METRIC |
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SUPERSEDING
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COMMERCIAL ITEM DESCRIPTION

PASTA SHELLS, STUFFED WITH CHEESE, IN SAUCE, FROZEN

The U.S. Department of Agriculture (USDA) has authorized the use of this Commercial Item Description (CID).

1. SCOPE. This CID covers frozen pasta shells, stuffed with cheese, in sauce (stuffed shells) packed in commercially acceptable containers, suitable for use by Federal, State, local governments, and other interested parties.

2. PURCHASER NOTES.

- 2.1 Purchasers shall specify the following:
 - Type(s) and noodle type(s) of stuffed shells desired (Sec. 3).
 - When analytical requirements are different than specified (Sec. 7.1).
 - When analytical requirements need to be verified (Sec. 7.2).
 - Manufacturer's/distributor's certification (Sec. 10.3) or USDA certification (Sec. 10.4).

2.2 Purchasers may specify the following:

- Food Defense Section 10.1: Food Defense System Survey (FDSS) (Sec 10.1.1), or Food Defense Addendum to Plant Systems Audit (PSA) (Sec 10.1.2), or (Sec. 10.1.2 with 10.2.1).
- Manufacturer's quality assurance (Sec. 10.2 with 10.2.1) or (Sec. 10.2 with 10.2.2).
- Packaging requirements other than commercial (Sec. 11).
- **3. CLASSIFICATION.** The stuffed shells shall conform to the following list which shall be specified in the solicitation, contract, or purchase order.

Types and noodle types.

Type I - Manicotti

Type II - Shells

¹ Not all options are available from every manufacturer. Check with the manufacturer/distributor for availability.

Type III - Rigatoni

Type IV - Other (as specified by the purchaser)

Noodle type 1 - Made with wheat flour²
Noodle type 2 - Made with semolina flour²
Noodle type 3 - Made with durum flour²

Noodle type 4 - Other³ (as specified by the purchaser)

4. MANUFACTURER'S/DISTRIBUTOR'S NOTES. Manufacturer's/distributor's products *shall meet* the requirements of the:

- Processing guidelines (Sec. 5).
- Salient characteristics (Sec. 6).
- Analytical requirements: as specified by the purchaser (Sec. 7).
- Manufacturer's/distributor's product assurance (Sec. 8).
- Regulatory requirements (Sec. 9).
- Quality assurance provisions: as specified by the purchaser (Sec. 10).
- Packaging requirements other than commercial: as specified by the purchaser (Sec. 11).

5. PROCESSING GUIDELINES.

- **5.1** <u>Processing.</u> The stuffed shells shall be processed in accordance with Current Good Manufacturing Practices (21 Code of Federal Regulations (CFR) Part 110).
- **5.2** <u>Food security</u>. The stuffed shells shall be processed and transported in accordance with the Food and Drug Administration's (FDA's) *Guidance for Industry: Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance.* ⁴ This guidance identifies the kinds of preventive measures food manufacturers, processors, or handlers may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions. The implementation of enhanced food security preventive measures provides for the security of a plant's production processes and includes the storage and transportation of pre-production raw materials, other ingredients, and postproduction finished product.
- **5.3** <u>Age requirement</u>. Unless otherwise specified in the solicitation, contract, or purchase order, the stuffed shells shall be manufactured not more than 90 days prior to delivery.

6. SALIENT CHARACTERISTICS.

² The lasagna noodles shall comply with the Allergen Declaration Requirements of the Federal Food, Drug, and Cosmetic Act (Section 403(w)(1))

³ Shall meet the Requirements for Specific Standardized Macaroni and Noodle Products. If used to specify a gluten-free product, the noodles shall comply with the Gluten-Free Labeling Requirements when they become finalized.

⁴http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm083075.htm

- **6.1** <u>Ingredients.</u> The stuffed shells shall contain cheese filling, sauce and spices, pasta shells, safe and suitable sweeteners and thickeners and may include vegetables. All ingredients shall be declared by their common or usual name in descending order of predominance by weight (21 CFR § 101.4(a)) unless exempted by 21 CFR § 101.100.
- **6.1.1** Cheese filling. The cheese filling shall contain ricotta and may include low moisture part-skim mozzarella (21 CFR § 133.158), Parmesan (21 CFR § 133.165), Cheddar (21 CFR § 133.113), American (pasteurized process cheese) (21 CFR § 133.169), Swiss (21 CFR § 133.195), and cottage cheese (21 CFR § 133.128) as optional cheeses. The cheese filling may contain egg products that shall comply with all applicable provisions of the Egg Products Inspection Act (9 CFR Part 590) and shall be declared on the food label in compliance with the Food Allergen Labeling and Consumer Protection Act of 2004.
- **6.1.2** <u>Sauce and spices.</u> The sauce shall contain tomato puree or tomato paste, diced tomatoes, onions, sweeteners, thickeners, and may contain vegetables, salt, and spices, including garlic and other spices common to tomato-based sauce.
- **6.1.3** Pasta shells. The stuffed shells shall comply with the FDA Standard of Identity for Macaroni Products (21 CFR § 139.110) or Standard of Identity for Enriched Macaroni Products (21 CFR § 139.115) or Standard of Identity for Noodle Products (21 CFR § 139.150) or Standard of Identity for Enriched Noodle Products (21 CFR § 139.155).
- **6.1.4** Additional ingredients. The stuffed shells may contain food ingredients permitted by the FDA for thickening, emulsifying, stabilizing, preserving, or enhancing flavor. Food additives or generally recognized as safe (GRAS) substances shall be of Food Chemicals Codex purity or US Pharmacopeia-National Formulary quality and meet the related FDA regulations on food additives or GRAS requirements.
- **6.1.5** Foreign material. All ingredients shall be clean, sound, wholesome, and free from foreign material such as plastic pieces, metal contaminants, including, but not limited to, ferrous, non-ferrous, and stainless steel, and evidence of rodent or insect infestation. All tomato products shall comply with the defect action levels specified in the FDA Defect Levels Handbook currently in effect on the date of the solicitation, contract, or purchase order.
- **6.2** <u>Finished product</u>. The finished stuffed shells shall show no evidence of spoilage, thawing and refreezing, or excessive heating (materially scorched).
- **6.2.1** Appearance. The overall appearance of the stuffed shells shall not be mushy or pasty and there shall not be excessive oil separation from the product. There shall be no foreign color to the product.

⁵ http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106890.htm

- **6.2.2** <u>Aroma and flavor</u>. The stuffed shells shall have an aroma and flavor characteristic of prepared cheese stuffed shells, and there shall be no foreign odors or flavors such as, but not limited to, burnt, scorched, stale, rancid, or moldy.
- **6.2.3** <u>Texture and consistency</u>. The texture of the pasta shells shall not be rubbery, mushy, or pasty. The sauce shall not be excessively thin, thick, or pasty. The cheese filling shall be smooth and of uniform consistency.

7. ANALYTICAL REQUIREMENTS.

7.1 <u>Analytical requirements.</u> Unless otherwise specified in the solicitation, contract, or purchase order, the stuffed shells shall comply with the following ranges and tolerances:

<u>Test</u>	Tolerance
Monosodium glutamate	Less than 2.27 g per 227 g or 8 oz (1 percent) of
(MSG)	finished product
Fat	Less than 10.0 g per 227 g or 8 oz of finished Product
Sodium	Less than 1,200 mg per 227 g or 8 oz of finished product
Standard Plate Count	Less than 50,000 CFU per g
Escherichia coli	Less than 3 per g using Most Probable Number
(E. coli)	(MPN) or less than 10 Colony Forming Units
	(CFU) per g
E. coli O157:H7	Shall be negative
Listeria monocytogenes	Shall be negative
(L. monocytogenes)	
Salmonella	Shall be negative

- **7.2 Product verification sampling.** When USDA verification of analytical requirements is specified in the solicitation, contract, or purchase order, analytical testing shall be performed on a composite sample. The composite sample shall be 1.134 kg (2.5 lb) per lot, prepared from a minimum of sixty representative subsamples or retail packages randomly selected from the lot.
- **7.3** <u>Analytical testing</u>. When specified in the solicitation, contract, or purchase order, the analyses shall be made in accordance with the following methods from the AOAC International Official Methods of Analysis (OMA) or the Bacteriological Analytical Manual (BAM) as specified below:

<u>Test</u>	Method
MSG	970.37
Fat	991.36, 2007.04, or 2008.06
Sodium	985.35 or 984.27
Standard Plate Count	990.12 or BAM Ch 3
E. coli	991.14, 998.08, 2011.17, or BAM Ch 4
E. coli O157:H7	2000.14, 2005.03, or BAM Ch 4A
L. monocytogenes	999.06, 2003.12, 2004.02, 2010.02, or BAM Ch 10
Salmonella	967.25, 967.27, 996.08, 2003.09, 2004.03, 2011.03,
	2011.17. or BAM Ch 5

- **7.4** Test results. Test results for MSG shall be reported to the nearest 0.1 percent. Test results for fat shall be reported to the nearest 0.1 g. Test results for sodium shall be reported to the nearest mg. The test results for standard plate count shall be reported to the nearest 100 CFU per g. The test results for *E. coli* shall be reported to the nearest MPN or CFU. The test results for *E. coli* O157:H7, *L. monocytogenes*, and Salmonella shall be reported as positive or negative. Any result not conforming to the analytical requirements shall be cause for rejection of the lot.
- **8. MANUFACTURER'S/DISTRIBUTOR'S PRODUCT ASSURANCE.** The manufacturer/ distributor shall certify that the stuffed shells provided shall meet the salient characteristics of this CID, conform to their own specifications, standards, and quality assurance practices, and be the same stuffed shells offered for sale in the commercial market. The purchaser reserves the right to require proof of conformance.
- 9. REGULATORY REQUIREMENTS. When applicable, the egg for the stuffed shells shall have been processed according to the provisions of the Egg Products Inspection Act and regulations promulgated thereunder. The delivered stuffed shells shall comply with all applicable Federal and State mandatory requirements and regulations relating to the preparation, packaging, labeling, storage, distribution, and sale of the stuffed shells in the commercial marketplace. Delivered stuffed shells shall comply with all applicable provisions of the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, and regulations promulgated thereunder. When a known allergen is included in the stuffed shells, the stuffed shells shall comply with the allergen labeling requirements of the Federal Food, Drug, and Cosmetic Act. When the stuffed shells are used for the National School Lunch Program, the stuffed shells shall comply with all applicable provisions of the Child Nutrition (CN) Programs.
- **10. QUALITY ASSURANCE PROVISIONS.** Purchaser shall specify 10.3, or 10.4; purchaser may specify 10.1 with 10.1.1, 10.1 with 10.1.2, 10.1.2 with 10.2.1, 10.2 with 10.2.1, or 10.2 with 10.2.2.

- **10.1** Food defense. When required in the solicitation, contract, or purchase order, a FDSS shall be conducted by USDA, Agricultural Marketing Service (AMS), Fruit and Vegetable Program (FV), Specialty Crops Inspection Division (SCI). Food defense requirements include a documented and operational food defense plan that provides for the security of a plant's production processes and includes the storage and transportation of pre-production raw materials and other ingredients and postproduction finished product. The plan shall address the following areas: (1) food security plan management; (2) outside and inside security of the production and storage facilities; (3) slaughter, when applicable, and processing, including all raw material sources; (4) shipping and receiving; (5) storage; (6) water and ice supply; (7) mail handling; (8) personnel security; and (9) transportation, shipping, and receiving.
- **10.1.1** <u>FDSS</u>. When required in the solicitation, contract, or purchase order, a FDSS shall be conducted by USDA, AMS, FV, SCI. The FDSS verifies that operators of food establishments have implemented measures to minimize the risk of tampering or other criminal actions against the food under their control. (An AMS, FDSS verifies the participating company's adherence to the FDA's "Guidance for Industry Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance.") For further information, see section 13.1 and 13.3.2.
- **10.1.2** <u>Food defense addendum to PSA</u>. When required in the solicitation, contract, or purchase order, a food defense addendum shall be conducted by USDA, AMS, FV, SCI auditors. This verifies that operators of food establishments have implemented measures to minimize the risk of tampering or other criminal actions against the food under their control. (*An AMS, FDSS, PSA verifies the participating company's adherence to the FDA's "Guidance for Industry Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance."*) For further information, see section 13.1 and 13.3.2.
- **10.2** Manufacturer's quality assurance. When required in the solicitation, contract, or purchase order, the product manufacturer shall be required to provide evidence, by certificate, that the manufacturing plant has undertaken one of the following quality assurance measures within 12 months prior to providing a bid, or no later than 10 business days from the date of the awarding of the contract. Failure to provide this documentation within the proper time frame may result in the contract being terminated for cause.
- **10.2.1** <u>PSA.</u> A PSA conducted by USDA, AMS, or other audit performed by a third party auditing service is required within 12 months prior to the date of the awarding of the contract. (An AMS PSA verifies the manufacturer's capability to produce products in a clean sanitary environment in accordance with 21 CFR Part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, and verifies that the manufacturer has in place an internal quality assurance program.)
- **10.2.2** <u>Plant survey.</u> A plant survey conducted by USDA, AMS, or other survey performed by a third party auditing service is required within 12 months prior to the date of the awarding of the contract. (An AMS plant survey audit verifies that, at the time of the survey, the manufacturer

produces products in a clean sanitary environment in accordance with 21 CFR Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food.)

- **10.3** <u>Manufacturer's/distributor's certification</u>. When required in the solicitation, contract, or purchase order, the manufacturer/distributor shall certify that the stuffed shells distributed meet or exceed the requirements of this CID.
- **10.4 USDA certification.** When required in the solicitation, contract, or purchase order that product quality and acceptability or both be determined, the SCI, FV, AMS, USDA, shall be the certifying program. SCI inspectors shall certify the quality and acceptability of the stuffed shells in accordance with SCI procedures, which include selecting random samples of the stuffed shells, evaluating the samples for conformance with the salient characteristics of this CID and other contractual requirements, and documenting the findings on official SCI score sheets or certificates. In addition, when required in the solicitation, contract, or purchase order, SCI inspectors will examine the stuffed shells for conformance to the U.S. Standards for Condition of Food Containers (7 CFR Part 42) in effect on the date of the solicitation, contract, or purchase order.
- **11. PACKAGING.** Preservation, packaging, packing, labeling, and case marking shall be commercial unless otherwise specified in the solicitation, contract, or purchase order.
- 12. USDA INSPECTION NOTES. When Section 10.4 is specified in the solicitation, contract, or purchase order, USDA certification shall include evaluation of the quality and condition of samples of stuffed shells and compliance with requirements in the following areas:
 - Processing guidelines (Sec. 5).
 - Salient characteristics (Sec. 6).
 - Analytical requirements when specified in the solicitation, contract, or purchase order (Sec. 7). When USDA analytical testing is specified, SCI inspection personnel shall select samples and submit them to the USDA, Science and Technology Programs (S&TP) laboratory for analysis.
 - Packaging requirements (Sec. 11 or as specified in the solicitation, contract, or purchase order).

13. REFERENCE NOTES.

13.1 <u>USDA certification</u>, <u>FDSS</u>, <u>Plant Survey</u>, <u>and PSA contact</u>. For a USDA certification, FDSS, Plant Survey, and PSA, contact the Chief, Inspection Branch, SCI, FV, AMS, USDA, STOP 0240, 1400 Independence Avenue, SW, Washington, DC 20250-0240, telephone (202) 720-2482, fax (202) 720-0393, or via E-mail: <u>Nathaniel.Taylor@ams.usda.gov</u>.

13.2 <u>Analytical testing and technical information contact</u>. For USDA technical information on analytical testing, contact a member of the Technical Service Staff, S&TP, AMS, USDA, STOP 0272, 1400 Independence Avenue, SW, Washington, DC 20250-0272, telephone (202) 690-0621 or via E-mail: <u>Alan.Post@ams.usda.gov</u> or <u>Ruihong.Guo@ams.usda.gov</u>.

13.3 Sources of documents.

13.3.1 Sources of information for nongovernmental documents are as follows:

Copies of the AOAC International OMA may be obtained from: **AOAC International, 481**North Frederick Avenue, Suite 500, Gaithersburg, MD 20877-2417, telephone (301) 924-7077. Internet address: http://www.aoac.org for nonmembers and http://www.eoma.aoac.org for members and AOAC OMA subscribers.

Copies of the Food Chemicals Codex and U.S. Pharmacopeia may be purchased from: United States Pharmacopeia Convention, 12601 Twinbrook Parkway, Rockville, MD 20877, telephone (800) 227-8772 or (301) 881-0666, Fax (301) 816-8148 or on the Internet at: http://www.usp.org.

13.3.2 Sources of information for governmental documents are as follows:

Applicable provisions of the U.S. Standards for Condition of Food Containers are contained in 7 CFR Part 42, the Egg Products Inspection Act in 9 CFR Part 590, the Fair Packaging and Labeling Act are contained in 16 CFR Parts 500 to 503, and the Federal Food, Drug, and Cosmetic Act are contained in 21 CFR Parts 1 to 199. These documents may be purchased from: Superintendent of Documents, New Orders, P.O. Box 979050, St. Louis, MO 63197-9000. Credit card (Visa, MasterCard, Discover/ NOVUS, and American Express) purchases may be made by calling the Superintendent of Documents on (866) 512-1800, (202) 512-1800. These documents may also be obtained free of charge on the Internet at: http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.

Copies of Guidance for Industry - Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance is available online from: FDA, Center for Food Safety and Applied Nutrition (CFSAN) on the Internet at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm083075.htm.

Copies of the FDA Bacteriological Analytical Manual (BAM) are available online from **FDA at:** http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm.

Copies of this CID, the U.S. Standards for Condition of Food Containers (7 CFR Part 42), and beneficial comments, recommendations, additions, deletions, clarifications, etc. and any data

which may improve this CID are available from or provided to: Chief, Standardization Branch, SCI, FV, AMS, USDA, STOP 240, 1400 Independence Avenue, SW, Washington, DC 20250-0240, telephone (202) 720-5021, Fax (202) 690-1527, via E-mail:

CIDS@ams.usda.gov, or on the Internet at:

www.ams.usda.gov/CommercialItemDescription.

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