USDA Agricultural Marketing Service

APPROVED

FEDERAL PURCHASE PROGRAM SPECIFICATION (FPPS) FOR COARSE GROUND BEEF ITEMS, FROZEN

Agricultural Marketing Service (AMS)
Livestock, Poultry, and Seed (LPS) Program
Food Safety and Commodity Specification (FSCS) Division
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100 SCOPE

101 This FPPS – Coarse Ground Beef (CGB) – 2015 is for use by the Department of Agriculture (USDA), AMS, Commodity Procurement (CP) Staff to procure frozen Coarse Ground Beef products.

200 APPLICABLE DOCUMENTS

210 The following documents are incorporated as part of this USDA, FPPS-CGB-2015:

210.1 Quality Assessment (QA) Division Procedures Manual.

210.2 Food Safety and Inspection Service (FSIS) Directive 10,010.1, Revision 3.

210.3 Applicable Supplement to AMS Master Solicitation.

300 CHECKLIST OF REQUIREMENTS

310 MATERIAL

311 The contractor's technical proposal must describe a process plan with a documented quality control program that includes procedures, records, forms, etc., that demonstrate conformance with the following AMS Checklist of Requirements. FSCS Division may request changes to the technical proposal at any time.

312 Domestic Origin and Harvest (Slaughter) Requirements

312.1 Quality Control Program - The harvester's quality control program must be documented in each contractor's technical proposal and have received a satisfactory onsite capability assessment by QA Division.

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Date Revised:

312.2 Boneless beef shall be derived from cattle harvested at facilities that comply with the following origin and harvest requirements.

312.2.1 Domestic Origin - All beef will originate from U.S. produced livestock as defined in the Master Solicitation and Supplement.

312.2.2 Humane Handling – All cattle shall be humanely handled in accordance with all applicable FSIS regulations and AMS requirements.

312.2.3 Residue Prevention – Harvest and production establishments must have a Hazard Analysis Critical Control Point (HACCP) system to control veterinary drug, pesticide, and environmental contaminant residues per FSIS regulations. Helpful information is available in the FSIS Compliance Guide for Residue Prevention 2013.

312.2.4 Spinal Cord Removal – All spinal cord tissue shall be removed during the harvesting process.

312.2.5 Pathogen Intervention Steps – The harvest process must include at least two pathogen intervention steps. One of the intervention steps must be a critical control point (CCP) in the supplier's FSIS recognized harvest process HACCP plan and the CCP intervention(s) must be scientifically validated to achieve a three-log reduction of enteric pathogens.

312.2.6 Carcass Testing - Routinely test carcasses for Shiga-toxigenic *Escherichia coli* O157 (including O157:H7 and O157:Non-Motile (NM); herein referred to as *E. coli* O157:H7) at CCP to verify effectiveness of interventions.

320 Boneless Beef Requirements

320.1 Quality Control Program - The boneless beef supplier's quality control program must be documented within each contractor's technical proposal and have received a satisfactory onsite capability assessment by QA Division prior to supplying materials for the program. Additionally, each plant is subjected to verification audits conducted by the QA Division during production activities that demonstrate their adherence to the documented quality control program.

320.2 Traceability – Boneless beef shall be traceable to sources that comply with the above domestic origin and harvest requirements.

320.3 Boneless beef commonly referred to by the industry as XF trimmings (e.g., Beef Fat with Visible Lean) is not allowed as a standalone raw material source for grinding.

320.4 Meat Recovery Systems

320.4.1 Mechanical Separation - Boneless beef that is mechanically separated from bone with automatic deboning systems, advanced lean (meat) recovery (AMR) systems or powered knives, will not be allowed.

320.4.2 Lean Finely Textured Beef (LFTB) – Use of LFTB is not permitted.

320.5 Handling - All boneless beef must be maintained in excellent condition. The contractor's technical proposal shall include detailed production scheduling that addresses time and temperature controls necessary to maintain excellent condition of the boneless beef.

320.5.1 Frozen boneless beef may be used provided it is ground into the final product within 60 days from the date of pack.

320.6 Objectionable Materials – The following objectionable materials shall be excluded:

320.6.1 Major lymph glands (prefemoral, popliteal, and prescapular), thymus gland, and the sciatic (ischiatic) nerve (lies medial to the outside round). All bone, cartilage, and the following heavy connective tissues:

320.6.1.1 White fibrous – Shoulder tendon, elbow tendon, silver skin (from the outside round), sacrociatic ligament, opaque periosteum, serous membrane (peritoneum), tendinous ends of shanks, gracilis membrane, patellar ligament (associated with the stifle joint), and achilles tendon.

320.6.1.2 Yellow elastin – Back strap and abdominal tunic.

320.7 Lot – A lot shall consist of approximately 2,000 pounds of boneless beef produced within a day, between "cleanup to cleanup" (see APPENDIX D) and that is from a single harvester or processor.

320.8 Microbial Testing - Samples from all lots of fresh chilled boneless beef, must be sent to an AMS designated laboratory (ADL). Samples from each lot will be tested for *E. coli O*157:H7*, Salmonella*, and indicator microorganisms. One sample from every 10 lots of fresh chilled boneless beef, selected at random by the ADL, will be tested for non-O157 STECs (O26, O45, O103, O111, O121, O145).

323.8.1 Sample Preparation and Handling - The ADL will be responsible for supplying procedures for sample preparation, and submission. The laboratory shall require suppliers to submit a sample submission form as an official record with each sample. The ADL will also be responsible for supplying shipping supplies (including sampling bags and shipping materials) to each supplier. Suppliers' technical proposal will include and describe sample collection and preparation procedures provided by the ADL.

323.8.2 Sample Selection

323.8.2.1 For Beef Manufacturing Trimmings – The sample will be selected as described within FSIS Directive 10,010.1 Revision 3 (N-60 Sections 8, 9 and NOTE).

323.8.2.2 For every lot of beef Manufacturing Trimmings, two (2) samples will be prepared from sixty five (65) pieces of trim from sixty five (65) different pieces of beef product. The sample for co-analysis of *E. coli* O157:H7, non-O157 STECs and *Salmonella* will be sixty (60) pieces and weigh 325 grams ± 10 percent; the sample for indicator microorganisms (aerobic plate count, total coliform and generic *E. coli*) will be five (5) pieces and weigh 25 grams ± 10 percent.

323.8.2.3 Alternative sampling methods may be used provided they are approved by AMS as equivalent to the manual excision protocols referenced in Section 323.9.2.1. The suppliers' technical proposal will include and describe any proposed alternative sample collection and preparation methods and procedures.

323.8.2.4 When boneless beef has been exposed to any anti-microbial treatment, no sample units shall be selected for at least 15 minutes after such treatment. All anti-microbial treatments (e.g. techniques and procedures) administered during production and post-production shall be described in the supplier's technical proposal.

323.8.2.5 If the contractor plans to do microbiological testing in addition to that required by AMS, the technical proposal must identify in detail such testing, including location of sample collection, frequency of sample collection, and intended use of testing results. AMS will make a determination of whether such additional sampling and testing constitutes "prescreening," in which case it will not be allowed.

323.8.3 Testing and Results

323.8.3.1 The microbiological testing for all organisms will be in accordance with the applicable AMS-approved testing methodologies.

323.8.3.2 Notification for presence of pathogens and exceeding critical limit criteria - When presence of *E. coli* O157:H7, non-O157 STECs, or *Salmonella* is confirmed positive or any critical limit is exceeded for indicator organisms:

323.8.3.2.1 The ADL will immediately notify FSIS and the FSCS Division of all confirmed pathogens.

323.8.3.2.2 When pathogen results are positive, FSIS and the FSCS Division will be notified by the boneless beef supplier of the final disposition of the affected lot.

323.8.3.2.3 When the critical limit is exceeded for indicator microorganisms, the boneless beef supplier will notify the FSCS Division of the final disposition of the affected lot.

323.8.3.3 The ADL will record all results on spreadsheets and calculate the process capability (CPU, Cl) for microbial tests performed on production lots as outlined in Section 323.9.4.

323.8.3.4 Any lot that tests positive for *E. coli* O157:H7, non-O157 STECs, or *Salmonella*, or exceeds the critical limit criteria of APPENDIX B cannot be used to produce ground beef or any other product purchased by USDA.

323.8.4 Statistical Process Capability – Boneless beef supplier compliance with microbial requirements will be based on the assessment of the calculated process capability (CPU, Cl) values derived from the individual combo test results representing one (1) 2,000 pound combo lot randomly selected by the ADL from every five (5) consecutive individual 2,000 pound combo lots produced each production day. In the event that a production day concludes with less than five (5) consecutive individual 2,000 pound combo lots, a randomly selected test result will be utilized from one of the remaining lots. The spreadsheets will be maintained so that process capability assessment on the twenty (20) lots can be determined as described within APPENDIX B. Test results involving all boneless beef offered for testing for AMS ground beef purchase programs will be monitored by AMS, the contractor, and the boneless beef supplier to determine individual lot acceptance and/or capability of their process according to APPENDIX B. Ineligible boneless beef suppliers may re-enter the program under conditional status provided corrective actions have been submitted for review and approved, implemented and a satisfactory onsite corrective action audit by QA Division has been conducted. Upon notification by the FSCS Division that the plan has adequately addressed the issues that resulted in the ineligible status determination, the boneless beef supplier may re-enter the program under conditional status.

323.8.5 Contractor's Responsibility - The contractor will require its boneless beef supplier(s) to provide results and process capability status (as applicable) involving each lot of boneless beef to be processed into ground beef for USDA. Test results and process capability status (as applicable) for individual lots shall be provided to the QA Division agent upon request. In the event a boneless beef supplier has been deemed ineligible, and wants to continue in the program, the ineligible boneless beef supplier may re-enter the program under conditional status provided corrective actions have been submitted for review and have been deemed approved, implemented and a satisfactory onsite corrective action audit by QA Division has been conducted. Upon notification by the FSCS Division that the plan has adequately addressed the issues that resulted in the ineligible status determination the boneless beef supplier may re-enter the program under conditional status.

323.8.6 Supplier request to remove samples from AMS testing must be submitted and approved by FSCS Division prior to sample removal from ADL testing.

324 Coarse Ground Beef Item Requirements

324.1 Quality Control Program - The Coarse Ground Beef items quality control program must be documented within the contractor's technical proposal and have received a satisfactory onsite capability assessment audit by QA Division.

324.2 Traceability – All Coarse Ground Beef items production must be traceable to the boneless beef lots and their associated microbial test results.

324.3 Handling - The contractor's technical proposal shall include detailed production scheduling that addresses time and temperature controls necessary to maintain excellent condition of the Coarse Ground Beef items. Coarse Ground Beef items shall be delivered within 60 days from date of pack.

324.4 Lot - For the purpose of microbiological testing, a lot is defined as the amount of finished Coarse Ground Beef product produced within a day, between "cleanup to cleanup" (see APPENDIX D) which must be further divided into sub-lots not to exceed 10,000 pounds.

324.5 Microbial Sampling and Testing Options – The Contracting Officer will specify in the purchase solicitation and corresponding documents TYPE 1 and TYPE 2 Coarse Ground Beef Products, which will determine the level of microbial testing required.

324.6 Microbial Testing – TYPE 1 - Coarse Ground Beef for Further Processing into Fully Cooked Items - All sub-lots of Coarse Ground Beef for Further Processing into Fully Cooked Items will be tested for all indicator microorganisms (aerobic plate count, total coliform and generic *E. coli*) after final grinding and before freezing. All samples will be sent to the ADL.

324.6.1 Sample Preparation and Handling - The ADL will be responsible for supplying procedures for sample preparation, and submission. The ADL shall require contractors to submit a sample submission form as an official record with each sample. Samples of TYPE 1 Coarse Ground Beef for Further Processing into Fully Cooked Items must be appropriately identified on the ADL sample submission form. The ADL will also be responsible for supplying shipping supplies (including sampling bags and shipping materials) to each contractor. Contractor's technical proposal will include and describe sample collection and preparation procedures provided by the ADL.

324.6.2 Sample Selection – Production processes of Coarse Ground Beef for Further Processing into Fully Cooked Items will be subject to the following sampling strategy:

324.6.2.1 Sub-lot Microbial Testing – For every sub-lot, one (1) original and reserve sample will be prepared from four (4) individual sample units for indicator organism (aerobic plate count, total coliform and generic *E. coli*) testing. The sub-lot samples will be 25 grams ± 10 percent randomly selected throughout each 10,000 pounds of production. The four (4) individual sample units shall be composited to produce a sample that represents the indicator organism test for each sub-lot. The contractor will describe in their technical proposal the procedure in which the four (4) sample units will be selected throughout the sub-lot to be composited for the indicator organism test. These samples shall be submitted to the ADL for analysis. The reserve samples will be held for testing in case the FSCS Division deems it necessary. The contractor will describe, in their technical proposal the method to be used to maintain the identity and traceability of each sub-lot. No more than 10,000 pounds shall be produced during each sub-lot, except for the last sub-lot produced in the lot may exceed the 10,000 pound limitation by five (5) percent.

324.6.3 Testing and Results - The samples from each sub-lot will be analyzed by the ADL for all organisms listed in APPENDIX B.

324.6.3.1 The microbiological testing for indicator microorganisms will be in accordance with the applicable AMS-approved testing methodologies.

324.6.3.2 Any sub-lot with any critical limit criteria noted in APPENDIX B that is exceeded will result in that sub-lot and adjoining sub-lots (one preceding and one following within a day, between “clean up to clean up”) being ineligible for this program or any other USDA purchase program. Other sub-lots produced within the lot unit will be deemed ineligible for this program unless the contractor can demonstrate a scientific or other data-supported basis for defining the sub-lot(s) relative to test results and why coarse ground beef produced from same source material that resulted in the ineligible determination should not be considered affected by the test results.

324.6.3.3 When any critical limit is exceeded for indicator microorganisms, FSIS and the FSCS Division will be notified by the contractor of the final disposition of the product.

324.6.3.4 The ADL will record all results on spreadsheets and calculate the process capability (CPU) for microbial tests performed on sub-lots as outlined in Section 324.6.3.5.

324.6.3.5 Statistical Process Capability - The ADL will record the results on spreadsheets and calculate the process capability (CPU) value for all sub-lot microbial tests performed. The spreadsheets will be maintained so that process capability may be determined according to the requirements within APPENDIX B. The spreadsheets will be maintained so that process capability assessment on each twenty (20) sub-lot grouping can be determined as described within APPENDIX B. Test results will be monitored by the contractor and FSCS Division to determine acceptability of the process according to APPENDIX B. Ineligible contractors may re-enter the program under conditional status provided corrective actions have been submitted for review and approved, implemented and a satisfactory onsite corrective action audit by QA Division has been conducted. Upon notification by the FSCS Division that the plan has adequately addressed the issues that resulted in the ineligible status determination, the contractor may re-enter the program under conditional status.

324.6.3.6 Contractor request to remove samples from AMS testing must be submitted and approved by FSCS Division prior to sample removal from ADL testing.

324.7 Microbial Testing – TYPE 2 - Coarse Ground Beef - All sub-lots of Coarse Ground Beef will be tested for *E. coli O*157:H7*, Salmonella*, and indicator microorganisms as listed in APPENDIX B after final grinding and before freezing. All samples will be sent to the ADL.

324.7.1 Sample Preparation and Handling - The ADL will be responsible for supplying procedures for sample preparation, and submission. The laboratory shall require contractors to submit a sample submission form as an official record with each sample. The ADL will also be responsible for supplying shipping supplies (including sampling bags and shipping materials) to each contractor. Contractor's technical proposal will include and describe sample collection and preparation procedures provided by the ADL.

324.7.2 Sample Selection – Production processes of Coarse Ground Beef will be subject to the following sampling strategy:

324.7.2.1 Sub-lot Microbial Testing – For every sub-lot, two (2) original and reserve samples will be prepared from four (4) individual sample units for each microbial test. The sub-lot samples will be 325 grams ± 10 percent for co-enrichment of *E. coli* O157:H7 and *Salmonella* and 25 grams ± 10 percent for indicator organism tests, respectively of finished ground beef, randomly selected throughout each 10,000 pounds of production. The four (4) individual sample units shall be composited to produce a sample that represents each microbial test for each sub-lot. The contractor will describe in their technical proposal the procedure in which the four (4) sample units will be selected throughout the sub-lot to be composited for each microbial test. These samples shall be submitted to the ADL for

analysis. The reserve samples will be held for testing in case the FSCS Division deems it necessary. The contractor will describe, in their technical proposal the method to be used to maintain the identity and traceability of each sub-lot. No more than 10,000 pounds shall be produced during each sub-lot, except for the last sub-lot produced in the lot may exceed the 10,000 pound limitation by five (5) percent.

324.7.3 Testing and Results - The samples from each sub-lot will be analyzed by the ADL for all organisms listed in APPENDIX B.

324.7.3.1 The microbiological testing for all organisms will be in accordance with the applicable AMS-approved testing methodologies.

324.7.3.2 Any sub-lot that tests positive for *E. coli* O157:H7 or *Salmonella,* or any critical limit criteria noted in APPENDIX B that is exceeded will result in that sub-lot and adjoining sub-lots (one preceding and one following within a day, between “clean up to clean up”) being ineligible for this program or any other USDA purchase program. Other sub-lots produced within the lot unit will be deemed ineligible for this program unless the contractor can demonstrate a scientific or other data-supported basis for defining the sub-lot(s) relative to test results and why Coarse Ground Beef produced from same source material that resulted in the ineligible determination should not be considered affected by the test results.

324.7.3.3 Notification for presence of pathogens or when critical limit is exceeded – When presence of *E. coli* O157:H7 or *Salmonella* is presumptive positive or confirmed positive; or any critical limit is exceeded for indicator organisms:

324.7.3.3.1 The ADL will immediately notify FSIS and the FSCS Division of all confirmed pathogens.

324.7.3.3.2 When pathogens results are positive, FSIS and the FSCS Division will be notified by the contractor of the final disposition of the product.

324.7.3.3.3 When the critical limit is exceeded for indicator microorganisms, FSIS and the FSCS Division will be notified by the contractor of the final disposition of the product.

324.7.3.3.4 Coarse Ground Beef associated with the positive pathogen test results or critical limit exceeded results will be ineligible for any USDA purchase program.

324.7.3.4 The ADL will record all results on spreadsheets and calculate the process capability (CPU, Cl) for microbial tests performed on sub-lots as outlined in Section 324.7.3.5.

324.7.3.5 Statistical Process Capability - The ADL will record the results on spreadsheets and calculate the process capability (CPU or CI) value for all sub-lot microbial tests performed. The spreadsheets will be maintained so that process capability may be determined according to the requirements within APPENDIX B. The spreadsheets will be maintained so that process capability assessment on each twenty (20) sub-lot grouping can be determined as described within APPENDIX B. Test results will be monitored by the contractor and FSCSD to determine acceptability of the process according to APPENDIX B. Ineligible contractors may re-enter the program under conditional status provided corrective actions have been submitted for review and approved, implemented and a satisfactory onsite corrective action audit by QA Division has been conducted. Upon notification by the FSCS Division that the plan has adequately addressed the issues that resulted in the ineligible status determination, the contractor may re-enter the program under conditional status.

324.7.3.6 Contractor request to remove samples from AMS testing must be submitted and approved by FSCS Division prior to sample removal from ADL testing.

330 PROCESSING

331 The contractor's technical proposal and process shall assure compliance with the following requirements:

331.1 Grinding and Blending

331.1.1 Coarse Ground Beef items - Boneless beef shall pass at least once through a grinding plate that is no smaller than ¾-inch or no larger than a 1.0-inch. Blending after final grinding is allowed only to the extent that it doesn't affect the appearance of the finished Coarse Ground Beef items.

331.1.2 Fat Break-Outs - The grinding, blending, and packaging process shall be conducted in a manner that precludes large fat "break outs" (solid chunks of fat greater than 1.0 cubic inch) or objectionable fat "smears" in the finished product.

331.2 Metal Detection - All product shall be free of metal contaminates. Detection of stainless steel, ferrous, and non-ferrous (e.g., lead, copper, and aluminum) metals is required. The contractor's technical proposal must identify and describe the equipment, location, detection procedure, sensitivity levels, frequency of equipment validation, and corrective action procedures.

331.3 Equipment – All equipment used to produce Coarse Ground Beef items for USDA shall be maintained and routinely checked for optimal performance.

340 STATE OF REFRIGERATION

341 Coarse Ground Beef items shall be frozen to 0°F within 72 hours after completion of the final grinding of the involved lot.

342 Coarse Ground Beef items will be stored, shipped, and delivered at temperatures that do not exceed 0°F.

350 FAT LIMITATIONS

351 The contractors will establish a target average of 15 percent fat. The upper and lower specifications limits will be 18 and 12 percent fat respectively. The target fat content will be declared on the shipping container label and the nutrition facts panel.

352 Contractor Process Assessment - The contractor shall declare the production lot size, laboratory, test method, and SPC methodologies in their technical proposal.

352.1 Sampling and testing - The contractor will randomly select four individual sample units (selected after initial grinding or blending) to be analyzed for fat content from each production lot destined for USDA. The sample unit size will be determined by the testing method used by the contractor's laboratory.

352.2 Recording results - The contractor will record the results on spreadsheets. The calculated process capability (Cpk/CPU) value (as discussed in APPENDIX A) will be used to determine if the process is in statistical control. Under contractor process assessment, no production lots shall be allowed delivery to USDA with average test results that are outside the upper or lower specification limits.

352.3 Process Capability Assessment - Twenty (20) consecutive production lot results (that include the last production lot) will be recorded on spreadsheets for capability assessment by the contractor and the AMS agent. The processor's capability (Cpk/CPU) shall be one or higher.

353 AMS Process Assessment – For the first 20 production lots, the AMS agent will direct the contractor to randomly select samples, each consisting of four sample units. For Coarse Ground Beef items, each initial sample unit shall not exceed 10 pounds. Initial sample units may be blended and/or further reduced in size. From each initial sample unit a final sample unit will consist of 200 – 300 grams each. Each sample unit shall be independent from those samples selected for contractor process assessment and sent to the ADL for fat analysis. The ADL will be responsible for supplying sampling protocol, all sample handling materials, and sampling methods (including sample unit size to be submitted to the ADL, preparation, handling of reserve samples, etc.) for sample preparation and submission. The ADL will record the results on spreadsheets and submit them to the contractor and AMS for comparison to the contractor's process assessment. After 20 consecutive results, the

contractor shall notify the FSCS Division immediately and declare what immediate corrective and preventative actions will be taken when:

353.1 The ADL calculated process average fat results (mean) varies more than one (1) percent from the contractor's calculated process average results, or;

353.2 The calculated process capability (Cpk/CPU) is less than one for results from either the contractor's designated laboratory or the ADL.

353.3 The contractor must notify the FSCS Division that the process is not capable for fat and then sample and test an additional 20 consecutive results that must meet the criteria for AMS Process Assessment. Change in status begins after a cause and effect analysis has been performed and corrective actions have been implemented. If the contractor remains in Unreliable Status after the additional 20 consecutive lots, a cause and effect analysis must be performed and corrective actions submitted within 5 business days to AMS for review and approval. If the contractor still remains in Unreliable Status after the second round of 20 consecutive lots a cause and effect analysis must be performed and corrective actions submitted within 5 business days to AMS for review and approval, implemented and a satisfactory AMS assessment audit has been completed. The FSCS Division reserves the right to deem a contractor as Unreliable for consideration on future contract awards when corrective or preventative actions are not adequate or effective or the contractor is unresponsive in declaring status or submitting corrective actions.

354 Continuous AMS Assessment – If AMS process assessment is satisfactory, the AMS agent will direct the contractor when to randomly select samples (each consisting of four sample units) from a production lot. No more than two production lot samples are sent to the ADL on a weekly basis. The ADL will continually record 20 consecutive results (always including the last recorded result as defined within APPENDIX D) on spreadsheets and submit the calculated process capability (Cpk/CPU) value to the contractor and AMS. The ADL's calculated process capability (Cpk/CPU) value will continually be compared to the contractor's calculated process capability (Cpk, CPU) value as each contractor's test result is recorded to conduct the AMS Process Assessment as described above (using 20 consecutive results).

360 PREPARATION FOR DELIVERY

361 The contractor's technical proposal and process will assure that all packaging, packing, closure, marking, and palletization comply with the National Motor Freight Regulations and FSIS regulations and the requirements listed below. The contractor also must have procedures for verifying the net weight of shipping containers.

362 Packaging and Packing

362.1 All immediate containers shall function as a tamper evidence indicator to provide added assure of product integrity through the method of sealing or closure.

362.2 Coarse Ground Beef items must be bulk packaged (with no packaging materials) directly into leak-proof shipping containers with fiberboard that is wax impregnated, has a moisture barrier coating, or have plastic laminated interior panels.

362.3 Style and Size of Shipping Containers - Only one style and size of immediate and shipping container may be used in any one delivery unit.

363 Shipping Container Net Weight

363.1 Using SPC tools, the contractor shall assure the following net weight:

363.1.2 Coarse Ground Beef items - will be packed to a net weight of 60 pounds.

364 Closure

364.1 Shipping containers will be closed by strapping, taping or gluing. When strapping is used, the initial closure (usually the bottom of container) shall be secured by the gluing or taping method.

365 Marking of Containers*

365.1 Shipping containers will have a printed code that includes the establishment number and is traceable to the production lot and date. All container markings shall include all information required by FSIS along with the additional information listed below:

365.2 Shipping Containers - Commercially marked shipping containers will include the information as follows:

365.2.1 USDA Shield (at least 2 inches high and appearing on the top of the container or on the principal display panel).

365.2.2 Applicable Purchase Order Number.

*All labeling shall be illustrated in the Contractor's technical proposal.

365.2.3 The product name and material number – Coarse Ground Beef for Further Processing into Fully Cooked Items and Coarse Ground Beef. Material Number 100154.

365.2.4 Fat Declaration – 15% Fat.

365.2.5 Nutrition Facts panel to include fat declaration of 15 grams of fat per 100 grams serving size.

365.2.6 Ingredient declaration (including single ingredient products).

365.2.7 An allergen statement in a format which complies with the Food Allergen Labeling and Consumer Protection Act (FALCPA) for any product which contains milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, soy or wheat; e.g. Allergen: This product contains _____.

366 Palletized Unit Loads

366.1 All products shall be stacked on new or well-maintained pallets and palletized with shrink wrap plastic.

367 Total Net Weights Per Delivery Unit

367.1 The delivery unit will be 42,000 pounds. No tolerances will be allowed.

368 Sealing

368.1 All products must be delivered to AMS assigned destinations under seal with tamper proof, tamper resistant, serially numbered, high security seals that meet the American Society for Testing and Materials Standard (ASTM) F1157-04 and/or the International Organization for Standards (ISO) 17712-2010 as required under the Master Solicitation. Seals shall be ⅛th-inch diameter cable, high-security bolt, or equivalent.

370 USDA QUALITY ASSURANCE

371 Warranty and Complaint Resolution

371.1 Warranty - The contractor will guarantee that the product complies with all specification requirements, technical proposal declarations, and provisions set forth in the Master Solicitation.

371.2 Complaint Resolution - Customer complaint resolution procedures will be included in the technical proposal. These procedures will include: a point of contact, investigation steps, intent to cooperate with AMS, and product replacement or monetary compensation. The procedures will be used to resolve product complaints from recipient agencies or AMS.

372 AMS Monitoring and Production Assessment

372.1 A QA Division agent must be present during the production of the finished product for all USDA coarse ground beef contracts. The QA Division agent will monitor and verify the processing steps, quality assurance activities, and any corrective actions to assure that all requirements outlined in the approved technical proposal are complied with. The QA Division agent will be conducting the monitoring and production verification in accordance with applicable QA Division procedures. Any deviations to contractual requirements will be reported to the contractor and FSCS Division. The FSCS Division will make all determinations as to the acceptability of the product relative to findings documented by the QA Division agent.

373 Control of Non-Conforming Product

373.1 The contractor must include a plan to assure that non-conforming product (i.e., boneless beef, coarse ground beef) is not delivered under USDA contracts. The plan must address 1) control and segregation of non-conforming product, 2) removal of any USDA markings, and 3) disposition of non-conforming product, including vendor notification in writing to the FSCS Division of final disposition (e.g., diverted to cooked product or destroyed).

374 Contractor Checkloading

374.1 Contractor will perform checkloading examinations at the time of shipment and issue contractor's certificate to accompany each shipment that includes all of the following information:

374.1.1 Purchase Order Number/Purchase Order Line Item Number;

374.1.2 Sales Order Number/Sales Order Line Item Number;

374.1.3 Destination of shipment;

374.1.4 Name of Product and applicable Material Number;

374.1.5 Shipping Date;

374.1.6 Production lot number(s) and date each lot was produced along with shipping container and immediate container code(s) and the code used that provides traceability to establishment number, production lot and date;

374.1.7 Count of shipping containers and total projected net weight in each production lot;

374.1.8 Identity of car or truck (car numbers and letters, seals, truck license, etc.) as applicable;

374.1.9 Contractor certification that product conforms with the applicable specification (FPPS-CGB-2015);

374.1.10 Count and projected net weight verified and;

374.1.11 Signature of company official responsible for checkloading.

APPENDIX A

DATA ENTRY AND PROCESS CAPABILITY VALUES

Data Entry

The ADL will record microbiological and fat test results on spreadsheets and to have those spreadsheets readily available to AMS and its contractors/suppliers. Quantitative (plate count) results will be expressed as colony forming units (CFU) per gram or per ml reflecting the original sample measurement. Test results will be entered as a whole number (i.e., no decimal places, no preceding < (less than) symbol). Qualitative results for *E. coli* O157:H7, each of the non-O157 STEC serotypes, and *Salmonella* will be recorded as a 1 for a positive results and as a 0 for negative results.

The ADL will provide the calculated process capability values (CPU, Cpk and Cl) in the spreadsheets so that the supplier's process capability assessment can be determined, as described in APPENDIX B.

Process Capability Values – CPU or Cpk

The process capability value (CPU or Cpk) is calculated by the ADL. CPU will be used for microbiological tests and for Beef Patties – 90/10 fat tests since these requirements only have an upper specification limit. Cpk will be used for fat testing requirements that have an upper and lower specification limit (see section 3.5). The upper specification limits (USL) for microbiological requirements will be found in APPENDIX B. The calculations for CPU and Cpk are as follows:

Calculation of process capability (CPU) with an upper specification limit only

Step 1. The first calculation will determine the Z-value (upper):

Z-value (upper) = (USL – Process Average) / Standard Deviation

Step 2. The Z-value divided by 3 will calculate the CPU:

CPU = Z-value (upper) / 3

Calculation of process capability (Cpk) with an upper and lower specification limit

Step 1. The first set of calculations will determine the smaller value of the two Z-values (upper or lower):

Z-value (upper) = (USL – Process Average) / Standard Deviation

Z-value (lower) = (Process Average – LSL) / Standard Deviation

Step 2. The smaller of the two Z-values (upper or lower) divided by 3 will calculate the Cpk.

CPU = Z-value (smaller value of the upper or lower) / 3

Process Capability Value – Cl

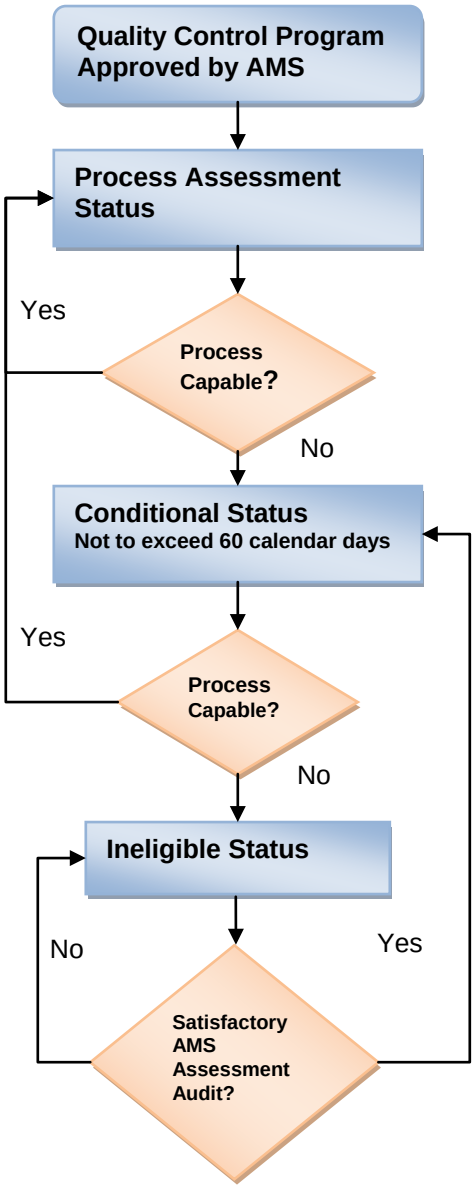
The central line (Cl; x-bar) is the process average or arithmetic mean that indicates the incidence of positive *E. coli* O157:H7 and *Salmonella* results. Results from non-O157 STECs are not used to calculate process capability.

APPENDIX B

AMS BONELESS & COARSE GROUND BEEF ITEMS PROCESS REQUIREMENTS FLOW CHART

Quality Control Program – Prior to bidding on ground beef contracts with the USDA, the documented quality control program as described within the approved technical proposal (raw material suppliers and grinders) must have received a satisfactory onsite capability assessment by QA Division. AMS will audit and monitor the program. The quality control program must specifically address management of microbial data to comply with the AMS Process Requirements Flow Chart and the following descriptions.

AMS PROCESS REQUIREMENTS FLOW CHART



Process Assessment Status - A process assessment involves sampling and testing of 20 consecutive lots or sub-lots (which will include the last recorded result as defined within APPENDIX D) of boneless beef (see Section 320.8.5) or Coarse Ground Beef items (see Section 324.7.3.5) destined for USDA contracts for the organisms listed within the table below.

Process Capable? – Flow chart decision step that involves test results for up to 20 consecutive SPC only lots or sub-lots (which will include the last recorded result) recorded in spreadsheets, where the process capability (CPU or CI) value is calculated (See APPENDIX A) for evaluation. A process that is not capable shall be declared to the FSCS Division immediately when results are known and will result in switching from process assessment status to conditional status or switching from conditional status to ineligible status when:

- The CPU values do not meet the levels specified in the table below;
- The CI values do not meet the levels specified in the table below for *Salmonella* or *E. coli* O157:H7;
- Two results exceed any of the critical limits in the table below; * or
- After 2 or more results, the CPU value is negative.*

*Immediate action will be taken prior to completion of 20 lots or sub-lots.

Conditional Status –To regain process capable status, the boneless beef supplier or contractor must notify the FSCS Division that the process is not capable, and then have 20 consecutive results that meet the **'Process Capable'** criteria within 60 calendar days or in accordance with a production schedule pre-approved by the FSCS Division. Change in status begins after a cause and effect analysis has been performed and corrective actions have been implemented. The boneless beef supplier or contractor may also declare itself ineligible at any time.

Ineligible Supplier/Contractor – An ineligible Boneless Beef Supplier or Ground Beef Contractor will not be allowed to supply boneless or ground beef products under USDA contracts until a cause and effect analysis has been performed and corrective actions have been submitted to AMS for review and approved, implemented and a satisfactory AMS assessment audit has been completed. Once satisfactorily becoming eligible, subsequent production will be under **Conditional Status.** The AMS FSCS Division reserves the right to declare a boneless beef supplier or ground beef contractor ineligible at any time.

AMS MICROBIAL REQUIREMENTS FOR BONELESS & GROUND BEEF			
Microbial Test	**USL (cfu)**	**Critical Limits (cfu)**	**CPU or Cl Value**
Standard Plate Count	50,000 / gram	100,000 / gram	CPU $\geq$ 1
Total Coliforms	100 / gram	1,000 / gram	CPU $\geq$ 1
E. coli	100 / gram	500 / gram	CPU $\geq$ 1
Salmonella		Positive (+) result / 25 grams	Cl $\leq$ 0.05
E. coli O157:H7		Positive (+) result / 325 grams	Cl $\leq$ 0.05

APPENDIX C

GLOSSARY OF TERMS

Cause and Effect Diagrams – A cause and effect analysis is used to identify the cause or source of non-conformities. It categorizes the source as derived from impact on a process presented by Human, Machinery, Material, Methods, Environment, and Measurement (Test). The Cause and Effect Diagram will assist in evaluating a process and assigning the appropriate control point (see Figure 1).

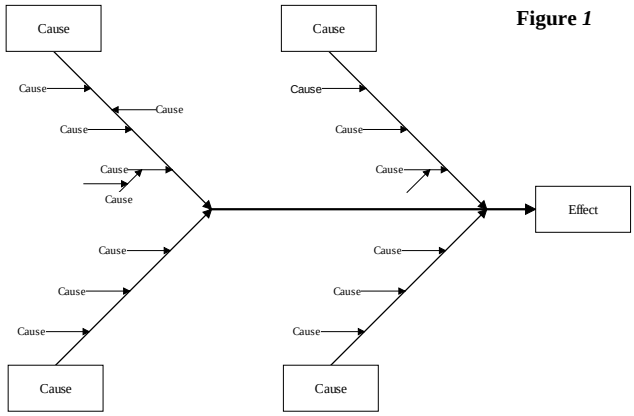


Figure *1*

"Cleanup to cleanup" - Part of a HACCP program that the establishment has in place to support statistically distinguishing one portion of production from another. Production destined for USDA contracts is to be commenced on clean equipment. "Cleanup to cleanup" may be an effective means of preventing cross contamination of one part of production to another with *E. coli O157:H7*. However, "cleanup to cleanup" without other supporting documentation may not be adequate to statistically distinguish one portion of production from another. If a sample analysis yields a positive result, any product produced in the same time frame with the same process or equipment is suspect, unless an intervention occurred that would indicate a change in the status of the process/equipment.

Control Charts – A control chart is a run chart with statistically derived upper and lower control limits (ucl and lcl). The control chart demonstrates if a process is in statistical control. When properly designed, control charts provide an early warning of problems allowing for adjustments to be made before production of non-conforming products. Microbial test results may be plotted on control charts for individual measurements and fat test results may be plotted on control charts featuring average and range of the fat test results (See Figure 2).

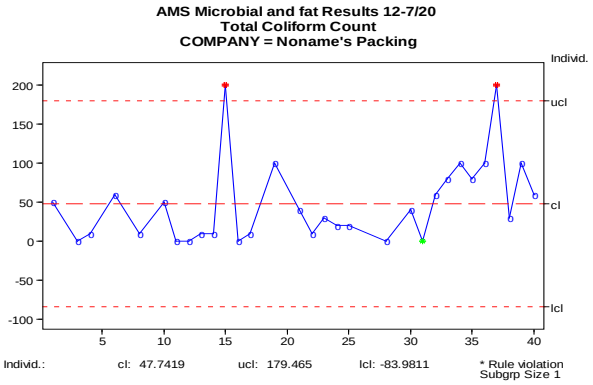
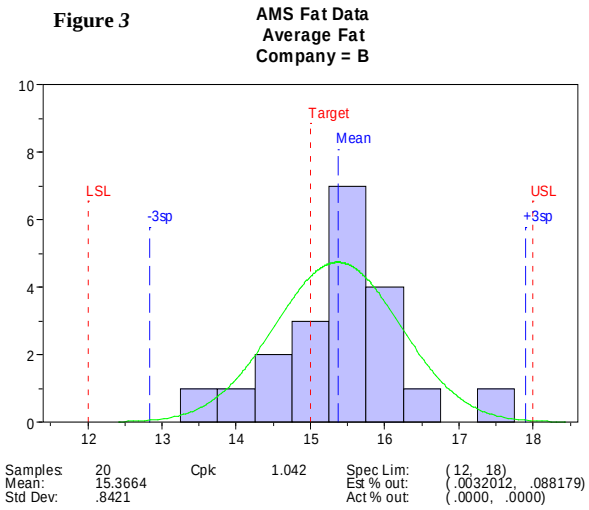


Figure *2*

Cpk – Process Capability Value (Cpk) is a capability analysis index used to determine if a process can meet specification limits. A Cpk value of 1 indicates that the process is producing at least 99.73% within the specification limit. Cpk values of 1 for many organizations have become the minimum requirement. However, the larger the Cpk values the better. Cpk differs from other process capability analyses since it considers the process average along with the distribution of test results. Since there is no lower specification limit for USDA microbial requirements, the calculation for Cpk will not involve relating the process average with a lower specification limit.

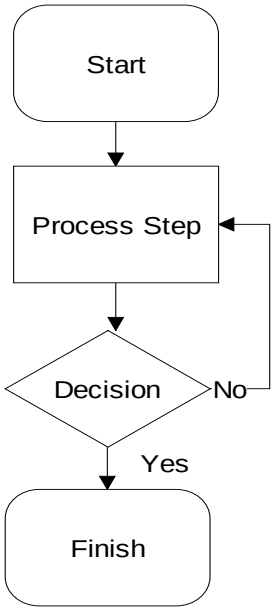
Figure *3*



CPU - Process Capability Value (CPU) is the same as Cpk except that there is no lower specification limit. The process performance index is correctly known as a Centered Process Capability Upper Specification Limit only (CPU) (See Figure 3).

Excellent Condition - All product must be in excellent condition (e.g., exposed lean and fat surfaces shall be of a color and bloom normally associated with the class, grade, and cut of meat and typical of meat which has been properly stored and handled). Cut surfaces and naturally exposed lean surfaces shall show no more than slight darkening or discoloration due to dehydration, aging, and/or microbial activity. The fat shall show no more than very slight discoloration due to oxidation or microbial activity. No odors foreign to fresh meat shall be present. Changes in color and odors characteristically associated with vacuum packaged meat in excellent condition shall be acceptable. Also, product shall show no evidence of mishandling. Beef must be maintained in excellent condition through processing, storage, and transit.

Figure *4*



Flow Charts – Flow charts depict all of the steps of a process. Standard symbols are used to identify the start, finish, processing steps and decision steps. It can be used to simplify a complex process so that it can be analyzed (Figure 4).

Histograms – The histogram shows a pictorial representation of the frequency of distribution of microbial test results over time. Sometimes referred to as process capability charts, histograms compare the distribution of the test results with AMS specification requirements. Use histograms along with control charts to better understand process capability (See Figure 3).

Pareto Diagrams – The Pareto diagram ranks the importance of different non-conformities. Typically, non-conformities are measured against frequency of occurrence. The Pareto analysis is helpful in identifying and justifying which problems will need to be solved first (see Figure 5).

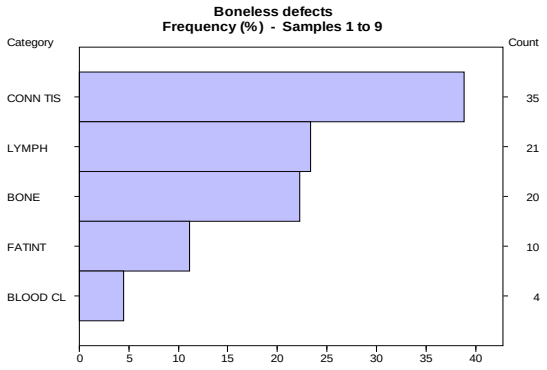
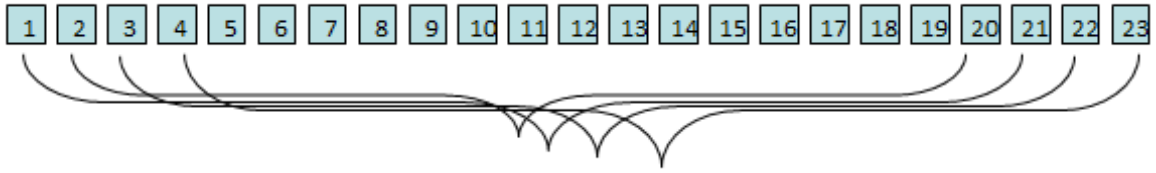


Figure 5

Process – For the purpose of this specification, a single process involves the input of a raw material on a production line with a value added activity resulting in a output that can is be further processed or meet a customer's need. A complex process involves output being another processes input. The production of ground beef is a complex process.

Process Capability Assessment on 20 consecutive lots – For the purpose of this specification, process capability assessments are conducted on data results from each lot for fat and microbial requirements. A process assessment involves sampling and testing of 20 consecutive lots (which always includes the last recorded result). Information from each lot will be evaluated with information from the preceding 19 lots (i.e., while in process assessment of the first 20 lots, the process was found to be capable, then assessment will continue on lot numbers 2-21). This has often been referred to as a 'Rolling 20'. This assessment takes into account process variations that may be attributed to product, management, sources, and time (see Figure 6).

Figure 6



Random Sampling – A process of selecting a sample from a lot whereby each unit in the lot has an equal chance of being selected and is representative of the lot's production.

Statistical Process Control (SPC) – SPC is the primary analysis tool of quality improvement. The objective of any quality improvement strategy is to identify and reduce the amount of variation. SPC analyzes the variation in a process and is the applied science that assists suppliers to collect, organize and interpret microbial and fat test results on processing of ground beef destined for USDA.

SPC provides tools to help measure, identify, and eliminate variation from customer requirements (see Table 1).

Table 1

Tools for Statistical Process Control	
Flow Charts	Scatter Diagrams
Pareto Diagrams	Run Charts
Cause and Effect Diagrams	Control Charts
Histograms	Capability Assessment

Upper and lower control limits (UCL and LCL) – Control limits are statistical calculations of the distribution of test results. Upper and lower control limits represent +/- 3 standard deviations of the process results. Data plotted outside the limits represent special causes of variation. A process may be considered "out of statistical control" when results are outside these limits. Upper and lower control limits are not to be confused with specification limits. A supplier wishing to be an eligible participant in the Coarse Ground Beef Program shall have a process that is capable of producing within the specification limits (See figure 2).

Upper and lower specification limits (USL and LSL) – Normally, the customer sets the specification limits. The objective of the Ground Beef Purchase Program is to procure from ground beef processors that are statistically capable of meeting the upper specification limits specified within the FPPS-CGB. The specification limits reflect customer needs (See Figure 3).