



# COMPLIANCE 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 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 this questionnaire and accompanying documents via:

**Method One:** e-mail completed questionnaire to [info@unitedsafetyagents.com](mailto: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](mailto:info@unitedsafetyagents.com); Phone: +1 (888) 551-7403; Fax: +1 (888) 557-2649; [UnitedSafetyAgents.com](http://UnitedSafetyAgents.com), or by Mail: 715 West Park Avenue, No. 222, Oakhurst, New Jersey 07755, United States of America.



## GENERAL INFORMATION

Company Name: \_\_\_\_\_ Today's Date: \_\_\_\_\_  
Factory Address: \_\_\_\_\_  
City: \_\_\_\_\_ Province: \_\_\_\_\_ Country: \_\_\_\_\_  
Office Address: \_\_\_\_\_  
City: \_\_\_\_\_ Province: \_\_\_\_\_ Country: \_\_\_\_\_  
FDA Registration No.: \_\_\_\_\_ DUNS No.: \_\_\_\_\_  
FDA Establishment Id.: \_\_\_\_\_ Phone No.: \_\_\_\_\_  
QC/QA's Name: \_\_\_\_\_ E-mail: \_\_\_\_\_

## SUPPLIER CLASS

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

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

## RESPONSIBILITIES for HAZARD CONTROLS

*Please select the appropriate response for each hazard type that your facility/operation controls.*

Is your factory/facility responsible for controlling Biological Hazards?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is your factory/facility responsible for controlling Chemical Hazards?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is your factory/facility responsible for controlling Physical Hazards?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is/Are product(s) in Ready-to-Eat form when exiting your factory/facility?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

## PRODUCTS SUPPLIED

*Please list the name (and variation) of each product that your facility/operation supplies.*

No. 01, Product Name: _____	Product No.: _____
No. 02, Product Name: _____	Product No.: _____
No. 03, Product Name: _____	Product No.: _____
No. 04, Product Name: _____	Product No.: _____
No. 05, Product Name: _____	Product No.: _____
No. 06, Product Name: _____	Product No.: _____

Resources

FDA Product Codes and Product Code Builder

## 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

### FREQUENCY *of* CONTROL VALIDATION

## FDA - IDENTIFIED CHEMICAL HAZARDS

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

- |  |                                       |  |                                     |
|--|---------------------------------------|--|-------------------------------------|
| <input type="checkbox"/> Drug residues     | <input type="checkbox"/> Heavy metals | <input type="checkbox"/> Industrial chemicals          | <input type="checkbox"/> Pesticides |
| <input type="checkbox"/> Mycotoxins/Toxins | <input type="checkbox"/> Radiological | <input type="checkbox"/> Unapproved colors & additives | <input type="checkbox"/> 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

### FREQUENCY *of* CONTROL VALIDATION

## FDA-IDENTIFIED ENVIRONMENTAL/PROCESS HAZARDS

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

- |   |   |
|---|---|
| <input type="checkbox"/> Recontamination with environmental pathogens.                                      | <input type="checkbox"/> Bacterial pathogen survival of a lethal treatment.                       |
| <input type="checkbox"/> Bacterial growth and/or toxin formation due to lack of time / temperature control. | <input type="checkbox"/> Recontamination due to lack of container integrity.                      |
| <input type="checkbox"/> Bacterial growth and/or toxin formation due to reduced oxygen packaging.           | <input type="checkbox"/> 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

### FREQUENCY of CONTROL VALIDATION

## FDA - IDENTIFIED PHYSICAL HAZARDS

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

- |                                 |                                |  |                                   |
|---------------------------------|--------------------------------|--|-----------------------------------|
| <input 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

### 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?
<b>Peanuts</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Tree Nuts</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Milk or Milk Derivatives</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Egg or Egg Products</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Fish</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Shellfish</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Soy</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Gluten</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Wheat</b>	<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
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
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
<b>ALL ALLERGENS</b>	<input type="checkbox"/> Absent	<input type="checkbox"/> Absent	<input type="checkbox"/> Absent

## DESCRIPTION of CONTROLS



## 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: \_\_\_\_\_

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: ☐ Yes ☐ No

Sieving of ingredients?

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 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:

## 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.

## 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.



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**CONFIRM CERTIFICATION** - Required**Representative's Name:** \_\_\_\_\_**Title:** \_\_\_\_\_**Today's Date:** \_\_\_\_\_