農林水産省補助事業

米国食品安全強化法

「ヒト向け食品に関する現行適正製造規範ならびに危害分析およびリスクに応じた予防管理」規則にかかる食品安全計画雛形（まんじゅう）
＜英語原文＞

2017 年 3 月

日本貿易振興機構（ジェトロ）

農林水産・食品部　農林水産・食品課

シカゴ事務所

本資料は、2015 年 8 月 31 日に最終化、同年 9 月 10 日に公表された米国食品安全強化法「ヒトが摂取する食品に関する予防的管理措置についての最終規則」に関して、米国の弁護士事務所 Olsson Frank Weeda Terman Matz PC(OFW)に委託をして食品安全計画の雛形（まんじゅう）を作成したものです。

＜Olsson Frank Weeda Terman Matz PC(OFW)＞
ウェブサイト： http://www.ofwlaw.com
コンタクト先：Mr.Bruce Silverglade, Principal Attorney
bsilverglade@ofwlaw.com

お役立ち度アンケートへのご協力のお願い

ジェトロでは、米国食品安全強化法（FSMA）への対応の参考とすることを目的に本調査報告書を実施しました。ぜひお役立ち度アンケートにご協力をお願いいたします。

◆本報告書のお役立ち度　（必須）

□役に立った　□まあ役に立った　□あまり役に立たなかった　□役に立たなかった

その理由をご記入ください。

◆本報告書をご覧になり、実際にビジネスにつながった例がありましたらご記入ください。（任意）

◆今後のジェトロの調査テーマについてご希望等がございましたら、ご記入願います。（任意）

◆貴社・団体名（任意）

◆お名前（任意）

◆メールアドレス（任意）

◆企業規模　（必須）　　□大企業　　□中小企業　　□その他

FAX 送信先：03-3582-7378　ジェトロ農林水産・食品課宛

本アンケートはインターネットでもご回答頂けます

（ https://www.jetro.go.jp/form5/pub/afa/fsma ）

※お客様の個人情報につきましては、ジェトロ個人情報保護方針に基づき、適正に管理運用させていただきます。また、上記のアンケートにご記載いただいた内容については、ジェトロの事業活動の評価および業務改善、事業フォローアップ、今後の調査テーマ選定などの参考のために利用いたします。

【報告書名：米国食品安全強化法「ヒト向け食品に関する現行適正製造規範ならびに危害分析およびリスクに応じた予防管理」規則にかかる食品安全計画雛形（まんじゅう）＜英語原文＞】

はじめに

本調査報告書は、2015 年 8 月 31 日に最終化、同年 9 月 10 日に公表された米国食品安全強化法「ヒト向け食品に関する現行適正製造規範ならびに危害分析およびリスクに応じた予防管理」（PCHF）規則に関して、食品安全計画の策定のための参考資料として「まんじゅう（黒糖まんじゅう）」を例に作成した雛形（英語原文）である。

食品安全計画の様式は PCHF 規則では規定されていない。またそれぞれの施設によって設備や製品、製造工程などは個々に異なるため、本報告書に記載された内容はあくまで一例である。実際の事業者の食品安全計画は、この雛形に、施設固有の管理すべき危害や予防管理手順を修正・追加することによって、適切なものとなる点に留意いただきたい。

なお、ジェトロは他にも「冷凍チャーハン」「味噌」「ドレッシング」の雛形を作成しているので、参考にしていただきたい。

本調査報告書が米国食品安全強化法（FSMA）への対応の一助となれば幸いである。

2017 年 3 月

日本貿易振興機構（ジェトロ）
農林水産・食品部　農林水産・食品課
シカゴ事務所

Table of Contents

1. Preventive Controls Plan Overview 2
2. Flow Chart 6
3. Product Description 8
4. Generic Preventive Controls Plan 10
5. Example - Training Document 51
6. Example - Storage Area GMP Audit 53
7. Example - Generic Recall Program 55
8. Example - Reanalysis Form 70
9. Example - Equipment Calibration Log 72
10. Example - Corrective Action Record 74
11. Example - Metal Detection Log 76
12. Example - Batch Formulation Log 78

1. Preventive Controls Plan Overview

Preventive Controls Plan Overview

The United States Food and Drug Administration's (FDA) Preventive Controls for Human Food regulation provides a proactive and systematic approach to food safety. It is similar to other risk-based food safety programs such as the FDA low-acid canned food regulations, FDA Seafood HACCP regulations and the United States Department of Agriculture's (USDA) Food Safety and Inspection Service's (FSIS) HACCP regulations.

- Preventive control programs are structured to work in conjunction with, and be supported by, other relevant programs such as Good Manufacturing Practices (GMPs), good agriculture practices and good transportation practices.
- A preventive controls plan incorporates controls that go beyond those that would be managed as Critical Control Points (CCP) in the traditional Hazard Analysis Critical Control Points (HACCP) framework. While CCPs may be included (most commonly for process steps that are critical for the safety of the food), the preventive controls plan also includes controls for hazards related to food allergens, sanitation, suppliers and any other hazards requiring a preventive control. While CCPs are associated with a maximum and/or minimum value, other preventive controls will use parameters and values that will not have a precise critical limit.
- Also, a deviation of some preventive controls may only require an immediate correction (such as re-cleaning a production line prior to start-up of production) rather than a formal corrective action that includes product risk evaluations and development of preventive measures. Moreover, the validation activities (demonstrating the controls actually work) may be less rigorous for some preventive controls than others such as those that would qualify as a CCP under a HACCP approach.
- The FDA regulation requires that the original records or true copies be retained for at least two (2) years after the date they were prepared. Records supporting the process and its adequacy, such as validation studies, must be retained as long as necessary to support the operation and then at least two (2) years after their use is discontinued. Other details may be found in the regulation.
- All records and documents must include information adequate to identify the plant or facility (*e.g.*, name, and when necessary, the address of the plant or facility).
- If a facility identifies the need for a preventive control when it completes its hazard analysis, it must then also have a written **recall plan** (***see* Supp. #48** for an example of a recall plan).
- Good Manufacturing Practices (GMPs) are addressed in 21 C.F.R. Part 117, Subpart B. Areas addressed by the GMP regulations include personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, warehousing and distribution, holding and distribution of human food by-products for use as animal food, and defect action levels. When doing a hazard analysis, it may be determined that some GMPs may need to rise to the level of a preventive control as it is determined that it is controlling a hazard. For example, if you run product containing wheat flour on a production line and then must change to run a product without wheat flour, you would need to clean the production line to ensure that no allergen cross-contact occurred and wheat was not still present on the line. In this case, the sanitation process would rise to the level of a preventive control.
    - For example, in the Brown Sugar Steamed Buns, some GMPS you would monitor during steps 1 – 8 are as follows:

- Ensure receiving dock and warehouse doors are kept closed when not in use and that all dock brushes and seals prevent access by pests or rodents.
- Ensure that there are no uncovered or damaged containers of ingredients, products or product packaging.
- Ensure that all ingredients are stored correctly if they contain various types of allergens.
- Ensure there are no uncovered glass bulbs or broken glass in the area.
- Ensure that all containers are properly labeled with ingredient statements and no unapproved items are stored in the same area as product (*e.g.*, cleaning chemicals).

- During steps 16, 25, 26, 28 and 29, also may monitor the following:
  - Ensure that product containers are properly covered to prevent accidental contamination from occurring.
  - Ensure that containers/lots/batches are properly labeled and also have the times the containers/lots/batches were generated if important to the process.
  - If containers/lots/batches of product must be left uncovered, ensure that the overheads are clean and free from anything that may fall onto the product.
  - Ensure there is limited access to stored product so that it does not become accidentally contaminated.
  - Ensure the product is used in the proper order to prevent out-of-date product.
- During steps 17 – 30 where product may be open to the environment, the following GMPs may be monitored:
  - Ensure the overheads are monitored on a routine basis to ensure that there is no condensation that could drip into exposed product.
  - Ensure there is no loose paint or debris that could fall into product.
  - Ensure there are no loose nuts or bolts or other pieces of equipment.
  - Ensure there is not product or ingredients left on the floor for extended times.
  - Ensure that trash is in proper containers and they are not overflowing.
  - Ensure that product does not remain in production areas for too long if the ingredients are temperature-sensitive and the production area is not refrigerated.
  - Ensure that personnel who are handling the product have on frocks and are wearing disposal gloves to prevent direct contact with the product.
  - Ensure that personnel do not wear jewelry in the production area and all personnel have hair restraints and beard nets if needed.
  - Ensure that all facility/room entries are kept closed and there is no ability for pests or insects to enter the area.
- During steps 30 – 34, the following may be monitored:
  - Ensure that labels are correct on all boxes and shipping containers.
  - Ensure that boxes are not damaged and wooden shipping pallets are in adequate condition to prevent product damage.

        - Ensure that trucks are clean, not damaged, and free of debris, pests, and evidence of rodents prior to loading with product.
    - All individuals working in a facility or warehouse are required by regulation to have documentation on file that they have been training in the necessary GMPs appropriate to the job they are performing, in addition to any additional food safety training, to ensure compliance with a facility's food safety plan (*see* 21 C.F.R. § 117.4).
- Supply Chain Preventive Controls – This is one type of a preventive control. When in a hazard analysis, it is determined that a supplier controls the identified hazard; a company must implement a supply chain preventive control. For example, if you are purchasing processed cheese for to put on top of a cooked omelet, the supplier is ensuring that the cheese has been processed using a lethality step to control microbiological hazard (pathogens). Since the supplier is controlling this hazard, as you are not cooking the cheese, you must put in place a supply chain preventive control program to verify that the supplier is performing the lethality process acceptably. Supply chain preventive controls are identified at the receiving steps in a hazard analysis.

This generic plan was developed to serve as a guide. The document provides the framework for the development of a Preventive Control Plan for Brown Sugar Steamed Buns. This generic plan is not intended to be used "as is" for your plant specific preventive control plan. It includes the required steps from the regulations as well as recommendations by FDA.

Since each processor of Brown Sugar Steamed Buns needs to conduct a hazard analysis for their own unique operation, this provides resources to assist in the development of the plant-specific plan. The document includes suggestions (in red) where there are decision points in the process.

Additionally, there are suggested formats for forms included even though there is no specific format required by the regulation.

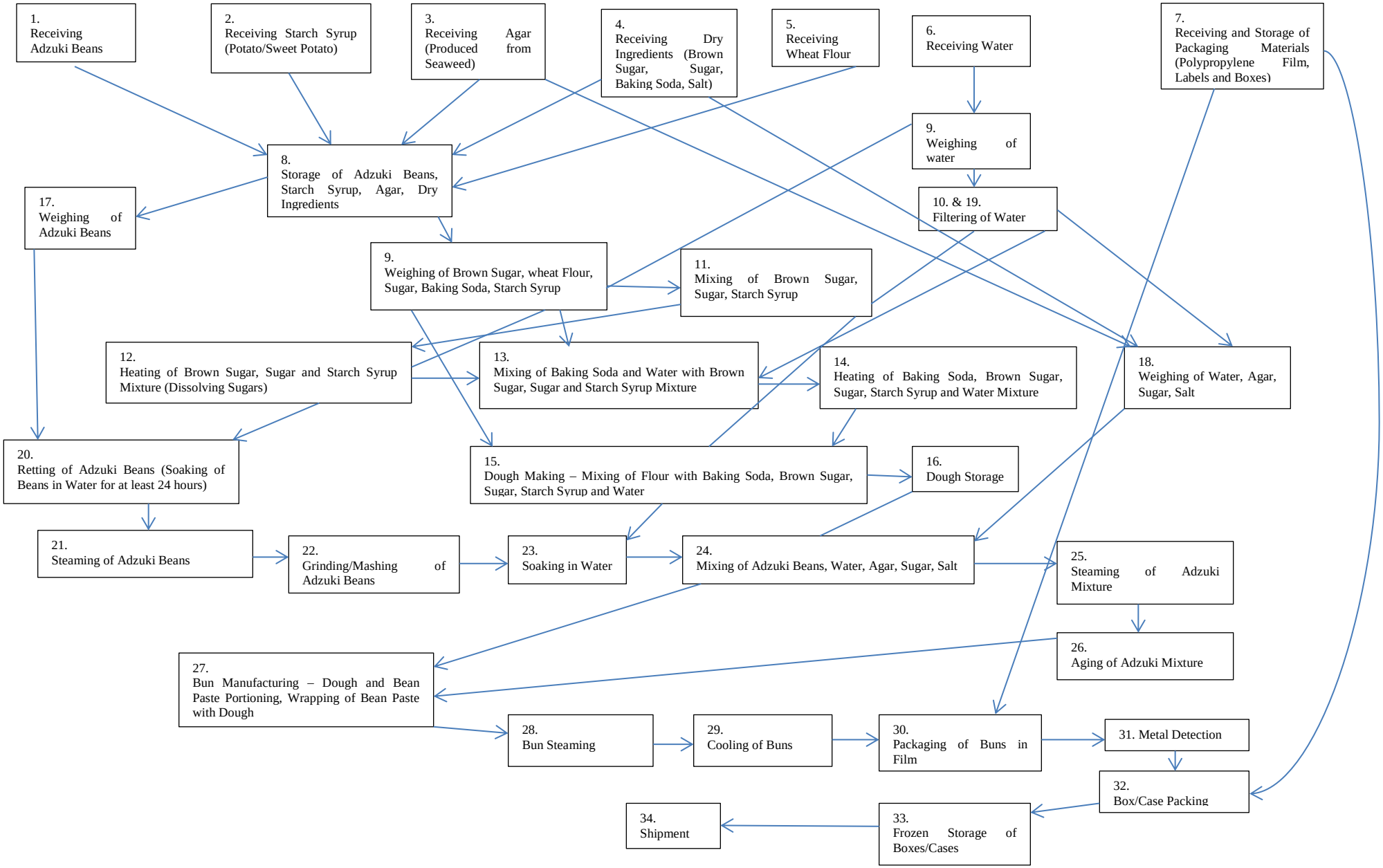
Examples include those identified below from the Supplements list. These procedures and records would be used in implementation of this food safety plan and may be used or modified for use in any facility. There is no regulatory requirement on how procedures or forms must look.

Examples include those identified in the list of Supplements as follows:

#35, Example – SOP Inspection Sifters
#37, Example – Storage Area GMP Audit.
#38, Example – GMP Inspection of Production Areas Audit
#40, Example – PC Form Dough Storage
#41, Example – Employee Training Document
#42, Example – Metal Detection Log
#46, Example – Corrective Action Record
#48, Example – Generic Recall Plan
#49, Example – Reanalysis Form
#50, Example – Equipment Calibration Log

2. Flow Chart

Brown Sugar Steamed Buns
Flowchart



3. Product Description

PLANT NAME(regulation requires that facility name, address be present on forms)	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Product Description Distribution, Consumers and Intended Use[1]

Product Name(s)	Brown Sugar Steamed Buns
Product Description, including Important Food Safety Characteristics	Frozen, ready-to-eat brown sugar steamed buns (A general description of the product & processing method, assembly, & family of products included in the category. If it is relevant to product safety, properties like preservatives, water activity and pH should be listed here.)
Ingredients	Wheat flour[2], adzuki beans, sugar, brown sugar, salt, baking soda, starch syrup, agar, water (Assumed order of predominance – will need to correct if inaccurate) (A list of ingredients, in order of predominance, which may be grouped or transferred from the product label.)
Packaging Used	Polypropylene film used to package individual buns. Packaged buns (12) are boxed in paper package. (A general description of the packaging, including modified atmosphere or vacuum packaging if used)
Intended Use	Frozen distribution for heat and serve consumption (Describe the normal expected use of the food (*e.g.*, ready-to-eat, raw), and where it is sold (*e.g.*, retail, food service, schools, hospitals, *etc.*). If an un-intended use is likely, this should also be identified (*e.g.*, eating product that contains raw eggs without cooking)).
Intended Consumers	General population (Food specifically designed for susceptible populations *e.g.*, hospitals, schools, may require more stringent controls because these foods will be consumed by an at-risk population.)
Shelf Life	Frozen shelf life is XX. Thawed shelf life is 4 days. (List intended shelf-life.)
Labeling Instructions related to Safety	Keep frozen until ready-to-use. (Provide thawing instructions if necessary.) Refrigerate any leftovers. (Include label instructions relevant to food safety e.g., storage condition such as refrigeration, cooking instruction.)
Storage and Distribution	Stored and distributed frozen (List method of distribution *e.g.*, refrigerated, frozen)

Approved: Signature: Print name:	**Date**:

[1] Parameters involving quality should not be listed on the food safety product description. Quality parameters should be kept separate from the food safety preventative control plan.

[2] If enriched flour is used, the ingredients must be sub-listed in ingredient statement above.

4. Generic Preventive Controls Plan

Generic Preventive Control Plan
For Brown Sugar Steamed Buns

Facility Name:
Facility Address:

We have added and made assumptions on some steps in the process. Each facility should ensure that the flowchart and hazard analysis match the steps in its process.

Plant Manager:

Plant Manager Signature:
(The preventive control regulation requires in 21 C.F.R. § 117.310 that the owner, operator or agent in charge of the facility, which could include, must sign and date the food safety plan upon initial completion of the plan and upon any later modification.)

ISSUED:
REVISED:

Preventive Controls Food Safety Team

(The team should consist of individuals with different specialties and experience with the facility's processes and procedures. The Food Safety team should include members who are directly involved with the plant's daily operations and may include personnel from maintenance, production (including equipment experts), sanitation, quality assurance, engineering, purchasing, and laboratory, if applicable. These individuals develop the food safety plan under the oversight of a Preventive Controls Qualified Individual (PCQI), and verify on-going implementation of the food safety system.)

Examples of Participants on a Food Safety Team:

- General Manager
- Preventive Controls Qualified Individual (required) (Supp. #41)
- QA/Technical Service Manager
- QA Supervisor/HACCP Coordinator/Food Safety Manager
- Plant Superintendent
- Packaging Supervisors
- Purchasing Manager
- Processing Supervisors
- Kitchen Supervisors
- Logistics Manager
- Plant Engineer
- Plant Change Agent

PROCESS CATEGORIES AND INGREDIENTS*

(This form is useful to list out ingredients and categories of ingredients and other items used in product production. The ingredients listed below are examples of how a product could be broken into its components.)

Spices/Flavorings	Food Additives	Preservatives/Acidifiers
Other	**Proteins**	**Packaging Materials**
Water** Brown Sugar Sugar Baking Soda Agar Salt	Adzuki Beans Wheat Flour	Polypropylene Film Paperboard
Allergens		
Wheat flour		

* All ingredients and suppliers of those ingredients should be evaluated prior to purchase of the respective ingredient to determine whether or not the ingredient and/or suppler has been involved in a food safety event such as a recall or an outbreak. The supplier and ingredient should be researched in databases relevant to the supplier and the source of the ingredient. For example, in the U.S. it would be expected that as part of a product evaluation into its safety, the Centers for Disease Control and Prevention's (CDC) "The Foodborne Outbreak Online Database" (https://wwwn.cdc.gov/foodborneoutbreaks/) would be reviewed as well as the Food and Drug Administration's (FDA) "Recalls, Market Withdrawals, Safety Alerts" (http://www.fda.gov/Safety/Recalls/) for any concerns that might involve the ingredient and/or the supplier of a respective ingredient. This information should be used in determining the likelihood of a particular hazard to occur.

** Water may or may not be used as an ingredient in product produced. Regardless, any water used for hand washing and sanitation should be potable. The facility should have in its files documentation, on at least an annual basis, that the water used in the facility meets regulatory requirements for potable use. This may be in a form of a letter from the local municipal water supplier stating the water being delivered to the facility meets all local and national standards and it details what those standards are and when it was tested.

ISSUED:
REVISED:

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

HAZARD ANALYSIS

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control? Yes	Do any Potential Food Safety Hazards Require a Preventive Control? No	Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step? Yes	Is the Preventive Control Applied at this Step? No
1.Receiving Adzuki Beans (Dried)	B – *Salmonella*, *B. cereus*, Shiga toxin-producing *E. coli*, *C. perfringens*, *C. botulinum*	X		Vegetative and spore-forming pathogens have been known to contaminate dried legumes, but can be controlled using a lethality process and the low water activity later in the process. (Supp. #1, 25, 26)	Process Preventive Control – subsequent thermal treatment step		X
					Process Preventive Control – subsequent water activity		X
	C – Mycotoxin	X		Mycotoxin production could occur during growth or primary process. (Unless there is an in-house control step to reduce the level of mycotoxins that may be present on incoming dried beans, there must be a supply chain program as mycotoxins would then need to be controlled by the supplier. Based on Supplement #2, incoming dried beans could be washed with a solution of <5% NaCl for one minute to reduce the incoming load.) (Supp. #1, 2, 3, 25)	Supply Chain Preventive Control	X	
	C – Radiological (Whether this is a hazard depends on where the beans are grown)	X		Radiological hazard may result from accidental contamination such as release from a nuclear facility or damage to a nuclear facility during a natural disaster (Supp. #4, 25)	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified auditor	X	
	C- Pesticides (If exporting product to the U.S., pesticides and their usage is		X	No history of unapproved pesticides or findings of residual levels above tolerance that would require pesticides to be addressed as a supplier preventative control (Supp. #5, 6, 25)			

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	regulated by the U.S. Environmental Protection Agency (EPA), which establishes tolerance levels as well as what pesticide may be used.)						
	C – Economically motivated hazard (While a rare occurrence, hazards may be introduced for purposes of economic gain. Only adulteration that affects food safety should be addressed in the Food Safety Plan. Examples have included the addition of melamine to	X		Economically motivated hazard (Supp. #7, 8, 9)	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified audit	X	

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	dairy products in China. While this may be rare, it must be reviewed for each step in the process. Generally, economically motivated hazards are controlled though a supply-chain program. You only must focus on economic adulteration that has a history of resulting in a hazard in food.)						
	P – Metal	X		Pieces of metal may be present in raw material or introduced during the harvesting process from equipment used or the environment. This can be controlled by subjecting the product to metal detection (Supp. #10, 11)	Process Preventive Control – metal detection at subsequent step		X (Can be done on receiving or after

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
							bun production.)
	P – Foreign Material: Stones		X	Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on the size and shape of the stones, they present a hazard for dental injury or choking. Depending on size and shape of the object, it may cause choking, injury or other adverse health effects. FDA's Health Hazard Evaluation Board has supported regulatory action against products with hard, sharp and pointed fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. **The Food Safety Team should address only those hazards reasonably like to cause injury**. Product is reviewed at receiving following GMPs prior to use to ensure no foreign materials are present from the transportation and storage of the product (Supp. #10, 28)			
2.Receiving Starch Syrup (Potato/Sweet Potato)	B – None Identified		X	No history of biological hazards with starch syrup. (Supp. #12, 25)			
	C – None Identified		X	No history of chemical hazards with starch syrup. (Supp. #25)			
	C – Radiological (Whether this is a hazard depends on where the beans are grown)	X		Radiological hazard may result from accidental contamination such as release from a nuclear facility or damage to a nuclear facility during a natural disaster (Supp. #4)	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified auditor	X	
	C – Economically	X		Economically motivated hazard (Supp. #7, 8, 9)	Supply Chain Preventive Control – Approved supplier and third party	X	

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	motivated hazard				supplier audit by qualified audit		
	P – None Identified (We believe that if this is food-grade purchased syrup that any concerns with foreign materials would have been addressed at an earlier step in its production process.)		X	There is no history of the purchased syrup having physicals hazards. (Supp. #25)			
3.Receiving Agar (Produced From Seaweed)	B – Gammaproteobacteria, *Vibrio*		X	While harvested seaweed may contain various biological hazards such as pathogens and viruses, the drying and then extraction process used in the production of food-grade agar addresses these concerns (Supp. #13, 14)			
	B – *Salmonella*	X		While agar has the potential to become contaminated after processing, a lethality step later in the process addresses this concern.	Process Preventive Control – subsequent thermal treatment step		X
	C – Pesticides (If exporting product to the U.S., pesticides and their usage is regulated by the U.S. Environmental		X	This product is not known to have an issue with pesticides. (The use of unapproved pesticides or findings of residual levels above tolerance would require pesticides to be addressed as a supplier preventative control) (Supp. #5, 6, 16, 19, 25)			

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	Protection Agency (EPA), which establishes tolerance levels as well as what pesticide may be used.)						
	C- Dioxins (Dioxins may or may not be a concern depending on the location of harvest of the seaweed used in the production of the agar.)		X	The findings of residual levels would require dioxins to be addressed as a supplier preventative control (Supp. #16, 17, 18, 25)	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified audit	X	
	C- Iodine, Heavy Metals (Iodine or heavy metals may or may not be a concern depending on the location of harvest of the seaweed used in the production of the agar.)		X	The findings of residual levels above tolerance would require iodine and/or heavy metals to be addressed as a supplier preventative control (Supp. #15, 16, 25)	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified audit	X	
	C – Radiological	X		Radiological hazard may result from accidental	Supply Chain Preventive	X	

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	(Whether this is a hazard depends on where the seaweed is harvested.)			contamination such as release from a nuclear facility or damage to a nuclear facility during a natural disaster (Supp. #4, 25)	Control – Approved supplier and third party supplier audit by qualified auditor		
	C – Economically motivated hazard	X		Economically motivated hazard (Supp. #7, 8, 9)	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified audit	X	
	P – None Identified		X	This ingredient is not known to contain physical hazards. (Supp. #25)			
4.Receiving Dry Ingredients (Brown Sugar, Sugar, Baking Soda, Salt)	B – None Identified		X	These ingredients are not known to contain biological hazards. (Supp. #25)			
	C – Unapproved Colors and Additives in Brown Sugar, Sugar and Salt		X	These ingredients are not known to be at risk for containing unapproved colors upon review of current import alerts. (Supp. #25, 34)			
	C – Economically motivated hazard	X		Economically motivated hazards would need to be addressed using a Supply Chain Preventive Control if determined to be of concern with the specific ingredient. (Supp. #7, 8, 9)	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified audit	X	
	P – None Identified		X	These ingredients are not known to have concerns with physical hazards. (Supp. #25)			
5.Receiving Wheat Flour	B – Mycotoxin	X		Mycotoxin production could occur during growth or primary process of flour. (Supp. #20, 25)	Supply Chain Preventive Control	X	

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	B – Shiga toxin-producing *E. coli*, *Salmonella*, *B. cereus*, *L. monocytogenes*	X		Pathogens have been known to contaminate flour. If flour was received with ≤ 12% moisture level, pathogen growth will be controlled. However these hazards are addressed in subsequent thermal treatment step.(Supp. #20, 25)	Process Preventive Control – subsequent thermal treatment step		X
	C – Radiological (Whether this is a hazard depends on where the wheat is grown)	X		Radiological hazard may result from accidental contamination such as release from a nuclear facility or damage to a nuclear facility during a natural disaster (Supp. #4)	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified auditor	X	
	C – Economically motivated hazard	X		Economically motivated hazard (Supp. #7, 8, 9)	Supply Chain Preventive Control – Approved supplier and third party supplier audit by qualified audit	X	
	C – Allergen (Product must be labeled to address allergens of concern in the country to which product is exported. The U.S. requires that milk, egg, peanut, tree nuts (by species), fish	X		Wheat is an allergen that must be labeled to inform consumers. (Supp. #23)	Allergen Preventive Control – allergen labeling at later step in the process		X
		X		(If products containing other allergens also produced in the facility, allergen cross-contact must also be addressed. *see* Supp.#24)	Sanitation Preventive Control – at a subsequent step in the process if needed to prevent cross-contact		X

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	(by species), crustacean shellfish, wheat, and soy be labeled.)						
	P – None Identified		X	Flour is not known to contain physical hazards. Flour is also sifted through a 60 mesh screen (250 microns) as a good manufacturing practice (GMP) to ensure no foreign materials are present from transportation and storage. (*See* example in Supp. #36 –on how a program should be designed for monitoring the sifting operation. May need to modify depending on whether your operation is in-line or a batch process.) (Supp. #25, 28, 29, 36)			
6.Receiving Water	B – *Campylobacter*, *Salmonella*, *Shigella*, *Vibrio cholera*, *Yersinia entercolitica*, Shiga toxin-producing *E. coli*, *Cyclospora*, Hepatitis A, SRSV		X	Biological hazards are potential contaminates of water. If well water is sourced, it should be tested at some frequency after in-house treatment to ensure it meets acceptable potable water standards. If water is obtained from a municipality, certificates of potability should be on file. (Supp. #27)			
	C – Radiological (Whether this is a hazard depends	X		Radiological hazard may result from accidental contamination such as release from a nuclear facility or damage to a nuclear facility during a natural disaster	Supply Chain Preventive Control – Approved supplier and third party	X	

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	on where the water is sourced)			(Supp. #4)	supplier audit by qualified auditor		
	P – None Identified		X	No physical hazards have been identified in potable water.			
7.Receiving and Storage Of Packaging Materials (Polypropylene Film, Labels and Boxes)	B – None Identified		X	Purchasing specifications require that all materials have on file a letter of guarantee from the manufacturer that states these products are approved for their intended use. (Supp. #17, 30, 47)			
	C – Chemical Residues		X	Purchasing specifications require that all materials have on file a letter of guarantee from the manufacturer that states these products are approved for their intended use. (Supp. #17, 30, 47)			
	C – Allergen: Wheat	X		Product label must declare all allergens present in the product. (Supp. #23)	Allergen Preventive Control – label review for allergen information (Label review may be done at the receiving step, but should also be performed when label is applied to the finished product to ensure the proper label is used.)	X	
	P – None Identified		X	The storage area is reviewed to ensure that all products are properly stored in intact containers. (The facility should have a GMP program that addresses proper storage of packaging materials. The program should include that the storage area is reviewed at some frequency. The program should include corrective actions that will occur if issues are identified. Personnel involved in ensuring proper storage of packaging materials should be trained in this procedure and that training should be documented. *See*			

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
				Supp. #37)			
8.Storage of Adzuki Beans, Starch Syrup, Agar, Dry Ingredients	B – Mycotoxin	X		Mycotoxin level can increase during storage of wheat flour if the environment has a high moisture level. Flour and beans stored in tightly sealed containers preventing moisture gain would eliminate the potential hazard. (Having a procedure that ensures flour and dry beans are received and stored to prevent moisture absorption would eliminate the need for a preventive control at this step.) (Supp. #20)	Maintain beans and flour at <12% moisture level for mycotoxin control	X	
	B – Shiga toxin-producing *E. coli*, *Salmonella*	X		Improper storage that would increase moisture levels may result in growth. (Supp. #20) (Having a procedure that ensures flour and dry beans are received and stored to prevent moisture absorption would eliminate the need for a preventive control at this step.)	Maintain wheat flour <12% moisture level for pathogen control	X	
					Process Preventive Control – subsequent thermal treatment step		X
	C – None Identified		X	The storage area is reviewed to ensure that all products are properly stored in intact containers. (The facility should have a GMP program that addresses proper storage of ingredients. The program should include that the storage area is reviewed at some frequency. The program should include corrective actions that will occur is issues are identified. Personnel involved in ensuring proper storage of ingredients should be trained in this procedure and that training should be documented. *See* Supp. #37)			
	P – None Identified		X	The storage area is reviewed to ensure that all products are properly stored in intact containers. (The facility should have a GMP program that addresses proper storage of ingredients. The program should include that the storage area is reviewed at some frequency. The program should			

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
				include corrective actions that will occur is issues are identified. Personnel involved in ensuring proper storage of ingredients should be trained in this procedure and that training should be documented. *See* Supp. #37)			
9.Weighing of Brown Sugar, Wheat Flour, Sugar, Baking Soda, Starch Syrup, Water	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – Foreign Material		X	Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on size and shape of the object, it may cause choking, injury or other adverse health effects. FDA's Health Hazard Evaluation Board has supported regulatory action against products with hard, sharp and pointed fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. **The Food Safety Team should address only those hazards reasonably like to cause injury**. Dry ingredients are sifted through a 60 mesh screen (250 micron) prior to mixing. (If there is an opportunity that foreign material could be introduced during the weighing process from the environment, this can be addressed with a GMP program to ensure that the equipment and the area directly over the exposed product is reviewed on a routine basis. *See* Supp.#38) (Supp. #10, 35)			
10.Filtering of Water	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P –None Identified		X	While you indicate that filtering is done to remove foreign substances such as metal, rubber, and plastic, we find it			

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
				difficult to comprehend that this would be in your water source and coming out of a water system. If filtration is done at this step to remove something such as calcium carbonate in the water, this would be considered a GMP process.			
11.Mixing of Brown Sugar, Sugar and Starch Syrup	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – Metal	X		Pieces of metal may be introduced during the mixing process from equipment used. This can be controlled by subjecting the product to metal detection. (Supp. #10, 11)	Process Preventive Control – metal detection at subsequent step		X
	P – Foreign Material		X	Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on size and shape of the object, it may cause choking, injury or other adverse health effects. FDA's Health Hazard Evaluation Board has supported regulatory action against products with hard, sharp and pointed fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. **The Food Safety Team should address only those hazards reasonably like to cause injury**. (If there is an opportunity that foreign material could be introduced into the mixer from the environment, this can be addressed with a GMP program to ensure that the equipment and the area directly over the exposed product is reviewed on a routine basis. *See* Supp. #38) (Supp. #10)			
12.Heating of Brown Sugar, Sugar and Starch Syrup Mixture (Dissolving Sugar)	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	P – Foreign Material		X	Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on size and shape of the object, it may cause choking, injury or other adverse health effects. FDA's Health Hazard Evaluation Board has supported regulatory action against products with hard, sharp and pointed fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. **The Food Safety Team should address only those hazards reasonably like to cause injury**. (If there is an opportunity that foreign material could be introduced during the heating process from the environment, this can be addressed with a GMP program to ensure that the equipment the area directly over the exposed product s reviewed on a routine basis. *See* Supp. #38) (Supp. #10)			
13.Mixing of Baking Soda and Water With Brown Sugar, Sugar and Starch Syrup Mixture	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process			
	P – Metal	X		Pieces of metal may be introduced during the mixing process from equipment used. This can be controlled by subjecting the product to metal detection. (Supp. #10, 11)	Process Preventive Control – metal detection at subsequent step		X
	P – Foreign Material		X	Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on size and shape of the object, it may cause choking, injury or other adverse health effects. FDA's Health Hazard Evaluation Board has supported regulatory action against products with hard, sharp and pointed fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. **The Food Safety Team should address only those hazards reasonably like to cause injury**. (If there is an			

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
				opportunity that foreign material could be introduced during the mixing process from the environment, this can be addressed with a GMP program to ensure that the equipment the area directly over the exposed product is reviewed on a routine basis. *See* Supp. #38) (Supp. #10)			
14.Heating of Baking Soda, Brown Sugar, Sugar, Starch Syrup and Water Mixture	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – Foreign Material		X	Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on size and shape of the object, it may cause choking, injury or other adverse health effects. FDA's Health Hazard Evaluation Board has supported regulatory action against products with hard, sharp and pointed fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. **The Food Safety Team should address only those hazards reasonably like to cause injury**. (If there is an opportunity that foreign material could be introduced during the heating process from the environment, this can be addressed with a GMP program to ensure that the equipment the area directly over the exposed product is reviewed on a routine basis. *See* Supp. #38) (Supp. #10)			
15.Dough Making - Mixing of Flour with Baking Soda, Brown Sugar, Sugar, Starch Syrup and Water mixture	B – Shiga toxin-producing *E. coli*, *Salmonella*, *L. monocytogenes*	X		Pathogens are known to be present in flour. The introduction of moisture may cause growth to occur. (Supp. #20, 25)	Process Preventive Control – subsequent thermal treatment step		X
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	P – Metal	X		Pieces of metal may be introduced during the mixing process from equipment used. This can be controlled by subjecting the product to metal detection. (Supp. #10, 11)	Process Preventive Control – metal detection at subsequent step		X
	P – Foreign Material		X	Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on size and shape of the object, it may cause choking, injury or other adverse health effects. FDA's Health Hazard Evaluation Board has supported regulatory action against products with hard, sharp and pointed fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. **The Food Safety Team should address only those hazards reasonably like to cause injury.** (If there is an opportunity that foreign material could be introduced into the mixer from the environment, this can be addressed with a GMP program to ensure that the equipment the area directly over the exposed product is reviewed on a routine basis. *See* Supp. #38) (Supp. #10)			
16. Dough Storage (This step was added as it appears the dough may be processed immediately or stored at room temperature or in a refrigerator.)	B –Shiga toxin-producing *E. coli*, *Salmonella*, *Listeria monocytogenes*, *Staphylococcus aureus*	X		Pathogens have been known to contaminate flour. *Staphylococcus aureus* is also of concern in dough with no yeast, and can produce toxins if dough is not further processed in a timely manner or refrigerated. (Supp. #20, 31, 36, 40)	Process Preventive Control – time and temperature of dough and dough storage prior to bun making	X	
					Process Preventive Control – subsequent thermal treatment step		X
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – None		X	Product is properly stored in covered containers. (Supp.			

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	Identified			#37, 38)			
17.Weighing of Adzuki Beans	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process			
	P – Foreign Material		X	Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on size and shape of the object, it may cause choking, injury or other adverse health effects. FDA's Health Hazard Evaluation Board has supported regulatory action against products with hard, sharp and pointed fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. **The Food Safety Team should address only those hazards reasonably like to cause injury**. (If there is an opportunity that foreign material could be introduced into the product from the environment during weighing, this can be addressed with a GMP program to ensure that the equipment and the area directly over the exposed product is reviewed on a routine basis. *See* Supp. #38) (Supp. #10)			
18.Weighing of Water, Agar, Sugar, Salt	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process			
	P – Foreign Material		X	Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on size and shape of the object, it may cause choking, injury or other adverse health effects. FDA's Health Hazard Evaluation Board has supported regulatory action against products with hard, sharp and pointed fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. **The**			

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
				Food Safety Team should address only those hazards reasonably like to cause injury. (If there is an opportunity that foreign material could be introduced into the product from the environment during weighing, this can be addressed with a GMP program to ensure that the equipment and the area directly over the exposed product is reviewed on a routine basis. *See* Supp. #38) (Supp. #10)			
19.Filtering of Water	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – Foreign Material		X	While you indicate that filtering is done to remove foreign substances such as metal, rubber, and plastic, we find it difficult to comprehend that this would be in your water source and coming out of a water system. If filtration is done at this step to remove something such as calcium carbonate in the water, this would be considered a GMP process.			
20.Retting of Adzuki Beans (Soaking of Beans in Water for Least 24 Hours)	B – *Salmonella*, *B. cereus*, Shiga toxin-producing *E. coli*, *C. perfringens*, *C. botulinum*	X		Pathogens are known to contaminate dried legumes. (Supp. #20, 26)	Process Preventive Control – subsequent thermal treatment step		X
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process			
	P – None Identified		X	Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on size and shape of the object, it may cause choking, injury or other adverse health effects. FDA's Health			

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
				Hazard Evaluation Board has supported regulatory action against products with hard, sharp and pointed fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. **The Food Safety Team should address only those hazards reasonably like to cause injury**. (If there is an opportunity that foreign material could be introduced into the product from the environment during retting this can be addressed with a GMP program to ensure that the equipment and the area directly over the exposed product is reviewed on a routine basis. *See* Supp. #38) (Supp. #10)			
21.Steaming of Adzuki Beans	B – *Salmonella, B. cereus,* Shiga toxin-producing *E. coli, C. perfringens, C. botulinum*	X		Cooking the adzuki beans to an internal temperature of ≥ 75°C and maintaining that product for at least one (1) minute will kill the vegetative pathogens. Beans are steamed at 90°C for 10 minutes. (Supp. #31)	Process Preventive Control – Minimum internal temperature and hold time (Bean internal temperature and hold time may be based on the chart in Supp. #31, page 172.)	X	
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process			
	P – None Identified		X	Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on size and shape of the object, it may cause choking, injury or other adverse health effects. FDA's Health Hazard Evaluation Board has supported regulatory action against products with hard, sharp and pointed fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. **The Food Safety Team should address only those hazards reasonably like to cause injury**. (If there is an opportunity that foreign material could be introduced into the product from the environment during weighing, this			

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
				can be addressed with a GMP program to ensure that the equipment and the area directly over the exposed product is reviewed on a routine basis. *See* Supp. #38) (Supp. #10)			
22. Grinding/Mashing of Adzuki Beans (Based on the provided flowchart, it does not appear that the product is removed from the cooking vessel. Based on this fact, we made the assumption that product is "mashed" or "ground" in the vessel. If this is not the case, the flow chart and the hazard analysis needs to be reanalyzed to address that process.)	B –*Listeria monocytogenes*	X		*Listeria monocytogenes* can be introduced to product post-lethality exposure to the environment. (Supp. #20, 21, 4, 44, 45)	Process Preventive Control – subsequent thermal treatment step	X	
	B – *C. perfringens, C. botulinum*			*C. perfringens, C. botulinum* can produce toxins if product is not chilled in a timely manner or if product temperature is not maintained at ≥ 57°C. If product temperature goes below 57°C, but remains above 10°C, you must determine the **maximum accumulative holding time** to prevent toxin formation. (Supp.#31, pages 168-169) (After the steaming lethality step occurs, you must consider the accumulative time that product will remain between 10°C and 57°C. until you reduce the water activity with the addition of the agar and sugar.)	Process Preventive Control – Holding time and temperature to prevent toxin formation		X
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – Metal	X		Pieces of metal may be introduced during the grinding process from equipment used. This can be controlled by subjecting the product to metal detection. (Supp. #10, 11)	Process Preventive Control – metal detection at subsequent step		X
	P – Foreign Material		X	Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on size and shape of the object, it may cause choking, injury or other adverse health effects. FDA's Health Hazard Evaluation Board has supported regulatory action against products with hard, sharp and pointed fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. **The**			

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
				Food Safety Team should address only those hazards reasonably like to cause injury. (If there is an opportunity that foreign material could be introduced into the product from the environment during grinding, this can be addressed with a GMP program to ensure that the equipment and the area directly over the exposed product is reviewed on a routine basis. *See* Supp. #38) (Supp. #10)			
23. Soaking in Water	B – *Listeria monocytogenes*		X	*Listeria monocytogenes* can be introduced to product post-lethality exposure to the environment. (Supp. #20, 21, 4, 44, 45)	Process Preventive Control – subsequent thermal treatment step		X
	B – *C. perfringens, C. botulinum*			*C. perfringens, C. botulinum* can produce toxins if product is not chilled in a timely manner or if product temperature is not maintained at ≥57°C. If product temperature goes below 57°C, but remains above 10°C, you must determine the **maximum accumulative holding time** to prevent toxin formation. (Supp.#31, pages 168-169) (After the steaming lethality step occurs, you must consider the accumulative time that product will remain between 10°C and 57°C. until you reduce the water activity with the addition of the agar and sugar.)	Process Preventive Control – holding time and temperature to prevent toxin formation	X	
	C- None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – None Identified		X	No physical hazards are introduced or enhanced at this step in the process.			
24.Mixing of Adzuki Beans, Water, Agar, Sugar, and Salt	B –*Listeria monocytogenes*	X		*Listeria monocytogenes* can be introduced to product post-lethality exposure to the environment. (Supp. #20, 21, 4, 44, 45)	Process Preventive Control – subsequent thermal treatment step		X
	C – None		X	No chemical hazards are introduced or enhanced at this			

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	Identified			step in the process.			
	P – Metal	X		Pieces of metal may be introduced during the mixing process from equipment used. This can be controlled by subjecting the product to metal detection. (Supp. #10, 11)	Process Preventive Control – metal detection at subsequent step		X
	P – Foreign Material		X	Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on size and shape of the object, it may cause choking, injury or other adverse health effects. FDA's Health Hazard Evaluation Board has supported regulatory action against products with hard, sharp and pointed fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. **The Food Safety Team should address only those hazards reasonably like to cause injur**y. (Supp. #10)			
25.Steaming of Adzuki Bean, Water, Agar, Sugar and Salt Mixture	B - *C. perfringens*, *C. botulinum*, *Listeria monocytogenes*	X		Cooking the adzuki beans to an internal temperature of ≥ 90°C and maintaining that product temperature for at least ten (10) minute will kill the vegetative pathogens as well as inactivate Non-Proteolytic *C. botulinum* Type B. In addition, water activity controls the growth of these pathogens. (Supp. #31)	Process Preventive Control – Minimum internal temperature and hold time	X	
					Process Preventive Control – Control water activity ≤ 0.86	X	
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – None Identified		X	No physical hazards are introduced or enhanced at this step in the process.			

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
26.Aging of Adzuki Bean, Water, Agar, Sugar and Salt Mixture (at Room Temperature)	B - *Listeria monocytogenes*	X		*Listeria monocytogenes* can be introduced to product post-lethality exposure to the environment. (While there is a steaming step after bun manufacture, unless the internal temperature of the bean paste in the bun at the end of bun steaming reaches ≥74°C, you must control the introduction of *L. monocytogenes* from this step in the process forward with the use of sanitation and good manufacturing practices and verify its effectiveness with a monitoring program.) However, it is unable to grow at less than a water activity of 0.92. Supp.# 21, 22, 26, 31, 43, 44, 45)	Sanitation control	X	
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – None Identified		X	No physical hazards are introduced or enhanced at this step in the process. (There should be a GMP program in place that ensures the product is covered while aging to prevent the introduction of any foreign material. If this is not the case, a program should be in place to ensure that the area above the open product will not introduce foreign material including condensation. *See* Supp. #38)			
27.Bun Manufacturing - Dough and Bean Paste Portioning, Wrapping of Bean	B - *Staphylococcus aureus*	X		*Staphylococcus aureus* is a potential hazard in dough with no yeast. (Supp. #20, 31 – page 167, 36) (If buns are formed and filled by hand, there is the possible introduction of *S. aureus* to the product.).	Process Preventive Control – subsequent thermal treatment step		X

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
Paste with Dough	B – *Listeria monocytogenes*, Shiga toxin-producing *E. coli*, *Salmonella*			*Listeria monocytogenes* can be introduced to product by post-lethality exposure to the environment. (While there is a steaming step after bun manufacture, unless the internal temperature of the bean paste in the bun at the end of bun steaming reaches ≥74°C, you must control the introduction of *L. monocytogenes* with the use of sanitation and good manufacturing practices and verify its effectiveness with a monitoring program.) *E. coli* and *Salmonella* have been known to contaminate flour (recent outbreaks). (Supp. #20, 21, 43, 44, 45)			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – Metal	X		Pieces of metal may be introduced during the bun making process. This can be controlled by subjecting the product to metal detection. (Supp. #10, 11)	Process Preventive Control – metal detection at subsequent step		X
	P – Other Foreign Material		X	Physical hazards include any potentially harmful extraneous matter not normally found in food. Depending on size and shape of the object, it may cause choking, injury or other adverse health effects. FDA's Health Hazard Evaluation Board has supported regulatory action against products with hard, sharp and pointed fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. **The Food Safety Team should address only those hazards reasonably like to cause injury.** (Supp. #10)			
28.Bun Steaming (Conversion of Dough to Bread)	B - *Staphylococcus aureus*, *Listeria monocytogenes*, Shiga toxin-producing *E.*	X		Cooking the buns to an internal temperature of ≥ 75°C and maintaining that product for at least one (1) minute will kill the vegetative pathogens. Buns steamed at 98°C for 10 minutes. (Supp. #20, 31) (Buns must be cooked to ≥ 90°C for quality characteristics.)	Process Preventive Control – Minimum internal temperature and hold time	X	

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
	coli, Salmonella						
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – None Identified		X	No physical hazards are introduced or enhanced at this step in the process.			
29.Cooling of Buns (Room Temperature)	B – *Listeria monocytogenes*	X		*Listeria monocytogenes* can be introduced to un-packaged product post-lethality exposure to the environment. (Supp. #21, 25, 43, 44, 45)	Sanitation Control – prevents contamination	X	
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – None Identified		X	No physical hazards are introduced or enhanced at this step in the process. (There should be a GMP program in place that ensures the product is covered while cooling to prevent the introduction of any foreign material. If this is not the case, a program should be in place to ensure that the area above the open product will not introduce foreign material including condensation. *See* Supp. #38)			
30.Packaging of Buns in Polypropylene Film	B – *Listeria monocytogenes*	X		*Listeria monocytogenes* can be introduced to unpackaged product post-lethality by the environment. (Supp. #21, 25, 43, 44, 45)	Sanitation Control – prevents contamination	X	
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – None Identified		X	No physical hazards are introduced or enhanced at this step in the process.			
31.Metal Detection of Packaged Buns	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P - Metal	X		Pieces of metal may be present in raw material or	Process Preventive Control	X	

ISSUED:
REVISED:

Ingredient/Processing Step	Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step B = Biological; C = Chemical including Radiological; P = Physical	Do any Potential Food Safety Hazards Require a Preventive Control?		Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.)	What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard? (Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control)	Is the Preventive Control Applied at this Step?	
		Yes	No			Yes	No
				introduced during the manufacture process from equipment used. This can be controlled by subjecting the product to metal detection. (Supp. #10, 11)	– metal detection		
32.Box/Cases Packing	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – None Identified		X	No physical hazards are introduced or enhanced at this step in the process.			
33. Frozen Storage of Boxes/Cases (The flowchart must be updated to include the freezing step.)	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – None Identified		X	No physical hazards are introduced or enhanced at this step in the process.			
34.Shipment	B – None Identified		X	No biological hazards are introduced or enhanced at this step in the process.			
	C – None Identified		X	No chemical hazards are introduced or enhanced at this step in the process.			
	P – None Identified		X	No physical hazards are introduced or enhanced at this step in the process.			

Preventive Controls Plan

Process Control	Hazard	Preventive Control Parameters	Monitoring				Corrective Action / Corrections	Record Keeping	Verification
			What	How	Freq.	Who			
Suppler Chain Preventive Control – Mycotoxin in Beans, Wheat Flour	Mycotoxin	Received from an Approved Supplier approved on XX (date supplier(s) was approved, Supplier must be approved prior to receiving ingredients)	(Monitoring not required for supply-chain applied preventive controls.) (While monitoring is not required, there should be a procedure that identifies a qualified individual to review and document that each incoming shipment is received from an approved supplier.)				(The below are considered "corrections" as corrections may be used for minor and isolated problems that do not directly affect product safety.) The Qualified Individual can reject shipments received from an unapproved supplier. Alternatively, the ingredient can be used in food for research only or other non-sales. The PCQI could make a determination to temporarily approve the supplier if adequate documentation is provided. The Qualified Individual will determine the root cause and implement measures to prevent reoccurrence. All steps in 21 CFR 117.150(a)(2) will be met.	Incoming Receiving Record Bill of Lading Copy of audit report by a qualified auditor obtained from the supplier Record showing use for research or non-sale item if applicable Correction/Corrective Action Records (Supp. #46) Reanalysis Form (Supp. #49)	PCQI ensures the reviews of the initial and annual audit of the supplier by the qualified auditor. PCQI ensures the reviews of the receiving record log within 7 days. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.) PCQI ensures the review of the corrections record within 7 days. (Considerations for appropriate verification can include: • What does the hazard analysis suggest about the nature of the hazard? • Are preventive controls applied by the supplier or the supplier's supplier? • What are the supplier's procedures, processes and practices related to safety for the ingredient or raw material? • Has FDA issued warning letters or import alerts related to the supplier's compliance? • Do your historical test or audit results for the supplier indicate a trend – positive or negative? • Have the supplier's corrective actions to past issues been appropriate and timely? • Are the supplier's storage or transportation practices appropriate?)

ISSUED:
REVISED:

Preventive Controls Plan

Process Control	Hazard	Preventive Control Parameters	Monitoring				Corrective Action / Corrections	Record Keeping	Verification
			What	How	Freq.	Who			
Process Preventive Control - Metal Detection (Metal detection may occur at one or more steps in the process.)	Metal	Metal detector is present and operating and no metal fragments that would cause injury or choking are in the product that passes through the functioning metal detector.	All product passes through the functioning metal detector	Product passes through a functional metal detector, which detects and rejects ferrous Y mm, non-ferrous –Y mm, stainless – Y mm. (The company will have to support the size of the seeded samples used. The PCQI will oversee the validation and supporting material provided by the company for each step in the process.)	Hourly during production. (The company will have to support the frequency used.)	Qualified Individual (A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold, clean and safe food as appropriate to the individual's assigned duties)	A Qualified Individual will take appropriate corrections or corrective actions (this includes actions to identify and correct the problem, action to prevent reoccurrence, all affected product is evaluated for safety, and all affected food is prevented from entering commerce is adulterated). (In the event of an unanticipated food safety event, a re-analysis of the food safety plan or the appropriate portion of the plan would be required. Any reanalysis of the food safety plan must be done by a Preventive Controls Qualified Individual (PCQI). A PCQI is a Qualified Individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized by FDA or is otherwise qualified through job experience to develop and apply a food safety system.) The Qualified Individual will determine the root cause and implement measures to prevent reoccurrence. All steps in 21 CFR 117.150(a)(2) will be met.	Metal Detection Log (Supp. #42) Validation records for setting and frequency Metal Detector Calibration Record Corrective Action Report (Supp. #46) Reanalysis Form (Supp. #49)	Review of documentation within 7 working days is ensured by the PCQI. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.) Verification will include the following: Direct observation of monitoring a minimum of once a week. The metal detector will be calibrated annually by the manufacturer to detect standardized metal slugs. (Note - The company could also use the recommendations of the manufacturer to have a different qualified individual perform periodic calibration.)

ISSUED:
REVISED:

Preventive Controls Plan

Process Control	Hazard	Preventive Control Parameters	Monitoring				Corrective Action / Corrections	Record Keeping	Verification
			What	How	Freq.	Who			
Allergen Preventive Control - Labeling of Allergens	Allergens: wheat	All finished product labels declare allergens present in the product.	Ingredients in the product produced (as per product mixing record) matches the ingredient statement on the finished product label.	Visual review of product mixing records to confirm accuracy of product produced. Visual review of finished product labels for correct allergen declaration.	Every batch of product produced.	Qualified Individual	If the mixing record does not reflect the product being produced, the Qualified Individual will retain product to identify whether the product was formulated correctly and can be labeled and released. If the finished product label does not contain the correct allergen declarations, the labels will be corrected or destroyed, Product will not be released without proper labeling. The Qualified Individual will determine the root cause and implement measures to prevent reoccurrence. All steps in 21 CFR 117.150(a)(2) will be met.	Product Mixing Record Finished Product Labels Check Form Corrections/Corrective Action Record (Supp. #46) Reanalysis Form (Supp. #49)	PCQI will ensure review of records within 7 working days. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.) PCQI will ensure there is a direct observation of the product being made and ensure that it matches the description on the mixing record.
Process Preventive Control - Storage Of Beans And Wheat Flour (If these products are received in containers that prevent moisture absorption, the concern would only apply to open containers that can not be tightly closed to prevent moisture adsorption.)	Increase in mycotoxin and pathogen growth	Maintaining moisture level in product at ≤ 12% OR Store to ensure that moisture level in product does not increase above 12%. (This can be achieved by storing product in tightly sealed containers to prevent moisture absorption or by controlling the environmental conditions in the storage area that ensures the product moisture level stays ≤12% moisture.)	Measure moisture level in product OR Ensure that storage area environment is maintained to prevent increase of product moisture levels.	Heat samples of flour in oven and determine moisture level. (Supp. #51) OR Monitor environmental parameters such as temperature and humidity of the storage area.	Frequency of testing will depend on the product storage container and the length of time product remains in storage. Environmental monitoring frequency is contingent on how well the environmental parameters can be controlled.	Qualified Individual	If product moisture levels increase above 12%, product should be retained and management notified. The Qualified Individual will determine the root cause and implement measures to prevent reoccurrence. All steps in 21 CFR 117.150(a)(2) will be met.	Product Moisture Level Form Storage Area Condition Log Correction/Corrective Action Records (Supp. #46) Reanalysis Form (Supp. #49)	PCQI will ensure review of records within 7 working days. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.)

ISSUED:
REVISED:

Preventive Controls Plan

Process Control	Hazard	Preventive Control Parameters		Monitoring				Corrective Action / Corrections	Record Keeping	Verification
				What	How	Freq.	Who			
Process Preventive Control - Grinding of Adzuki Beans	*C. botulinum*, *C. perferingens*	Product temperature does not remain between 57°C, and 10°C for more than maximum accumulative hold time		Temperature and accumulative time adzuki bean mixture is held	Calibrated and accurate thermometer	Each batch of product every 30 minutes once product is at or below 57°C.	Qualified Individual	If the allowable maximum accumulative hold time of product is more than allowed, product will be retained and corrective action taken. The Qualified Individual will determine the root cause and implement measures to prevent reoccurrence. All steps in 21 CFR 117.150(a)(2) will be met.	Cooling Record Equipment Calibration Log (Supp. #50) Correction/Corrective Action records (Supp. #46) Reanalysis Form (Supp. #49)	PCQI will ensure review of records within 7 working days. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.) Thermometer Accuracy and Calibration Checks (Accuracy of thermometers are typically done on a daily basis using ice slurry or boiling water. Calibration of the thermometer is done periodically checking the equipment against an NIST standardized thermometer to ensure accuracy. (Supp. #32, 33))
		Internal temp	**Maximum hold time**							
		Any time above 26°C	1 hour							
		Any time above 26°C	4 hours if no more than 1 hour is above 21°C							
		Any time above 21°C but never above 26°C	2 hours							
		Never above 26°C	4 hours if no more than 2 hours are above 21°C							

ISSUED:
REVISED:

Preventive Controls Plan

Process Control	Hazard	Preventive Control Parameters	Monitoring				Corrective Action / Corrections	Record Keeping	Verification
			What	How	Freq.	Who			
Process Preventive Control - Steaming Adzuki Bean Mixture (Agar, Sugar, Salt, Beans, Water)	*C. perfringens*, *C. botulinum*, *Vegetative Pathogens*	Bean mixture is held for a minimum of 10 minutes at ≥ 90°C	Measure time once bean mixture reaches ≥90°C	Use a calibrated temperature to determine when mixture reaches ≥90°C and then time the process to ensure temperature is held at least 10 minutes	Each batch/vessel	Qualified Individual	If product is not ≥90°C, continue to cook until temperature is reached. If product does not reach temperature required or vessel will not hold temperature for ten minutes, place product on hold and take corrective measures. All steps in 21 CFR 117.150 (a)(2) will be met.	Cooking Time And Temperature Log Equipment Calibration Log (Supp. #50) Correction/Corrective Action records (Supp. #46) Reanalysis Form (Supp. #49)	PCQI will ensure review of records within 7 working days. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.) .
Water Activity (Aw) – Adzuki Bean Mixture	Vegetative and spore forming pathogens	Water activity is < 0.86 within adzuki mixture	Water activity of finished product is < 0.86	Calibrated and accurate equipment (Place the type of equipment used here to measure the water activity)	Each batch of product	Qualified Individual	If the product water activity is not < 0.86, the Qualified Individual will ensure product continues to cook until the product meets the water activity requirement. The Qualified Individual will determine the root cause and implement measures to prevent reoccurrence. If finished product did not meet the water activity requirement, the product will be reworked or destroyed. All parts of 21 CFR § 117.150(2)(a) will be met.	Water Activity Record Equipment Calibration Log (Supp. #50) Correction/Corrective Action records (Supp. #46) Reanalysis Form (Supp. #49)	PCQI will ensure review of records within 7 working days. . (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.) (Accuracy checks and calibration of equipment are typically done based on the frequency recommended by the manufacturer. Additional considerations for frequency include the conditions of use and the known "drift" of the equipment.) (Accuracy checks are done routinely to ensure the equipment continues to function as intended under plant conditions. Calibration is done periodically to ensure the equipment remains accurate and reliable.)
Process Preventive Control - Dough Storage	*Staphylococcus aureus*, *Listeria monocytogenes*, Shiga	Product temperature does not remain between 57°C, and 10°C for more than	Temperature and accumulative time dough is held	Calibrated and accurate thermometer	Each batch of dough every 30 minutes once product is	Qualified Individual	If the allowable maximum accumulative hold time of product is more than allowed, product will be placed on hold and corrective action taken.	Cooling Record Equipment Calibration Log (sup. #50)	PCQI will ensure review of records within 7 working days. . (While the regulation requires records review within 7 working days of completion. it is highly recommended that this be done on a

ISSUED:
REVISED:

Preventive Controls Plan

Process Control	Hazard	Preventive Control Parameters		Monitoring				Corrective Action / Corrections	Record Keeping	Verification
				What	How	Freq.	Who			
	toxin-producing *E. coli*, *Salmonella*	maximum accumulative hold time				at or below 57°C		The Qualified Individual will determine the root cause and implement measures to prevent reoccurrence. All steps in 21 CFR 117.150(a)(2) will be met.	Correction/Corrective Action records (Supp. #46) Reanalysis Form (Supp. #49)	daily basis. When issues are identified during the review, corrective action is required.) Thermometer Accuracy and Calibration checks (Accuracy of thermometers is typically done on a daily basis using ice slurry or boiling water. Calibration of the thermometer is done periodically checking the equipment against an NIST standardized thermometer to ensure accuracy. (Supp. #32, 33))
		Internal Temp	**Maximum hold time**							
		Above 21°C	2 hours							
		Above 21°C	4 hours if no more than 2 hours are between 21°C and 57°C							
		At anytime above 10°C but never above 21°C	5 hours							
		Internal product temp or ambient air temp . is below 10° throughout hold time	No time limit							

ISSUED:
REVISED:

Preventive Controls Plan

Process Control	Hazard	Preventive Control Parameters	Monitoring				Corrective Action / Corrections	Record Keeping	Verification
			What	How	Freq.	Who			
Process Preventive Control - Steaming Adzuki Beans	*Listeria monocytogenes*, Shiga toxin-producing *E. coli*, *Salmonella*, *B. cereu*,	Cooking to an internal temperature of ≥ 75°C and maintaining that product for at least one (1) minute will kill the vegetative pathogens.	Internal product temperature is ≥ 75°C. and maintained at that temperature for at least 1 minute.	Calibrated and accurate thermometer	Each batch of product	Qualified Individual	If the product temperature is not ≥ 75°C and maintained at that temperature for at least 1 minute, the Qualified Individual will ensure product continues to cook until the product meets the cook requirements. The Qualified Individual will determine the root cause and implement measures to prevent reoccurrence. If finished product did not meet the minimum temperature and time requirements, the product will be reworked or destroyed. All parts of 21 CFR § 117.150(a)(2)will be met.	Cooking Record Equipment Calibration Log (Supp. #50) Correction/Corrective Action Records (Supp. #46)	PCQI will ensure review of records within 7 working days. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.) (Accuracy of thermometers is typically done on a daily basis using ice slurry or boiling water. Calibration of the thermometer is done periodically checking the equipment against an NIST standardized thermometer to ensure accuracy. (Supp. #32, 33))
Process Preventive Control - Steaming Buns	*Staphylococcus aureus*, *Listeria monocytogenes*, *Shiga toxin-producing E. coli*, *Salmonella*	Cooking to an internal temperature of ≥ 75°C and maintaining that product for at least one (1) minute will kill the vegetative pathogens. (Validation study should be conducted to verify thermal lethality parameters are adequate to ensure lethality was achieved throughout all products.)	Internal product temperature is ≥ 75°C. and maintained at that temperature for at least 1 minute	Calibrated and accurate thermometer	Each batch of product	Qualified Individual	If the product temperature is not ≥ 75°C and maintained at that temperature for at least 1 minute, the Qualified Individual will ensure product continues to cook until the product meets the cook requirements. The Qualified Individual will determine the root cause and implement measures to prevent reoccurrence. If finished product did not meet the minimum temperature and time requirements, the product will be reworked or destroyed. All parts of 21 CFR § 117.150(a)(2)will be met.	Cooking record Equipment Calibration Log (Supp. #50) Correction/Corrective Action records (Supp. #46)	PCQI will ensure review of records within 7 working days. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.) Validation study (Accuracy of thermometers is typically done on a daily basis using ice slurry or boiling water. Calibration of the thermometer is done periodically checking the equipment against an NIST standardized thermometer to ensure accuracy. (Supp. #32, 33))

ISSUED:
REVISED:

Preventive Controls Plan

Process Control	Hazard	Preventive Control Parameters	Monitoring				Corrective Action / Corrections	Record Keeping	Verification
			What	How	Freq.	Who			
Sanitation Preventive Control - Sanitation Of The Bun Cooking Area, Cooling And Packaging Areas For Finished Bun Products.	*Listeria monocytogenes* (*Listeria monocytogenes* can contaminate the product exposed to the environment after it has been cooked. This area requires special product handling, employee hygiene and sanitation. Many food companies have separate colored outer clothing, mops and cleaning supplies to prevent cross contamination with the raw product area. A separate document includes "Best Practices" that may be incorporated into a GMP.)	Prevent post-lethality contamination of product with *Listeria monocytogenes*	The bun cooking equipment/ area, cooling and packaging equipment/ areas are evaluated for cleanliness. Sanitizer strength is measured prior to application in the area *e.g.*, quaternary ammonium at 200 -400 ppm. All employees entering the area are wearing the designated outwear, hairnets and gloves.	Visual observation of the bun cooking equipment/area, cooling and packaging equipment/areas for cleanliness. Test strips are used to measure sanitizer strength. Employees entering the area are visually observed to be wearing the designated outwear, hairnets and gloves.	The bun cooking equipment/ area, cooling and packaging equipment/ areas are observed for cleanliness before start of operations. Sanitizer strength is measured prior to use. Employees in the area are visually observed for proper attire at start up, and every two hours during production.	Qualified Individual	If the equipment/areas are observed unclean prior to operations, the operations are not permitted to start until the areas are recleaned and reinspected. If the sanitizer strength is not appropriate, it is remade or adjusted prior to using. If employees are not wearing appropriate attire for the areas, they are instructed to put on the appropriate attire. (It is important to note that the Qualified Individual will need to assess whether the failure to wear proper attire may have led to potential cross-contamination of product.) If no product is involved, corrections will be taken. If product is affected, corrective actions will be taken that meet all requirements in 21 CFR § 117.150(a)(2).	Daily Sanitation Record Sanitizer Strength Record (Note- many companies include the sanitizer strength on the Daily Sanitation Record) Environmental Testing Program Records Laboratory results Correction/Corrective Action Records (Supp. #46) Reanalysis Form (Supp. #49)	PCQI will ensure review of records within 7 working days.. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.) Environmental Testing Program (Environmental Testing applies to ready-to-eat foods that are exposed to the environment after processing and before packaging. The program should include the location and number of sites tested; timing and frequency of sampling; analytical method used; laboratory; and corrective action procedures for findings. An example Environmental Testing Program is included. Supp. #43)

ISSUED:
REVISED:

List of Supplements for Preventive Control Plan

1. ICMSF. *Microbial Ecology of Food Commodities*. Second Edition. 2005. Vol. 6. Chapter 9 – Nuts, oilseeds, and dried legumes. Kluwer Academic/Plenum Publishers. New York, New York. pg. 440-466.
2. Mislivec, PB, Dieter, CT, Bruce, VR. 1975. Mycotoxin-producing potential of mold flora of dried beans. *Appl Microbiol*. 29(4):522-6.
3. Kurata, H., H. Tanebe, K. Kanota, S. Udagawa, and M. Ichinoe. 1968. Studies on the population of toxigenic fungi in foodstuffs. IV. Aflatoxin-producing fungi isolated from foodstuffs in Japan. *J. Food Hyg. Soc. Jpn*. 9:29-34.
4. World Health Organization. 2011. FAQs: Japan nuclear concerns. Accessed October 18, 2016: http://www.who.int/hac/crises/jpn/faqs/en/index7.html
5. Environmental Protection Agency. Regulation of Pesticide Residues on Food. Accessed October 18, 2016: https://www.epa.gov/pesticide-tolerances
6. Food and Drug Administration. "Guidance for Industry: Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations". May 2005. Accessed October 18, 2016: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm077918.htm
7. Congressional Research Service. 2014. "Food Fraud and "Economically Motivated Adulteration" of Food and Food Ingredients." Jan. 2014. Accessed October 18, 2016: https://www.fas.org/sgp/crs/misc/R43358.pdf
8. Everstine K., Spink, J., and Kennedy, S. 2013. "Economically Motivated Adulteration (EMA) of Food: Common Characteristics of EMA Incidents." *J. Food Prot*. 76(4): 723-735.
9. Michigan State University Food Fraud Initiative. "Food Fraud Reference Sheet." Accessed October 18, 2016: http://foodfraud.msu.edu/wp-content/uploads/2014/08/flyer-FF-Reference-Sheet-Final.pdf
10. Food and Drug Administration Health Hazard Evaluation Board, "CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects," 2005. Accessed October 18, 2016: http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074554.htm
11. Olsen, AR. 1998. "Regulatory Action Criteria for Filth and Other Extraneous Materials: Review of Hard or Sharp Foreign Objects as Physical Hazards in Food." *Regulatory Toxicology and Pharmacology*. 28:181-189.
12. ICMSF. *Microbial Ecology of Food Commodities*. Second Edition. 2005. Vol. 6. Chapter 12 – Sugar, syrups and honey. Kluwer Academic/Plenum Publishers. New York, New York. pg. 534-537.
13. Michalak, I., Chojnacka, K. 2014. Algal extracts: Technology and advances. *Engineering in Life Sciences*. 14(6): 581-591.
14. Singh, R.P. and Reddy, C.R.K. 2014. Seaweed–microbial interactions: key functions of seaweed-associated. *FEMS Microbiol Ecol*. 88: 213–230.
15. Food and Drug Administration, "Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed," 2000. Accessed October 18, 2016: http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm077969.htm
16. van der Spiegel, M., Noordam, M.Y., and van der Fels-Klerx, H.J.. 2012. Safety of Novel Protein Sources (Insects, Microalgae, Seaweed, Duckweed, and Rapeseed) and Legislative Aspects for Their Application in Food and Feed Production. *Comprehensive Reviews in Food Science and Food Safety*. 12: 662-678.
17. Uemura, H., Arisawa, K., Hiyoshi, M., Satoh, H., Sumiyoshi, Y., Morinaga, K., Kodama, K., Suzuki, T., Nagai, M., Suzuki, T., 2008. PCDDs/PCDFs and dioxin-like PCBs: Recent body burden levels and their

determinants among general inhabitants in Japan, *Chemosphere*, 73(1): 30-37. http://dx.doi.org/10.1016/j.chemosphere.2008.05.066.

18. Imano, S., Wada, A., Nakamura, T., Ochiai, M. 2010. Concentration analysis of dioxins in Tokyo bay by seawater -bottom sediment interaction model. *Journal of the Japan Society for Marine Surveys and Technology*. 22(2): 9-21.
19. Food and Drug Administration. 1995. "CPG 575.100 Pesticide residues in food and feed – enforcement criteria." Accessed October 18, 2016: http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm123236.htm
20. ICMSF. *Microbial Ecology of Food Commodities*. Second Edition. 2005. Vol. 6. Chapter 8 – Cereals and Cereal Products. Kluwer Academic/Plenum Publishers. New York, New York. pg. 409-421.
21. Swaim, J., 2016. "Requirement for *Listeria* Control Program and Best Practices to Control *Listeria*." Developed to provide summary of suggestions for controlling *Listeria monocytogenes* under the United States FDA and Preventive Controls for Human Food rule.
22. ICMSF. *Microorganisms in Foods 5. Characteristics of Microbial Pathogens.* 1996. Chapter 8 – *Listeria monocytogenes*. Kluwer Academic/Plenum Publishers. New York, New York. p. 148.
23. Food and Drug Administration. 2006 "Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Final Guidance." Accessed October 18, 2016: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm059116.htm.
24. Jackson, L.S., Fadwa M. Al-Taher,2 Mark Moorman,3 Jonathan W. Devries, J.W. Tippett, R. Swanson, K., Fu, T., Salter, R. George Dunaif, G., Susan Estes, S., Albillos, S. and Gendel, S.M. 2008. Cleaning and other control and validation strategies to prevent cross-contact in food processing operations. *J. Food Prot*. 71(2):445-458.
25. Food and Drug Administration. 2016. "Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food, Appendix 1: Potential Hazards for Foods and Processes." Accessed October 18, 2016: http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM517402.pdf.
26. IFT Press. *Water Activity in Foods – Fundamentals and Applications.* Appendix D Minimum Water Activity Limits for Growth of Microorganisms. 2007. Blackwell Publishing Professional. Ames, Iowa. pg. 405.
27. ICMSF. *Microbial Ecology of Food Commodities*. Second Edition. 2005. Vol. 6. Chapter 14 – Water. Kluwer Academic/Plenum Publishers. New York, New York. pg. 574-586.
28. Food and Drug Administration. 1998. "Defect Levels Handbook." Accessed October 19, 2016: http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm056174.htm#CHPTD
29. Dosland, O. 2014. Effective Prevention of Insect Infestation in Flour. www.qualityassurancemag.com. Accessed October 19, 2016: http://www.qualityassurancemag.com/article/qa1214-insect-infestation-flour-prevention/
30. USA, 21 CFR. § 7.13 Suggested Forms of Guaranty. Accessed October 19, 2016: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=7.13
31. Food and Drug Administration. 2016. "Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food, Appendix 3: Bacterial Pathogen Growth and Inactivation." Accessed October 19, 2016: http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM517405.pdf.
32. Flores, N.C., Boyle, E.A.E.. 2000. "Thermometer Calibration Guide." Kansas State University Agricultural Experiment Station and Cooperative Extension Service. Accessed October 20, 2016: https://www.asi.k-state.edu/doc/meat-science/thermometer-calibration-guide-2.pdf.

33. University of Wisconsin - Madison Center for Meat Process Validation. 2008. "Example – SOP for Calibration of Thermometer." Accessed October 20, 2016: https://meathaccp.wisc.edu/prerequisite_programs/assets/SOP%20Thermometer.pdf
34. Food and Drug Administration. 2016. "Import Alert 45-02: Detention Without Physical Examination and Guidance of Foods Containing Illegal and/or Undeclared Colors." Accessed October 20, 2016: https://www.accessdata.fda.gov/cms_ia/importalert_118.html.
35. Example - SOP Inspection Sifters
36. Kraft Foods. 2010. Supplier and External Manufacturer HACCP Manual. Accessed October 20, 2016: http://www.mondelezinternational.com/~/media/MondelezCorporate/uploads/downloads/procurement/Supplier_HACCP_Manual.pdf.
37. Example – Storage Area GMP Audit.
38. Example - GMP Inspection of Production Areas Audit
39. Stier, R. Shipping and Receiving for Food Safety. *Food Safety Magazine*. Accessed October 20, 2016: http://www.foodsafetymagazine.com/magazine-archive1/junejuly-2012/shipping-and-receiving-for-food-safety/.
40. Example – PC Form Dough Storage
41. Example – Employee Training Records
42. Example – Metal Detection Log
43. Example – Generic Listeria Environmental Monitoring Program
44. Food Safety Preventive Controls Alliance. 2016 FSPCA Preventive Controls For Human Food Training Curriculum, Appendix 5. Version 1.2. pg. 495-504.
45. Food Safety Preventive Controls Alliance. 2016 FSPCA Preventive Controls For Human Food Training Curriculum , Appendix 6. Version 1.2. pg. 507-526.
46. Example – Corrective Action Record
47. Sample Letters of Guarantee for Packaging
48. Example – Generic Recall Plan
49. Example – Reanalysis Form
50. Example – Equipment Calibration Log
51. North Dakota State University Wheat Quality and Carbohydrate Research. 2015. "Flour Analysis". Accessed October 26, 2016: https://www.ndsu.edu/faculty/simsek/wheat/flour.html.

5. Example - Training Document

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Training

In addition to the Preventive Controls Qualified Individual(s), each facility will be required to have Qualified Individuals. Qualified Individuals are defined as "a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment." The Qualified Individuals should be trained for the job they are expected to perform at the facility and a copy of the training records should be maintained.

As a reminder, the Preventive Controls Qualified Individual (PCQI) is considered a qualified individual that has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system. The certification of the PCQI should also be maintained on file at the facility.

Example Training form

PRODUCT(S): Brown Sugar Steamed Buns		
PLANT NAME:	**ISSUE DATE:**	
ADDRESS:	**SUPERSEDES:**	

Training on Proper Sampling Technique for Environmental Monitoring – training conducted to ensure quality assurance personnel assigned to collect samples understand that a swab must be 30.5 cm by 30.5 cm and the goal is to identify the high risk part of the equipment for swabbing

Name	Signature	Date

6. Example - Storage Area GMP Audit

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

STORAGE AREA GMP AUDIT

STORAGE AREA	ACCEPT -ABLE	UNACCEP- TABLE	CORRECTIVE ACTION
1. RETURNED GOODS: CONTROLED PROPERLY SPOILS INTO SPOILS CAGE.			
2. PALLET TRANSFER STATION FUNCTIONS			
3. GENERAL HOUSEKEEPING.			
4. GENERAL EMPLOYEES PRACTICES.			
5. COMBO BINS OF WOOD, CARDBOARD, MISC. GARBAGE TO BE DISCARDED WHEN FULL.			
6. TRANSPORT CARRIERS MUST BE ADEQUATELY PROTECTED.			
7. PROPER STORAGE AREA TEMPERATURE TO BE MONITORED DAILY			
8. SAFEGUARD ALL PRODUCTS AGAINST POTENTIAL LEAKS AND DRIPS AND NOTIFY PROPER PERSONNEL IMMEDIATELY.			
9. CLEAN UNDER PALLET FLOW RACKS AS NEEDED.			
10. MAKE SURE PRODUCTS ARE LOADED ON CLEAN TRUCKS.			
11. NO GUM CHEWING, JEWELRY, OR WATCHES IN DISTRUBUTION CENTER.			

AUDITOR _____ DATE _____

TIME_____

7. Example - Generic Recall Program

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Company Name Recall Program

Recall Plan

FDA requires a Recall Plan whenever the hazard analysis identifies any hazard that requires a preventive control.

The goals of a product recall

A product recall is intended to protect public health. Your first goal is to regain control of all potentially hazardous products. If this goal is met, the recall is successful. Sometimes you'll have to also work toward a second goal: telling the public about the potentially hazardous product and how to dispose of it.

Basic principles of conducting a product recall

There are basic principles that will make execution of your recall plan effective.

1. Use a lot or date code on all products.
2. Designate (ahead of time!) a person who will be in charge of the recall.
3. Designate (ahead of time!) a person who will talk with the media.
4. Keep good records of your wholesale customers so you can easily contact them.
5. Have a plan for informing the public.
6. Have model press releases and customer-contact scripts ready (ahead of time!).
7. Work with regulators.
8. Act quickly – if in doubt take the safer course of action.
9. Practice your recall plan with a "dry run."

PRODUCT RETRIEVAL POLICY

Company Name will maintain an effective warning and retrieval system for products that threaten public health, violate government regulations, or do not meet standards.

A. Introduction

Issued:
Revised:

Product recalls involve the removal of product from the market which are adulterated, misbranded, or otherwise in violation of federal/state statute or regulation. Recalls may be firm-initiated or USDA/FDA - requested. The term "recall" is used when there is reason to believe a product in commerce is adulterated or misbranded under the provisions of the Federal Meat Inspection Act, Poultry Products Inspection Act or Food Drug and Cosmetic Act. A Recall does not include a market withdrawal or stock recovery that is completed by the firm.

B. Recall Classifications:

Class I - This is a health hazard situation in which there is a reasonable probability that the product will cause serious adverse health consequences or death.

Class II - This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.

Class III - This is a routine situation where the use of the product will not cause adverse health consequences.

Market Withdrawals involve the removal of product from the market which are below quality standards or minor regulatory infraction that would not cause the product to be adulterated or misbranded.

Code Dates/Records

1. All products produced by. will have a legible code date that is produced by a code dating system which identifies the day and year of production.

2. **Company Name** will maintain all such records pertaining to product for no less than two years from production date.

D. Responsibilities

1. The decision to initiate a recall is the responsibility of the President or, in that person's absence, the General Manager. The decision to assume the responsibility for a recall activity previously initiated by a supplier/regulatory agency will be made by the President. The proper execution of a recall depends on the Recall Coordinator and the Recall Team, a standby group of personnel that is vital to the success of the recall action plan.

2. The Recall Officer directs all activities of the Recall Team, which is composed of the Recall Coordinator, and representatives of the following departments: (and hone fax and email for these individuals)

Department	**Representative**	**Alternative**
Recall Officer/Coordinator		
Marketing		
Legal		
Food Safety Team		
Plant Operations		
Preventive Controls Team/Quality Assurance		
IT/Accounting		
Call Center Operations		

The personnel and alternates assigned to the Recall Team are listed above. (**add real names and include only the people you will have on your team)**

.

The major responsibilities of the Recall Team are to:

1. Evaluate pertinent facts, information, and reports to confirm the degree of the hazard, the recall class, recall depth, and appropriate regulatory agency notification.
2. Create the form of written notification of the recall decision to use for all affected customers.
3. Notify distribution with instructions for the recall, including all product information and directives to stop shipments.
4. Develop a recovery force, which will prepare recall forms, conduct supplier notification and customer notification.
5. Establish lines of communication within the company, with the media, the insurance carrier, and with the appropriate regulatory agencies.

6. Prepare recall letters and press releases.

7. Implement effectiveness checks to verify receipt of all recall communications.

8. Maintain a log of all recall events.

9. Evaluate recall facts to assist in correcting errant manufacturing or distribution practices.

10. Identify and implement procedures for terminating the recall.

11. Evaluate the recall process to seek improvement in performing future recalls.

E. The responsibility of individuals and alternates on the Recall Team are as follows: **(*Define for your operations – these are ideas…)***

Recall Officer Responsibilities

1. Evaluate preliminary information concerning suspected health hazards, quality defects, or product adulteration, and obtain product samples, if necessary.

2. Coordinate efforts with Quality Assurance staff and food safety personnel to make a preliminary analysis of the suspected hazard.

3. If a health hazard is confirmed and the President decides to recall, call an immediate Recall Team meeting; coordinate and direct all activities of the recall procedure.

4. Coordinate and direct all activities involved in the disposition of recalled product.

5. Coordinate and direct all activities necessary to correct errant distribution practices.

6. Coordinate and direct internal communications.

7. In the event of regulatory agency involvement, participate in discussions and maintain records.

Recall Coordinator Responsibilities

1. Implement effectiveness checks.

2. Maintain a log of all recall events.

Marketing Responsibilities

1. In conjunction with the Recall Officer and Recall Team, prepare all external communications and function as media contact.

Legal Department Responsibilities

1. Ensure that a recall of product meets all applicable legal requirements.

2. Advise Recall Officer on appropriate actions to be taken to protect the rights of the company and its officials.

3. Review communications with regulatory agencies.

4. Assist in final drafting of information for release to the public.

Quality Assurance Responsibilities

1. Receive complaint information and document on Customer Complaint form.

2. Assist Recall Coordinator in making preliminary analysis of potential hazard.

3. Notify plant of initiation of recall action and stop production of suspect product.

4. Obtain all analytical lot information, lot records, product codes, ship dates, code dates, etc., to trace destination of suspect product.

5. Obtain suspect product sample when possible and arrange for shipment to designated laboratory for analysis.

6. Isolate documents and impound product at our facility, warehouse and distribution outlets.

7. Supervise and document the retrieval of suspect product from the customer.

8. Assist in isolating and impounding any raw materials or packaging components responsible for the product deficiency.

9. Confirm and document destruction of returned product if final disposition requires destruction.

10. Retain and provide security for any product samples or materials as requested by the Legal Department.

11. Execute an annual mock recall to assess effectiveness of procedures.

Sales and Call Center Responsibilities

(You may not have a call center- if a large recall and you do not – you may contract with someone to assist with calls… or you may need to increase the volume or your voice mail as you will receive a huge volume of calls and you do not want customers to think you are unavailable!)

1. Receive complaint information and document.

2. Assist Quality Assurance in obtaining product from customers when available.

3. Assist Quality Assurance in coordinating recall notification.

4. Document the dollar amounts payable to the customer.

5. Coordinate replacement of suspect product.

Accounting Responsibilities

1. Ensure that we have assessed and accounted for all costs associated with recall.

2. Ensure a timely recovery of all recall costs.

3. Advise Recall Officer of the status and extent of the supplier's insurance coverage.

4. Notify Company product liability carrier of the recall situation and keep carrier advised as necessary

ORGANIZATION AND COMMUNICATION GUIDELINES

A. Complaints: Notification of any physical illness or of any potentially serious product defect or complaint is to be communicated directly to the Recall Officer (or designee) and the Legal Department.

B. Preliminary Analysis of Hazard: If the Recall Officer, with the advice of the Quality Assurance and Legal Departments, determines that the complaint is an isolated instance, invalid, or does not involve any substantial hazard or quality defect, it is to be handled as a normal product quality complaint.

C. Product Recalls and Withdrawals: When there is reasonable evidence that a potential problem that could warrant a recall may exist, the findings are to be communicated by the Recall Officer to the President and the Recall Team. In consultation with legal counsel, the Recall Officer will recommend to the President actions to be taken, including what, if any, additional information needs to be developed and whether the appropriate regulatory agencies should be notified. The Recall Officer will continue to investigate the complaint to confirm the presence or absence of hazards or defects, utilizing all information available.

Decisions not to withdraw or recall a product are to be communicated internally to the Recall Team and to the regulatory agency involved (if such agency was

previously informed of the possibility of recall or withdrawal). Subsequent activity would then be the same as in handling a normal product quality complaint.

Decisions to recall will be communicated immediately to the Recall Team and to the appropriate regulatory agency. The Recall Officer will direct all recall activities as described previously. In the event of a recall initiated by a supplier or regulatory agency, the Recall Officer will immediately notify the Recall Team, and will direct all recall activities as specified in Recall Responsibilities of this manual.

D. Communication with Media and Customers:

(Practice this during mock recalls! Make sure phone lists are up to date. Make sure your employees know not to speak to the media. Have a friend show up in a van, wearing a suit holding a microphone and try to interview them on the way out the door. Will they answer questions????)

In the event of a recall, external communications with customers and the news media are critical to recalling the product and avoiding damaging publicity. Therefore, all communication with the media will be handled by Director of Marketing. All communications concerning possible recalls, stock recoveries or market withdrawals should follow company confidentiality guidelines. The Recall Team will approve all communications with customers. Where emergency situations exist, telephone, facsimile transmission, post cards or letters will be used in notifying customers and in locating product for return. To demonstrate that the company is acting in the customer's best interest, and to avoid publication of erroneous information, position statements will be prepared by the Director of Marketing for response to news media inquiries. Such information will be coordinated with the regulatory agency involved and given to the news media voluntarily. Accurate, timely communications with regulatory agencies is important; contact with the agency and release of information to the press will be made only when credible facts are available.

All internal communications regarding a recall and its progress are to be made by the Recall Coordinator and the Director of Marketing. Their statements will

describe the situation as it then exists. All calls from the media or the general public must be referred to Director of Marketing.

RECALL PROCEDURES

A. Receive Complaint: Customer complaints are normally directed to the Customer Service Representative for handling. If a potentially serious complaint is brought to the attention of the CSR, the Recall Officer and the Legal Department must be notified immediately. Documentation of all pertinent information as required. When available, suspect product will be obtained for shipment to designated laboratories.

B. Assessment of Public Health Significance: Based upon evidence and advice supplied by Quality Assurance and other departments, the President will determine the need to initiate immediate recall. In the event of any recall, the Recall Officer will order that all inventories of the product be impounded. The speed with which a product recall is put into effect is critical. Regulatory agencies require assurance that a recall will be carried out effectively and quickly.

C. Formal Notification of Regulatory Agency: The Recall Officer will notify the Recall Team when it becomes necessary to initiate a product recall. The Recall Officer will consult with legal counsel to ensure compliance with government regulations, and to determine company liability for seizures, injunctions, and prosecutions. When the decision to recall is made, the Recall Officer will communicate directly with the appropriate regulatory agency. The notice to regulatory agencies must include:

- Reason for recall
- Brand names
- Product names
- Packaging (Type & Size)
- Package codes (Use by/Sell by)
- Packaging dates
- Photos of label or package

- Case codes
- Count/case
- Production dates
- Distribution areas
- School lunch (yes/no)
- Department of Defense (yes/no)
- Internet or catalog sales (yes/no)
- Amount produced (pounds)
- Amount held at establishment
- Amount distributed (pounds/cases)
- Distribution level (depth of the recall, if known)

Copies of actual or proposed communication strategies and proposed recall strategies should also be shared with the agency.

Action Plan

1. Notification of potential problem.

2. Recall Team Group Meeting.

    a. Identify Problem - Recall officer

    b. Establish severity and magnitude - Team members

    c. Determine Scope of Recall by reviewing records

Distribution records are maintained as necessary to facilitate identification and location of products that are recalled. These records can be used to quickly provide FDA or USDA/FSIS with requested information regarding product distribution. Records such as bills of sale, invoices, and shipping papers are kept with respect to each transaction in which any livestock, poultry or poultry food, meat or meat food product purchased, sold, shipped, received or otherwise handled by the establishment in connection with any business subject to the FMIA or PPIA. These records include names and address of consignees, shipment method, date of shipment, etc.

    d. Decision of Action Mode - Recall Officer

    e. Clarification of objectives and assignments - Recall Coordinator

3. Action Mode

   a. Establish code date (s) of suspect product and total amount of product produced - Quality Control/Operations

   b. Establish location of all suspect product – Distribution

   c. Retain product in-house/Verify Quantity - Quality Control

   d. Notify customers/brokers/outside storage facilities to retain all suspect product/Verify Quantity – Distribution (Sample letters are attached that will be updated to include specific situations as necessary)

   e. Determine quantity of suspect product under retention (total available or under company control) - Quality Control-Shipping

   f. FDA notification – Class 1 recalls require a Reportable Food Registry report to be filed within 24 hours. All recalls should also include a notification to the local District Office to allow their input into recall.

   g. USDA notification- (USDA requires notification of recalls within 24 hours of initiating the recall) -Recall Officer

   h. Media coverage needed – Marketing Department

   (Media contacts reference in back of plan)

   i. Media Contact – Director of Marketing

4. Communication

   It will be the responsibility of each member of the recall Action Team to notify the Recall officer of any information obtained in indicating the possible need for product recall, market withdrawal, or stock recovery. This may be in the form of customer complaints, sales-broker comments, in-house findings, USDA or FDA notifications, etc. The Recall Officer will then make the decision as to whether a Recall Action Team meeting is needed.

   The initial meeting should be designed to either offer direction to group members as to information needed or to review information, identify real or potential problems, and formulate recommendation for action.

All information obtained thereafter should be forwarded to the Recall Coordinator. This information will be reviewed with the Recall Officer for reassessment of previous decisions and problem status.

5. Product Retrieval

Product is to be returned to a central or controlled location. Strict inventory of incoming suspect product must be maintained. Suspect product must remain under QC Hold tags until disposition decision has been made. Any condemnation of product should be supported with appropriate evaluation and testing by an independent agency. It is also recommended to obtain the assistance of an independent expert to verify that appropriate actions have been taken.

Procedure:

a. Designate location for return of suspect product.

b. Establish written handling procedures for suspect product. This should be submitted to FDA or USDA for approval. It must include sorting guidelines. This usually involves the categories: 1. Good product (acceptable for use under USDA and company standards.) 2. Questionable product (this product is either suitable for correction/reconditioning or subject to further testing, and 3. Condemned.

c. Designate person (s) responsible for supervision of suspect product receipt and handling.

d. Suspect product should be itemized by category (1,2,3 above)

e. Records for "Questionable Product" must be maintained. This product is to remain under QA Hold Tags until corrected &/or further testing results are available.

f. Condemned product is to be denatured as per USDA guidelines and records prepared and retained for all condemned products.

g. Condemned product could be sent to a landfill per USDA guidelines and approval.

6. Effectiveness Checks

The purpose of effectiveness checks is to verify that all consignee/customers involved in the recall have received notification about the recall and have taken appropriate

action. This is a means of assessing the progress and efficacy of a recall. FDA or FSIS will verify our effectiveness checks.

To assess the effectiveness of our recall, the recall team will compile the following information:

a. Pounds of each type of product implicated in the recall.
b. Labeling information for each product.
c. How much of the product is still "in house" or at other locations?
d. How many customers were affected?
e. How did we contact each customer?
f. Do we have documentation of the customers?
g. Do we have a written response acknowledging receipt of the recall information?
h. What actions were taken with the product? Who is responsible for these actions?
i. If the product was destroyed, was destruction witnessed and documented by responsible personnel? Were FDA/FSIS personnel present?
j. Do we have written documentation of
    1. When problem was identified?
    2. When customers were notified

7. Recall Assessment
The recall team will regularly report the results of the effectiveness of our efforts to retrieve the product to FSIS in order to keep them apprised of the status of recalls in progress. These reports will contain the following information unless otherwise specified:

1. The number of consignee/customers notified of the recall
2. The dates notifications were made
3. The method of notification
4. The number of consignee/customers responding to the recall communication
5. The quantity of product each consignee/customer had on hand at the time the communication was received.
6. The number of consignee/customers that did not respond
7. The quantity of product returned or held by each consignee/customer
8. An estimated time of completion of the recall.

8. Recall Conclusion

The recall will conclude when all the available portion of total suspect product produced has been located and handled appropriately as deemed necessary by FDA or FSIS and company guidelines. Refer to FSIS Directive 8080.1 Rev 4 Attachment 3

for the complete FSIS Recall effectiveness checks and recall termination requirements or FDA's Guidance for Industry: Product Recalls, Including Removals and Corrections for recall termination.

9. Recall Follow-up

   The recall team will evaluate the recall to determine whether things could be handled differently, and what if any improvements should be made to the plan.

   Further the Recall Team conducts a mock recall at least annually to verify the effectiveness of the plan.

Media Contact Information

Add local newspaper contacts and local media contacts – if you can get to know some one at these locations before a crisis – all the better!!!!

8. Example - Reanalysis Form

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

The FDA defines reanalysis of the food safety plan as "A verification procedure to assure that the Food Safety Plan remains valid and the food safety system is operating according to the plan". FDA requires a reanalysis at least every three (3) years; whenever a significant change in product or process occurs; when there is new information that becomes available about potential hazards associated with the food; when there is an unanticipated problem; and when a preventive control is ineffective.

Example Reanalysis Report

PRODUCT(S): Brown Sugar Steamed Buns		
PLANT NAME:	**ISSUE DATE**	
ADDRESS:	**SUPERSEDES**	

Food Safety Plan Reanalysis Report

(Add rows as needed if different plans are used for different products)

Checklist	**Date reviewed and initials of reviewer**	**Update needed Yes/No**	**Date Updated Completed:**	**Person (PCQI) Completing the Update** (initial of
List of Food Safety Team				
List of products and processes in place at facility				
Product flow diagrams				
Hazard Analysis				
Sanitation Preventive Controls				
Food Allergen Preventive Controls				
Process Preventive Controls				
Supply-chain Preventive Control Program				
Recall Plan				

9. Example - Equipment Calibration Log

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

EQUIPMENT CALIBRATION LOG

Equipment exists in the facility that requires periodic calibration. The frequency of calibration is dependent on the type of equipment used. **Direct Observation of the equipment being calibrated is indicated by the letters "D.O." and the initials of the person doing the direct observation in the space to the left of the "Date" column.**

* Dispose thermometer when adjustment is greater than 2°C.
* pH calibration slope range: 90.0- 105.0

Type of Equipment	Accuracy Check Frequency	Calibration Frequency
pH Meter	Daily	Daily
Water activity equipment	(per manufacture recommendations)	(per manufacture recommendations)
Thermometer	Daily	Quarterly
Portable Scales	Weekly	Yearly

Date	Time	ID for Equipment Calibrated	Water Activity Reading	Mercury Thermometer Reading (°C)	Thermometer Reading (°C)	pH Reading	Comments*	Operator Initials

Reviewed By: _____ Date:_____

Issued:
Revised:

10. Example - Corrective Action Record

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

CORRECTIVE ACTION REPORT

Date of Report: _____ Date of Incidence: _____

Preventive Control Deviation: _____

Description of **Deviation** (Include pounds, lot number and all details - ATTACH SEPARATE SHEET IF REQUIRED).

Document Completed By: _____

QA Personnel Notified: _____ Manager Notified: _____

Corrective Action Taken (To be completed by QA).

Prevention

Final **Disposition** of Affected Product

Signature & Date Required By:

Plant Manager: _____

QA Manager: _____

cc: Plant Manager, Director of Technical & VP Operations.

This corrective action response meets the requirements set forth in FDA Regulation 21 C.F.R. § 117.150(a)(2)
- ❖ Identify and correct the cause of the deviation,
- ❖ Action taken to reduce the likelihood the deviation will occur again,
- ❖ All affected product is evaluated for safety, and
- ❖ Prevent distribution into commerce of product adulterated as a result of the deviation.

Issued:
Revised:

11. Example - Metal Detection Log

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Metal Detection Log **Date: _____**

Time	Batch	Product	Metal Detector (Yes)	Visual Inspection	Initial	Corrective Action

Metal Detector Specifications: Y mm ferrous, Y mm non-ferrous; and Y mm stainless. Frequency- ?
*Needs to be defined per specification

Supervisor (Name and Date): _____

Issued:
Revised:

12. Example - Batch Formulation Log

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Batch Formulation Log

Date:			
Product: Onion Dressing	Part No.		

Batch #	Pounds of Product (Actual amount)	Rec. Lot No.	Foreign Material?	Off Odor, Color, or Appearance?	**Batch #**	Pounds of Product (Actual amount)	Rec. Lot No.	Foreign Material?	Off Odor, Color, or Appearance?
Grated Onions			YES / NO	YES / NO	Grated Onions			YES / NO	YES / NO
Vinegar			YES / NO	YES / NO	Vinegar			YES / NO	YES / NO
Citron Fruit Juice			YES / NO	YES / NO	Citron Fruit Juice			YES / NO	YES / NO
Salt			YES / NO	YES / NO	Salt			YES / NO	YES / NO
Sugar			YES / NO	YES / NO	Sugar			YES / NO	YES / NO
Spice			YES / NO	YES / NO	Spice			YES / NO	YES / NO
Xanthan Gum			YES / NO	YES / NO	Xanthan Gum			YES / NO	YES / NO
Vegetable Oil			YES / NO	YES / NO	Vegetable Oil			YES / NO	YES / NO
Total Batch Wt.⇒		(Monitoring) Qualified Individual's Initials		Time	Total Batch Wt. ⇒		(Monitoring) Qualified Individual's Initials		Time

Batch #	Pounds of Product (Actual amount)	Rec. Lot No.	Foreign Material?	Off Odor, Color, or Appearance?	**Batch #**	Pounds of Product Actual amount)	Rec. Lot No.	Foreign Material?	Off Odor, Color, or Appearance?
Grated Onions			YES / NO	YES / NO	Grated Onions			YES / NO	YES / NO
Vinegar			YES / NO	YES / NO	Vinegar			YES / NO	YES / NO
Citron Fruit Juice			YES / NO	YES / NO	Citron Fruit Juice			YES / NO	YES / NO
Salt			YES / NO	YES / NO	Salt			YES / NO	YES / NO
Sugar			YES / NO	YES / NO	Sugar			YES / NO	YES / NO
Spice			YES / NO	YES / NO	Spice			YES / NO	YES / NO
Xanthan Gum			YES / NO	YES / NO	Xanthan Gum			YES / NO	YES / NO
Vegetable Oil			YES / NO	YES / NO	Vegetable Oil			YES / NO	YES / NO
Total Batch Wt.⇒		(Monitoring) Qualified Individual's Initials		Time	Total batch Wt. ⇒		(Monitoring) Qualified Individual's Initials		Time

Verification

Signature_____Date_____

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Monitoring and Verification procedures are detailed on the back of this document.

Monitoring: The Qualified Individual shall continuously monitor the ingredients as they are being added to the mixer. If the presence of foreign material is found or product is found to be off odor, color, or appearance or foreign material is identified, the Qualified Individual shall stop running product and notify management and document the finding. Management shall implement appropriate corrective action. (Management shall document immediate corrective action, including disposition of product, and measures to prevent reoccurrence on the Corrective Action Record.)

Verification: A Qualified Individual shall verify that the record has been completed correctly and any issues requiring corrective actions resulted in a Corrective Action Record.

米国食品安全強化法「ヒト向け食品に関する現行適正製造規範ならびに危害分析およびリスクに応じた予防管理」規則にかかる食品安全計画雛形（まんじゅう）＜英語原文＞

2017 年 3 月作成

日本貿易振興機構（ジェトロ）農林水産・食品部　農林水産・食品課
〒107-6006　東京都港区赤坂 1-12-32
Tel.　03-3582-5186