

SECTION C

This document covers shelf stable granola in a flexible pouch for use by the Department of Defense as a component of operational rations.

C-1 ITEM DESCRIPTION

PCR-G-003, GRANOLA, PACKAGED IN A FLEXIBLE POUCH, SHELF STABLE

Types and packages.

Type.

Type I - With milk and blueberries

Packages.

Package A - Meal, Cold Weather (MCW)
Package B - Food Packet, Long Range Patrol (LRP)
Package C - Meal, Ready-to-Eat (MRE)

C-2 PERFORMANCE REQUIREMENTS

A. Product standard. A sample shall be subjected to first article (FA) or product demonstration model (PDM) inspection as applicable, in accordance with the tests and inspections of Section E of this Performance-based Contract Requirements (PCR) document. The approved sample shall serve as the product standard. Should the contractor at any time plan to, or actually produce the product using different raw material or process methodologies from the approved Product Standard, which result in a product non comparable to the Product Standard, the contractor shall arrange for a new or alternate FA or PDM approval. In any event, all product produced must meet all requirements of this document including Product Standard comparability.

B. Shelf life. The packaged product shall meet the minimum shelf life requirement of 36 months at 80°F.

C. Dry product.

(1) Appearance. The dry product shall be a mixture of rolled oats, white powder, and freeze-dried blueberries. The packaged food shall be free from foreign materials.

PCR-G-003
18 September 2007
W/Change 02 26 Sep 08

(2) Odor and flavor. The dry product shall have a coconut, toasted grain, sweet, dairy odor and flavor and a mild blueberry flavor. The packaged food shall be free from foreign odors and flavors.

(3) Texture. The dry product shall be a free flowing mixture of powder, oat flakes, and distinct blueberries.

(4) Net weight. The average net weight shall be not less than 57 grams. No individual pouch shall have a net weight of less than 52 grams.

D. Rehydrated product.

(1) Appearance. The rehydrated product shall be a mixture of distinct oat flakes, dark blue blueberries, and purple milky liquid.

(2) Odor and flavor. The rehydrated product shall have a coconut, toasted grain, sweet, dairy, mild berry odor and flavor. The rehydrated product shall be free from foreign odors and flavors.

(3) Texture. The rehydrated product shall be chewy and firm with fibrous coconut and soft, moist blueberries in a liquid with a creamy milk mouthfeel. When rehydrated per instructions, the product shall have some free liquid and an even distribution of moisture throughout the granola and blueberries.

E. Palatability and overall appearance. The finished product shall be equal to or better than the approved product standard in palatability and overall appearance.

F. Analytical requirements.

(1) Protein. The protein content shall be not less than 11.0 percent.

(2) Fat content. The fat content shall be not less than 12.0 percent and not greater than 20.0 percent.

(3) Sodium content. The sodium content shall be not greater than 150 milligrams per 100 grams.

(4) Moisture. The moisture content shall be not greater than 5.0 percent.

(5) Oxygen content. The oxygen content of the filled and sealed pouch shall not exceed 0.30 percent.

PCR-G-003
18 September 2007
W/Change 02 26 Sep 08

G. Microbiological requirements. The aerobic plate count shall be not greater than 50,000 per gram in four of five samples and not greater than 75,000 per gram in any individual sample. ~~The *Escherichia coli* count shall have no positive tubes in the standard 3 tube most probable number (MPN) technique.~~ **The *Escherichia coli* count shall be less than 3 MPN per gram (no positive tubes in the standard 3 tube most probable number (MPN) technique) or less than 10 Colony Forming Units (CFU) per gram (findings indicate zero colonies (CFU) per plate or zero tubes producing gas for MPN).** The *Salmonella* test shall be negative per 25 grams of product.

Comment [U1]: Natick case ES08-138, (DSCP-SS-08-16878) Change 02, 26 Sep 08 lines 3-4, delete "The *Escherichia coli* count shall have . . . technique.", insert "The *Escherichia coli* count shall be less than 3 MPN per gram (no positive tubes in the standard 3 tube most probable number (MPN) technique) or less than 10 Colony Forming Units (CFU) per gram (findings indicate zero colonies (CFU) per plate or zero tubes producing gas for MPN)."

H. Ingredient requirements.

(1) U.S. Extra Grade Instant Nonfat Dry Milk. Instant nonfat dry milk shall be U.S. Extra Grade, as defined in the U.S. Standards for Grades of Nonfat Dry Milk (spray process). The nonfat dry milk shall be fortified with vitamin D and vitamin A. The nonfat dry milk shall be spray dried not more than six months prior to the time the finished granola cereal is filled into the pouch and the pouch sealed. The nonfat dry milk shall be *Salmonella* free.

(2) Freeze-dried blueberries. The granola cereal shall contain not less than 8.0 percent freeze-dried blueberries by weight.

C-3 MISCELLANEOUS INFORMATION

THE FOLLOWING INGREDIENTS ARE FOR INFORMATION ONLY. THIS IS NOT A MANDATORY REQUIREMENT.

A. Ingredients. Granola (rolled oats, brown sugar, soy oil, unsweetened coconut, sesame seeds, wheat germ, natural vanilla flavor), nonfat dry milk, freeze-dried blueberries, cream powder (sweet cream, lecithin, tocopherols, ascorbyl palmitate), vanilla powder (sugar, corn starch, dextrose, natural and artificial vanilla flavors).

SECTION D

D-1 PACKAGING

A. Packaging. Fifty-seven grams of product and one oxygen scavenger shall be packaged in a preformed barrier pouch as described below. The pouch is intended to be used as a unit pack and a rehydrating pouch for the granola cereal.

(1) Preformed pouches.

a. Pouch material. The preformed pouch shall be fabricated from 0.002 inch thick

PCR-G-003
18 September 2007
W/Change 02 26 Sep 08

ionomer or polyethylene film laminated or extrusion coated to 0.00035 inch thick aluminum foil which is then laminated to 0.0005 inch thick polyester. Tolerances for thickness of plastic films shall be plus or minus 20 percent and tolerance for the foil layer shall be plus or minus 10 percent. The material shall show no evidence of delamination, degradation, or foreign odor when heat sealed or fabricated into pouches. The material shall be suitably formulated for food packaging and shall not impart an odor or flavor to the product. The material shall be approved for addition of hot water (less than or equal to 212°F). For package A (MCW), the complete exterior surface of the pouch shall be colored white overall with a color in the range of 37778 through 37886 of FES-STD-595, Colors Used in Government Procurement. For package B (LRP) and package C (MRE), the exterior surface of the pouch shall be uniformly colored in the range of 20219, 30219, 30227, 30279, 30313, 30324 or 30450 of FED-STD-595, Colors Used in Government Procurement.

b. Pouch construction. The pouch shall be a flat style preformed pouch having inside dimensions of $4\text{-}7/8 \pm 1/8$ by $7\text{-}1/2 \pm 1/8$ inches. The pouch shall be made by heat sealing three edges with $3/8$ inch ($- 1/8$, $+ 3/16$ inch) wide seals. The side and bottom seals shall have an average seal strength of not less than 6 pounds per inch of width and no individual specimen shall have a seal strength of less than 5 pounds per inch of width when tested as specified in E-6,B(1)a. Alternatively, the pouch shall exhibit no rupture or seal separation greater than $1/16$ inch or seal separation that reduces the effective closure seal width to less than $1/16$ inch when tested for internal pressure resistance as specified in E-6,B(1)c. A tear nick, notch or serrations shall be provided to facilitate opening of the filled and sealed pouch. A $1/8$ inch wide lip may be incorporated at the open end of the pouch.

c. Pouch filling and sealing. Product and one oxygen scavenger shall be inserted into the pouch. The pouch shall be sealed. The closure seal width shall be a minimum of $1/8$ inch. The closure seal shall be free of foldover wrinkles or entrapped matter that reduces the effective closure seal width to less than $1/16$ inch. Seals shall be free of impression or design on the seal surface that would conceal or impair visual detection of seal defects. The average seal strength of the closure seal shall be not less than 6 pounds per inch of width and no individual specimen shall have a seal strength of less than 5 pounds per inch of width when tested as specified in E-6,B(1)b. Alternatively, the filled and sealed pouch shall exhibit no rupture or seal separation greater than $1/16$ inch or seal separation that reduces the effective closure seal width to less than $1/16$ inch when tested for internal pressure resistance as specified in E-6,B(1)c.

(2) Oxygen scavenger. The oxygen scavenger shall be constructed of materials that are safe for direct and indirect food contact, and shall be suitable for use with edible products. The oxygen scavenger shall be in compliance with all applicable FDA regulations.

D-2 LABELING

A. Pouches. Each pouch shall correctly and legibly labeled. Printing ink shall be permanent black ink or other, dark, contrasting color which is free of carcinogenic elements. The label shall contain the following information:

- (1) Name and flavor of product (letters not less than 1/8 inch high)
- (2) Ingredients
- (3) Date 1/
- (4) Net weight
- (5) Name and address of packer
- (6) "Nutrition Facts" label in accordance with the Nutrition Labeling and Education Act (NLEA) and all applicable FDA regulations
- (7) Directions:
 1. Allow water just chemically purified to stand 30 minutes before adding to granola cereal.
 2. Open pouch and remove oxygen scavenger.
 3. Add 2-4 ounces (scant 1/6 canteen cup) of water to pouch.
 4. Stir and consume promptly (within 1 hour).

1/ Each pouch shall have the date of pack noted by using a four-digit code beginning with the final digit of the current year followed by the three digit Julian day code. For example, 14 February 2007 would be coded as 7045. The Julian day code shall represent the day the product was packaged into the pouch.

D-3 PACKING

A. Packing for shipment to ration assembler. Not more than 40 pounds of pouched product shall be packed flat in layers in a fiberboard shipping container constructed in accordance with style RSC-L, class domestic, variety SW, grade 200 of ASTM D 5118, Standard Practice for Fabrication of Fiberboard Shipping Boxes. Each container shall be securely closed in accordance with ASTM D 1974, Standard Practice for Methods of Closing, Sealing, and Reinforcing Fiberboard Shipping Containers.

D-5 MARKING

A. Shipping containers. Shipping containers shall be marked in accordance with DSCP FORM 3556, Marking Instructions for Boxes, Sacks, and Unit Loads of Perishable and Semiperishable Subsistence.

SECTION E INSPECTION AND ACCEPTANCE

The following quality assurance criteria, utilizing ANSI/ASQ Z1.4, Sampling Procedures and Tables for Inspection by Attributes, are required. Unless otherwise specified, Single Sampling Plans indicated in ANSI/ASQ Z1.4 will be utilized. When required, the manufacturer shall provide the Certificate(s) of Conformance to the appropriate inspection activity. Certificate(s) of Conformance not provided shall be cause for rejection of the lot.

A. Definitions.

(1) Critical defect. A critical defect is a defect that judgment and experience indicate would result in hazardous or unsafe conditions for individuals using, maintaining, or depending on the item; or a defect that judgment and experience indicate is likely to prevent the performance of the major end item, i.e. the consumption of the ration.

(2) Major defect. A major defect is a defect, other than critical, that is likely to result in failure, or to reduce materially the usability of the unit of product for its intended purpose.

(3) Minor defect. A minor defect is a defect that is not likely to reduce materially the usability of the unit of product for its intended purpose, or is a departure from established standards having little bearing on the effective use or operation of the unit.

B. Classification of inspections. The inspection requirements specified herein are classified as follows:

(1) Product standard inspection. The first article or product demonstration model shall be inspected in accordance with the provisions of this document and evaluated for overall appearance and palatability. Any failure to conform to the performance requirements or any appearance or palatability failure shall be cause for rejection of the lot. The approved first article or product demonstration model shall be used as the product standard for periodic review evaluations. All food components that are inspected by the USDA shall be subject to periodic review sampling and evaluation. The USDA shall select sample units during production of contracts and submit them to the following address for evaluation:

US Army Research, Development, and Engineering Command
Natick Soldier Research, Development, and Engineering Center
AMSRD-NSC-CF-F
15 Kansas Street
Natick, MA 01760-5018

One lot of each item produced shall be randomly selected during each calendar month of

production. Two (2) sample units shall be randomly selected from that one production lot. The two (2) sample units shall be shipped to Natick within five working days from the end of the production month and upon completion of all USDA inspection requirements. The sample units will be evaluated for the characteristics of appearance, odor, flavor, texture and overall quality.

(2) Conformance inspection. Conformance inspection shall include the examinations and the methods of inspection cited in this section.

E-5 QUALITY ASSURANCE PROVISIONS (PRODUCT)

A. Product examination. The finished product shall be examined for compliance with the performance requirements specified in Section C of this Performance-based Contract Requirements document utilizing the double sampling plans indicated in ANSI/ASQ Z1.4. The lot size shall be expressed in pouches. The sample unit shall be the contents of one pouch. The inspection level shall be S-3 and the acceptable quality level (AQL), expressed in terms of defects per hundred units, shall be 1.5 for major defects and 4.0 for minor defects. Defects and defect classifications are listed in table I.

TABLE I. Product defects 1/ 2/ 3/ 4/ 5/

Category	Defect
<u>Major</u>	<u>Minor</u>
	<u>Dry product</u>
101	Product not as specified.
	<u>Appearance</u>
102	Dry product not a mixture of rolled oats, white powder, and freeze-dried blueberries.
103	Pouch does not contain one intact oxygen scavenger.
104	Tear or hole or open seal in oxygen scavenger.
	<u>Odor and flavor</u>
105	Dry product not coconut or not toasted grain or not sweet or not dairy odor or flavor, or not mild blueberry flavor.
	<u>Texture</u>

PCR-G-003
18 September 2007
W/Change 02 26 Sep 08

201 Dry product not a free flowing mixture of powder, oat flakes, and distinct blueberries.

TABLE I. Product defects 1/ 2/ 3/ 4/ 5/ continued

<u>Category</u>		<u>Defect</u>
<u>Major</u>	<u>Minor</u>	
		<u>Net weight</u>
		202 Net weight of an individual pouch less than 52 grams. <u>6/</u>
		<u>Rehydrated product</u>
		<u>Appearance</u>
		203 Rehydrated product not a mixture of distinct oat flakes, dark blue blueberries, and purple milky liquid.
		<u>Odor and flavor</u>
106		Rehydrated product does not have a coconut or toasted grain or sweet or dairy or mild berry odor or flavor.
		<u>Texture</u>
		204 Rehydrated product not chewy or not firm or not with fibrous coconut or not with soft, moist blueberries or not in a liquid with a creamy milk mouthfeel.
		205 When rehydrated per instructions, product does not have some free liquid or does not have an even distribution of moisture throughout the granola or blueberries.

1/ Presence of any foreign materials such as, but not limited to dirt, insect parts, hair, glass, wood, or metal, or any foreign odors or flavors such as, but not limited, to burnt, scorched, rancid, sour, stale, musty or moldy shall be cause for rejection of the lot. Foreign flavor is not applicable to dry product.

2/ Finished product not equal to or better than the approved product standard in palatability and overall appearance shall be cause for rejection of the lot. Palatability is not applicable to dry product.

3/ The age requirement for U.S. Extra Grade Instant Nonfat Dry Milk shall be verified by a

producer's CoC.

4/ The producer shall provide a USDA Grading Certificate indicating that the instant nonfat dry milk used in the formulation met all the requirements for U.S. Extra Grade Instant Nonfat Dry Milk.

5/ The percentage of blueberry component shall be determined using the following procedure: The total contents of twenty pouches shall be weighed and the blueberry ingredient of the composite shall be separated and weighed separately. The percentages of the blueberry component shall be determined and the results reported to the nearest 0.1 percent. A Certificate of Conformance (CoC) for the mixture is an alternative method of acceptance. Any nonconformance shall be cause for rejection of the lot.

6/ Sample average net weight less than 57 grams shall be cause for rejection of the lot.

B. Methods of inspection.

(1) Shelf life. The contractor shall provide a Certificate of Conformance that the product has a 36 month shelf life when stored at 80°F. Government verification may include storage for 6 months at 100°F or 36 months at 80°F. Upon completion of either storage period, the product will be subjected to a sensory evaluation panel for appearance and palatability and must receive an overall score of 5 or higher based on a 9 point hedonic scale to be considered acceptable.

(2) Net weight examination. The net weight of the filled and sealed pouches shall be determined by weighing each sample on a suitable scale tared with a representative empty pouch. Results shall be reported to the nearest 1 gram.

(3) Analytical. The sample to be analyzed shall be a composite of eight filled and sealed pouches which have been selected at random from the lot. The composite sample shall be prepared and analyzed in accordance with the following methods of the Official Methods of Analysis (OMA) of AOAC International:

<u>Test</u>	<u>Method Number</u>
Protein	992.15, 984.13
Fat	985.15
Sodium	985.35
Moisture	925.09

For protein, fat, and moisture, test results shall be reported to the nearest 0.1 percent. For sodium, test results shall be reported to the nearest milligram. Verification will be conducted

PCR-G-003
18 September 2007
W/Change 02 26 Sep 08

through actual testing by a Government laboratory. Any nonconforming results shall be cause for rejection of the lot.

(4) Oxygen content. Eight filled and sealed pouches shall be randomly selected from one production lot and individually tested for oxygen content in accordance with any USDA approved test method. Testing shall be accomplished after the filled and sealed pouches have been allowed to equilibrate at room temperature for not less than 96 hours from the time of sealing. Test results shall be reported to the nearest 0.01 percent. Verification will be conducted through actual testing by a Government laboratory. Any individual result not conforming to the oxygen content requirement shall be cause for rejection of the lot.

(5) Microbiological. Five filled and sealed pouches shall be selected at random from the lot regardless of lot size. The pouched product shall be individually tested for microbiological levels in accordance with the Official Methods of Analysis of the AOAC, for Aerobic Plate Count method 966.23 or 990.12 and for *E. coli*, method 991.14 966.24 or the method on page 4.05, Section F, Chapter 4, 8th edition, FDA Bacteriological Analytical Manual (BAM). The diluent shall be added to each sample and allowed to stand for 15 minutes before blending the sample. *Salmonella* testing shall be in accordance with the Official Methods of Analysis of the AOAC, method 967.26 or 986.35 or 996.08. Any result not conforming to the microbiological requirements shall be cause for rejection of the lot.

Comment [U2]: Natick ES08-138, (DSCP-SS-08-16878) change 02, 26 Sep 08 line 4, after "*E. coli*, method", insert "991.14,"

NOTE: The following conditions apply for *Salmonella* and microbiological testing:

a. For prepackaged product received from a supplier and is not further processed, the contractor will furnish a Certificate of Analysis that the product represented is *Salmonella* negative and meets all microbiological requirements.

b. For bulk product received, the contractor is responsible for providing a certificate of analysis stating that the bulk product is *Salmonella* negative and meets all microbiological requirements. USDA *Salmonella* and additional microbiological testing is required for each end item lot and shall be the basis for lot acceptance with respect to *Salmonella* and other microbiological testing requirements.

E-6 QUALITY ASSURANCE PROVISIONS (PACKAGING AND PACKING MATERIALS)

A. Packaging.

(1) Pouch material certification. A Certificate of Compliance may be accepted as evidence that the characteristics listed below conform to the specified requirements.

PCR-G-003
18 September 2007
W/Change 02 26 Sep 08

<u>Requirement</u>	<u>Requirement paragraph</u>	<u>Test procedures</u>
Thickness of films for laminated material	D-1,A(1)a	As specified in ASTM D 2103 <u>1/</u>
Aluminum foil thickness	D-1,A(1)a	As specified in ASTM B 479 <u>2/</u>
Laminated material identification and construction	D-1,A(1)a	Laboratory evaluation.
Color of laminated material	D-1,A(1)a	Visual evaluation by FED-STD-595 <u>3/</u>

1/ ASTM D 2103 Standard Specification for Polyethylene Film and Sheeting

2/ ASTM B 479 Standard Specification for Annealed Aluminum and Aluminum-Alloy Foil for Flexible Barrier, Food Contact, and Other Applications

3/ FED-STD-595 Colors Used in Government Procurement

(2) Unfilled preformed pouch certification. A Certificate of Compliance may be accepted as evidence that unfilled pouches conform to the requirements specified in D-1,A(1)a and b. When deemed necessary by the USDA, testing of the unfilled preformed pouches for seal strength shall be as specified in E-6,B(1)a.

(3) Filled and sealed pouch examination. The filled and sealed pouches shall be examined for the defects listed in table II. The lot size shall be expressed in pouches. The sample unit shall be one filled and sealed pouch. The inspection level shall be I and the acceptable quality level (AQL), expressed in terms of defects per hundred units, shall be 0.65 for major defects and 2.5 for minor defects.

TABLE II. Filled and sealed pouch defects 1/

Category		Defect
<u>Major</u>	<u>Minor</u>	
101		Tear or hole or open seal.
102		Seal width less than 1/16 inch. <u>2/</u>
103		Presence of delamination. <u>3/</u>
104		Unclean pouch. <u>4/</u>
105		Pouch has foreign odor.
106		Any impression or design on the heat seal surfaces which conceals or impairs visual detection of seal defects. <u>5/</u>
107		Not packaged as specified.
	201	Label missing or incorrect or illegible.
	202	Tear nick or notch or serrations missing or does not facilitate opening.
	203	Seal width less than 1/8 inch but greater than 1/16 inch.
	204	Presence of delamination. <u>3/</u>

1/ Any evidence of rodent or insect infestation shall be cause for rejection of the lot.

PCR-G-003
18 September 2007
W/Change 02 26 Sep 08

2/ The effective closure seal is defined as any uncontaminated, fusion bonded, continuous path, minimum 1/16 inch wide, from side seal to side seal that produces a hermetically sealed pouch.

3/ Delamination defect classification:

Major - Delamination of the outer ply in the pouch seal area that can be propagated to expose aluminum foil at the food product edge of the pouch after manual flexing of the delaminated area. To flex, the delaminated area shall be held between the thumb and forefinger of each hand with both thumbs and forefingers touching each other. The delaminated area shall then be rapidly flexed 10 times by rotating both hands in alternating clockwise- counterclockwise directions. Care shall be exercised when flexing delaminated areas near the tear notches to avoid tearing the pouch material. After flexing, the separated outer ply shall be grasped between thumb and forefinger and gently lifted toward the food product edge of the seal or if the separated area is too small to be held between thumb and forefinger, a number two stylus shall be inserted into the delaminated area and a gentle lifting force applied against the outer ply. If separation of the outer ply can be made to extend to the product edge of the seal with no discernible resistance to the gentle lifting, the delamination shall be classified as a major defect. Additionally, spot delamination of the outer ply in the body of the pouch that is able to be propagated beyond its initial borders is also a major defect. To determine if the laminated area is a defect, use the following procedure: Mark the outside edges of the delaminated area using a bold permanent marking pen. Open the pouch and remove the contents. Cut the pouch transversely not closer than 1/4 inch ($\pm 1/16$ inch) from the delaminated area. The pouch shall be flexed in the area in question using the procedure described above. Any propagation of the delaminated area, as evidenced by the delaminated area exceeding the limits of the outlined borders, shall be classified as a major defect.

Minor - Minor delamination of the outer ply in the pouch seal area is acceptable and shall not be classified as a minor defect unless it extends to within 1/16 inch of the food product edge of the seal. All other minor outer ply delamination in the pouch seal area or isolated spots of delamination in the body of the pouch that do not propagate when flexed as described above shall be classified as minor defects.

4/ Outer packaging shall be free from foreign matter which is unwholesome, has the potential to cause pouch damage (for example, glass, metal filings) or generally detracts from the clean appearance of the pouch. The following examples shall not be classified as defects for unclean:

**PCR-G-003
18 September 2007
W/Change 02 26 Sep 08**

a. Foreign matter which presents no health hazard or potential pouch damage and which can be readily removed by gently shaking the package or by gently brushing the pouch with a clean dry cloth.

b. Dried product which affects less than 1/8 of the total surface area of one pouch face (localized and aggregate).

5/ If doubt exists as to whether or not the sealing equipment leaves an impression or design on the closure seal surface that could conceal or impair visual detection of seal defects, samples shall be furnished to the contracting officer for a determination as to acceptability.

B. Methods of inspection.

(1) Seal testing. The pouch seals shall be tested for seal strength as required in a, b, or c, as applicable.

a. Unfilled preformed pouch seal testing. The seals of the unfilled preformed pouch shall be tested for seal strength in accordance with ASTM F 88, Standard Test Method for Seal Strength of Flexible Barrier Materials. The lot size shall be expressed in pouches. The sample unit shall be one unfilled pouch. The sample size shall be the number of pouches indicated by inspection level S-1. Three adjacent specimens shall be cut from each of the three sealed sides of each pouch in the sample. The average seal strength of any side shall be calculated by averaging the three specimens cut from that side. Any average seal strength of less than 6 pounds per inch of width or any test specimen with a seal strength of less than 5 pounds per inch of width shall be classified as a major defect and cause for rejection of the lot.

b. Pouch closure seal testing. The closure seals of the pouches shall be tested for seal strength in accordance with ASTM F 88. The lot size shall be expressed in pouches. The sample unit shall be one pouch. The sample size shall be the number of pouches indicated by inspection level S-1. For the closure seal on preformed pouches, three adjacent specimens shall be cut from the closure seal of each pouch in the sample. For the form-fill-seal pouches, three adjacent specimens shall be cut from each side and each end of each pouch in the sample. The average seal strength of any side, end or closure shall be calculated by averaging the three specimens cut from that side, end or closure. Any average seal strength of less than 6 pounds per inch of width or any test specimen with a seal strength of less than 5 pounds per inch of width shall be classified as a major defect and cause for rejection of the lot.

c. Internal pressure test. The internal pressure resistance shall be determined by pressurizing the pouches while they are restrained between two rigid plates. The lot size shall be expressed in pouches. The sample unit shall be one pouch. The sample size shall be the

number of pouches indicated by inspection level S-1. If a three seal tester (one that pressurizes the pouch through an open end) is used, the closure seal shall be cut off for testing the side and bottom seals of the pouch. For testing the closure seal, the bottom seal shall be cut off. The pouches shall be emptied prior to testing. If a four-seal tester (designed to pressurize filled pouches by use of a hypodermic needle through the pouch wall) is used, all four seals can be tested simultaneously. The distance between rigid restraining plates on the four-seal tester shall be equal to the thickness of the product +1/16 inch. Pressure shall be applied at the approximate uniform rate of 1 pound per square inch gage (psig) per second until 14 psig pressure is reached. The 14 psig pressure shall be held constant for 30 seconds and then released. The pouches shall then be examined for separation or yield of the heat seals. Any rupture of the pouch or evidence of seal separation greater than 1/16 inch in the pouch manufacturer's seal shall be considered a test failure. Any seal separation that reduces the effective closure seal width to less than 1/16 inch (see table II, footnote 2/) shall be considered a test failure. Any test failure shall be cause for rejection of the lot.

C. Packing.

(1) Shipping container and marking examination. The filled and sealed shipping containers shall be examined for the defects listed in table III below. The lot size shall be expressed in shipping containers. The sample unit shall be one shipping container fully packed. The inspection level shall be S-3 and the AQL, expressed in terms of defects per hundred units, shall be 4.0 for major defects and 10.0 for total defects.

TABLE III. Shipping container and marking defects

Category		Defect
<u>Major</u>	<u>Minor</u>	
101		Marking missing or incorrect or illegible.
102		Inadequate workmanship. 1/
	201	More than 40 pounds of product.

1/ Inadequate workmanship is defined as, but not limited to, incomplete closure of container flaps, loose strapping, inadequate stapling, improper taping, or bulged or distorted container.

SECTION J REFERENCE DOCUMENTS

DSCP FORMS

DSCP FORM 3556 Marking Instructions for Boxes, Sacks, and Unit Loads of Perishable and Semiperishable Subsistence

GOVERNMENT STANDARD

Food and Drug Administration Bacteriological Analytical Manual (BAM)

FEDERAL STANDARD

FED-STD-595 Colors Used in Government Procurement

NON-GOVERNMENTAL STANDARDS

AMERICAN SOCIETY FOR QUALITY (ASQ)

ANSI/ASQ Z1.4-2003 Sampling Procedures and Tables for Inspection by
Attributes

ASTM INTERNATIONAL

B 479-06 Standard Specification for Annealed Aluminum and
Aluminum-Alloy Foil for Flexible Barrier, Food
Contact, and Other Applications

D 1974-98 (2003) Standard Practice for Methods of Closing, Sealing,
and Reinforcing Fiberboard Boxes

D 2103-05 Standard Specification for Polyethylene Film and
Sheeting

D 5118/D 5118M-05ae1 Standard Practice for Fabrication of Fiberboard
Shipping Boxes

F 88-07 Standard Test Method for Seal Strength of Flexible
Barrier Materials

AOAC INTERNATIONAL

Official Methods of Analysis (OMA) of the Association of Analytical Chemists
International

PCR-G-003
18 September 2007
W/Change 02 26 Sep 08

For DSCP Website Posting

AMSRD-NSR-CF-F

26 September 2008

TO: DSCP-FTRE

SUBJECT: ES08-138 (DSCP-SS-08-16878); Request for substitution for Granola with Milk & Blueberries, PCR-G-003; product failed micro testing due to positive *E. coli* reading; 3 lots tested (lots 8223, 8244, and 8246)

Date received: 10 September 08

Date due: 24 September 08

Date replied: 26 September 08

1. In response to the questions on microbiological requirements from a contractor, Natick formed a team to evaluate current microbiological standards for PCR-G-003, Granola, Packaged in Flexible Pouch, Shelf Stable.
2. Natick received historical USDA microbiological results for this product and 59 lots have been tested since 12/14/2007. Only lots 8223, 8244 and 8246 did not meet the microbiological requirements for *E. coli*. All other microbiological requirements were met by all of the lots produced thus far.
3. The contractor uses this specific method for *E. coli* testing: AOAC Official Method 991.14, 3 M Petrifilm Method, 1 ml at 1:10 dilution, 25 gram sample.
4. Natick correspondence with USDA Agricultural Marketing Service, Field Laboratory Services, Gastonia, NC provides an explanation of the two specified test methods for *E. coli* testing, the Petrifilm method (plate method) and the Most Probable Number-tube method (MPN). The results for these two tests are given respectively as Colony Forming Units (CFU) per gram and Most Probable Number (MPN) per gram.
“Because of the way they are mathematical derived, MPN and CFU are not convertible, and results must be recorded either as CFU per gram or MPN per gram. MPN is derived as a maximum likelihood estimate. When zero tubes in the test produce gas the result is given as < 3. This result actually represents a statistical range of 0 to 11 colonies. It is not given in tables because the calculation requires dividing by zero which is not possible. CFUs are determined by counting the number of colonies on a petrifilm plate and multiplying that number of colonies by the reciprocal of the dilution. If zero colonies are present on the plate

PCR-G-003
18 September 2007
W/Change 02 26 Sep 08

a statistical adjustment is made and the result is given as < 1 times the reciprocal of the dilution.” Since the method specified by OFD is based on a one to ten dilution “the result for zero colonies would be < 10 , with a represented statistical range of 0 to 9.999 colonies.” Thus, absence of bacterial contamination for both the plate method and the MPN method is stated in reports differently, but still requires a finding of zero colonies and is represented statistically as somewhere between one and about ten colonies.

5. Natick submits the following changes to PCR-G-003, Granola, Packaged in a Flexible Pouch, Shelf Stable, for all current, pending and future contracts until the document is formally amended or revised:

a. C-2, G. Microbiological Requirements, lines 3-4, delete “The *Escherichia coli* count shall have . . . technique.”, insert “The *Escherichia coli* count shall be less than 3 MPN per gram (no positive tubes in the standard 3 tube most probable number (MPN) technique) or less than 10 Colony Forming Units (CFU) per gram (findings indicate zero colonies (CFU) per plate or zero tubes producing gas for MPN).”

b. E-5, B., (5) Microbiological, line 4, after “*E. coli*, method”, insert “991.14,”