農林水産省補助事業

米国食品安全強化法

外国供給業者検証プログラム（FSVP）参考モデル（冷凍チャーハン）

＜英語原文＞

2018 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

本仮訳は、2015 年 11 月 27 日に公表された米国食品安全強化法「外国供給業者検証プログラム」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 FSVP の参考モデルを作成したものです。

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調査を実施しました。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）
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その理由をご記入ください。

◆本仮訳をご覧になり、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_vp ）

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【調査名：米国食品安全強化法　外国供給業者検証プログラム（FSVP）参考モデル（冷凍チャーハン）＜英語原文＞】

はじめに

本調査報告書は 2015 年 11 月 27 日に公表された米国食品安全強化法「外国供給業者検証プログラム」（FSVP）規則に関して、FSVP の策定のための参考資料として「冷凍チャーハン」を例に作成した参考モデルである。

FSVP では、まず「外国供給業者の評価」「危害分析」を行わなくてはいけない。そしてその結果行うべき検証活動も文書化が必要となる。加えて、検証活動の実施状況を証明する「記録」の保存も求められている。

外国供給業者検証プログラム（FSVP）の様式は、規則では規定されていない。また、食品医薬品局（FDA）による様式例も公表されていない。そのため、ジェトロは規則の要件や関連の情報をもとに本報告書を作成した。FSVP の対象となる在米の輸入業者が、FSVP を文書化する際の一助として、本報告書をご活用いただければ幸いである。

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 FSVP は、供給業者の状況や食品によって異なるため、この参考モデルに、固有の管理すべき危害や検証活動を追加・修正することによって、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 FSVP の例を示した記入フォームも作成しているので、あわせて参考にしていただきたい。

2018 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
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Chapter 1 General Information

Section 1.1 FSVP Rule – Basic Information Regarding FSVP Rule

This generic plan was developed to serve as a guide. The document provides the framework for the development of a FSVP Plan for Frozen Fried Rice. This generic plan is not intended to be used "as is" for your imported frozen fried rice product as each Foreign Supplier of frozen fried rice needs to be evaluated separately and may require different verification steps. This FSVP plan includes the required steps from the regulations as well as recommendations by FDA.

Since each FSVP Importer of Frozen Fried Rice needs to develop a FSVP plan for each Foreign Supplier and the food they produce, this provides resources to assist in the development of the Foreign Supplier/Food-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.

Food Safety Modernization Act

The FDA Food Safety Modernization Act (FSMA) was enacted on January 4, 2011. FSMA represents a major reform of the food safety provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and significantly expands the powers of the Food and Drug Administration (FDA) to regulate food.

FSMA contains many new regulatory requirements for the food industry, including:

- Food facilities that are required to register with FDA must renew their registration every two years.
- Food facilities required to register with FDA must perform a hazard analysis and implement preventive controls as part of a food safety plan.
- Food importers must implement Foreign Supplier Verification Programs and verify their foreign suppliers.

FSMA also grants FDA many new powers, including the following:

- FDA now has the authority to order a recall.
- FDA has the authority to administratively detain an article of food based only on a reasonable belief that the food is adulterated or misbranded.
- FDA has the power to suspend a food facility's registration, and thereby prevent it from introducing food into commerce, if FDA determines there is a reasonable probability that food from that facility could cause serious adverse health consequences or death to humans or animals.

Foreign Supplier Verification Programs

FDA's final rule on Foreign Supplier Verification Programs (FSVP) requires importers of food to develop, maintain, and follow an FSVP to ensure the foods they import meet FDA food safety standards. The final rule and FDA explanatory materials are available at: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm.

Depending on the FSVP importer, the food being imported, and the foreign suppliers, compliance with the FSVP Rule started on May 30, 2017 with phased-in compliance dates through 2020. Compliance dates for the FSVP Rule are dependent on: the importer; size of the foreign supplier; and when the foreign supplier must meet the requirements for the Preventive Controls for Human or Animal Food Rules or the Produce Safety Rule. Updated compliance date information can be viewed here: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm540944.htm.

It is important to understand the definition of importer under the FSVP Rule. Historically, many in the food industry have only considered the Custom Boarder Protection (CBP) importer as the "importer of record". New under the FSVP Rule, another definition of "importer" has been declared. The FSVP Importer will be identified by entry filings by the CBP Importer. Importantly, the FSVP Importer will be held accountable by FDA if requirements for the FSVP Rule are not met or there are issues with the imported food.

Under the FSVP regulations, an "importer" is defined as the U.S. owner or consignee of a food offered for import. The "U.S. owner or consignee" is defined as the person in the U.S. who at time of entry owns the food, has purchased the food, or has agreed in writing to purchase the food. If there is no U.S. owner or consignee at time of entry, the importer is the U.S. agent or representative of the foreign owner or consignee at time of entry, as confirmed in a signed statement of consent to serve as the FSVP importer.

The FSVP rule includes exemptions and modified requirements in certain situations. These include foods imported for research or evaluation, food imported by "very small importers" (importers with average annual sales of human food of <$1 million), and food imported from certain small foreign suppliers. There is no exemption for intracompany shipments of food, but the fact that the importer and foreign supplier are part of the same corporate family may be taken into account in determining appropriate verification activities.

The FSVP Importer is required to implement an FSVP plan that provides assurances that the ***foreign supplier of each imported food*** is producing the food in compliance with FDA's preventive controls regulations or FDA's produce safety regulations, as applicable (or processes and procedures that provide at least the same level of public health protection) and with the prohibitions against adulteration and misbranding due to the presence of undeclared allergens. Specifically, the FSVP Importer is required to do the following:

- *Perform A Hazard Analysis For Each Food Produced By Its Supplier That It Imports To Identify Hazards Requiring A Control Measure* – This hazard analysis must be conducted by a qualified individual[1] and should identify "known or reasonably foreseeable" food safety hazards based on the food. Hazards should be evaluated to determine if the hazards needs a control. The hazard analysis should be complete with justifications for decisions and be properly documented. A written hazard analysis is required even if no hazards are identified.
- *Perform an Evaluation of the Risk Posed by the Food and the Foreign Supplier's Performance Record* – The evaluation of risk of the food produced by the foreign supplier should be based on the hazard analysis. Points to consider during the evaluation include nature of the hazard, who controls the hazard, and the foreign supplier's food safety performance. The performance of the foreign supplier should include an evaluation of food safety practices, food safety history and other factors like storage and transportation of food prior to importation.
- *Approve Foreign Suppliers Prior To Importation Of Products* – Foreign suppliers must be approved *prior* to importation of the food. The approval should consider the hazard analysis, who and where any hazards are being controlled, and the evaluation of the foreign supplier's performance. Food from unapproved foreign suppliers may be imported on a temporary basis, provided the FSVP Importer conducts adequate verification activities before importing the food.
- *Establish Written Procedures That Only Food From Approved Foreign Suppliers Are Imported* – The FSVP Importer needs to establish written procedures to ensure only food from approved foreign suppliers are being imported. This is typically the initial verification activity a FSVP Importer develops and conducts.
- *Determine And Conduct Verification Activities To Verify That Its Foreign Suppliers Are Adequately Controlling The Hazards Identified As Requiring A Control* – Verification activities must be determined by the FSVP Importer's qualified individual and focus on ensuring the hazards identified are controlled in the food being imported. The frequency of these activities must be identified and should consider who is controlling the hazard and who will be conducting the verification activity. If the FSVP Importer has determined that a "reasonable probability" that exposure to a hazard will lead to a serious adverse health consequence or death to humans or animals (SAHCODHA); then an initial[2] and annual onsite audit needs to be conducted. Examples of verification activities that demonstrate hazards are being controlled are not limited to, but could include: audits, sampling of food, review of food safety records like temperature control or environmental monitoring programs, employee training records, *etc*.
- *Take and Document Appropriate Corrective Actions* – Should an FSVP Importer determine that the food being imported no longer meets the U.S. level of public health protection, is adulterated, violates allergen labeling provisions, or the hazards identified in the FSVP plan are not being controlled; corrective actions must be taken. A qualified individual must determine what corrective actions are

[1] The hazard analysis may be provided by the foreign supplier for review by the FSVP Importer's Qualified Individual. Or the FSVP Importer's Qualified Individual would be responsible to prepare the hazard analysis.
[2] The initial audit must be done prior to the food being imported for the first time.

needed based on the deficiency. The investigation into the food safety issues, the corrective actions taken, and any subsequent changes to the FSVP plan must be documented.

- *Reevaluate the FSVP Plan When Information Indicates A New Food Safety Risk Or At Least Every 3 Years* – A reevaluation of the FSVP plan should occur at any time new information may indicate your previous evaluations of the food risk and supplier may have changed. If reevaluation has not occurred within 3 years of the FSVP plan being implemented, a FSVP Importer must reevaluate the FSVP plan. All reevaluations should be documented as well as corrective actions that may have resulted from that reevaluation.
- *The FSVP Importer Must be Identified* – The FSVP Importer must be identified by the CBP Importer during entry filings. The FSVP Importer will be identified by name, DUNS number, and email address. The FSVP Importer information will be sent to FDA and FDA will consider that FSVP Importer the responsible party for meeting all obligations of the FSVP Rule. If no FSVP Importer is identified on CBP entry documents, the food product will be denied entry into the U.S.
- *Maintain Required Records And Provide Them To FDA Upon Request* – A FSVP Importer must retain all appropriate records for their FSVP plan. These records demonstrate a FSVP Importer's regulatory compliance. Records should be legible and signed and dated. FDA allows the flexibility about storing records offsite, but need to be provided to FDA within 24 hours of request for review. All records required by the FSVP Rule can be inspected and copied by FDA, upon request. Records should be retained for at least 2 years after creation or discontinuation of use. Essentially, the only way FDA will know if the FSVP Importer is meeting FSVP regulatory requirements is through record review. So the importance of ensuring comprehensive records are maintained is paramount.

Compliance Date Extensions

The following compliance dates under the FSVP Rule have been extended:

- Written Assurances – The requirement for written assurances has been delayed by FDA for an additional two years. Written assurances are required from customers when it is determined your customer is controlling a hazard. The regulation requires that the FSVP Importer must disclose in documents accompanying the food that the specific hazards associated with the food are not being controlled and the customer must acknowledge annually that they are controlling the hazard – this acknowledgement by the customer is what has been delayed.. If the customer is not controlling the hazard, but another entity is further down the distribution chain, the FSVP Importer disclosure must also include a clause that the customer agrees to only sell the food to entities that will control the hazard.

What to Expect in an FSVP Inspection

FSVP Importers should be prepared to share with FDA, at the minimum, during an FDA FSVP inspection.

- Acknowledgement of which foods you are the FSVP Importer for. This will require prior communication with the CBP Importer and your foreign supplier, as all foreign suppliers need to be approved before their food can be imported in the U.S.
- A written hazard analysis for each product; even if no hazards are identified.
- Documented evaluation of the approved foreign supplier's food safety performance.
- Written procedures on how you approved foreign suppliers.
- Documented verification activities of your FSVP plan and all associated records you have determined are need to support that hazards identified are being adequately controls.
- Documented corrective actions, as appropriate.
- Documented reevaluations, as appropriate.

- Other food safety records and documentations, you, the FSVP Importer have determined are needed to support the food being imported meets the FSVP Rule requirements and has the same public health production as domestically produced food. Examples could include foreign supplier employee training records, GMP compliance records, sanitary transportation records, *etc*.

Section 1.2 FSVP Importer Information

- Frozen Fried Rice Foreign Supplier

FSVP Importer: ABC Trade Company

FSVP Address: 1-2-3 CA USA

DUNS Number: 123456789

FSVP Plan: **Frozen Fried Rice Plan**

Section 1.3 Other Information – Self-assessment checklist

FSVP Importer: ABC trade company, USA

DUNS #: 123456789

This self-assessment checklist is a brief summary of some of the elements needed within a FSVP plan and, if applicable to the food you import, would need to be addressed in your written FSVP Plan. The self-assessment checklist is a resource that can be used to identify the key components of your written FSVP, as may be applicable to the food you import and your Foreign Supplier's operations. It will also be a helpful resource to identify areas where the FSVP Importer may need to identify a Qualified Individual to conduct the relevant activities. The FSVP Importer may need several Qualified Individuals if importing a wide range of products as the Qualified Individual should be someone who is familiar with the production of the specific product being imported.

Preventive Control Measure (as may be applicable to the imported food and your foreign supplier's operations)	Do you have written details OR written evidence demonstrating that this is being adequately addressed?
Determination and Control of Hazards of the Imported Food	
The biological, chemical and physical hazards are identified AND the food is treated or processed to eliminate any such hazards that present a risk of contamination.	Yes No Not applicable
Sanitation and Pest Control at the Foreign Supplier's Establishment	
The establishment, conveyances, and equipment used are clean and in sanitary condition, and the cleaning and sanitation is conducted in a manner that does not present a risk of contaminating the food.	Yes No Not applicable
The establishment is protected against the entry of animals that could contaminate the food (e.g. insects and rodents) and such measures do not present a risk of contamination of the food.	Yes No Not applicable
Non-food chemicals agents (sanitizers, etc.) are labelled, suitable, and used in a way that does not pose a risk of contamination of the food.	Yes No Not applicable
Conveyance and Equipment at the Foreign Supplier's Establishment	
Conveyances and equipment are appropriate for the food and activity being conducted and are designed, constructed, and maintained to function as intended and prevent contamination of the food.	Yes No Not applicable
Separate conveyances or equipment are used strictly for handling contaminated material, waste or any other inedible substances and identified accordingly.	Yes No Not applicable
Foreign Supplier's Establishment	
The area around the establishment does not pose a risk of contamination of the food (e.g., pollution, garbage, rodents, insects).	Yes No Not applicable
The interior of the facility or conveyance is designed, constructed and maintained to prevent the food from being contaminated.	Yes No Not applicable
The facility or conveyance is designed, constructed and maintained so that the movement of people and things within, into and out of the facility or conveyance are controlled and do not present a risk of contamination of the food..	Yes No Not applicable
Food that presents a health risk, that is exempt from the FDA Regulations under is labelled and kept in a designated area to prevent contamination of any other food.	Yes No Not applicable
Lighting is sufficient, can be cleaned and food is protected from lighting breakage.	Yes No Not applicable
Ventilation is sufficient and can be maintained and cleaned to prevent unclean air from affecting the food.	Yes No Not applicable

Preventive Control Measure (as may be applicable to the imported food and your foreign supplier's operations)	Do you have written details OR written evidence demonstrating that this is being adequately addressed?
Temperature and humidity are maintained as appropriate for the food.	Yes No Not applicable
Contaminated material and waste, including sewage, are removed in a way and at a frequency that does not pose a risk of contamination of the food.	Yes No Not applicable
Hand cleaning stations and washrooms are sufficient to meet the needs of the establishment and are cleaned and maintained.	Yes No Not applicable
Water, ice, or steam that comes in contact with a food does not pose a risk of contamination of the food and its supply is adequate for the activity being conducted.	Yes No Not applicable
Unloading, Loading and Storing at the Foreign Supplier's Establishment	
Conveyances used to transport food to or from the establishment are designed, constructed, and maintained to prevent contamination of the food. The conveyances are in good condition, temperature/humidity controlled as appropriate for the food, and used in a manner to prevent contamination of the food.	Yes No Not applicable
Unloading, loading, and storage of a food, food animals, and non-food (e.g., cleaning agents, packaging materials, sanitizers, equipment) are done in a way that does not present a risk of contamination of a food.	Yes No Not applicable
Competency of Employees at the Foreign Supplier's Establishment	
Employees are competent and qualified to carry out their duties.	Yes No Not applicable
Hygiene at the Foreign Supplier's Establishment	
Everyone in an area where food is manufactured, prepared, stored, packaged, or labelled follows hygienic practices as per CGMPs.	Yes No Not applicable
Communicable Diseases Control at the Foreign Supplier's Establishment	
Anyone suffering from a communicable disease or open infected lesion is prevented from being in an area where the person's condition presents a risk of contamination of the food.	Yes No Not applicable
Investigation and Notification, Complaints and Recall	
There are procedures in place for investigation and they are implemented.	Yes No
Is the Foreign Supplier in compliance with all FDA regulations?	Yes No
There are procedures in place for recall and a recall simulation and they are implemented.	Yes No

Chapter2 FSVP Plan for Frozen Fried Rice from XYZ Foreign Supplier

Section 2.1 Imported Food Product Description – Frozen Fried Rice

FSVP Importer: ABC trade company, USA

DUNS #: 123456789

FOREIGN SUPPLIER INFORMATION

Foreign Supplier Name: XYZ Tokyo **(**The name of the foreign supplier of the frozen fried rice and the below information regarding this supplier will be placed here and below.)

Foreign Supplier Address: 1-2-3, XX-ku, Tokyo, Japan

Foreign Supplier Owner/Operator/Agent in Charge: XYZ Taro

Foreign Supplier Preventative Control Qualified Individual: XYZ Jiro

Foreign Supplier FDA Registration Number: 111ZZZ

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 o products included in the category. If it is relevant to product safety, properties lik 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 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), & 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)

Section 2.2 Foreign Supplier Evaluation– Frozen Fried Rice

FSVP Importer: ABC trade company, USA

DUNS #: 123456789

FSVP Qualified Individual: ABC Hanako

The FSVP Qualified Individual must evaluate and approve the Foreign Supplier prior to importing product into the United States. This Evaluation and Approval needs to be documented. The FSVP Qualified Individual should determine if the Foreign Supplier produces frozen fried rice product that meets all FDA requirements for safe and wholesome product. This would include an evaluation of the Foreign Supplier's food safety practices and history, whether Foreign Supplier has been found in violation of FDA requirements, storage conditions, transportation conditions, etc. Below is a checklist designed to assist the FSVP Qualified Individual determine if the FSVP Importer should approve the Foreign Supplier for import of a particular product – in this case – Frozen Fried Rice.

The FSVP Qualified Individual can use another entity's Evaluation (cannot be an evaluation conducted by the Foreign Supplier) when conducting their evaluation. In addition, a qualified individual MUST have conducted the evaluation performed by the other entity. The FSVP Qualified Individual MUST document their review and their assessment, which should be included in the FSVP Plan.

FOREIGN SUPPLIER INFORMATION

Foreign Supplier Name: XYZ Tokyo

Foreign Supplier Address: 1-2-3, XX-ku, Tokyo, Japan

Foreign Supplier Owner/Operator/Agent in Charge: XYZ Taro

Foreign Supplier Preventative Control Qualified Individual: XYZ Jiro

Foreign Supplier FDA Registration Number: 111ZZZ

ISSUED:
REVISED:

Preventive Control Measure (as may be applicable to the imported food and your foreign supplier's operations)	**Evaluation of the Foreign Supplier's Food Safety System**	**Determining Verification Frequency** (Frequency would be dependent on how comfortable you are with the Foreign Supplier – for example, with a new supplier, you may want to verify each shipment for a period of time versus someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly in that case.)	**Approval Information**
Determination and Control of Hazards of the Imported Food			
Biological, chemical and physical hazards that may present a risk of contamination of a food are identified and you are assured that these hazards have been prevented or eliminated control measures shown by evidence obtained from your foreign supplier to be effective.	1) Review and evaluate Foreign Supplier's Food Safety Plan (Preventive Control Plan) to determine adequacy of controls and all food safety system components that demonstrate the process is controlling any hazards. (This would include not only the hazard analysis but all components including but not limited to Supplier Programs, Allergen Control Program, and Environmental Monitoring Program, testing results, and review of pH, Water Activity, cooking, written procedures and corrective actions.)	1) Quarterly or when information indicates that FSVP Plan may no longer control hazards. (Examples: Quarterly or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.) Quarterly review Supplier/ Allergen Control/ Environmental Monitoring Program findings and corrective actions. Random product testing (Approximately every 3rd shipment could be a frequency the FSVP Qualified Individual determines provides acceptable verification.).	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
Which hazard(s) in the food result in Serious Adverse Health Consequence or Death to Humans or Animals (SAHCODHA hazard)? Any SAHCODHA hazards identified require an onsite audit prior to approval and *at least* annually. Physical Hazard: Metal Biological Hazard: *Salmonella, Bacillus cereus, Listeria monocytogenes* Chemical Hazard: Allergens (soy, eggs)	1) Audit documents (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)	1) Before approval, and then annually or an alternative timeframe, as determined by the FSVP Qualified Individual provided there is equal assurances the hazards are being controlled.	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
The food is subjected to a process or treatment necessary to eliminate any biological, chemical or physical hazard	1) Review and evaluate Foreign Supplier's Food Safety Plan (Preventive Control Plan) to determine adequacy of	1-3) Quarterly or when information indicates that FSVP Plan may no longer control hazards Annually or	Approved: Yes

Preventive Control Measure (as may be applicable to the imported food and your foreign supplier's operations)	Evaluation of the Foreign Supplier's Food Safety System	Determining Verification Frequency (Frequency would be dependent on how comfortable you are with the Foreign Supplier – for example, with a new supplier, you may want to verify each shipment for a period of time versus someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly in that case.)	Approval Information
that might be present and that presents a risk of contamination to the food.	controls and all food safety system components that demonstrate the process is controlling any hazards. (This would include not only the hazard analysis but also all components including but not limited to Supplier Programs, Allergen Control Program, and Environmental Monitoring Program, testing results, and review of pH, Water Activity, cooking, written procedures, corrective actions, and all appropriate records.) 2) Audit documents 3) Inspection records from relevant Japanese food safety governmental agency(ies).	when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
Sanitation and Pest Control at the Foreign Supplier's Establishment			
The establishment, equipment and conveyances are clean and in a sanitary condition, and the cleaning and sanitation is conducted in a manner that does not present a risk of contamination of the food.	FSVP Importer's Qualified Individual has reviewed Audit documents, Foreign Supplier written sanitation procedures, and inspection records from relevant Japanese food safety governmental agency(ies) if available. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
The establishment is protected against the entry of animals that could contaminate the food (e.g. insects and	FSVP Importer's Qualified Individual has reviewed Audit documents and inspection records from relevant	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be	Approved: Yes

Preventive Control Measure (as may be applicable to the imported food and your foreign supplier's operations)	Evaluation of the Foreign Supplier's Food Safety System	Determining Verification Frequency (Frequency would be dependent on how comfortable you are with the Foreign Supplier – for example, with a new supplier, you may want to verify each shipment for a period of time versus someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly in that case.)	Approval Information
rodents), non-essential animals are barred entry into the facility or conveyance and measures taken in this regard do not present a risk of contamination of the food.	Japanese food safety governmental agency(ies) if available. Foreign Supplier provides Letter of Guarantee. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)	when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
Non-food chemicals (sanitizers, etc.) are properly and clearly identified, are suitable for its intended use, do not present a risk of contamination of a food, and are handled and used in a way that does not pose a risk of contamination of the food.	FSVP Importer's Qualified Individual has reviewed Audit documents and Foreign Supplier written sanitation procedures. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
Conveyances and Equipment at the Foreign Supplier's Establishment			
Conveyances and equipment must be appropriate for the food and activity being conducted.	FSVP Importer's Qualified Individual has reviewed Audit documents and inspection records from relevant Japanese food safety governmental agency(ies) if available. Foreign Supplier provides Letter of Guarantee. (Audit cannot be performed by Foreign	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018

Preventive Control Measure (as may be applicable to the imported food and your foreign supplier's operations)	Evaluation of the Foreign Supplier's Food Safety System	Determining Verification Frequency (Frequency would be dependent on how comfortable you are with the Foreign Supplier – for example, with a new supplier, you may want to verify each shipment for a period of time versus someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly in that case.)	Approval Information
	Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)		Qualified Individual that Conducted Evaluation: ABC Hana ko
Separate conveyances or equipment are used for handling contaminated material, waste or any other inedible substances, be identified as reserved for that purpose.	FSVP Importer's Qualified Individual has reviewed Audit documents and Foreign Supplier written procedures. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
Foreign Supplier's Establishment			
Unless measures are taken to eliminate the risk, the land forming part of the establishment must not present a risk of contamination of a food and the establishment must not be located near any place or thing (e.g., pollution, garbage, rodents, insects) that presents a risk of contamination of a food.	FSVP Importer's Qualified Individual has reviewed Audit documents and inspection records from relevant Japanese food safety governmental agency(ies) if available. Foreign Supplier provides Letter of Guarantee. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation.	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako

Preventive Control Measure (as may be applicable to the imported food and your foreign supplier's operations)	**Evaluation of the Foreign Supplier's Food Safety System**	**Determining Verification Frequency** (Frequency would be dependent on how comfortable you are with the Foreign Supplier – for example, with a new supplier, you may want to verify each shipment for a period of time versus someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly in that case.)	**Approval Information**
	Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)		
The interior of the facility or conveyance is of sanitary design to prevent the accumulation of contaminants (e.g., dust, dirt, micro-organisms, food products) and to permit effective maintenance, cleaning and sanitizing.	FSVP Importer's Qualified Individual has reviewed Audit documents and inspection records from relevant Japanese food safety governmental agency(ies) if available. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
The facility or conveyance must be designed, controlled and maintained in a manner so that the movement of people and things are controlled and the movement does not present a risk of contamination of the food.	FSVP Importer's Qualified Individual has reviewed Audit documents and inspection records from relevant Japanese food safety governmental agency(ies if available). (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
Incompatible activities and anything that presents a risk of contamination of	FSVP Importer's Qualified Individual has reviewed Audit documents and	Annually or when information indicates that FSVP Plan may no	Approved: Yes

Preventive Control Measure (as may be applicable to the imported food and your foreign supplier's operations)	**Evaluation of the Foreign Supplier's Food Safety System**	**Determining Verification Frequency** (Frequency would be dependent on how comfortable you are with the Foreign Supplier – for example, with a new supplier, you may want to verify each shipment for a period of time versus someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly in that case.)	**Approval Information**
a food and any non-food item that is manufactured, prepared, stored, packaged or labelled in the establishment, must be separated by physical or other effective means.	Foreign Supplier written procedures. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)	longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
Upon arrival at an establishment, food that presents a risk of injury to human health, or has been returned after export is identified as such and kept in a designated area within the establishment. Any other measures necessary to prevent contamination of any other food in the establishment must be taken.	FSVP Importer's Qualified Individual has reviewed Audit documents and Foreign Supplier written procedure. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)s	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
Lighting is appropriate for the food and activity being conducted, can be repeatedly cleaned (and, if applicable, sanitized) and not present a risk of contamination of the food in the event of breakage.	FSVP Importer's Qualified Individual has reviewed Audit documents and inspection records from relevant Japanese food safety governmental agency(ies) if available. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor,	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako

Preventive Control Measure (as may be applicable to the imported food and your foreign supplier's operations)	**Evaluation of the Foreign Supplier's Food Safety System**	**Determining Verification Frequency** (Frequency would be dependent on how comfortable you are with the Foreign Supplier – for example, with a new supplier, you may want to verify each shipment for a period of time versus someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly in that case.)	**Approval Information**
	dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)		
The facility or conveyance is equipped with a ventilation system that: • functions as intended; • provides sufficient air exchange to provide clean air and to remove unclean air and odors that might affect the food; • is accessible; • can be maintained and is capable of withstanding repeated cleaning; and • if necessary, is able to be disassembled for cleaning, maintenance and inspection.	FSVP Importer's Qualified Individual has reviewed Audit documents and inspection records from relevant Japanese food safety governmental agency(ies) if available. Foreign Supplier provides Letter of Guarantee. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
Temperature and humidity in a facility or conveyance are maintained at levels appropriate for the food and the activity being conducted. Any heating, cooling or humidity-control system must: • function as intended; • be equipped with necessary instruments that control, indicate and, if required, record the temperature and humidity levels; • be accessible; • be capable of withstanding repeated cleaning; and • if necessary, be able to be disassembled for cleaning, maintenance and inspection.	FSVP Importer's Qualified Individual has reviewed Audit documents and inspection records from relevant Japanese food safety governmental agency(ies) if available. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
The establishment is equipped with means to remove and dispose of contaminated materials and waste, including a drainage, sewage and	FSVP Importer's Qualified Individual has reviewed Audit documents and inspection records from relevant Japanese food safety governmental	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer	Approved: Yes

Preventive Control Measure (as may be applicable to the imported food and your foreign supplier's operations)	**Evaluation of the Foreign Supplier's Food Safety System**	**Determining Verification Frequency** (Frequency would be dependent on how comfortable you are with the Foreign Supplier – for example, with a new supplier, you may want to verify each shipment for a period of time versus someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly in that case.)	**Approval Information**
plumbing system capable of withstanding repeated cleaning and that functions as intended. Contaminated materials and waste must be removed and disposed of at sufficient frequency to prevent contamination of a food and in a way that does not present a risk of contamination of the food.	agency(ies) if available. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)	complaints, FDA communication, recall of similar product, etc.)	Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
There are hand cleaning and sanitizing stations, drinking water stations, break rooms, change rooms and washrooms (including lavatories and showers) in the establishment as necessary to meet the needs of the establishment. They must: • be appropriately equipped and appropriate in number and size for the number of persons using them; • be located in the establishment and reasonably accessible to the persons using them; • be capable of withstanding repeated cleaning and, if applicable, sanitizing; • for the hand cleaning and sanitizing stations, supply water at a temperature and pressure for effective cleaning of hands; and • for the lavatories, not provide direct access to any area where a food is manufactured, prepared, stored, packaged or labelled.	FSVP Importer's Qualified Individual has reviewed Audit documents and inspection records from relevant Japanese food safety governmental agency(ies) if available. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
Water, ice or steam that comes in contact with a food, any system that supplies water must meet FDA requirements.	FSVP Importer's Qualified Individual has reviewed Audit documents and inspection records from relevant Japanese food safety governmental	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer	Approved: Yes

Preventive Control Measure (as may be applicable to the imported food and your foreign supplier's operations)	Evaluation of the Foreign Supplier's Food Safety System	Determining Verification Frequency (Frequency would be dependent on how comfortable you are with the Foreign Supplier – for example, with a new supplier, you may want to verify each shipment for a period of time versus someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly in that case.)	Approval Information
	agency(ies) if available. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)	complaints, FDA communication, recall of similar product, etc.)	Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
As appropriate for the food and the activity conducted, the establishment must be supplied with: • water adequate in quantity, temperature, pH and pressure to meet the needs of the establishment; • steam and ice that is adequate in quantity and steam that is adequate in pressure to meet those needs. The above must be applied in a manner that does not present a risk of contamination.	FSVP Importer's Qualified Individual has reviewed Audit documents and inspection records from relevant Japanese food safety governmental agency(ies) if available. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)	Annually or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
Unloading, Loading and Storing at the Foreign Supplier's Establishment			
Conveyances used to convey food to or from the establishment and that are unloaded or loaded at the establishment must be: • designed, constructed, and maintained to prevent contamination of the food • constructed of, and maintained using materials that are suitable, for their intended use and, if the materials present a risk of	FSVP Importer's Qualified Individual has determined that conveyances used in the production of frozen fried rice are appropriate to ensure all food safety hazards are prevented, significantly minimized and does not introduce new hazards. Review of Audit documents and inspection records from relevant Japanese food safety governmental agency(ies) if available. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako

Preventive Control Measure (as may be applicable to the imported food and your foreign supplier's operations)	Evaluation of the Foreign Supplier's Food Safety System	Determining Verification Frequency (Frequency would be dependent on how comfortable you are with the Foreign Supplier – for example, with a new supplier, you may want to verify each shipment for a period of time versus someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly in that case.)	Approval Information
contamination, that are durable, capable of withstanding repeated cleaning and, if applicable sanitizing, and free of any noxious constituent • capable of maintaining the temperature and humidity at levels that are appropriate for that food and, if necessary, be equipped with instruments that control, indicate and record those levels • of sound construction and in good repair • clean and in sanitary condition at the time of unloading or loading. In addition, the conveyance must not contain or have contained animals, pest control products or any other material or substance that represents of a risk of contamination of the food.	verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)		
Unloading and loading of a food or onto a conveyance must be conducted in a manner that does not present a risk of contamination of a food.	FSVP Importer's Qualified Individual may want to review Foreign Supplier's written procedures.	Annually or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
Storage of a food, and of non-food items used in the manufacture, preparation, storage, packaging or labelling of a food (e.g., cleaning agents, packaging materials, sanitizers, equipment, starter products), are conducted in a way that does not present a risk of contamination of a food.	FSVP Importer's Qualified Individual may want to review Foreign Supplier's written procedures, especially for allergenic items, and inspection records from relevant Japanese food safety governmental agency(ies) if available.	Annually or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako

Preventive Control Measure (as may be applicable to the imported food and your foreign supplier's operations)	**Evaluation of the Foreign Supplier's Food Safety System**	**Determining Verification Frequency** (Frequency would be dependent on how comfortable you are with the Foreign Supplier – for example, with a new supplier, you may want to verify each shipment for a period of time versus someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly in that case.)	**Approval Information**
Competency of Employees at the Foreign Supplier's Establishment			
Employees and others involved in the manufacturing, preparing, storing, packaging or labelling of a food, are competent and qualified to carry out their duties.	FSVP Importer's Qualified Individual may want to review Employee Training Records for CGMPs and food safety training records for certain employees. Foreign supplier letter of guarantee and employee and training policy	Annually or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
Hygiene at the Foreign Supplier's Establishment			
Everyone in an area where food is manufactured, prepared, stored, packaged, or labelled, follows CGMPs.	FSVP Importer's Qualified Individual may want to review Current Good Manufacturing Practices of the foreign supplier, relevant audits, and inspection records from relevant Japanese food safety governmental agency(ies) if available. (Audit cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
Investigation and Notification, Complaints and Recall			
There are procedures in place for investigation and they are implemented.	FSVP Importer's Qualified Individual may want to review Foreign Supplier's written procedures.	Annually or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako

Preventive Control Measure (as may be applicable to the imported food and your foreign supplier's operations)	**Evaluation of the Foreign Supplier's Food Safety System**	**Determining Verification Frequency** (Frequency would be dependent on how comfortable you are with the Foreign Supplier – for example, with a new supplier, you may want to verify each shipment for a period of time versus someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly in that case.)	**Approval Information**
Is the Foreign Supplier in compliance with all FDA regulations?	FSVP Importer's Qualified Individual may want to review Food Safety Preventive Control Plan and labeling of product.	Annually or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako
There are procedures in place for recall and a recall simulation and they are implemented.	FSVP Importer's Qualified Individual may want to review Recall Plan since Hazard Analysis contains a hazard needing a preventive control.	Annually or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	Approved: Yes Date: Jan 31st, 2018 Qualified Individual that Conducted Evaluation: ABC Hanako

Section 2.3 Foreign Supplier Hazard Analysis – Frozen Fried Rice

FSVP Importer: ABC trade company, USA

DUNS #: 123456789

FSVP Qualified Individual: ABC Hanako

The FSVP Qualified Individual should develop the hazard analysis or determine if a hazard analysis from another entity is appropriate to review. The Hazard Analysis MUST be written regardless of outcome. Should the FSVP Qualified Individual review another entity's Hazard Analysis, the FSVP Qualified Individual needs to review it and the food safety plan for adequacy and document the assessment that the other entity's foods safety plan is appropriate. The other entity's food safety plan must have been developed by a qualified individual (ex. PCQI).

The following is an example of a generic hazard analysis for Frozen Fried Rice created by the Frozen Fried Rice Foreign Supplier's Preventive Controls Qualified Individual.

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.

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
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 chemicals should be considered such as cleaning chemicals, pesticides, industrial chemicals, drug residues or radiological hazards.)	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. #3)	Process control – acidification of steamed rice with citric acid to pH ≤ 4.3 at a subsequent step. Subsequent cook step		B – No

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
	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	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, 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.)			

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
	C - Radiological	C – yes (whether this is a hazard depends on where the rice is grown)		C – Radiological – hazard may result from accidental contamination such as accidental release from a nuclear facility or damage to a nuclear facility during a natural disaster. (Supp. #36)	Supply chain control – approved supplier and 3rd party supplier audit by qualified auditor	C – Radiological – yes	
	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 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.	C – yes		C – economically motivated hazard (Supp. #36, 37, 38)	Supply chain control – approved supplier and 3rd party supplier audit by qualified auditor		C – no

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		YES	NO			YES	NO
	You only must focus on economic adulteration that has a history of resulting in a hazard in food.) P – Stones P - Metal	P – yes	P - no	P – Stones – depending on 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 product to metal detection. (Supp. #5, 32)	Process control – metal detection at subsequent step	P – Metal – yes (Metal detection can be done on received rice or after washing and	

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		YES	NO			YES	NO
	P - Other foreign material		P – no	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 injury. (Supp. #5, 32)		steaming.)	

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		YES	NO			YES	NO
Receiving soy sauce	B – none 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 – none (Countries may set allowable concentrations, manner of use and maximum allowable residues for certain chemicals.) P – none	C – yes	B - no C – no P – no	B – none – high salt levels inhibit bacterial growth by decreasing the water activity to <0.85. (Supp. #6) 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

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		YES	NO			YES	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
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 additives. Countries may set allowable concentrations, manner		B- no C- no				

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		YES	NO			YES	NO
	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* C- none P – none	B- yes	B – no C – no P - 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	

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		YES	NO			YES	NO
Receiving Liquid Eggs	B- *Salmonella* C – allergens P – None	B- yes C- Yes	 P – no	*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 other products must be controlled.	Process control - subsequent cooking step Allergen Control – allergen labeling at other steps Sanitation controls – at a subsequent step if non-egg containing products are made to prevent cross-contact		No No No

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		YES	NO			YES	NO
Receiving Raw vegetables	B – *Salmonella; Listeria monocytogenes* C- Pesticides P – Foreign material		B – no C- no P- 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 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.	Subsequent cooking step		No

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		YES	NO			YES	NO
Receiving laminated bags and labels	B- none C – chemical residues C – Allergen P – none	 C – yes	B – no C – no P – 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) 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	

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		YES	NO			YES	NO
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				
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)			

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		YES	NO			YES	NO
Wash rice and steam	B – *B. cereus*, C – none P – none		B – no C – no P – 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 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	

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		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 P – none	B – yes	C – no P – 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.)	

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		YES	NO			YES	NO
Quick freeze the finished fried rice	B – *Listeria monocytogenes*, B – *B. cereus* C – none P – none	B – yes 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) B – *B. cereus* – growth of sporeformers can occur if product is not chilled rapidly. (Supp. #2)	Sanitation control – prevents contamination Process control – fried rice is chilled to a temperature of ≤ °C. in ≤ 4 hours.	Yes Yes	
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	

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		YES	NO			YES	NO
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				

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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? • Have the supplier's corrective actions to past issues been appropriate and timely? • Are the supplier's storage or transportation practices appropriate?)

Preventive Controls Plan

Process Control	Hazard	Critical Limits	Monitoring				Corrective Action / Corrections	Record Keeping	Verification
			What	How	Freq.	Who			
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 determine the root cause and implement measures to prevent reoccurrence. If product went to cooking without proper pH adjustment, it will be destroyed.	pH record Daily pH Meter Accuracy Record Calibration Record Corrective action record	The PCQI will review all records within 7 days. (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.)

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.

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 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.)	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.)

ISSUED:
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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.

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Section 2.4 Foreign Supplier Verification Plan– Frozen Fried Rice

FSVP Importer: ABC trade company, USA
DUNS #: 123456789

FSVP Qualified Individual: ABC Hanako

The FSVP Importer's Qualified Individual should determine the verification activities and verification findings of the foreign supplier producing frozen fried rice product to ensure that it meets all FDA requirements for safe and wholesome product, and controls the hazards identified in the hazard analysis.

Foreign Supplier Verification must provide assurance that hazards requiring a control in the food being imported are continually being significantly minimized or prevented. You must have written procedures for determining which verification activities are appropriate for the food and the foreign supplier.

Below is a checklist designed to assist the FSVP Qualified Individual if the Foreign Supplier is continuing to produce product approved for import, by the FSVP Importer, by controlling the hazards identified. If the FSVP Qualified Individual determines that hazards are not being controlled, then appropriate corrective actions must be taken.

- The following is an example using the generic hazard analysis for Frozen Fried Rice created by the Frozen Fried Rice Foreign Supplier's Preventive Controls Qualified Individual.

The frequencies of verification activities below are based on the Frozen Fried Rice Hazard Analysis and Preventive Controls plan and are examples of what a FSVP Qualified Individual may deem adequate. All frequencies must be determined based on the actual foreign supplier and the related hazard analysis and food safety plan.

FOREIGN SUPPLIER INFORMATION

Foreign Supplier Name: XYZ Tokyo

Foreign Supplier Address: 1-2-3, XX-ku, Tokyo, Japan

Foreign Supplier Owner/Operator/Agent in Charge: XYZ Taro

Foreign Supplier Preventative Control Qualified Individual: XYZ Jiro

Foreign Supplier FDA Registration Number: 111ZZZ

ISSUED:
REVISED:

Principle	Describe how the Hazard is being controlled effectively through actions taken by you, your foreign supplier or other means.	**Frequency that this is verified** (Frequency would be dependent on how comfortable you are with the Foreign Supplier – For example, with a new supplier, you may want to verify each shipment for a period of time. For someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly.)	**Verification Information** (Verification is conducted by the FSVP Importer's Qualified Individual.)
Describe all biological, chemical and physical (BCP) hazards that have been identified as presenting a risk of contamination of the food to be imported. (This information should be developed from the food safety plan) Physical Hazard: Metal Biological Hazard: *Salmonella, Bacillus cereus, Listeria monocytogenes* Chemical Hazard: Allergens (soy, eggs)	(This information should be developed from the food safety plan) 1) Review of Supplier Programs, Allergen Control Program, and Environmental Monitoring Program. 2) In-house random finish product sampling for *Listeria monocytogenes* 3) Review of pH, Water Activity, cooking, written procedures and corrective actions.	1) Quarterly or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.) Quarterly review Environmental Monitoring Program findings and corrective actions. 3) Random (approximately every 3rd shipment or alternative timeframe as determined by the FSVP Qualified Individual. The frequency should be identified.) 4) Quarterly or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	1) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako 2) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako 3) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako 4) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako
Which hazard(s) in the food result in Serious Adverse Health Consequence or Death to Humans or Animals (SAHCODHA hazard)? Any SAHCODHA hazards identified require an onsite audit prior to approval and *at least* annually. (This information should be developed from the food safety plan) Physical Hazard: Metal Biological Hazard: *Salmonella, Bacillus cereus, Listeria monocytogenes*	1) Audit documents (Cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted	1) Annually or an alternative timeframe, as determined by the FSVP Qualified Individual provided there is equal assurances the hazards are being controlled.	1) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako

Principle	Describe how the Hazard is being controlled effectively through actions taken by you, your foreign supplier or other means.	Frequency that this is verified (Frequency would be dependent on how comfortable you are with the Foreign Supplier – For example, with a new supplier, you may want to verify each shipment for a period of time. For someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly.)	Verification Information (Verification is conducted by the FSVP Importer's Qualified Individual.)
Chemical Hazard: Allergens (soy, eggs)	deficiencies.)		
Describe the control measures used to prevent or eliminate the BCP hazards and that there is evidence that such measures are effective. (This information should be developed from the food safety plan.) Physical Hazard: Metal (Metal Detection) Biological Hazard: *Salmonella* (Supplier Program - Spices; Process Control – Cooking), *Bacillus cereus* (Process Control – pH Adjustment; Process Control – Cooking; Process Control – Water Activity), *Listeria monocytogenes* (Process Control – Cooking; Sanitation Control – Quick Freeze and Packaging Areas For Finished Fried Rice) Chemical Hazard: Allergens (soy, eggs) (Labeling of Allergens)	(This information should be developed from the food safety plan) 1) Audit documents (Cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.) 2) Inspection records from FDA and/or relevant Japanese food safety governmental agency(ies) if available. 3) In-house random finish product sampling for *Listeria monocytogenes* 4) Foreign supplier metal detection record, pH monitoring, Water Activity, and cooking records and all associated corrective action records	1-2) Annually or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.) 3) Random (approximately every 3rd shipment or alternative timeframe as determined by the FSVP Qualified Individual. The frequency should be identified.) 4) Quarterly or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	1) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako 2) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako 3) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako 4) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako
Describe any applicable critical control points and related control measures. (This information should be developed from the food	(This information should be developed from the food safety	1) Quarterly or when information indicates that FSVP Plan may no longer control hazards. (This could be when	1) Date Verified: Feb 28th, 2018

Principle	Describe how the Hazard is being controlled effectively through actions taken by you, your foreign supplier or other means.	Frequency that this is verified (Frequency would be dependent on how comfortable you are with the Foreign Supplier – For example, with a new supplier, you may want to verify each shipment for a period of time. For someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly.)	Verification Information (Verification is conducted by the FSVP Importer's Qualified Individual.)
safety plan.) Physical Hazard: Metal Detection (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.) Biological Hazard: • Supplier Program – Spices: *Salmonella* (Received from an Approved Supplier) • Process Control – Cooking: *Bacillus cereus, Salmonella, L. monocytogenes* (Cooked to an internal temperature ≥ 75C. and maintained at that temperature for at least 1 minute.) • Process Control – pH Adjustment: *Bacillus cereus* (pH of the steamed rice is adjusted to ≤ 4.3 prior to the cooking step) • Process Control – Water Activity: *Bacillus cereus* (Water activity is < 0.85) • Sanitation Control – 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.) Chemical Hazard: Labeling of Allergens (All finished product labels declare allergens present in the product.)	plan.) 1) Metal Detection - All product passes through the functioning metal detector 2) Supplier Program – Qualified Individual reviews Foreign Supplier's Supplier Program. 3). Labeling of Allergens (Soy, Eggs) - Ingredients in the product produced (as per product mixing record) matches the ingredient statement on the finished product label. 4) Process Control – pH Adjustment - Steamed rice is ≤4.3 pH prior to cooking 5) Process Control – Cooking - Internal product temperature is ≥ 75C. and maintained at that temperature for at least 1 minute 6) Process Control – Water Activity - Water activity of finished product is < 0.85. 7) Sanitation Control – Quick Freeze and Packaging Areas For Finished Fried Rice - 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.	you have received consumer complaints, FDA communication, recall of similar product, etc.) 2) Every 6 months or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.) 3) Quarterly or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.) 4) Quarterly or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.) 5) Quarterly or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.) 6) Quarterly or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	FSVP Qualified Individual that Verified: ABC Hanako 2) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako 3) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako 4) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako 5) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako 6) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako 7) Date Verified: Feb 28th, 2018

Principle	Describe how the Hazard is being controlled effectively through actions taken by you, your foreign supplier or other means.	**Frequency that this is verified** (Frequency would be dependent on how comfortable you are with the Foreign Supplier – For example, with a new supplier, you may want to verify each shipment for a period of time. For someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly.)	**Verification Information** (Verification is conducted by the FSVP Importer's Qualified Individual.)
		7) Quarterly or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	FSVP Qualified Individual that Verified: ABC Hanako
Ensure you have evidence showing that related control measures are effective at each critical control point. (This information should be developed from the food safety plan.) 1) Metal Detection - All product passes through the functioning metal detector 2) Supplier Program – Qualified Individual reviews Foreign Supplier's Supplier Program. 3). Labeling of Allergens (Soy, Eggs) - Ingredients in the product produced (as per product mixing record) matches the ingredient statement on the finished product label. 4) Process Control – pH Adjustment - Steamed rice is ≤4.3 pH prior to cooking 5) Process Control – Cooking - Internal product temperature is ≥ 75C. and maintained at that temperature for at least 1 minute 6) Process Control – Water Activity - Water activity of finished product is < 0.85. 7) Sanitation Control – Quick Freeze and Packaging Areas For Finished Fried Rice - 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.	(This information should be developed from the food safety plan.) 1) FSVP Qualified Individual reviews Metal Detection Log, Calibration and Validation Records of Equipment and Corrective Action Records 2) FSVP Qualified Individual reviews Incoming Receiving Record, Copy Of Audit Report Findings Of Supplier, and Corrective Action Records 3) FSVP Qualified Individual reviews Product Mixing Record, Finished Product Labels and Corrective Action Records 4) FSVP Qualified Individual reviews pH Records, Calibration and Validation Records of Equipment, and Corrective Action Records 5) FSVP Qualified Individual reviews Cooking Records, Calibration and Validation Records of Equipment, and Corrective Action Records 6) FSVP Qualified Individual reviews Water Activity Records, Calibration and Validation Records of Equipment, and	1) Quarterly or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.) 2) Quarterly or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.) 3) Quarterly or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.) 4) Quarterly or when information indicates that FSVP Plan may no longer control hazards (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.) 5) Quarterly or when information indicates that FSVP Plan may no longer control hazards. (This could be when	1) Date Verified: Feb 28th, 2018: FSVP Qualified Individual that Verified: ABC Hanako 2) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako 3) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako 4) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako 5) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako

Principle	Describe how the Hazard is being controlled effectively through actions taken by you, your foreign supplier or other means.	**Frequency that this is verified** (Frequency would be dependent on how comfortable you are with the Foreign Supplier – For example, with a new supplier, you may want to verify each shipment for a period of time. For someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly.)	**Verification Information** (Verification is conducted by the FSVP Importer's Qualified Individual.)
	Corrective Action Records 7) FSVP Qualified Individual reviews Daily Sanitation Records, Sanitizer Strength Records, Environmental Testing and Program Records, Laboratory Results and Corrective Action Records	you have received consumer complaints, FDA communication, recall of similar product, etc.) 6) Quarterly or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.) 7) Quarterly or when information indicates that FSVP Plan may no longer control hazards. (This could be when you have received consumer complaints, FDA communication, recall of similar product, etc.)	6) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako 7) Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako
Ensure there are procedures to verify the preventive control plan complies with all applicable FDA Regulations	Rely on Audit documents and inspection records from FDA and relevant Japanese food safety governmental agency(ies) if available. (Audits cannot be performed by Foreign Supplier. Audit must consider all food safety standards deemed important for verification by the FSVP Importer's Qualified Individual, be performed by a qualified auditor, and must include a review of the Foreign Supplier's written food safety plan and its implementation. Also the following must be included in documentation of the Audit: audit procedures, qualification of the auditor, dates of the audit, conclusions of the audit, and corrective actions taken in response to noted deficiencies.)	On-going	Date Verified: Feb 28th, 2018 FSVP Qualified Individual that Verified: ABC Hanako

Principle	Describe how the Hazard is being controlled effectively through actions taken by you, your foreign supplier or other means.	**Frequency that this is verified** (Frequency would be dependent on how comfortable you are with the Foreign Supplier – For example, with a new supplier, you may want to verify each shipment for a period of time. For someone you have been dealing with for a long time and not had issues with – you may want to verify quarterly.)	**Verification Information** (Verification is conducted by the FSVP Importer's Qualified Individual.)
You have documents that substantiate that the preventive control plan has been implemented as per above steps	Documents supporting the above steps (e.g., certification, test results, specification sheets, etc.) are stored on-site or available upon request by FDA.	On-going	Date Verified: Feb 28th, 2018: FSVP Qualified Individual that Verified: ABC Hanako

Section 2.5 Foreign Supplier Corrective Actions – Frozen Fried Rice

FSVP Importer: ABC trade company, USA
DUNS #: 123456789

FSVP Qualified Individual: ABC Hanako

If the FSVP Qualified Individual determines that hazards are not being controlled, then appropriate corrective actions must be taken. The FSVP Qualified Individual would need to notify the Foreign Supplier of the issue and provide all pertinent information for them to adequately address the issues. This would include the Foreign Supplier taking corrective actions. The FSVP Qualified Individual would then review the corrective actions taken and approve the Foreign Supplier's corrective actions and any new procedures to determine if the food safety system is in control of the hazards. The FSVP Qualified Individual may determine additional verification activities are needed as well as reevaluating the FSVP plan.

Below is a checklist designed to assist the FSVP Qualified Individual if the Foreign Supplier is continuing to produce product approved for import by the FSVP Importer.

- The following is an example using the generic hazard analysis for Frozen Fried Rice created by the Frozen Fried Rice Foreign Supplier's Preventive Controls Qualified Individual. Also included in an example of a Corrective Action Report.

FOREIGN SUPPLIER INFORMATION

Foreign Supplier Name: XYZ Tokyo

Foreign Supplier Address: 1-2-3, XX-ku, Tokyo, Japan

Foreign Supplier Owner/Operator/Agent in Charge: XYZ Taro

Foreign Supplier Preventative Control Qualified Individual: XYZ Jiro

Foreign Supplier FDA Registration Number: 111ZZZ

ISSUED:
REVISED:

Principle	Describe Corrective Action Process
Ensure there are corrective action procedures for each critical control point (This information should be developed from the food safety plan.) Physical Hazard: Metal Detection (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.) Biological Hazard: • Supplier Program – Spices: *Salmonella* (Received from an Approved Supplier) • Process Control – Cooking*: Bacillus cereus, Salmonella, L. monocytogenes* (Cooked to an internal temperature ≥ 75C. and maintained at that temperature for at least 1 minute.) • Process Control – pH Adjustment: *Bacillus cereus* (pH of the steamed rice is adjusted to ≤ 4.3 prior to the cooking step) • Process Control – Water Activity: *Bacillus cereus* (Water activity is < 0.85) • Sanitation Control – 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.) Chemical Hazard: Labeling of Allergens (All finished product labels declare allergens present in the product)	1) Any corrective action response meets the requirements set forth in FDA Regulation 21 C.F.R. Subpart L § 1.508. A corrective action report will be developed by the FSVP Qualified Individual and findings communicated appropriately to the Foreign Supplier by the FSVP Importer. • 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.

Example:

FSVP IMPORTER NOTIFICATION TO FOREIGN SUPPLIER
HAZARDS NOT CONTROLLED BY FOREIGN SUPPLIER DURING THE PRODUCTION OF FROZEN FRIED RICE

Date of Report: _____

Foreign Supplier: _____

Foreign Supplier's Address: _____

Foreign Supplier's Owner/Operator/Agent in Charge: _____

Date of Incidence Where Hazards Not Controlled: _____

Hazards Control Deviation: _____Metal Fragments found by customer_____

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

(This description should be as specific as possible and include all pertinent information regarding production dates, product codes, lot numbers and when imported into the U.S. (if available)

Date FSVP Importer Determined Hazard Deviation: _____

Corrective Action Taken (To be reviewed by FSVP Qualified Individual)_

Collected metal fragments reported by consumer/customer and sent to Foreign Supplier with description of hazard not controlled. All product in U.S. was held pending discussion with Foreign Supplier and final product disposition decision. Requested Foreign Supplier send corrective actions, verification activities to document that hazard is under control for review by the FSVP Qualified Individual).and actions for FSVP Qualified Individual review.

Date of Corrective Actions and all associated documents Received from Foreign Supplier:

_____

Date of Review of Corrective Actions and all associated documents: (FSVP Qualified Individual should review all corrective actions and associated type and frequency of verification activities by the Foreign Supplier to determine if food safety system is back into control. If not, FSVP Qualified Individual can request additional verification activities, as appropriate, or discontinue use of the Foreign Supplier for this food product.) _____

Date of FSVP Plan Reanalysis: _____(The FSVP Plan must be revaluated if the FSVP Importer is aware of new information that may affect your food and foreign supplier performance evaluation.)_____

Changes to FSVP Plan, if needed: (Need to document any changes and fill out appropriate Reanalysis Record.)

Additional Verification Activities (duration) Required of Foreign Supplier:

Final **Disposition** of Affected Product

(Describe what happened to affected product. Should it not be released into commerce, document disposition activities.)

Document Completed By: _(FSVP Qualified Individual)_____

Signature & Date

Qualified Individual: _____

FSVP Importer: _____

This corrective action response meets the requirements set forth in FDA Regulation 21 C.F.R. Subpart L § 1.508

- ❖ 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.

Section 2.6 Template for Record Review of Foreign Supplier Documentation

Foreign Supplier: _____

Food Product: _____

Documents Reviewed _____

Date of Review: _____

General Nature of Records (ATTACH SEPARATE SHEET IF REQUIRED) _____

Conclusions of Review (ATTACH SEPARATE SHEET IF REQUIRED). _____

Corrective Actions (ATTACH SEPARATE SHEET IF REQUIRED). _____

Date of Corrective Action Report: _____

Document Review Completed By: (FSVP Qualified Individual)_____

Section 2.7 Example of Corrective Action Report

Date of Report: _____

Foreign Supplier: _____

Foreign Supplier's Address: _____

Foreign Supplier's Owner/Operator/Agent in Charge: _____

Date of Incidence Where Hazards Not Controlled: _____

Hazards Control Deviation: _____

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

FSVP Importer Notified: _____

Corrective Action Taken (To be reviewed by FSVP Qualified Individual)

Date of Corrective Actions Received from Foreign Supplier: _____

Date of Review of Corrective Actions and all associated documents: _____

Date of FSVP Plan Reanalysis: _____

Changes to FSVP Plan , if needed:

Additional Verification Activities Required of Foreign Supplier, if needed:

Final **Disposition** of Affected Product

Document Completed By: _ _____

Signature & Date

Qualified Individual: _____

FSVP Importer: _____

This corrective action response meets the requirements set forth in FDA Regulation 21 C.F.R. Subpart L § 1.508

- ❖ 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.

Section 2.8 Example of FSVP Reanalysis Report

FSVP Plan Reanalysis Report

(The FSVP Plan must be reevaluated at least every 3 years or at any time you (FSVP Importer) are aware of new information that may affect your food and foreign supplier performance evaluation.)

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

Checklist	**Date reviewed and initials of FSVP Qualified Individual**	**Update needed Yes/No**	**Date Updated Completed:**	**FSVP Qualified Individual Completing the Update** (initial of
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				

FSVP Importer DUNS #	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Section 2.9 Example of FSVP Recall Program

Recall Plan

FDA does not require a Recall Plan for a FSVP Importer, but it is a good business practice to have one.

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

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 examples/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 with requested information regarding product distribution.

    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. Media coverage needed – Marketing Department

(Media contacts reference in back of plan)

h. 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 for approval. It must include sorting guidelines. This usually involves the categories: 1. Good product (acceptable for use under FDA 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 could be sent to a landfill per FDA 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 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 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 FDA 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 and company guidelines. Refer to 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.

FSVP Importer **DUNS #:**	**ISSUE DATE**	**PAGE**
ADDRESS	**SUPERSEDES**	**PRODUCT CODE**

Media Contact Information

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

米国食品安全強化法　外国供給業者検証プログラム（FSVP）参考モデル（冷凍チャーハン）
＜英語原文＞

2018 年 3 月作成

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