

SUPPLEMENT 603 TO THE
AMS MASTER SOLICITATION
FOR THE PURCHASE OF
FROZEN BISON PRODUCTS
FOR DISTRIBUTION TO
FEDERAL FOOD AND
NUTRITION ASSISTANCE
PROGRAMS

APPROVED

Agricultural Marketing Service (AMS) Livestock and Poultry (LP) Program Standards and Specification Division (SSD) Room 2628-S, STOP 0258 Phone: (202) 690-3148

Supersedes: Supplement 603 March 2021

Effective: March 2022

100 OVERVIEW

This document provides additional program requirements for the purchase of Frozen Bison Products by the Department of Agriculture (USDA), including the applicable Federal Purchase Program Specification (FPPS) (**Exhibit A**).

200 INSTRUCTIONS TO POTENTIAL SUPPLIERS

- The frozen Bison products shall be purchased on a competitive bid basis from qualified suppliers who have met the requirements described in this Section. Interested suppliers may submit a technical proposal at any time during the purchase program. Suppliers should allow 10 working days, from USDA's receipt of the technical proposal for notification of evaluation results. A supplier is deemed eligible upon notification of approval of the technical proposal by the Standards and Specification Division (SSD).
- Submission of a technical proposal is not binding on USDA. Supplier eligibility for USDA purchase programs will be based on the technical approval of the supplier as well as the completion of additional contractor requirements described in the AMS Master Solicitation for Commodity Procurements, this Supplement, and/or a separately issued Solicitation. Actual purchases shall be described in the AMS Master Solicitation for Commodity Procurements and Solicitations.
- 230 Documentation Requirements
- 231 Technical Proposal Requirement
- 231.1 Include a detailed description of the Bison product(s) offered and each of the production steps that are taken to meet or exceed the minimum product requirements set forth in the FPPS. (Plan/Do)

- 231.2 Describe all the quality assurance methods used to verify conformance to all requirements. This shall include the monitoring and measurements taken during the process to verify conformance with each requirement. All measurement results shall be recorded and made available to AMS. (Check)
- 231.3 Identify all corrective actions to be taken if deviations from contractual and specification requirements occur during production, and all preventative actions to be taken to preclude a reoccurrence. (Act)
- 231.4 The technical proposal shall follow the format as shown in **Exhibit C**. Technical proposals should be brief and concise.
- 231.5 The technical proposal shall be preceded by the following, as required by the template:
- 231.5.1 Table of Contents listing the major areas as they appear in the technical proposal, and
- 231.5.2 List of attachments and forms provided in the technical proposal with the applicable document name and reference number.
- The SSD shall review each technical proposal to determine if it is adequate and shall notify the supplier of the status and their eligibility to bid.

300 INSTRUCTIONS FOR SUBMISSION OF TECHNICAL PROPOSAL

- The following procedures establish the acceptable minimum requirements for the format and content of the technical proposal:
- The Government has provided a technical proposal format to be used in preparing the technical proposal (see **Exhibit C**). The supplier shall submit the technical proposal as an email file attachment to TechnicalApprovals@usda.gov and Steve.Whisenant@ams.usda.gov). The technical proposal shall be saved in a non-portable document file format (not PDF, e.g., Microsoft Word). The technical proposal shall be submitted in its entirety. If the file size of the technical proposal is too large to send in a single email, it may be divided and sent in multiple emails (i.e., Part 1, Part 2, Part 3, etc.). The collection of attachments and appendices may be submitted as a separate document as well.
- While it is not the desire of the Government to penalize a supplier for non-compliance with formatting instructions, technical evaluators may have difficulty evaluating the technical proposal to the fullest extent possible if the proposal is not presented in the proper format. Technical evaluators shall not be required to search other subsections or sections of the supplier's technical proposal for information requested in the evaluation.
- 320 Technical Proposal Revisions

- 321 Changes to a supplier's technical proposal may be submitted at any time or at the request of the SSD. All technical proposal revisions shall meet the following criteria:
- Any changes to a technical proposal made by the supplier after its initial submittal is approved shall be accomplished by submitting an entire technical proposal. A cover letter shall be submitted with the changes identified and an explanation of the need for the change. The supplier shall include the revision date and the appropriate page number(s).
- 321.2 Changes from the original technical proposal shall be highlighted and deletions in strikeouts.

400 ASSESSMENT BY THE QUALITY ASSESSMENT (QA) DIVISION

- Once a supplier is notified by the SSD that the technical proposal meets the applicable criteria, the Quality Assessment (QA) Division shall contact the supplier to set up a pre-award onsite capability assessment audit of the facility's processes, food security plan, and quality control program used to produce the product(s) to determine the supplier's ability to meet contractual requirements.
- 420 Pre-Award Onsite Capability Assessment Audit
- 421 Food Defense Assessment
- 421.1 The QA Division shall conduct a food defense audit that shall include, but is not limited to, a thorough evaluation of the supplier's food defense plan. Documentation shall support the supplier's food defense plan. If the report demonstrates that the food defense plan is inadequate, the supplier shall be notified by the SSD that they are ineligible to bid. The supplier shall have an opportunity to correct identified deficiencies, modify the food defense plan and resubmit a brief description for further consideration. Eligibility shall depend on whether the modifications demonstrate compliance with the food defense plan.
- 422 Harvesting Requirement
- The QA Division shall conduct monthly harvesting and humane handling audits based on the requirements stated in the attached FPPS and the company's approved technical proposal. Documentation shall support the supplier's adherence to meeting the harvesting and humane handling requirements as set forth in the FPPS.
- 423 Documentation shall support:
- 423.1 the production of the Bison product that complies with the applicable FFPS and the potential supplier's approved technical proposal, and
- 423.2 the supplier's food security plan. In addition, the audit shall consist of the review of records related to purchasing, receiving, production, quality control, inventory and shipping records, and interviews with management and production personnel.

- Upon completion of the onsite capability assessment, the auditor shall provide either a verbal or email notification of the audit findings to the SSD to determine (based on the audit findings), supplier eligibility to bid. Supplier shall be notified by the SSD and the official final report shall be sent once released from the QA Division.
- If the audit findings demonstrate that the process or food security plan is inadequate, the applicant shall be notified by the SSD that they are ineligible to bid. The supplier shall have an opportunity to correct identified deficiencies, modify the process, food security plan, and/or technical proposal, and resubmit for further consideration.
- 424.2 Eligibility shall depend on whether the modifications demonstrate that:
- 424.2.1 the process is capable of delivering Bison product(s) in compliance with the FPPS,
- 424.2.2 the supplier is in compliance with the food security plan,
- 424.2.3 a successful QA Division corrective action audit is conducted, and
- 424.2.4 the supplier complies with other applicable contractual requirements.
- 430 Post-Award Assessment Audit
- Eligible suppliers who receive contracts shall have their documented food security plan, technical proposal, and supporting documentation readily available for review by the SSD or AMS agents. Records may be maintained on hard copy or electronic media. However, records maintained as electronic media shall be made available in printed form immediately upon request by the SSD or AMS agents.
- The QA Division shall conduct an onsite audit of the supplier's facility(s) and processes when production commences for the first contract awarded. Additional audits shall be conducted as determined by the SSD, but not less than once per month for suppliers with continuous or multiple contracts, or once per contract for intermittent suppliers. At the discretion of the SSD, more frequent audits may be conducted when audit deficiencies are detected.
- 440 Post-Award Actions
- Any deviation from contractual requirements shall be immediately reported by the contractor to the Contracting Officer and SSD. The Contracting Officer or SSD shall notify the supplier regarding eligibility to continue to participate as a supplier.
- Suppliers shall assure that the delivered product complies with the provisions of the FPPS, the applicable assessment by AMS, and the supplier's technical proposal approved by the SSD.
- The cost of all audit, product monitoring, and certification services performed by the AMS agents shall be borne by the supplier. This includes, but is not limited to, audits, examinations, supervision, official documentation, and related services.

Questions concerning charges and the availability of AMS agents can be directed to USDA/AMS, LPS Program's QA Division field office or the Director of the QA Division, LPS Program, AMS, USDA, Room 3953-S, STOP 0258, 1400 Independence Avenue, SW, Washington, DC 20250-0258, telephone (202) 720-3271.

500 QA DIVISION MONITORING AND EVALUATION PROGRAM

Eligible suppliers who receive USDA contracts must have a QA Division agent present during the production of the frozen bison products. The QA Division agent will monitor and verify the production based on the contractor's approved technical proposal and the FPPS. The contractor must provide a copy of the approved technical proposal and have the supporting documentation readily available for review by the AMS agent. Records may be maintained on hard copy or electronic media; however, records maintained as electronic media will be made available in printed form immediately upon request by AMS or its agents.

600 ANIMAL WELFARE REQUIREMENTS

The contactor and all subcontractors must meet the animal handling and welfare requirement set forth the in the attached **Exhibit B (FPPS-BHW-2022)**.

700 RESPONSIBILITIES AND ELIGIBILITY

- Facilities used in fulfilling USDA contracts must be operating under the provisions of the Voluntary Exotic Animal Inspection Program of the FSIS contained in Title 9 C.F.R. Subpart 352. The firm must also be approved under an AMS pre-award supplier capability assessment audit prior to submitting an offer under this Supplement. Firms must also comply with the provisions of FSIS Final Rule for Pathogen Reduction; Hazard Analysis and Critical Control (HACCP) Systems.
- Subcontractors or suppliers of frozen bison products are: (1) ineligible if they are currently delivering late on USDA contracts or USDA-approved subcontracts, and late delivery is not due to causes beyond their control; and (2) non-responsible if they are not operating under the provisions of the Voluntary Exotic Animal Inspection Program of the FSIS contained in Title 9 C.F.R. Subpart 352 or have been suspended or debarred under the provisions of 48 C.F.R. Subpart 9.4

600 DOMESTIC ORIGIN CERTIFICATION CLAUSE

The supplier shall include the below domestic origin certification clause in its entirety in all subcontracts for meat or meat products used in fulfilling any contracts awarded under this Supplement and Master Solicitation. The burden of proof of compliance is on the Contractor. All raw materials shall be shipped in containers labeled as "Domestic Only Product" on the principal display panel and the bill of lading accompanying the shipment shall contain the statement "Domestic Only Product."

700 CERTIFICATE OF CONFORMANCE (COC)

In addition to the referenced payment documents required in the Master Solicitation, please include a copy of the Contractor's Certificate of Conformance (**Exhibit D**).

800 CONTRACTOR CHECKLOADING

- 810 Contractor shall perform checkloading examinations as described in the FPPS at the time of shipment and issue a contractor's certificate to accompany each shipment that includes all of the following information:
- 810.1 Purchase Order Number,
- 810.2 Sales Order and Sales Order Item Number,
- 810.3 Name of product and material number,
- 810.4 Shipping Date,
- 810.5 Production lot number(s) and date each lot was produced,
- 810.6 Count of shipping containers and total projected net weight in each production lot,
- 810.7 Identity of car or truck (car numbers and letters, seals, truck license, etc.) as applicable
- 810.8 Destination of shipment,
- 810.9 Count and projected net weight verified, and
- 810.10 Sample average fat content analysis of each production lot of ground bison.

900 EXHIBITS



APPROVED

FEDERAL PURCHASE PROGRAM SPECIFICATION (FPPS) FOR GROUND BISON AND BISON STEW MEAT, FROZEN Agricultural Marketing Service (AMS)
Livestock and Poultry (LP) Program
Standards and Specification Division (SSD)
Room 3932-S, STOP 0258
Phone: (202) 690-3148

Supersedes: FPPS BIS 2016 – Changes from previous requirements in blue

Effective: March 2021

100	SCOPE
110	This FPPS – Ground Bison and Bison Stew Meat (BIS) – 2021 is for use by the Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Commodity Procurement (CP) Staff for the procurement of frozen ground bison and bison stew meat. For this program, AMS shall utilize the Institutional Meat Purchase Specifications (IMPS) descriptions and requirements for beef for stewing as specification requirements for the production of bison stew meat.
200	APPLICABLE DOCUMENTS
210	The following documents are incorporated as part of this USDA FPPS-BIS-2021:
210.1	Quality Assessment (QA) Division Procedures Manual.
210.2	Food Safety and Inspection Service (FSIS) Directive 10,010.1, Revision 4.
210.3	Applicable Supplement to AMS Master Solicitation for Commodity Procurements.
210.4	IMPS General Requirements, effective June 1996.
210.5	IMPS for Fresh Beef Products, Series 100, effective November 2014.
210.6	IMPS Quality Assurance Provisions, effective June 1997
300	ORDERING DATA: TO BE SPECIFIED BY THE PURCHASER

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310 GROUND BISON AND BISON STEW MEAT

- 311 (Section in the IMPS 100 Series) For the purpose of this FPPS, references to "Beef for Stewing" (IMPS Item No. 135A) are changed to Bison Stew Meat.
- The ground bison and bison stew meat shall be produced from bison harvested in, and the finished product shall be prepared and handled in, an establishment(s) operating under the Voluntary Exotic Animal Inspection Program of the USDA, Food Safety and Inspection Service (FSIS) and shall comply with the Sanitation Performance Standards provisions of 9 CFR 416.1-416.6.
- Ground Bison Ground bison shall be produced from fresh bison cuts and trimmings from any portion of the carcass, which yields product that meets the end item requirements. Frozen, boneless bison may be used provided it is ground into the final product within 60 days from date of pack.
- 312.2 Bison Stew Meat Bison stew meat shall be prepared from fresh bison cuts and trimmings from any portion of the carcass, which yields product that meets the end-item requirements for IMPS Item 135A.

320 MATERIAL

- The contractor's technical proposal shall describe a process that includes procedures, records, forms, etc. that demonstrate conformance with the following Checklist of Requirements and have received a satisfactory onsite capability assessment by the QA Division.
- The contractor shall ensure, through their technical proposal that the product complies with the MATERIAL section of IMPS Item No. 135A for bison stew meat, and the following additional criteria:
- 322.1 Domestic Origin All bison shall originate from U.S. produced livestock as defined in the Master Solicitation for Commodity Procurements and Supplement.
- 322.2 Harvest Requirements Contractor shall have documentation and a program in place that verifies the source of raw materials used in each lot of production. All bison shall be harvested in facilities that comply with the following additional requirements:
- 322.2.1 Humane Handling All bison shall be humanely handled in accordance with all applicable FSIS regulations and AMS requirements.
- Pathogen Intervention Steps The harvest process shall include at least two pathogen intervention steps. One of the intervention steps shall be a critical control point (CCP) in the supplier's FSIS recognized harvest process HACCP plan and the CCP intervention(s) shall be scientifically validated to achieve a three-log reduction of enteric pathogens.

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- 322.2.3 Spinal Cord Removal – All spinal cord tissue shall be removed during the harvesting process. 322.2.4 Traceability – Boneless bison shall be traceable to sources that comply with the above domestic origin and harvest requirements. 322.2.5 Residue Prevention – Harvest and production establishments shall 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. 322.3 Mechanical Separation – Bison meat that is mechanically separated from bone with automatic deboning systems, advanced meat (lean) recovery (AMR) systems, or powered knives shall not be allowed. 322.4 Objectionable Materials – The following objectionable materials shall be excluded: 322.4.1 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: 322.4.1.1 White fibrous – Shoulder tendon, elbow tendon, silver skin (from the outside round), sacrosciatic ligament, opaque periosteum, serous membrane (peritoneum), tendinous ends of shanks, gracilis membrane, patellar ligament (associated with the stifle joint), and achilles tendon. 321.4.1.2 Yellow elastin – Back strap and abdominal tunic. 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 Ground Bison - Boneless bison shall be ground twice, with the final grind passing through a 1/8-inch grinding plate. Blending after final grinding is allowed only to the extent that it doesn't affect the appearance of the finished ground bison. 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
- 331.2 Ground Bison Processing –Frozen, boneless bison may be used provided it is ground into the final product within 60 days from date of pack.

of fat greater than 1.0 cubic inch) or objectionable fat "smears" in the

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finished product.

- 331.3 Ground bison production shall be traceable to the boneless bison lots and their associated microbial test results. 331.4 Bone Collector / Extruder System – A bone collector/extruder system shall be in operation to remove remaining bone, cartilage, and heavy connective tissue during the final grind of product. 332 Bison Stew Meat – Bison stew meat shall comply with the following additional requirements: 332.1 Bison Stew Meat Processing – Bison Stew Meat shall be processed to meet the end item requirements listed within IMPS Item No. 135A. 332.2 Dicing – The meat shall be either hand-diced or mechanically diced (grinding is not permitted). 332.3 Handling – To facilitate dicing, meat may be frozen and/or tempered one time only. 332.4 Shank or Heel Meat – No shank or heel meat is permitted. 333 Ground bison and bison stew meat shall be delivered within 60 days of production date. 340 METAL DETECTION 341 All products shall be free of metal contaminants. Detection of stainless steel, ferrous, and non-ferrous (e.g., lead, copper, and aluminum) metals is required. The contractor's technical proposal shall identify and describe the equipment, location, detection procedure, sensitivity levels, frequency of equipment validation, and corrective action procedures. 400 STATE OF REFRIGERATION 410 All finished bison products shall be frozen to an internal temperature of not higher than 0°F (-17.8°C) within 72 hours from the time of final fabrication of the lot. 500 **FAT LIMITATIONS** 510 Ground Bison 510.1 The average fat content shall not exceed 10 percent, and the number of
 - panel on the package label. The fat content shall be certified by AMS in accordance with IMPS QAPs. The 4 individual fat results shall be put into ascending order from the lowest to the highest value for evaluation (e.g., 8.30, 9.79, 10.63, and 11.20). The 4 individual fat test results shall be

grams of fat per 112 gram serving shall be declared in the nutritional facts

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used to calculate average, median and range. Results not meeting the following requirements shall cause rejection of the lot:

- 510.1.1 Average The average of the 4 individual results cannot exceed 10 percent (e.g., average of the 4 test results = 9.98).
- Median The median, which is the average of the middle two test results, cannot deviate from the average of the four individual samples by more than 2.0 percent (e.g., median is equal to the average of 9.79 and 10.63 = 10.21).
- 510.1.3 Range The difference between the highest and lowest test results cannot exceed 5 percent (e.g., 11.20 8.30 = 2.90).
- 511 Bison Stew Meat
- 511.1 Surface and seam fat shall not exceed \(\frac{1}{4} \)-inch in thickness at any point.
- PACKAGING AND PACKING The contractor's technical proposal and process shall 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 shall have procedures for verifying the net weight of shipping containers.
- Packaging All immediate containers (casings or packages) shall function as a tamper evidence indicator to provide added assurance of product integrity through the method of sealing or closure.
- Package Net Weight Ground bison and bison stew meat shall be packaged as specified within the Contracting Officer's invitation:
- 610.1.1 Ground Bison 110001 1-pound.
- 610.1.2 Bison Stew Meat 100085 1-pound.
- Package Method Ground bison and bison stew meat shall be packaged using one of the following methods:
- 610.2.1 Mechanical Packaged Mechanically packaged into tamper-proof commercial casings.
- Vacuum Packaged Vacuum packaged in accordance with the IMPS General requirements.
- 620 Packing.
- 620.1 Shipping Container Net Weight.

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620.1.1 Ground Bison – Forty (40) 1-pound packages of ground bison shall be packed into non-perforated shipping containers to a net weight of 40 pounds, without slack filling or overfilling. Spacers or fillers may not be used to satisfy this requirement. 620.1.2 Bison Stew Meat - Forty (40) 1-pound packages of bison stew meat shall be packed into non-perforated shipping containers to a net weight of 40 pounds, without slack filling or overfilling. Spacers or fillers may not be used to satisfy this requirement. 620.2 Style and Size of Container – Only one style and size of shipping containers may be used in any one delivery unit. 620.3 Commingling – Commingling of ground bison and bison stew meat in the same shipping container shall not be allowed. 630 Closure – Shipping containers shall 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. 640 Marking of Containers* – Immediate and shipping containers shall be labeled to include all information required by FSIS regulations. In addition, each immediate and shipping container shall have the following markings: 640.1 Immediate Container – Each immediate container (package) shall have the following information included on commercially labeled packages. 640.1.1 Name of Product. Safe Handling Instructions. 640.1.2 640.1.3 "Best-if-used-by" Date – A date that is 365 calendar days from the date of production. 640.1.4 Traceability Code – A code that is traceable to production lot and date. 640.1.5 Nutrition Fact Panel – Include fat declaration for number of grams of fat per 112 grams (ready-to-cook) serving. 640.1.6 FSIS Establishment Number and any other FSIS required markings. 640.2 Shipping container – The following markings shall be included on the shipping containers:

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^{*}All primary and shipping container labeling illustrations shall be provided within the technical proposal.

- Appendix A Shipping containers shall be marked in accordance with Appendix A. However, contractors may vary the placement of the required information shown in Appendix A. Additional markings (e.g., company bar codes, logos, etc.), that are consistent with all other commercial labels may be included.
- 640.2.2 Traceability Code A code that is traceable to production lot and date.
- Nutrition Fact Panel Include fat declaration for number of grams of fat per 112 grams (ready-to-cook) serving (Optional).
- The appropriate product name and material number listed in the table below for each of the items.

<u>Item</u>	Material Number
Ground Bison, Frozen – 1-pound	110001
Bison Stew Meat, Frozen – 1-pound	100085

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



- 640.2.6 Purchase Order Number.
- 640.2.7 Ingredient declaration (including single ingredient products).
- 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 _____.
- 650 Palletized Unit Loads
- All products shall be stacked on new or well-maintained pallets and palletized with shrink wrap plastic.
- 660 Lot Size and Delivery Unit:
- Lot Size For finished product, the lot size shall not exceed the amount specified by the purchaser as a delivery unit.

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700 **USDA CERTIFCATION** 710 Product Shall Be Certified By USDA, AMS, QA Division – AMS agents shall perform examinations in accordance with IMPS General Requirements, IMPS QAPS, and QA Division Instructions and as specified below: 710.1 Product Examinations. 710.1.2 Bison Stew Meat – Refer to LOT ACCEPTANCE CRITERIA section for diced items within QAPS. In TABLE 100 H, delete defect numbers 218 in its entirety. Replace defect number 218 with the following defect: 710.1.2.1 Presence of any portion of the popliteal, prescapular, or prefemoral 218 lymph glands or any other exposed lymph glands measuring 1.0 inch or more in one dimension and 0.5 inch in a second dimension. 710.1.2.2 Delete defect 194 in its entirety. Insert the following note at the bottom of the table: 710.1.2.3 Note: The presence of any non-meat components not listed as defects above (e.g., spinal cord, organ tissue, foreign materials, etc.) shall cause rejection of the product by AMS. 710.2 Fat Content Analysis – Fat content analysis for Ground Bison shall be in accordance with the QAPS and FAT LIMITATIONS section of this specification. 710.3 Traceability Code – Stamping (sealing) of shipping containers by the AMS agent is not required. The AMS agent shall ensure that each primary and shipping container has a traceability code that is traceable to a production lot and date. 710.4 All USDA bison products shall be stored, shipped, and delivered at temperatures that do not exceed 0°F. 720 Purchase Unit Size – The purchase unit size for ground bison and bison stew meat is 40,000 pounds net weight (1,000 shipping containers) plus the amount for use in making box fills at the time of laboratory sample withdrawal. 730 Sealing 731.1 All products shall 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) 17712-2013 as required under the Master Solicitation. Seals shall

be 1/8th-inch diameter cable, high-security bolt, or equivalent.

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800 MICROBIOLOGICAL REQUIREMENTS FOR GROUND BISON

- 800.1 Boneless Bison for Grinding.
- 800.1.1 Lot A lot shall consist of a single combo sized bin of approximately 2,000 pounds of boneless bison produced within a day, between "cleanup to cleanup" and that is from a single harvester or from a single processor.
- Microbial Testing Samples from all lots of fresh chilled boneless bison shall be sent to an AMS designated laboratory (ADL). Samples from each lot shall be tested for *E. coli* O157:H7, *Salmonella*, and indicator microorganisms.
- Sample Preparation and Handling The ADL shall be responsible for supplying sampling procedures for sample selection, preparation, and submission. The laboratory shall require suppliers to submit a sample submission form as an official record with each sample. The laboratory shall also be responsible for supplying shipping supplies (including sampling bags and shipping materials) to each supplier. Suppliers' technical proposal shall include and describe sample collection and preparation procedures provided by the ADL.
- For Bison Manufacturing Trimmings The sample shall be selected as described within FSIS Directive 10,010.1 Revision 4 (N-60 Sections 8, 9 and NOTE).
- For every lot of Bison Manufacturing Trimmings, two samples shall be prepared from 65 pieces of trim from 65 different pieces of bison product. The sample for co-enrichment of *E. coli O157:H7* and *Salmonella* shall be 60 pieces and weigh 325 grams ± 10 percent; the sample for indicator microorganisms (aerobic plate count, total coliform and generic E. coli) shall be five pieces and weigh 25 grams ± 10 percent.
- When boneless bison 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.
- 800.2 Testing and Results.
- The microbiological testing for all microbes shall be in accordance with the applicable AMS-approved testing methodologies.
- Notification for presence of pathogens and exceeding critical limit criteria When presence of *E. coli* O157:H7 or *Salmonella* is presumptive positive or confirmed positive or any critical limit is exceeded for indicator microbes, the ADL shall immediately notify FSIS (pathogens only) and the Standards and Specification Division (SSD).

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- 800.2.3 The ADL shall record results on spreadsheets for each Microbial Testing performed on each approximately 2,000-pound lot.
- 800.2.4 Any lot that tests positive for *E. coli* O157:H7 or *Salmonella* or exceeds the critical limit criteria for indicator microbes set forth in Appendix B cannot be used to produce ground bison or any other product purchased by USDA.
- 800.2.5 Any lot subjected to microbial analysis by FSIS or other regulatory authority that results in a positive finding for E. coli O157:H7 or Salmonella or exceeds the critical limit criteria for indicator microbes set forth in Appendix B cannot be used to produce ground bison or any other product purchased by USDA.
- 810 Ground Bison Microbial Requirements.
- 810.1 Lot – For the purpose of microbiological testing, a lot is defined as the amount of finished ground bison product produced within a day, between "cleanup to cleanup" which shall be further divided into sub-lots not to exceed 10,000 pounds.
- 810.1.2 Microbiological Testing – All lots of ground bison shall be tested for all microbes listed in Appendix B after final grinding and before freezing. All samples shall be sent to the ADL.
- 810.1.3 Sample Preparation and Handling – The ADL shall be responsible for supplying sampling procedures for sample selection, preparation, and submission. The laboratory shall require suppliers to submit a sample submission form as an official record with each sample. The laboratory shall also be responsible for supplying shipping supplies (including sampling bags and shipping materials), to each supplier. Suppliers' technical proposal shall include and describe sample collection and preparation procedures provided by the ADL.
- Sample Selection Production processes of ground bison shall be subject 810.1.4 to the following sampling strategy.
- 810.1.4.1 Sub-lot Microbial Testing – For every sub-lot, two original and reserve samples shall be prepared from four individual sample units for each microbial test. The sub-lot samples shall 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 bison, randomly selected throughout each 10,000 pounds of production. The four individual sample units shall be composited to produce a sample that represents each microbial test for each sub-lot. The contractor shall describe in their technical proposal the procedure in which the four sample units shall 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 shall be held for testing in case the SSD deems it

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necessary. The contractor shall 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 percent.

- 810.1.5 Testing and Results The sample from each sub-lot shall be analyzed by the ADL for all microbes listed in Appendix B.
- The microbiological testing for all microbes shall be in accordance with AMS-approved testing methodologies.
- 810.1.5.2 Any sub-lot that tests positive for *E. coli* O157:H7, *Salmonella*, or any critical limit criteria for indicator microbes set forth in Appendix B that is exceeded shall result in that sub-lot and adjoining sub-lots (one preceding and one following within "clean up to clean up") being ineligible for this program or any other USDA purchase program. Additionally, any sub-lot subjected to microbial analysis by FSIS or other regulatory authority that results in a positive finding for E. coli O157:H7 or Salmonella or exceeds the critical limit criteria for indicator microbes set forth in Appendix B shall result in that sub-lot and adjoining sub-lots being ineligible for this program or any other USDA purchase program. Other sub-lots produced within that lot unit shall 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 ground bison produced from same source material that resulted in the ineligible determination should not be considered affected by the test results.
- 810.1.5.3 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; any critical limit is exceeded for indicator microbes:
- 810.1.5.4 The ADL shall record results on spreadsheets for each test performed on each sub-lot.
- 810.1.5.5 The ADL shall immediately notify FSIS (pathogens only) and the SSD.
- 810.1.5.6 The ground bison associated with the positive pathogen test results or critical limit is exceeded results shall be ineligible for any USDA purchase program.

900 PRODUCT ASSURANCE

- 900.1 WARRANTY AND COMPLAINT RESOLUTION
- 900.1.1 Warranty The contractor shall guarantee that the product complies with all specification requirements, technical proposal declarations, and provisions set forth in the Master Solicitation.

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- 900.1.2 Complaint Resolution – Customer complaint resolution procedures shall be included in the technical proposal. These procedures shall include: a point of contact, investigation steps, intent to cooperate with AMS, and product replacement or monetary compensation. The procedures shall be used to resolve product complaints from recipient agencies or AMS.
- 900.2 NON-CONFORMING PRODUCT
- 900.2.1 The contractor shall include a plan and supporting documentation to ensure that non-conforming product (i.e., boneless bison, ground bison, bison stew meat) is not delivered under USDA contracts. The plan shall address 1) control and segregation of non-conforming product, 2) removal of any USDA markings, and 3) disposition of non-conforming product, including vendor documentation of final disposition (e.g., diverted to cooked product or destroyed).
- 900.3 AMS Monitoring and Production Assessment
- 900.3.1 A QA Division agent shall be present during the production of the finished product for all USDA Bison contracts. The QA Division agent shall 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 shall be conducting the monitoring and production verification in accordance with applicable QA Division procedures and IMPS General Requirements and QAPS. Any deviations to contractual requirements shall be reported to the contractor and SSD. The SSD shall make all determinations as to the acceptability of the product relative to findings documented by the QA Division agent.
- 900.4 Contractor Checkloading
- Contractor shall perform checkloading examinations at the time of 900.4 shipment and issue contractor's certificate to accompany each shipment that includes all of the following information:
- 900.4.1 Purchase Order Number/Purchase Order Line Item Number;
- 900.4.2 Sales Order Number/Sales Order Line Item Number;
- 900.4.3 Destination of shipment;
- 900.4.4 Name of Product and applicable Material Number;
- 900.4.5 Shipping Date;

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900.4.6	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;
900.4.7	Count of shipping containers and total projected net weight in each production lot;
900.4.8	Identity of car or truck (car numbers and letters, seals, truck license, etc. as applicable;
900.4.9	Sample average fat content analysis of each production lot for ground bison only (calculated to 2 decimal places, e.g., 8.25);
900.4.10	Contractor certification that product conforms with the applicable specification (FPPS-BIS-2021);
900.4.11	Count and projected net weight verified and;
900.4.12	Signature of company official responsible for checkloading.

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APPENDIX A

SHIPPING CONTAINER MARKINGS: COMMERCIALLY LABELED SHIPPING CONTAINERS SHALL INCLUDE THE INFORMATION SHOWN BELOW. MANUFACTURER'S NAME AND ADDRESS SHALL APPEAR. THE NUTRITION FACTS PANEL, USDA SYMBOL, AND DONATED STATEMENT SHALL BE BLACK, FLAT, WATERFAST, AND NONSMEARING. THE USDA SYMBOL SHALL BE AT LEAST 2.0 INCHES HIGH. ALL OTHER PRINTING OR STENCILING SHALL BE OF A SIZE AND CONTRASTING COLOR TO STAND OUT PROMINENTLY AND COMPLY WITH THE USDA-FSIS REGULATIONS OR STATE REGULATIONS.

PERISHABLE FROZEN - STORE AT 0°F (-17.8°C)	
Boxes shall include Safe Handling instructions in accordance with FSIS Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry.	
U.S. DEPARTMENT OF ACRICULTURE FOOD *****	
Nutrition Facts Successive In purispective Colors	
Product Name Material Number PACKED LOT# NAP PASSED BY DEPARTMENT OF AGRECULTURE EST. 38 Purchase Order No. KEEP FROZEN	

NOTES: DATE PACKED SHALL BE THE MONTH, DAY, AND YEAR OF PACKING.

SERIAL PURCHASE ORDER NUMBER SHALL BE FURNISHED BY USDA. LOT NO. AND BOX NO. MAY BE PLACED ON THE SAME LINE OR AS SHOWN ABOVE. BOX NUMBERS SHALL BE SEQUENTIAL.

PER 9 CFR 317.4 & 317.5, PRIOR APPROVED LABELS NEED NOT BE RESUBMITTED. CONTRACTORS THAT DO NOT HAVE APPROVED LABELS ON FILE SHALL SUBMIT LABELS IN SKETCH FORM ONLY TO THE APPROPRIATE USDA, FSIS, OR STATE AGENCY.

Approved by DBJ Date Issued: 04/26/04 Date Revised: 03/24/21

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APPENDIX B

AMS MICROBIAL REQUIREMENTS FOR BONELESS & GROUND BISON		
Microbial Test	Critical Limits (cfu)	
Standard Plate Count	100,000 / gram	
Total Coliforms	1,000 / gram	
E. coli	500 / gram	
Salmonella	Positive (+) result / 325 grams	
E. coli O157:H7	Positive (+) result / 325 grams	

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APPROVED

FEDERAL PURCHASE PROGRAM SPECIFICATION (FPPS) FOR BISON HANDLING AND WELFARE Agricultural Marketing Service (AMS) Livestock and Poultry (LP) Program Standards and Specification Division (SSD) Room 2628-S, STOP 0258 Phone: (202) 690-3148

Supersedes: FPPS-BHW-2021 March 2021

Effective: March 2022

100 GENERAL

This document is for use by the Department of Agriculture (USDA), AMS, LP Program to ensure that the bison handling and welfare requirements for Federal nutrition assistance programs reflect industry best practices.

110 PROGRAM APPROACH

All bison harvest facilities that supply raw materials from bison for the production of AMS destined finished products must develop and implement a written program that is consistent with a systematic approach to humane bison handling and welfare as outlined in 69 FR 54625. The program will ensure proper bison handling and welfare techniques are conducted from the time the transportation conveyance enters the facility's premises through the stunning and exsanguination of the bison.

120 PROGRAM SUBMISSION

The program will be submitted as a supporting document to the organization's approved technical proposal and must address the requirements outlined in **Section 200 – PROGRAM COMPONENTS**.

200 PROGRAM COMPONENTS

The contractor must ensure that any facility that harvests bison has a:

210 MANAGEMENT COMMITMENT

- 211 Steering Committee (internal) which is ultimately accountable for bison handling and welfare initiatives within the organization.
- 212 Mission Statement on bison handling and welfare that is distributed to all employees and conspicuously displayed at the premises.

220 TRAINING PROGRAM 1, 2

- 221 Training program on Bison Handling and Welfare that:
- 221.1 is provided to all employees interacting with bison;
- 221.2 covers the North American Meat Institute (NAMI) Recommended Animal Handling Guidelines & Audit Guide: A Systematic Approach to Animal Welfare.
- 221.3 is facilitated by an employee that has earned and maintained a certification of bison handling and welfare training, such as that offered through the Professional Animal Auditor Certification Organization (PAACO) or an equivalent.
- 221.4 is conducted no less frequently than once a year for each designated employee; and,
- 221.5 requires signed documentation from each employee and confirmation by signature of the designated, certified trainer upon successful completion of training.

230 QUALITY MANAGEMENT PLAN 1, 2

- 231 Written quality management plan (internal) which addresses all provisions of Chapter 4: Transportation Audit Guidelines, 7 Core Criteria and Chapter 5: Auditing Animal Handling and Stunning, 7 Core Criteria, of the NAMI Recommended Animal Handling Guidelines & Audit Guide: A Systematic Approach to Animal Welfare, found at the following web site address:
- 231.1 http://animalhandling.org/producers/guidelines audits
- 232 This internal quality management plan must also provide for routine assessment and monitoring of humane handling through the use of a numerical scoring system conducted by a trained employee.
- All bison harvest facilities that supply raw materials for the production of AMS 233 destined finished products must have a fully functioning back-up stunning device onsite wherever bison stunning is performed.

Approved by DBJ Date Issued: 10/28/10

Date Revised: 03/01/22

¹Guidlines and audit criteria specified for cattle in Chapter 4: Transportation Audit Guidelines, 7 Core Criteria and Chapter 5: Auditing Animal Handling and Stunning, 7 Core Criteria, of the NAMI Recommended Animal Handling Guidelines & Audit Guide: should be emulated, to the extent possible, for bison.

²Core Criteria 5: Vocalization in Chapter 5: Auditing Animal Handling and Stunning 7 Core Criteria of the AMI Recommended Animal Handling Guidelines and Audit Guide shall be amended to so that vocalization only is evaluated at the lead up chute prior to the restrainer with five percent or less vocalization being an acceptable score. Grunting should not be counted.

240 REGULATORY OVERSIGHT

241 Bison/carcasses that are inspected and passed by the Food Safety Inspection Service (FSIS) are eligible for AMS purchase programs.

300 PROGRAM EVALUATION AND ELIGIBILITY

- The program will be audited (external) by AMS or a firm accredited by AMS. The accreditation of the firm will be conducted by the Quality Assessment Division (QAD) through the **USDA ISO Guide 17065 Program.**
- Audit findings will be communicated to the establishment's Food Safety and Inspection Service (FSIS) Inspector in Charge (IIC) or designee.

310 AUDIT FORMAT

- 311 Audits will be conducted utilizing the following format:
- **TRANSPORTATION SEGMENT (CHAPTER 4:** NAMI Recommended Animal Handling Guidelines & Audit Guide: A Systematic Approach to Animal Welfare).
- 312.1 Audited organizations must pass Core Criteria 1 and 6 with a minimum scoring of excellent, Core Criteria 2 through 5 with a minimum scoring of acceptable and Core Criteria 7 must be adhered to with full compliance (zero tolerance) each time an audit is performed. ^{1, 2}
- 313 ANIMAL HANDLING AND STUNNING SEGMENT (CHAPTER 5: NAMI Recommended Animal Handling Guidelines & Audit Guide: A Systematic Approach to Animal Welfare).
- 313.1 Audited organizations must adhere to Core Criteria 1, 2, 6 and 7 with full compliance (zero tolerance) and to Core Criteria 3, 4 and 5 with a minimum scoring of Acceptable each time an audit is performed. ^{1, 2, 3}
- 313.2 The auditor shall inform FSIS and organization officials in writing of all audit findings, including any observations of missed stuns and/or bison regaining sensibility following stunning, upon completion of the audit during the exit interview.

Approved by DBJ
Date Issued: 10/28/10
Date Revised: 03/01/22

¹Guidlines and audit criteria specified for cattle in Chapter 4: Transportation Audit Guidelines, 7 Core Criteria and Chapter 5: Auditing Animal Handling and Stunning, 7 Core Criteria, of the NAMI Recommended Animal Handling Guidelines & Audit Guide: should be emulated, to the extent possible, for bison.

²Core Criteria 5: Vocalization in Chapter 5: Auditing Animal Handling and Stunning 7 Core Criteria of the AMI *Recommended Animal Handling Guidelines and Audit Guide* shall be amended to so that vocalization *only* is evaluated at the lead up chute <u>prior</u> to the restrainer with five percent or less vocalization being an acceptable score. Grunting should not be counted.

³Religious harvest (Kosher and Halal) shall be exempt from the AMS auditing of Core Criteria 6: Effective Stunning.

320 INITIAL AUDIT

Initial audit must be performed prior to award of contracts.

330 AUDIT FAILURE

If an audit is failed for any of the Core Criteria, the organization is not eligible to provide product until such a time that corrective and preventative actions are approved by the Standards and Specification (SS) Division, implemented and proven effective.

340 AUDIT FREQUENCY AND STATUS

- 341 STANDARD Until four (4) consecutive successfully passed audits are attained, an audit must be conducted within 3 months of the previous audit.
- MONTHLY If at any time an audit identifies any of the Core Criteria not meeting the pass requirements while in the STANDARD phase, auditing will be required to be conducted on a monthly basis once corrective and preventative actions have been approved by the SS Division, implemented and proven effective. This schedule will be for a period of time until four (4) successive audits are found to meet the passing requirements noted in **SECTION 310 – AUDIT FORMAT**; at which time audits shall be conducted on the STANDARD basis.
- MONTHLY If at any time an audit identifies any of the Core Criteria not meeting the pass requirements while in the STANDARD phase, auditing will be required to be conducted on a monthly basis once corrective and preventative actions have been approved by the SS Division, implemented and proven effective. This schedule will be for a period of time until four (4) successive audits are found to meet the passing requirements noted in **SECTION 310 – AUDIT FORMAT**; at which time audits shall be conducted on the STANDARD basis.
- If four successfully conducted audits are sequentially completed within a oneyear period while in STANDARD auditing phase, the facility may move to a SEMI-ANNUAL audit basis.
- 344 SEMI-ANNUAL Semi-annual audits may continue until such time that a failed audit is reported or a period of greater than six months has elapsed without any audits being performed; at which time the audits must resume as described for STANDARD audits.
- 345 FOR-CAUSE Any official enforcement actions issued by FSIS for missed stuns or for an animal regaining sensibility following stunning shall result in an immediate for-cause bison handling and welfare audit by AMS. Subsequent audit frequency will be determined by results of the AMS audit, as described above.

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400 SS DIVISION

- The SS Division can declare an organization's Bison Handing and Welfare Program out of compliance at any time.
- The organization shall immediately notify the SS Division when any bison handling and welfare official enforcement action is issued by FSIS.

Cover Page:

Company Name

Company Address

Contact Person, including title, phone number, including emergency contact information, e-mail address (shall be authorized to represent the company).

Technical Proposal for: [Supplement Number] and [FPPS]

Table of Contents (all pages and attachments shall be number and identified – any attachments shall be identified and referenced in the Technical Proposal).

The technical proposal should document a quality control program that includes procedures, records, forms, pictures, etc., which demonstrates conformance with the following checklist of requirements:

100	SCOPE
200	APPLICABLE DOCUMENTS
300	ODERING DATA
310	ITEMS
320	MATERIAL
322	IMPS Requirements
322.1	Domestic Origin of Meat Component
322.2	Harvest Requirements
322.2.1	Humane Handling
322.2.2	Pathogen Intervention Steps
322.2.3	Spinal Cord Removal
322.2.4	Traceability
0000	M 1 : 10 ::

Mechanical Separation

Boneless bison requirements

Approved by DBJ Date Issued: 06/10/12 Date Revised: 03/02/22

PROCESSING

322.3

322.4

330

331.1	Ground bison processing
331.2	Traceability
331.3	Bone collector/extruder system
332	Bison stew meat
332.1	Bison stew meat processing
332.2	Dicing
332.3	Handling
332.4	Shank or heel meat
333	Production date
340	METAL DETECTION
400	STATE OF REFRIGERATION
500	FAT LIMITATIONS
510	Ground bison
511	Bison stew meat
600	PACKAGING AND PACKING
610	Packaging
620	Packing
630	Closure
640	Marking of containers

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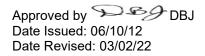
Palletized unit loads

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700	USDA CERTIFICATION
710	Product examinations
720	Lot size
730	Contractor Checkloading
800	MICROBIOLOGICAL REUIREMENTS FOR GROUND BISON
800.1	Lot
800.1.2	Microbial testing
800.1.3	Sample preparation and handling
800.1.4	Bison manufacturing trimmings
800.2	Testing and results
810	Ground bison microbial requirements
810.1	Lot
800.1.2	Microbiological testing
800.1.3	Sample preparation and handling
800.1.4	Sample selection
800.1.5	Testing and results
900	PRODUCT ASSURANCE
900.1	Warranty and complaint resolution
900.2	Non-conforming product

Attachments or Appendixes - Please attach all referenced documents with the applicable document name and reference number.



UNITED STATES DEPARTMENT OF AGRICULTURE AGRICULTURAL MARKETING SERVICE LIVESTOCK AND POULTRY PROGRAM

CERTIFICATE OF CONFORMANCE FOR THE PROCUREMENT OF FROZEN BISON PRODUCTS

CERTIFICATE OF CONFORMANCE

I certify the following:

(1) On [delivery date(s)], [Supplier's name] furnished the (insert the appropriate commodity description) called for by Purchase Order Number _via [Carrier] under Sales Order
Number/Item number(s):
(2) The (insert the appropriate material name) is of the quality specified and conforms in all respects with the purchase order requirements, including [Supplier's name] Technical Proposal as approved by the AMS, LP Program, SSD.
(3) Product identification, (i.e. production lot number(s)) is in the quantity shown on the attached acceptance document.
(4) Supplier assures all meat or meat products used in fulfilling this contract was produced in the United States as defined in the AMS Master Solicitation Section I.E.
Date:
Signature:
(Signed by an officer or representative authorized to sign offers) Title: