

Guidance for Beef Grinders to Better Protect Public Health

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

Based upon sporadic cases, outbreaks, and product recalls involving *Escherichia coli* (*E. coli*) O157:H7, FSIS has concluded that guidance can help grinders to develop and implement procedures that better protect public health. This guide is intended to illustrate how grinders can avail themselves of opportunities to minimize food safety hazards associated with their products. It does not prescribe regulatory requirements under the Federal Meat Inspection Act (FMIA).

The guidance provided in this document is premised on three main points.

- First, grinders should structure their operations in a manner that takes into account the safety of their raw materials and their potential product safety responsibilities through to the end user.
- Second, grinders should realize that they are in an excellent position to implement process and distribution controls that reduce public health concerns associated with ground beef contaminated with *E. coli* O157:H7.
- 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 (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 specify purchase requirements related to incoming raw materials, to process raw materials under processing and recordkeeping controls designed to ensure the safety and traceability of their products, and 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 packages. This guidance material, through several guiding principles and associated detailed explanations and recommendations, is intended to identify how grinding operations can reduce public health risk.

Processing operations are presently required to have SSOP's (Sanitation Standard Operating Procedures) and a few are already required to have functional HACCP (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}. Grinding operations not already required to have HACCP plans are encouraged to develop and implement their

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.

HACCP plans earlier than required as soon as possible³. Although this guidance material highlights issues associated with ground 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.

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 are advised to purchase raw materials from suppliers that maintain such records. In addition, they are advised to keep records regarding the disposition of their products to enable tracing their products forward to consumers and back to suppliers. In instances where grinders do not control their products through distribution and retail sale, the chain of records necessary to trace products that raise a public health concern should not be broken. Intermediate handlers, such as distributors and wholesalers, should assume responsibility for keeping 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 of 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). 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 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)⁴, and because it produces severe and sometimes fatal consequences at a very low infectious dose. Buchanan and Doyle (1997)⁵ 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 heat processing or integrated lethality using fermentation or pH is the only approved method of making food harboring *E. coli* O157:H7 safe for consumption. 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 in order to reduce, as much as possible, the likelihood that the pathogen is present in the finished product. The Agency issued on February 1, 1998, FSIS Directive 10,010.1

³ Federal Register: January 30, 1998 (Volume 63, Number 20) p. 4622

⁴ 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.

Texas Food Industry Association v. Espy, 870F.supp.143,149,(W. D. Tex.1994)

⁵ 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.

Microbiological Testing Program For *Escherichia coli* O157:H7 in Raw Ground Beef, which provides current instructions to FSIS personnel for selecting, collecting, and submitting ground beef samples.

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 to Better Protect Public Health may also be requested by fax or mail from FSIS Public Outreach, 202-720-9063; Room 1180 South Building, Washington D.C. 20250. Comments regarding this guide should be directed to William J. Hudnall, at 202-205-0495, and fax at 202-401-1760.

This guide is an updated version of the guidance material that FSIS made available to the public in March 1998. It has been modified 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 public meeting at which each of these organizations presented guidelines along with FSIS' guidance material. This is the first update of the Agency's Guidance.

Section I. Guiding Principles:

These guiding principles are supplemented with suggested procedures in Section II.

- A. Grinders should determine the specifications for microbial safety that are necessary to ensure that their products will be safe and should only accept starting materials and ingredients that meet their specifications. In developing such specifications, grinders should consider the intended use for the starting materials and ingredients and what, if any, pathogen reduction actions by their suppliers would be beneficial.
- B. Grinders should keep abreast of new technologies and interventions that could be introduced into their processes to help prevent adulterated products or to identify product that is adulterated before it enters commerce.
- C. Grinders should develop and implement 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.
- D. Grinders should implement controls to identify and segregate for special handling, product that pose a greater risk of being adulterated. Alternate outlets, such as diversion to FSIS inspected or state-inspected processors that employ a bacterial kill-step (such as cooking), should be acquired for such products.
- 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 health risk is identified that results in recalling product that is suspected of presenting a potential hazard to the public.
- F. In cooperation with their customers, grinders should develop and implement handling and distribution procedures that will not compromise the safety of their ground products once those products leave their establishments.
- G. Grinders 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 can help to assure consumers that product found to have *E. coli* O157:H7 can be made safe by thorough cooking. Steps are available to ensure that product presumed or known to have *E. coli* O157:H7 is made safe as opposed to destroying it.

Section II. Suggested Procedures for the Guiding Principles

Receiving Meat (Guiding Principles A and B)

- Develop purchase specifications to ensure receipt of safe and wholesome incoming raw materials. Purchase specifications should take the end use of the product into consideration. For example, purchase specifications for raw materials for processing products with potentially high risk end use, such as raw patties, should include either:
 - 1) microbial specifications, and testing by supplier or grinder, or
 - 2) supplier operation under HACCP plans with critical control points (CCP's) that address pathogen intervention or anti-microbial programs, such as hot water rinses, acid spray, steam pasteurization, or irradiation*.

**The Food and Drug Administration amended its regulations to include use of a source of radiation to treat refrigerated or frozen meat in December 1997. FSIS is currently preparing rulemaking on procedural and labeling requirements.*
- Require suppliers to maintain records of farm source or slaughter plant to facilitate traceback.
- Examine condition of transport for sanitation-related and other product handling concerns, including:
 - 1) sanitation of the carrier or truck
 - 2) presence of cracks, debris, foreign material, or off-odor
 - 3) condition of insulation and door seals
 - 4) temperature inside transport vehicles and of meat
 - 5) length of time of transport.
- Examine and record condition of raw material:
 - 1) Note and document species identity, origin, age and temperature of both refrigerated and frozen materials, supply source, boning date/slaughter date.
 - 2) Conduct organoleptic examination (appearance, smell, 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.
- Identify and separate incoming material according to the potential risk of the product's end use. Small mass products such as raw beef patties are "higher risk" because they are thin, are cooked for a short time, are preferred not fully cooked by some consumers, and the internal temperature is not easily obtained. Large mass products such as meat loaf or chili are "lower risk" because they are denser and are cooked evenly for a longer time. Ready-to-eat (RTE) products such as cooked beef patties are "lower risk" because these are subjected to a processing step lethal to pathogens.

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

Storage of Raw Material (Guiding Principle C)

- Develop 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 (Guiding Principles C, D, E)

- Observe and record pre-operational and operational SSOP conformance, including those for equipment, floor, ceilings, walls, and employees. Adopt testing (e.g., microbial, ATP bioluminescence) to measure effectiveness of SSOP.
- Develop a lotting or sub-lotting system for coding and tracking purposes. Assign lot numbers that will enable tracking lot to 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 can be restricted to a subset of the plant's production between cleanups.
- Separate processing of meat into lower risk and higher risk categories. 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.
Separation of raw materials into these two categories (i.e. lower risk and higher risk) will prevent possible cross contamination among products with different handling history.
- 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.
 - 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 in general, adequately cooked before consumption. In diversifying, 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 and the processing room 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, use only rework meat from the immediately preceding lot or shift, and not more than the past 24 hours. 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 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 trimmings added (i.e., trimmings not from the same batch or lot as the rest of the raw materials)
 - Monitor the time and temperature of finished products, e.g., freezing of beef patties.
 - Test for *E. coli* O157:H7 during the grinding operation. 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 that take into account industry action to reduce the presence of *E. coli* O157:H7. FSIS has instructed inspection program personnel that (unless

otherwise directed) they are not to collect samples at an inspected establishment which makes only raw ground products that are tested daily for *E. coli* O157:H7, that are made from boneless beef lot which is certified to have tested negative for *E. coli* O157:H7, or that are made from carcasses which are subjected to a valid pathogen reduction intervention, the effectiveness of which is routinely verified and confirmed by testing, so long as no sample has tested positive for *E. coli* O157:H7, in the past six months.

Testing may help to determine whether to divert to other products. Because of the low incidence of E. coli O157:H7 in meat, testing is not a guarantee of the absence of the pathogen, and the amount and frequency of sampling from different volumes of meat being processed will vary. The point of sampling, whether raw material or the finished product, will also vary, depending on the condition of the raw material, whether there was previous testing, the system of controls in the plant, and the type of finished product.

Packaging, Cooling, and Storage (Guiding Principle C)

- 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 (Guiding Principle F)

- Develop and maintain an inventory control schedule for products in storage. The FIFO inventory control schedule could also be used at this point.
- Transport coded products in clean, sanitized, temperature-controlled and well-maintained carriers to distributors.
- Maintain records of primary and secondary distributors.
- 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 plant and been out of the control of the plant.
- Develop an in-house recall plan 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, reason for the recall, areas of distribution, contact person within the company.

Recordkeeping System (Guiding Principle G)

- 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 should 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.

Education (Guiding principle H)

- Grinding plants that have developed programs to educate their employees, distributors, food handlers, and consumers of the risks of foodborne illness associated with the production of ground beef products should continually monitor and update their programs. If needed, training in the language understood by food handlers and other employees should be provided.
- Grinding plants without such programs should develop training and educational programs for employees, distributors, food handlers, and consumers on the microbiological risks that may be associated with ground beef products, and on measures to prevent foodborne illness. Training in the language understood by the people concerned should be provided, if necessary.
- Safe handling instructions are currently 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).

A list of already developed free materials that may aid grinding plants in training and education may be ordered by mail or fax from the FSIS Public Outreach and Communications Office at (202) 720-9352 or FAX (202) 720-9063. Many free educational materials are also accessible on the FSIS web site <http://www.fsis.usda.gov>. 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> .

FLOW PROCESS DIAGRAM FOR RAW GROUND BEEF PROCESSING AND RECOMMENDATIONS

