TECHNICAL REPORT
NATICK/TR-20/011

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SURVIVAL OF *SALMONELLA ENTERICA* IN LOW MOISTURE MILITARY RATION PRODUCTS

by
Genevieve Flock
Michelle Richardson
Dominique Pacitto
Courtney Cowell
Nate Anderson
Patrick Marek
and
Andy Senecal

June 2020

Final Report
October 2015 – October 2019

U.S. Army Combat Capabilities Development Command Soldier Center
Natick, Massachusetts 01760-5000

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REPORT DOCUMENTATION PAGE

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1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
03-06-2020	Final	October 2015-October 2019

4. TITLE AND SUBTITLE

SURVIVAL OF *SALMONELLA ENTERICA* IN LOW MOISTURE MILITARY RATION PRODUCTS

5a. CONTRACT NUMBER

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER
0603118A

6. AUTHOR(S)
Genevieve Flock, Michelle Richardson, Dominique Pacitto, Courtney Cowell, Nate Anderson, Patrick Marek and Andy Senecal

5d. PROJECT NUMBER
JSN 12-07

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Combat Capabilities Development Command-Soldier Center
ATTN: FCDD-SCC-STI
10 General Greene Avenue, Natick, MA 01760-5000

8. PERFORMING ORGANIZATION REPORT NUMBER
NATICK/TR-20/011

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution is unlimited.

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Non-typhoidal *Salmonella* is a foodborne pathogen that has one of the highest incidences of hospitalizations and deaths. The foodborne illness symptoms can include fever, abdominal pain, diarrhea, nausea and vomiting. The high incidence of foodborne illness coupled with a large number of outbreaks in commercial low moisture foods (LMF) such as peanut butter prompted Army researchers to investigate *S. enterica* survivability in LMF rations. The majority of LMF are not cooked prior to consumption so contamination at the time of manufacture could lead to illness when consumed by the soldier. In addition, military rations are prepositioned and can be stored for up to 3 years at various climate conditions therefore, this study evaluated various storage temperatures to simulate conditions in the field. LMF products in this study were chosen based on categories outlined by Institute of Food Safety and Health; peanut butter, mocha desert bar, dehydrated egg, chocolate protein drink and cran-raspberry first strike bar. Previous studies identified potential synergistic effect on *S. enterica* survival in high fat, low water activity foods such as peanut butter. This experiment expanded on these predictions and evaluated foods with varying compositions which undergo unique storage requirements prior to consumption.

15. SUBJECT TERMS

BACTERIA	CONTAMINATION	INFECTIOUS DISEASES	PATHOGENIC BACTERIA
DIARRHEA	STRAINS(BIOLOGY)	MILITARY PERSONNEL	SALMONELLA ENTERICA
MOISTURE	GASTROENTERITIS	FOODBORNE ILLNESSES	
INFECTION	ENTERIC BACTERIA	GASTROINTESTINAL DISEASES	
SALMONELLA	BACTERIAL DISEASES	PATHOGENIC MICROORGANISMS	

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Genevieve Flock
U	U	U	UU	28	19b. TELEPHONE NUMBER *(include area code)* (508) 206-3352

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SURVIVAL OF *SALMONELLA ENTERICA* IN LOW MOISTURE MILITARY RATION PRODUCTS

1. INTRODUCTION

This technical report documents results of *Salmonella enterica* survivability in six low moisture military ration products. The study was performed at the Combat Capabilities Development Command Soldier Center (CCDC SC) between October 2015 and October 2019. A part of the study was contracted to Dr. Nate Anderson at the Food and Drug Administration Institute of Food Safety and Health (FDA IFSH) to conduct mocha dessert bar production and storage studies with *S. enterica* inoculated whey powder to understand survivability in production settings and with alteration of pH. Studies were conducted at IFSH from September 2018 to September 2019.

Non-typhoidal *Salmonella* is a foodborne pathogen which has one of the highest incidences of hospitalizations and deaths. The foodborne illness symptoms can include fever, abdominal pain, diarrhea, nausea and vomiting [1]. Within U.S. Armed Forces personnel there was an average rate of 12.4 Non-typhoidal *Salmonella* cases per 100,000 from 2007-2016 [2]. In addition, the Center for Disease Control has estimated that for each culture-confirmed case there are an average of 29 unreported cases [3]. This identification of a high number of cases in both the general population and the U.S. Armed Forces suggests an increased need for research in the area of *S. enterica* survivability in food. Also, the high incidence of foodborne illness coupled with a large number of outbreaks in commercial low moisture foods (LMF) such as peanut butter prompted Army researchers to investigate *S. enterica* survivability in LMF rations. The majority of LMF are not cooked prior to consumption so contamination at the time of manufacture could lead to illness when consumed by the soldier. In addition, military rations are prepositioned and can be stored for up to 3 years at various climate conditions; therefore, this study evaluated various storage temperatures to simulate conditions in the field. LMF products in this study were chosen based on categories outlined by FDA IFSH Low Moisture Food Safety Task Force: Peanut butter and mocha desert bar for the high fat emulsification category, dehydrated egg mix for the granular category, chocolate protein drink for the powder/bulk solids category and cran-raspberry first strike bar for the composite category. Previous studies identified potential synergistic effect on *S. enterica* survival in high fat, low water activity foods such as peanut butter[4]. This experiment expanded on these predictions and evaluated foods with varying compositions which undergo unique storage requirements prior to consumption.

2. MATERIALS AND METHODS

2.1 Test Bacteria

The bacterial strains utilized were *Salmonella enterica* serovar Agona ATCC 51597, *Salmonella enterica* serovar Enteritidis ATCC BAA-1045, *Salmonella enterica* serovar Montevideo ATCC BAA-710, *Salmonella enterica* serovar Tennessee ATCC 10722 and *Salmonella enterica* serovar Typhimurium ATCC BAA-14028. Stock cultures of the strains were kept frozen (-80 °C) with 20% glycerol and streaked working plates were stored at refrigeration temperatures (4 °C) on trypticase soy agar (TSA; Difco Laboratories Inc., Detroit, MI, USA). The strains were double cultured by transferring a single colony from a TSA plate to 10 mL of tripticase soy broth (TSB; Difco) followed by transferring 100 µL after 6 h of growth to a fresh TSB test tube. After ~12 h of growth, the cultures were used for inoculation.

2.2 Preparation of *S. enterica* dry inoculum

Using a protocol modified from Beuchat et al.[5], 1 mL of each *S. enterica* strain was inoculated separately onto 150 mm TSA plates in duplicate and incubated at 37 °C for 24 h. Following incubation, the bacterial lawn was collected with 9 mL of sterile 1% buffered peptone water (BPW; Difco) for each 150 mL TSA plate. A t-shaped spreader was used to gently remove the bacterial lawn from each plate and a pipette was used to transfer the suspension into 50 mL centrifuge tubes. Tubes were centrifuged at 3500 RPM for 30 min followed by careful removal of the supernatant and resuspension of the pellet in 2 mL of 1% BPW. The concentrated bacteria was then transferred equally to four pre-weighed sterile 250 mL beakers. The weights of the beaker and liquid inoculum were then recorded. The inoculum was dried for 48 h in a desiccator at 25 ^{o}C and the dried weight was recorded.

The weight of the inoculum in each beaker was deduced and calculations were made to achieve 0.05% bacterial inoculum to 0.95% food ingredient. The determined ratio of carrier ingredient was mixed with the dried bacteria utilizing a sterile metal spatula. Following mixing, inoculated carrier ingredient contained in the beakers was returned to the desiccator for 24 h of equilibration at 25 °C. After further desiccation, water activity of the inoculated ingredient was verified to be within an acceptable range compared to the water activity of the un-inoculated ingredient.

2.3 Production of LMF products

All ration products were produced according to performance-based contract requirements (PCRs). For the ration products mocha dessert bar (PCR-D-004 dessert bar, Packaged in a flexible pouch, shelf stable), chocolate protein drink (PCR-C-082B, chocolate protein drink powder, packaged in a flexible pouch, shelf stable), cran-raspberry first strike bar (PCR-F-001A, first strike bars, shelf stable) and dehydrated boil-in-bag (BIB) eggs (PCR-E-017B, egg mix, reduced cholesterol, pasteurized, uncooked dehydrated boil-in-bag pouch), the inoculated and dried carrier ingredients were combined with the remaining product ingredients in a mixer (R602V Series E, Robo Coupe USA ® Ridgeland, MS) (Figure 1). Following mixing, 40 g of each food was transferred to tri-laminate pouches and were sealed under 25psi vacuum with a vacuum impulse sealer (Model No. AIE-610GA, American International Electric Inc.). For the

peanut butter ration products (Thermo Pac, LLC, Stone Mountain Georgia), a 0.5 mL inoculum containing the 5 serovars of *S. enterica* suspended in peanut oil with 1% lecithin was added directly to the peanut butter in tri-laminate pouches followed by hand mixing and vacuum sealing. For freeze dried beef stew (PCR-B-015, beef stew, cooked, dehydrated, packaged, in a brickpack pouch, shelf stable), a wet inoculum containing the 5 serovars of *S. enterica* was added to the wet product and thoroughly mixed followed by freeze drying with a FreeZone 6 freeze dryer (Labconco Kansas City, MO) to the required water activity. Then, 20 g of the freeze dried product was transferred to tri-laminate pouches and vacuum sealed. All of the low moisture ration items were divided into three equal groups for storage at 4 °C (~39 °F), 25 °C (~77 °F) and 40 °C (~104 °F). Two batches were produced for each product except for freeze dried beef stew, which was produced in three batches and peanut butter which were inoculated individually.

Two cran-raspberry first strike bar sets were included after an observation of the rapid decrease in *S. enterica* following the first enumeration time point. The first cran-raspberry bar was produced with apple powder as the carrier ingredient for inoculation, which has a pH of 4. It was hypothesized that the low pH of the carrier ingredient could have an effect on survivability of *S. enterica* in the bar. Therefore, a second cran-raspberry bar was produced with neutral whey powder as the carrier ingredient for inoculation with a pH of 7.

2.4 Enumeration of *S. enterica*

Enumeration was performed by quantitative dilution and plating on selective Hektoen Enteric agar (HE; Oxoid Remel Lenexa, KS) and non-selective agar, TSA. Samples from each stress condition were evaluated for *S. enterica* viability at 0, 1, 3, 6, 9, 12, 18, 24, 30 and 36 months. At each sampling time point, 10 g from three pouch replicates from each temperature storage condition (4 °C, 25 °C and 40 °C) were added to sterile stomacher bags. Each bag was diluted with 90 mL of BPW and stomached (Stomacher 400 Circulator, Seward Bohemia, NY) for 2 min at 230 rpm and stored at room temperature for 1 h to allow for cell recovery following addition of dilution buffer. Dilutions were made in sterile 9 mL BPW tubes and 100 µL of two dilution tubes based on previous quantitative estimates were spread plated in duplicate on TSA and HE agar plates and incubated at 37 °C for 24 h.

2.4.1 Water Activity and pH

The water activity of all samples was measured at 25 °C using a water activity meter (Aqualab Model series 3, Decagon Devices Inc., Pullman, USA) with a sensitivity of 0.003. Measurements of pH were recorded for each sample with an HI 4222 pH meter (Hanna Instruments, Smithfield, RI).

3. RESULTS

Storage of all LMF rations at 40 °C showed a decrease in log CFU/g of *Salmonella enterica* indicating that storage time and temperature have a significant effect on survivability. The time and temperature effect can be observed in Table 1 in terms of percent survivability of *S. enterica* in experimental LMF ration products. The cran-raspberry first strike bar had the earliest observed reduction in *S. enterica* survivability among all LMF rations. For both carrier ingredient cran-raspberry bar types stored at 40 °C, a significant reduction in *S. enterica* was observed after 1 month for the bar produced with apple powder as the carrier ingredient and after 3 months for the whey powder. In addition, the cran-raspberry bars were enrichment negative in BPW alone and with enrichment supplements (sodium pyruvate or ferioxamine). Ration items with higher pH (Table 2) such as the mocha dessert bar and chocolate protein drink were enrichment positive in BPW alone and did not require enrichment supplements up to 18 months of storage. BIB eggs and freeze dried beef stew LMF ration products had the highest percentage survivability at 40 °C storage with 76% surviving in BIB eggs after 36 months of storage.

Normalized data at 2 years of storage showed the highest percentage survivability in BIB eggs and freeze-dried beef stew at 40 °C. Comparatively, the cran-raspberry first strike bar (apple and whey inoculated) demonstrated the lowest percentage survivability at 25 °C and 40 °C. This suggests that the overall matrix, pH and water activity may play a role in *S. enterica* survivability.

Dr. Nate Anderson of the FDA observed rapid cooling of the mocha dessert bar following oil addition during simulated production (Figure 2). As observed in Figure 2, the high temperature of 109.9 °F (43.3 °C) is only maintained for a brief time and drops to 94.6 °F (34.8 °C) after 6 min and is then maintained at 86 °F (30 °C) for the remainder of the mixing time (Figure 3). This length of time is insufficient to be considered a control step for foodborne pathogen mitigation in this production process. Similarly, modification of the mocha dessert bar pH from 6 to 4.3 did not significantly reduce the survivability of *S. enterica* (Figure 4).

These results demonstrate the need for additional research on ways to control *S. enterica* in LMF to enhance soldier protection against food safety threats. In addition, experiments on the mocha dessert bar production process (Figures 3 and 4) indicate the importance of sourcing ingredients with certificates of analysis which show negative testing for *S. enterica* due to the lack of an adequate temperature control step. An increased focus on ingredient sourcing and certification will play an important role in pathogen risk mitigation.

Table 1. *S. enterica* Percent Survivability by Month in LMF Ration Products

LMF Product	Storage Temp.	1 M	3 M	6 M	12 M	18 M	24 M	30 M	36 M
Cran-raspberry First Strike Bar (Whey)	4°C 25°C 40°C		 29	 0#		97 44	97 29	96	
Cran-raspberry First Strike Bar (Apple Powder)	4°C 25°C 40°C	 21	 0#	 53	98 0#	93	93	93	
Mocha Dessert Bar	4°C 25°C 40°C			 23	 0+				91 80
Chocolate Protein Drink	4°C 25°C 40°C				 38	 0*			100 87
Peanut Butter	4°C 25°C 40°C				 48	 0*			96 87
Dehydrated Boil-in-Bag Eggs	4°C 25°C 40°C								97 86 76
Freeze Dried Beef Stew	4°C 25°C 40°C						98 91 61		

Key: # No growth when enriched, + Growth when enriched in BPW with sodium pyruvate and ferioxamine, * Growth when enriched in BPW

Table 2. S. enterica Log Loss in LMF Ration Products

LMF Product	Water Activity (a_w)	pH	24 months log loss		% surviving
Cran-raspberry First Strike Bar (Whey)	0.517	4.56	4°C 25°C 40°C	- 0.26 - 6.18 - 8.74	97 29 0
Cran-raspberry First Strike Bar (Apple Powder)	0.495	4.37	4°C 25°C 40°C	- 0.56 - 8.09 - 8.09	93 0 0
Mocha Dessert Bar	0.43	6.71	4°C 25°C 40°C	- 0.53 - 1.50 - 8.28	95 84 0
Chocolate Protein Drink	0.346	6.71	4°C 25°C 40°C	- 0 - 0.37 - 7.46	100 95 0
Peanut Butter	0.21	6.12	4°C 25°C 40°C	- 0 - 0.81 - 7.59	100 89 0
Dehydrated Boil-in-Bag Eggs	0.091	7.0	4°C 25°C 40°C	- 0.2 - 0.92 - 1.72	97 88 78
Freeze Dried Beef Stew	0.077	6.19	4°C 25°C 40°C	- 0.14 - 0.80 - 3.44	98 91 61

4. DISCUSSION AND CONCLUSION

The experimental parameters of time and temperature of storage, LMF matrix composition, pH and water activity had an effect on the survivability of *S. enterica* in each of the 6 LMF ration products. The LMF products were chosen to represent a range of pH and water activity ($a_{w)}$) with the cran-raspberry first strike bar representing the lowest pH of 4.37 and the highest a_w of 0.495 and freeze dried beef stew with a moderate pH of 6.19 and the lowest a_w at 0.077. The pH seemed to have a major effect on *S. enterica* survivability with the greatest reduction in log CFU/g observed in the cran-raspberry bars at 25 °C and 40 °C storage. Conversely, *S. enterica* survived to a higher percentage throughout storage time in products with higher pH such as in the mocha dessert bar and chocolate protein drink (Table 2). Physical composition of different products appears to have an effect after 1 year of storage. LMF ration products with a higher fat content in combination with a more neutral pH such as peanut butter and mocha dessert bar showed greater percentage survivability at 25 °C compared to the cran-raspberry bar with lower fat and lower pH.

The most rapid reduction in survivability of *S. enterica* was observed in the cran-raspberry bar. This is most likely due to the acidic conditions of the bar with a pH below 5. This observation led to a future project proposal to investigate antimicrobials for effectiveness in reducing *S. enterica* survivability. If effective antimicrobials are found they could be recommended for inclusion in ration items as an additional hurdle in a food product to prevent food borne pathogen contamination risk.

Prevention of cross-contamination needs to be prioritized at all stages of production for LMF ration products. Sources of contamination can be personnel, clothing, footwear, manufacturing equipment, addition contaminated ingredients post-pasteurization and numerous other pathways [5]. These sources need to be considered when developing a Food Safety Plan or Hazard Analysis and Critical Control Point (HACCP) Plan in order to reduce risk of foodborne pathogens entering the product (Appendix I). Ingredient sourcing with certificates of analysis showing negative *S. enterica* testing; proper handling and separation of raw ingredients from finished products; and microbiological testing of finished product reduce risk.

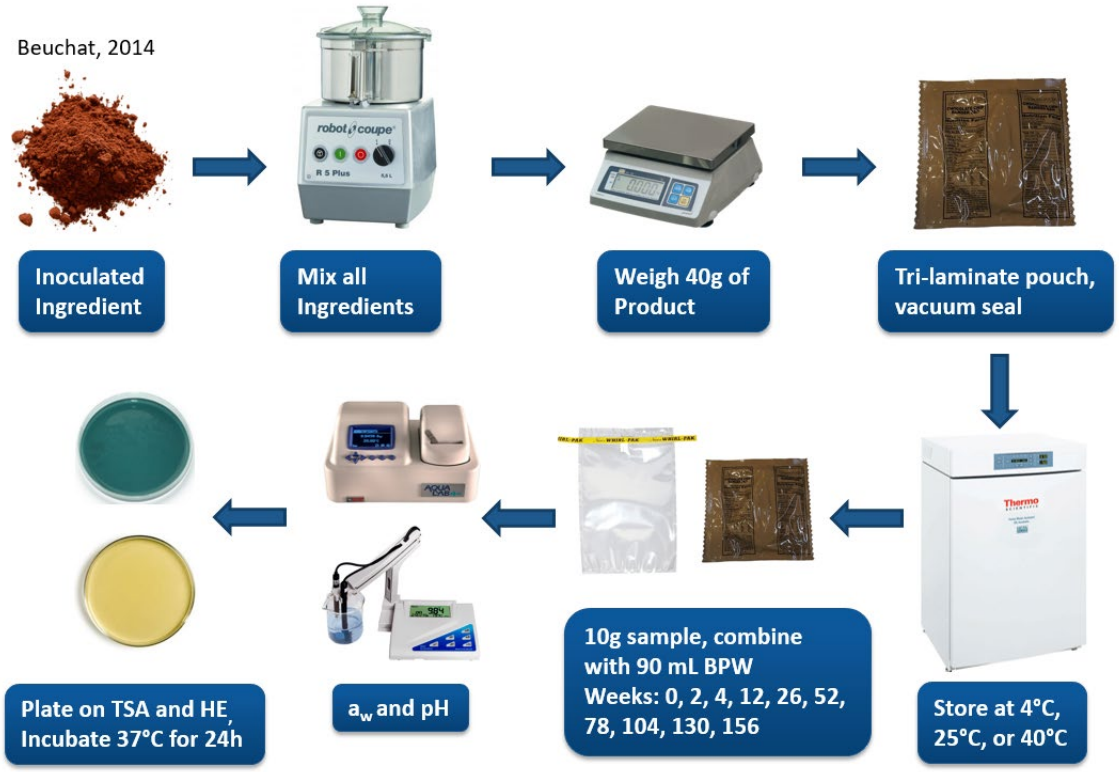

Figure 1. Low Moisture Foods Production Method

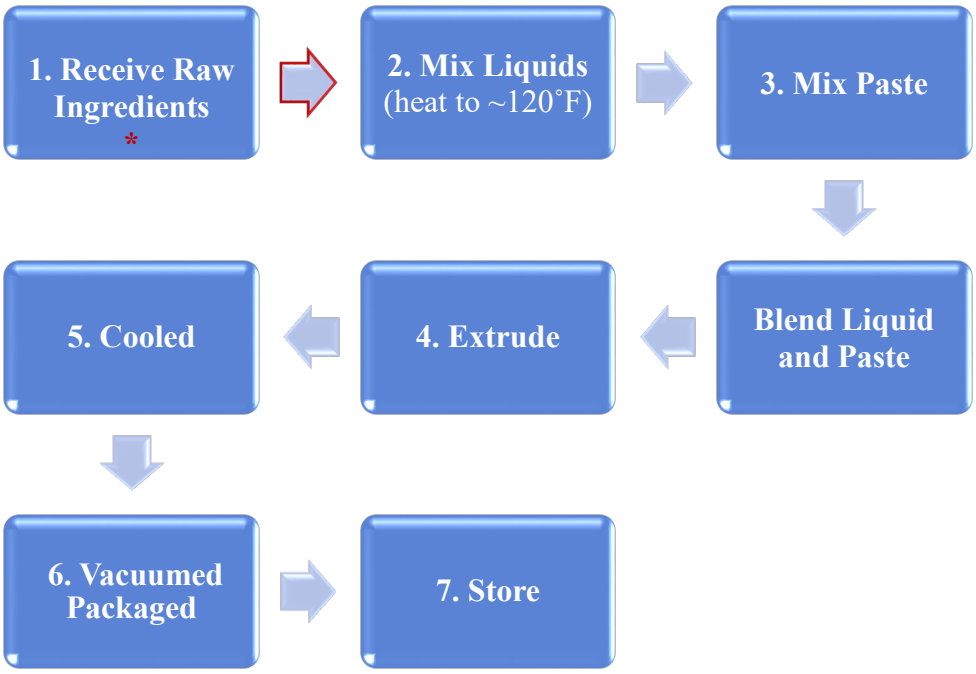

Figure 2. Mocha Dessert Bar Production Process

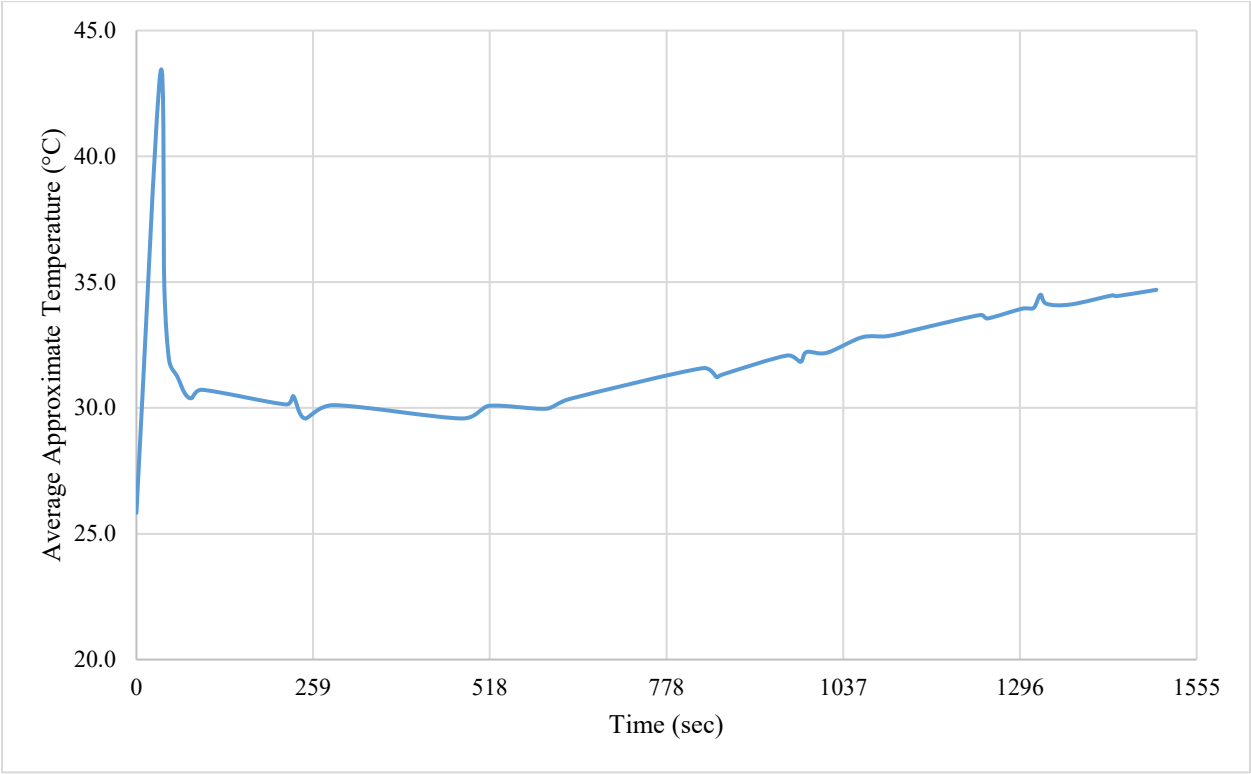

Figure 3. Approximate Average Temperature of Oil during Mocha Dessert Bar Production

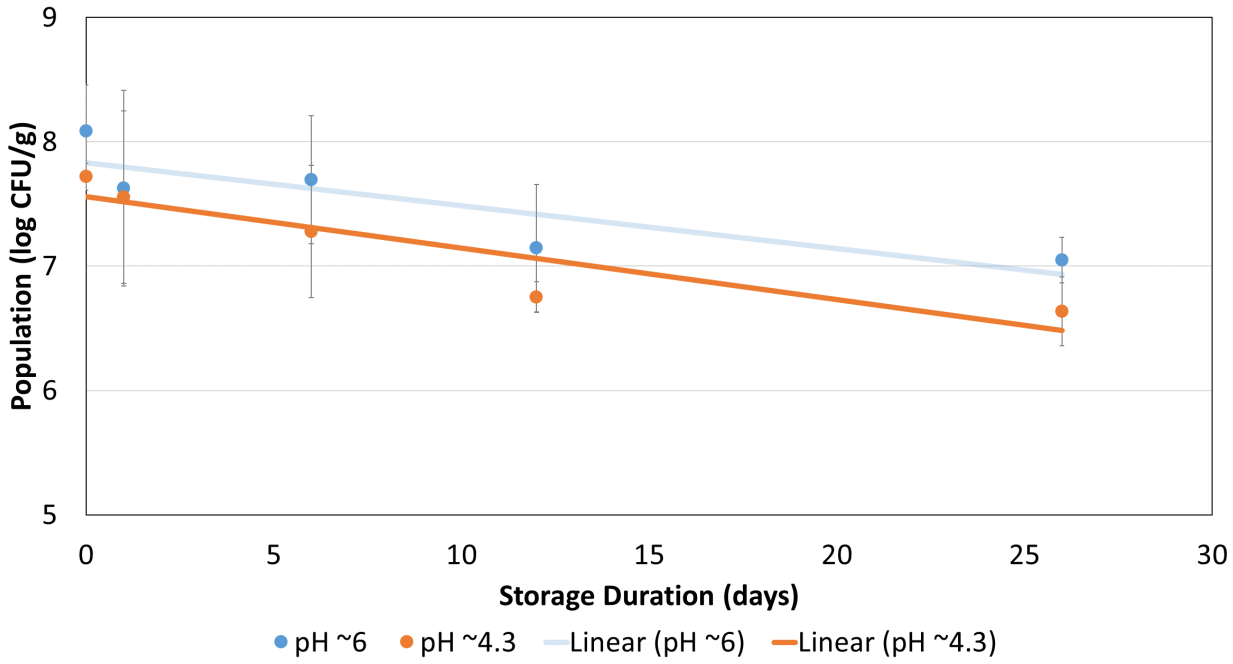

Figure 4. Effect of pH modification on *S. enterica* Survivability in Mocha Dessert Bars

This document reports research undertaken at the U.S. Army Natick Soldier Research, Development and Engineering Center, Natick, MA, and has been assigned No. NATICK/TR- 20/011 in a series of reports approved for publication.

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APPENDIX
Generic HACCP Model

Combat Feeding Directorate

Generic HACCP Model, Not Heat Treated, Shelf Stable Bar Products, First Strike Bar and Dessert

HACCP Plan – Bars Products

PRODUCT DESCRIPTION

COMMON NAME:

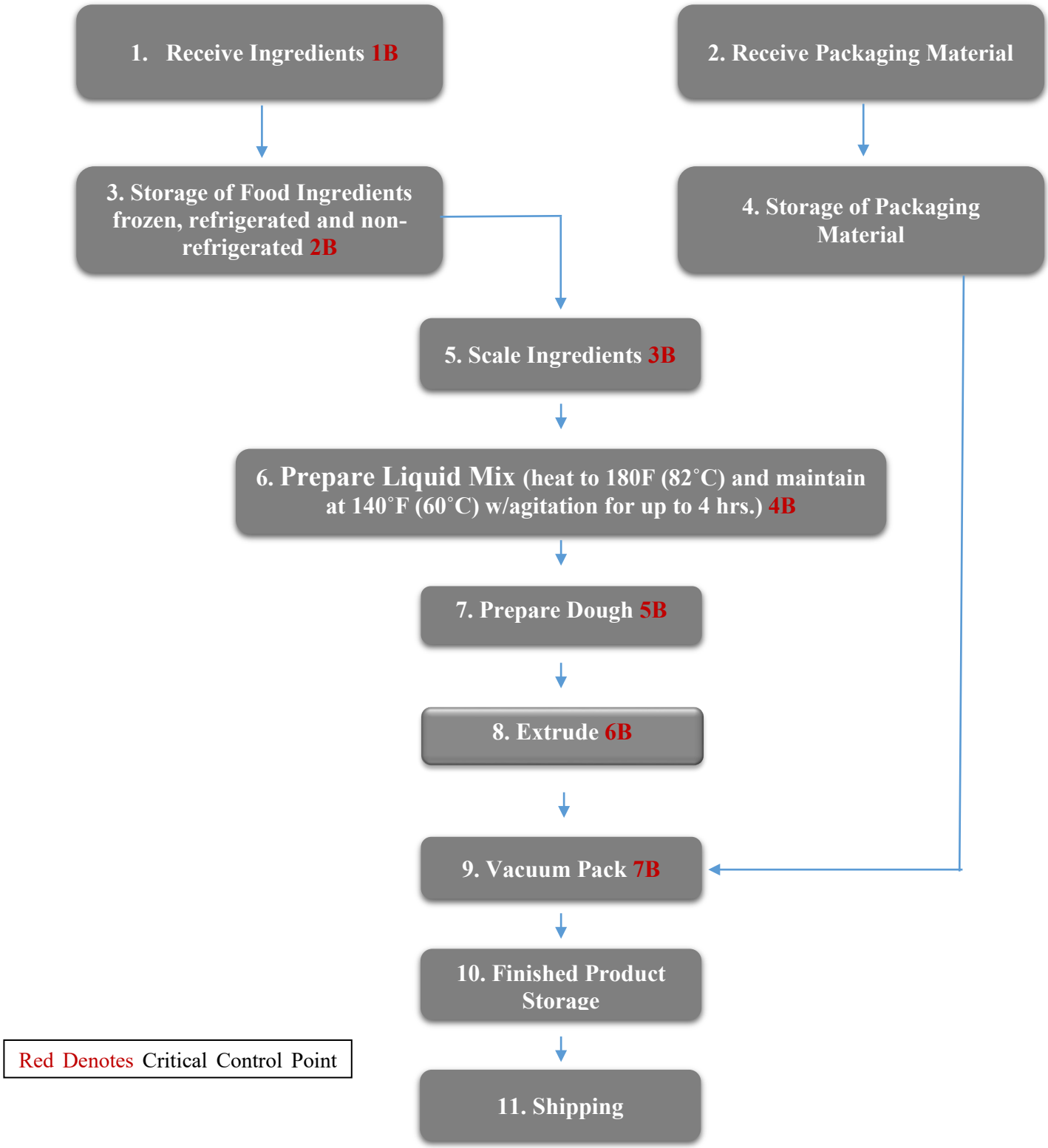
HOW IS IT TO BE USED?	Shelf stable ration component
DESCRIPTION OF CUTSOMER	Warfighter
TYPE OF PACKAGE?	Tri-laminated pouch consisted of ionomer or polyethylene film laminated or extrusion coated to aluminum foil laminated to polyester.
LENGTH OF SHELF LIFE, AT WHAT TEMPERATURE?	6 months at 100°F or 3 years at 80°F
WHERE WILL IT BE SOLD:	Nor for retail sale to consumers. Sold to DLA and/or ration producers
LABELING INSTRUCTIONS:	As required by PCR-F-001, FIRST STRIKE™ BARS, SHELF STABLE, section D-2 LABELING and PCR-D-004, DESSERT BAR, PACKAGED IN A FLEXIBLE POUCH, SHELF STABLE
IS SPECIAL DISTRIBUTION CONTROL NEEDED?	No, Bars Product Time/Temp control not needed

PRODUCTS/INGREDIENTS USED TO PRODUCE PRODUCT:

RTE Meat Poultry and Byproducts	Non-meat Food Ingredients	Binders/Extenders
N/A	Apple Nuggets Apple Powder, Low Moisture Canola Oil Chocolate Chip, Semisweet Chocolate Wafers Cocoa Powder Corn Syrup Cream Cheese Powder Crisp Rice Crystalline Fructose Date Plum Prep Dextrose Dried Cranberries Freeze Dried/Spray Dried Coffee Glycerin Lecithin Maltodextrin Non-Fat Dry Milk, Nutty Corn Nutty Rice Palm Oil Peanut Butter Peanut Flour Peanuts, Dry Roasted Raspberry Filling Rice Bran Concentrate Spray Dried Cream Powder Sugar Titanium Dioxide Walnuts Whey Protein Concentrate Wild Cherry Red	N/A
Spices/Flavorings	**Restricted Ingredients**	**Preservatives/Acidifiers**
Apple Pie Spice Banana Extract Coffee Flavor Raspberry Natural/Artificial Flavor Vanilla Extract Vanilla Flavor	Ascorbyl Palmitate Butylated Hydroxyanisole Caffeine Mixed Tocopherols Vitamin Premixes	N/A
Other Non-Meat Food Ingredients	**Packaging Material**	
N/A	Tri-laminated Pouch	

Generic HACCP Process Flow Diagram

Process Category: RTE
Products: Bars



Red Denotes Critical Control Point

HAZARD ANALYSIS – Bars Products

1. Ingredient or Process Step	2. Potential food safety hazard introduced, controlled, enhanced or reduced at this step	3. Is the potential food safety hazard significant? (Risk:Severity) (Reasonably likely to occur)	4. Justification for decision (Basis for reasonably likely to occur)	5. If yes, what control measures can be applied to prevent the significant hazard(s)?	6. Is this step a critical control point (CCP)?
1. Receiving Ingredients	*Biological:* **Pathogen contamination** *Salmonella* spp. *Escherichia coli* 0157:H7	Y	Pathogen may be presented incoming in low moisture ingredients because of improper pasteurization, handling, storage or transport Pathogen Survivability possible	CoC (Certificate of Conformance). Receiving, reduce risk of accepting product that has been mishandled. Handling should be minimized CoC from suppliers indicating ingredients are from an approved source. Receiving SOP (Standard Operating Procedures) ensures ingredients are not accepted if they have been improperly handled. Storage SOP ensures proper storage conditions.	**1B**
	Chemical: **Allergens**				
	Physical: **Foreign material**				No
2. Receiving Packaging Materials	*Biological:* None	No	Low risk, not likely to occur.	CoC from suppliers	No
	Chemical: None	No	Low risk, not likely to occur.	CoC from suppliers	No
	Physical: **Foreign material**	No	Low risk, not likely to occur.	CoC Visual inspection.	No

1. Ingredient or Process Step	2. Potential food safety hazard introduced, controlled, enhanced or reduced at this step	3. Is the potential food safety hazard significant? (Risk:Severity) (Reasonably likely to occur)	4. Justification for decision (Basis for reasonably likely to occur)	5. If yes, what control measures can be applied to prevent the significant hazard(s)?	6. Is this step a critical control point (CCP)?
3. Storage of Food Ingredients (frozen, refrigerated, non-refrigerated)	*Biological*: **Pathogen contamination** *Salmonella* spp. *Escherichia coli* 0157:H7	Yes	Potential of pathogens are likely to grow if temperature is not maintained at or below a level to prevent growth Pathogens may grow if Sanitation Standard Operation Procedures (SSOPs) are not followed Survivability can't be controlled by subsequent steps(process and storage)	Pathogens are unlikely to grow if the product is maintained at proper temperatures (SSOP for storage) SOP uses alarms and continuous surveillance. Separate unprocessed product from processed products to prevent recontamination.	**2B**
	Chemical: None	No	Low risk, not likely to occur.		No
	Physical: None	No	Low risk, not likely to occur.		No
4. Storage of Packaging Material	Biological: None	No	Low risk, not likely to occur		No
	Chemical: None	No	Low risk, not likely to occur		No
	Physical: None	No	Low risk, not likely to occur		No
5. Scale Ingredients	*Biological:* **Pathogens** *Salmonella* spp. *Escherichia coli* 0157:H7 *Staphylococcus aureus*	Yes	Potential contamination from equipment, environment, and workers Survivability can't be controlled by subsequent steps(process and storage)	Minimal handling by healthy workers. Minimize scaling time. Clean and inspect scales and utensils prior to scaling Use GMPs (Good Manufacturing Practices) and SSOPs	**3B**
	Chemical: None	No	Low risk, not likely to occur.		No
	Physical: None	No	Low risk, not likely to occur.		No

1. Ingredient or Process Step	2. Potential food safety hazard introduced, controlled, enhanced or reduced at this step	3. Is the potential food safety hazard significant? (Risk:Severity) (Reasonably likely to occur)	4. Justification for decision (Basis for reasonably likely to occur)	5. If yes, what control measures can be applied to prevent the significant hazard(s)?	6. Is this step a critical control point (CCP)?
6. Prepare Liquid Mix	*Biological*: **Pathogens** *Salmonella* spp. *Escherichia coli* 0157:H7 *Staphylococcus aureus*	Yes	Potential contaminants from equipment, environment, and workers Heating to 180 ˚F (82 ˚C) and maintaining at 140˚F (60 ˚C). ***Not a validated kill step.*** Survivability can't be controlled by subsequent steps(process and storage)	Minimal handling by healthy workers Minimize time between mixing and heating Maintain, clean and inspect equipment prior to preparation, and heating. Use GMPs and SSOPs	**4B**
	Chemical	No	Low risk, not likely to occur.		No
	Physical: Foreign Material	No	Low risk, not likely to occur.	Maintain, clean, and inspect equipment. Screen product (metal detectors)	No
7. Prepare Dough	*Biological*: **Pathogens** *Salmonella* spp. *Escherichia coli* 0157:H7 *Staphylococcus aureus*	Yes	Potential contaminants from equipment, environment, and workers	Minimal handling by healthy workers Minimize time between mixing and extrusion Maintain, clean and inspect equipment prior to preparation. Use GMPs and SSOPs	**5B**
	Chemical	No	Low risk, not likely to occur.		
	Physical:	No	Low risk, not likely to occur.		

1. Ingredient or Process Step	2. Potential food safety hazard introduced, controlled, enhanced or reduced at this step	3. Is the potential food safety hazard significant? (Risk:Severity) (Reasonably likely to occur)	4.Justification for decision (Basis for reasonably likely to occur)	5.If yes, what control measures can be applied to prevent the significant hazard(s)?	6. Is this step a critical control point (CCP)?
8. Extrude	*Biological:* **Pathogens** *Salmonella* spp. *Escherichia coli* 0157:H7 *Staphylococcus aureus*	Yes	Potential contaminants from equipment, environment, and workers a_w will not support growth of pathogenic organism, however, bacterial survival possible if contaminated	Minimal handling by healthy workers; minimize time between extrusion and packaging Maintain, clean and inspect equipment prior to grinding Use GMPs and SSOPs	**6B**
	Chemical	No	Low risk, not likely to occur.		
	Physical	No	Low risk, not likely to occur.		
9. Vacuum Pack	*Biological:* **Pathogens** *Salmonella* spp. *Escherichia coli* 0157:H7 *Staphylococcus aureus*	Yes	Potential contamination from packaging material, equipment, environment, and workers	Protect product from contamination during filling and sealing. Minimal handling by healthy workers. Maintain, clean, and inspect equipment prior to packaging. Use GMPs & SSOPs Test final product, certificate of analysis (COA)	**7B**
	Chemical:	No	Low risk, not likely to occur.		
	Physical:	No	Low risk, not likely to occur.		
10. Finished Product Storage	*Biological*:	No	Low risk, not likely to occur.		
	Chemical:	No	Low risk, not likely to occur.		
	Physical:	No	Low risk, not likely to occur.		
11. Shipping	*Biological*:	No	Low risk, not likely to occur.		
	Chemical:	No	Low risk, not likely to occur.		
	Physical:	No	Low risk, not likely to occur.		

GENERIC HACCP PLAN
PROCESS CATEGORY: Ready-to-Eat Shelf Stable
PRODUCT: Bars Products

CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
Receiving Ingredients **1B**	Certificate of Conformance (CoC) ensuring ingredients meet required specification. Ensure receiving temperatures for refrigerated items are below 40°F	Receiving personnel verify each shipment for approved sources and CoC Receiving personnel verify temperature for each shipment	Receiving Log Corrective Action Log	Annual audit of suppliers for HACCP plans and pathogen testing	Reject products from unapproved sources. Contact suppliers when CoC does not accompany shipment. If receiving temperature is exceeded, discard
Storage of Food Ingredients (frozen, refrigerated, non-refrigerated) **2B**	Raw product areas not to exceed 40 °F in chill rooms; 28 °F in tempering rooms; nor 10 °F in freezer Protect from cross contamination	Develop storage SOPs. Maintenance personnel check and record raw product storage area temperature twice daily. Continuous temperature recorders set to activate alarm if limits are exceeded	Room Temperature Log. Thermometer Calibration Log Corrective Action Log	Maintenance supervisor verifies accuracy of Room Temperature Logs. QA checks calibration of thermometers used for monitoring & verification for accuracy daily, and calibrates within 2 °F accuracy.	Product placed on hold when temperature deviation occurs. QA Inspects and product will be either fully cooked or condemned. QA will identify the cause of the deviation and prevent reoccurrence. Maintenance conducts repairs as needed.

HACCP PLAN **PROCESS CATEGORY:** Ready-to-Eat Shelf Stable **PRODUCT:** Bars Products					
CCP# and Location	**Critical Limits**	**Monitoring Procedures and Frequency**	**HACCP Records**	**Verification Procedures and Frequency**	**Corrective Actions**
Scale Ingredients **3B**	Personnel must wear gloves and be free from illness.	Production supervisor monitors all employees for compliance. QA performs walk through inspections every hour.	Sanitation Walk Through Log. Corrective Action Log.	Plant Manager and QA Manager review Sanitation Walk Through Logs daily.	Personnel not wearing gloves will be immediately removed from line. Personnel showing signs of illness will not be allowed to work in this area.
Prepare Liquid Mix **4B**	Personnel must wear gloves and be free from illness.	Production supervisor monitors all employees for compliance. QA performs walk through inspections every hour	Batch Log. Thermometer calibration Log. Corrective Action Log.	Production supervisor signs each Batch Log. QA calibrates thermometers daily.	Personnel not wearing gloves will be immediately removed from line. Personnel showing signs of illness will not be allowed to work in this area. If above are identified, product since last walk-through will be placed on HOLD and tested for the presence of salmonella.
Prepare Dough **5B**	Personnel must wear gloves and be free from illnesses.	Production supervisor monitors all employees for compliance. QA performs walk through inspections every hour.	Sanitation Walk Through Log. Batch Log. Corrective Action Log.	Plant Manager and QA Manager review Sanitation Walk Through Logs daily.	Personnel not wearing gloves will be immediately removed from line. Personnel showing signs of illness will not be allowed to work in this area. If above are identified, product since last walk-through will be placed on HOLD and tested for the presence of salmonella.

GENERIC HACCP PLAN **PROCESS CATEGORY:** Ready-to-Eat Shelf **PRODUCT:** Bars Products					
CCP# and Location	**Critical Limits**	**Monitoring Procedures and Frequency**	**HACCP Records**	**Verification Procedures and Frequency**	**Corrective Actions**
Extrude **6B**	Personnel must wear gloves and be free from illnesses.	Production supervisor monitors all employees for compliance. QA performs walk through inspections every hour.	Sanitation Walk Through Log. Batch Log. Corrective Action Log.	Plant Manager and QA Manager review Sanitation Walk Through Logs daily.	Personnel not wearing gloves will be immediately removed from line. Personnel showing signs of illness will not be allowed to work in this area. If above are identified, product since last walk-through will be placed on HOLD and tested for the presence of salmonella.
Vacuum Package **7B**	Personnel must wear gloves and be free from respiratory illnesses. Each package must contain an oxygen scavenger sachet	Production supervisor monitors all employees for compliance. QA performs walk through inspections every half hour.	Sanitation Walk Through Log. Batch Log. Inventory Pull Sheets. Corrective Action Log.	Plant Manager and QA Manager review Sanitation Walk Through Logs daily. Production supervisor signs each Batch Log. Verification testing	Personnel not wearing gloves will be immediately removed from line. Personnel showing signs of illness will not be allowed to work in this area. If above are identified, product since last walk-through will be placed on HOLD and tested for the presence of salmonella spp. Lots affected are placed on HOLD when any deviation