Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products

Guidance for Minimizing Impact Associated with Food Safety Hazards in Raw Ground Meat and Other FSIS Regulated Products

Based upon sporadic cases, outbreaks, product recalls, and in-depth verification reviews, involving *Escherichia coli (E. coli)* O157:H7, and failures of grinding plants to meet the *Salmonella* performance standards, FSIS has concluded that guidance can help grinders and suppliers of boneless beef and trim products to develop and implement procedures that better protect public health. This guide is intended to illustrate how grinders and suppliers of boneless beef and trim products (hereafter referred to as 'suppliers') can implement controls to minimize food safety hazards, such as *E. coli* O157:H7 and *Salmonella* associated with ground beef. This guideline does not prescribe regulatory requirements under the Federal Meat Inspection Act (FMIA).

FSIS initially made this guidance material available to the public in March 1998. (http://www.fsis.usda.gov/oa/haccp/gbg99.htm). FSIS modified the first guideline in response to the suggestions and comments by several organizations and to incorporate some details on rework and product recall plan derived from the guidance provided by the National Meat Association and the American Meat Institute. This type of incorporation was discussed during the April 22, 1998 public meeting at which each of these organizations presented guidelines along with FSIS' guidance material. FSIS is updating this guidance material for the second time in order to add guidance to suppliers of boneless beef and trim products, add guidance for reducing *Salmonella* in these products, and to include Agency policy changes that could have a significant impact on beef grinding establishments with regards to contamination with *E. coli* O157:H7.

FSIS is basing the guidance in this document on three main points.

- First, grinders and their suppliers should address hazards from pathogens such as *E. coli* O157:H7 and *Salmonella* in their raw materials, as they are responsible under HACCP to identify and address all hazards reasonably likely to occur.

- Second, grinders and their suppliers should realize that they are in an excellent position to implement process and distribution controls that address public health hazards associated with ground beef, such as *E. coli* O157:H7 and *Salmonella.*

- Third, there must be an emphasis throughout the production and distribution chain on maintaining the records that are necessary to identify, trace, and retrieve from commerce any ground beef products that may pose a threat to public health.

Grinding operations and their suppliers (which traditionally buy raw materials from one or more sources and sell the processed products to others) have a primary responsibility and unique opportunity to: 1) specify purchase requirements related to incoming raw materials; 2) to process

raw materials under processing and recordkeeping controls designed to ensure the safety and traceability of their products; and 3) to distribute products to destinations in a manner such that products can be effectively recalled if food safety hazards are identified. Putting aside any legal considerations, it is essential that grinding operators assume that they are responsible for their products until the products' end use. This is especially true for grinding operators who produce products in retail-ready (case-ready) packages.

This guidance material contains several guiding principles and associated detailed explanations and recommendations and is intended to identify how grinding operations and their suppliers can improve public health. Although this guidance material highlights issues associated with beef, the guidance can be applied to most raw products. This guide is not intended to be prescriptive, in a regulatory sense, but rather offers examples of opportunities to improve food safety through purchase requirements, increased process control, and recordkeeping.

Processing operations are required to have Sanitation SOP's (Sanitation Standard Operating Procedures) and PR/HACCP (Pathogen Reduction/Hazard Analysis Critical Control Points) systems. This guidance material is specifically designed to augment these activities, especially the development and operation of a HACCP plan[1, 2]. The PR/HACCP rule was implemented by USDA/FSIS to ensure the safety of meat and poultry products. The PR/HACCP rule requires that plants identify critical control points in their processes where there are hazards reasonably likely to occur and develop methods to control them. The PR/HACCP rule also included *Salmonella* Performance Standards for slaughter and grinding establishments (9 CFR 310.25 (b), 381.94 (b)). FSIS conducts testing for *Salmonella* to verify that plants are meeting the standards.

FSIS does not use the *Salmonella* test results to condemn products[3] because *Salmonella* has not been considered by FSIS to be an adulterant in raw meat and poultry. The results are being used to verify that HACCP systems are effective in controlling contamination with *Salmonella* and other pathogens. The *Salmonella* performance standards are based on a public health judgement that reducing the percentage of product with *Salmonella* will reduce the risk of foodborne illness[4]. Establishments should demonstrate that they are able to control the occurrence of pathogens in their product by producing products that consistently meet the standard.

The pathogen *E. coli* O157:H7 is of particular concern to grinding operations because it is considered an adulterant in ground beef (Taylor, 1994; Texas Food Industry Association v. Espy)[5], and because it produces severe and sometimes fatal consequences at a very low

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1 USDA, FSIS (1997) Generic HACCP Model for Raw, Ground Meat and Poultry Products, HACCP-3.

2 USDA, FSIS (1997) Generic HACCP Model for Beef Slaughter, HACCP-13.

3 http://fsis.usda.gov/oa/background/salmtest3.htm

4 http://fsis.usda.gov/OPPDE/rdad/FRPubs/01-013N/Derfler.htm

5 Taylor, M. (1994) Change and Opportunity: Harnessing Innovation To Improve The Safety of the Food Supply Speech given at the American Meat Institute Annual Convention, San Francisco, California, September 29, 1994.

infectious dose. In considering raw meat and poultry processing, Buchanan and Doyle (1997)[6] emphasized that "HACCP plans that do not include a lethal step that kills pathogens are more complex, since the focus is on risk reduction instead of risk elimination." At present, applying a lethal step such as irradiation, heat processing, or integrated lethalities using salt, nitrite, fermentation, or reduced pH is the only approved method of making food known to be harboring *E. coli* O157:H7 safe for consumption. Decontamination interventions, such as antimicrobials, can significantly reduce the levels of *E. coli* O157:H7 and other pathogens when the control measures are effectively implemented, validated, and verified. Microbiological testing, when properly designed, can be used to verify that control measures are working. However, results from microbiological testing can provide only a limited measure of assurance that this pathogen is not present. Total reliance upon sampling is inadequate because *E. coli* O157:H7, if present, is present sporadically and at extremely low levels. Therefore, microbiological testing should be used in combination with strict process controls that include intervention methods, in order to reduce, as much as possible, the likelihood that the pathogen is present in the finished product. Any ground beef found to be contaminated with *E. coli* O157:H7 must be treated to inactivate the pathogen (e.g., processed into ready-to-eat product); otherwise it is deemed adulterated.

FSIS has had a microbiological testing program for *E. coli* O157:H7 in raw ground beef since 1994. The FSIS testing is designed to verify the effectiveness of the control measures in place at individual grinding establishments. For the last 5 years, the prevalence of *E. coli* O157:H7 has increased, as reported by the testing program. The level is below 1.0 % of the total numbers tested. The increase might be partly due to better surveillance or better analytical methods used. Since the implementation of the testing program, some establishments have started their own process control programs including end product testing for the pathogen and some have required their suppliers to have similar programs for process control and for testing. These measures, together with the use of effective antimicrobial decontamination methods and sanitation programs would provide evidence that the prevalence of *E. coli* O157:H7 in ground beef is reduced if properly implemented and verified. Microbiological testing for process control and testing for *E. coli* O157:H7 in finished products would provide a greater assurance that product is being properly handled.

Records that facilitate trace back and trace forward are essential whenever there is an outbreak of foodborne illness. Although grinding operators may not have access to records of the farm sources of their raw material, or records maintained by the plants that slaughter, dress, and bone their raw materials, they should purchase raw materials from suppliers that maintain such records. Intermediate handlers, such as distributors and wholesalers, are also required to keep adequate records regarding the disposition of ground beef products that pass through their hands. The Federal Meat Inspection Act (FMIA) requires that every person, firm, or corporation engaged in buying or selling meat food products must maintain records that fully and correctly disclose all transactions in its business subject to the FMIA (21 USC 642). The recordkeeping requirements are set out in Title 9, Code of Federal Regulations, Section 320 (9 CFR 320).

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[6] Buchanan, R. L., and Doyle, M. P. (1997) Foodborne disease significance of *Escherichia coli* O157:H7 and other enterohemorrhagic *E. coli*. Food Technol. 51(10): 69-76.

Grinders are advised to impress upon all intermediate handlers of their products the importance of records that will facilitate the efficient retrieval from consumers of ground beef products that are a public health concern.

The guide consists of two sections: Section I., Guiding Principles; and Section II., Suggested Procedures For Grinding Operations. This material will be continually updated and made available through the FSIS internet web page located at http://www.fsis.usda.gov. Copies of this Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products may also be requested from the Docket Office, at 202-720-5627, Rm. 102, 300 12th St. SW, Washington D.C. 20250-3700. Comments regarding this updated guide should be directed to Philip Derfler at 202-720-2709, and fax at 202-720-2025**.**

Section I. Guiding Principles:
These guiding principles are supplemented with suggested procedures in Section II.

A. Grinders and their suppliers should determine microbial specifications necessary to ensure product safety, and should only accept starting materials and ingredients that meet their specifications. In developing such specifications, grinders and their suppliers should consider the intended use for the starting materials and ingredients and determine what, if any, pathogen reduction actions by their suppliers would be beneficial.

B. Grinders and their suppliers should develop and implement manufacturing processes and packaging procedures to maintain or improve the microbial integrity of their starting materials in order to ensure that they produce safe consumer products.

C. Grinders and their suppliers should keep abreast of new technologies and interventions that could be incorporated into their processes to help prevent or identify adulterated product before it enters commerce.

D. Grinders and their suppliers should implement controls to identify product that poses a greater risk of being adulterated, and segregate it for special handling. Such product should be diverted to processing that employs a bacterial kill-step (such as cooking).

E. Grinders should develop and implement rework, carry-over, and lot designation procedures that reflect an acceptable degree of product exposure (i.e., economic risk) in the event that a public health risk is identified that results in product recall.

F. Grinders and their suppliers should develop and implement handling and distribution procedures that will not compromise the safety of their products once those products leave their establishments.

G. Grinders and their suppliers should develop a system of records, which fits into a farm-to-table continuum, that will facilitate trace back to the suppliers and trace forward to the distributors in the event that a public health risk is identified.

H. Grinders should consider both the intended use of their product (hotel, restaurant, institution, or home setting) and the most vulnerable potential user, and should provide information and education aimed at minimizing the potential for foodborne illnesses at the level of the ultimate consumer. Moreover, such information and education could help to assure consumers that product found to have *E. coli* O157:H7 and *Salmonella* can be made safe by thorough cooking and appropriate sanitary handling. Sanitary handling is critical in order to ensure that low levels of pathogens do not grow to numbers injurious to health, and to prevent cross-contamination with other foods and contact surfaces.

Section II. Suggested Procedures

This section includes subsections on guidance for suppliers of boneless beef and trim products, and guidance for grinders. A flow process diagram for ground beef processing and recommendations, intervention treatments for meat parts and comminuted meat, and discussion on the use of indicator organisms are found in Appendix 1-3.

GENERAL CONSIDERATIONS

The following important factors play a major role in preventing the cross contamination of products with pathogens such as *E.coli* O157:H7 and *Salmonella* during trimming and grinding.

- Grinding establishments should reassess their HACCP plans to determine if *E. coli* O157:H7 contamination is a hazard reasonably likely to occur in their production process, in light of certain available scientific data on the pathogen.

- Suppliers and grinders should be aware of increasing evidence of higher prevalence of *E. coli* O157:H7 in cattle in the months of April through September, and higher prevalence detected in raw meat in those months. There is also an increased number of reported cases of foodborne illness due to *E. coli* O157:H7 in that time period, which may include other exposures aside from ground beef. Establishments should account for this in their HACCP systems by increasing the frequency of verification, by applying more vigorous decontamination methods, or by having stricter purchase specifications. However, the increase in prevalence during these months does not mean that the pathogen does not represent a hazard on other months. Establishments should address the hazard posed by the pathogen all year round, but with increased vigilance during high prevalence months.

- Purchase specifications programs, which include microbial specifications, are an essential part of a plant's food safety system that can prevent microbial hazards in incoming materials to be carried over to the end product. Purchase specification programs for raw materials for ground beef production should be incorporated as a CCP in the HACCP plan. Establishments can also incorporate their purchase specifications in their Sanitation SOP or other programs such as prerequisite programs. Information concerning the control measure being addressed by the Sanitation SOP or prerequisite program is supporting documentation that must be documented in the hazard analysis. The effectiveness of the Sanitation SOP or prerequisite program should be validated and continuously verified.

- Sanitation procedures should prevent cross-contamination from equipment, personnel, traffic, air flow, tables, and floors to product.

- Continuous refrigeration or prompt freezing is essential to prevent microbial growth. Temperature of the raw materials at receipt and during processing and the time of holding at those temperatures affect the growth and multiplication of microorganisms.

- Intervention methods to reduce or eliminate *E. coli* O157:H7, *Salmonella,* and other microorganisms *(e.g. E. coli biotype 1, coliforms, Enterobacteriaceae,* APC as possible indicators of process control*)* are an essential part of process decontamination methods for use on meat parts and comminuted meat (Appendix 2). A discussion on the use of indicator organisms to assess the presence of *E. coli* O157:H7 and *Salmonella* is found in Appendix 3.

- Processors should determine the effectiveness (microbial reduction) of their antimicrobial intervention methods by validation and verification and provide supporting documentation.

- To test product for *E. coli* O157:H7 and *Salmonella,* use of FSIS methods or equivalent is recommended. The most recent update to the FSIS testing methods (MLG, 3rd edition, 1998) is found on the FSIS web site: http://www.fsis.usda.gov/OPHS/microlab/mlgbook.htm

- The establishment's monitoring and verification results from the HACCP system, the Sanitation SOP plan, generic *E. coli* testing results and *Salmonella* testing results should always be analyzed and correlated to determine any trends and to find out the source of contamination or growth. This may require additional reassessment of the HACCP plan or the Sanitation SOP.

A. GUIDANCE FOR SUPPLIERS OF BONELESS BEEF AND TRIM PRODUCTS

Numerous In Depth Verification Reviews of grinding establishments have shown that grinders need guidance to prevent adulteration by *E. coli* O157:H7 and to meet the *Salmonella* Performance Standards. Among IDV findings are that establishments: did not identify *E. coli* O157:H7 and *Salmonella* as hazards reasonably likely to occur; don't have microbial purchase specification requirements of their suppliers; do not monitor temperature as specified in their HACCP plan; and do not always take apart equipment parts for cleaning. To aid grinders in the purchase of raw materials that have low prevalence for these pathogens, FSIS developed this Guidance for Suppliers of Boneless Beef and Trim Products.

Raw materials for ground beef include boneless beef, beef trim of different fat content, bull meat, head meat, cheek meat, diaphragm (skirt), esophagus (weasand), advanced meat recovery products (AMR), lean finely textured beef (LFTB) and PDCB (partially defatted chopped beef, for use in beef patties). Some of these materials undergo several processing steps and could be contaminated very easily. Grinders are dependent on their suppliers to eliminate or reduce any bacterial hazards because controls to reduce the risk of *E. coli* O157:H7, *Salmonella*, and other microbial hazards when the product is still intact may be among the best ways to control these hazards. Following is suggested guidance for producers of boneless beef or trim intended for ground beef.

Starting Materials: Carcass, Primal or Subprimal

The starting materials -- carcasses, primals, and subprimals -- should be free of adulterating hazards, e.g., *E. coli* O157:H7, because the process of breaking and producing boneless beef and trim will spread any bacteria present. While *Salmonella* is not an adulterant in trim, an excessive prevalence may cause a grinder customer to fail the *Salmonella* Performance Standards.

- **Require suppliers (e.g., slaughter establishments) to have implemented a controlled intervention to reduce or eliminate bacterial hazards.**

  a) Suppliers of boneless beef and trim products should develop purchase specifications which specify that their raw materials come from slaughter establishments that apply one or more intervention/antimicrobial treatments validated to reduce or eliminate microorganisms on carcasses. Purchase specification programs for ground beef production should be incorporated as a CCP in the HACCP plan. Establishments can also incorporate their purchase specifications in their Sanitation SOP or other programs such as prerequisite programs provided that the control measures are adequately addressed in the hazard analysis and the control measures are verified as being effective.

  Intervention treatments such as steam pasteurization, organic acid spray, hot water treatment and steam vacuuming were found to be effective, when used alone or in combination, in reducing the number of *E. coli* O157:H7, *Salmonella* and other microorganisms (e.g. *E. coli* biotype 1, coliforms, *Enterobacteriaceae*, APC) on carcasses. Most slaughter establishments apply one or more intervention or decontamination methods to comply with the zero fecal tolerance. Suppliers should validate and verify the relative reduction of microorganisms resulting from the decontamination method(s) used. The reduction of microorganisms resulting from the decontamination/intervention methods should be maintained in subsequent processing steps by control of temperature and cross-contamination.

  FSIS has developed Guidance for Beef Slaughter Operations, which includes methods for effective intervention/decontamination during beef slaughter operations, including time, temperature, concentration, pressure parameters and reduction of microorganisms resulting from the interventions. It is available on the FSIS web site.

  b) Other sources for purchase specifications for reference purposes include industry trade groups, university extension service, professional associations and consultants.

  c) If boneless beef and trim products such as head meat, cheek meat, bull meat, skirts, weasand, LFTB, PCDB or AMR are produced at boning establishments or supplied to grinders, ensure that these products receive the same treatment and handling as for carcasses, primals, or subprimals. Thus, these products should meet the same microbial

specifications as for carcasses, primals, and subprimals. Alternatively, keep these products separate from ordinary boneless beef and trim product.

- **Implement a verification step before accepting ingredients.**

a) Product receiving temperature is a common CCP. But product temperature only verifies that the shipping temperature may have been adequate. Product temperature would not detect nor indicate the presence of bacterial hazards.
b) Visual inspection. This is a quick step but will only detect gross defects and perhaps minor defects. Thus, many negatives may be misleading.
c) Imaging system. Emerging technology is providing imaging systems that can detect invisible fecal or fecal-associated contamination.
d) Microbial assay. Confirmed results may not be available quickly so this choice would be more suitable for rating a supplier or providing feedback.
e) Review supplier's verification that accompanies the shipment showing that buyer's specifications are met. This is a quick step and addresses the issues but requires trust in the supplier.

- **Implement an intervention or surface treatment before breaking.**

a) Deciding which treatment to use
There are several sources for expert guidance on the latest developments in effective carcass treatments to reduce or eliminate the microbial load on incoming carcasses, primals, or subprimals. Among the sources of expertise are the State Extension Service meat specialists, industry trade groups, professional associations, and consultants. FSIS has in its web site the Guidance for Beef Slaughter Operations, which include methods for effective intervention or temperature, concentration and pressure parameters and resulting microbial reductions.
b) Controlling the Treatment
In addition to selecting a treatment, it is important to implement it in a controlled and effective manner. Implementing the necessary controls is just as important as selecting an appropriate treatment.
1) Critical Limits: Some of the critical limits include: (a) concentration and amount of organic acid spray, (b) speed and proximity of the steam vacuum head over the meat surface, and (c) temperature of the hot water.
2) Verification
(a) Take measurements to verify that critical limits are being met. Measurement may include testing the acidity of the organic acid spray or simply a pH measurement. Watching and timing the steam vacuum operator, measuring the steam line pressure, and periodically taking a temperature may be appropriate for this intervention treatment. These measurements will generate a record to show compliance to customers' requirements and for internal audit.
(b) In addition to recording the critical limits of the intervention, another type of

testing should be used to show that the intervention method is effective. This second kind of verification testing might include periodic microbial analyses of product surfaces, drip, or product contact surfaces. This might also include periodic microbial analyses of the final product. However, with this type of testing, it would be difficult to identify where in the process a problem had originated.

Breaking and Trimming

Sanitation and time/temperature combinations are two essential controls.

- **Sanitation prevents introduction of new bacterial hazards to the controlled ingredients.**

The objective is to maintain the clean condition of the carcass, primal, or subprimal starting material.

a) Sanitation SOPs should have already addressed and verified the cleanliness of equipment, processing room, employees and implements.
b) Systematic sanitizing of belts and implements will break the chain of any contamination that slips through. Thus, rather than the contaminant being spread throughout the lot, it will be stopped or at least diminished.
c) Employees are in continuous contact with the product. Therefore, sanitation training and education, as well as supervision, are crucial. Some establishments have determined that a good business practice is to retain capable employees with rewards rather than continuously train new employees. In addition to keeping the processing areas clean and in good repair and keeping employee areas clean and in good repair set a personal tone for the operation. These are management choices but can indirectly affect the product.
d) Desirable practices to instill in employees are:
   1) Removing outer clothing when leaving the processing area.
   2) Practicing personal hygiene, such as proper handwashing after using the toilet or before entering processing area.
   3) Cleaning hands, gloves, and implements between carcasses, primals, or subprimals.

- **Time/Temperature Control**

This control would prevent growth of bacteria (including spoilage bacteria) that may have penetrated the system of controls.

a) Reductions of microorganisms as a result of interventions should be maintained by controlling the time and temperature of holding the treated product in subsequent steps.
b) Time and temperature are tightly linked. At a temperature of 50°F (10°C), bacterial multiplication takes about twice the time as it does at a temperature of 57°F (14°C). On the other hand, at a temperature of 43°F (6°C), bacterial multiplication takes about twice the time as it does at 50 °F (10°C), depending on other intrinsic factors.
c) Room temperature is perhaps the most common critical limit that establishments select for raw processing areas. It is advisable to control and monitor product temperature and

product contact surfaces. Room temperature directly affects the critical sites which are the product and product contact surfaces.

Storage and Shipping

Sanitation and time/temperature combinations are two essential controls. Proper sanitation would prevent introduction of new bacterial hazards to the finished product. During storage and shipping, the product is moved to a more controlled environment. Time and temperature control will prevent growth of bacteria (including spoilage bacteria) that may have penetrated the system of controls.

- **Clean shipping containers.**

  Verify that the supplier is meeting your needs and requirements, and that your operation is storing and assembling the containers in a sanitary manner.

- **Meat in a shipping container is a large thermal mass**.

  Whether the product is in a 60-pound box or a one ton combo bin, the distance from the center to the surface (where heat is removed) is much greater than the size of the individual pieces. Because distance is directly proportional to heat transfer (the smaller the distance from the center, the shorter time it takes for temperature to change), the container's internal temperature will change slowly. Thus, it is crucial that all product going into the container be cold or chilled as the container is filled. An acceptable practice is to "snow" the product with CO_2 as it is layered in a container.

- **The shipping method can affect the product and profit**.

  Receiving feedback from customers on receiving condition and temperature will help in rating and choosing a reputable **shipping method**.

Verification and Records

The following records should be kept and verified:

- Suppliers of raw materials, intervention methods used during slaughter processing, and/or which suppliers meet the purchase specifications.
- The type of raw material received, whether carcass, primal, or subprimal, and whether purchase specifications are met.
- The type of products supplied, e.g. boneless beef, trim, cheek meat, or head meat.
- Results/effectiveness of any intervention method applied.
- Temperature of processing room and of product.
- Packaging material or containers used and source and lot codes.
- Shipping methods used.
- Product codes and dates for recording and tracking establishments that the boneless beef

and trim products were distributed to.
- Customer feedback as to whether products supplied met microbial specifications and other requirements, disposition of products.
- Frequency of verification should be part of the records kept to ensure that specifications are met in an on-going systematic manner.

B. GUIDANCE FOR GRINDERS

Receiving Meat

As mentioned before in this document, raw materials for ground beef include manufacturing trimmings from intact cuts of beef, head meat, cheek meat, diaphragm, AMR products, LFTB, and PDCB (for beef patties). Grinders receive raw materials from slaughter/boning/processing establishments and from boning/processing establishments. Grinders that are part of the slaughter establishment have the advantage of knowing the slaughter and boning processes used and the food safety controls applied during slaughter and boning to reduce contamination by *E. coli* O157:H7 and *Salmonella.* Grinding establishments that receive raw materials from other suppliers (slaughter or boning establishments) should determine the food safety controls that their suppliers use to reduce contamination by *E. coli* O157:H7 and *Salmonella.* It is important that pathogens are at very low levels, because the process of grinding will spread the pathogens throughout the product and can cause contamination across product and equipment.

- Develop a purchase specifications program to ensure receipt of safe and wholesome incoming raw materials. Purchase specification programs for ground beef production should be incorporated as a CCP in the HACCP plan. Establishments can also incorporate their purchase specifications in their Sanitation SOP or other programs such as prerequisite programs. Purchase specifications, as documented in the hazard analysis and verified, should include among others:

  1) microbial specifications for pathogens *E. coli* O157:H7 *and Salmonella* and for other microorganisms *(e.g. E. coli biotype 1, coliforms, APC)*

  2) pathogen testing by supplier, designed to find the organism if it were present and to verify process control, showing negative findings

  3) verification pathogen testing by grinder, designed to find the organisms if it were present and to verify process control, showing negative findings

  4) supplier operation under HACCP plans with critical control points (CCPs) that address pathogen intervention or anti-microbial programs, such as hot water rinses, acid spray, steam pasteurization, steam vacuuming, irradiation, and others. Appendix 2 includes approved antimicrobial treatments for comminuted meat and meat parts.

  Frequency of verification should be part of the records kept to ensure that specifications are met in an on-going systematic manner.

- Require suppliers to maintain records of farm source or slaughter plant to facilitate traceback.

- Grinders should record pertinent information about their supplier of raw materials such as: name, point of contact, phone number, supplier lot number, production date, and any other identifying information that would be useful if the supplier is later notified of an *E.coli* O157:H7 positive product.

    - Examine condition of transport for sanitation-related and other product handling concerns, including:
        1) sanitation of the carrier or truck
            a) presence of cracks, debris, foreign material, or off-odor
            b) condition of insulation and door seals
        2) temperature inside transport vehicles and of meat
        3) duration of transport.

    - Grinders receiving product from more than one supplier should prevent any mixing of product from different suppliers. Keeping product from different suppliers separate will prevent any potentially *E. coli* O157:H7-contaminated source material from adulterating source materials from other suppliers. By separating raw materials from different suppliers, grinders will be able to identify the potential source of any *E. coli* O157:H7-contaminated product should the pathogen be detected. If ground beef produced from raw materials coming from a supplier is confirmed positive for *E. coli* O157:H7, FSIS intends to notify the supplier that they may have supplied *E .coli* O157:H7-positive product to a grinding establishment or retail facility.

    - Examine and record condition of raw material:
        1) Note and document species identity, temperature of both refrigerated and frozen materials, supply source, and boning date/slaughter date.
        2) Conduct visual examination for any defects or abnormalities.
        3) Check integrity of immediate container, protective covering, or other packaging materials used.
        4) Document type of raw materials (e.g., trimmings, cheek meat, finely textured product, and product resulting from advanced meat recovery systems, and other comminuted products which have undergone additional handling and processing).
        5) Verify that all units are appropriately marked or coded for trace back purposes.

    - Affix grinding operation's code after acceptance of raw materials for tracking purposes.

Storage of Raw Material

Develop a storage schedule for incoming materials to facilitate product identification and inventory control and to maintain package/pallet integrity. Raw materials can be rotated using a First In-First Out (FIFO) system or a plant specified product rotation/inventory control schedule.

- Determine which units will be refrigerated or frozen, and for how long.

- Record specific locations, times, dates, and temperature of storage.

- Provide ample spaces between boxes or pallets to allow for air circulation.

- Monitor and record temperature of meat during storage.

- If material is to be thawed, monitor and record time and temperature of thawing.

Grinding Process including weighing, coarse grinding, blending, mixing, final grinding, and forming

- Raw materials received from different suppliers should not be mixed during the grinding operation. Grind raw materials from each supplier separately from those from other suppliers, and code appropriately to reflect the supplier. By grinding raw materials from different suppliers separately, grinders will be able to identify the potential source of any *E. coli* O157:H7-contaminated product should the pathogen be detected. If ground beef produced from raw materials coming from a supplier is confirmed positive for *E. coli* O157:H7, FSIS intends to notify the supplier that they may have supplied *E .coli* O157:H7-positive product to a grinding establishment or retail facility.

- Develop a lotting or sub-lotting system for coding and tracking purposes. Assign lot numbers that will enable tracking the lot from the raw material source up to the finished products. Lotting can be based on a full day's production or production from clean-up to clean-up. All lots produced between clean-ups would be implicated in any public health-based action (e.g., recall). Unless based on the specific circumstances, the problem may be restricted to a subset of the plant's production between clean-ups.

- Separate processing of meat into lower risk and higher risk categories. Lower risk materials are those that pass the microbial purchase specifications, or those that came from suppliers that have effective antimicrobial intervention methods, or those materials where *E. coli* O157:H7 or *Salmonella* were not detected.

Separation can be by processing lines, lots, shifts, or production day. Large processing plants may be able to use different processing lines for different categories. In small plants, the categories can be separated by shifts or lots, in which case, processing of **"**lower risk" raw materials should always precede "higher risk" raw materials. For example, rework can be classified as high risk material, and should be added or processed towards the end of the shift. *Separation of raw materials into these two categories (i.e. lower risk and higher risk) will prevent possible cross contamination among products with different risk.*

- Divert "higher risk" meat to:
  1) RTE product such as fully cooked beef patties. RTE processing incorporates a kill-step such as heat processing or cooking to eliminate pathogens including *E. coli*

O157:H7. If the product is found to be contaminated with *E. coli* O157:H7, it must be processed into a ready-to-eat product, or it would be considered to be adulterated.

2) Large mass products such as meat for meat loaf or chili. This diversion will help ensure adequate heat processing of the product before consumption, because these large mass products are more fully and evenly cooked than thin meat patties.

Diverting "higher risk" meat to RTE or large mass product processing is an in-house method to reduce the risk of foodborne illness because these products are generally, adequately cooked before consumption. Grinders that have no facilities for processing RTE products need outlets for their "higher risk" products. Grinders should obtain a list of federally and state inspected establishments that can process ground beef RTE products.

- Monitor and record temperature of the meat ingredients and meat products during the whole operation.

- Develop a rework tracking system
  1) Estimate the amount of meat for the production shift or day, so that the amount of carry-over or rework (excess raw materials at the end of the production period that are not in final product form) is minimal, or there is no rework at all.
  2) If rework is unavoidable, controls should be instituted to prevent this practice from incriminating a whole week's or month's production if a food safety hazard is identified
  3) Include all rework with "higher risk" meat and process at the last shift or the end of the production day; or divert all rework to RTE product processing.
  4) Develop a recording system for rework that includes the time, quantity, area, and processing step it was collected from, the original lot or batch number/code, and the code of the lot or batch it was added to or included in.

- Develop contingency plans or strategies to address unprocessed raw materials remaining due to line failure or not meeting specifications. Maintain adequate records of the origin, handling, and disposition of these raw materials.

- Maintain a record of source, handling, and amount of outside raw meat ingredients added (i.e., trimmings not from the same batch or lot as the rest of the raw materials)

- Monitor the time/temperature profile of finished products, e.g., during freezing of beef patties.

- Antimicrobial intervention methods such as the use of acidified sodium chlorite can be applied on the unpackaged ground product. A validated procedure for application should be used to ensure effective microbial reduction. Irradiation as an intervention method can be applied on the packaged product.

- Test finished product for *E. coli* O157:H7 as a means of verifying process control. Design the testing program to find the organism if it were present. To reduce the risk of a recall, hold the product until the test results confirm that none has been detected. FSIS Directive 10,101.1 on Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef sets out instructions for sampling ground beef.

- Test finished product for *Salmonella* as a means of verifying process control. Design the testing program to find the organism if it were present. Testing for *Salmonella* would also help in meeting specifications of buyers of the finished ground product.

- Products that test positive for *E. coli* O157:H7 must be diverted to ready-to-eat product , irradiated, or condemned. Use the test results as a trigger to reassess the effectiveness of the process controls. Do not ignore process control and verification test results.

- Review and evaluate Sanitation SOP records to identify possible trends. Determine whether
  1) identified trends correlate with microbiological findings of *Salmonella* performance standards testing;
  2) trends are associated with specific changes in personnel, schedules, or equipment;
  3) trends are related to specific shifts;
  4) documentation of Sanitation SOP observations are consistent among employees monitoring Sanitation SOP effectiveness.

  Identifying the trends would lead to the relevant corrective action.

Packaging, Cooling, and Storage

- Monitor temperature or frozen condition of finished product during the packing operation.

- Use only clean food grade immediate container liners.

- Monitor finished product package integrity (seal, durability).

- Monitor and record the temperature of the refrigerator/freezer and the product during storage.

- Include production code and sell-by-date on package label, in addition to the required handling statement and safe handling instructions.

- Install a time-temperature indicator on the package to indicate adequate temperature of storage, distribution, and display (in grocery and other retail establishments).

Shipping, Handling, and Distribution

- Develop and maintain an inventory control schedule for products in storage. The First in First Out (FIFO) inventory control schedule could also be used at this point.

- Transport coded products in clean, temperature-controlled and well-maintained carriers to distributors.

- Maintain records of primary and secondary distributors and customers.

- Develop recommendations for distributors concerning the safe handling, distribution, and coding of the finished products.

- Maintain and record product temperature and package integrity during loading, unloading, and holding of finished products.

- Separate and divert to "higher risk" any product that was returned after having left the establishment and been out of its control. Dispose or divert according to the food safety hazard posed by the returned material.

- Develop an in-house recall plan and use it to test the efficiency of the plant's recording or coding system. Conducting product recovery drills (mock recalls) regularly can determine and assess the ongoing effectiveness of the recall plan. A practical and effective recall plan that is understood by all employees should contain the following elements:
    1) step-by-step procedures to follow in the event of product recall
    2) list of people who will take part in any recall activities, including their assignments, business and home phone numbers
    3) measures to retrieve documentation identifying the product coding system and product designation
    4) measures to retrieve product distribution records
    5) means of coordinating recall with regulatory authority or authorities
    6) means of notifying distributors, wholesalers, retailers and customers
    7) measures for assuring the speedy return of recalled product
    8) methods for disposition of recalled product

The following information should be given to regulatory authorities and press: product name, product brand name, product codes, amount of product recalled, reason for the recall, areas of distribution, and contact person within the company.

Verification and Recordkeeping

- Develop a recording or coding system so that each shipping container or a retail-ready package of ground beef has trace back and trace forward codes.
  A coding system could be as simple as indicating the shift, date and production line. For example, a code of 1/020898/2 would mean produced on 'first shift of February 8, 1998, line 2'. Corresponding records of all incoming products used on February 8, by shift and line, would enable full trace back to sources.

- These codes would facilitate tracking or trace back to the farm source, slaughter plant, and boning plant; a determination whether the meat was reconditioned, had intervention treatment, or had rework meat added to it; and a determination of the dates of slaughter and fabrication, lot number, storage, and transport records.

- Encourage primary and secondary distributors to maintain a record of the companies to which they supply finished products. This will ensure effective trace forward of all products, if the need arises.
  Thorough recordkeeping, including tracing back and forward, will facilitate recall efforts. This will make possible rapid identification of sources of microbial contamination leading to containment of any product that could result in foodborne illness and public health implications. This will minimize the economic impact of recalls on affected plants, by narrowing down implicated products to a certain lot or production code.

- The following should be verified and recorded:

  1) Suppliers of raw materials, intervention methods used during slaughter, boning, processing, and whether the purchase specifications are met.
  2) The type of raw material received, whether boneless beef, trim, cheek meat, or head meat and whether the purchase specifications are met, including temperature of product upon receipt and microbial specifications.
  3) Results/effectiveness of any intervention method applied.
  4) Temperature of processing room and of product.
  5) Packaging material or containers used and time and temperature of storage.
  6) Shipping materials used and time and temperature of shipping.

Education

- Grinding plants should develop programs to train and educate their employees, distributors, food handlers, or consumers of the risks of foodborne illness associated with the production of ground beef products and on measures to prevent foodborne illness. Establishments should continually monitor and update their programs. If needed, training in the language understood by food handlers and other employees should be provided.

- Safe handling instructions are required on the labels of not-ready-to-eat products when distributed to consumers, hotels, restaurants, or similar institutions [9 CFR 317.2(1)]. Grinding plants should include handling information on products distributed between establishments.

- Grinding plants should include cooking instructions that are targeted to the specific purchaser (e.g., product distributed to institutions with elderly, young, or immunocompromised

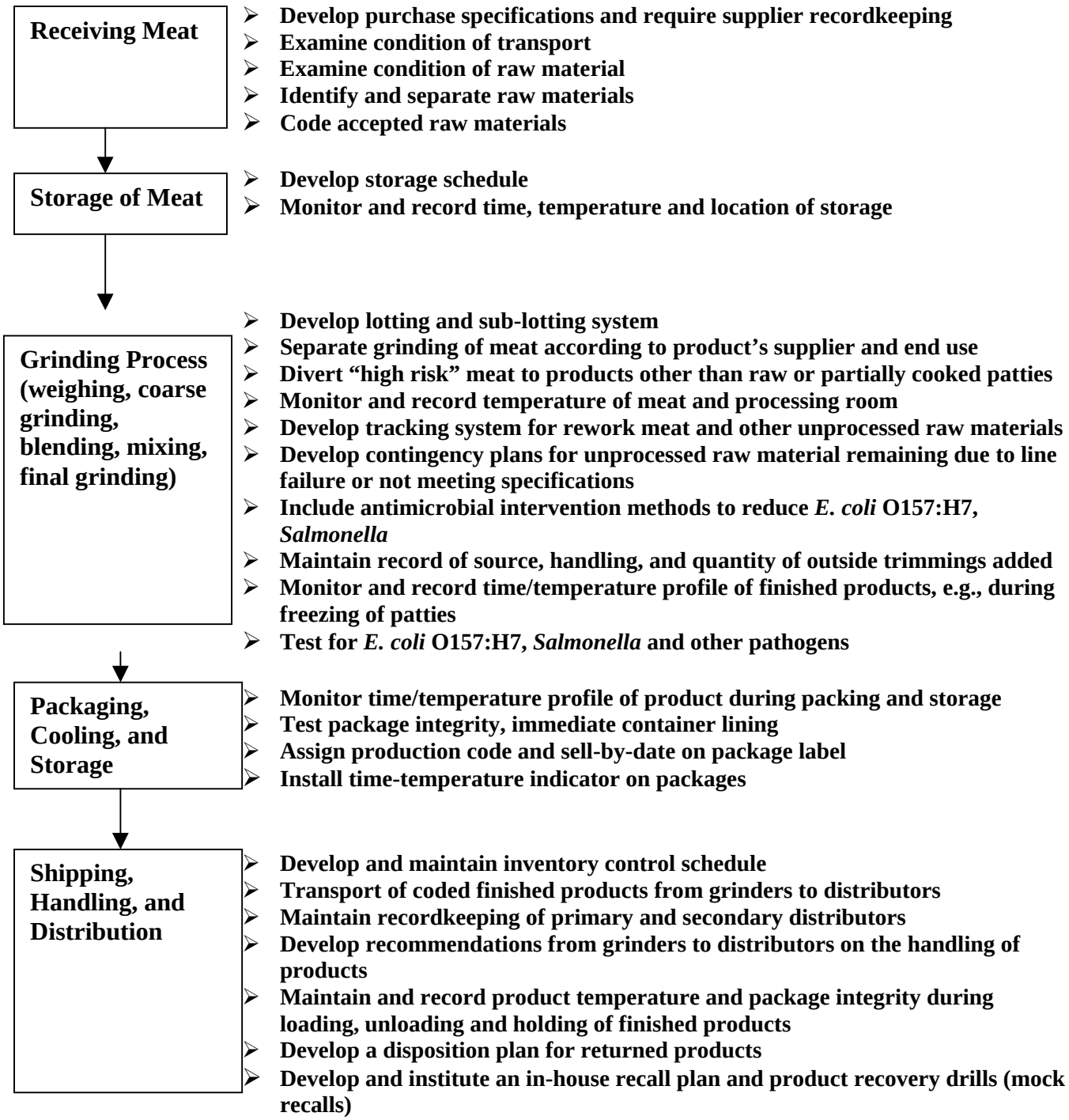
populations should include more rigorous cooking and handling instructions than those provided for the general population).

- *Raw meat products with altered appearances due to additives or processing should be conspicuously identified as such, e.g., 'raw meat balls' or raw spiced beef*'.

A list of free materials that may aid grinders and their suppliers in training and education may be ordered by mail or fax from the FSIS Food Safety and Education Staff at (202) 720-9352 or FAX (202) 720-9063. Many free educational materials, such as the Generic HACCP Models are also accessible on the FSIS web site http://www.fsis.usda.gov. For any questions on meat and poultry, call the Meat and Poultry Hotline at 1-800-535-4555. Other educational and training materials are also accessible via USDA/FDA Foodborne Illness Education Center at: http://www.nal.usda.gov/fnic/foodborne/foodborn.htm

APPENDIX 1

FLOW PROCESS DIAGRAM FOR RAW GROUND BEEF PROCESSING AND RECOMMENDATIONS



APPENDIX 2

INTERVENTION TREATMENTS FOR MEAT PARTS AND COMMINUTED MEAT

The following section describes studies on the use of antimicrobial decontamination methods as interventions to reduce microbial load. Establishments should determine the level of effectiveness of their antimicrobial decontamination methods with regards to reduction of specific pathogens and indicator organisms. Establishments should validate these methods according to the processes they use. The following antimicrobial treatments have been approved for reduction of pathogens in meat parts and comminuted meat: acidified sodium chlorite, lactoferrin, ozone, and irradiation.

Acidified Sodium Chlorite.
Acidified sodium chlorite was approved as an antimicrobial agent on processed, comminuted or formed meat food products (unless precluded by the standard of identity in 9 CFR 319) prior to packaging of the food for commercial purposes, in accordance with current industry standards of good manufacturing practices (FR vol. 66, no. 114, pp. 31840-31841, June 13, 2001). Acidified sodium chlorite may be applied as a spray or dip at levels that result in sodium chlorite concentrations of 500 to 1200 ppm, in combination with any GRAS acid at levels sufficient to achieve a pH of 2.5 to 2.9 (21 CFR 173.325). When used as such, acidified sodium chlorite is considered a secondary direct additive and does not have to be declared on the label of the treated product. Any meat treated with acidified sodium chlorite and found to retain water will need to disclose that fact in the labeling in accordance with the Final rule on "Retained Water in Raw Meat and Poultry Products; Chilling Requirements" (FR vol. 66, no. 6 pp. 1749-1772, Jan. 9, 2001).

A study showed the effectiveness of acidified sodium chlorite (ASC) in reducing the counts of *E. coli* O157:H7 and *Salmonella typhimurium* when inoculated onto various hot-boned individual beef carcass surface regions: inside round, outside round, brisket, flank, and clod (Castillo, A., L.M. Lucia, G. K. Kemp and G.R. Acuff. 1999. Reduction of *Escherichia coli* O157:H7 and *Salmonella typhimurium* on beef carcass surfaces using acidified sodium chlorite. J. Food Protect. 62:6:580-584). The pathogens were reduced by 3.8 to 3.9 log cycles by water wash followed by phosphoric acid-activated ASC spray, and by 4.5 to 4.6 log cycles by water wash followed by citric acid-activated ASC spray. The sprays consisted of applying 140 ml of the appropriate sanitizing solution for 10 seconds at 69 kPa. Use of water wash alone resulted in 2.3 log reduction.

Milk-Derived Lactoferrin
Milk-derived lactoferrin was approved for use as a component of an antimicrobial spray that contains up to 2 % lactoferrin applied to uncooked beef. (Gras Notice No. GRN 000067, FDA). This antimicrobial was approved for use on carcasses and meat parts only, not for comminuted meats. The maximum concentration to be used is 3.26 milliliters spray per

kilogram beef (or 6.2 milligrams lactoferrin per kilogram of beef). The GRAS Notice included a requirement that milk-derived lactoferrin be declared on the labels of meat to which it was added. The use of lactoferrin on beef carcasses and cuts (as well as products made from these lactoferrin-treated materials) should be labeled with a statement, e.g., "treated with lactoferrin from milk".

A review of the microbial activity of activated lactoferrin has shown that it can extend the retail display life of treated steaks by 1.7 to 2.5 days for case-ready packaged steaks compared to non-treated steaks in conventional packages (Naidu, A.S. 2002. Activated lactoferrin-a New Approach to Meat Safety. Food Technol. 56:(:3):40-45). This review also cited a study where 1% activated lactoferrin was used in combination with a series of antimicrobial treatments (cold water, lactic acid, hot water). The study has shown that there was a 99.99% detachment of *E. coli* O157:H7 per gram of beef tissue when activated lactoferrin was added to the series of antimicrobial treatments, and 72.2 % detachment when activated lactoferrin was not added. The acid rinses and hot water washes reduced E. coli O157:H7 to a significant level. The addition of activated lactoferrin effectively sanitized the contaminated beef surface by removing debris and residual bacteria.

Ozone

Ozone was approved (21 CFR 173.368) as a secondary food additive that can be safely used in the treatment, storage and processing of foods, including meat and poultry (unless such use is precluded by standards of identity in 9 CFR, Parts 319 and 381 Subpart P). Ozone may be used in contact with food in the gaseous or aqueous phase in accordance with current industry standards of good manufacturing practice. It may be used as an antimicrobial in meat and poultry products, including ground meats.

Irradiation

The Food and Drug Administration amended its regulations in December 1997 to include use of a source of radiation to treat refrigerated or frozen meat (21 CFR 179.26). On December 23, 1999, USDA, FSIS approved and published the final rule on the Irradiation of Meat Food Products (Federal Register, vol. 64, no. 246, pp. 72419-72166). This rule provides for the use of ionizing radiation at dosages of up to 4.5 kilogray (kGy) for treating refrigerated, and up to 7.0 kGy for treating frozen uncooked meat, meat byproducts, and certain other meat food products to reduce levels of foodborne pathogens and extend product shelf-life. The rule provided maximum dosage that can effectively reduce the levels of pathogens including *E. coli* O157:H7 and *Salmonella.* The general requirements, including labeling requirements for these irradiated products are found in 9 CFR 424.22. Meat grinding and boning establishments can now irradiate meat for grinding and ground beef in bulk or in retail packages to reduce or eliminate *Salmonella* and eliminate adulteration with *E. coli* O157:H7. In the following table, Monk et al., (1995) summarized studies on irradiation of meat and poultry products showing resistance of foodborne microorganisms when exposed to irradiation at certain temperatures and atmospheric environment.

Resistance of foodborne microorganisms to irradiation*

Microorganism	Product/ Medium	Temp ° C	Atmosphere	D_{10} (kGy)
E. coli O157:H7	ground beef	0	vacuum	0.27 +/- 0.03
	ground beef (low fat)	16 +/-1	air	0.307
		4 +/- 1	air	0.241
	ground beef (high fat)	16 +/- 1	air	0.306
		4 +/- 1	air	0.251
	mechanically	0	air	0.26 +/-0.01
	deboned chicken	0	vacuum	0.27 +/-0.01
		-5	air	0.44 +/-0.03
Salmonella	ground beef (low fat)	-16 +/-1	air	0.756-0.800
		4 +/-1	air	0.621-0.624
	ground beef (high fat)	-16 +/-1	air	0.675-0.745
		4 +/-1	air	0.618-0.661
Salmonella anatum	filet americain	18-20	air	0.45
	ground beef	18-20	air	0.67
Salmonella panama	filet americain	18-20	air	0.41
	ground beef	18-20	air	0.66
Salmonella stanley	filet americain	18-20	air	0.61
	ground beef	18-20	air	0.78
Salmonella typhimurium	filet americain	18-20	air	0.37
	ground beef	18-20	air	0.55
	minced pork	10	air	0.403-0.860
		10	CO_2 : N_2 (1:3)	0.394-0.921
	mechanically deboned chicken	-20	air	0.45 +/-.01 – 0.70 +/-.07
		-20	vacuum	0.48 +/- .06 – 0.79 +/- .08
		20	air	0.52 +/- .01 - 0.56 +/- .03
		20	vacuum	0.52 +/- .01- 0.56 +/- .03
	minced chicken	4	air	0.436-0.502
		4	CO_2	0.442-0.540
		4	N_2	0.550-0.662

Resistance of foodborne microorganisms to irradiation*

Microorganism	Product/ Medium	Temp ° C	Atmosphere	D_{10} (kGy)
	roast beef	NS	air	0.569-0.067
Listeria monocytogenes	minced chicken meat	NS	air	0.417-0.553
	minced pork	10	air	0.573-0.648
		10	CO_2: N_2 (1:3)	0.602-0.709
	mechanically deboned chicken	2-4	air	0.27-0.77
	roast beef	NS	air	0.644+/-0.061
	ground beef (low fat)	4 +/-1	air	0.578-0.589
		-16 +/-1	air	0.558-0.610
	ground beef (high fat)	4 +/-1	air	0.507-0.574
		-16 +/-1	air	0.524-0.575
Campylobacter jejuni	filet americain	18-20	micro-aerophilic	0.08-0.11
	ground beef	18-20	micro-aerophilic	0.14-0.16
	ground beef	-30 +/-10	air	0.315
		0-5	air	0.161
		30 +/-10	air	0.174

* Excerpted from the Monk, J. D., L. R. Beuchat, and M. P. Doyle. 1995. Irradiation inactivation of food-borne microorganisms. J. Food Protect. 58:2:197-208.

APPENDIX 3

The Use of Indicator Organisms to Assess the Presence of *E. coli* O157:H7 and *Salmonella*

There have been questions as to the practicality of testing for *E. coli* O157:H7 and *Salmonella* as a HACCP verification activity during slaughter and meat processing operations. These questions arise for these pathogens because they are not uniformly distributed, a negative test is not an assurance that the pathogen is absent, and because *E. coli* O157:H7 is known to occur sporadically, and is present at low levels. Testing for indicator organisms in lieu of testing for *E. coli* O157:H7 and *Salmonella* has been proposed because indicator testing costs less, is simpler and of shorter time/duration. The indicator organisms commonly used are total aerobic plate count (APC), coliforms, thermo-tolerant coliforms, *E. coli*, enterococci and *Enterobacteriaceae.*

Indirect tests as a means of detecting possible pathogens in water and foods have been in use for some time. These indirect tests use index, indicator, marker or surrogate organisms. The terms "index", "marker", "simulator" or "surrogate" were suggested to refer to organisms whose presence at certain levels indicates the possible occurrence of pathogens. The term "indicator organisms " or "hygiene marker organisms" are those whose detection is indicative of a failure in GMP or integrated system control which results in a food product of unacceptable microbiological quality (Brodsky, M.N. 1995. "The benefits and limitations of using index and indicator microorganisms in verifying food safety", Presented at the meeting on the "Role of microbiological testing in verifying food safety" May 1-2 1995, Philadelphia, PA). Testing for index organisms serve to predict the presence of pathogens, while indicator organisms serve to assess process control.

A review by J. Johnson (1996, Predictive microorganisms as an indication of pathogen contamination. AMSA Reciprocal Meat Conference Proceedings, vol.49) enumerates the characteristics of ideal index organisms (most of which are incorporated in the guidance below). The review of the scientific literature did not reveal any evidence of a direct relationship between the commonly used groups of index organisms and the presence or absence of pathogens on meat and poultry.

The review discussed the difficulties in establishing index organisms. One issue is the impact of non-homogeneous distribution of both index and pathogenic organisms in meat and poultry. Index organisms may be concentrated in one part of the carcass or the meat, which is not necessarily the same location where the pathogens are concentrated. Another consideration is whether the effects of control/decontamination/intervention methods on index organisms are similar to the effects on the pathogens. Organisms may react differently or have different survival rates as a result of the application of organic acid sprays depending on their acid tolerance. Some members of the coliform and *Enterobacteriaceae* groups are reported to be capable of growth at refrigeration temperatures, and therefore may not be good indices for assessing adequacy of refrigeration of meat and poultry. In addition, the relationship of the

number of index organisms to that of the target pathogen could change at different points in the slaughter or processing line.

Indicator organisms are especially useful for validating process implementation and verifying process control (AMSA, 1999. The Role of Microbiological Testing in Beef Food Safety Programs. The Scientific Perspective. Consensus of the 1999 Symposium). Pathogen testing is not useful for verification purposes because pathogens usually occur at low levels and are distributed non-randomly. However, pathogen testing as a means of HACCP verification is useful if incidence is high, distribution is random, and numbers are high enough to permit detection.

Tests for indicator organisms may be used successfully when there is sufficient data collected to establish or indicate a relationship between the occurrence or level of a pathogen or toxin and the indicator organism (AMSA, 1999). Data can be collected from studies using indicator organisms which parallel the data in a challenge study performed with inoculated pathogen in another or the same study. If a similar and consistent reduction or control can be established, then control of the indicator organism can be reliably used to indicate expected pathogen control in commercial application.

There are some studies on the use of various indicator organisms to determine the effect of intervention methods used to control pathogens in slaughter operations. Unfortunately, studies on the effects of carcass decontamination methods on *E. coli* O157:H7 and on indicator organisms were done separately, so that correlation of the effect on *E. coli* O157:H7 and indicator organisms cannot be established.

FSIS undertook an analysis of existing Agency ground beef testing program data to compare the incidence of *E. coli* O157:H7 and generic *E. coli* (unpublished) for the years 1998, 1999 and 2000 (up to July). The results show that the correlations are not strong enough to support the use of generic *E. coli* testing in lieu of testing for *E. coli* O157:H7. Therefore, at this time, testing for any organism other than *E. coli* O157:H7 would not be acceptable validation of a CCP to prevent, eliminate, or reduce *E. coli* O157:H7. However, if at some point in the future, establishments can demonstrate through studies, that there is an organism that can be used as an indicator for *E. coli* O157:H7, this organism could be used for validation of CCPs addressing *E. coli* O157:H7.

The Agency will encourage exploring the applicability and effectiveness of the use of indicator organisms in studies designed to demonstrate correlation in the reduction of indicator organisms with reduction of *E. coli* O157:H7 and *Salmonella*. The Agency is using the term “indicator organism” because the test for the organism will assess the presence of *E. coli* O157:H7 and *Salmonella,* and at the same time indicate process control. FSIS is providing its current thinking on when testing for indicator organisms can be used instead of testing for the pathogens, *E. coli* O157:H7 and *Salmonella*. Research studies or challenge experiments should demonstrate correlation between indicator organisms and *E. coli* O157:H7 with the following pointers:

1. Characteristics of indicator organisms used for the study must include:

- a history of constant ecological association with the target pathogen in the environment where contamination originates
- being present when the target pathogen is present, and occur in greater numbers compared to the target organism
- a reliable and defined quantitative relationship with the target pathogen;
- growth requirements and growth rates identical to those of the target pathogen;
- reacting in similar manner to adverse conditions/processing as the target pathogen;
- being easily differentiated from other microorganisms;
- being easily and rapidly detectable.

2. The study must include both the indicator organism and *E. coli* O157:H7 or *Salmonella,* and be subjected to the same conditions and same decontamination methods. The level/quantity of both the indicator organism and *E. coli* O157:H7 or *Salmonella* must be determined/measured before and after the application of the decontamination method(s) using FSIS methods (Microbiology Laboratory Guidebook 3rd edition, 1998 at http://www.fsis.usda.gov/OPHS/microlab/mlgbook.htm) or equivalent.

3. Decontamination studies on carcasses will be applicable to carcasses only, while studies on trimmings or ground beef will be applicable to trimmings and ground beef, respectively.

3. Sufficient data indicating constant correlation between the level of indicator organism and that of *E. coli* O157:H7 or *Salmonella* must be collected. Data should establish that a statistically significant quantitative reduction of the indicator organism at the specific step in processing consistently achieved a constant reduction of *E. coli* O157:H7 or *Salmonella.*

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) Subcommittee on Microbiological Performance Standards for Raw Meat and Poultry in their report included additional recommendations to assure scientific sufficiency in using an indicator organism in lieu of a specific pathogen for measurement against a performance standard. (http://www.fsis.usda.gov/OPHS/NACMCF/rep_stand.htm).