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Request For Variance

State Form 51184 (12-02)

Food Protection Program

OCT 22 2012

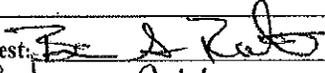
FOOD PROTECTION PROGRAM  
INDIANA STATE DEPT. OF HEALTH

INDIANA STATE DEPARTMENT OF HEALTH

Telephone: 317/233-7360

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<b>1. Individual Submitting Request:</b>		Date: <u>10 / 1 / 2012</u>	
Name: <u>Brian Rote</u>		Telephone: <u>(219) 871-1546</u>	Fax: <u>(219) 871-1547</u>
Mailing Address: <u>5718 Franklin st.</u>		Email: _____	
	<small>Number &amp; Street</small>		
	<u>Michigan City</u>	<u>IN</u>	<u>46360</u>
<small>P.O. Box</small>	<small>City</small>	<small>State</small>	<small>Zip Code</small>
<b>2. Person/Organization Seeking Variance:</b>			
Name: <u>Texas Corral</u>		Email: _____	
Mailing Address: <u>5718 Franklin st.</u>			
	<small>Number &amp; Street</small>		
	<u>Michigan City</u>	<u>IN</u>	<u>46360</u>
<small>P.O. Box</small>	<small>City</small>	<small>State</small>	<small>Zip Code</small>
<b>3. Food Establishment(s) for Which Variance is Sought</b>			
Include the following information for each food establishment: (List here or attach additional pages if necessary)			
• Physical Location (if different than mailing address): <u>same as above</u>			
• Mailing Address: _____			
<small>(Number, Street, City, State, &amp; Zip Code)</small>			
• Telephone Number: ( ) _____ Fax Number: ( ) _____			
• Person at each retail food establishment most responsible for supervising: _____			
<b>4. State how the proposal varies from each rule requirement, citing relevant rule sections by number:</b>			
(Attach additional pages if necessary)			
See attached page 1 of the proposal.			
<b>5. Explain how the potential public health hazards and/or nuisances will be alternatively addressed by the proposal. Include supporting studies, Hazard Analysis Critical Control Point (HACCP) Plan(s), standard sanitation operating procedures, and/or any other evidence: (Attach additional pages, if necessary.)</b>			
Please see attached HACCP documentation pages 1-12 of 48: labeled Flavorseal Cook chill HACCP. The standard operating procedures address all potential health issues.			

<p><b>6. List how the proposal demonstrates the following (if applicable to the request):</b></p> <p>A) How the proposal differs from what is common and usual in similar industry situations:  6a. This proposal allows us to take the food product through the "Danger Zone" much quicker than other commonly used methods.</p> <p>B) How the proposal is unique and not addressed in existing rules or law:  6b. Cook and Chill foods are not unique, it is just unique to be done on premis</p> <p>C) How the proposal does not diminish the protection of public health:  6c. This proposal will result in better protecting the public health as it will bring product through the "Danger Zone" much more quickly than previous methods utilized. Furthermore, with the implementation of the proposed HACCP plan, there will be much more monitoring of temperatures and logs that can be referenced in the future.</p> <p>D) How the proposal is based on new scientific or technological principle(s):  n/a</p> <p>E) How the implementation of the variance would be practical:  The Variance would allow for a much faster cooling method to further reduce the potential for time/temperature abuse. Furthermore, it is a much safer way to handle food throughout the kitchen in 1g1 portions .</p>	
<p><b>7. Explain how the person/organization seeking the variance will assure that all provisions of a granted variance will be enacted at each food establishment for which a variance has been granted:</b></p> <p>7. The G.M. will hold a training session to properly train all individuals and management on the proper use of the machine and the subsequent records and logs that need to be maintained to insure the process' integrity.</p>	
<p><b>8. List all affected parties known by the person/organization seeking a variance, including all affected regulatory authorities: (Attach additional pages if necessary)</b></p> <p>Indiana Department of Health.  Laporte County Health Department</p>	
<p><b>9. Attach copies of any related variances, waivers or opinions issued by other governmental agencies.</b></p>	<p><b>For Office Use Only</b></p>
<p><b>10. Signature of Individual Making Request:</b> </p> <p>Printed Name, Title: <u>Bryan Rote G.M.</u></p>	

**4. State how the proposal varies from each rule requirement, citing relevant rule sections by number:**

Texas Corral respectfully requests a variance to 410 IAC 7-24-195 reduced oxygen packaging criteria. Our proposal requests that Texas Corral be allowed to submit HACCP plans and SOP materials that reflect current operating practices across the USA that are aligned with the 2007 supplement to the 2005 FDA food code sections 3-502.12 (D). this section allows for the preparation of Cook Chill foods without a variance when all aspect of section 3-502.12 (D) are met. These provisions are reproduced below.

**3-502.12 Reduced Oxygen Packaging, Criteria**

(D) except as specified under (C) of this section, a Food Establishment may package food using a Cook Chill or Sous Vide process without obtaining Variance if:

(1) the food establishment implements a HACCP plan that contains the information as specified under 8-201.14(D).

(2) The food is:

(a) Prepared and consumed on the premises, or prepared and consumed off the premises but within the same business entity with no distribution or sale of the bagged product to another business entity or the consumer..

(b) Cooked to heat all parts of the food to a temperature and for a time as specified under 3-401.11

(c) Protected from contamination after cooking as specified under part 3-4.

(d) Placed in a package or bag with an oxygen barrier and sealed before cooking, or placed in a package or bag and sealed immediately after cooking, and before reaching a temperature below 135 degrees F.

(e) Cooled to 41 degrees F. in the sealed package or bag as specified under 3-501.14 and subsequently:

(i) Cooled to 34 degrees F. within 48 hours of reaching 41 degrees F. and held at that temperature until consumed or discarded within 30 Days after the date of preparation.

(ii) Cooled to 34 degrees F. within 48 hours of reaching 41 degrees F., removed from refrigeration equipment that maintains 34 degrees F. food temperature and then held at 41 degrees F. or less for no more than 72 hours, at which time the food must be consumed or discarded;

(iii) Cooled to 38 degrees F. or less within 24 hours of reaching 41 degrees F. and held there for no more than 72 hours from packaging , at which time the food must be consumed or discarded, or

(iv) held frozen with no shelf life restriction while frozen until consumed or used.

Page 1

**HACCP-based  
Food Safety Program**  
**No-variance required**  
*exceeds US FDA model Food Code requirements*

**FLAVORSEAL**  
A C M S C O M P A N Y

✓ **Cook chill HACCP**

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## A. Cook-chill and sous vide US FDA model food code requirements

The following is summary of the 2009 US FDA model Food Code Section 3-502.12. It specifies the requirements for cook-chill and sous vide food manufacturing at retail. Under the model Food Code if an operator creates and uses a HACCP program meeting the requirements below, they are not required to submit a variance request. It is important that the operator verify with their regulatory authority if section 3-502.12 has been adopted by them into their local food code.

### Based on the US FDA model food code (2005 and 2009) a FOOD ESTABLISHMENT that PACKAGES FOOD using a cook-chill or sous vide process shall:

REQUIREMENT	ADDRESSED
Implement a HACCP plan that contains the information as specified under 8-201.14(D)	This document
Ensure the food is prepared and consumed on the PREMISES, or prepared and consumed off the premises but within the same business entity with no distribution or sale of the packaged product to another business entity or the consumer	GMP 3
Ensure the food is cooked to heat all parts of the food to a temperature and for a time as specified under 3-401.11	HACCP COOKING CCP
Ensure the food is protected from contamination before and after cooking as specified under 3-302 through 3-307.	GMP / SOP 2
Ensure the food is placed in a package with an oxygen barrier and sealed before cooking, or placed in a package and sealed immediately after cooking and before reaching a temperature below 57°C (135°F)	HACCP BAGGING CCP
Ensure the food is cooled to 5°C (41°F) in the sealed package or bag as specified under 3-501.14	HACCP COOLING1 CCP
OPTION 1. And subsequently cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held at that temperature until consumed or discarded within 30 days after the date of packaging	HACCP COOLING2 CCP & GMP / SOP4
OPTION 2. And subsequently cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), removed from refrigeration equipment that maintains a 1°C (34°F) food temperature and then held at 5°C (41°F) or less for no more than 72 hours, at which time the food must be consumed or discarded	HACCP COOLING2 CCP & GMP / SOP4
OPTION 3. And subsequently cooled to 3°C (38°F) or less within 24 hours of reaching 5°C (41°F) and held there (38°F) for no more than 72 hours from packaging, at which time the food must be consumed or	HACCP COOLING2 CCP & GMP / SOP4

discarded.	
Ensure the food is held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily	GMP / SOP 4
Ensure the food if transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation	GMP / SOP 4
Ensure the food is labeled with the product name and the date packaged	GMP / SOP 3
Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP plan	GMP / SOP 6
Make such records available to the regulatory authority upon request, and hold such records for at least 6 months	GMP / SOP 6
<b>Required Good manufacturing practices and standard operating procedures</b>	
Implement written operational procedures as specified under 3-502.12 (B)(5) and a training program as specified under 3-502.12 (B)(6)	All SOPs GMP / SOP 5
Includes operational procedures that prohibit contacting ready-to-eat food with bare hands as specified under 3-301.11(B)	GMP / SOP 1
Includes operational procedures that identify a designated work area and the method by which: physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination	GMP / SOP 2
Includes operational procedures that delineate cleaning and sanitation procedures for food contact surfaces	GMP / SOP 2
Includes operational procedures that describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the concepts required for a safe operation, equipment and facilities, and procedures (GMPs and SOPs)	GMP / SOP 5
<b>Required recordkeeping (forms)</b>	
Process log (CCP monitoring, deviations and corrections)	
Refrigeration temperature logs (manual and continuous)	
Expiration, discard, and reheating log	
Thermometer calibration log	
Employee training log	
References above refer to the 2009 model US FDA Food Code. Items are addressed in four types of documents: HACCP, good manufacturing policies (GMPs), standard operating procedures (SOPs), and records (RECs).	

## B. Product description-cook chill foods

Formulations/recipes are found in section H.

1. Product name(s)	Cook-chill foods: Black Bean Soup, Chili, Steak mushrooms, all Soups of the day
2. How is the product to be used & who's the intended consumer?	These products are intended for general consumer use. Consumers may be immunocompromised as part of the general population.
4. Type of packaging and servings	Special low oxygen transfer rate packaging is used. Servings vary per product
5. Shelf life	3 Days at 41 degrees or lower
6. Where will the product be sold?	In-house foodservice direct to consumer
7. Labeling instructions	<p>Product name _____ Cook chill</p> <p style="text-align: center;"><b>Ready to REHEAT</b></p> <p>Manufacture date _____</p> <p>Date and time reached 41°F _____</p> <p>Use or discard by _____</p> <p style="text-align: center;"><b><i>IMPORTANT: This product must be stored at ≤ 41°F and has a limited shelf life.</i></b></p>
8. Special distribution control	Ensure the food is prepared and consumed on the premises, or prepared and consumed off the premises but within the same business entity with no distribution or sale of the packaged product to another business entity or the consumer. Refrigeration and shelf lives are described in this document.

HACCP Coordinator Brian Rote Date:6/7/12

Sign this document after first review, then anytime it is modified. If needed, indicate here that the document is a revised version. Save the original to the HACCP Program Change Log file.

### C. Flow diagram cook chill foods

*You must edit these steps to match your exact process.*

Step No.	Step Name	Step Description
1.	Purchasing	All raw materials are purchased from approved suppliers.
2.	Receiving	Raw ingredients received and inspected at the loading dock by an employee.
3.	Storage	Raw ingredients are placed into storage either in room temperature racks, refrigerator or freezer.
4.	Thawing	If needed, frozen foods shall be thawed in the refrigerator for 24-48 hours.
5.	Ingredient Assembly	Raw ingredients are assembled to prepare foods.
6.	Cooking	Foods are cooked by boiling .
7.	Bagging	Employees manually ladle approx. 1 gal. food into food grade 3 mil boil-in bags. Bags are sealed.
8.	Heat sealing and labeling	Bags are heat sealed. Completed labels are applied to each bag.
9.	Cooling	layers of bags are placed in Ice Water Bath made in a 20 gallon food grade plastic bin. Bags are rotated every 15 min. Ice is refreshed every 30 minutes. (Operation performed outside of cooler). Bags are cooled to 41°F.
10.	Refrigeration	Bags are maintained at ≤41°F for approved shelf life of 72 hours. Note: 2013 Food Code will reflect a 7 day shelf life in the bag.
11.	Reheating for hot holding	Bags of product are removed from the cooler and placed inside boiling water to reheat. Bags must be heated to ≥165°F.
12.	Hot holding	Food products are maintained at ≥135°F.
13.	Leftover refrigeration	Leftovers from hot holding may be cooled following step 9 in shallow pans and refrigerated at ≤41°F for the balance of the 7 day date marking shelf life.
14.	Service	

HACCP Coordinator Brian Rote Date 6/7/12

Validated by \_\_\_\_\_ Date \_\_\_\_\_

### D. Hazard analysis cook-chill raw materials

<i>Raw Materials</i>				
Ingredient or Material	Potential Hazards Introduced, Controlled, Enhanced or Reduced	Is this Hazard Reasonably Likely to Occur?	Justification for Decision to Determine Significance	Control Measures (Barriers)
<i>B-biological, C-chemical, and P-physical hazards</i>				
<b>Bags</b>	C-plastic may not be food grade or heat stable	C-yes		Purchasing specifications
<b>Meats and Poultry</b>	B- Vegetative pathogens, e.g. <i>E. coli</i> , <i>Salmonella</i> , and <i>Listeria monocytogenes</i> .  Sporeforming pathogens: <i>Clostridium botulinum</i> , <i>C. perfringens</i> , and <i>Bacillus cereus</i>  Parasites may be associated with meats (pork – <i>Trichinella</i> )  P – no common hazard C – no common hazard	B- yes P – no C – no	USDA FSIS Meat and Poultry Hazards and Controls Guide, 2005 Model FDA Food Code	Vegetative pathogens – cooking and cross contamination control
<b>Starches</b>				<i>C. botulinum</i> and <i>B. cereus</i> – controlled by refrigeration below 41°F
<b>Vegetables</b>				Psychrotrophic <i>C. botulinum</i> controlled by time-temperature limits
<b>Fruits</b>				<i>L. monocytogenes</i> controlled by cooking (sous vide) and bagging at ≥145°F and cross contamination control (Cook-chill)
<b>Spices</b>				<i>C. perfringens</i> is controlled by rapid cooling and refrigeration below 41°F.

HACCP Coordinator        Brian Rote    Date 6/7/12

Validated by \_\_\_\_\_ Date \_\_\_\_\_

**E. Hazard analysis cook-chill process**

Process Step	Potential Hazards Introduced, Controlled, Enhanced or Reduced	Is Hazard Likely to Occur?	Control Measure and Food Code Standard
1. Purchasing	Hazards are indicated in raw materials analysis		
2. Receiving	B- outgrowth of pathogens	yes	Control measures are thoroughly described in Food Code 3-501.11 and 3-501.16.
3. Storage	B- outgrowth of pathogens	yes	
4. Thawing	B- outgrowth of pathogens	yes	Thawing under refrigeration as described in the Food Code 3-501.13.
5. Ingredient Assembly	B- outgrowth of pathogens, environmental pathogens	yes	Prevention of contamination 3-302 through 3-307. Foods will be cooked at a later step.
6. Cooking	B- destruction of vegetative pathogens	yes	Proper Cooking temperature achieved per Food Code 3-401.11
7. Bagging	B- introduction of environmental pathogens	yes	Bagging temperature $\geq 135^{\circ}\text{F}$ per 3-502.12
8. Heat sealing and labeling	B-pathogen outgrowth due to improper shelf life monitoring	yes	Labeling is required on each bag per 3-502.12.

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9. Cooling	B- outgrowth of <i>C. perfringens</i>	yes	Cooling rapidly is required per 3-501.14 & 15.
10. Refrigeration	B- outgrowth of psychrotrophic <i>C. botulinum and Listeria monocytogenes</i>	yes	Refrigeration must be maintained at $\leq 41^{\circ}\text{F}$ per 3-502.12 (D)(2)(e)(iii). Amended shelf life accepted for 2013 food code allows 7 day shelf life..
11. Reheating for hot holding	B- outgrowth of psychrotrophic <i>C. botulinum and Listeria monocytogenes</i>	yes	Reheating to $\geq 165^{\circ}\text{F}$ will kill <i>L. monocytogenes</i> per 3-403.11.
12. Removal from bags	none	no	
13. Hot holding	B- outgrowth of pathogens	yes	Maintaining foods $\geq 135^{\circ}\text{F}$ will prevent growth of pathogens per 3-501.16.
14. Leftover cooling and refrigeration	B-outgrowth of pathogens	yes	Cooling following step 9 followed by refrigeration $\leq 41^{\circ}\text{F}$ unpackaged in shallow pans for maximum 7 days from manufacture. This step is permissible by an interpretation of USFDA CFSAN.NOTE: Amended shelf life accepted for 2013 food code allows 7 day shelf life <b>in the bag.</b>
15. Service	none	no	

*B-biological hazard*

HACCP Coordinator \_\_\_ Brian Rote Date: 6/7/12

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### F. HACCP plan cook chill

<b>Cook-Chill HACCP</b>							
Process Step	Hazards	CCP FC SOP	Critical Limits	Monitoring	Corrective Actions	Records	Verification
1. Purchasing	B- Pathogens C- bags	FC	Purchase foods and bags only from approved suppliers.	Bags must be food grade and heat stable.		Supplier List	Supplier Verification Letters
2. Receiving	B- Outgrowth of pathogens	FC	Cold foods received $\leq 41^{\circ}\text{F}$ . Frozen foods rec'd frozen. Products immediately refrigerated or frozen	Employee monitors receiving temps.	Reject any ingredient that is $42^{\circ}\text{F}$ or above or reject any frozen product that shows signs of having been thawed.	Receiving Log	- Records reviewed by supervisor. - Observe employee performing temperature measurement.
3. Storage	B- Outgrowth of pathogens	FC	Refrigerated foods must remain $\leq 41^{\circ}\text{F}$ . Frozen foods must remain frozen. Dry foods must be stored properly.	Monitor temperature of refrigerator twice daily or via refrigeration SOP.	If ambient temperature $>41^{\circ}\text{F}$ , check foods. If foods $>41^{\circ}\text{F}$ , discard. Repair equipment.	Refrigerator Temperature Log	- Thermometers calibrated once weekly. - Records reviewed by supervisor. - Observe employee
4. Thawing	B- Outgrowth of pathogens	FC	All thawing done in refrigerator.				
5. Ingredient Assembly	B- Outgrowth of pathogens	FC	Minimize 41-135°F to less than 1h during preparation.	Time	Return ingredients to refrigeration or begin cooking within 1h.	Process Log	- Records reviewed by supervisor. - Observe employee.

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6. Cooking	B- Outgrowth of pathogens	CCP1	Cook $\geq 145^{\circ}\text{F}$ for 15s. If meat is comminuted raise time to 3 minutes. Alternative cooking methods are listed in Appendix A.	Monitor temperature and time of cooking	Continue Cooking	Process Log	- Records reviewed by supervisor. - Observe employee.
7. Bagging	B- Outgrowth of pathogens, environmental or hygiene contamination	CCP2	Bagged foods must not be $< 135^{\circ}\text{F}$ .	Employee will monitor food temperature during bagging measuring at least one bag every 15 minutes.	If food temperature is $< 135^{\circ}\text{F}$ , reheat foods to full cooking temperature.	Process Log	- Records reviewed by supervisor. - Observe employee.
8. Heat sealing and labeling	none	SOP	Labels required to determine shelf life	Each bag must have a label.	All unlabeled or mislabeled product must be discarded.		
9. Cooling	B- Outgrowth of pathogens	CCP3	Cool from 135 to $70^{\circ}\text{F}$ within 2h and $70-41^{\circ}\text{F}$ within 4 h. Goal is to cool to $41^{\circ}\text{F}$ within 2 h.	Employee will monitor cooling by measuring three bags from different locations of the cooling tub. Bags will be massage mixed, then folded over probe.	Refresh ice to obtain rapid cooling. If $\geq 71^{\circ}\text{F}$ after 2h reheat to $165$ deg. F. for min. 15 sec. If temp. does not go from $70-41^{\circ}\text{F}$ within 4h, discard.	Safe Cooling Chart	- Records reviewed by supervisor. - Observe employee.
10. Refrigeration	B- Outgrowth of psychrotrophic pathogens	oCCP* SOP	Maintain bagged foods $\leq 41^{\circ}\text{F}$	Refrigerator electronically monitored and manually verified 2X daily.	If ambient temperature $>41^{\circ}\text{F}$ , then check bagged foods. If bagged foods $>41^{\circ}\text{F}$ , discard.	Refrigeration Log	- Records reviewed by supervisor. - Observe employee.
11. Reheating	B- Outgrowth of	FC	Reheat to $165^{\circ}\text{F}$	Monitor temperature of	Continue	Expiration,	

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	pathogens	(15 s)	food.	reheating.	discard, and reheating log	
13. Hot holding	B- Outgrowth of pathogens FC	Hot hold $\geq 135^{\circ}\text{F}$	Monitor temperature of food.	Immediately adjust hot holding equipment.	Hot holding Log	
14. Leftover cooling	B - Outgrowth of pathogens FC	Cool from 135 to 70°F within 2h and 70-41°F within 4 h.	Employee will monitor cooling by measuring food temperature.	If $\geq 71^{\circ}\text{F}$ after 2h discard food. If temp. does not go from 70-41°F within 4h, discard.	Process Log	- Records reviewed by supervisor. - Observe employee.
15. Leftover refrigeration	B - Outgrowth of psychrotrophic pathogens FC	Maintain foods $\leq 41^{\circ}\text{F}$	Refrigerator temperature manually verified 2X daily.	If ambient temperature $> 41^{\circ}\text{F}$ , then check foods. If foods $> 41^{\circ}\text{F}$ , discard.	Refrigeration Log	- Records reviewed by supervisor. - Observe employee.

FC-Food Code; SOP-Standard operating Procedure; CCP-Critical Control Point; oCCP

\*Because refrigeration is critical, but involves foods from multiple "batches" it is controlled using an "operational" CCP. This CCP is covered in the refrigeration GMP and SOP program and not in the HACCP Plan.

HACCP Coordinator          Brian Rote          Date          6/7/12

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### G. CCP summary cook chill

<i>Cook-chill</i>				
CCP	Description	Critical Limit	Monitoring Procedures	Corrective Actions
CCP1	Cooking	165 degree F. for min 15 sec.	<b>What:</b> Temperature <b>How:</b> Use a calibrated thermometer. Insert into center of meat roasts or mix foods well then measure. <b>Frequency:</b> Each batch <b>Responsible Person:</b> Cook	Continue Cooking
CCP2	Bagging	All foods must be bagged $\geq 135^{\circ}\text{F}$	<b>What:</b> Temperature <b>How:</b> Use a calibrated thermometer. Insert into center of meat roasts or mix foods well then measure. <b>Frequency:</b> Every 15 min. <b>Responsible Person:</b> Cook	Recook foods based on CCP1
CCP3	Cooling1	135 to 70°F within 2h and 70-41°F within 4 h. (U.S. FDA Food Code)	<b>What:</b> temperature & time <b>How:</b> Using a calibrated thermometer. Mix bag ingredients well by massage, fold bag over probe, then measure. <b>Frequency:</b> 3 bags per batch, each batch <b>Responsible Person:</b> Cook	If temperature is not dropping quickly consider adding more ice. If temperature has not reached 70°F within 2h discard food. Record in deviation and discard log. If temperature does not go from 70-41°F within 4h, discard. Record in deviation log.
oCCP1	Refrigeration	$\leq 41^{\circ}\text{F}$ required	<b>What:</b> temperature <b>How:</b> A) Place a calibrated thermometer in unit. Read manually 2X daily. B) 24/7 continuous monitoring using a digital thermocouple and datalogger. <b>Frequency:</b> A) 3 bags per batch, each batch <b>Responsible Person:</b> Cook	If temperature of ambient is above 41°F, check food bags. If temperature of foods is $\leq 41^{\circ}\text{F}$ , then enter in log book as safe. If foods are above 41°F discard. Record discards in deviation and discard log.

HACCP Coordinator Brian Rote Date 6/7/12