



UNITED SAFETY AGENTS
F S V P
COMPLIANCE PLAN

MAX VAN PELS, INCORPORATED

Name of FSVP Importer

INVERSIONES HANDAL FAJARDO, S. DE R.L.

Name of Foreign Supplier

HONDURAN DRIED ALLSPICE | INTENDED FOR FURTHER PROCESSING

Name of Product

SEPTEMBER 25, 2018 / SEPTEMBER 30, 2021

Date of Initial Verification / Reverification

SEPTEMBER 30, 2022

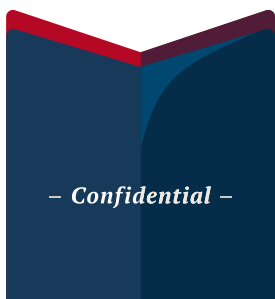
Date of FSVP Plan Expiration

VERIFICATION COMPLETE | APPROVED FOR IMPORT

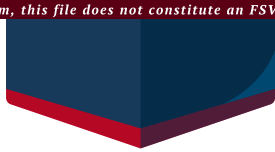
Result of Verification

NUMBER 04

Version



– Confidential –



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NOTICE of REDACTION



This FSVP Plan has been partially redacted and is intended for review purposes only. All food safety documents are subject to change without notice, may contain non-binding recommendations, and should be considered uncontrolled.

Any documents provided by a foreign supplier are considered to be the property of that foreign supplier and may contain information which is privileged, confidential, and protected. Any reproduction, distribution or other use of these documents without the consent of the foreign supplier is prohibited.

Please contact United Safety Agents with any questions or concerns.

Supplier: Inversiones Handal Fajardo, S. de R.L. Product: Honduran Dried Allspice – Further Processing Required

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Sept. 12, 2021 Review End: Sept. 30, 2021

UNITED STATES CODE of FEDERAL REGULATIONS

The following are or may be applicable to this product/supplier, FSVP Importer should confirm & comply independently.

- 101.** §101.1–101.108. Food Labeling.
- 106.** §106.1–106.160. Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, & Notifications.
- 110.** §110.3–110.110. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food.
- 111.** §111.1–111.610. Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.
- 112.** §112.1–112.213. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.
- 113.** §113.3–113.100. Thermally Processed Low-Acid Foods Pkged in Hermetically Sealed Containers.
- 114.** §114.3–114.100. Acidified Foods.
- 117.** §117.1–117.475. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.
- 120.** §120.1–120.25. Hazard Analysis and Critical Control Point (HACCP) Systems.
- 121.** §121.1–121.401. Mitigation Strategies to Protect Food Against Intentional Adulteration.
- 123.** §123.3–123.28. Fish and Fishery Products.
- 129.** §129.1–129.80. Processing/Bottle Drinking Water.
- 131.** §131.3–131.206. Milk and Cream.
- 133.** §133.3–133.196. Cheeses & Related Products.
- 135.** §135.3–135.160. Frozen Desserts.
- 136.** §136.3–136.180. Bakery Products.
- 137.** §137.105–137.350. Cereal Flours.
- 139.** §139.110–139.180. Macaroni & Noodle Products.
- 145.** §145.3–145.190. Canned Fruits.
- 146.** §146.3–146.187. Canned Fruit Juices.
- 150.** §150.110–150.160. Fruit Butters, Jellies, Preserves, and Related Products.
- 152.** §152.126. Fruit Pies.
- 155.** §155.3–155.201. Canned Vegetables.
- 156.** §156.3–156.145. Vegetable Juices.
- 158.** §158.3–158.170. Frozen Vegetables.
- 160.** §160.100–160.190. Eggs and Egg Products.
- 161.** §161.30–161.190. Fish and Shellfish.
- 163.** §163.5–163.155. Cacao Products.
- 164.** §164.110–164.150. Tree Nut and Peanut Products.
- 165.** §165.3–165.110. Beverages.
- 166.** §166.40–166.110. Margarine.
- 168.** §168.110–168.180. Sweeteners and Table Sirups.
- 169.** §169.3–169.182. Food Dressings and Flavorings.
- 170.** §170.3–170.285. Food Additives.
- 179.** §179.21–179.45. Irradiation in the Production, Processing and Handling of Food.
- 190.** §190.6. Dietary Supplements.
- 501.** §501.1–501.110. Animal Food Labeling.
- 507.** §507.1–507.215. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.
- 570.** §570.3–570.280. Food Additives.
- 579.** §579.12–579.40. Irradiation in the Production, Processing, & Handling of Animal & Pet Food.

Note: List is not exhaustive. Other regulations may be applicable.

Supplier: Inversiones Handal Fajardo, S. de R.L. Product: Honduran Dried Allspice – Further Processing Required

Agent(s): Claudio Innocenti (PCQI, Member, USA LLC) Review Start: Sept. 12, 2021 Review End: Sept. 30, 2021

21 C.F.R. § 1.500 – § 1.514

The following section(s) of the FSVP regulation is/are or may be particularly relevant to this product/supplier.

- §1.500.** What Definitions Apply to This Subpart?
- §1.501.** To What Foods Do the Requirements in This Subpart Apply?
- §1.502.** What Foreign Supplier Verification Program (FSVP) Must I Have?
- §1.503.** Who Must Develop My FSVP and Perform FSVP Activities?
- §1.504.** What Hazard Analysis Must I Conduct?
- §1.505.** What Evaluation for F. Supplier Approval & Verification Must I Conduct?
- §1.506.** What Foreign Supplier Verification and Related Activities Must I Conduct?
- §1.507.** What Requirements Apply When I Import Food That Cannot Be Consumed Without the Hazards Being Controlled or for Which the Hazards Are Controlled After Importation?
- §1.508.** What Corrective Actions Must I Take Under My Foreign Supplier Verification Program?
- §1.509.** How Must the Importer Be Identified at Entry?
- §1.510.** How Must I Maintain Records of My FSVP?
- §1.511.** What FSVP Must I Have If I Am Importing A Food Subject to Certain Requirements in the Dietary Supplement Current Good Manufacturing Practice Regulation?
- §1.512.** What FSVP May I Have If I Am A Very Small Importer or I Am Importing Certain Food from Certain Small Foreign Suppliers?
- §1.513.** What FSVP May I Have If I'm Importing Certain Food from A Country with An Officially Recognized Food Safety System?
- §1.514.** What Are Some Consequences of Failing to Comply with the Requirements of FSVP?

NOTES & COMMENTS

FSVP 21 CFR §1.500–§1.514

This product falls – at least in part – under the jurisdiction of the United States Food and Drug Administration (FDA), and does not qualify for an exemption in Title 21, Code of Federal Regulations, Chapter I, Sub-chapter A, Part 1, Subpart L, §1.501. As the FSVP Importer's Qualified Individual (as the term is defined in §1.503) United Safety Agents – through the actions of this FSVP Plan's identified "Agent(s)" – has performed all actions required by FSVP and has presented this FSVP Plan for the review of this product's FSVP Importer. Please refer to pages twenty-eight through thirty-six for substantiation of the FSVP QI's / PCQI's credentials.

Preventive Controls Rule 21 CFR Part 117/507

This product is not in Ready-to-Eat form and can not be consumed without the control of certain biological, chemical, physical hazards (as cited in the relevant Hazard ANALYSIS & DETERMINATION section(s)). Per §1.507, an FSVP Disclosure statement will be required for uncontrolled hazard(s). Thus, FSVP Importer will rely on its customer, who is subject to the requirements for hazard analysis and risk-based preventive controls in subpart C of part 117 or subpart C of part 507 of Title 21, of the Code of Federal Regulations to ensure that the identified hazard(s) will be significantly minimized or prevented; and has or soon will disclosed in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and will annually obtain written assurances, subject to the requirements of paragraph (c) of this section, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard(s). For reference, a copy of FDA-provided guidance has been enclosed and is entitled "Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act".

Supplier: Inversiones Handal Fajardo, S. de R.L. Product: Honduran Dried Allspice – Further Processing Required

Agent(s): Claudio Innocenti (PCQI, Member, USA LLC) Review Start: Sept. 12, 2021 Review End: Sept. 30, 2021

DESIGNATION of ROLES & SUMMARY of REVIEW

FOREIGN SUPPLIER VERIFICATION PROGRAM IMPORTER

Company Name: Max Van Pels, Incorporated FDA FEI: 1000170905

Physical Address: 111 Central Park Avenue, No. 480 DUNS No.: 06-498-5161

City: Hartsdale State: New York, 10530 Country: United States

Mailing Address: 111 Central Park Avenue, No. 480

City: Hartsdale State: New York, 10530 Country: United States

Phone Number: +1 (914) 761-3390 Email Address: maxvanpels@verizon.net

Name of Representative(s): Mr. Edward W. Sands Title: President

FOREIGN SUPPLIER &/OR MANUFACTURER as defined by §1.500

Company Name: Inversiones Handal Fajardo, S. de R.L. FDA FFR: 10270253502

Manufacturing Address: 2Avenue, 10 Street, Medina, Plaza Pell FDA FEI: _____

City: San Pedro Sula Province/Territory: Cortes, CT110 Country: Honduras

Office Address: Barrio Medina, 10 Calle, 2 Da Avenue

City: San Pedro Sula Province/Territory: Cortes, CT110 Country: Honduras

Phone Number: (504) 2550-9253 Email Address: gandonie@gmail.com

Name of Representative(s): Mr. Marvin Handal & Neptaly Lopez Title: Commercial Rep. / QC

QUALIFIED INDIVIDUAL(s) & AGENT(s)

Agent/QI Name: Claudio Innocenti Signature: 

Title: Partner & Preventive Controls Qualified Individual. Date: Sept 30, 2021

SUMMARY of REVIEW

Details of Product(s)	Is foreign supplier expected to implement controls for			Comments
	Biological Hazards	Chemical Hazards	Physical Hazards	
Honduran Dried Allspice. Intended for industrial use.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> <i>Undetermined</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> <i>Undetermined</i>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> <i>Undetermined</i>	Verified & Approved. — See Addendum.
	<input type="checkbox"/> FSVP Importer	<input type="checkbox"/> FSVP Importer	<input type="checkbox"/> FSVP Importer	
	<input checked="" type="checkbox"/> Disclosure	<input checked="" type="checkbox"/> Disclosure	<input type="checkbox"/> Disclosure	
	<input checked="" type="checkbox"/> Customer	<input checked="" type="checkbox"/> Customer	<input type="checkbox"/> Customer	

Preventive Control or Disclosure Rqd.: Per §117, §507, §111 and/or §1.507, Notice is required when FSVP Importer or FSVP Importer's customer will be responsible for controlling hazards. See "Hazard Analysis & Determination" section(s) and "Addendum" section for additional information. ■ Required ■ Recommended ■ Confirm efficacy of previously applied control(s)

Supplier: Inversiones Handal Fajardo, S. de R.L. Product: Honduran Dried Allspice – Further Processing Required

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Sept. 12, 2021 Review End: Sept. 30, 2021

REGISTER of SUBSTANTIATING DOCUMENTS



HAZARD ANALYSIS

Requested Required Received Reviewed

NOTES Inversiones Handal Fajardo, S. de R.L.'s HACCP Plan / Flow Chart received.

Dated: Not Dated.

Plan Entitled: Flow Chart - Allspice.

Note: We respectfully request that an unabridged copy of the supplier's HACCP/HARPC Plan be provided for evaluation.



ON-SITE AUDIT

Requested Required Received Reviewed

NOTES No substantiating information provided by Inversiones Handal Fajardo, S. de R.L.

Note: We respectfully request that a full copy of the supplier's annual on-site audit report be provided.



SAMPLING OR TESTING RESULTS

Requested Required Received Reviewed

NOTES Product arrives to the United States in unsterilized form. The FSVP Importer (Max Van Pels, Inc.) causes sterilization to be performed (EtO - Ethylene Oxide/Steam Sterilization) and verifies that the sterilization process was effective through laboratory testing to be done by an ISO 17025-accredited laboratory (Certified Laboratories, Inc.) for noted microbiological hazards. Certificate of Analysis is kept on file with FSVP Importer.

Note: We respectfully request that recent certificate(s) of analysis be provided for testing conducted to determine that product has been effectively processed to control for all FDA identified biological and chemical hazards (preferably by an ISO 17025-accredited laboratory).



OTHER FOOD SAFETY RECORDS

Requested Required Received Reviewed

NOTES Completed Foreign Supplier FSVP Questionnaire received.

Dated: February 12, 2020.

Completed by: Mr. Marvin Handal.

Note: No changes to supplier's food safety program have been reported.

Completed Foreign Supplier FSVP Questionnaire received.

Dated: September 12, 2019.

Completed by: Mr. Marvin Handal.



PRODUCT LABELING

Requested Required Received Reviewed

NOTES Product is considered to be a raw agricultural commodity. Product Specifications for Allspice received.

Safety Data Sheet for Allspice received. Allergen Statement for Honduran Allspice received.

Note: USA's assessment of product(s) labeling is restricted to a label(s)' allergen disclosure statement and should not be interpreted to mean that the label(s) meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food Allergen Labeling and Consumer Protection Act (FALCPA), or any other applicable section of 21 CFR Part 101.. USA recommends that FSVP Importer independently confirm that product label(s) is in compliance with all regulations prior to import.

Supplier: Inversiones Handal Fajardo, S. de R.L. Product: Honduran Dried Allspice – Further Processing Required

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Sept. 12, 2021 Review End: Sept. 30, 2021

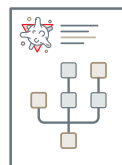
VERIFICATION FREQUENCY for UPDATED DOCUMENTS

21 C.F.R., §1.505, §1.506, and §1.510 require that all FSVP records be updated and maintained. Depending on USA’s review and determination of the supplier’s compliance history and food safety program, receipt of the following food safety documents are recommended accord to their individually-marked time interval.



FACILITY FOOD SAFETY PLAN

- if a change or update occurs
- annual basis (*regardless of change*)
- other: _____



RECALL PLAN

- if a change or update occurs
- annual basis (*regardless of change*)
- other: _____



HACCP PLAN / HARPC PLAN

- if a change or update occurs
- annual basis (*regardless of change*)
- other: _____



PRODUCT LABEL

- if a change or update occurs
- annual basis (*regardless of change*)
- other: _____



ON-SITE AUDIT RESULTS

- if a change or update occurs
- annual basis (*regardless of change*)
- other: _____



QUALIFICATIONS

- if a change or update occurs
- annual basis (*regardless of change*)
- other: _____



LABORATORY TESTING RESULTS

- if positive results are returned
- if recall or import refusal occurs
- if inspection occurs
- on an annual basis
- on a per-batch/shipment basis
- Chemical Biological
- other: _____



IMPLEMENTATION RECORDS

- if recall or import refusal occurs
- if inspection occurs
- on an annual basis
- on a per-batch/shipment basis
- other: _____



FDA REGISTRATION

- if a change or update occurs
- bi-annual basis (*regardless of change*)



FSVP QUESTIONNAIRE

- if a change or update occurs
- annual basis (*regardless of change*)
- other: _____



FACILITY LICENSE

- if a change or update occurs
- annual basis (*regardless of change*)
- not applicable



NOTES

All documents used for FSVP verification and approval must be re-acquired at least one every three years or sooner, per above.

unitedsafetyagents.com/documents



Supplier: Inversiones Handal Fajardo, S. de R.L. Product: Honduran Dried Allspice – Further Processing Required

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Sept. 12, 2021 Review End: Sept. 30, 2021

INITIAL VERIFICATION ACTIVITIES

To confirm that all relevant or identified food safety hazards requiring a control have been significantly minimized or prevented, the below enumerated activities were used to initially verify Honduran Allspice (“product” or “imported product”), supplied by Inversiones Handal Fajardo, S. de R.L. (“supplier” or “foreign supplier”), imported by Max Van Pels, Inc. (“importer” or “FSVP importer”):

RELEVANT FOOD SAFETY RECORDS, including a review of the foreign supplier's relevant food safety records, including Inversiones Handal Fajardo, S. de R.L.'s Hazard Analysis and Critical Control Plan (“HACCP Plan”); food safety plan/program; implementation records; and internal monitoring procedures. Per §1.506(d)(1)(ii)(C) and (e)(1)(iii), documentation of each record, including the dates of review, the general nature of the records reviewed, the conclusions of the review, and documentation that the review was conducted by a FSVP qualified individual were completed.

OTHER APPROPRIATE SUPPLIER VERIFICATION ACTIVITIES, including a review of Inversiones Handal Fajardo, S. de R.L.'s compliance history, including whether Inversiones Handal Fajardo, S. de R.L. is the subject of an FDA Warning Letters; Import Alerts; or other FDA compliance actions related to food safety. Per §1.506(d)(1)(ii)(D) and (e)(1)(iv)(B), documentation of each activity conducted in accordance with paragraph (e)(1)(iv), including a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by a FSVP QI were completed.

NOTE

Per §1.506(d)(3), Max Van Pels, Inc. relied on the determination of appropriate foreign supplier verification activities made by an entity other than the foreign supplier (USA) and reviewed and assessed whether the determination was appropriate. Max Van Pels, Inc. has documented its review and assessment, including documenting that the determination of appropriate verification activities was made by a FSVP QI. Max Van Pels, Inc.'s attestation of review and assessment can be found on page number nine of this FSVP. USA's certifications and qualifications can be found on page numbers twenty-eight through thirty-six of this FSVP.

Product arrives to the United States in unsterilized form. The FSVP Importer (Max Van Pels, Inc.) causes sterilization to be performed (EtO - Ethylene Oxide/Steam Sterilization) and verifies that the sterilization process was effective through laboratory testing to be done by an ISO 17025-accredited laboratory (Certified Laboratories, Inc.) for noted microbiological hazards. Certificate of Analysis is kept on file with FSVP Importer.

Supplier: Inversiones Handal Fajardo, S. de R.L. Product: Honduran Dried Allspice – Further Processing Required

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: Sept. 12, 2021 Review End: Sept. 30, 2021

ONGOING VERIFICATION ACTIVITIES

To confirm that all relevant or identified food safety hazards requiring a control, for Honduran Allspice (“product” or “imported product”), supplied by Inversiones Handal Fajardo, S. de R.L. (“supplier” or “foreign supplier”), continue to be significantly minimized or prevented prior to public distribution, up-to-date versions of all documents used during the initial FSVP verification and approval processes will be re-acquired at least once every three years – or sooner, per the following document-specific requirements:

An updated version of Inversiones Handal Fajardo, S. de R.L.'s FOOD SAFETY PLAN will be required if any change or update occurs. Inversiones Handal Fajardo, S. de R.L. has been informed of this ongoing requirement and USA will confirm annually that the version on file remains current and faithfully illustrates all processes, monitoring procedures, etc., or acquire and review Inversiones Handal Fajardo, S. de R.L.'s most up-to-date copy.

Confirmation that Inversiones Handal Fajardo, S. de R.L.'s FOOD FACILITY REGISTRATION remains active with FDA will be made annually by USA.

The supplier's COMPLIANCE STANDING/HISTORY will be checked by USA via FDA's Data Dashboard annually – at a minimum – or sooner in the event that USA is made aware of new information.

NOTE

USA's assessment of the product's labeling is restricted to the label's allergen disclosure statement and should not be interpreted to mean that the label meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food Allergen Labeling and Consumer Protection Act (FALCPA), or all other applicable sections of 21 CFR Part 101. It shall remain Max Van Pels, Inc.'s responsibility to independently confirm that the product label follows all regulations prior to import.

Product arrives to the United States in unsterilized form. The FSVP Importer (Max Van Pels, Inc.) causes sterilization to be performed (EtO - Ethylene Oxide/Steam Sterilization) and verifies that the sterilization process was effective through laboratory testing to be done by an ISO 17025-accredited laboratory (Certified Laboratories, Inc.) for noted microbiological hazards. Certificate of Analysis is kept on file with FSVP Importer.

FREQUENCY of VERIFICATION ACTIVITIES

All Ongoing Verification Activities will be conducted and re-conducted at their individually noted frequency, as appropriate to confirm that each hazards requiring a control continues to be significantly minimized or prevented by the supplier. Or, if not controlled by the supplier, is properly disclosed to the appropriate party. Document frequency-specific determinations can be found on page number twelve of FSVP.

Note: It is understood that the above actions are applicable only if USA continues to serve as the FSVP QI.

Supplier: Inversiones Handal Fajardo, S. de R.L. Product: Honduran Dried Allspice – Further Processing Required

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Sept. 12, 2021 Review End: Sept. 30, 2021

REVISION LOG for FSVP PLAN

Version No.	Date of Change	Description of Revision
No. 01	Sept. 28, 2018.	Product and supplier underwent initial FSVP verification.
No. 02	Sept. 29, 2019.	Foreign Supplier and product underwent annual verification. Additional and/or updated food safety documents were requested, received, and added to FSVP. FSVP content and format was updated to reflect recent FDA Guidance document(s) and/or regulatory statues that became applicable since initial verification, or previous reverification.
No. 03	Sept. 29, 2020.	Foreign Supplier and product underwent annual verification. Additional and/or updated food safety documents were requested, received, and added to FSVP. FSVP content and format was updated to reflect recent FDA Guidance document(s) and/or regulatory statues that became applicable since initial verification, or previous reverification.
No. 04	Sept. 30, 2021.	Foreign Supplier and product underwent annual verification. Additional and/or updated food safety documents were requested, received, and added to FSVP. FSVP content and format was updated to reflect recent FDA Guidance document(s) and/or regulatory statues that became applicable since initial verification, or previous reverification.

**Describing a Hazard That Needs Control in Documents Accompanying the Food, as
Required by Four Rules Implementing the FDA Food Safety Modernization Act:
Guidance for Industry. *Draft Guidance.***

D. FDA’s Recommendations Regarding the FSVP Regulation Disclosure Statement.

1. How to describe the identified hazard.

We believe that, in practice, the FSVP regulation disclosure statement will be required mostly for biological hazards, because the FSVP regulation disclosure statement only applies when an importer has identified a hazard requiring a control, but that control has not been applied prior to importation, or by the importer if the importer is a manufacturer or processor. In the case of most chemical and physical hazards, a chemical or physical hazard that an importer identifies as requiring a control would most likely be controlled by the first manufacturing/processing facility in the supply/distribution chain. For example, an animal food vitamin pre-mix manufacturer that is a foreign supplier could identify the chemical hazard “nutrient toxicity” in the vitamin ingredients it receives from its supplier. The pre-mix manufacturer would evaluate the potency of the individual vitamin ingredients prior to manufacturing the pre-mix, controlling the nutrient toxicity hazard by combining the vitamin ingredients at an appropriate ratio. In this scenario, the pre-mix manufacturer would not pass the chemical hazard on to a future customer for control. Likewise, an importer that is a manufacturing/processing facility that receives produce RACs from a foreign supplier likely would establish and implement a control for physical hazards such as stones that get into the RACs as a result of harvesting.

For biological hazards, we will consider an importer that describes the “identified hazard” using a general term (e.g., “microbial pathogens,” “microorganisms of public health significance”) rather than a specific biological hazard (e.g., *Salmonella* or *Listeria monocytogenes*) to be in compliance with the requirements for the FSVP regulation disclosure statement. Such a statement adequately communicates the key safety information. Regardless of whether the establishment that receives food from the importer accompanied by such a disclosure statement is subject to the CGMP requirements, the preventive controls requirements, or both the CGMP and preventive controls requirements in part 117 or part 507, that establishment is responsible for taking appropriate steps to ensure that biological hazards applicable to that food are controlled before the food reaches the consumer.

For chemical and physical hazards, an importer that chooses to rely on its customers to control chemical and physical hazards (instead of controlling the hazards itself or verifying that the hazards have been controlled prior to importation) would be subject to the requirements of the FSVP regulation disclosure statement. We expect such an importer to describe the identified chemical or physical hazard using a specific term (e.g., “mycotoxins,” “aflatoxin,” “stones”) that adequately communicates the key safety information regarding the chemical or physical hazard that needs to be controlled. Referring to physical or chemical hazards using a general term only does not provide a customer with sufficient information to address the hazard.

PLEASE NOTE: Suggested wording for FSVP Regulation Disclosure Statement has been included on page number three. This Statement should accompany all applicable product via Documents of the trade (such as labels, labeling, bill of lading, shipment-specific certificates of analysis, and other documents or papers associated with the shipment that a food safety manager for the customer is likely to read).

FSVP REGULATION DISCLOSURE STATEMENT - EXAMPLE

As required by 21 CFR 117.136(a)(2)(i), (3)(i), & (4)(i); **this food is not processed to control [identified hazard*].**

* If biological hazard, general description is sufficient (e.g., “microbial pathogens”).

* If chemical or physical hazard, specific description required (e.g., “mycotoxins,” “stones”).

Supplier: _____ Product: _____

Agent(s): _____ Review Start: _____ Review End: _____

CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Claudio Innocenti

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:
Foreign Supplier Verification Programs
delivered by Lead Instructor

Bob Bauer
completed on
05/13/2021


 Robert Brackett, VP and Director
 Institute for Food Safety and Health



 Gerald Wojtala, Executive Director
 International Food Protection Training Institute



 Steve Mandernach, Executive Director
 Association of Food and Drug Officials


Certificate # 31d8ad94

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Claudio Innocenti

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:
FSPCA Preventive Controls for Animal Food
delivered by Lead Instructor

Charles Nolan
completed on
07/09/2020


 Robert Brackett, VP and Director
 Institute for Food Safety and Health



 Gerald Wojtala, Executive Director
 International Food Protection Training Institute



 Susan M. Hays, Executive Director
 Association of American Feed Control Officials


Certificate # 223faa17

Supplier: _____ Product: _____

Agent(s): _____ Review Start: _____ Review End: _____

CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

CLAUDIO INNOCENTI

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:
Foreign Supplier Verification Programs
delivered by Lead Instructor

Bob Bauer
completed on
09/14/2018


 Robert Brackett, VP and Director
 Institute for Food Safety and Health



 Gerald Wojtals, Executive Director
 International Food Protection Training Institute



 Joseph Corby, Executive Director
 Association of Food and Drug Officials


Certificate # d2e9c287



Produce Safety
ALLIANCE

Certificate of Training

is awarded to

Claudio Innocent

in recognition for having successfully completed
the Produce Safety Alliance course:
PSA Grower Training Course
Delivered by PSA Lead Trainers and/or PSA Trainers
**Cara Fraver, Laura McDermott, Yolanda Gonzalez,
Lindsey Pashow**


 ASSOCIATION OF FOOD
& DRUG OFFICIALS
SINCE 1898


 Joseph Corby
 Executive Director, AFDO


 Elizabeth A. Bihn, Ph.D.
 Produce Safety Alliance Director

Class Number
NY-180712-GR

Grower ID Number
50447

Training Date and Location
7/12/2018-7/12/2018
Voorheesville, NY

Supplier: _____ Product: _____

Agent(s): _____ Review Start: _____ Review End: _____

CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

CLAUDIO INNOCENTI

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:
Foreign Supplier Verification Programs
delivered by Lead Instructor

Bob Bauer
completed on
05/31/2018


 Robert Brackett, VP and Director
 Institute for Food Safety and Health



 Gerald Wojtala, Executive Director
 International Food Protection Training Institute



 Joseph Corby, Executive Director
 Association of Food and Drug Officials


Certificate # d2e9c287

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

CLAUDIO INNOCENTI

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:
Foreign Supplier Verification Programs
delivered by Lead Instructor

Bob Bauer
completed on
09/14/2017


 Robert Brackett, VP and Director
 Institute for Food Safety and Health



 Gerald Wojtala, Executive Director
 International Food Protection Training Institute



 Joseph Corby, Executive Director
 Association of Food and Drug Officials


Certificate # d2e9c287

Supplier: _____ Product: _____

Agent(s): _____ Review Start: _____ Review End: _____

CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT


 FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE
CERTIFICATE OF TRAINING
 is awarded to
CLAUDIO INNOCENTI
 in recognition for having successfully completed
 the Food Safety Preventive Controls Alliance course:
FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD
 delivered by Lead Instructor
Amanda Evans
 completed on
07/25/2017

 <small>Robert Brackett, VP and Director Institute for Food Safety and Health</small>	 <small>Gerald Wojtals, Executive Director International Food Protection Training Institute</small>	 <small>Joseph Corby, Executive Director Association of Food and Drug Officials</small>
 <small>IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH ILLINOIS INSTITUTE OF TECHNOLOGY</small>	 <small>INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE</small>	 <small>AFDO</small>

Certificate # 2d697331

Supplier: _____ Product: _____

Agent(s): _____ Review Start: _____ Review End: _____

QUALIFICATIONS of SUPPORTING QI

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

WILLIAM BARBER

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:
FSPCA Preventive Controls for Human Food
delivered by Lead Instructor
Mirasol Mohal
completed on
06/05/2019


 Robert Brackett, VP and Director
 Institute for Food Safety and Health



 Gerald Wojtala, Executive Director
 International Food Protection Training Institute



 Steve Mandernach, Executive Director
 Association of Food and Drug Officials


Certificate # ed6f0b58

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

William Barber

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:
Foreign Supplier Verification Programs
delivered by Lead Instructor
tina coil
completed on
06/13/2017


 Robert Brackett, VP and Director
 Institute for Food Safety and Health



 Gerald Wojtala, Executive Director
 International Food Protection Training Institute




 Joseph Corby, Executive Director
 Association of Food and Drug Officials


Certificate # 917b0241

Supplier: _____ Product: _____

Agent(s): _____ Review Start: _____ Review End: _____

QUALIFICATIONS of SUPPORTING QI



This is to certify that

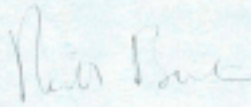

William Barber

Has been awarded the




Level 4 Award in HACCP Management for Food Manufacturing
500/6523/3

PASS

Date of Award
10 November 2016



Richard Burton
Head of Qualifications

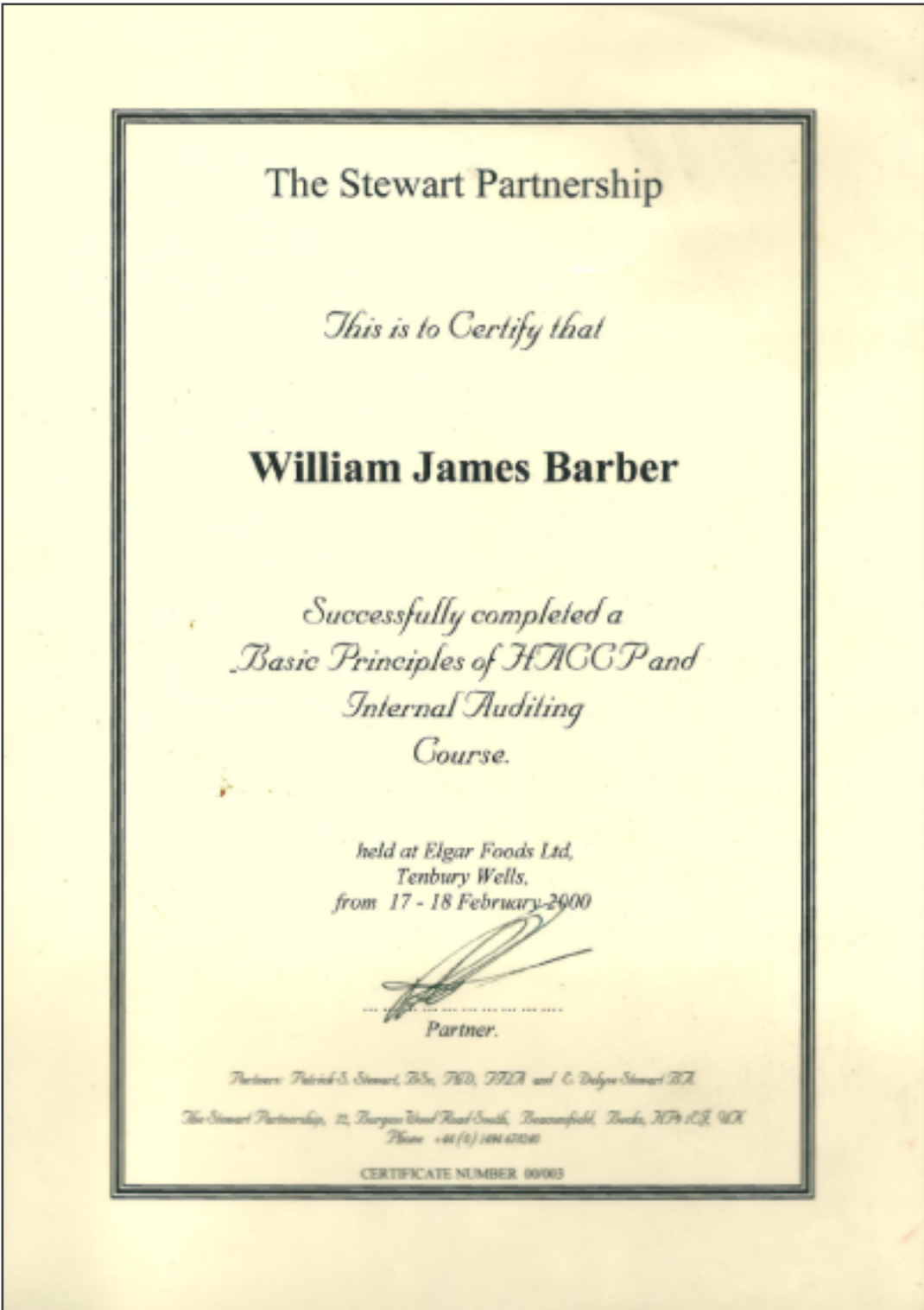


526405 101116 1107147

Supplier: _____ Product: _____

Agent(s): _____ Review Start: _____ Review End: _____


QUALIFICATIONS of SUPPORTING QI



Supplier: _____ Product: _____

Agent(s): _____ Review Start: _____ Review End: _____

QUALIFICATIONS of SUPPORTING QI



NATIONAL VOCATIONAL QUALIFICATION
LEVEL 3 NVQ IN FOOD AND DRINK MANUFACTURING OPERATIONS
 (Q1054402)


IS AWARDED TO
WILLIAM BARBER

THE HOLDER HAS A NUMBER OF FORMAL UNIT CREDITS BY WHICH THIS AWARD WAS ACHIEVED


AWARDED SEPTEMBER 2007 0719/024307 A/1 24203/PXC4025/1/1 303/64

Michael Howell
 M Howell
 Chairman
 The City and Guilds of London Institute

C Humphries
 C Humphries
 Director-General
 The City and Guilds of London Institute



Qualifications and Curriculum Authority



The City and Guilds of London Institute founded 1878 and incorporated by Royal Charter 1996.
 The City & Guilds Group comprises City & Guilds, C&G, City & Guilds 1878 and City & Guilds 1968.

Supplier: _____ Product: _____

Agent(s): _____ Review Start: _____ Review End: _____

QUALIFICATIONS of SUPPORTING QI



**CERTIFICATE OF UNIT CREDIT TOWARDS
NATIONAL VOCATIONAL QUALIFICATION
LEVEL 3 NVQ IN FOOD AND DRINK MANUFACTURING OPERATIONS**

**IS AWARDED TO
WILLIAM BARBER**

WHO ATTENDED PERSHORE GROUP OF COLLEGES

**AND WAS SUCCESSFUL IN THE
FOLLOWING TEN UNITS**

CONTROL AND MAINTAIN QUALITY WITHIN MULTI-STAGE MANUFACTURING OPERATIONS	U1024734
RESOLVE PROBLEMS IN MULTI-STAGE MANUFACTURING OPERATIONS	U1024735
MAINTAIN AND IMPROVE HEALTH AND SAFETY WITHIN THE WORKPLACE	U1024736
MAINTAIN AND IMPROVE HYGIENE AND PRODUCT SAFETY WITHIN THE WORKPLACE	U1024737
CONTRIBUTE TO THE ACHIEVEMENT OF ORGANISATIONAL AND PERSONAL GOALS	U1026661
PROVIDE INFORMATION TO SUPPORT DECISION MAKING	U1026144
MONITOR AND MAINTAIN THE HANDLING AND STORAGE OF MATERIALS	U1024742
IMPLEMENT QUALITY ASSURANCE SYSTEMS	U1027820
DEVELOP A FOOD AND DRINK PRODUCT	U1050274

CONTINUED

AWARDED SEPTEMBER 2007 0709/024307A/124203/PXC4025/1/13/03/64

Michael Howell

M Howell
Chairman
The City and Guilds of London Institute

C Humphries

C Humphries
Director-General
The City and Guilds of London Institute



The City and Guilds of London Institute founded 1879 and incorporated by Royal Charter 1900.
The City & Guilds Group comprises City & Guilds, ILM, City & Guilds NPTC and City & Guilds WAB.



Supplier: _____ Product: _____

Agent(s): _____ Review Start: _____ Review End: _____

SUBSTANTIATING DOCUMENTS



This FSVP plan is based – at least in part – on the following foreign supplier-provided food safety documents. All substantiating documents have been reviewed and assessed by United Safety Agents LLC.

Note Foreign supplier-provided documents are considered to be the property of that foreign supplier and may contain information which is privileged, confidential, and protected. Any reproduction, distribution or other use of these documents without the express written consent of the foreign supplier is prohibited. Enclosed documents are meant for review purposes only and are subject to change without notice. Documents may contain non-binding recommendations and are uncontrolled.

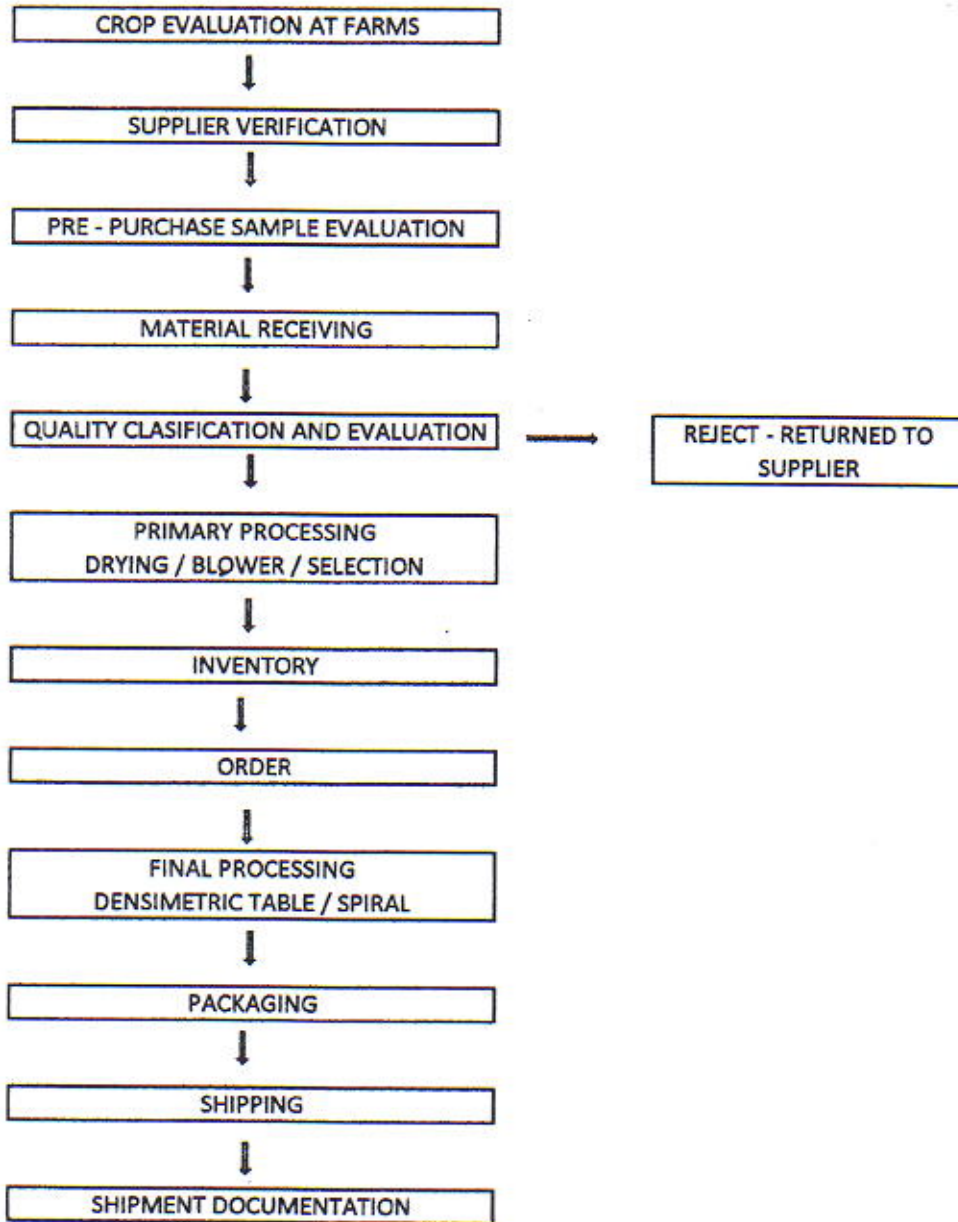
INVERSIONES HANDAL FAJARDO S.DE R.L.

BARRIO MEDINA, 10 CALLE, 2DA AVENIDA S.E. PLAZA PELL LOCAL NO. 1

TELEFONO No. 2550 9253 P.O BOX 3432 SAN PEDRO SULA HONDURAS

R.T.N. 05019002069361 E - MAIL hanfainversiones@hotmail.com

FLOW CHART ALLSPICE

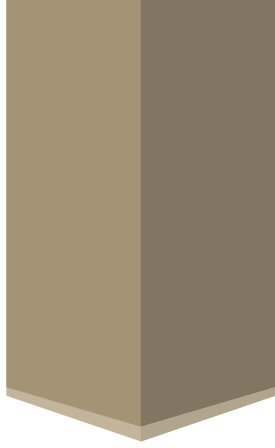


FOR INVERSIONES HANDAL FAJARDO

**INVERSIONES
HANDAL FAJARDO
S. DE R. L.**



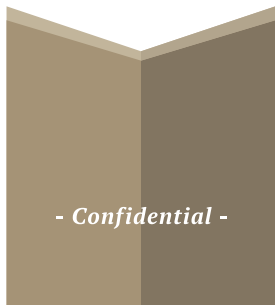
REVIEWED BY
CLAUDIO INNOCENTI, PCQI
REVIEWED ON OR ABOUT
Sept. 25-30, 2018.



FOREIGN SUPPLIER

F S V P

QUESTIONNAIRE



B A C K G R O U N D

The Foreign Supplier Verification Program (FSVP) was published by the FDA on November 27, 2015. FSVP is fundamentally concerned with food safety. As a validly designated and qualified United States (U.S.) representative, United Safety Agents LLC's (USA) FDA-mandated goal is to verify that a product's innate physical, chemical and biological hazards are being controlled in a manner that provides at least the same level of public health protection as the FDA's domestic standards (Preventive Controls Rule or Produce Safety Rule). In order to accomplish this goal, documentation of your company's processes, procedures and control methods will be required.

C O N F I D E N T I A L I T Y

All information shared will remain strictly privileged and confidential and will only be used during FSVP verification activities. An accurate and truthful response is required to successfully complete your company's FSVP verification.

I N S T R U C T I O N S

We respectfully request that you complete the following sections to the best of your ability and with as much detail as possible. All sections are required, unless explicitly noted otherwise. **Complete via computer, do not print.**

Upon completion: Please return Questionnaire and accompanying documents via:

Method One: email completed questionnaire to info@unitedsafetyagents.com

Method Two: upload completed questionnaire to USA's [ShareFile](#)

C O N T A C T

If you have any questions or require additional information, please contact United Safety Agents LLC directly via Email: info@unitedsafetyagents.com, Phone: +1 (888) 551-7403, Fax: +1 (888) 557-2649, UnitedSafetyAgents.com, or by Mail: 715 W. Park Avenue, No. 222, Oakhurst, New Jersey 07755-9998, United States of America.

This document contain information which is privileged, confidential, and protected. If you are not the addressee, note that any disclosure, copying, distribution, or use of the contents of this message is prohibited. If you have received this document in error, please destroy it and notify info@unitedsafetyagents.com immediately. Document may contain non binding recommendations. United Safety Agents LLC provides assistance to businesses with FDA/FSVP compliance and has no affiliation with the United States' Food and Drug Administration.

GENERAL INFORMATION

Company Name: _____ Today's Date: _____

Factory Address: _____

City: _____ Province: _____ Country: _____

Office Address: _____

City: _____ Province: _____ Country: _____

FDA Registration No.: _____ Website: _____

QC/QA's Name: _____ Title: _____

Phone No.: _____ Email: _____

TraceGains' Account Name: _____

SUPPLIER CLASS

Please select all actions/roles that apply to your facility/operation.

- | | | | |
|--|--|----------------------------------|--------------------------------------|
| <input type="checkbox"/> Manufacturer (Raw Material) | <input type="checkbox"/> Processor | <input type="checkbox"/> Packer | <input type="checkbox"/> Re-Packer |
| <input type="checkbox"/> Manufacturer (Finished Product) | <input type="checkbox"/> Distributor | <input type="checkbox"/> Shipper | <input type="checkbox"/> Warehouse |
| <input type="checkbox"/> Importer (US-based) | <input type="checkbox"/> Exporter (Non US-based) | <input type="checkbox"/> Broker | <input type="checkbox"/> Other _____ |

PRODUCT CATAGORY

Please select a category or categories of product(s) that your facility/operation handles.

- | | | | |
|---|--------------------------------------|--|--------------------------------------|
| <input type="checkbox"/> Bakery | <input type="checkbox"/> Beverage | <input type="checkbox"/> Chocolate/Candy | <input type="checkbox"/> Dairy |
| <input type="checkbox"/> Dressings/Condiments | <input type="checkbox"/> Egg | <input type="checkbox"/> Food Additives | <input type="checkbox"/> Game Meat |
| <input type="checkbox"/> Fruits | <input type="checkbox"/> Vegetables | <input type="checkbox"/> Grains | <input type="checkbox"/> Nuts |
| <input type="checkbox"/> Oil | <input type="checkbox"/> Snack Foods | <input type="checkbox"/> Spice | <input type="checkbox"/> Other _____ |

PRODUCTS SUPPLIED

Please list the name (and variation) of each product that your company supplies to Customer.

Product No. 01: _____ Product No. 06: _____

Product No. 02: _____ Product No. 07: _____

Product No. 03: _____ Product No. 08: _____

Product No. 04: _____ Product No. 09: _____

Product No. 05: _____ Product No. 10: _____

FDA IDENTIFIED BIOLOGICAL HAZARDS

FDA-identified Biological Hazards associated with the product(s) that your company supplies.

- | | | | |
|---|--|--|--|
| <input type="checkbox"/> Bacillus cereus | <input type="checkbox"/> Clostridium botulinum | <input type="checkbox"/> C. perfringens | <input type="checkbox"/> Brucella spp. |
| <input type="checkbox"/> Campylobacter spp. | <input type="checkbox"/> Pathogenic E. coli | <input type="checkbox"/> Salmonella spp. | <input type="checkbox"/> S. aureus |
| <input type="checkbox"/> L. monocytogenes | <input type="checkbox"/> Trichinella spiralis | <input type="checkbox"/> Giardia lamblia | <input type="checkbox"/> Shigella spp. |

CRITICAL CONTROLS for BIOLOGICAL HAZARDS

Please select and describe the method by which Biological Hazard(s) are controlled. Please be as detailed as possible. Include time/temperature, chemical names, or any other information.

- Heat
- Chemical
- CGMPs
- Testing
- Other

DESCRIPTION of CRITICAL CONTROLS

FREQUENCY of CONTROL VALIDATION

FDA IDENTIFIED ENVIROMENTAL/PROCESS HAZARDS

FDA-identified Environmental Hazards associated with the product(s) that your company supplies.

- Recontamination with environmental pathogens.
- Bacterial pathogen survival of a lethal treatment.
- Bacterial growth and/or toxin formation due to lack of time / temperature control.
- Recontamination due to lack of container integrity.
- Bacterial growth and/or toxin formation due to reduced oxygen packaging.
- Bacterial growth and/or toxin formation due to poor formulation control.

CRITICAL CONTROLS for ENVIROMENTAL/PROCESS

Select and describe the method(s) by which Environmental/Process Hazard(s) are controlled. As detailed as possible.

- Heat
- Chemical
- CGMPs
- Testing
- Other

DESCRIPTION of CRITICAL CONTROLS	

FREQUENCY of CONTROL VALIDATION	

FDA IDENTIFIED CHEMICAL HAZARDS

FDA-identified Chemical Hazards associated with the product(s) that your company supplies.

- Drug residues
- Heavy metals
- Industrial chemicals
- Pesticides
- Mycotoxins/Toxins
- Radiological
- Unapproved colors & additives
- Other

CRITICAL CONTROLS for CHEMICAL HAZARDS

Select and describe the method(s) by which Chemical Hazard(s) are controlled. Please be as detailed as possible.

- CGMPs
- Testing
- Other

DESCRIPTION of CRITICAL CONTROLS

FREQUENCY of CONTROL VALIDATION

FDA IDENTIFIED PHYSICAL HAZARDS

FDA-identified Chemical Hazards associated with the product(s) that your company supplies.

- Metal
- Glass
- Extraneous Matter
- Plastics
- Stones
- Wood
- Natural Component of Food
- Other

CRITICAL CONTROLS for PHYSICAL HAZARDS

Select and describe the method(s) by which Physical Hazard(s) are controlled. Please be as detailed as possible.

- CGMPs
- Testing
- Raw Material Inspection
- Filter
- Screen
- Metal Detector
see below
- Magnet
- X-Ray
- Radar
- Other

DESCRIPTION of CRITICAL CONTROLS	

FREQUENCY of CONTROL VALIDATION	

Metal detection standards	Ferrous: _____ mm
	Non Ferrous: _____ mm
	Stainless Steel: _____ mm

ALLERGEN & CROSS CONTAMINATION CONTROLS

Component or Ingredient	Present in product?	Present on same equipment?	Present in same facility?
Product Name: _____		Product code: _____	
Peanuts	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Tree Nuts	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Milk or Milk Derivatives	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Egg or Egg Products	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Fish	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Shellfish	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Soy	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Gluten	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Wheat	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Celery	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Sesame	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Mustard	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Sulfates	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Lupin	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Seeds	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Monosodium Glutamate	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Grains	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Colorings	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Aflatoxins	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

Please write product's allergen statement (e.x. product is processed in a facility that..)

ONSITE AUDITING INFORMATION

Does the manufacturing/processing site have a recognized GFSI certification (BRC, SQF, Etc.)? Yes No

If Yes; Please provide a copy of the **full audit report** (written in English).

What standard is the GFSI certification? _____

If No; 1. Does the site have documented quality manual? Yes No

2. Does the site have documented internal hygiene audits? Yes No

3. Does the site have documented quality system audits? Yes No

4. Does the site have documented process audits? Yes No

CLEANING INFORMATION

Does the site have documented hygiene procedures in place? Yes No

Does the site have a designated hygiene team? Yes No

Are all cleaning staff formally trained? Yes No

Do the cleaning schedules include: Chemicals used? Yes No

Concentration levels? Yes No

Dilution method? Yes No

Please list the chemical type(s) used on all food contact lines and surfaces:

STAFF HYGIENE INFORMATION

Have all staff undergone formal food hygiene training? Yes No

In-house hygiene training? Yes No

Accredited hygiene training? Yes No

Training level certification obtained: _____

Are staff issued protective clothing? Yes No

Are operatives required to cover head/facial hair within the processing/manufacturing area? Yes No

Are adequate toilet and hand washing facilities provided? Yes No

Are hand-washing/swabbing validation checks carried out? Yes No

What is the total number of staff employed on site? _____

PEST CONTROL

Is a pest control contractor employed? Yes No

If yes, please provide: Name of contractor used: _____

Number of yearly visits: _____

If no, by what means is pest prevention carried out? _____

HACCP & TACCP & VACCP

Does a fully documented and audited HACCP system exist for the site? Yes No

Has a hazard analysis study been completed for each site operation? Yes No

Does the business have a trained & certified in-house HACCP team? Yes No

If yes, please provide copies of current & relevant HACCP training certificates.

Does the business outsource the HACCP management to a certificated consultant? Yes No

If yes, please provide copies of current & relevant HACCP training certificates.

Are records maintained for all CCPs? Yes No

Does the HACCP system include the following: Sieving of ingredients? Yes No

Sieving of finished products? Yes No

Glass & hard plastic breakage procedure? Yes No

Metal detection of final product? Yes No

Magnets within the mixing & filling stages? Yes No

Do you use blue metal detectable plasters in the manufacturing/processing areas? Yes No

Please detail any other prevention systems used on site: _____

Has a full threat assessment of your supply chain been conducted & tested? Yes No

Please provide details: _____

Has a full product vulnerability assessment within the supply chain been conducted & tested? Yes No

Please provide details: _____

TRACEABILITY

Does full traceability exist for all products supplied to your customer base? Yes No

If yes, please give details of traceability codes on the final packaging: _____

RAW MATERIAL

Are materials used by your company sourced from approved suppliers? Yes No

Are certificates of conformance/analysis received for all raw ingredients? Yes No

Are raw materials positively released before use? Yes No

Please describe your supplier approval system:

FINISHED / PACKED PRODUCT

Are finished / packed products positively released? Yes No

Are reference samples from finished packed product retained? Yes No

Are finished product submitted to an 17025:2005 accredited laboratory for validation purposes? Yes No

If yes, please give details of the testing routines conducted:

CUSTOMER COMPLAINTS

Does a formal customer complaint procedure exist? Yes No

Please describe your customer complaint procedure.

RECALL / IMPORT ALERT / FOOD SAFETY ISSUE

Has your company ever experienced a recall or other food safety related issue of any kind? Yes No

If yes, please describe fully.

C E R T I F I C A T I O N

I certify the information I provided on and in connection with this form is true, accurate and complete. I also understand that any false statements or deliberate omissions on this document or any other document I file with United Safety Agents, LLC may be grounds for disqualification from successful Foreign Supplier Verification Program (FSVP) approval or, if discovered after FSVP approval takes place, could result in my company's FSVP approval status being revoked or terminated, and may result in my shipment being rejected from entry into the United States. I confirm that all products that my company trades are in compliance with the Food Safety Modernization Act and all other U.S & FDA Food Safety legislation.

< **CONFIRM CERTIFICATION** - Required

Representative's Name: _____

Title: _____

Today's Date: _____

SAFETY DATA SHEET

1. Identification
Item Description: DRIED ALLSPICE (pimenta dioica)
Contact Address: Inversiones Handal Fajardo – Barrio Medina, 10 Calle, 2Da. Ave, S.E. Plaza Pell
Emergency Contact phone: 2550-9253
Email: gandonie@gmail.com

2. Hazard(s) identifications
No hazardous ingredients.

3. Composition/Information on Ingredients				
Name	CAS	EINECS	Exposure Limits	
	n/a	n/a	None.	Skin irritant. Skin sensitizer Eye irritant

4. First Aid Measures	
Eye Contact	Wash eyes with water; obtain medical advice if irritation persists.
Skin Contact	Not a primary irritant for normal skin.
Ingestion	n/a

5. Fire Fighting Measures	
Extinguishing Media:	Water, Carbon Dioxide, Dry Chemical Powder
Combustion Products:	Smoke, Carbon Dioxide, Carbon Monoxide
Exposure Hazards:	Irritant
Protective Equipment:	Standard
Special Fire Fighting Equipment:	Standard
Flash Point:	n/a
Unusual Fire Hazards:	None

6. Accidental Release Measures	
Personal Precautions:	Remove all sources of ignition. Ensure adequate ventilation. If necessary use respiratory protection. Protective clothing should be worn, i.e. safety glasses or goggles and gloves. Evacuate personnel to safe areas.
Clean up Methods:	Sweep up or vacuum spilled material and dispose of in accordance with local, state and federal requirements.

7. Handling and Storage	
Handling:	Use in a well-ventilated area. Keep away from heat and sources of ignition. No smoking, eating or drinking. Refer to section 8 for suitable protective equipment. Adopt best Manual Handling considerations when handling, carrying and dispensing.
Storage:	Keep containers tightly closed in a cool, well-ventilated area. Keep away from oxidizing agents, heat and open flame. Keep in properly labelled containers.



Claudio Innocenti
Member

8. Exposure Controls/Personal Protection
 No PPE Required

9. Physical and Chemical Properties

Appearance:	Typical
Odor:	Typical
Flash Point:	n/a
Specific Gravity:	n/a
Solubility in Water:	n/a

10. Stability & Reactivity

Stability:	Stable
Materials to avoid:	Avoid odor-absorbing items
Conditions to avoid:	Heat, sparks, open flames

11. Toxicological Information
 There is no toxicological data available on this product.

12. Ecological Information
 There is no ecological data available on this product.

13. Disposal Considerations
 Incineration or sanitary landfill in accordance with local, state and federal regulations.

14. Transport Information
 Not regulated as dangerous goods by USDOT, IATA or IMDG

15. Regulatory Information

All ingredients appear on TSCA inventory.

SARA 302 Hazards:	None
SARA 313 (TRI) Chemicals:	None

16. Other Information
 The information contained herein is, to the best of our knowledge, accurate. Since the use of this information and the conditions of handling and use are beyond our control, it is the user's obligation to determine conditions of safe use of this product.



INVERSIONES HANDAL FAJARDO, S. DE R. L.

BARRIO MEDINA, 10 CALLE, 2DA. AVE. S. E. PLAZA PELL
R.T.N. # 05019002069361 LOCAL NO.1 TELE. 2550-9253

Tariff # / Harmonization Code Statement

We ship to the United States:

Allspice (pimenta dioica), Harmonization code 0904208000

Sincerely,



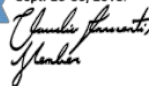
Signature

Sr. Marvin Handal
Gerente General

INVERSIONES
HANDAL FAJARDO
S. de R. L.



REVIEWED BY
CLAUDIO INNOCENTI, PCQI
REVIEWED ON OR ABOUT
Sept. 25-30, 2018.



INVERSIONES HANDAL FAJARDO, S. DE R. L.
BARRIO MEDINA, 10 CALLE, 2DA. AVE. S. E. PLAZA PELL
R.T.N. # 05019002069361 LOCAL NO.1 TELE. 2550-9253

GLUTEN STATEMENT

To whom it may concern

Re. Allspice- Pimenta Dioica

To the best of our knowledge, the items we sell do no contain Glutens.
We work with the natural plants, native to our region. The Plants are grown,
collected, dried, and processed using traditional and natural methods.



Marvin Handal
General Manager
INVERSIONES HANDAL FAJARDO,S DE RL.



REVIEWED BY
CLAUDIO INNOCENTI, PCQI.
REVIEWED ON OR ABOUT
Sept. 25-30, 2018.



INVERSIONES HANDAL FAJARDO, S. DE R. L.

BARRIO MEDINA, 10 CALLE, 2DA. AVE. S. E. PLAZA PELL
R.T.N. # 05019002069361 LOCAL NO.1 TELE. 2550-9253

Non GMO Statement

Item: Honduran Allspice (pimenta dioica L.)

We ship only allspice berries grown naturally that are harvested and dried traditionally in our mountains. To the best of our knowledge allspice does not contain genetically modified organisms.



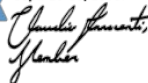
Signature

Sr. Marvin Handal
Gerente General

**INVERSIONES
HANDAL FAJARDO**
S. de R. L.



REVIEWED BY
CLAUDIO INNOCENTI, PCQI.
REVIEWED ON OR ABOUT
Sept. 25-30, 2018.



Member

INVERSIONES HANDAL FAJARDO, S. DE R. L.

BARRIO MEDINA, 10 CALLE, 2DA. AVE. S. E. PLAZA PELL
R.T.N. # 05019002069361 LOCAL NO. 1 TELE. 2550-9253

Nutritional Information Statement - Allspice

Proximate Composition of Allspice (100 g, Edible Portion)

Water	8.5 g	Phosphorus	113 mg
Food energy	263 kcal	Potassium	1044 mg
Protein	6.1 g	Sodium	77 mg
Fat	8.7 g	Zinc	1 mg
Total carbohydrate	72.1 g	Ascorbic acid	39.2 mg
Fiber	21.6 g	Thiamin	0.1 mg
Ash	4.7 g	Riboflavin	0.1 mg
Calcium	661 mg	Niacin	2.9 mg
Iron	7 mg	Vitamin A	540 IU
Magnesium	135 mg		

Sincerely,

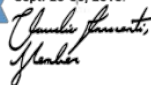

Signature

Sr. Marvin Handal
Gerente General

**INVERSIONES
HANDAL FAJARDO
S. de R. L.**



REVIEWED BY
CLAUDIO INNOCENTI, PCQI
REVIEWED ON OR ABOUT
Sept. 25-30, 2018.


Innocenti

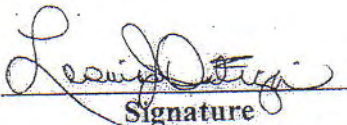
INVERSIONES HANDAL FAJARDO, S. DE R. L.

BARRIO MEDINA, 10 CALLE, 2DA. AVE. S. E. PLAZA PELL
R.T.N. # 05019002069361 LOCAL NO.1 TELE. 2550-9253

Allergen Statement

Item: Honduran Allspice (pimenta dioica L.)

We ship only allspice berries grown naturally that are harvested and dried traditionally in our mountains. To the best of our knowledge this item does not contain allergens.



Signature

Sr. Marvin Handal
Gerente General

INVERSIONES
HANDAL FAJARDO
S. de R. L.



REVIEWED BY
CLAUDIO INNOCENTI, PCQI.
REVIEWED ON OR ABOUT
Sept. 25-30, 2018.



Handwritten signature of Claudio Innocenti, PCQI Member.

INVERSIONES HANDAL FAJARDO, S. DE R.L.

BARRIO MEDINA, 10 CALLE, 2DA AVE. S.E PLAZA PELL

LOCAL #1, SAN PEDRO SULA

TELEFONO: (504) 2550-9253

email: hanfainversiones@hotmail.com

website: www.inversioneshandalfajardo.com

Product Specification

Product Name:	<i>Allspice.</i>
Latin Name:	<i>Pimenta Dioica L. (Family Myrtaceae).</i>
Form:	<i>Globular, round shape.</i>
Color:	<i>Dark reddish brown.</i>
Flavor:	<i>Tastes like a blend of nutmeg cinnamon, clove and peppercorn.</i>
Odor:	<i>Pleasant aroma similar to clove.</i>
Country of Origin:	<i>Honduras.</i>
Quality:	<i>ASTA Cleanliness Specification(Grade A).</i>

Chemical Information

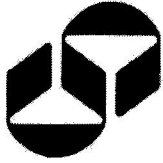
	Min	Max
Volatil Oil:	2.3	
Moisture Content:		12.5
Ash:		6.0
Acid - insoluble ash:		1.0

Packaging:	<i>Polypropylene bags 50 kgs. Weight.</i>
Storage Conditions:	<i>Between 65-75 °F with 60%-65% humidity.</i>
Duration of Storage:	<i>Provided that the recommended. storage conditions are complied with, allspice may be kept for up to 24 months.</i>



REVIEWED BY
CLAUDIO INNOCENTI, PCQI.
REVIEWED ON OR ABOUT
Sept. 25-30, 2016.

Claudio Innocenti
Inspector



Certified Laboratories, Inc.

Full Service Laboratory • Established 1926

Certificate of Analysis

A.A. SAYIA & COMPANY, INC.
ONE NEWARK STREET P.O. M9
HOBOKEN, NJ 07030
ATT: PETER SAYIA

REPORT #: 143645
PROJECT ID: NY07717-1908-002
REPORT DATE: 8/7/19
PRINT DATE: 8/7/19

LAB #: 460513

DATE RECEIVED: 8/5/19

PRODUCT: ALLSPICE - HONDURAN

PACKAGE: IN SEALED PACKAGE

SAMPLE ID: IHFN-01

ANALYTE

STEAM VOLATILE OIL

RESULT UNITS

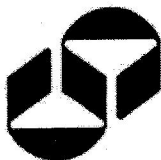
3.14 ml/100g

METHOD REFERENCE

ASTA METHOD 5.2 & 16.0

Hesham A. Elgaali
Hesham A Elgaali
Laboratory Director

END OF REPORT



Certified Laboratories, Inc.

Full Service Laboratory • Established 1926

Certificate of Analysis

A.A. SAYIA & COMPANY, INC.
ONE NEWARK STREET P.O. M9
HOBOKEN, NJ 07030
ATT: PETER SAYIA

REPORT #: 153333
PROJECT ID: NY07717-1908-006
REPORT DATE: 8/23/19
PRINT DATE: 8/23/19

LAB #: 501259

DATE RECEIVED: 8/20/19

PRODUCT: ALL SPICE HONDURAN
PACKAGE: IN SEALED PACKAGE
SAMPLE ID: SAMPLE # IHFN-01

<u>ANALYTE</u>	<u>RESULT</u> <u>UNITS</u>	<u>METHOD REFERENCE</u>
ASH	4.74 %	ASTA 3.0, ASTA 4.0
ACID INSOLUBLE ASH	0.14 %	ASTA 3.0, ASTA 4.0
MOISTURE BY DISTILLATION	9.20 %	ASTA 2.0

Hesham A. Elgaali
Hesham A Elgaali
Laboratory Director

END OF REPORT

Inversiones Handal Fajardo, S, DE R.L.

Barrio Medina, 10 Calle

2Da. Ave., S. E. Plaza Pell

San Pedro Sula, HONDURAS

Allergen Statement

7/1/21

We are a Honduran manufacturer and processor specializing in Allspice (Pimienta Dioica L.) that is grown in our region. The allspice that we sell grows naturally in the mountainous region near our factory. Our Allspice is not cultivated; it is propagated through managed forestry. We take all steps available to us to insure the purity of the product. Our cleaning is specific and methodical so that foreign matter as well as incidental allspice plant matter is removed from the whole allspice berries that we ship.

While we appreciate your questionnaire on allergens we have no means to test our product for the 65 allergens on your questionnaire. We do not think they are present in our product but we do not have the ability to test for the presence of un-seeable allergens.

Sincerely,

< name of exporter >



**ANNUAL FSVP
RECERTIFICATION
QUESTIONNAIRE**

for

**UNITED SAFETY AGENTS
FSVP COMPLIANCE
PROGRAM**





OVERVIEW of QUESTIONNAIRE

As required by Title 21 of the United States Code of Federal Regulations, part 1, subpart L, §1.505 and §1.506; all substantiating information and/or documentation for a supplier's food safety program must be maintained and updated over time. Please complete this Questionnaire to the best of your ability and return your completed copy to United Safety Agents. Once received, United Safety Agents will issue an updated and renewed Letter of Consent for your continued use during U.S. Customs entry.

CONTACT

If you have any questions or require additional information, please contact United Safety Agents LLC directly via Email: info@unitedsafetyagents.com, Phone: +1 (888) 551-7403, Fax: +1 (888) 557-2649, UnitedSafetyAgents.com, or by Mail: 715 W. Park Avenue, No. 222, Oakhurst, New Jersey 07755-9998, United States of America.

HELPFUL LINKS

United Safety Agents' Website	Website
Register of Entries Portal <i>(for FSVP Agency Only)</i>	Portal
Foreign Supplier Verification Program (FSVP)	Website
List of Food Safety Documents for FSVP	Document
FSVP Supplier Questionnaire	Document
Additional Useful Information & Links	Website

OTHER CONSIDERATIONS

This document may contain information which is privileged, confidential, and protected. Any disclosure, copying, distribution, or use of the contents of this message is prohibited. Document may contain Non-binding recommendations. United Safety Agents LLC provides FDA/FSVP compliance services to businesses and has no direct affiliation with the FDA.



FSVP CERTIFICATION QUESTIONNAIRE

Name of Company: Inversiones Handal Fajardo S de R.L.

Mailing Address: Postal mail # 3432 San Pedro Sula, Honduras

City: San Pedro Sula Province: Country: Honduras

Is factory/facility responsible for controlling Biological Hazards? Yes No

Is factory/facility responsible for controlling Chemical Hazards? Yes No

Is factory/facility responsible for controlling Physical Hazards? Yes No

If you answered yes to any, please provide the following information:

Factory Address: 2Ave. 10St. Medina, Plaza Pell

City: San Pedro Sula Province: Country: Honduras

Factory Phone: +504 2550 92 53 Factory E-mail Address: hanfainversiones@hotmail.com

FDA Registration No.: 10270253502 Name of QC/QA: Neptaly Lopez

To the best of your knowledge...

Within the past 400 days; has your facility's Food Safety Program been revised in any way? Yes No

If yes or unsure, please provide current Food Safety Program.

Within the past 400 days; has any change occurred to product's ingredients? Yes No

If yes or unsure, please provide current Ingredient List / Specifications.

Within the past 400 days; has your facility's HACCP Plan been revised in any way? Yes No

If yes or unsure, please provide current HACCP Plan.

Within the past 400 days; have your facility's Allergen Control Procedures been revised? Yes No

If yes or unsure, please provide current Allergen Control Procedures.

Within the past 400 days; has any change occurred to Product Labeling? Yes No

If yes or unsure, please provide a copy of product's labeling.

Continues onto next page

FSVP CERTIFICATION QUESTIONNAIRE

Continued: To the best of your knowledge...

Within the past 400 days; has your facility's Annual Onsite Audit Report expired or been updated? Yes No

If yes, please provide a current version.

Within the past 400 days; has your facility undergone a recall, for any reason? Yes No

If yes, please provide substantiating documents.

Within the past 400 days; has facility been recently inspected by the U.S. FDA? Yes No

Within the past 400 days; have any food items been stopped, held, or rejected by U.S. Customs? Yes No

Within the past 400 days; has U.S. FDA issued a Warning Letter to facility or product(s)? Yes No

Within the past 400 days; has any batch/lot tested positive for a biological or chemical hazard(s)? Yes No

Within the past 400 days; has your facility's conformance with FSVP changed in any way? Yes No

Are any products considered to be 'Ready To Eat' when leaving facility? Yes No

Would you like to share any additional information? Yes No

include any additional information that you would like to share below.

CERTIFICATION

By entering your name below, you certify that the information provided on and in connection with this form is true, accurate, and complete to the best of your knowledge. You understand that any false statements or deliberate omissions on this document – or any other document – that you provide to United Safety Agents may be grounds for disqualification from successful FSVP verification or, if discovered after FSVP approval takes place, could result in your product's FSVP approval status being revoked or terminated, and may result in your products or shipments being rejected from entry into the U.S.

Representative's Name: Marvin Handal

Title: General Manager

Date: 12/2/20

Transcription of Response Yes No

* you certify that representative's information was transcribed from USA's online form.

ALLSPICE

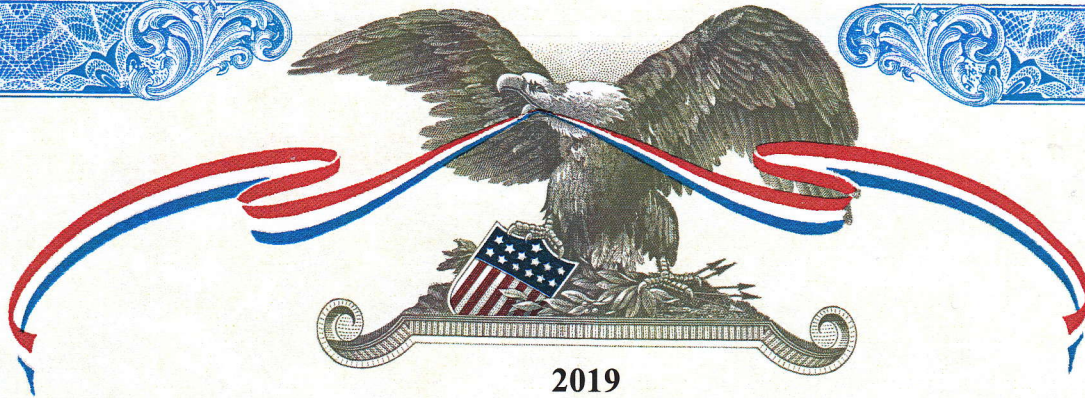
IHFN-01

P.O. 4501803678

NET WT: 50 KGS

PRODUCT OF

HONDURAS



CERTIFICATE OF REGISTRATION

This certifies that:

**Inversiones Handal Fajardo S. de R.L.
S.P.S. Medina 2ave 10st Plaza pell
San Pedro Sula, Cortes 3432
Honduras**

is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as currently effective on the date hereof by Registrar Corp:

U.S. FDA Registration No.: **10270253502**
U.S. Agent for FDA **Registrar Corp**
Communications: 144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

This certificate affirms that the above stated facility is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as effective by Registrar Corp as of the date hereof, and Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until December 31, 2019, unless such registration has been terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp ★
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

Russell K. Statman

Russell K. Statman
Executive Director
Registrar Corp
Dated: December 15, 2018

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Warning Letters

Learn about the types of warning letters on FDA's website. (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters)

- Matters described in FDA warning letters may have been subject to subsequent interaction between FDA and the letter recipient that may have changed the regulatory status of issues discussed in the letter.
- To obtain additional available information, contact FDA. Requests to FDA for agency records should be sent to: Food and Drug Administration Division of Freedom of Information (HFI-35), 5630 Fishers Lane, Rockville, MD 20857. Instructions for how to submit an FOI request can be found at How to Make a FOIA Request. (/how-make-foia-request)

Search

Inversiones Handal

Showing 0 to 0 of 0 entries (filtered from 3,206 total entries)

Filters



Issuing Office

Letter Issue Date

Letters with Response or Closeout

Posted Date **Year**

Show entries

Posted Date ▼	Letter Issue Date ▲	Company Name ▲	Issuing Office ▲	Subject ▲
No matching records found				

Showing 0 to 0 of 0 entries (filtered from 3,206 total entries)



(../index.htm)

Data Dashboard Home(../index.htm) Compliance Dashboards > (../cd/index.htm)

FSMA Data Search > (index.htm) How to Use the Dashboard(../howto.htm)

Glossary(../glossary.htm) API(../api/index.htm) Contact Us(../contact.htm)

Home(../index.htm) > FSMA Data(index.htm) > Firm/Supplier Evaluation Resources

Firm/Supplier Evaluation Resources

The FDA firm and supplier database available on this site includes data associated with inspections classification, inspections citations, compliance actions, recalls, and imports.

Search by Firm Name or FEI Number  Help

2000041477
No data found

Three FDA FSMA rules (Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals>); Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food>); and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-animal-food>)) require that importers and facilities perform certain risk-based activities to verify that their suppliers are meeting applicable U.S. food safety standards. Under these rules, you must evaluate, among other things, the applicable FDA food safety regulations and information relevant to the

supplier's compliance with those regulations, including whether the supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation.

Below is a list of publicly available resources that can be used to meet the requirement set out in these regulations as well as information on their use:

[Collapse All](#) | [Expand All](#)

- ▼ **Warning Letters**
- ▼ **Import Alerts**
- ▼ **Recalls**
- ▼ **Import Refusals**
- ▼ **Inspection Classifications**
- ▼ **Other Compliance Resources**

Contact

Questions and comments pertaining to the FDA Data Dashboard and source data may be directed by email to:

FDADashboard@fda.hhs.gov
 (mailto:FDADashboard@fda.hhs.gov)

[Dashboard Home](#)
 (./index.htm)

[Compliance Dashboards](#)
 (./cd/index.htm)

[Inspections](#)
 (./cd/inspections.htm)

[Compliance Actions](#)
 (./cd/complianceactions.htm)

[Recalls](#)
 (./cd/recalls.htm)

[Imports Summary](#)
 (./cd/impsummary.htm)

[FSMA Data Search](#)
 (index.htm)

[Firm/Supplier Evaluation Resources](#)
 (fser.htm)

[Approved VQIP Importers](#)
 (vqip.htm)

[TPP](#)

[Help](#)
[How to Use the Dashboard](#)
 (./howto.htm)

[Glossary](#)
 (./glossary.htm)

[API](#)
 (./api/index.htm)

[Contact Us](#)
 (./contact.htm)

[Import Refusals](#)
(../cd/imprefusals.htm)

[Participants](#)
(tpp.htm)

[Imports Entry](#)
(../cd/impentry.htm)

Language Assistance Available: [Español](#)

- (<https://www.fda.gov/about-fda/about-website/language-assistance-services#spanish>) | [繁體中文](#)
- (<https://www.fda.gov/about-fda/about-website/language-assistance-services#chinese>) | [Tiếng Việt](#)
- (<https://www.fda.gov/about-fda/about-website/language-assistance-services#vietnamese>) | [한국어](#)
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- (<https://www.fda.gov/about-fda/about-website/language-assistance-services#arabic>) | [Kreyòl Ayisyen](#)
- (<https://www.fda.gov/about-fda/about-website/language-assistance-services#creole>) | [Français](#)
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- (<https://www.fda.gov/about-fda/about-website/language-assistance-services#italian>) | [Deutsch](#)
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- (<https://www.fda.gov/about-fda/about-website/language-assistance-services#farsi>) | [English](#)
- (<https://www.fda.gov/about-fda/about-website/language-assistance-services#english>)

Accessibility (https://www.fda.gov/about-website/accessibility)	Careers (https://www.fda.gov/about-website/careers)	FDA Basics (https://www.fda.gov/transparency/fda-basics)	FOIA Information (https://www.fda.gov/information/freedom-information)	No FEAR Act (https://www.fda.gov/no-fear-act)	Nondiscrimination Notice (https://www.fda.gov/about-website/fda-nondiscrimination-notice)	Website Policies (https://www.fda.gov/about-website/policies)
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Search Results

FEI Number	Firm Name	Physical Address	Mailing Address	Note
2000041477	Inversiones Handal Fajardo	S.P.S. Medina 2ave 10st Plaza Pell, San Pedro Sula, Cortes, CT1100, HN	Barrio Medina, 10 Calle2 Da Ave, San Pedro Sula, Cortes, CT1100, HN	This name and address is being returned because the name or address of the firm entered has been updated. See the FAQ for additional information.

U.S. FOOD & DRUG ADMINISTRATION
FOREIGN SUPPLIER VERIFICATION PROGRAM

Recertification Questionnaire Submission

} Foreign Supplier
} **Inversiones Handal Fajardo S. de R.L.**
} Date: 1921-09-20

As required by 21 C.F.R., §1.506 (a); (a)(2); (b); (c); and elsewhere, all foreign supplier verification procedures and activities are to be conducted and/or re-conducted at a frequency appropriate to the relevant procedure/activity and the corresponding hazard profile for the relevant food. Based upon United Safety Agents' (USA) assessment of Inversiones Handal Fajardo S. de R.L.'s operation, an annual recertification request for updated information and food safety documents has been sent out. The following pages contain the specifics of USA's request, along with Inversiones Handal Fajardo S. de R.L.'s corresponding responses to each inquiry. *Note: Most questions can be properly interpreted, if preceded by "Within the past 400 days;"*

START

01) Has Inversiones Handal Fajardo S. de R.L.'s Food Safety Plan or Program been revised in any way?

Response: **No**

02) Has Inversiones Handal Fajardo S. de R.L.'s HACCP Plan been revised in any way?

Response: **No**

03) Has any change occurred to Inversiones Handal Fajardo S. de R.L.'s product Ingredients?

Response: **No**

04) Has Inversiones Handal Fajardo S. de R.L.'s Allergen Control Procedure been revised in any way?

Response: **No**

05) Has any change occurred to Inversiones Handal Fajardo S. de R.L.'s product Labeling?

Response: **No**

06) Has Inversiones Handal Fajardo S. de R.L.'s Onsite Audit report expired or been updated?

Response: **No**

U.S. FOOD & DRUG ADMINISTRATION
FOREIGN SUPPLIER VERIFICATION PROGRAM

Recertification Questionnaire Submission

} Foreign Supplier
} **Inversiones Handal Fajardo S. de R.L.**
} Date: 1921-09-20

07) Has Inversiones Handal Fajardo S. de R.L. undergone a recall, for any reason?

Response: **No**

08) Has Inversiones Handal Fajardo S. de R.L. been inspected by the United States Food & Drug Administration?

Response: **No**

09) Have any food items been stopped, held, or rejected by U.S. Customs, for any reason?

Response: **No**

10) Has the U.S. FDA issued Inversiones Handal Fajardo S. de R.L. a Warning Letter in relation to its facility or product(s)?

Response: **No**

11) Does Inversiones Handal Fajardo S. de R.L. perform laboratory analysis on its product(s)?

Response: **Yes**

12) Has any batch or lot tested positive for any biological or chemical hazard?

Response: **No**

13) Has Inversiones Handal Fajardo S. de R.L.'s conformance with FSVP, or its appendant regulations, changed in any way?

Response: **No**

14) Are Inversiones Handal Fajardo S. de R.L.'s products considered to be "Ready To Eat" when leaving its facility?

Response: **Yes**

14a) What hazard(s) remain uncontrolled?

Response:

15) Would you like to share any additional information?

Response:

15a) Additional information:

U.S. FOOD & DRUG ADMINISTRATION
FOREIGN SUPPLIER VERIFICATION PROGRAM

—
Recertification Questionnaire Submission

} Foreign Supplier
} **Inversiones Handal Fajardo S. de R.L.**
} Date: 1921-09-20

Response:

C E R T I F I C A T I O N: By entering your name below, you certify that the information provided on and in connection with this form is true, accurate, and complete to the best of your knowledge. You understand that any false statements or deliberate omissions on this document – or any other document – that you provide to United Safety Agents may be grounds for disqualification from successful FSVP verification or, if discovered after FSVP approval takes place, could result in your product's FSVP approval status being revoked or terminated, and may result in your products or shipments being rejected from entry into the United States.

Certified by: **Marvin Handal**

Date of Certification: **1921-09-20**

Email Address of Respondent: **hanfainversiones@hotmail.com**

—
END



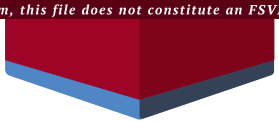
SUPPLIER QUESTIONNAIRE

for

U.S. IMPORT ENTRY
UNDER FSVP



- Confidential -



OVERVIEW of REGULATIONS

The Foreign Supplier Verification Program (FSVP) was published by the FDA on November 27, 2015. FSVP is fundamentally concerned with food safety. As a validly designated and qualified United States (U.S.) representative, United Safety Agents LLC's (USA) FDA-mandated goal is to verify that a product's innate physical, chemical and biological hazards are being controlled prior to public consumption, and in a manner that provides at least the same level of public health protection as the FDA's domestic standards (*Preventive Controls Rule, Produce Safety Rule, etc.*). To accomplish this goal, insight into each product's production process and control methods will be required.

INSTRUCTIONS

We respectfully request that every entity/facility that controls any food safety hazard complete this Questionnaire. All sections are required, unless explicitly noted otherwise. **Complete via computer, do not print.**

Upon completion: Please return this questionnaire and accompanying documents via:

Method One: e-mail completed questionnaire to info@unitedsafetyagents.com

Method Two: upload completed questionnaire to USA's [ShareFile](#)

CONFIDENTIALITY

All information shared will remain strictly privileged & confidential and will ONLY be used during FSVP certification activities. An accurate and truthful response is required to successfully complete your company's FSVP certification. This document contains information which is privileged, confidential, and protected. Any disclosure, copying, distribution, or use of the contents of this message is prohibited. Document may contain Non-binding recommendations. United Safety Agents provides FSVP compliance services to businesses and has no direct affiliation with the FDA.

CONTACT

If you have any questions or require additional information, please contact United Safety Agents LLC directly via Email: info@unitedsafetyagents.com; Phone: +1 (888) 551-7403; Fax: +1 (888) 557-2649; UnitedSafetyAgents.com, or by Mail: 715 West Park Avenue, No. 222, Oakhurst, New Jersey 07755, United States of America.



FDA - IDENTIFIED BIOLOGICAL HAZARDS

FDA-identified Biological Hazards associated with the product(s) that your company supplies.

- | | | | |
|---|--|--|--|
| <input type="checkbox"/> Bacillus cereus | <input type="checkbox"/> Clostridium botulinum | <input type="checkbox"/> C. perfringens | <input type="checkbox"/> Brucella spp. |
| <input type="checkbox"/> Campylobacter spp. | <input type="checkbox"/> Pathogenic E. coli | <input type="checkbox"/> Salmonella spp. | <input type="checkbox"/> S. aureus |
| <input type="checkbox"/> L. monocytogenes | <input type="checkbox"/> Trichinella spiralis | <input type="checkbox"/> Giardia lamblia | <input type="checkbox"/> Shigella spp. |

Resources



Appendix 1



Description of Hazard



Bad Bug Book

CRITICAL CONTROLS for BIOLOGICAL HAZARDS

Please select and describe the method by which Biological Hazard(s) are controlled. Please be as detailed as possible. Include time/temperature, chemical names, or any other information.

- Heat
- Chemical
- CGMPs
- Testing
- Other

DESCRIPTION of CRITICAL CONTROLS

Please list and fully describe each / every Supply Chain, Preventative, or Critical Control used to manage each of the above cited FDA-identified hazard(s):

START:

We take samples of the product and send to the laboratory to the following analyzes:

- Pathogenic E. coli
- Salmonella spp

FREQUENCY of VALIDATION

At what frequency are the above control(s) validated? (ex: per shift, month, annually)

START:

All the lots

U. S. FDA HAZARD PROFILE

Category Name: Herbs and Spices.

Category Number: 4 / 5 / 6.

Storage Type: Shelf-Stable

Resource

U.S. FDA Product Category Hazard Profiles – Appendix 1

FDA - IDENTIFIED CHEMICAL HAZARDS

FDA-identified Chemical Hazards associated with the product(s) that your company supplies.

- Drug residues Heavy metals Industrial chemicals Pesticides
 Mycotoxins/Toxins Radiological Unapproved colors & additives Other

Resources



Appendix 1



Description of Hazard



Bad Bug Book

CRITICAL CONTROLS for CHEMICAL HAZARDS

Select and describe the method(s) by which Chemical Hazard(s) are controlled. Please be as detailed as possible.

- CGMPs
 Testing
 Other

DESCRIPTION of CRITICAL CONTROLS

Please list and fully describe each / every Supply Chain, Preventative, or Critical Control used to manage each of the above cited FDA-identified hazard(s):

START:
We sent the batch samples to the laboratory for the following analyzes:
-Mycotoxins
-Pesticides

FREQUENCY of VALIDATION

At what frequency are the above control(s) validated? (ex: per shift, month, annually)

START:
All the lots.

U. S. FDA HAZARD PROFILE

Category Name: Herbs and Spices.
Category Number: 4 / 5 / 6.
Storage Type: Shelf-Stable

Resource

U.S. FDA Product Category Hazard Profiles – Appendix 1

FDA - IDENTIFIED ENVIRONMENTAL / PROCESS HAZARDS

FDA-identified Environmental Hazards associated with the product(s) that your company supplies.

- Recontamination with environmental pathogens.
- Bacterial growth and/or toxin formation due to lack of time / temperature control.
- Bacterial growth and/or toxin formation due to reduced oxygen packaging.
- Bacterial pathogen survival of a lethal treatment.
- Recontamination due to lack of container integrity.
- Bacterial growth and/or toxin formation due to poor formulation control.

Resources  Appendix 1  Description of Hazard  Bad Bug Book

CRITICAL CONTROLS for ENVIRONMENTAL HAZARDS

Select and describe the method(s) by which Environmental Hazard(s) are controlled. Be as detailed as possible.

- Heat
- Chemical
- CGMPs
- Testing
- Other

DESCRIPTION of CRITICAL CONTROLS	
	<p>Please list and fully describe each / every Supply Chain, Preventative, or Critical Control used to manage each of the above cited FDA-identified hazard(s):</p> <p>START:</p>

FREQUENCY of VALIDATION	
	<p>At what frequency are the above control(s) validated? (ex: per shift, month, annually)</p> <p>START:</p>

U. S. FDA HAZARD PROFILE	
	<p>Category Name: Herbs and Spices. Category Number: 4 / 5 / 6. Storage Type: Shelf-Stable</p>

Resource  U.S. FDA Product Category Hazard Profiles – Appendix 1

FDA - IDENTIFIED PHYSICAL HAZARDS

FDA-identified Physical Hazards associated with the product(s) that your company supplies.

- | | | | |
|---|--------------------------------|--|-----------------------------------|
| <input checked="" type="checkbox"/> Metal | <input type="checkbox"/> Glass | <input type="checkbox"/> Extraneous Matter | <input type="checkbox"/> Plastics |
| <input type="checkbox"/> Stones | <input type="checkbox"/> Wood | <input type="checkbox"/> Natural Component of Food | <input type="checkbox"/> Other |

Resources



Appendix 1



Description of Hazard



Bad Bug Book

CRITICAL CONTROLS for PHYSICAL HAZARDS

Select and describe the method(s) by which Physical Hazard(s) are controlled. Please be as detailed as possible.

- CGMPs
- Testing
- Raw Material Inspection
- Filter
- Screen
- Metal Detector
see below
- Magnet
- X-Ray
- Radar
- Other

DESCRIPTION of CRITICAL CONTROLS

Please list and fully describe each / every Supply Chain, Preventative, or Critical Control used to manage each of the above cited FDA-identified hazard(s):

START:
We use several steps in the product cleaning process:
-Quality product inspection
-Blower
-Sieve: Food grade stainless steel 3.1mm mesh
-Magnetic greeds: Neodymium magnets, Gousse 8,000
-Metal detector: Sensitivity (mm) FE= 1.8 NFE= 2.0

FREQUENCY of VALIDATION

At what frequency are the above control(s) validated? (ex: per shift, month, annually)

START:
All the product pass the process

U. S. FDA HAZARD PROFILE

Category Name: Herbs and Spices.
Category Number: 4 / 5 / 6.
Storage Type: Shelf-Stable

Metal detection standards

Ferrous: <u>1.8</u> mm
Non-Ferrous: <u>2.0</u> mm
Stainless Steel: _____ mm

Resource

U.S. FDA

Hazard Profile – Appendix 1

ALLERGEN & CROSS-CONTAMINATION CONTROLS

Component or Ingredient	Present in product?	Present on same equipment?	Present in same facility?
Peanuts	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Tree Nuts	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Milk or Milk Derivatives	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Egg or Egg Products	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Fish	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Shellfish	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Soy	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Gluten	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Wheat	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Sesame	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Celery	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Mustard	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Sulfates	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Monosodium Glutamate	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Colorings	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Aflatoxins	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
ALL ALLERGENS	<input checked="" type="checkbox"/> Absent	<input checked="" type="checkbox"/> Absent	<input checked="" type="checkbox"/> Absent

DESCRIPTION of ALLERGENIC CONTROLS

Our facility is exclusive for allspice, there is no entry of another product.

ONSITE AUDITING INFORMATION

Does the manufacturing/processing site have a recognized GFSI certification (BRC, SQF, Etc.)? Yes No

If Yes; Please provide a copy of the **full audit report** (written in English).

What standard is the GFSI certification? _____

If No; 1. Does the site have a documented quality manual? Yes No

2. Does the site undergo internal hygiene audits? Yes No

3. Does the site undergo quality system audits? Yes No

4. Does the site undergo process audits? Yes No

CLEANING INFORMATION

Does the site have documented hygiene procedures in place? Yes No

Does the site have a designated hygiene team? Yes No

Are all cleaning staff formally trained? Yes No

Do the cleaning schedules include: Chemicals used? Yes No

Concentration levels? Yes No

Dilution method? Yes No

Please list the chemical type(s) used on all food contact lines and surfaces:

STAFF HYGIENE INFORMATION

Have all staff undergone formal food hygiene training? Yes No

In-house hygiene training? Yes No

Accredited hygiene training? Yes No

Training level certification obtained: _____

Are staff issued protective clothing? Yes No

Are operatives required to cover head/facial hair within the processing/manufacturing area? Yes No

Are adequate toilet and hand washing facilities provided? Yes No

Are hand washing/swabbing validation checks carried out? Yes No

What is the total number of staff employed on site? _____

PEST CONTROL

Is a pest control contractor employed? Yes No

If yes, please provide: Name of contractor used: Fumigadora Enamorado

Number of yearly visits: 12

If no, by what means is pest prevention carried out? _____

HACCP & TACCP & VACCP

Does a fully documented and audited HACCP system exist for the site? Yes No

Has a hazard analysis study been completed for each site operation? Yes No

Does the business have a trained & certified in-house HACCP team? Yes No

If yes, please provide copies of current & relevant HACCP training certificates.

Does the business outsource the HACCP management to a certificated consultant? Yes No

If yes, please provide copies of current & relevant HACCP training certificates.

Are records maintained for all CCPs? Yes No

Does the HACCP system include the following: Sieving of ingredients? Yes No

Sieving of finished products? Yes No

Glass & hard plastic breakage procedure? Yes No

Metal detection of final product? Yes No

Magnets within the mixing & filling stages? Yes No

Do you use blue metal detectable plasters in the manufacturing/processing areas? Yes No

Please detail any other prevention systems used on-site: _____

Has a full threat assessment of your supply chain been conducted & tested? Yes No

Please provide details: _____

Has a full product vulnerability assessment within the supply chain been conducted & tested? Yes No

Please provide details: _____

TRACEABILITY

Does full traceability exist for all products supplied to your customer base? Yes No

If yes, please give details of traceability codes on the final packaging: All the batches that enter our facility

RAW MATERIAL

Are materials used by your company sourced from approved suppliers? Yes No

Are certificates of conformance/analysis received for all raw ingredients? Yes No

Are raw materials positively released before use? Yes No

Please describe your supplier approval system:

the farmers bring their product to our facility, if the product meets the quality requirements the product is accepted, and the farmers enter in our list of suppliers.

FINISHED / PACKED PRODUCT

Are finished / packed products positively released? Yes No

Are reference samples from finished / packed products retained? Yes No

Are finished products submitted to an 17025:2005 accredited laboratory for validation purposes? Yes No

If yes, please give details of the testing routines conducted:

We do to the allspice the analyzes requested by the client, example:

-Asta especifications -Total ash
-Volatil oil -Ash insoluble
-Moisture

CUSTOMER COMPLAINTS

Does a formal customer complaint procedure exist? Yes No

Please describe your customer complaint procedure.

-File a written complaint
-is resolved as requested

RECALL / IMPORT ALERT / FOOD SAFETY ISSUE

Has your company ever experienced a recall or other food safety related issue of any kind? Yes No

If yes, please describe fully.

CERTIFICATION

I certify that the information I provided on and in connection with this form is true, accurate and complete. I also understand that any false statements or deliberate omissions on this document or any other document I file with United Safety Agents, LLC may be grounds for disqualification from successful Foreign Supplier Verification Program (FSVP) approval or, if discovered after FSVP approval takes place, could result in my company's FSVP approval status being revoked or terminated, and may result in my shipments being rejected from entry into the United States. I confirm that all products that my company trades are in compliance with the Food Safety Modernization Act and all other U.S. & FDA Food Safety legislation.

CONFIRMATION - REQUIRED

Representative's Name: Marvin Handal

Title: General Manager

Today's Date: _____

