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（記入フォーム）

＜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。

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はじめに

本資料は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）規則に関して用意した記入フォーム（Word）である。

　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。ただし、規則上必須要件とされている「外国供給業者の評価」「危害分析」は全てのFSVPに含めなくてはいけない。そしてその結果行うべき検証活動も文書化が必須となる。加えて、検証活動の実施状況を証明する「記録」の保存も求められる。

これら規則上必須とされている事項をふまえ、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、本フォームをご活用いただければ幸いである。

なお、ジェトロはFSVPの具体例を示した参考モデル（冷凍チャーハン）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

シカゴ事務所

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## Section 0 Self-assessment checklist

**FSVP Importer: DUNS #:**

**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.**

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| **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 |

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| **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 |

## Section 1 Template for Imported Food Product Description

**FSVP Importer: DUNS #:**

**FOREIGN SUPPLIER INFORMATION**

**Foreign Supplier Name: (**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:**

**Foreign Supplier Owner/Operator/Agent in Charge:**

**Foreign Supplier Preventative Control Qualified Individual: Foreign Supplier FDA Registration Number:**

|  |  |
| --- | --- |
| **Product Description Distribution, Consumers and Intended Use** | |
| **Product Name(s)** | Product Name |
| **Product Description, including Important Food Safety Characteristics** | (A general description of the product & processing method, assembly, & family of  products included in the category. If it is relevant to product safety, properties like preservatives, water activity & pH should be listed here.) |
| **Ingredients** | (A list of ingredients, which may be grouped or transferred from the product label.) |
| **Packaging Used** | (A general description of the packaging, including modified atmosphere or vacuum  packaging if used) |
| **Intended Use** | (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** | (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** | (Include label instructions relevant to food safety e.g., storage condition such as  refrigeration, cooking instruction.) |
| **Storage and Distribution** | (List method of distribution e.g., refrigerated, frozen) |

## Section 2 Template for Foreign Supplier Evaluation

**FSVP Importer: DUNS #:**

**FSVP Qualified Individual:**

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.

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:

Foreign Supplier Address:

Foreign Supplier Owner/Operator/Agent in Charge:

Foreign Supplier Preventative Control Qualified Individual: Foreign Supplier FDA Registration Number:

ISSUED:

REVISED:

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| **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. (This information should be developed from the food safety plan) | (As determined by the FSVP Qualified  Individual.)  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.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| 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: (This information should be developed from the food safety plan)  Biological Hazard: (This information should be developed from the food safety plan)  Chemical Hazard: (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.) | 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/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| The food is subjected to a process or treatment necessary to eliminate any biological, chemical or physical hazard | (As determined by the FSVP Qualified | (As determined by the FSVP | Approved: Yes/No |

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| **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. (This information should be developed from the food safety plan) | Individual.) | Qualified Individual.) | Date:  FSVP Qualified Individual that Conducted Evaluation: |
| **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. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| The establishment is protected against the entry of animals that could contaminate the food (e.g. insects and 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. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| 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. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| **Conveyances and Equipment at the Foreign Supplier's Establishment** | | | |

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| **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** |
| Conveyances and equipment must be appropriate for the food and activity being conducted. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| Separate conveyances or equipment are used for handling contaminated material, waste or any other inedible substances, be identified as reserved  for that purpose. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| **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. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| 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. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |

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| **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** |
| 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. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| Incompatible activities and anything that presents a risk of contamination of 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. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| 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. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| 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. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| 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 | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |

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| **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** |
| 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. |  |  |  |
| 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. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| The establishment is equipped with means to remove and dispose of contaminated materials and waste, including a drainage, sewage and 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. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| 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 | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified |

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| **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** |
| 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. |  |  | Individual that Conducted Evaluation: |
| Water, ice or steam that comes in contact with a food, any system that supplies water must meet FDA requirements. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| 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 | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |

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| **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. |  |  |  |
| **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 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. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| 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. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |

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| **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** |
|  |  |  |  |
| 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. | (As determined by the FSVP Qualified  Individual.). | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| **Competency of Employees at the Foreign Supplier's Establishment** | | | |
| Employees and others involved in the manufacturing, preparing, storing, packaging or labelling of a food, or in the slaughter of food animals, are competent and qualified to carry out their duties. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| **Hygiene at the Foreign Supplier's Establishment** | | | |
| Everyone in an area where food is manufactured, prepared, stored, packaged, or labelled, or where food animals are slaughtered, follows CGMPs. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| **Investigation and Notification, Complaints and Recall** | | | |
| There are procedures in place for investigation and they are implemented. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |
| Is the Foreign Supplier in compliance with all FDA regulations? | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No |

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| **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** |
|  |  |  | Date:  FSVP Qualified Individual that Conducted Evaluation: |
| There are procedures in place for recall and a recall simulation and they are implemented. | (As determined by the FSVP Qualified  Individual.) | (As determined by the FSVP Qualified Individual.) | Approved: Yes/No  Date:  FSVP Qualified Individual that Conducted Evaluation: |

## Section 3 Template for Foreign Supplier Hazard Analysis

**FSVP Importer: DUNS #:**

**FSVP Qualified Individual:**

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).

**PROCESS CATEGORIES AND INGREDIENTS**

|  |  |  |
| --- | --- | --- |
| **Spices/Flavorings** | **Food Additives** | **Preservatives/Acidifiers** |
|  |  |  |
| **Other** | **Proteins** | **Packaging Materials** |
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| Allergens |  |  |
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| 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 | 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 |

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| 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 | 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 |

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| 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 | 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 |

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| **Process**  **Control** | **Hazard** | **Critical**  **Limits** | **Monitoring** | | | | **Corrective Action / Corrections** | **Record Keeping** | **Verification** |
| **What** | **How** | **Freq.** | **Who** |
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| **Process**  **Control** | **Hazard** | **Critical**  **Limits** | **Monitoring** | | | | **Corrective Action / Corrections** | **Record Keeping** | **Verification** |
| **What** | **How** | **Freq.** | **Who** |
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**List of Supplements for Preventive Control Plan**

## Section 4 Template for Foreign Supplier Verification Plan

**FSVP Importer: DUNS #:**

**FSVP Qualified Individual:**

The FSVP Qualified Individual should determine the verification activities and verification findings of the foreign

supplier producing a 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.

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:

Foreign Supplier Address:

Foreign Supplier Owner/Operator/Agent in Charge:

Foreign Supplier Preventative Control Qualified Individual: Foreign Supplier FDA Registration Number:

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| **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: (This information should be developed from the food safety plan)  Biological Hazard: (This information should be developed from the food safety plan)  Chemical Hazard: (This information should be developed from the food safety plan) | (This information should be developed from the food safety plan)  . | (As determined by the FSVP Qualified Individual.) | Date Verified:  FSVP Qualified Individual that Verified: |
| **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: (This information should be developed from the food safety plan)  Biological Hazard: (This information should be developed from the food safety plan)  Chemical Hazard: (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.) | 1) Annually (or an alternative timeframe, as determined by the FSVP Qualified Individual provided there is equal assurances the hazards are being controlled.) | Date Verified:  FSVP Qualified Individual that Verified: |
| **Describe the control measures used to** | (This information should be | (As determined by the FSVP | Date Verified: |

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| **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.) |
|  |  |  |  |
| **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: Identified Specific Hazard  (Type of Preventive Control)  Biological Hazard: Identified Specific Hazard  (Type of Preventive Control)  Chemical Hazard: Identified Specific Hazard  (Type of Preventive Control) | developed from the food safety plan) | Qualified Individual.) | FSVP Qualified Individual that Verified: |
| **Describe any applicable critical control points and related control measures**. (This information should be developed from the food safety plan)  Physical Hazard: Type of Preventive Control  (Critical Limits)  Biological Hazard: Type of Preventive Control  (Critical Limits)  Chemical Hazard: Type of Preventive Control  (Critical Limits) | (This information should be developed from the food safety plan)  (Typically this is what is being monitored for the Preventive Control) | (As determined by the FSVP Qualified Individual.) | Date Verified:  FSVP Qualified Individual that Verified: |
| **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)  (Preventive Control)- (What is performed to ensure the hazard is controlled.) | (This information should be developed from the food safety plan) | (As determined by the FSVP Qualified Individual.) | Date Verified:  FSVP Qualified Individual that Verified: |

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| **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.) |
|  |  |  |  |
| **Ensure there are procedures to verify the preventive control plan complies with all applicable FDA Regulations** | (As determined by the FSVP Qualified Individual.) | (As determined by the FSVP Qualified Individual.) | Date Verified:  FSVP Qualified Individual that Verified: |
| **You have documents that substantiate that the preventive control plan has been implemented as per above steps** | (As determined by the FSVP Qualified Individual.) | (As determined by the FSVP Qualified Individual.) | Date Verified:  FSVP Qualified Individual that Verified: |

## Section 5 Template for Foreign Supplier Corrective Actions

**FSVP Importer: DUNS #:**

**FSVP Qualified Individual:**

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.

**FOREIGN SUPPLIER INFORMATION**

Foreign Supplier Name:

Foreign Supplier Address:

Foreign Supplier Owner/Operator/Agent in Charge:

Foreign Supplier Preventative Control Qualified Individual: Foreign Supplier FDA Registration Number:

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| **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: Preventive Control (Critical Limit of Preventive  Control.)  Biological Hazard: Preventive Control (Critical Limit of Preventive  Control.)  Chemical Hazard: Preventive Control (Critical Limit of Preventive  Control.) | 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. |

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## Section 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 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 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)

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| **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 |  |  |  |  |

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## Section 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.

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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

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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.

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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.

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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.

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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.

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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.

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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.

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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)

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- 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

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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

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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?

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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](http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm) 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.

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**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（記入フォーム）＜英語原文＞

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