or identified for intended use and for recall or market withdrawal purposes.

Specific items must be considered regarding loading and shipping a product. A designated employee must evaluate and document the condition of the trailer, container and carriers of finished products prior to loading the products. When evaluating the trailer, the employee should look for:

1. Cleanliness of trailer — No foreign materials, dirt, free of debris, free of off odors, no signs of pests or rodents.
2. Temperature of trailer — Temperature of the trailer must be acceptable to maintain finished-product temperatures.
3. Condition of trailer door — Trailer door seals must be intact to control temperature.
4. General trailer condition — void of cracks, insulation in good condition, etc.

All finished products must be handled properly to maintain their condition. Therefore, the time the finished products remain on the loading and receiving docks must be controlled based on the temperature of the docks. The loading/shipping employees must be aware of the finished products being transported and the proper handling techniques for these products.

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. Hold or maintain control 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 ensure that temperatures were maintained during the transport segment to the customer.

Package integrity must be maintained during loading/shipping and delivery to the customer. Product identification must also be maintained through loading and shipping to ensure that the finished products can be traced if needed for recall and/or market withdrawal purposes.

Regarding security, trucks must be sealed for load security and the security of the trailer. Plant security may address driver identity – including copies of each driver's license and each driver's tractor trailer identification to minimize risk to customers and

grinding operators.

Just as standards are being elevated within processing facilities, the same measures need 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 a verification system be in place to ensure 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, which must include:

1. mock recalls conducted on a periodic basis to ensure that the program works as planned
2. identification and tracking of raw materials, packaging, and finished products
3. all raw materials (meat, non-meat ingredients) from packaging materials to the finished product.
4. Identification of all suppliers, customers, distributors and others involved in the process including a record of their contact information. A primary and secondary contact must be available, especially for after hours and weekends. The contact records must include phone numbers, fax numbers and emails.

The more details that are put in place prior to a problem, the easier the recall or withdrawal will be when a problem occurs. An example program is provided in **Appendix E.**

B. PLANT SECURITY

Plant security systems must address the security of the raw materials and finished products, 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 checkpoint 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.

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

Other Food Security Models are also available from USDA-FSIS and through the Food and Drug Administration; FDA's web link is: https://www.fda.gov/food/food-defense-tools-educational-materials/food-defense-plan-builder.

VII. PRODUCT HANDLING FOR MICROBIAL TESTING OF FINISHED PRODUCTS

A. CONDUCTED BY THE ESTABLISHMENT

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 the 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.

Grinders can also use finished-product testing to establish a lot-minimization system. The process for implementing this type of testing program will vary depending on the finished product(s) being produced and the amount of risks 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 Laboratory Information Management System (LIMS) -Direct 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:

a) FSIS personnel are required to notify the plant prior to pulling the sample to allow the plant to hold the lot or sub-lot.
b) 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.
c) The plant should define the scope of the finished product 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 Testing*

As stated above, plants are encouraged to participate in the LIMS-Direct 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.).

VIII. HACCP IN A GRINDING OPERATION

HACCP is a process control system designed to prevent, eliminate or reduce food safety hazards to an acceptable level. The establishment must consider biological, physical, and chemical food safety hazards. Ground beef is a raw product that has no scientific CCP (critical control point) for preventing, eliminating or reducing microbial food safety hazards, such as *E. coli* O157:H7, to an acceptable level. (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 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 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.

This document was developed by members of the Beef Industry Food Safety Council. Best Practice documents are ever evolving, and as changes or new information becomes available, these documents will be reviewed and updated. Questions or suggestions are welcome and should be addressed to BIFSCo at bifsco@beef.org.

IX. APPENDICES

A. TITLE 21 FOOD AND DRUGS PART 110 – CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

B. PROCESS FLOW CHARTS

1. *100% Ground Beef Fresh – Page 27*
2. *100% Ground Beef Frozen Beef Patties & Bulk Iqf – Page 28*

C. GROUND BEEF LOTTING – PAGE 29

D. RAW MATERIAL INSPECTION REPORT – PAGE 30

E. RECALL RECORDS

1. *Product Recall Diary of Events – Page 31*
2. *Summary of Documents – Mock Recall – Page 32*

F. FORMULATION RECORD – PAGE 33

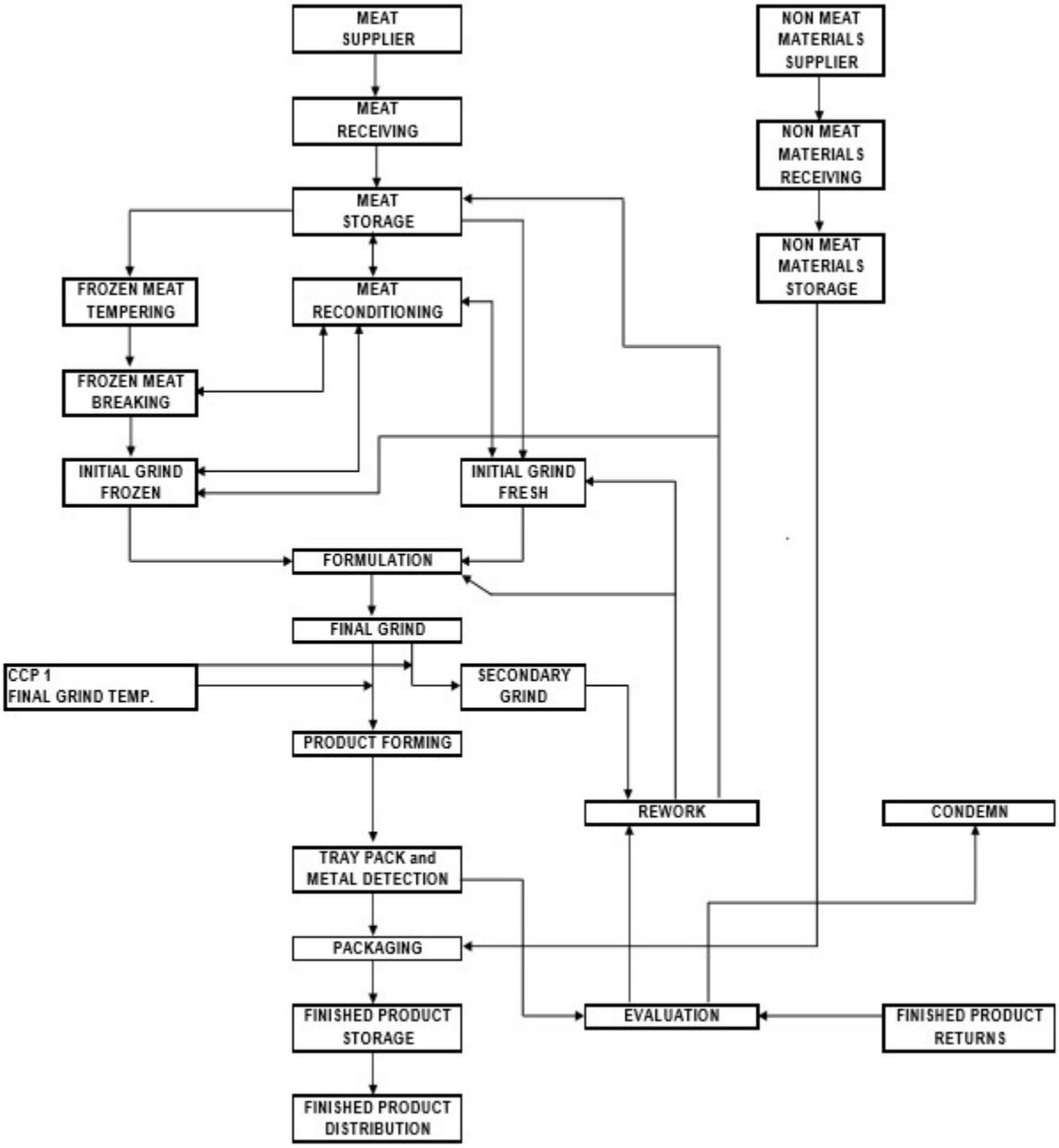
G. SAFE AND SUITABLE INGREDIENTS FOR MEAT AND POULTRY PRODUCTS (FSIS DIRECTIVE 7120.1)

H. GUIDE TO *E. COLI* O157:H7 TESTING OF RAW GROUND BEEF AND RAW GROUND BEEF COMPONENTS (FSIS DIRECTIVE 10,010.1; 10,010.2)

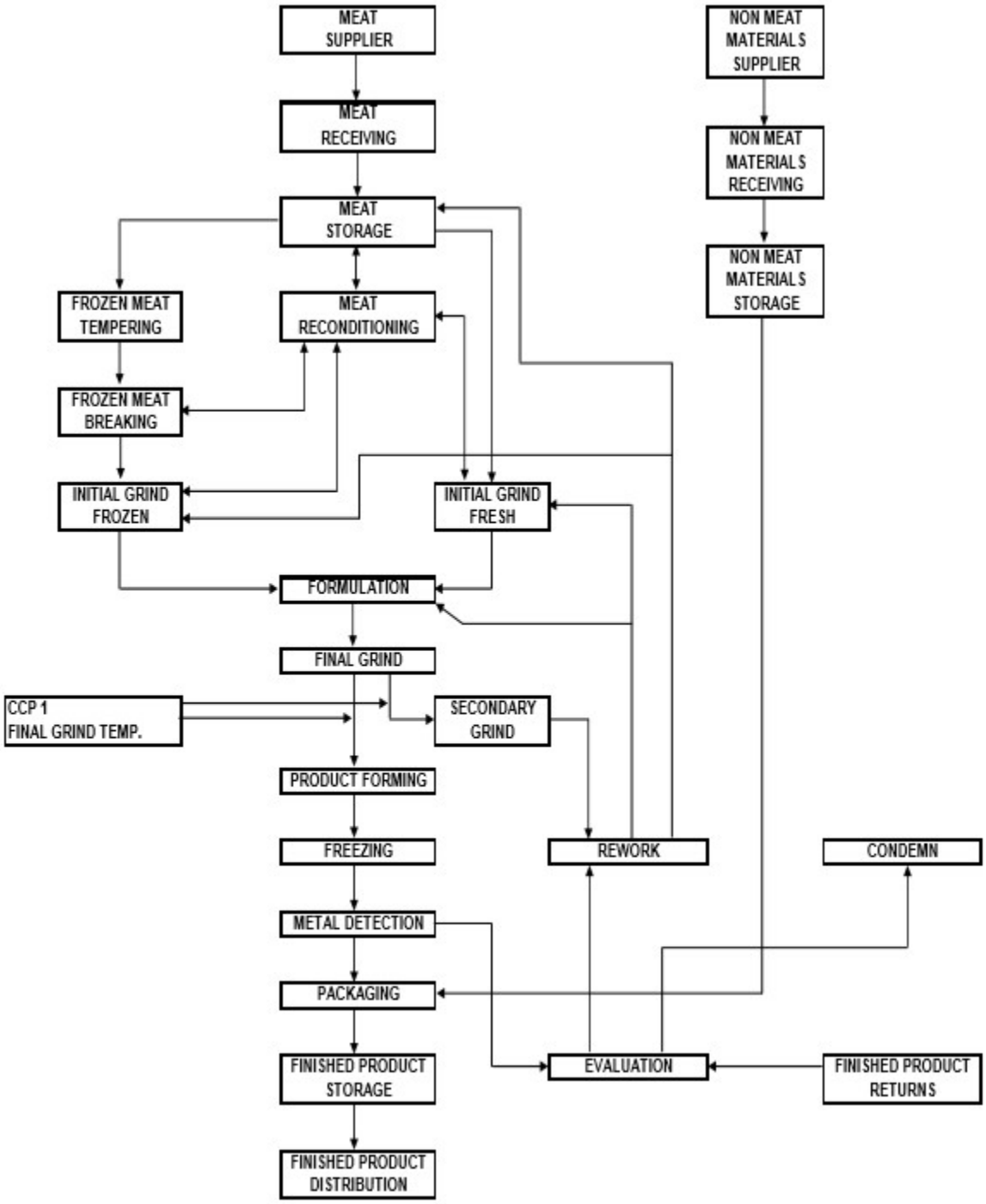
I. LOADING PLAN CHECKLIST – PAGE 34

Appendix B – Process Flow Charts

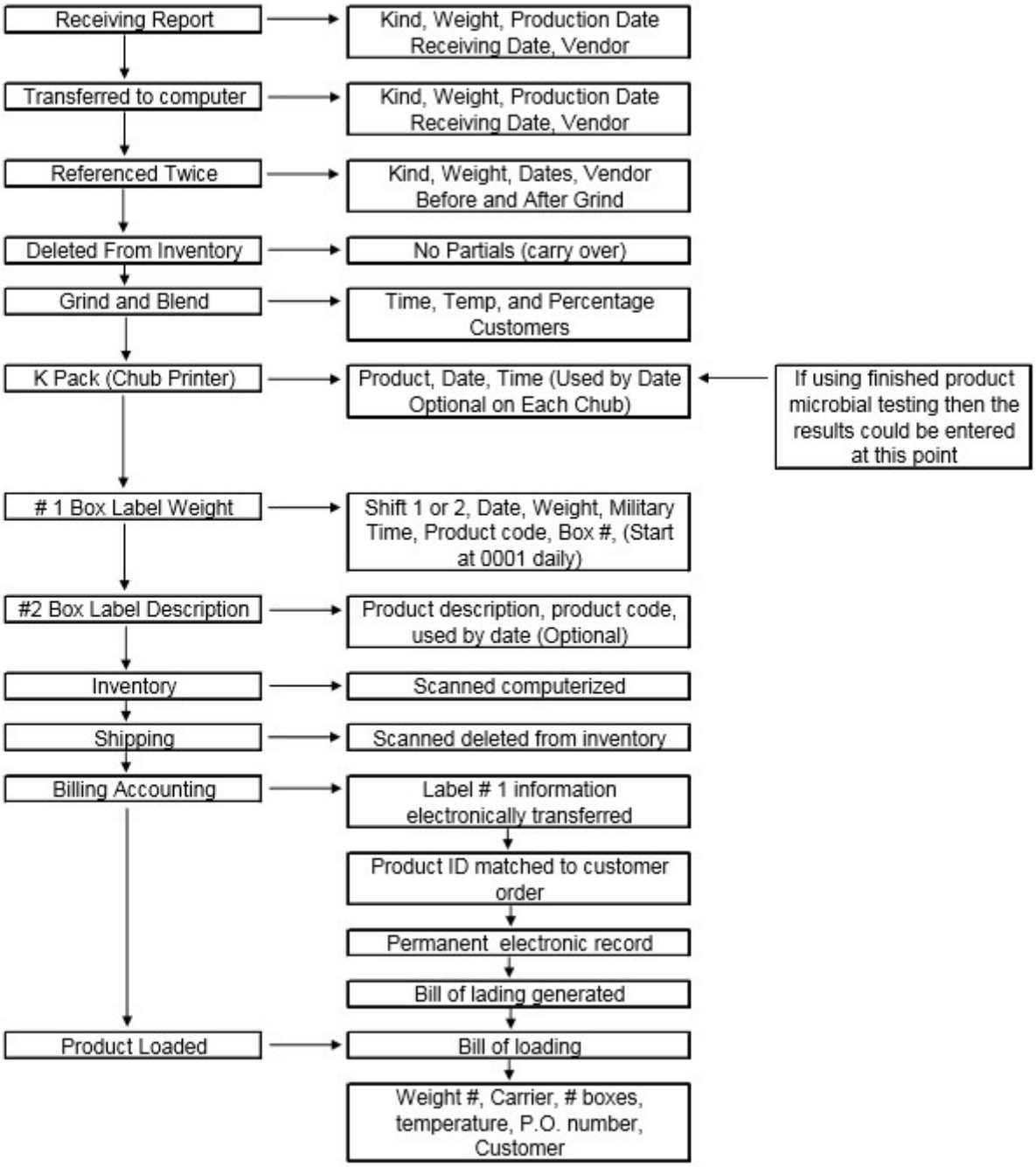
1. Flow Chart - 100% Ground Beef Fresh Map



2. Flow Chart - 100% Ground Beef Frozen Beef Patties & Bulk IQF



Appendix C – Ground Beef Lotting



Appendix D – Raw Material Inspection Report

August 2009 Version

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

Quality Control Technician: _____ **Date:** _____

Supplier: _____ **Est. #** _____ **R/D :** _____

Product : _____ **P/D :** _____

Temperature: _____ **(degrees F)** **Bacterial Sample Taken :** **YES** **NO**

COLOR	**Excellent**	**Good**	**Fair**	**Poor**	**Bad**
ODOR	**Excellent**	**Good**	**Fair**	**Poor**	**Bad**

MOISTURE: _____ **FAT:** _____

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

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

INSPECTION COMMENTS: _____

_____

_____

Reviewed: **Date:**

Appendix E – Recall Records

1. 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 SITUTATION:
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: _____
_____
_____

2. 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

Appendix F – Formulation Record

FOR EXAMPLE ONLY

Formulation Sheet

Date:
Shift: 0
Product: 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									
2nd Frozen Supply									
L. F. T. B. Supply									
Fresh Lean Supply									
Fresh Trim Supply									
Frozen Trim Supply									
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

Appendix I – Loading Plan Checklist

LOADING PLAN CHECKLIST (FRESH PRODUCT)

ORDER#_____ **CUSTOMER** _____ **CARRIER**_____

Loader: _____ **Pallets In:** _____

	Initials
Have trailer wheels been chocked? **SAFETY REQUIREMENT.**	
Trailer has been checked for signs of tampering	
Do the interior walls have cracks, holes, or exposed insulation?	
Are the walls, doors, and floor clean?	
Has the trailer been pre-cooled and set at 28 degrees?	
Are the door seals intact (no light showing through)?	
Ensure that all product is palletized and wrapped.	
Record Product temperature on drawing at right	
Have driver keep reefer running during loading.	
Temperature recoder on Load? **Required on all loads!**	
Administration: _____	
Verify and transfer all required information to Bill Of Lading	
Record seals and ensure placement on trailer.	
Obtain additional info. from driver: License number, printed name	
Distribute and maintain copies of all information.	

Recorder# _____

Seal # _____

TIME IN _____

TIME OUT _____

Reefer

1	2
3	4
5	6
7	8
9	10
11	12
13	14
15	16
17	18
19	20
21	22
23	24

Revised: 10/16/2008 Document # 80.10

I have received my product in good condition

_____