「ヒトが摂取する食品に関する現行適正製造規範ならびに危害分析及びリスクに応じた予防的管理措置」の食品安全計画雛形（冷凍チャーハン）＜英語原文＞

２０１６年３月

日本貿易振興機構（ジェトロ）

シカゴ事務所

農林水産・食品課

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（冷凍チャーハン）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

目次

1.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 CCPs in the traditional 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.

This generic plan was developed to serve as a guide. The document provides the framework for the development of a Preventive Control Plan for Frozen Fried Rice. 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 the FDA. Since each processor of Fried Rice 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.

2. Frozen Fried Rice Product Flow Chart

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

Frozen Fried Rice packed in film – laminated bag (Water Activity＜0.85)

*The time/temperature for cooking and freezing, and pH and water activity must be scientifically validated and support must be maintained with the food safety plan.

Receive Dry Goods

1. Rice
2. Soy Sauce and other seasonings (pepper, salt)
3. Cooking Oil
4. Citric Acid
5. Food Additives

Receive Packaging Material

1. Laminated bags
2. Labels for individual bags

Bags may be pre-labeled or labels may be applied after sealing bags

3. Labels for storage/shipping containers

Receive Refrigerated Ingredients

1. Liquid Eggs
2. Vegetables (carrots, onions, potatoes, garlic)

Store Refrigerated Ingredients

Wash vegetables and peel and cut

Dry Good Storage

Wash Rice and Steam

Confirm NO metal contaminations (This process may occur prior to washing and steaming rice.)

Decrease pH by adding pH adjustment agents

5. Cooking fried rice
   a) Heat a pan and put cooking oil into it
   b) Add the liquid eggs to the pan and stir while pan is over the heat
   c) Add steamed pH adjusted rice to the pan and continue to stir over the heat
   d) Add all washed, peeled and cut vegetables to the pan and continue to stir over the heat
   e) Add soy sauce, pepper, salt and food additives
   f) Complete the fried rice by heating to an internal temperature of ≥ 75℃* and maintain at this temperature for at least one minute

6. Quick Freeze the fried rice to product temperature ≤0° C in less than 4 hours*

8. Package
   a) Package the prepared fried rice in small film-laminated bag
   b) Bag must be properly labeled

9. Confirm NO metal contaminations.

10. Pack bags into labeled storage/shipping containers

11. Store storage/shipping containers in a freezer (≤0° C)

12. Ship products in labeled shipping containers at ≤0° C

3. Frozen Fried Rice Product Description

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

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

Product Name(s)	Frozen Fried Rice
Product Description, including Important Food Safety Characteristics	**Frozen, ready-to-eat fried rice with eggs;** water activity <0.85 (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 & pH should be listed here.)
Ingredients	Rice, liquid eggs, carrots, onions, potatoes, garlic, cooking oil, soy sauce, seasonings, pH adjusting agents (citric acid), other food additives (A list of ingredients, which may be grouped or transferred from the product label.)
Packaging Used	Laminated bags (A general description of the packaging, including modified atmosphere or vcuum 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), & 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	(List intended shelf-life.)
Labeling Instructions related to Safety	Keep frozen until ready to use. 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**:

4. Frozen Fried Rice Production Process Narrative

Process Narrative

This Process Narrative is provided to permit a common vision of this process. There is no requirement for an establishment to create such a document; however, a Process Description may be useful to guide in the development of the hazard analysis and also to orient auditors. Other documents outside of the Food Safety Plan may substitute for a Process Narrative, such as ingredient specifications, product specifications, production instructions, standard operating procedures, etc. This Process Narrative is not complete nor does it represent any existing process. It is provided only as an example of what might be included.

PRODUCT(S) Fried Rice	**PAGE**	
PLANT NAME:	**ISSUE DATE**	
ADDRESS:	**SUPERSEDES**	

Receiving Ingredients and Packaging:

Ingredients and raw materials are purchased from reputable suppliers that comply with internationally recognized food safety and quality systems. For each ingredient, the same brand is used consistently to minimize variation. Ingredients are stored according to manufacturers' recommendations when specified.

- **Receiving packaging**: Corrugated shippers, paperboard trays and laminated bags are received in bulk. Specifications require food grade material for trays and laminated bags that are compatible with frozen storage of food products. Labeled cartons are reviewed for conformance with product allergen requirements and ingredients.
- **Receiving shelf stable ingredients**:
  - *Salt*: Received in 10-pound bags from our distributor. Specifications require food grade salt.
  - *Cooking oil*: The cooking oil is a high quality soybean oil. It is received from our distributor in 10-gallon jugs.

  All other ingredients would need to be listed.
- **Receiving refrigerated ingredients**:
  - *Eggs*: Refrigerated, pasteurized liquid eggs, processed to meet regulatory requirements, are received in 20-pound, bag-in-box containers from our sole source supplier, in refrigerated trucks.

  All other ingredients would need to be listed.

Storing Ingredients and Packaging:

- **Packaging storage**: Labeled cartons and individual bags are stored in the dry storage room in the packaging area. Laminated bags are stored in sealed containers to protect from contamination. Packaging is used First-In-First-Out.

- **Ambient ingredient storage**: Salt and pan release oil are stored in the dry storage room in the ingredient area, arranged by ingredient code number. All containers are sealed to avoid allergen cross-contact and cross-contamination during storage. Ingredients containing food allergens are identified and stored in specific locations with like allergenic ingredients, unless allergen cross-contact is not reasonably likely to occur.

- **Refrigerated ingredient storage**: Pasteurized liquid eggs are stored in separate designated areas in a cooler that is kept at ≤0°C) and used within code date. No open containers are returned to the cooler to minimize the potential for allergen cross-contact with egg allergens.

Steam ingredients: A full description of each step in your process would need to be provided – one example provided below.

Metal Detect:

Wash and Cut Vegetables:

Cook: Heat a pan and put cooking oil into it. Add the pasteurized liquid eggs to the pan and stir while the pan is over the heat. Add steamed pH adjusted rice to the pan and continue to stir over the heat. Add all washed, peeled and cut vegetables to the pan and continue to stir over the heat. Add soy sauce, pepper, salt and food additives. Complete the fried rice by heating to an internal temperature of ≥ 75°C and maintain at this temperature for at least one minute before removing from the heat.

Quick Freeze:

Package:

Metal Detection:

Frozen storage:

Frozen shipping:

5. Generic Preventive Control Plan

Generic Preventive Control Plan

Preventive Controls Qualified Individual:

PLANT MANAGER:

ISSUED:
REVISED:

Preventive Controls Food Safety Team

(The team should consist of individuals with different specialties and experience with the facilities 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, 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. #22)
– 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
Paprika Spice Extracts Natural Spices Liquid Smoke Garlic Onion Rosemary Caramel Coloring		Citric Acid Antioxidant Erythorbate Ascorbic Acid
Other	**Proteins**	**Packaging Materials**
Rice Water* Nitrogen Gas Carbon Dioxide (Dry Ice)	Liquid egg Non-fat dry milk	Vacuum Bags Film Labels Overwraps
Allergens		
Soy Whey (milk) Egg		

*Water may or may not be used as ab ingredient in product produced. Regardless, any water used for handwashing 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.

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
Receiving Rice	B –*Bacillius cereus* C – Arsenic (Heavy metals such as arsenic, can become part of a food without being intentionally added. Other unintentionally or incidentially added	B – yes	C - no	B – Cooked rice is a cause of *B. cereus* emetic-type food poisoning. The microorganism is frequently present in uncooked rice, and its heat-resistant spores survive cooking but may be controlled by acidification. The levels present at receiving of the uncooked, dry rice are not hazardous as long as the rice remains dry. (Supp. #1, 2) C – Arsenic – FDA analyzed 1300 samples of rice in 2013 and determined the values presented no immediate or short term health consequences. The FDA is continuing studies regarding potential long-term effects. (Supp.	Process control – acidification of steamed rice with citric acid to pH ≤ 4.3 at a subsequent step. Subsequent cook step		B – No

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
	chemicals should be considered such as cleaning chemicals, pesticides, industrial chemicals, drug residues or radiological hazards.) C – Pesticides (If exporting product, be aware that coutries may not have the same tolerance levels for certain pesticides, and may not even permit the use of certain pesticides.) C - Allergen		C – no C - no	#3) C – Pesticides – the use of unapproved pesticides or findings of residual levels above tolerance would require pesticides to be addressed as a supplier preventive control. (Supp. #14) C – Allergen - while rice is considered one of the least allergenic foods that humans regularly ingest,			

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
	C - Radiological	C – yes (whether this		very few cases of rice allergy have been reported in the medical literature. As rice is used as a main ingredient, it will be declared on the label. (Supp. #4) (This statement holds true if all products produced in the facility contain rice. If not, controls must be in place to ensure that no cross-contact can occur from receiving through to finished packaging. In that case, programs would need to be in place for storage, equipment and utensils, employee handling, etc.) C – Radiological – hazard may result from accidental contamination such as	Supply chain control – approved supplier and 3rd party supplier audit by qualified auditor Supply chain control	C – Radiological – yes	C – no

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
	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	is a hazard depends on where the rice is grown) C – yes		accidental release from a nuclear facility or damage to a nuclear facility during a natural disaster. (Supp. #36) C – economically motivated hazard (Supp. #36, 37, 38)	– approved supplier and 3rd party supplier audit by qualified auditor		

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
	addition of melamine to 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 – Stones		P - no	P – Stones – depending on			

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	P – yes		the size and shape of the stones, they may present a hazard for dental injury or choking. Stones are frequently heavier than the ingredient material, thus washing steps, flotation, riffle tanks and similar steps can remove stones from the process. The Food Safety Team should assess the frequency of observation of stones to determine if they present a hazard requiring a preventive control. P – Metal – pieces of metal may be present in raw material or introduced during the harvesting process from equipment used. This can be controlled by subjecting the	Process control – metal detection at subsequent step	P – Metal – yes (Metal detection can be done on received	

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 - Other foreign material		P – no	product to metal detection. (Supp. #5, 32) P – Other foreign material – 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 (7mm) to 1.0 inches (25mm) in length. The Food Safety Team should address only those hazards reasonably likely to cause		rice or after washing and steaming.)	

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
				injury. (Supp. #5, 32)			

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
Receiving soy sauce	B – none		B - no	B – none – high salt levels inhibit bacterial growth by decreasing the water activity to <0.85. (Supp. #6)			
	C – Allergen – soy (If exporting product, it is important to consider what the receiving country requires under food allergen labeling. While many countries recognize the same allergens as the USA (milk, egg, peanut, tree nuts, fish, crustacean shellfish, wheat, and soy), other countries have alternative allergens that require labeling.)	C – yes		C – Soy – this is an allergen that must be labeled to inform consumers. If non-soy-containing products are also produced in the same facility; allergen cross-contact with other products must be controlled. (Supp. #7)	Allergen control – allergen labeling at later steps in the process Sanitation controls – at a subsequent step if needed to prevent cross-contact		No No

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
	C – none (Countries may set allowable concentrations, manner of use and maximum allowable residues for certain chemicals.) P – none		C – no P – no				
Receiving cooking oil	B – none C – Allergen (The source of cooking oil must be determined as some may be considered allergens e.g., peanut oil, soy oil, sesame oil, fish oil, etc.) P – none		B – no C – no P – no	C – Allergen – If there is an allergen in the oil, it must be labeled to inform consumers. If the source of the oil is not also used in all other products produced in the facility; allergen cross-contact with other products must be controlled. (Supp. #8, 9, 10)	Allergen control – if there is an allergen in the oil, allergen labeling at later steps in the process Sanitation controls – at a subsequent step if needed to prevent cross-contact		No No

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
Receiving citric acid and food additives	B – none C – none (Food additives are chemical substances added during product formulation. These could also include color additives, preservatives such as sulfites, and nutritional		B- no C- no				

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
	additives. Countries may set allowable concentrations, manner of use and maximum allowable residues for certain chemicals.) P – none		P- no				
Receiving dry seasonings (pepper, salt, other dry spices)	B – *Salmonella* B – *C. perfringens, B. cereus*	B- yes	B – no	*Salmonella* has been known to contaminate spices, esp. pepper. Treated spices are used so this hazard is unlikely. (Supp. #11, 12, 20) *C. perfringens* and *B. cereus* spores may be found in spices but cannot grow in the dry spice or in the fried rice during the processing time. (Supp. #12, 20)	Supply chain control – pasteurization treatment for the dry spices	Yes	

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
	C- none P – none		C – no P - no				
Receiving Liquid Eggs	B- *Salmonella* C – allergens	B- yes C- Yes		*Salmonella* is a contaminant in liquid eggs. Receipt of refrigerated eggs and storage at ≤ 5°C. (Supp. 13) C – Eggs are an allergen that must be labeled to inform consumers. (Supp. #8) If non-egg-containing products are also produced in the same facility; allergen cross-contact with	Process control - subsequent cooking step Allergen Control – allergen labeling at other steps Sanitation controls – at a subsequent step if non-egg containing		No No No

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 – None		P – no	other products must be controlled.	products are made to prevent cross-contact		
Receiving Raw vegetables	B – *Salmonella; Listeria monocytogenes* C- Pesticides		B – no C- no	B – Pathogens may be present in raw produce. Receipt and storage of raw vegetables at ≤ 5°C. (Supp. #13) C – Pesticides – the use of unapproved pesticides or findings of residual levels above tolerance would	Subsequent cooking step		No

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		P- no	require pesticides to be addressed as a supplier preventive control. (Supp. #14) P – If there is a history of finding foreign material in the raw vegetables at receiving then the company would need to consider the need for a preventive control at this step.			
Receiving laminated bags and labels	B- none C – chemical residues		B – no C – no	C – Chemical residues -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. #15, 24)			

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
	C – Allergen P – none	C – yes	P – no	C – Allergen - Product labels must declare all allergens present in the product. (Supp. #7, 8)	Allergen control – label review for allergen information. (Label review may be done at the receiving step but should also be performed when applied to the finished product to ensure the proper label is used.)	Yes	
Storage of packaging and dry ingredients (rice, soy, citric acid, food additives, pepper, salt, other dry spices)	B – none C – none P – none		B – no C – no P – no				

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
Storage of refrigerated ingredients (liquid eggs, raw vegetables)	B – *Listeria monocytogenes, Salmonella*, C – none P – none		B – no C – no P – no	B – Pathogen growth to levels that render the cook step ineffective is not likely to occur. (Supp. #16)			
Wash rice and steam	B – *B. cereus*,		B – no	B – B. cereus - If the steamed rice is held at room temperature, the spores may germinate and multiply. The toxin produced can survive heating (such as steaming) and the product must be further processed (cooked) or placed into refrigeration within 4 hours. The process typically moves in a continuous fashion and therefore no preventive			

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
	C – none P – none		C – no P – no	control is needed at this step. (Supp. #2)			
Metal detection	B – none C – none P – metal	P – yes	B – no C – no	P – Metal – pieces of metal may be present in raw material or introduced during the harvesting process from equipment used. (Supp. #5, 32)	Process control – metal detection	Yes	

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
pH adjust steamed rice	B – *B. cereus* C – none P – none	B – yes	C – no P – no	B – *B. cereus* - Spores lose their heat resistance in acidic environments. Therefore, the pH is adjusted to ≤ 4.3 prior to the cooking step. (Supp. #2, 30)	Process control – rice adjusted to pH of ≤ 4.3.	Yes	
Cook fried rice (all ingredients are added at this step)	B – *Salmonella, Listeria monocytogenes, B. cereus* C – none	B – yes	C – no	B – pathogens – cooking the fried completed fried rice to an internal temperature of ≥ 75°C and maintaining that product for at least one (1) minute will kill the vegetative pathogens and a low water activity will suppress growth. (Supp. #18, 19,31)	Process control – minimum internal temperature and hold time of finished fried rice. Process control – water activity of the finished product is < 0.85	Yes Yes (this step may occur at another location.)	

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 – none		P – no				
Quick freeze the finished fried rice	B – *Listeria monocytogenes,*		B – yes	B – *L. monocytogenes* - *Listeria monocytogenes* can be introduced to un-packaged product post-lethality by the environment. (Supp. #17, 25, 28)	Sanitation control – prevents contamination	Yes	
	B – *B. cereus*		B – yes	B – *B. cereus* – growth of sporeformers can occur if product is not chilled rapidly. (Supp. #2)	Process control – fried rice is chilled to a temperature of ≤ °C. in ≤ 4 hours.	Yes	
	C – none		C – no				
	P – none		P – no				

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
Packaging	B – *Listeria monocytogenes* C – none P – none		B – yes C – no P – no	B – *L. monocytogenes* - *Listeria monocytogenes* can be introduced to un-packaged product post-lethality by the environment. (Supp. #17, 25, 28)	Sanitation control – prevents contamination	Yes	
Metal Detection	B – none C – none P – metal	P – yes	B – no C – no	P – Metal – metal-to-metal contact during process. (Supp. #5, 32)	Process control – metal detection	Yes	
Place packaged product into storage/shipping containers and store in freezer	B – none C – none P – none		B – no C – no P – no				

Preventive Controls Plan

Process Control	Hazard	Critical Limits	Monitoring				Corrective Action / Corrections	Record Keeping	Verification
			What	How	Freq.	Who			
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 X mm, non-ferrous –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 re-analysis 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.)	Metal Detection Log Validation records for setting and frequency Metal Detector Calibration Record Corrective Action Report	Review of documentation within 7 working days by the PCQI. (While the regulation requires records review by the PCQI within 7 working days of completion; it is highly recommended that this be done by the PCQI on a daily basis. When issues are identified during the PCQI 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.)

Preventive Controls Plan

Process Control	Hazard	Critical Limits	Monitoring				Corrective Action / Corrections	Record Keeping	Verification
			What	How	Freq.	Who			
Receipt of Pasteurized Spices	Salmonella	Received from an Approved Supplier approved on (date supplier(s) was roved, 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.)				(The below are considered "corrections" as corrections may be used for minor and isolated problems that do not directly impact 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.	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 Corrections record	PCQI reviews the initial and annual audit of the supplier by the qualified auditor. PCQI reviews the receiving record log within 7 days. PCQI will review 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?

Preventive Controls Plan

Process Control	Hazard	Critical Limits	Monitoring				Corrective Action / Corrections	Record Keeping	Verification
			What	How	Freq.	Who			
									• Have the supplier's corrective actions to past issues been appropriate and timely? • Are the supplier's storage or transportation practices appropriate?)
Labeling of allergens	Allergens: soy, eggs	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 place product on hold 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.	Product Mixing Record Finished Product Labels Corrections / Corrective Action Record	PCQI will review records within 7 working days. PCQI will directly observe the product being made and ensure that it matches the description on the mixing record.
pH Adjustment of rice	*B. cereus*	pH of the steamed rice is adjusted to ≤ 4.3 prior to the cooking step	Steamed rice is ≤4.3 pH prior to cooking	Calibrated and accurate pH meter	Each batch of steamed rice prior to cooking	Qualified Individual	If pH is not ≤ 4.3 pH, the product is held until the pH is corrected to ≤4.3 pH. The Qualified Individual will	pH record Daily pH Meter Accuracy Record	The PCQI will review all records within 7 days. (Accuracy checks and calibration of equipment are

Preventive Controls Plan

Process Control	Hazard	Critical Limits	Monitoring				Corrective Action / Corrections	Record Keeping	Verification
			What	How	Freq.	Who			
							determine the root cause and implement measures to prevent reoccurrence. If product went to cooking without proper pH adjustment, it will be destroyed.	Calibration Record Corrective action record	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.)

Cook	*Salmonella, B. Cereus, Listeria monocytogenes*	Cooked to an internal temperature ≥ 75C. and maintained at that temperature for at least 1 minute.	Internal product temperature is ≥ 75C. 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 ≥ 75C. 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.	Cooking record Daily Thermometer Accuracy Record Thermometer Calibration Record Corrective action record	The PCQI will review all records within 7 days. (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. #33, 34))
Water activity	*B. cereus*	Water activity is < 0.85	Water activity of finished product is < 0.85	Calibrated and accurate equipment (Place the type of equipment used here that is used to measure the water activity)	Each batch of product	Qualified Individual	If the product water activity is not < 0.85, 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.	Water Activity record Daily Accuracy Equipment Record Calibration Record Corrective action record	The PCQI will review all records within 7 days.

Preventive Controls Plan

Sanitation of the Quick Freeze and Packaging areas for finished fried rice	*Listeria monocytogenes*	Cleaning and sanitizing of the quick freeze and packaging areas where finished product is exposed after it has achieved lethality and prior to packaging All employees in the area (including maintenance, supervisors) must wear identified outer clothing, hairnets and gloves (Listeria monocytogenes can contaminate the product that is exposed to the environment after it has been cooked. This area	The quick freeze is evaluated for cleanliness. Sanitizer strength is measured prior to application in the area e.g., quaternary ammonium at 200 -400 ppm. Employees entering the area are wearing the designated outwear, hairnets and gloves.	Visual observation of the quick freeze area 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 area is 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 area is observed unclean prior to operations, the operations are not permitted to start until the area is cleaned. If the sanitizer strength is not appropriate, it is adjusted prior to using. If employees are not wearing appropriate attire for the area, 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 the Environment Testing Program identifies positive findings the actions outlined in the Environmental testing program will be followed and documented. (Supp. #21, 26, 27, 28)	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	The PCQI will review all records within 7 days. 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.)

		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.)							

List of Supplements for Preventive Control Plan

1. MN Dept of Agriculture Dairy and Food Inspection Division, *Acidified Rice HACCP Plans, Time, or Temperature Controls*, MN Food Safety Partnership – Plus Sushi /HACCP Training
2. University of FL, The Institute of Food and Agricultural Sciences Extension (IFASE), Preventing Foodborne Illness: Bacillus cereus and Bacillus anthracis
3. FDA: Arsenic in Rice and Rice Products
4. Teshima, Reiko, Division of Novel Foods and Immunochemistry, National Institute of Health Sciences, "Regulation of foods containing allergens in Japan"
5. FDA Health Hazard Evaluation Board, "CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects," 2005.
6. University of Nebraska – Lincoln Extension, Institute of Agriculture and Natural Resources, "GMPs for Sauces and Dressings"
7. FDA, "Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4) October 2006
8. International Organization of the Flavor Industry, INFORMATION LETTER N°1484, "Update on Food Allergy Labeling in Japan" Oct. 2, 2013.
9. Jackson, et.al. 2008. Cleaning and other control and validation strategies to prevent cross-contact in food processing operations. J. Food Prot. 71(2):445-458.pg. 10-25
10. University of Nebraska – Lincoln, Food Allergy Research and Resource Program (FARRP) "Components of an Allergen Control Plan"
11. FDA, Draft Risk Profile: Pathogen and Filth in Spices, Dec. 2014.
12. ICMSF. Microorganisms in Foods. 1998. Vol. 6. Chapter 7 – Spices, dry soups and oriental flavorings. Pp. 274-291. Blackie Academic & Professional. New York.
13. FDA Center for Food Safety and Nutrition (CSFAN, "Bad Bug Book, second edition"
14. FDA, "Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed," 2000.
15. Sample Letters of Guarantee for Packaging
16. Tompkin, Bruce, "The significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50°F," Joint FSIS/FDA Conference on Time/Temperature, Nov. 1996.
17. Tompkin Bruce, Virginia N. Scott, Dane T. Bernard, William H. Sveum, Kathy S. Gombas, 1999. "Guidelines to Prevent Post-Processing Contamination from *Listeria monocytogenes*." J. Food Prot. Vol. 19, No. 8, pp. 551-562.

18. ERS, LTD., prepared for New Zealand Ministry for Primary Industries "*Bacillus.cereus*," Aug. 2015.
19. FDA, "Water Activity in Foods," Jan. 2015.
20. Department of Health, Victoria, Australia, "Report on a Survey of Spices for the presence of Pathogens," A national survey conducted under the Coordinated Food Survey Plan with participation by food regulatory agencies in Australia.
21. Example – Environmental Testing Program.
22. Example – Employee Training Records.
23. Example – Reanalysis Form.
24. USA, 21 C.F.R. § 7.13 Suggested Forms of Guaranty.
25. Tompkin, Bruce, 2002. "Control of *Listeria monocytogenes* in the Food-Processing Environment." J. Food Prot. Vol. 65, No. 4, pp. 709-725.
26. Tompkin, Bruce, 2004. "Environmental sampling – A tool to verify the effectiveness of preventive hygiene measures." Presented at the 36th Symposium of the Swiss Society of Food Hygiene, Zurich, Oct. 2003, Mitt. Lebensm. Hyg. 95, 45-51 (2004).
27. Swaim, Jolyda, 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.
28. USDA-Food Safety and Inspection Service, "Compliance Guidelines to Control *Listeria monocytogences* in Post-lethality Exposed Ready-to Eat Meat and Poultry Products." Jan. 2014.
29. Example – Recall Plan.
30. ICMSF. 1980. pH and Acidity. In Microbial Ecology of Foods. Vol. 1. Factors Affecting Life and Death of Microorganisms. Academic Press, Inc. pp. 92-111.
31. Beuchat, Larry R., *et. al.*, 2013. "Low-Water Activity Foods: Increased Concern as Vehicles of Foodborne Pathogens." J. Food Prot. Vol. 76, No. 1, pp. 150-172..
32. Olsen, Alan R. "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. Vol. 28 p 181-189. 1998.
33. Flores, Nancy C., Elizabeth A.E. Boyle, 2000. "Thermometer Calibration Guide." Kansas State Univ. Agricultural Experiment Station and Cooperative Extension Service. Jan. 2000.

34. Example – SOP for Calibration of Thermometer. Univ. of Wis. – Madison Center for Meat Process Validation. 2008.
35. World Health Organization (WHO). 2011. FAQs: Japan nuclear concerns.
36. Congressional Research Service. 2014. "Food Fraud and "Economically Motivated Adulteration" of Food and Food Ingredients." Jan. 2014.
37. Everstine, Karen, John Spink, Shaun Kennedy, 2013. "Economically Motivated Adulteration (EMA) of Food: Common Characteristics of EMA Incidents." J. Food Prot. Vol. 76, No. 4, pp. 723-735.
38. Michigan State University Food Fraud Initiative. "Food Fraud Reference Sheet."

6. Example Records

-Record Examples for Fried Rice

-Example of Training Document

Cook Record Example

Hazard: Vegetative pathogens such as *Salmonella, B. cereus. L monocytogens*

Parameters, values or critical limits:

Who, How, Frequency: Qualified Individual checks each batch of finished product temperature is ≥75 °C and held for at least 1 minute

DATE:

Time	Batch Number	Temperature (°C)	Time held at Temperature	Qualified Individual Initials

Date of Review:	
PCQI Signature of Review:	

Metal Detection Record Example

Hazard: Metal inclusion

Critical limits:

1) All of the product passes through an operating metal detector and
2) No metal fragments that would cause injury or choking are in the product passing through the metal detector

Procedure: Pass X mm ferrous and Y mm non-ferrous and stainless standard wands through detector hourly occurs to assure equipment is functioning.

Date: _____

Time	**Product**	**Lot Number**	**Detector present and on (Yes/No)**	**Detector rejects ferrous, non-ferrous, and stainless**	**Qualified Individual (Initials)**
PQCI Verification Reviewer Signature:			**Date of Review:**		

[2] X and Y values are determined during equipment calibration.

Allergen Label Check Record

Hazard: Allergens – soy and eggs

Parameters: All finished product labels must declare the allergens present in the finished product – soy and eggs.

Date	**Time**	**Product**	**Lot Number**	**Proper Label Applied (Yes/No)**	**Qualified Individual**
PCQI Verification Signature:				**Date of Review:**	

Daily Sanitation Control Record

Date: _____

Sanitation Area and Goal	Pre- Op Time:	Time	Time	Time	Time	PRIOR TO USE	Comments and Corrections	Operator Initials
Condition & Cleanliness of Food Contact Surfaces								
Sanitizer Strength • Sanitizer Type: Quaternary ammonium compound Strength: 200-400ppm+								
All employees entering area are wearing designated outerwear								
All employees wearing hairnets and gloves								

* S = Satisfactory, U = Unsatisfactory
+ Enter ppm measured per test strip

PCQI Verification signature:	Date:

Corrective Action Record

Corrective action records are maintained by the Food Safety Team Leader. An example of the Corrective Action Form follows.

Corrective Action Form	
Date of Record:	Code or Lot Number:
Date and Time of Deviation:	
Description of Deviation:	
Actions Taken to Restore Order to the Process:	
Person (name and signature) of Person Taking Action:	
Amount of Product Involved in Deviation:	
Evaluation of Product Involved with Deviation:	
Final Disposition of Product:	
PCQI Review (Name and Signature):	Date of Review:

Daily Thermometer Accuracy Check

Verification: Check each thermometer daily for accuracy. Temperature must be ±1°C from standard.

Date of Calibration	Instrument Number	Boiling Water Temp (100±1°C)*	Ice Bath Temp (0±1°C)	Temperature within Specification (Yes/No)	Qualified Individial (Initials)
PCQI Verification Reviewer Signature:				Date of Review:	

* Temperature adjustments may be needed for different altitudes

Annual Thermometer Calibration Log

Verification: Send each thermometer to Accurate Instrument Checker Lab for calibration twice a year. Temperature must be ±2°F (1°C) from standard. Keep records of results on file.

Date of Calibration	Instrument Number	Method of Calibration	Calibration Results	Temperature within Specification (Yes/No)	Qualified Individual (Initials)
PCQI Verification Reviewer Signature:				Date of Review:	

Receiving Record Example

This teaching example is not realistic for many companies because there is only one ingredient requiring a supply-chain-applied control. Most companies have receiving procedures and many require approved suppliers for both quality and safety considerations. Your standard receiving records may be suitable as the record verifying that raw materials and other ingredients requiring a supply-chain-applied control come from an approved supplier if it is set up to do so. A check list, a bar code scan, a computer spread sheet and other methods could be used to verify receipt from approved supplier locations. Use a format that works for your organization, keeping in mind that the record must be created when the activity occurs and that the activity must be verified by or under the supervision of a preventive controls qualified individual.

Supplier Audit Verification

Purpose: Review of 3rd party audit for suppliers of supply-chain-applied control		
Supplier Name, location		
Date of Review		
Date audit conducted		
Audit procedures in the report (yes/no and comments)		
Audit performed by (e.g., certification body name)		
General audit conclusion		
Required corrective action(s) noted		
Supplier response to corrective action		
Trends noted from previous reports		
Conclusions of the review		
PCQI Review by:		Date:

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 Completing the Update** (initial of sign)
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				

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) Fried Rice		
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

7. Example Reanalysis Form

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) Fried Rice		
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				

8. Generic Recall Program

PLANT NAME	ISSUE DATE	
ADDRESS:	SUPERSEDES	

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

PLANT NAME	ISSUE DATE	
ADDRESS:	SUPERSEDES	

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

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.

C. 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.

PLANT NAME	ISSUE DATE	
ADDRESS:	SUPERSEDES	

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!!!!

「ヒトが摂取する食品に関する現行適正製造規範ならびに危害分析及びリスクに応じた予防的管理措置」の食品安全計画雛形（冷凍チャーハン）＜英語原文＞

2016 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