



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.



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 _____ |

RESPONSIBILIE 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? Yes No
- Is your factory/facility responsible for controlling Chemical Hazards? Yes No
- Is your factory/facility responsible for controlling Physical Hazards? Yes No
- Is/Are product(s) in Ready-to-Eat form when exiting your factory/facility? Yes No

PRODUCTS SUPPLIED

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

01) Product Name: _____ Product Code (*optional*): _____
02) Product Name: _____ Product Code (*optional*): _____
03) Product Name: _____ Product Code (*optional*): _____
04) Product Name: _____ Product Code (*optional*): _____
05) Product Name: _____ Product Code (*optional*): _____
06) Product Name: _____ Product Code (*optional*): _____

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 VALIDATION

U.S. FDA HAZARD PROFILE

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

FREQUENCY of VALIDATION

U.S. FDA HAZARD PROFILE

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 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.

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 VALIDATION

U.S. FDA HAZARD PROFILE

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 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 VALIDATION

U.S. FDA HAZARD PROFILE

Metal Detection Standards

Ferrous: _____ mm
 Non-Ferrous: _____ 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 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
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
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
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
ALL ALLERGENS	<input type="checkbox"/> Absent	<input type="checkbox"/> Absent	<input type="checkbox"/> Absent

DESCRIPTION of ALLERGENIC 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: Yes No

Chemicals used?

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 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.

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

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 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.

C O N F I R M A T I O N - R E Q U I R E D

Representative's Name: _____

Title: _____

Today's Date: _____