



UNITED SAFETY AGENTS
F S V P
COMPLIANCE PLAN

ECCO UN POCO LLC

Name of FSVP Importer

CASCINA FONTANE SOC. AGR. SEMPLICE

Name of Foreign Supplier

HAZELNUT PASTE | FOR COMMERCIAL USE

Name of Product

JULY 21, 2019 / JULY 08, 2021

Date of Initial Verification / Reverification

JULY 09, 2021

Date of FSVP Plan Expiration

VERIFICATION COMPLETE | APPROVED FOR IMPORT* | PER-BATCH COAS REQUIRED

Status of Review

NUMBER 02

Version



– Confidential –



TABLE of CONTENTS

* * *

I. Overview of FSVP Plan	Pg. 03
<i>Instructions for Client, Definitions, and Confidentiality & Term</i>	
II. Foreign Supplier Verification Procedures	Pg. 04 to 06
III. Frequency of Verification Procedures	Pg. 06
IV. Use of Approved Suppliers Only	
V. Corrective Actions	
VI. Identification of FSVP Importer	
VII. Code of Federal Regulations (C.F.R.) Assessment	Pg. 07
VIII. 21 C.F.R. §1.500-14 Assessment	Pg. 08
IX. Attestation of Client's Review & Assessment	Pg. 09
X. Entity Information & Executive Summary of Review	Pg. 10
<i>FSVP Importer, foreign Supplier, FSVP Qualified Individual(s)</i> <i>&/or FSVP Agent(s), and Summary of Assessment.</i>	
XI. FSVP Documentation Checklist	Pg. 11
<i>Hazard Analysis, On-site Audit, Sampling or Testing Results</i> <i>Other Food Safety Records, and Product Labeling.</i>	
XII. Ongoing Document Requirements	Pg. 12
XIII. FDA Compliance Actions & Regulatory History	Pg. 13
XIV. Log of Revisions / Version Numbers	Pg. 14
XV. Analysis of Biological Hazard(s)	Pg. 15
XVI. Analysis of Chemical Hazard(s)	Pg. 16
XVII. Analysis of Allergenic Hazard(s)	Pg. 17
XVIII. Analysis of Environmental & Process Hazard(s)	Pg. 18
XIX. Analysis of Physical Hazard(s)	Pg. 19
XX. Assessment of Foreign Supplier	Pg. 20 to 21
<i>Supplier Procedures, Processes & Practices, Performance-</i> <i>History, and Approval or Denial Notes.</i>	
XXI. General Food Safety Information & Review	Pg. 22 to 23
XXII. Addendum	Pg. 24 to 26
XXIII. FSVP Agent's Certifications & Qualifying Documents	Pg. 27 to 35
XXIV. Foreign Supplier's Documentation	Pg. 36 ↪

OVERVIEW of FSVP PLAN

Title 21 of the Code of Federal Regulations requires that “. . . for each food you import; you must develop, maintain, and follow an FSVP [Foreign Supplier Verification Program] that provides adequate assurances that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the Federal Food, Drug, and Cosmetic Act. . .” for each product (and each foreign supplier of each product) that our client imports, United Safety Agents (USA) has been engaged to undertake and successfully complete all requisite actions on our client’s behalf; to analyze, verify, build and maintain this FSVP plan, that our client will now use to keep in compliance with FSVP regulations.

INSTRUCTIONS

Please review this FSVP plan in its entirety and sign where indicated. 21 C.F.R., §1.510 requires that this FSVP plan be kept on file for a minimum of two years after its use is discontinued. All records must be legible and stored to prevent deterioration or loss. If requested in writing by FDA, you must send records to the Agency electronically, or through another means that delivers the records promptly. Off-site storage of records, including records maintained by other entities in accordance with §1.504, §1.505, or §1.506, is permitted if such records can be retrieved and provided on-site within 24 hours of FDA’s request for review. Electronic records are considered to be on-site if they are accessible from an on-site location. Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter. **Please contact United Safety Agents immediately to report a change in a foreign supplier’s process or status**, in the case of an FDA inspection, or with any questions that you may have by email: info@unitedsafetyagents.com, by fax: +1 (888) 557-2649, or by telephone: +1 (888) 551-7403.

TERMS & DEFINITIONS

FSVP Importer (Importer): The importer, is the U.S. owner or consignee of an article of food that is being offered for import into the United States. **U.S. owner or consignee** means the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

Foreign Supplier (Supplier): The foreign supplier or supplier is the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States.

Qualified Individual (QI): Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under this subpart.

Verified &/or Approved: Verified & approved means only that actions were taken to fulfill regulatory obligations. It does NOT mean that the subject product of this FSVP plan is ready for consumption in its current state.

RULES of USE

This document is considered privileged, proprietary, and confidential. It may not be reproduced in whole, or part, nor may it be shared with any third party – including a customer – without the prior written consent of United Safety Agents. All FSVP plans and are bound under the terms of the Agreement which has been made between your company and United Safety Agents. Please see <https://www.unitedsafetyagents.com/rulesofuse> for more information.

FOREIGN SUPPLIER VERIFICATION PROCEDURES

21 C.F.R., §1.506 (a), (a)(2), (b), and (c) require that written procedures are established and followed to ensure that food is imported from approved suppliers only and that these procedures provide adequate assurance that the hazards requiring a control in the imported food have been significantly minimized or prevented. 21 C.F.R., §1.506 (d) requires that “. . . Except as provided in paragraphs (d)(2) and (3) of this section, before importing a food from a foreign supplier, [an FSVP Importer] must determine and document which verification activity or activities listed in paragraphs (d)(1)(ii)(A) through (D) of this section, as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the food [an FSVP Importer] obtain[s] from the foreign supplier is produced in accordance with paragraph (c) of this section. Verification activities must address the entity or entities that are significantly minimizing or preventing the hazards or verifying that the hazards have been significantly minimized or prevented (e.g., when an entity other than the grower of produce subject to part 112 of this chapter harvests or packs the produce and significantly minimizes or prevents the hazard or verifies that the hazard has been significantly minimized or prevented, or when the foreign supplier's raw material supplier significantly minimizes or prevents a hazard). The determination of appropriate supplier verification activities must be based on the evaluation of the food and foreign supplier conducted under §1.505.” As an FSVP Agent or Qualified Individual, USA's FDA-mandated goal is to verify that a product's innate physical, chemical and biological hazards are being controlled in a manner that is at least equivalent to the FDA's domestic standards. In order to accomplish this goal, documentation of a foreign supplier's processes, procedures and control methods will be required. Understanding that all foods may not share identical hazards - their control(s) also not being identical - USA utilizes a variety of foreign supplier verification activities to verify that a food's hazards have been significantly minimized or prevented. USA's determination of appropriate supplier verification activities is based on an evaluation of a specific food, its relevant hazards, and its corresponding foreign supplier. The following activities may be used to satisfy the requirements of 21 C.F.R., §1.506 (a), (a)(2), (b), (c), and (d):



A foreign supplier's Hazard Analysis and Critical Control Point (*HACCP*) plan may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's HACCP plan will be included within this FSVP plan.



An onsite audit of a foreign supplier's facility may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's onsite audit report will be included within this FSVP plan.



Sampling and testing of a food may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's reviewed sampling and testing results will be included within this FSVP plan.



A foreign supplier's relevant food safety record(s) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's relevant food safety record(s) will be included within this FSVP plan.

Continued onto next page.

FOREIGN SUPPLIER VERIFICATION PROCEDURES

Continued from previous page.



Certifying documents for a foreign supplier's Qualified Individual(s) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the certifying documents for a foreign supplier's Qualified Individual(s) will be included within this FSVP plan.



A food's nutritional label(ing) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the food's nutritional label(ing) will be included within this FSVP plan.



Completion of the FSVP Importer's Supplier Assessment Questionnaire and/or the FSVP Importer's Allergen and Intolerance Questionnaire may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the completed Questionnaire(s) will be included within this FSVP plan.



Documentation that a foreign supplier is in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and that the food is within the scope of that official recognition or equivalency determination, and that the foreign supplier of the food is in good compliance standing with the food safety authority of the country in which the foreign supplier is located may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of all substantiating documents will be included within this FSVP plan.



Documentation that a foreign supplier meets the definition of a qualified facility (*as defined by §117.3 or §507.3*) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of all substantiating documents will be included within this FSVP plan.



The FSVP Importer may rely upon performance of activities by other entities. If the FSVP Importer relies upon supplier verification activities conducted by another entity, the FSVP Importer will review and assess the results of these activities. Notation and documentation of the FSVP Importer's review and assessment will be recorded in this FSVP plan, including documenting that the determination of appropriate verification activities was made by a Qualified Individual.



When the FSVP Importer determines that a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the FSVP Importer will require a copy of the foreign supplier's annual on-site audit results. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's annual on-site audit results will be included within this FSVP plan. After initial verification, the FSVP Importer will require that the foreign supplier provide copies of their annual on-site results at least annually thereafter.

Continued onto next page.

FOREIGN SUPPLIER VERIFICATION PROCEDURES

Continued from previous page.



It may be required that the FSVP Importer conduct or obtain documentation of other (not previously mentioned) appropriate supplier verification activity(s) based on the foreign supplier's performance and the risk associated with the food. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the supplier verification activity(s) will be included within this FSVP plan.

FREQUENCY of VERIFICATION PROCEDURES

All above noted foreign supplier verification procedures and activities will be conducted and/or re-conducted at a frequency appropriate to the relevant procedure/activity and the corresponding hazard profile for the relevant food. Please refer to document-specific notes found on pg. 11, Ongoing Document Requirements found on pg. 12, Additional Recommendations found on pg. 21, and Verification Timeline found on pg. 23 for information about the frequency of verification procedures.

USE of APPROVED SUPPLIERS ONLY

Food and/or food-related products should only be imported from foreign suppliers that have been verified to the standards of FSVP. Prior to importation, all steps necessary to successfully verify that a foreign supplier's food safety processes and procedures meet the requirements of FSVP (*and other applicable regulations*), must be undertaken. Once complete, the product specific FSVP plan - created by United Safety Agents - will denote a supplier's status on the Title Page of each plan. Importation may occur if the following three parameters are met: 1) the FSVP plan's status does not read "Denied" or other wording denoting that product is not currently approved for import; 2) the date of importation will fall within one calendar year (*365 days*) from the plan's noted "Review End" date, and 3) there are no outstanding issues or changes in the supplier's processes and/or procedures since the noted "Review End" date.

CORRECTIVE ACTIONS

The FSVP Importer will take prompt corrective actions if it determines that a foreign supplier does not produce food consistent with the written assurance, and in compliance with applicable processes and procedures that provide same level of protection as FDA requirements. If the FSVP Importer determines by means other than verification activities that a foreign supplier does not produce food in compliance with applicable processes and procedures that provide the same level of protection as FDA requirements, it will conduct an investigation to determine whether the FSVP should be modified accordingly. Such corrective actions are dependent upon the specific circumstances of the deviation but could include: the complete discontinued use of the foreign supplier, or the discontinued use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed.

IDENTIFICATION of FSVP IMPORTER

The FSVP Importer will ensure that, for each line entry, the following information is provided to U.S. Customs and Border Protection: 01) FSVP Importer's Business Name; 02) FSVP Importer's Electronic Mail Address; and 03) The FSVP Importer's FDA acceptable UFI (*Unique Facility Identifier*) such as a DUNS number.

Supplier: Cascina Fontane Soc. Agr. Semplice

Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC)

Review Start: June 19, 2021 Review End: July 08, 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: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 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 27 through 35 for substantiation of the FSVP QI's / PCQI's qualifications and certifications.

Product is intended for commercial use only and will be used by FSVP Importer's commercial operation.

Based upon the information and documentation provided to USA before the above noted Review End date, this supplier may NOT have implemented sufficient measures – or certified that sufficient measures are in place – to effectively control FDA identified hazards. However, supplier has provided sufficient documentation (laboratory testing results) to confirm that a given batch is free from FDA identified hazards.

UPER BATCH LABORATORY TESTING RESULTS FOR ALL FDA-IDENTIFIED BIOLOGICAL AND CHEMICAL HAZARDS REQUIRED.

Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

DESIGNATION of ROLES & SUMMARY of REVIEW

FOREIGN SUPPLIER VERIFICATION PROGRAM IMPORTER

Company Name: Ecco un Poco LLC FDA FEI: 3015449317

Physical Address: 8318 West 3rd Street DUNS No.: 09 933 6780

City: Los Angeles State: California, 90048-4311 Country: United States

Mailing Address: 531 S Kenmore Avenue, Apt 300

City: Los Angeles State: California, 90020-2546 Country: United States

Phone Number: +1 (310) 595-0466 Email Address: eccounpoco@gmail.com

Name of Representative(s): Mr. Alessandro Restelli Title: Commercial Rep.

FOREIGN SUPPLIER &/OR MANUFACTURER as defined by §1.500

Company Name: Cascina Fontane Soc. Agr. Semplice FDA FFR: 10168521158

Manufacturing Address: Via Del Molino 3 FDA FEI: 3015549701

City: Castino Province/Territory: Cuneo, 12050 Country: Italy

Office Address: Via Del Molino 3

City: Castino Province/Territory: Cuneo, 12050 Country: Italy

Phone Number: +39 3282168587 Email Address: info@cascinafontane.it

Name of Representative(s): Ms. Cristina Boffano Title: QA / QC

QUALIFIED INDIVIDUAL(s) & AGENT(s)

Agent/QI Name: Claudio Innocenti Signature: 

Title: Partner & Preventive Controls Qualified Individual. Date: July 08, 2021

Agent/QI Name: William J. Barber Signature: 

Title: Preventive Controls Qualified Individual. Date: July 08, 2021

SUMMARY of REVIEW

Details of Product(s)	Is foreign supplier expected to implement controls for			Comments
	Biological Hazards	Chemical Hazards	Physical Hazards	
Hazelnut Paste. Bulk, Intended for Commercial Use. PER BATCH LABORATORY TESTING RESULTS FOR ALL FDA-IDENTIFIED BIOLOGICAL AND CHEMICAL HAZARDS REQUIRED.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Undetermined	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Undetermined	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Undetermined	Verified & Approved - under - Close Monitoring Procedures. — See Addendum.
	<input checked="" type="checkbox"/> FSVP Importer	<input checked="" type="checkbox"/> FSVP Importer	<input checked="" type="checkbox"/> FSVP Importer	
	<input type="checkbox"/> Disclosure	<input type="checkbox"/> Disclosure	<input type="checkbox"/> Disclosure	
	<input type="checkbox"/> Customer	<input 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: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

REGISTER of SUBSTANTIATING DOCUMENTS



HAZARD ANALYSIS

Requested Required Received Reviewed

NOTES Cascina Fontane's HACCP Plan received.

Dated: Feb. 17, 2020.

Plan Entitled: Risk assessment manual for food products according to the H.A.C.C.P. method.

Version: No. 01.

Prepared By: Societ Semplice Agricola.

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 the supplier.

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 Certificate of Analysis received from supplier.

Dated: Vary, but are within 2020/2021

Tested for: biological and chemical hazards. (Salmonella, Aflatoxin B1, B2, G1, and G2)

Laboratory: BioQualita.

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).

PER BATCH LABORATORY TESTING RESULTS FOR ALL FDA-IDENTIFIED BIOLOGICAL AND CHEMICAL HAZARDS REQUIRED.



OTHER FOOD SAFETY RECORDS

Requested Required Received Reviewed

NOTES Completed Foreign Supplier FSVP Questionnaire received.

Dated: April 28, 2021. Completed by: Ms. Cristina Boffano

Note: Supplier has certified that their operation is not responsible for implementing controls for biological, chemical, or physical hazards. However, details of process controls received.

PCQI Certificate received.

Cascina Fontane's Goods inspection procedure on dispatch procedure received.

Cascina Fontane's Pre-operative and post-operative control procedure received.

Cascina Fontane's Procedure for analytical control and Production Checklist received.



PRODUCT LABELING

Requested Required Received Reviewed

NOTES Product Label received. Label clearly identifies all present allergens. Labeling is in compliance with Part 403(w) of the Federal Food, Drug, and Cosmetic Act in so far as it is not misbranded with respect to the presence of food allergens. See Analysis & Determination of Allergenic Hazard(s) for details.

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.

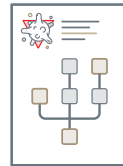
VERIFICATION FREQUENCY for UPDATED DOCUMENTS

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 according 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: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

FDA COMPLIANCE ACTIONS & REGULATORY HISTORY

21 CFR part 1, subpart L, §1.505(a)(1)(iii)(A)(C), and elsewhere requires that a foreign supplier’s compliance history be evaluated, including whether the foreign supplier is the subject of an FDA Warning Letter(s), Import Alert(s), or other FDA compliance action(s) related to food safety. The following constitutes the results of this evaluation.

RESULTS of EVALUATION

Date of Action	Description of Action
N/A	FDA Data Dashboard search results indicate that supplier's compliance history does not include FDA Warning Letters, Import Alerts, or other applicable compliance actions.

Covers: Cascina Fontane Soc. Agr. Semplice

FEI: 3015549701

Date: July 08, 2021

Note: Results may not be exhaustive. FSVP Importer should conduct independent inquiry.

Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

REVISION LOG for FSVP PLAN

Version No.	Date of Change	Description of Revision
No. 01	July 21, 2019	Product and supplier underwent initial FSVP verification.
No. 02	July 08, 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.

Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

ANALYSIS & DETERMINATION of BIOLOGICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
<input type="checkbox"/> <i>Bacillus cereus</i> <input type="checkbox"/> <i>Clostridium botulinum</i> <input type="checkbox"/> <i>C. perfringens</i> <input type="checkbox"/> <i>Brucella spp.</i> <input type="checkbox"/> <i>Campylobacter spp.</i> <input type="checkbox"/> <i>Pathogenic E. coli</i> <input checked="" type="checkbox"/> <i>Salmonella spp.</i> <input type="checkbox"/> <i>S. aureus</i> <input type="checkbox"/> <i>L. monocytogenes</i> <input type="checkbox"/> <i>Trichinella spiralis</i> <input type="checkbox"/> <i>Giardia lamblia</i> <input type="checkbox"/> <i>Shigella spp.</i> <input type="checkbox"/> <i>Other</i>	1	3	<p>Biological hazards can be effectively controlled through the utilization of a number of different control measures, including – but not limited to – the application of a heat and/or chemical kill-step, implementing and following raw material supplier approval procedures, subjecting raw material(s) and/or finished product(s) to laboratory testing, and/or through the utilization of a number of other appropriate control measures.</p> <p>———— SUPPLIER CONTROL MEASURES ————</p> <p>01. Supplier utilizes Heat Application (thermal kill step) to control hazards posed by biological agents. Details: Raw nuts are roasted (no time/temp) information provided by supplier.</p> <p>02. Supplier utilizes laboratory testing of finished product to verify that biological hazards have been effectively controlled. Details: Certificate of Analysis received. Dated: Vary, but are within 2020/2021 Tested for: biological and chemical hazards. Salmonella, Aflatoxin B1, B2, G1, and G2 Laboratory: BioQualita.</p> <p>03. All staff undergoes formal food hygiene training. 04. All staff issued protective clothing. 05. All production operatives are required to cover head/facial hair within the manufacturing area. 06. Adequate toilet and hand washing facilities provided. 07. Product is positively released.</p> <p>———— NOTE ————</p> <p>The production process does not include CCPs and O-PRPs, but all the procedures aimed at maintaining the best hygienic conditions are considered (Cleaning and sanitizing procedure, Pre and post-operative control procedure, Training procedure and operator information, Monitoring procedure rodents).</p> <p>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).</p>	<p>Based upon the information and documentation provided to USA before the above noted Review End date, this supplier may NOT have implemented sufficient measures – or certified that sufficient measures are in place – to effectively control FDA identified biological hazards.</p> <p>However, supplier has provided sufficient documentation (laboratory testing results) to confirm that a given batch is free from FDA identified biological hazards.</p> <p>————</p> <p>USA STRONGLY recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified biological hazards.</p> <p>————</p> <p>----- HAZARD PROFILE ----- ----- SOURCE -----</p> <p>Appendix 1 (Hazards Tables) Category: Other Nut and Seed. Category No.: 20. Subcategory: Single component Pastes. Storage: Shelf-Stable.</p>

Legend for Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.
 C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.
 P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.
Probability (P): Assesses the probability that the hazard will occur in the absence of controls. (§1.505, (c))
Severity (S): Assesses the severity of the illness or injury if the hazard were to occur. (§1.505, (c))
P. & S. Assessment Scale: 1 - Low, 2 - Moderate, 3 - High, S - Serious adverse health consequences or death.
Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

ANALYSIS & DETERMINATION of CHEMICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
<input type="checkbox"/> Drug residues <input type="checkbox"/> Heavy metals <input type="checkbox"/> Industrial chemicals <input type="checkbox"/> Pesticides <input checked="" type="checkbox"/> Mycotoxins/Toxins <input type="checkbox"/> Radiological <input type="checkbox"/> Unapproved colors & additives <input checked="" type="checkbox"/> Chemical hazards due to mis-formulation <input type="checkbox"/> Other	1	2	<p>Chemical hazards can be effectively controlled through the utilization of a number of different control measures, including – but not limited to – implementing and following appropriate raw material supplier approval procedures, and/or subjecting raw material(s) and/or finished product(s) to laboratory testing.</p> <p>_____ SUPPLIER CONTROL MEASURES _____</p> <p>01. Supplier utilizes raw material inspection and approval procedures to control for hazards posed by chemical agents prior to production.</p> <p>02. Supplier utilizes laboratory testing to verify that product is free from chemical hazards prior to release. Details: Certificate of Analysis received. Dated: Vary, but are within 2020/2021 Tested for: Salmonella, Aflatoxin B1, B2, G1, and G2 Laboratory: BioQualita.</p> <p>_____ NOTE _____</p> <p>The production process does not include CCPs and O-PRPs, but all the procedures aimed at maintaining the best hygienic conditions are considered (Cleaning and sanitizing procedure, Pre and post-operative control procedure, Training procedure and operator information, Monitoring procedure rodents).</p> <p>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).</p> <p>USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified chemical hazards.</p>	<p>Based upon the information and documentation provided to USA before the above noted Review End date, this supplier may NOT have implemented sufficient measures – or certified that sufficient measures are in place – to effectively control FDA identified chemical hazards.</p> <p>However, supplier has provided sufficient documentation (laboratory testing results) to confirm that a given batch is free from FDA identified chemical hazards.</p> <p>_____ USA STRONGLY Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified chemical hazards.</p> <p>----- HAZARD PROFILE ----- ----- SOURCE -----</p> <p>Appendix 1 (Hazards Tables) Category: Other Nut and Seed. Category No.: 20. Subcategory: Single component Pastes. Storage: Shelf-Stable.</p>

Legend for Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.
 C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.
 P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.
Probability (P): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))
Severity (S): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))
P. & S. Assessment Scale: 1 - Low, 2 - Moderate, 3 - High, S - Serious adverse health consequences or death.
Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

ANALYSIS & DETERMINATION of ALLERGENIC HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
<input checked="" type="checkbox"/> Undeclared allergens - Incorrect label <input checked="" type="checkbox"/> Undeclared allergens - Cross-contact ALLERGENS <input type="checkbox"/> Milk <input type="checkbox"/> Eggs <input type="checkbox"/> Fish <input type="checkbox"/> Shellfish (Crustacean) <input checked="" type="checkbox"/> Tree nuts <input type="checkbox"/> Peanuts <input type="checkbox"/> Wheat <input type="checkbox"/> Soybeans <input type="checkbox"/> Sesame*	3	3	<p>Allergens themselves can not be directly controlled. However, the presence of allergens – or a given allergen – can be controlled. The presence of allergenic hazards can be effectively controlled through the utilization of a number of control measures, including – but not limited to – staff training for common food allergens, avoiding cross-contact, and proper food labeling. These may be effective methods to ensure that allergens are not ingested by a person who will be experience a negative reaction.</p> <p>_____ SUPPLIER CONTROL MEASURES _____</p> <p>01. Supplier certifies that:</p> <p>A) there is one (1) allergen handled on site and present in product - Hazelnut which is disclosed on label.</p> <p>B) a documented allergen control program is in use.</p> <p>C) a dedicated process line and a documented cleaning procedure are in place to prevent contamination.</p> <p>D) all employees undergo allergen training and processes have been put in place to reduce the likelihood of cross contact or unintentional introduction of allergens into processing area.</p> <p>_____NOTE_____</p> <p>----- Labeling Requirements -----</p> <p>- Food Allergen Labeling and Consumer Protection Act -</p> <p>-----</p> <ul style="list-style-type: none"> - Nutritional information (not appliance to bulk). - Name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5). - Quantity of contents (21 CFR 101.7). - Statement of identity (21 CFR 101.3). - Presence of artificial flavoring, artificial coloring, or chemical preservative (21 CFR 101.22). - Ingredient statement if the product has two or more ingredients (21 CFR 101.4). - Presence of major food allergens (21 U.S.C. 343(w)). - Percent juice (21 CFR 101.30), when applicable. 	<p>Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control the hazard posed by allergenic adulteration.</p> <p>Note: USA's assessment of product(s) labeling is restricted to a label(s)' allergen disclosure statement and should not be interpreted to meant 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 applicable regulations prior to import.</p> <p>----- HAZARD PROFILE -----</p> <p>----- SOURCE -----</p> <p>Appendix 1 (Hazards Tables) Category: Other Nut and Seed. Category No.: 20. Subcategory:Single component Pastes. Storage: Shelf-Stable.</p>

Legend for Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.
 C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.
 P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.
Probability (P): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))
Severity (S): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))
P. & S. Assessment Scale: 1 - Low, 2 - Moderate, 3 - High, S - Serious adverse health consequences or death.
Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)
 *Per Food Allergy Safety, Treatment, Education and Research Act, food packages will need to reflect allergen labeling for sesame beginning on January 1, 2023.

ANALYSIS & DETERMINATION of ENVIRONMENTAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
<input checked="" type="checkbox"/> Recontamination with environmental pathogens. <input checked="" 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 poor formulation control. <input type="checkbox"/> Bacterial growth and/or toxin formation due to reduced oxygen packaging. <input type="checkbox"/> Other	1	2	<p>Hazards posed by ineffective processes or environmental pathways can be controlled by the utilization of Current Good Manufacturing Practices, positively releasing finished product, avoiding cross-contamination, carefully monitoring production process, subjecting raw material(s) and/or finished product(s) to laboratory testing, and/or through the utilization of a number of other appropriate control measures.</p> <p style="text-align: center;">———— SUPPLIER CONTROL MEASURES ————</p> <p>01. Hazard posed by recontamination with environmental pathogens is controlled through Current Good Manufacturing Practices.</p> <p>02. Supplier has implemented a cleaning program and environmental monitoring for microbiological and biological hazards.</p> <p>03. All product is positively released and hermetically sealed within plastic.</p> <p style="text-align: center;">———— NOTE ————</p> <p>The production process does not include CCPs and O-PRPs, but all the procedures aimed at maintaining the best hygienic conditions are considered (Cleaning and sanitizing procedure, Pre and post-operative control procedure, Training procedure and operator information, Monitoring procedure rodents).</p> <p>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).</p>	<p>Based upon the information and documentation provided to USA before the above noted Review End date, this supplier may NOT have implemented sufficient measures – or certified that sufficient measures are in place – to effectively control FDA identified environmental hazards.</p> <p>However, supplier has provided sufficient documentation (laboratory testing results) to confirm that a given batch is free from FDA identified environmental hazards.</p> <p>————</p> <p>USA STRONGLY recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified environmental hazards.</p> <hr/> <p style="text-align: center;">----- HAZARD PROFILE ----- ----- SOURCE -----</p> <p>Appendix 1 (Hazards Tables) Category: Other Nut and Seed. Category No.: 20. Subcategory: Single component Pastes. Storage: Shelf-Stable.</p>

Legend for Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.
 C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.
 P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.
Probability (P): Assesses the probability that the hazard will occur in the absence of controls. (§1.505, (c))
Severity (S): Assesses the severity of the illness or injury if the hazard were to occur. (§1.505, (c))
P. & S. Assessment Scale: 1 - Low, 2 - Moderate, 3 - High, S - Serious adverse health consequences or death.
Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

ANALYSIS & DETERMINATION of PHYSICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
<input checked="" type="checkbox"/> Metal <input checked="" 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	1	2	<p>Physical hazards can be effectively controlled through the utilization of a number of different control measures, including – but not limited to – the utilization of an operational and calibrated metal detector during and/or after the production process, sieving raw material and/or finished product, optical sorting machinery, visual inspection, appropriate and consistent raw material supplier approval methods, and/or through the utilization of a number of other appropriate control measures.</p> <p>———— SUPPLIER CONTROL MEASURES ————</p> <p>01. Supplier utilizes Raw material inspection, Filters, and Magnets to control hazards posed by physical agents.</p> <p>Stating: The freshly picked hazelnut is placed inside an air cleaner to eliminate foreign materials (stones, plastic, glass, metal). It is then calibrated and separated from the tastes by a grid. Once roasted the hazelnut is checked on a sorting tape to verify the quality of the product and to eliminate any foreign materials and shells. For the preparation of the pasta, the hazelnut is processed inside a mill with a magnet that eliminates any traces of metals and is eventually filtered.</p> <p>02. Glass and Breakable Plastic Program in use.</p> <p>03. Supplier sieves incoming ingredients and finished products.</p> <p>04. Product is not packaged in glass.</p> <p>———— NOTE ————</p> <p>We recommend that the supplier use an operational and calibrated metal detector during/after the production process to control for metal.</p>	<p>Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control physical hazards. Product is NOT in Ready-to-Eat form upon arrival to FSVP Importer.</p> <hr/> <p>----- HAZARD PROFILE ----- ----- SOURCE -----</p> <p>Appendix 1 (Hazards Tables) Category: Other Nut and Seed. Category No.: 20. Subcategory: Single component Pastes. Storage: Shelf-Stable.</p>

Legend for Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.
 C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.
 P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.
Probability (P): Assesses the probability that the hazard will occur in the absence of controls. (§1.505, (c))
Severity (S): Assesses the severity of the illness or injury if the hazard were to occur. (§1.505, (c))
P. & S. Assessment Scale: 1 - Low, 2 - Moderate, 3 - High, S - Serious adverse health consequences or death.
Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

ASSESSMENT of FOREIGN SUPPLIER

1.0 FOREIGN SUPPLIER INFORMATION

1.1. Supplier name: Cascina Fontane Soc. Agr. Semplice

1.2. Supplier address: Via Del Molino 3, Castino, Cuneo, 12050, IT

1.3. Products manufactured/supplied: Hazelnut Paste.

1.4. Is the supplier certified to a food safety standard and audited regularly? Yes No N/A

GFSI Standard: _____

1.5. Is the standard GFSI benchmarked/recognized? Yes No Other (see Addendum)

1.6. Has the supplier provided specifications? Yes No

1.7. Has the supplier completed a Supplier Assessment and an Allergen Questionnaire? Yes No

1.8. Have the supplier's specifications and/or completed questionnaires been evaluated by USA's PCQI(s)?

Yes No *PCQI(s):* C. Innocenti (PCQI Member, USA LLC)

2.0 SUPPLIER PROCEDURES, PROCESSES & PRACTICES

2.1. Does supplier follow current GMPs? Yes No

2.2. Does the supplier have SOP in place for each procedure in the production & release of product? Yes No N/A

2.3. Does the supplier have allergen controls in place to prevent cross-contamination? Yes No N/A

3.0 SUPPLIER PERFORMANCE HISTORY

3.1. Does the supplier have a HACCP/PC plan for each product manufactured for the importer? Yes No N/A

3.2. Has the supplier's HACCP/PC plan been reviewed and approved by USA's PCQI(s)? Yes No

PCQI(s): C. Innocenti (PCQI Member, USA LLC)

3.3. To the best of USA's knowledge, has the supplier been the subject of a public FDA Alert/Warning Letter?

Yes No N/A *Description:* No. Import Alert & Warning Letter search-results.

which were conducted on – or about – the Review End date, have been attached to this FSVP Plan.

3.4. Has the supplier supplied a product that needed to be recalled for a food safety reason? Yes No N/A

Description: No, as of this FSVP Plan's Review End date, USA has no knowledge

of any recall undertaken by supplier.

Continued onto next page.

Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

ASSESSMENT of FOREIGN SUPPLIER

3.0 SUPPLIER PERFORMANCE HISTORY *(Continued)*

3.5. Has the supplier supplied out of specification product excluding quality issues? Yes No N/A

3.6. Has importer conducted microbiological testing for all lots imported from the supplier? Yes No N/A

3.7. Has any lot tested positive for chemical, physical or biological hazards? Yes No N/A

Description of the incident and the corrective actions taken by the supplier: No, as of this FSVP Plan's Review End date, USA has no knowledge of any lot/batch testing positive for any FDA-identified hazard(s).

3.8. Has the supplier provided timely and adequate responses to all requests and issues related to food safety?

Yes No

Description: Yes, supplier (either directly, or through the FSVP Importer) has provided timely and adequate responses to our inquiries and requests.

4.0 SUPPLIER APPROVAL

4.1. Have USA's PCQI(s) identified and evaluated the known and reasonably foreseeable hazards for each product imported from the supplier and are there preventive controls in place to adequately control the hazards?

Yes No

PCQI(s): C. Innocenti (PCQI. Member, USA LLC)

4.2. After reviewing all hazards and the supplier's performance, have USA's PCQI(s) determined appropriate verification activities that will be conducted and documented on an ongoing basis to verify the preventive controls are effectively controlling the hazard(s)? Yes No

PCQI(s): C. Innocenti (PCQI. Member, USA LLC)

4.3. **Is the foreign supplier approved for import into the United States under this FSVP plan?** Yes No

Comments: Approved for import under strict receiving and monitoring procedures. Product may be uncontrolled. Hazards may be present.

Additional Recommendations:

USA STRONGLY recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified hazards.

This FSVP will expire one year from its above the above noted "Review End" date.

Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

REVIEW of GENERAL FOOD SAFETY PROGRAM

Claims Made Against Product

No claims have been made against the raw material / product type.

Overview of Foreign Supplier's Commercial Operation

Unknown.

Testing Program & Accreditation

Certificate of Analysis received from supplier. Dated: Vary, but are within 2020/2021
Tested for: biological and chemical hazards. (Salmonella, Aflatoxin B1, B2, G1, and G2) Laboratory: BioQualita.
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).

PER BATCH LABORATORY TESTING RESULTS FOR ALL FDA-IDENTIFIED BIOLOGICAL AND CHEMICAL HAZARDS REQUIRED. Alternatively, since the product is destined for further processing prior to public consumption, an FSVP disclosure statement can be issued to Ecco Un Poco's customer(s) if applicable.

Supplier & Product Allergen Information

Supplier certifies that: A) there are NO allergens handled on site, B) a documented allergen control program is in use, C) a dedicated process line and a documented cleaning procedure are in place to prevent contamination, D) all employees undergo allergen training and processes have been put in place to reduce the likelihood of cross contact or unintentional introduction of allergens into processing area.

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 applicable regulations prior to import.

Packaging Type & Shipping / Handling Requirements

Supplier certifies that packaging is accredited for food use. Ambient shipping and handling requirements.

Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

REVIEW of GENERAL FOOD SAFETY PROGRAM

Supplier GFSI Status & Historical Performance

FDA Data Dashboard search results indicate that supplier's compliance history does not include FDA Warning Letters, Import Alerts, or other applicable compliance actions.

Supplier/product will be re-assessed and re-verified to the standards of the Foreign Supplier Verification Program on an annual basis, or sooner if necessary.

Close Supplier Monitoring

YES. We recommend that FSVP Importer implement close supplier/product monitoring procedures for the foreseeable future.

USA STRONGLY recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified hazards.

General Comments & Verification Timeline

Products supplied by this supplier have been verified and are approved for import. Supplier/product will be re-assessed and re-verified to the standards of the Foreign Supplier Verification Program on an annual basis (or sooner if necessary). This FSVP will expire one year from its above the above noted "Review End" date.

NOTE

PER BATCH LABORATORY TESTING RESULTS FOR ALL FDA-IDENTIFIED BIOLOGICAL AND CHEMICAL HAZARDS REQUIRED.

Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

ADDENDUM

NOTE

Labeling Requirements

The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 requires food manufacturers to label food products that contain an ingredient that is or contains protein from a major food allergen in one of two ways.

The first option for food manufacturers is to include the name of the food source in parenthesis following the common or usual name of the major food allergen in the list of ingredients in instances when the name of the food source of the major allergen does not appear elsewhere in the ingredient statement. For example: Vanilla Waffers Ingredients: Enriched flour (wheat flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, partially hydrogenated soybean oil, and/or cottonseed oil, high fructose corn syrup, whey (milk), eggs, vanilla, natural and artificial flavoring) salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin (soy), mono-and diglycerides (emulsifier)

The second option is to place the word "Contains" followed by the name of the food source from which the major food allergen is derived, immediately after or adjacent to the list of ingredients, in type size that is no smaller than the type size used for the list of ingredients. For example: Contains Wheat, Milk, Egg, and Soy

Food Allergen Labeling and Consumer Protection Act

- Nutritional information (not appliance to bulk).
- Name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5).
- Quantity of contents (21 CFR 101.7).
- Statement of identity (21 CFR 101.3).
- Presence of artificial flavoring, artificial coloring, or chemical preservative (21 CFR 101.22).
- Ingredient statement if the product has two or more ingredients (21 CFR 101.4).
- Presence of major food allergens (21 U.S.C. 343(w)).
- Percent juice (21 CFR 101.30), when applicable.

CLOSE MONITORING PROCEDURES

IMPORTANT NOTE: PER BATCH LABORATORY TESTING RESULTS FOR ALL FDA-IDENTIFIED BIOLOGICAL AND CHEMICAL HAZARDS REQUIRED.

USA STRONGLY recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified hazards.

Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

A D D E N D U M



INTENTIONALLY
BLANK PAGE

Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

A D D E N D U M

INTENTIONALLY

BLANK PAGE

Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

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:
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

ILLINOIS INSTITUTE OF TECHNOLOGY


Gerald Wojtala, Executive Director
International Food Protection Training Institute

Certificate # 31d8ad94


Steve Mandernach, Executive Director
Association of Food and Drug Officials



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

ILLINOIS INSTITUTE OF TECHNOLOGY


Gerald Wojtala, Executive Director
International Food Protection Training Institute

Certificate # 223faa17


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


Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

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:
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


IFSH INSTITUTE FOR
FOOD SAFETY
AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY


INTERNATIONAL
FOOD PROTECTION
TRAINING INSTITUTE


AFDO

Certificate # d2e9c287





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: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

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:
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

ILLINOIS INSTITUTE OF TECHNOLOGY


Gerald Wojtal, Executive Director
International Food Protection Training Institute

INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE


Joseph Corby, Executive Director
Association of Food and Drug Officials


Certificate # d2e9c287


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

ILLINOIS INSTITUTE OF TECHNOLOGY


Gerald Wojtal, Executive Director
International Food Protection Training Institute

INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE


Joseph Corby, Executive Director
Association of Food and Drug Officials


Certificate # d2e9c287

Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

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

 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
---	---	--

 IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH KLINGBILT INSTITUTE OF TECHNOLOGY	 INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE	 AFDO
---	---	---

Certificate # 2d697331

Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT


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

INSTITUTE FOR
FOOD SAFETY
AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY


Gerald Wojtals, Executive Director
International Food Protection Training Institute

ifpti
Certificate # ed6f0b58


Steve Mandernach, Executive Director
Association of Food and Drug Officials



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

INSTITUTE FOR
FOOD SAFETY
AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY


Gerald Wojtals, Executive Director
International Food Protection Training Institute

ifpti
INTERNATIONAL
FOOD PROTECTION
TRAINING INSTITUTE
Certificate # 917b0241


Joseph Corby, Executive Director
Association of Food and Drug Officials


CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT



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



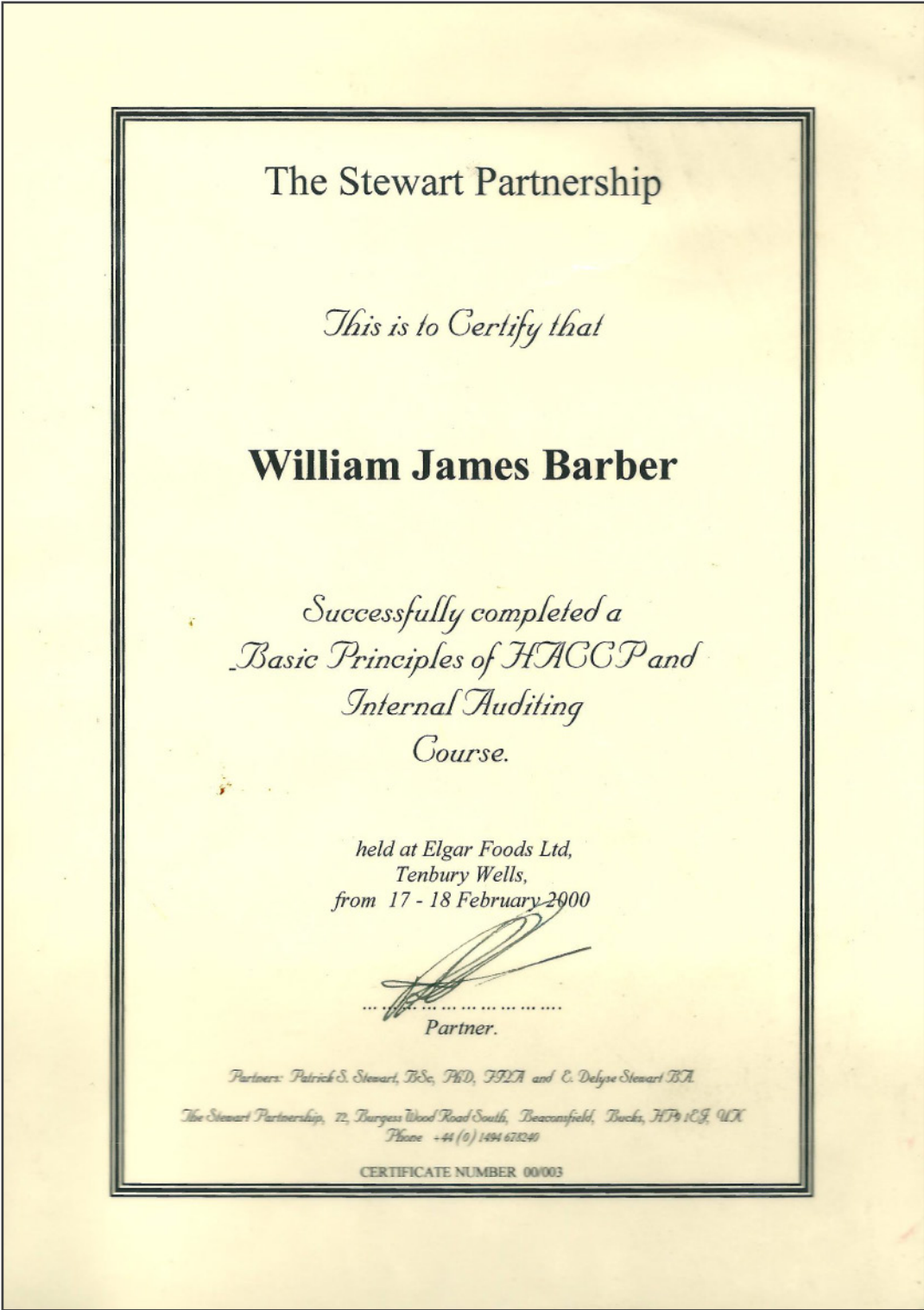
526405 101116 1107147



Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021


CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT



Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT



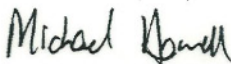
NATIONAL VOCATIONAL QUALIFICATION


**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 0709/024307A/124203/PXC4025/1/13/03/64


M Howell
Chairman
The City and Guilds of London Institute


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 1900.
The City & Guilds Group comprises City & Guilds, ILM, City & Guilds NPTC and City & Guilds HAB.

Supplier: Cascina Fontane Soc. Agr. Semplice Product: Hazelnut Paste | for Commercial Use.

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 19, 2021 Review End: July 08, 2021

CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT



**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	U1028661
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

M Howell
Chairman
The City and Guilds of London Institute

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

801



The City and Guilds of London Institute founded 1878 and incorporated by Royal Charter 1900.
The City & Guilds Group comprises City & Guilds, ILM, City & Guilds NPTC and City & Guilds HAB.

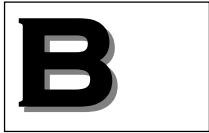


SUBSTANTIATING DOCUMENTS



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 All 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.



BIOQUALITÀ
SICUREZZA E QUALITÀ
PER L'AZIENDA
ALIMENTARE

DI ICARDI LAURA
C.SO ASTI, 27 GUARENE
CN CELL 335.7482661
TEL E FAX
0173.212501 E-
MAIL:lauraicardi@bioqualita.com

Risk assessment manual for food products according to the H.A.C.C.P. method

pursuant to Article 5 of EC / EU Regulation No. 852/2004

and acceptance of D.D. 15 October 2012, n. 692

Definition of guidelines for official control in the micro-enterprise

SELF TEST DOCUMENT

Cascina Fontane

Società Semplice Agricola

Via Molino 3, 12050 Castino

Laboratorio di Via Alba Cortemilia 50, Diano D'Alba CN

Revision 01 of 17/02/2020

SELF TEST DOCUMENT FOR THE FOOD COMPANY

**EC Regulation 852/2004
and acceptance
D.D. 15 October 2012, n. 692**
Definition of guidelines for official control in the micro-enterprise
(H.A.C.C.P.)

UPDATE OBJECRT

EC Regulation n.178 / 02 Traceability
EC Regulation n.852 / 2004 Hygiene of food products

CHANGES TABLE

Revision Index	Revision date	Changes description
00	09/05/2017	First issue

The Company Manager
Mrs Cristina Boffano

.....

SUMMARY

SELF TEST DOCUMENT 1
 COMPANY IDENTIFICATION 5
 CHAPTER 1 PURPOSE AND SCOPE OF THE MANUAL FOR THE SELF-TESTING
 ESTABLISHMENT 6
 CHAPTER 2 REGULATORY REFERENCES 7
 REGULATORY 7
 RULES 7
 CHAPTER 3, TERMS AND DEFINITIONS 8
 Terminology 8
 Abbreviations 10
 CHAPTER 4, DESCRIPTION AND ANALYSIS OF THE COMPANY 11
 Business activity; 11
 Company structure; 11
 Company Description; 11
 Description and examination of the Areas 12
 PLANT IDENTIFICATION 14
 Definition of raw materials and products; 15
 CHAPTER 5, ANALYSIS OF RISKS AND PLANNING OF CONTROLS 16
 APPLICATION OF THE PRINCIPLES OF THE HACCP SYSTEM 16
 APPLICATION OF THE SELF-CONTROL PLAN 17
 Company figures linked to self-control 17
 Corporate Manager (RA) 17
 Definition of the work group for self-control 18
 Definition of the production flow chart 19
 CHAPTER 5, HAZARDS IDENTIFICATION, DETERMINATION OF RISKS AND PREVENTIVE MEASURES FOR
 THEIR CONTROL 22
 Definitions 22
 Hazard identification methods 22
 Data collection 22
 Hazards identification 22
 Risk analysis methods 23
 Probability of damage (P) 23
 Gravity of the damage (G_D) 24
 Risk severity (G_R) 24
 Identification of CCPs 24
 CCP management 25
 CCP 25
 OPRP 25
 CP 26
 GMP or NBF 26
 Hazards identification and risk analysis roasted hazelnuts and other hazelnut-based semi-finished products - primary
 products 27
 MICROBIOLOGICAL DANGER 27
 CHEMICAL DANGER 27
 PHYSICAL DANGER 28
 BIOLOGICAL DANGER 29
 Hazards identification and oil risk analysis, praline hazelnuts and hazelnut based creams - processed products 30
 MICROBIOLOGICAL DANGER 30
 CHEMICAL DANGER 31
 PHYSICAL DANGER 32
 BIOLOGICAL DANGER 32
 CHAPTER 6, MONITORING, CRITICAL LIMITS, CORRECTIVE ACTIONS 34

Documentation structure	34
POI - Internal Operating Procedures	34
DS - Support Documents	35
Mod - Models	35
Responsibility	36
Identifying elements of a document	36
Distribution of documents	37
Documents from outside the organization	37
MACHINE and EQUIPMENT MANUALS.....	37
TECHNICAL AND SAFETY DATA SHEET PRODUCTS, PRODUCT LEAFLETS.....	37
CHAPTER 7 REGISTRATION OF THE SELF-CONTROL THAT IS GENERATED DURING THE PROCESSES, DEFINITION OF DOCUMENTATION REGISTRATION AND CONSERVATION METHODS	38
Autocontrol registration control	38
Responsibility	38
DOCUMENTS OF INTERNAL ORIGIN	38
TECHNICAL REGISTRATIONS	38
DOCUMENTS OF EXTERNAL ORIGIN	39
MANAGEMENT OF PAPER RECORDINGS.....	39
Storage mode	39

COMPANY IDENTIFICATION

Company name: Azienda Agricola Semplice Cascina Fontane
Administrative office: Via Molino, 3 12050 Castino CN
Operative headquarters / s: Via Alba Cortemilia 50, Diano D'Alba CN
Sector: processing and packaging of hazelnut products
RESPONSIBLE for the food company: Ms. Cristina Boffano
ASL territorially competent: CN2

MANAGER
Sig. Cristina Boffano

.....

CHAPTER 1 – PURPOSE AND FIELD OF APPLICATION OF THE MANUAL FOR THE SELF-TESTING OF THE ESTABLISHMENT

This Autocontrol Manual aims to describe the Self-Control Management System prepared by the Azienda Agricola CASCINA FONTANE for the purpose of:

- ✓ Comply with the requirements of EC / EU Reg. No. 852/2004.
- ✓ Obtain the pre-established quality from its Quality policy.
- ✓ Guarantee the health and hygiene of its products.
- ✓ Meet the expectations of customers, clients and especially end consumers.

The Manual defines: the organizational structure of the company, the internal responsibilities, the criteria and the binding principles to be followed in carrying out the activities, the references to the detailed documents prepared to manage individual management / operational activities of particular relevance or frequency of application.

The Manual complies with the requirements established by the EC / EU Reg. No. 852/2004 and includes the guidelines for the official control in the D.D. 15 October 2012, n. 692 which suggests a simplified management of the risk in small food businesses, with the reduction of bureaucratic burdens often not justified by a real need for health protection, considered essential not only to reduce costs and improve the competitiveness of businesses, but also to improve self-control directing it to actions of proven effectiveness.

The Autocontrol Manager ensures the adequacy and compliance of the Manual with the Regulation and guarantees that the specific management procedures contain all the provisions set out in the Manual and do not contain any of them in contrast with it. The Company Quality Manager verifies the document and the Company Manager approves it for application in the company.

CHAPTER 2 – REGULATORY REFERENCES

The reference documents of the Self-Control Plan are the following:

REGULATORY

- Regulation (EC) n. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of food products.
- D.D. 15 October 2012, n. 692, Definition of guidelines for official control in the micro-enterprise.
- Regulation (EC) n. 853/2004 of the European Parliament and of the Council of 29 April 2004 which establishes specific rules on hygiene for food of animal origin.
- Regulation (EC) n. 854/2004 of the European Parliament and of the Council of 29 April 2004 which establishes specific rules for the organization of official controls on products of animal origin intended for human consumption.
- Regulation (EC) n. 882/2004 of the European Parliament and of the Council of April 29, 2004 relating to official controls aimed at verifying compliance with feed and food law and animal health and welfare regulations.
- Regulation (EC) No. 178/2002 of the European Parliament and of the Council of January 28, 2002, which establishes the principles and general requirements of food legislation, establishes the European Food Safety Authority and establishes procedures in the field of food safety.
- Commission Regulation (EC) No. 2076/2005 of December 5, 2005, which establishes transitional provisions for the implementation of the regulations of the European Parliament and of the Council (EC) n. 853/2004, (CE) n. 854/2004 and (CE) n. 882/2004 and amending the regulations (CE) n. 853/2004 and (CE) n. 854/2004.
- EEC / CEEA / ECSC Decision No. 822 of 11/17/2003: Council Decision of 17 November 2003 concerning the accession of the European Community to the Codex Alimentarius Commission.
- Ordinary law of the Parliament No. 526 of 12/21/1999; Provisions for the fulfillment of obligations deriving from Italy's membership of the European Communities - Community Law 1999.
- Presidential Decree No. 327 of 03/26/1980; Regulation for the execution of Law no. 288 of 30 April 1962, and subsequent amendments, concerning the hygienic regulation of the production and sale of food and drink substances.
- Ordinary law of Parliament No. 283 of 04/30/1962; Amendment of Articles 242, 243, 247, 250 and 262 of the T.U. of health laws approved with R.D. 27 July 1934, n. 1265: Hygienic regulation of the production and sale of food and drink substances.

RULES

- UNI EN ISO 9000: 2015; Quality management systems - Fundamentals and terminology.
- UNI EN ISO 19011: 2011; Guidelines for audits of quality management and / or environmental management systems.
- International Technical Standard 01/01/2003 Codex Alimentarius. International Code of Recommended Practice. General Principles of Food Hygiene - CAC / RCP 1-1969, Rev. 4-2003 (issued by: Codex Alimentarius Commission).
- EC communication of 12/01/2000; WHITE PAPER ON FOOD SAFETY.
- Technical Standard UNI n ° 10854 of 12/31/1999; Agribusiness company - Guidelines for the design and implementation of a self-control system based on the HACCP method.
- International Technical Standard 01/04/1997; Guidebook for the preparation of HACCP Plans.
- FOOD CODE International Technical Standard - Annex V - HACCP Guidelines; issued by: FDA - Food and Drug Administration.

CHAPTER 3 – TERMS AND DEFINITIONS

Terminology

The definitions shown in the following documents apply to all self-control management documents:

- **EU / EU Regulation No. 852 of 04/29/2004**
- **EC / EU Regulation No. 178 dated 01/28/2002**
- **UNI EN ISO 9000 - Quality management systems - Fundamentals and terminology**

In particular, the following definitions are taken from **Reg CE / UE n° 852/2004**:

Self control: Set of procedures and methods to ensure and maintain the hygiene of food products during any activity carried out in the food sector (manufacture, processing, packaging, distribution, sale, administration, storage, transport).

Food hygiene: the measures and conditions necessary to control the hazards and guarantee the suitability for human consumption of a food product taking into account the intended use;

Establishment: each unit of a food business enterprise;

Competent authority: the central authority of a Member State responsible for ensuring compliance with the provisions of current legislation or any other authority to which this central authority has delegated this competence; the definition includes, where appropriate, the corresponding authority of a third country;

Equivalent: referring to different systems, means capable of achieving the same objectives;

Contamination: the presence or introduction of a hazard;

Drinking water: water complying with the minimum requirements established in Council Directive 98/83 / EC of 3 November 1998 on the quality of water intended for human consumption;

Boxing: placing a food product in a wrapper or container placed in direct contact with the food product in question, as well as said wrapper or container;

Packaging: placing one or more packaged food products in a second container, as well as said second container;

Hermetically closed container: container intended to prevent the penetration inside of hazards;

Treatment: any action that causes a substantial modification of the initial product, including heat treatment, smoking, salting, curing, drying, marinating, extraction, extrusion or a combination of these processes;

Unprocessed products: foodstuffs not subjected to treatment, including products that have been divided, separated, sectioned, sliced, boned, minced, skinned, crushed, cut, cleaned, trimmed, peeled, ground, chilled, frozen, frozen or thawed;

Processed products: food products obtained from the processing of unprocessed products. These products may contain ingredients necessary for their processing or to give them specific characteristics.

In particular, the following definitions are taken from **Reg (CE) n. 178/2002**:

Food (or «food product», or «foodstuff»): any processed or partially processed or unprocessed substance or product intended to be ingested, or reasonably expected to be ingested, by humans. This includes beverages, chewing gum and any substance, including water, intentionally incorporated into food during their production, preparation or treatment. It includes water where the values must be respected as established in Article 6 of Directive 98/83 / EC and subject to the requirements of Directives 80/778 / EEC and 98/83 / EC.

Food legislation: laws, regulations and administrative provisions concerning food in general, and food safety in particular, both in the Community and at national level; all phases of production, processing and distribution of food and also of feed produced for animals destined for food production or administered to them are included;

Food business: any public or private subject, with or without profit, which carries out any of the activities related to one of the phases of production, processing and distribution of food;

Food business operator: the natural or legal person responsible for ensuring compliance with the provisions of the food law in the food business under his control;

Retail: handling and / or processing of food and its storage at the point of sale or delivery to the final consumer, including distribution terminals, catering establishments, canteens of companies and institutions, restaurants and other similar catering facilities, stores, supermarket distribution centers and wholesale outlets;

Placing on the market: the holding of food or feed for sale, including the offer to sell or any other form, free or for payment, of sale, as well as the sale itself, distribution and other forms of sale proper;

Risk: function of the probability and severity of a harmful effect on health, resulting from the presence of a hazard;

Risk analysis: process consisting of three interconnected components: risk assessment, management and communication;

Risk assessment: scientifically based process consisting of four phases: hazard identification, hazard characterization, hazard exposure assessment and risk characterization;

Risk management: process, distinct from the risk assessment, consisting in examining alternatives for intervention by consulting the interested parties, taking into account the risk assessment and other relevant factors and, if necessary, making adequate prevention and control choices;

Risk communication: the interactive exchange, throughout the entire risk analysis process, of information and opinions regarding the elements of danger and risks, the factors connected to risk and the perception of risk, among those responsible for risk assessment, responsible for risk management, consumers, food and feed businesses, the academic community and others, including the explanation of risk assessment findings and the basis of risk management decisions;

Danger or danger element: biological, chemical or physical agent contained in a food or feed, or a condition in which a food or feed is found, capable of causing a harmful effect on health;

Traceability: the possibility of reconstructing and following the path of a food, a feed, an animal destined for food production or a substance intended or suitable to become part of a food or feed through all stages of production, of the transformation and distribution;

Production phases of transformation and distribution: any phase, including importation, starting from the primary production of an included food up to storage, transport, sale or supply to the final consumer including and, where relevant, import, production, processing, storage, transport, distribution, sale and supply of feed;

Primary production: all stages of production, breeding or cultivation of primary products, including harvesting, milking and livestock production prior to slaughter and including hunting and fishing and harvesting wild products;

Final consumer: the final consumer of a food product that does not use this product as part of a food business operation or activity.

In particular, the following definitions are taken from **UNI EN ISO 9000**:

Quality management system: management system to guide and monitor an organization with reference to quality.

Procedure: specified way to perform an activity or process.

Non-compliance: failure to meet a requirement.

Corrective action: action taken to eliminate the cause of a detected non-compliance, or other undesirable situations detected.

Preventive action: action taken to eliminate the cause of a potential non-compliance or other potentially undesirable situations.

Abbreviations

In the preparation of the documentation for self-control abbreviations are used to shorten and simplify the drafting. The abbreviations generally used are:

AC	:	Corrective action
AP	:	Preventive action
CCP	:	Critical Control Point
DL	:	Law Decree
DM	:	Ministerial Decree
DPR	:	Decree of the President of the Republic
G.U.	:	Official Journal of the Italian Republic
HACCP:		Hazard Analysis Critical Control Point
IO	:	Operating instruction
ISO	:	International Standard Organization
L	:	Law
NC	:	Non-compliance
POI	:	Internal Operating Procedure
RA	:	Business Manager
OSA	:	Food Sector Operator
RH	:	Responsible for self-control
SGA	:	Italian National Unification Body
SGQ	:	Quality Management System
UNI	:	Italian National Unification Body
VII	:	Internal Inspection
VIE	:	External Inspection

CHAPTER 4 – DESCRIPTION AND ANALYSIS OF THE COMPANY

Business activity;

The company cultivates and processes its own hazelnuts and, if necessary, purchases and processes local hazelnuts from other growers. Hazelnuts are of the Tonda Gentile Trilobata variety, whether or not registered with the IGP hazelnut consortium.



Piedmont Hazelnut Protection Consortium Corso Umberto I, 1 - Bossolasco (CN)

Sede Operativa: Via Alba 15, Castagnito (CN) Tel. 0173-210311 - Fax 0173-212223

Regulations in force since 09/18/2013

MINISTRY OF AGRICULTURAL FOOD AND FOREST POLICIES

DECREE 9 September 2013.

Modification of the production disciplinary of the denomination "Nocciola del Piemonte / Nocciola Piemonte", registered as a protected geographical indication pursuant to Regulation (EC) n. 1107 of the Commission of 12 June 1996, amended by Regulation (EC) n. 464/2004.

Company structure;

The objective of the company CASCINA FONTANE is to promote and market the IGP Piedmont Hazelnut with the direct cultivation of the product in the lands located in the municipalities of Castino and neighboring areas.

The production takes place in Castino, while the transformation, of which the present Manual, takes place in the laboratory of Diano D'Alba.

The company activity has continuity throughout the course of the year with peaks in the seasonal collection periods.

Company Description;

The processing company is located in the agricultural and peripheral area of the municipality of Diano d'Alba.

The activity consists of four rooms, namely: pantry / storage of raw materials, temperature-controlled cell for hazelnuts, roasting and processing laboratory, dressing room and toilet, office.

The company is very recent and equipped with entirely new equipment.

Description and examination of the Areas

The **shipping area** has a usable area of 8.5 square meters and a height of 3.00 m. The location is above ground, has natural ventilation.

The flooring has tiles, the walls are washable food paint with washable enamel up to 2 meters. There are protective devices against insects, rodents and pests.

The **production laboratory** is located above ground and has a useful surface area of 42.06 square meters with a height of 3.00 m.

Ventilation is natural.

The flooring has tiles, the walls are washable food paint with washable enamel up to 2 meters. There are protective devices against insects, rodents and pests.

The **deposit** located above ground, has an area of 15.5 square meters and a height of 3.00 m; the ventilation is natural and the flooring is tiled. Part of the space is occupied by a cold room for storing hazelnuts.

The walls are made of washable food paint and the room has protective devices against insects, rodents and weeds.

The **staff toilets** are located above ground, with a surface area of 3.06 square meters and a height of 3.00 meters. It has a natural and artificial aeration with extractor able to ensure at least 5 air changes per hour.

The flooring and walls are tiled.

It has accessories such as: an anteroom with self-closing door, a washbasin with non-manual control, a liquid soap dispenser, non-reusable towels.

The **locker room** is composed of a number of individual double-compartment lockers located in the anteroom, they are divided by sex and in sufficient numbers for the staff present.. It does not have toilets for the exclusive use of patrons.

The **equipment** available to the activity is:

For the storage of raw materials: 1 shelving and 1 refrigeration equipment.

For processing: worktops, steel sinks, hazelnut toaster, grinding machines, grinding and dough production, homogenizers, sorting belt, vibrating screen, dispenser.

For packaging, it has 1 vacuum machine.

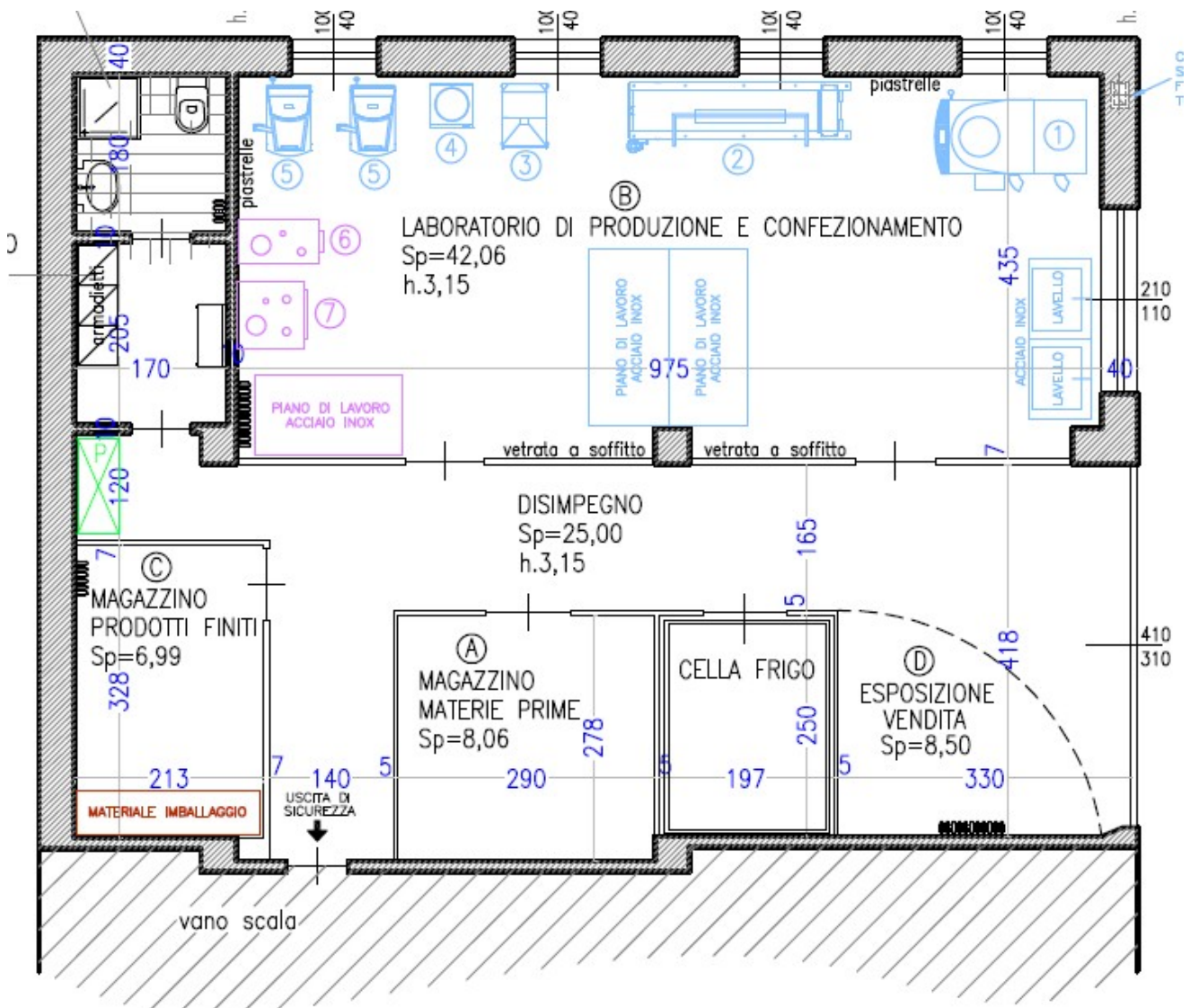
For cleaning utensils and crockery: 1 sink.

The **furnishings** available to the business are:

To store clean utensils, dishes and pots: lockable cabinets.

For waste collection: containers that can be operated by means of a pedal and with a non-recyclable collection bag.

It has a room or a cabinet for holding substances not intended for food.



PLANT IDENTIFICATION

Water distribution;

The company is served by drinking water from the municipality of Diano d'Alba. The distribution within the building is carried out by a private water system.

The methods for verifying water drinkability are described in the "Procedure for checking water drinkability".

Disposal of waste water and waste;

The typology of water waste is of the Urbani type, consisting of SEWAGE waste discharged in the Diano d'Alba Municipality conveyance plant.

SPECIAL-TOXIC / HARMFUL types of slurry are not produced.

The solid wastes produced by the activity are of the following types: solid urban wastes, delivered in the refuse collection service bin. No special solid or toxic / harmful waste is produced.

Electrical system and the possible presence of continuity units.

The company is served by distributed network electricity through a certified electrical system.

Definition of raw materials and products;

The main raw materials consist of:

Tonda Gentile Trilobata Piedmont hazelnuts (Nocciole Tonda Gentile Trilobata Piemonte)

Tonda Gentile Trilobata I.G.P. hazelnuts (Nocciole Tonda Gentile Trilobata I.G.P.)

Sugar

Cocoa Chocolate

Powdered milk

The products are represented by:

PRIMARY PRODUCTS

toasted whole hazelnuts various calibers

chopped hazelnuts various calibers

hazelnut flour

hazelnut paste

WORKED PRODUCTS

Toasted Piedmont IGP hazelnut oil

PGI Piedmont hazelnuts with praline toast

Hazelnut-based spreads

The spreadable creams are represented by products of different formulations in a phase of continuous evolution all creams are non-perishable and long-lasting, packaged in pots or drums for industry.

CHAPTER 5 – ANALYSIS OF RISKS AND PLANNING OF CONTROLS

APPLICATION OF THE PRINCIPLES OF THE HACCP SYSTEM

The application of the HACCP method within the company has included the following operations:

- 1) Definition of the work group for self-control
- 2) Definition of the flow chart
- 3) Identification of risks and preventive measures for their control
- 4) Identification of the CCPs by applying the decision tree for each phase of the process
- 5) Determination of critical limits for each CCP
- 6) Definition of a monitoring system for each CCP
- 7) Definition of corrective actions for any non-conformities
- 8) Definition of verification procedures
- 9) Definition of the documentation recording and storage methods

APPLICATION OF THE SELF-CONTROL PLAN

The application of the self-control plan provides for:

- Internal activity
- External activity

The internal activity is carried out by the company and takes shape in the application of the self-control plan.

The internal activity is divided into two phases; a planning and an implementation phase.

The main project activities are:

- Collaboration in the first design of the self-control plan
- Maintenance and review of the self-control plan
- Monitoring, verification and registration activities
- Implementation of corrective and preventive measures
- Staff training, information and education

The external activity is implemented by BioQuality technical consultants, consultancy and analysis laboratory.

The external activity is divided into:

- Support for setting up the self-control plan
- Definition of company tools for the execution of internal self-control
- Performing analysis on products and work environments
- Execution of audits on the correct application of the procedures and on the maintenance of the planned documentation (procedures, forms, records), (on demand)
- Staff training (on request)

Company figures linked to self-control

Business Manager (RA)

The Company Manager, defined OSA Food Sector Operator by EC Regulation 852/2004, is Mrs. Cristina Boffano owner of the company. The owner, assisted by the family, takes care of:

- ✓ Develop the general strategy, define the Self-Control Policy and objectives and disseminate them between company staff;
- ✓ Approve the documentation for the Self-control, the labeling and every document issued by the company;
- ✓ Authorize investments for purchases and approve the relevant suppliers;

It also performs the role of Self-Control Manager, manages and coordinates all the functions involved in the Self-Control System for related activities. In particular, the main responsibilities of the RH provide for:

- ✓ Coordinate all technical activities related to self-control;
- ✓ Supervise and possibly plan internal control activities (instrumental, manual, analytical);
- ✓ Plan and organize training and staff training based on business needs and suggestions from the staff themselves;
- ✓ Request external maintenance and calibration;
- ✓ Check the results of internal and analytical checks, activating any Corrective Actions;
- ✓ Take care of the application of the provisions of the various Procedures and Instructions, monitoring that the operations are carried out in such a way as to maintain compliance with the reference documents.

External consultants connected to the activities of Self-Control (HACCP)

The request for external professional figures must always be approved by RA.

External consultants can be introduced in the management and / or implementation of any of the activities related to the Self-Control. The transfer of tasks or the active participation of an external consultant or technician within the Self-Control System occurs after the technical functions have ascertained the possession of the required competences and a detailed contract has been stipulated that guarantees the company with regard to how much required and the consultant of the means necessary to perform his duties. The consultant who accepts one or more of the tasks listed in this document in the assignment in the above mentioned functions, assumes the responsibility.

Definition of the work group for self-control

In order to effectively develop, maintain and implement the company self-control, a working group was set up. The team figures have a common task in the design of the self-control plan in which everyone participates with their own experience and skills. Beyond the initial design it is the task of the team to implement and define any changes made necessary over time and to organize the complete revision of the system at least every two years.

Every member of the team's company carries out daily tasks for the maintenance and correct application of the defined self-control plan. The external members carry out the tasks for which they are appointed and detailed in the respective assistance contracts.

Definition of the production flow chart

The flow chart is a schematic representation of the succession over time of the operations performed. The working group has therefore analyzed all the operations carried out in the company from receiving goods to the preparation of orders and delivery so as to define the succession of the same. For the sake of practicality and clarity, the various flows were then combined into guide flows common to categories of work considered cumulative based on the following characteristics:

The same procedure as the operations

Identical features in the technological process

Involvement of the same work areas

Involvement of the same equipment and facilities

Involvement of staff with identical duties and training

The detailed description of the processing phases within the company is essential for the preparation of a targeted self-control plan with the identification of the main critical points.

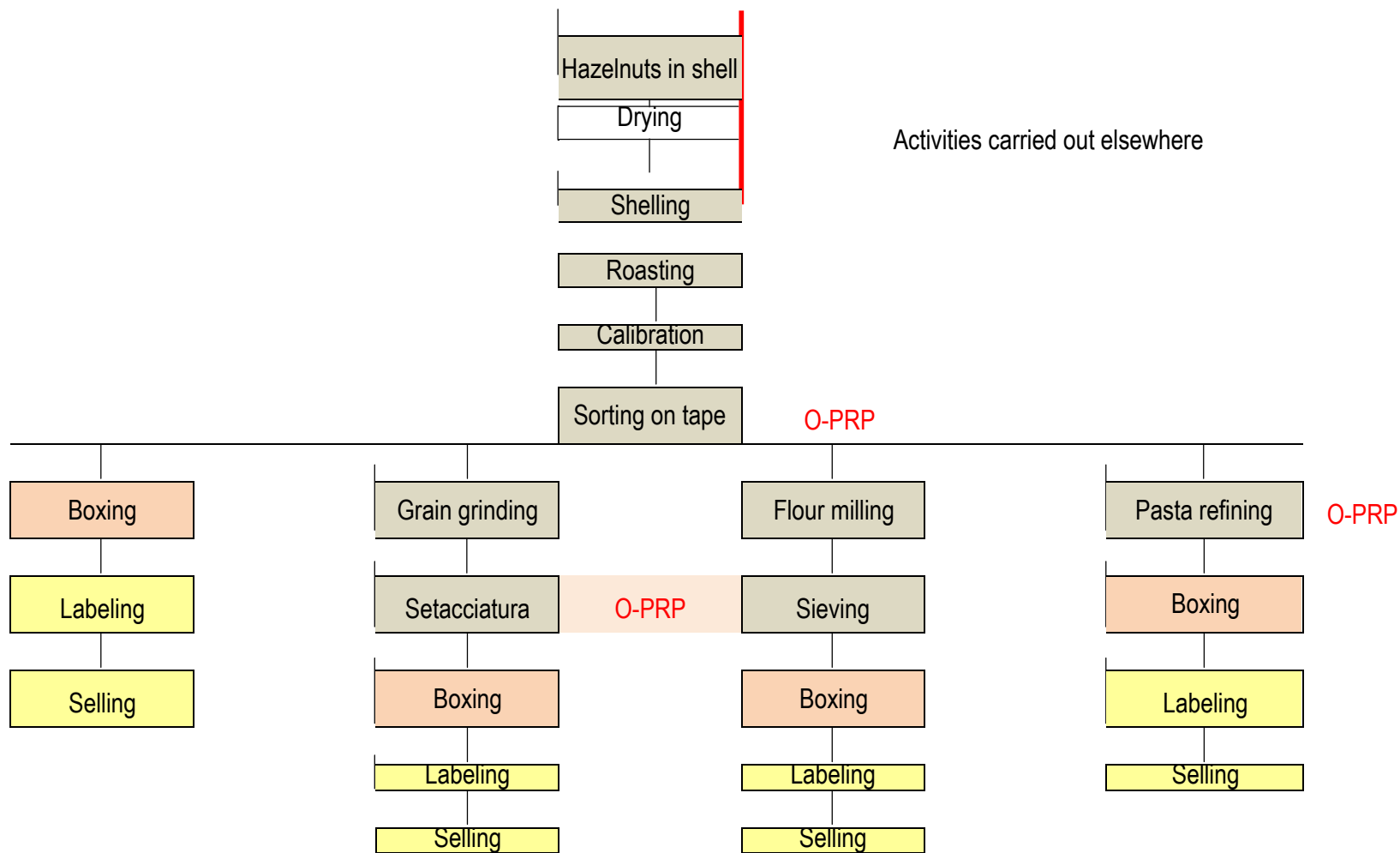
The block diagram system with numbering and phase identification was used.

Since all the PRIMARY products originate by successive steps from the same raw material, if it processes a single flow chart with multiple outputs.

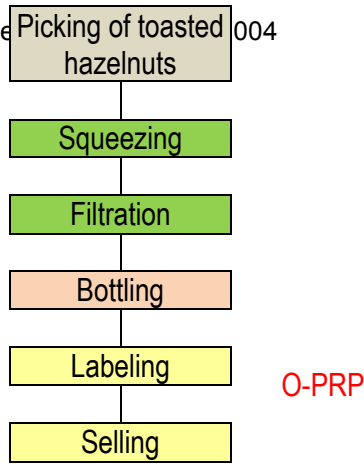
Then the diagrams of the processed products follow:

- Toasted Piedmont IGP hazelnut oil
- PGI Piedmontese hazelnuts with praline
- Hazelnut-based spreads

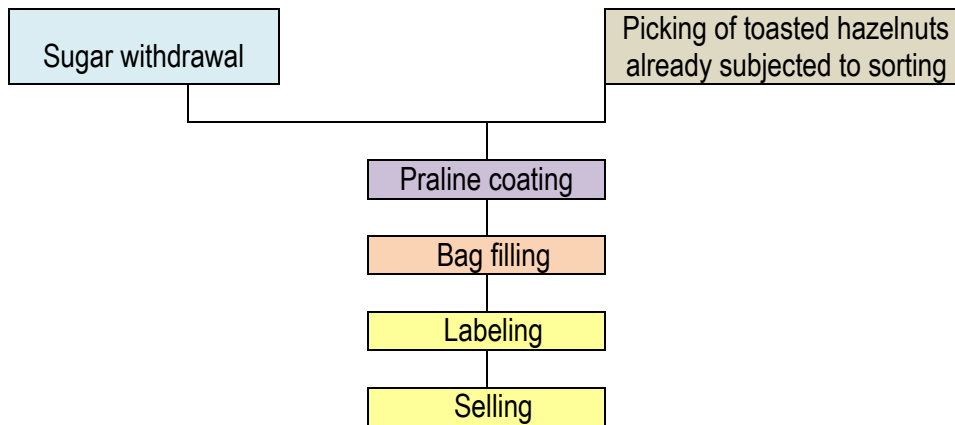
The flow diagrams already show the O-PRP indication (see description) as shown in the following chapter dedicated to risk analysis.



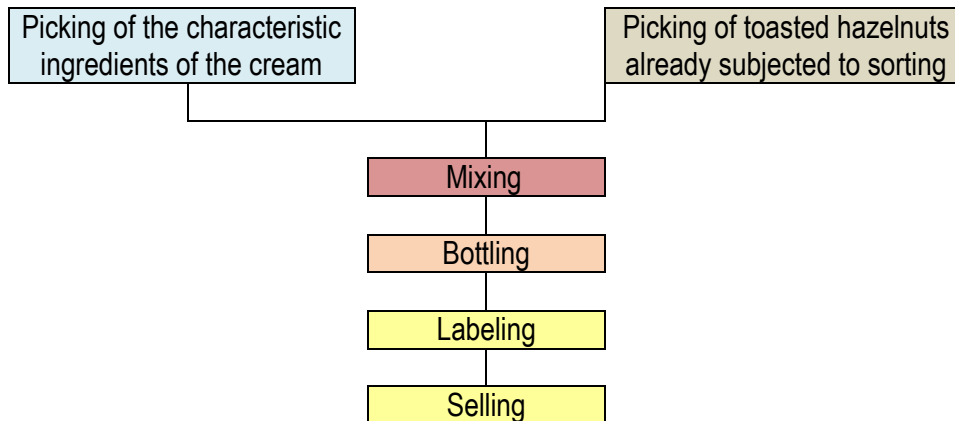
Roasted hazelnut oil



Praline hazelnuts



Hazelnut creams



CHAPTER 5 – HAZARDS IDENTIFICATION, DETERMINATION OF RISKS AND PREVENTIVE MEASURES FOR THEIR CONTROL

Definitions

DANGER: *presence or potential presence of a factor with harmful effect on health.*

RISK: *function of the probability and severity of a harmful effect on health, resulting from the presence of a hazard.*

PREVENTIVE MEASURES: *solutions or activities designed to reduce the likelihood that a given hazard will manifest itself or to limit its severity.*

Hazard identification methods

Many of the professional figures present in the company, as well as external experts in the sector, were involved in identifying the hazards.

The professionals have taken on the task of coordinating the collection of useful information, actively participating in the identification of the dangers, assessing the risks and identifying the CCPs and processing the documents of the Self-Control System proving the analysis carried out and the management of the phases to be kept under control.

Data collection

The collection of all the necessary reputed data has been implemented through:

- Interviews with company staff;
- Examination of the company plans;
- Examination of production processes, recipes, flow charts;
- Analysis of raw materials, processing aids, primary packaging;
- Examination of the Self-control plan in place in the company and of the activities carried out in this regard.

Hazards identification

The company staff was involved in identifying the dangers due to the healthiness of the products made in the company and consequent on the raw materials, the production process and any other activity. A list of hazards suggested by the working group was initially developed and based on:

Analysis of the collected data
Analysis of the analysis previously performed historical memory
Experience and technical knowledge of external consultants;
Experience of the company staff;
Suggestions taken from scientific publications, Good Practice Manuals, sector magazines.

The list of potential dangers thus elaborated has been carefully analyzed by external experts and internal staff in order to draw up a reasoned list for each work and department.

The list will be updated whenever this identification procedure is repeated. The revision occurs whenever changes to departments, recipes, raw materials, technological adjuvants, production or packaging processes or other can represent sources of new dangers, modify the risk of incidence or the effects of hazards already identified or even eliminate dangers.

The review of the dangers consequently also involves updating the risk assessment and identifying the CCPs. This activity is organized as needed by RH / RA.

Before proceeding to the risk assessment, the dangers are thoroughly studied in order to elaborate every possible solution that allows to eliminate them or reduce their incidence or effects..

Risk analysis methods

The whole working group and all the company personnel were involved in the reasoning that led to ascribe to each identified danger a severity index G_R , obtained by combining its probability of manifestation with the severity of the damage caused by its occurrence.

$$G_R = G_D \times P$$

Probability of damage (P)

The likelihood of a hazard occurring, which means that the defective product reaches the consumer (frequency of dangerous events over time) is calculated on the basis of:

- Historical incidence of danger
- Experience of the active staff at that stage of work
- General or specific technical notions

The probability is therefore defined objectively with a number with the following meanings:

- $0 < P < 1$ *unlikely damage*
- $P = 1$ *damage of which there is at least one documented case*

$1 < P < 2$ *intermediate probability damage (some documented cases)*

$2 < P < 3$ *high probability damage*

Gravity of the damage (G_D)

The severity of the damage to the consumer's health is calculated on the basis of:

Scientific data on food hygiene and medicine

Knowledge of epidemiology of biological agents and toxicity of chemical agents

Commercial destination of the product

Gravity is therefore defined objectively with a number with the following meanings:

$0 < G_D < 1$ *minor damage (problems that can be cured without medical intervention)*

$G_D = 1$ *medical intervention or hospitalization (24 hours)*

$1 < G_D < 2$ *damage of intermediate severity (hospitalization for checks and treatment 3-5 days)*

$2 < G_D < 3$ *very serious damage (possible lethality for subjects at risk)*

Risk severity (G_R)

The value of the severity of the risk is obtained by multiplying probability by the severity of the damage.

The value obtained takes on the following meanings:

$0 < G_R < 1$ *modest severity*

$1 < G_R < 3$ *damage of intermediate gravity*

$3 < G_R < 9$ *high severity damage*

For hazards with a modest severity index, documented prevention systems are generally not provided, according to average gravity, the actual need is assessed, in the case of high severity, a documented system is always envisaged.

The assignment of the representative values of incidence and severity, the risk precisely, is reported on the list of hazards described in the previous paragraph. The same audit criteria described in the previous paragraph also apply to the identification of risks.

Identification of CCPs

The identification of the CCP critical "points" in processes and manufacturing, is carried out following the indications.

The identification of CCPs is carried out by applying the "Decision Tree", proposed by the Codex Alimentarius, for each phase of the process for which unresolved risks have been identified through the application of preventive measures.

The identification of the CCPs is updated each time the risk assessment is reviewed for the reasons described in the previous chapters. This activity is organized as needed by RH.

CCP management

The company manages all the risks identified for its products because the quality policy implemented requires the maximum commitment to obtain the best possible results in terms of quality and healthiness of its products. Due to the management methods adopted, the risks are identified as shown below:

CCP

CCPs are the identified risks, following the application of the decision tree, as Critical Control Points, that is to say the phases to be kept under careful control because the overrun of defined standards implies the onset of the danger. They are managed through prescriptive procedures that define, the persons in charge of the procedure, the parameters to be monitored, the monitoring procedures, the critical limits, the emergency actions and the corrective actions in case of non-compliance, the control verification methods themselves, the procedures for recording and storing the documentation.

The management of CCPs has absolute precedence over all the activities of the Self-Control System.

The general PRPs are defined (see below) as "basic conditions and activities (of food safety) necessary to maintain a hygienic environment throughout the food chain suitable for the production, management and supply of safe finished products and safe food for human consumption". **Operational PRPs**, on the other hand, are related to the specific activity and / or product and are essential for controlling the probability of introducing hazards and / or contaminating the food product within specific process activities.

To clarify the difference between the general PRPs and the operational PRPs, we report an example: any food industry must control the danger related to the contamination of the product by pieces of hard glass / plastic that could derive from broken windows, of plastic for protecting the plants, of neon etc Control of hard glasses / plastics is a general prerequisite, therefore, any food industry will have to adopt all the necessary precautions

and monitoring to avoid this type of contamination. However, in addition to controlling the general danger deriving from glass and hard plastics in the plant, a glass-filling industry will also have the problem of having to monitor the integrity of the glass in the jars in which the products are packaged. In this case, we are in the presence of an operational prerequisite, linked to the particular activity (bottling) carried out by the organization.

CP

The CPs are the risks identified, following the application of the decision tree, as "non-CCP", but which in any case represent phases on which it is possible to maintain a sort of control. CP are those phases in which a non-critical risk may occur, but in any case undesirable, and for which the company policy prefers to intensify the operational attention.

They are managed through prescriptive procedures that define, the persons in charge of the procedure, the parameters to be kept under control with the monitoring methods and the critical limits if applicable, the emergency actions and the corrective actions in case of non-compliance, the registration and conservation methods of the documentation.

GMP or NBF

GMP is the acronym of Good Manufacturing Practice or Good Manufacturing Standards, also identified with the Italian acronym NBF.

In this group, those activities carried out to manage hazards involving multiple phases or departments are generally considered a threat to the plant's hygienic and / or environmental conditions. For example, a GMP is the fight against rodents; these animals are a danger for all the premises and for all the phases of production entailing dangers related to hygiene, the deterioration of raw materials, products, packaging, and potential vehicle of pathologies, even significant ones. The management of this phase is therefore considered necessary in the structuring of an effective Self-Control System.

They are managed through prescriptive procedures that define, the persons in charge of the procedure, the parameters to be kept under control with the monitoring methods and the critical limits if applicable, the emergency actions and the corrective actions in case of non-compliance, the registration and conservation methods of the documentation.

Hazard identification and risk analysis of toasted hazelnuts and other semi-processed hazelnut based products - *primary products* -

MICROBIOLOGICAL DANGER

The microbiological danger is limited as the low moisture content as well as the high fat content and the low water activity value constitute a limit to the growth and proliferation of degradative bacteria and an absolute limit to the survival of pathogens such as Salmonella and Listeria. Last but not least, the risk is reduced by the thermal roasting process and limited because these products are consumed only after further processing.

In any case, the company has put in place procedures to limit the possibility of contamination and pollution of the products (Personnel hygiene procedure, Staff training procedure, Cleaning and sanitation procedure) as well as periodic analytical checks.

Gravity of the damage	$G_D =$	1	The characteristics of humidity and oily percentage make hazelnuts and semi-finished products unsuitable for the proliferation of bacterial forms, especially enteric pathogens conveyed with food.
Probability of damage	$P =$	0	The transformation to which these semi-finished products are generally subjected eliminates the microbiological risk for the consumer.
Severity of danger	$G_R = G_D \times P$	0	The microbiological danger for the product is negligible. Nevertheless the company has activated all the necessary procedures to carry out the workings in compliance with the best hygienic conditions.

CCP: in the production process CCPs are not recognized due to the microbiological danger.

O-PRP: in the production process we do not recognize O-PRP due to the microbiological danger.

CHEMICAL DANGER

The chemical danger is identified in the potential presence of harmful foreign substances dissolved or dispersed in the product. They can already be present in the raw materials deriving from post-harvest treatments or during periods of storage (fumigants, preservatives, improved treatments, production accidents).

The variety of compounds found to be dangerous or considered as precautionary is extremely vast; the company guarantees with:

- ✚ Own hazelnuts Quaderno di Campagna (software for farm management)
- ✚ Purchased hazelnuts: selection of trusted suppliers of proven seriousness on the market and who can guarantee compliance with the EU protection regulations (Supplier selection procedure).

A source of chemical pollutants is also represented by the possibility that detergent and sanitizing residues or products used in maintenance (e.g. lubricants) can reach the product by contact because they are not completely removed with rinses or mistakenly used. The risk was tackled with prevention by structuring a cleaning and sanitizing procedure that uses easily rinsed products suitable for use in the food company and managing maintenance operations (maintenance procedure). Furthermore, some machines, such as hazelnut paste refiner, cannot be washed with water and detergents but only with oil.

Gravity of the damage	$G_D =$	2	The multiplicity of chemicals that can potentially reach the food chain is so vast and often hidden. This leads to assessing the relevant severity index.
Probability of damage	$P =$	1	Relying on local or in any case serious and controlled supply chains as well as on-farm prevention bring the likelihood of manifestation to low levels.
Severity of danger	$G_R = G_D \times P$	2	The chemical danger deserves above all attention from the company as the risk cannot be completely excluded with simple controls or analytical investigation.

CCP: in the production process CCPs are not recognized due to the chemical danger. No phase or process can, subject to monitoring, eliminate or reduce the risk to acceptable levels.

O-PRP: in the production process we do not recognize O-PRP due to the chemical danger.

PHYSICAL DANGER

The physical risk is identified in the potential presence of foreign substances in the product that are harmful because they could injure the oral cavity or the digestive canal. Foreign bodies may already be present in the raw materials or be introduced with processing. For the shelled product, the risk is eliminated with the sorting phase on tape, which is identified as O-PRP (in fact the phase was not specifically inserted to eliminate the risk, but it is an indispensable procedure for the product which also guarantees effectiveness in the reduction of danger) For semi-finished products such as grain and flour, the useful phase for the elimination of risk is sieving, a phase that is identified as O-PRP (this phase is also essential in the realization of the product but it also has the advantage of eliminating foreign bodies). For the pastes, the same refining process eliminates foreign bodies (the product must pass through thin extruders that act like a sieve).

Gravity of the damage	$G_D =$	2	Foreign bodies can cause injuries to the oral cavity and digestive tract.
Probability of damage	$P =$	1	Sorting, sieving and extrusion guarantee the products even if attention procedures are in any case implemented, attention in production and prevention can greatly limit the danger.
Severity of danger	$G_R = G_D \times P$	2	Sorting, sieving and extrusion are O-PRP.

CF. In the production process O-PRP are not recognized for the physical danger.

O-PRP: in the production process we recognize O-PRP for physical danger.

orting	whole hazelnuts
ieving	grains
xtrusion	paste

BIOLOGICAL DANGER

Biological danger means the dangers of contamination or damage to the product deriving from the use of goods or environments by insects or small animals. Insects can be typical weed species of foodstuffs, such as moth, or occasional opportunistic species such as flies. The animals are generally small rodents mostly represented by field mouse and gray roof mouse. Since there are no outdoor operations on loose goods, pigeons and birds in general are not present. A further danger is represented by lepidopterans typical of hazelnuts such as Ephestia and Tignola.

- ⇒ The probability that the danger occurs is very low because the pest control strategies adopted by the company are sufficient to contain the risk.
- ⇒ The severity is high because many pests can be the cause of important contamination or the noticeable deterioration of foodstuffs.

The company has adopted strategies to reduce risk:

The opening windows are shielded by mosquito nets. The doors of the production departments and warehouses are kept closed. Rodent monitoring is carried out on its own with catches, both for rodents and moths, while it is planned to use a specialized company in the event of an infestation (*Procedure for the control of rodents, insects and other unwanted animals*)

For the reasons set out above, the following indices of gravity and probability of biological danger have been ascribed:

Gravity of the damage	GD =	3	The danger can cause serious moderate damage to health due to the microbiological pollution that infestations promote.
Probability of damage	P =	1	The probability of occurrence is low because the product is stored in a cell where pests do not find acceptable nesting conditions. A product attacked by parasites will be conspicuously obvious to the consumer who will avoid consumption.
Severity of danger	GR = GD x P	3	The biological danger is unlikely to pose a health risk. The fact remains that the sale of products in poor condition or hygienic is not permitted and in addition to legal risk it represents a serious commercial and image damage. The company has activated all the procedures necessary to conduct the work in compliance with the best hygienic conditions and to prevent any possible infestation.

CCP: in the production process CCPs are not recognized due to the microbiological danger.

O-PRP: in the production process we do not recognize O-PRP due to the microbiological danger.

CHEMICAL DANGER

The chemical danger is identified in the potential presence of harmful foreign substances dissolved or dispersed in the product. For hazelnuts, they can already be present in the raw materials deriving from post-harvest treatments or in the periods of conservation suffered (fumigants, preservatives, improved treatments, production accidents). The variety of compounds found to be dangerous or considered as precautionary is extremely vast; the company guarantees with:

- ✚ Own hazelnuts Quaderno di Campagna (software for farm management)
- ✚ Purchased hazelnuts: selection of trusted suppliers of proven seriousness on the market and who can guarantee compliance with the EU protection regulations (Supplier selection procedure).
- ✚ For the other ingredients (spreadable creams) you can buy branded products or from qualified suppliers (Supplier selection procedure).

A source of chemical pollutants is also represented by the possibility that detergent and sanitizing residues or products used in maintenance (eg lubricants) can reach the product by contact because they are not completely removed with rinses or mistakenly used. The risk was tackled with prevention by structuring a cleaning and sanitizing procedure that uses easily rinsed products suitable for use in the food company and managing maintenance operations (maintenance procedure).

Gravity of the damage	$G_D =$	2	The multiplicity of chemicals that can potentially reach the food chain is so vast and often hidden. This leads to assessing the relevant severity index.
Probability of damage	$P =$	1	Relying on local or in any case serious and controlled supply chains as well as on-farm prevention bring the likelihood of manifestation to low levels.
Severity of danger	$G_R = G_D \times P$	2	The chemical danger deserves above all attention from the company as the risk cannot be completely excluded with simple controls or analytical investigation.

CCP: in the production process CCPs are not recognized due to the chemical danger. No phase or process can, subject to monitoring, eliminate or reduce the risk to acceptable levels.

O-PRP: in the production process we do not recognize O-PRP due to the chemical danger.

CCP: in the production process CCPs are not recognized for the physical danger.

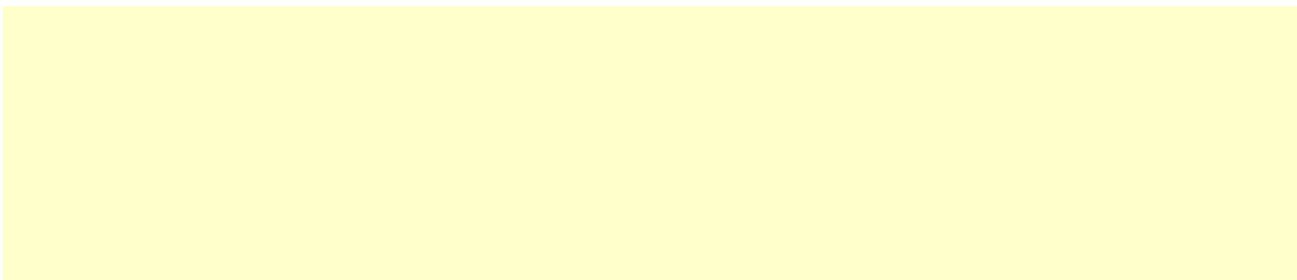
O-PRP: in the production process we recognize O-PRP for physical danger.

Sorting whole hazelnuts

PHYSICAL DANGER
Sieving grains

The physical risk is identified in the potential presence of foreign substances in the product that are harmful because they could injure the oral cavity or the digestive canal. Foreign bodies may already be present in the raw materials or be introduced with processing. For praline hazelnuts, the risk is eliminated with the phase of sorting on tape undergone by the hazelnuts, which is identified as O-PRP (in fact the phase was not specifically inserted to eliminate the risk, but it is an indispensable procedure for the product that it also guarantees effectiveness in the reduction of the danger) For hazelnut oil, the useful phase for the elimination of risk is filtration, a phase that is identified as O-PRP (also this phase is essential in the realization of the product but it also has the advantage to eliminate foreign bodies). For creams, the same refining process eliminates foreign bodies (the product must pass through thin extruders that act like a sieve).

Gravity of the damage	$G_D =$	2	Foreign bodies can cause injuries to the oral cavity and digestive tract.
Probability of damage	$P =$	1	Sorting, sieving and extrusion ensure the products even if attention procedures are in any case implemented, attention in production and prevention can greatly limit the danger.
Severity of danger	$G_R = G_D \times P$	2	Sorting, sieving and extrusion are O-PRP.



BIOLOGICAL DANGER

Biological danger means the dangers of contamination or damage to the product deriving from the use of goods or environments by insects or small animals. Insects can be typical weed species of foodstuffs, such as moth, or occasional opportunistic species such as flies. The animals are generally small rodents mostly represented by field mouse and gray roof mouse. Since there are no outdoor operations on loose goods, pigeons and birds in general are not present. A further danger is represented by lepidopterans typical of hazelnuts such as Ephestia and Tignola.

⇒ The probability that the danger occurs is very low because the pest control strategies adopted by the company are sufficient to contain the risk.

⇒ The severity is high because many pests can be the cause of important contamination or the noticeable deterioration of foodstuffs.

The company has adopted strategies to reduce risk:

The opening windows are shielded by mosquito nets. The doors of the production departments and warehouses are kept closed. Rodent monitoring is carried out on its own with catches, both for rodents and moths, while it is planned to use a specialized company in the event of an infestation (*Procedure for the control of rodents, insects and other unwanted animals*)

For the reasons set out above, the following indices of gravity and probability of biological danger have been ascribed:

Gravity of the damage	GD =	3	The danger can cause serious moderate damage to health due to the microbiological pollution that infestations promote.
Probability of damage	P =	1	The probability of occurrence is low because the product is stored in a cell where pests do not find acceptable nesting conditions. A product attacked by parasites will be conspicuously obvious to the consumer who will avoid consumption.
Severity of danger	GR = GD x P	3	The biological danger is unlikely to pose a health risk. The fact remains that the sale of products in poor condition or hygienic is not permitted and in addition to legal risk it represents a serious commercial and image damage. The company has activated all the procedures necessary to conduct the work in compliance with the best hygienic conditions and to prevent any possible infestation.

CCP: for the identified danger there are no control actions aimed at eliminating the risk.

O-PRP: in the production process they do not recognize O-PRP for biological danger.

The production process does not include CCPs and O-PRPs, but all the procedures aimed at maintaining the best hygienic conditions are considered (Cleaning and sanitizing procedure, Pre and post-operative control procedure, Training procedure and operator information, Monitoring procedure rodents and weeds).

CHAPTER 6 – MONITORING, CRITICAL LIMITS, CORRECTIVE ACTIONS

Documentation structure

The self-control manual is the document that manages the entire project designed to manage the self-control within the plant in accordance with what is required and required by EC / EU Reg. No. 852/2004. It contains company data on the structure, production, flow diagrams, raw materials and products, tasks and responsibilities for self-control are defined, the application methods of the self-control plan are described and the definition of the hazards, identification of risks and CCPs through application of the decision tree for each stage of the process.

The management of critical control points, CCP and O-PRP, of the phases still considered critical, CP, and of generalized danger situations, GMP, are managed through more streamlined documents described in detail below:

POI - Internal Operating Procedures

The procedures are documents prepared specifically to provide complete and detailed instructions in the performance of specific activities, technical, productive or managerial. They generally refer to clearly identifiable work phases and require a high degree of detail. They are developed for example for the control of CCPs and O-PRPs, for control or production operations, to regulate important management phases for food quality and hygiene.

Each procedure defines:

- The activity to which it refers is the purpose
- Implementing responsibilities
- Implementation methods
- Frequencies or situations in which the monitoring and controls to be carried out must be implemented
- Control and monitoring methods and any instructions The limit values provided
- Emergency and corrective actions in the event of non-compliance

Each POI is divided into the following paragraphs:

⇒ Purpose: identifies the final objectives of the activities described.

- ⇒ Field of application: defines the field of application of the document and its validity (functions, sectors, service lines, activities, etc.).
- ⇒ Terminology and abbreviations: gives a definition of the most important terms; it can also list any abbreviations used.
- ⇒ Responsibility: indicates the function responsible for carrying out the activities and / or checking them; it can also identify an internal reference body responsible for providing advice and interpretation regarding the procedure.
- ⇒ Operating modes: define the object of the procedure and therefore the activities to be performed and the methods to be adopted to achieve the established objectives, the actions to be performed and their logical sequence, the requirements to be followed. For greater clarity this paragraph can be replaced by one or more paragraphs with a more specific title.
- ⇒ Normative and bibliographical references: the documents referred to in the procedure or referred to for the correct execution of the activities are listed by code and title. In order of importance may be: European, state and regional laws, contractual documents, national / international standards, internal company procedures, operating instructions and manuals, etc.
- ⇒ Modules and attachments: contains the list by code, number and / or header / title of the printouts to be used and any supporting attachments.

The procedures used in the company are listed in the appropriate list.

DS - Support Documents

The term Support Documents refers to all those documents that do not follow a fixed structural scheme. They can have prescriptive or informative value. In this group, for example, flow charts, organization charts, floor plans, summary or explanatory tables, signage, this solution has the purpose of keeping under control even the particular documentation which is in any case an essential part of the Self-Control System.

Mod - Models

The monitoring and control records provided by the Self-Monitoring System are recorded on computer or paper forms. In the first case the modules are accessible only by the personnel in charge through a password and made unmodifiable through a sending system which, activated at the end of the registration as confirmation or closure of the file, makes the data unmodifiable. Paper forms are filled in with indelible ink and only by authorized personnel. They are identified by the date of compilation and the signature of the compiler.

Responsibility

Responsibilities for drawing up, identifying, verifying and approving, distributing and filing the prescriptive documents are the Corporate Responsible.

The responsibilities for completing the self-control registration documents are indicated directly in the procedures that refer to them.

All functions must:

- Propose changes and / or new procedures and instructions to the RH;
- Draw up the procedures / instructions in collaboration with the competent staff in accordance with the applicable legislation.

Identifying elements of a document

Each document prepared for the design, analysis and management of the self-control system contains the following elements (where necessary and applicable):

- Company name and plant identification;
- Title and / or name of the document;
- Revision index (progressive numerical index starting from "0" and continuing with "1", "2", etc.);
- Issue date (not provided for modules);
- Name of the function and signature of the persons responsible for drafting, verifying (when required) and approval (not provided for modules);
- Page numbering, with indication of the total number of pages.

Documents coming from outside the company (standards, technical specifications, etc.) are managed using the original identification.

The task of uniquely identifying each document is the responsibility of the Company Manager.

Distribution of documents

The documents can be distributed in two forms: controlled and uncontrolled.

In the Company's Self-Control Management System all documents are considered controlled.

The distribution of the documentation in a controlled form is carried out by the company manager.

Uncontrolled distribution is limited to the delivery of a specific revision of the document (the one valid at the time of distribution) and does not include the withdrawal of outdated revisions and the delivery of future updates. Of course, the uncontrolled distribution is recorded on the copy under the heading "Distribution" (Distribution: Controlled Not controlled).

Documents from outside the organization

External editorial documents that contain mandatory or optional requirements for the performance of the activities are verified by a responsible for:

- ⇒ Ensure that the prescriptions / information contained are known;
- ⇒ Check for any changes with respect to previous documents, check their applicability and feasibility with the external part (in case they are not mandatory);
- ⇒ Proceed with the implementation of the prescriptions contained.

They are described in detail below. The consultation of these documents does not take place through the circulation of copies, but by consulting them in the archive available to the interested functions.

MACHINE MANUALS and EQUIPMENT

They are technical documents subjected to verification by the Company Manager during the acceptance of the equipment, they are listed in the sheet of the equipment to which they refer and they are kept, in original form from the office available to the team for the Self-control.

TECHNICAL AND SAFETY DATA SHEET PRODUCTS, LEAFLET PRODUCTS

These documents are also subject to verification by the Company Manager.

They are listed in a special register and are kept in original form by the office available to the self-control team.

CHAPTER 7 – REGISTRATION OF THE SELF-CONTROL THAT IS GENERATED DURING THE PROCESSES, DEFINITION OF DOCUMENTATION RECORDING AND CONSERVATION.

Autocontrol registration control

This chapter describes the methods of identification of the Self-Control records that are generated during the processes, the description of the methods of collection, storage, evaluation, conservation, the activities carried out to ensure that the documentation of registration of the activities included in the Management System Self-control is under control, to allow the verification of the application of the rules defined in the prescriptive documents and the evaluation of the effectiveness of the group for the Self-control.

Responsibility

Responsibilities for completing the quality registration documents are indicated directly in the procedures that refer to them.

All the personnel who come into contact with the registration documents treat them in such a way as to guarantee traceability and correlability, protection and usability, confidentiality..

DOCUMENTS OF INTERNAL ORIGIN

They are standardized forms for the recording of activities, in order to guarantee the completeness of the information gathered without weighing down the work.

The compilation of these documents must take place in a complete and legible manner, all the items must be properly completed, or crossed out and / or declared as NA (not applicable) if they are not necessary. The compilation must end with the date and the signature of the assigned personnel.

TECHNICAL REGISTRATIONS

These are the records that relate to the production and process verification activities and guarantee the traceability of the recorded phase and of the supporting data.

Technical records are made as the work progresses on the various modules prepared and / or on the production books. Any corrections to the documents are made by canceling the original data so that it remains legible and countersigned, without deleting data or deleting pages; if the data is corrected, the reason for the correction is also reported.

DOCUMENTS OF EXTERNAL ORIGIN

They are documents of external origin that document the relationships with customers, suppliers, external technicians, consultants, control bodies.

MANAGEMENT OF PAPER RECORDINGS

The activities planned for managing the documentation in paper format are described below.

Storage mode

The filing methods are such as to guarantee, in any case, the correct conservation and easy availability of individual documents, data security and confidentiality.

All documentation is kept for at least **3 years**.

SELF-CHECK DOCUMENT FOR THE FOOD COMPANY.
pursuant to Article 5 EC / EU Reg. No. 852/2004
D.D. 15 October 2012, n. 692

Goods inspection procedure on dispatch

Cascina Fontane

Società Semplice Agricola

Via Molino 3, 12050 Castino

Laboratorio di Via Alba Cortemilia 50, Diano D'Alba CN

REVISION INDEX: 01

REVISION DATE: 17/02/2020

DISTRIBUTION:

CONTROLLED

NOT CONTROLLED

INDEX

INDEX.....	1
Purpose and field of application.....	2
Field of application.....	2
Responsibility.....	2
Shipment verification procedure.....	2
Registration.....	3
Normative and bibliographical references.....	5
Modules and attachments.....	5

Purpose and field of application

The company exclusively produces products packaged in waterproof protective packaging, labeled for direct distribution to the final consumer, non-perishable and long-life.

The purpose of this procedure is to verify the suitability and conformity of the goods being shipped, for all the parameters that can be verified at this stage, ie:

- ⇒ Complete and legible labeling
- ⇒ Product not expired
- ⇒ Packaging integrity and cleanliness
- ⇒ Adequacy of secondary packaging
- ⇒ Adequacy of the means of transport used for shipment

for

- ⇒ Avoid placing compromised, damaged or unsuitable goods on the market
- ⇒ Avoid placing goods with incomplete or unreadable consumer information on the market
- ⇒ Evaluate the reliability of the carriers chosen for the shipments

Field of application

This procedure applies every time goods are sold and delivered.

Responsibility

The verification of the outgoing goods is carried out directly by the appointed warehousemen. RH defines the control parameters and intervenes in the case of NC or anomalies reported by the same verifier

Shipment verification procedure

When the orders are prepared, the shipping agent works in the order as detailed below:

- ⇒ Takes delivery of the accompanying documentation prepared by the administrative office.
- ⇒ Prepare the order by checking each piece for:
 - ⇒ Complete and legible labeling

- ⇒ Expiration date
 - ⇒ Packaging integrity and cleanliness
 - ⇒ Adequacy of secondary packaging
 - ⇒ Adequacy of the means of transport used for shipping by following the instructions in the table below
 - ⇒ He proceeds with the preparation of packages and pallets
 - ⇒ Check the conditions of the means of transport for the parameters detailed in the table below which also shows the limits of acceptability, corrective actions and indications on any necessary activities following the occurrence of non-compliance
 - ⇒ Authorize the load
- ⇒ If the controls had unfavorable results for one or more parameters, implement the measures indicated in the respective tables
- ⇒ If the employee considers help in his assessments to be appropriate, he can request the intervention of the production managers, the office and the RH himself
- ⇒ In case of doubt or suspicion, the employee is required to make the most restrictive choice

Registration

There is no registration of the checks carried out on the shipment.

In case of anomalies, defects, blocking of the goods, a Non-Conformity is opened, then managed as detailed in the specific procedure.

GOODS CHECK AT SHIPMENT			
Parameters to be verified	Acceptability limits	Corrective actions	Any necessary activities following the occurrence of non-compliance
Packing	The goods must have intact, clean packaging, with clearly legible indications and labels	Segregate the goods with damaged packaging, insufficiently protective, dirty, with not clearly legible indications and labels	Report the NC to the Manager
Goods: packaging integrity and cleanliness	As far as possible determine: the goods must be in good condition, undamaged, free from abnormal odors and colors, swelling, signs of infestation, clean, free of substances and foreign bodies. The packages must be intact, without spills, not swollen, not compromised by blows	Segregate goods with anomalies. In case of doubt, consult and request the intervention of the production managers (experts) and / or the Manager	Report the NC to the Manager
Goods: labeling	The label must be complete, legible and complete. On the package must be present lot and expiration date	Segregate goods with anomalies. In case of doubt, consult and request the intervention of the Manager	Report the NC to the Manager
Goods: deadline	The goods must have an expiration date of at least 3 months at the date of shipment. In any case, inform the customer of the proximity of the deadline	Segregate goods with anomalies. In case of doubt, consult and request the intervention of the Manager	Report the NC to the Manager
Goods: secondary packaging	The secondary packaging must be intact, clean, adequate for the product	Segregate goods with anomalies. In case of doubt, consult and request the intervention of the Manager	Report the NC to the Manager
Table for checking the means of transport AT SHIPMENT			
Co-transport	Goods of different nature and in particular must not be co-transported: non-BIO goods, GMO goods, chemicals, detergents, materials not intended for the food industry, odorous or filthy materials, damaged goods, waste, earth, plants, animals.	Refuse the load in any case	Report the NC to the Manager
Type of vehicle	The vehicle must have a closed load compartment. For tipper trucks the doors and walls must be intact and well closed. For tarpaulins and curtain sides, the tarpaulins must be tightly closed.	Refuse the load in any case	Report the NC to the Manager
Load compartment	It must be clean, intact. It must not have wet, greasy, stains of substances that are difficult to identify	Refuse the load in any case	Report the NC to the Manager
Load stop	The load must have been properly stopped, there must be no overturned, stacked goods	Refuse the load in any case	Report the NC to the Manager

Normative and bibliographical references

Modules and attachments

SELF-CHECK DOCUMENT FOR THE FOOD COMPANY
pursuant to Article 5 EC / EU Reg. No. 852/2004
D.D. 15 October 2012, n. 692

Procedure for controlling the processing of ground hazelnuts

Cascina Fontane

Società Semplice Agricola

Via Molino 3, 12050 Castino

Laboratorio di Via Alba Cortemilia 50, Diano D'Alba CN

REVISION INDEX: 01

REVISION DATE: 17/02/2020

DISTRIBUTION:

CONTROLLED

NOT CONTROLLED

INDEX

INDEX.....	1
Process of checking in the minced hazelnut processing	2
Assumptions	2
Purpose and field of application	2
Responsibility	2
Operating modes	2
Application.....	3
Acceptability limits, corrective actions.....	3
Documentation Archiving	3
Normative and bibliographical references	4
Modules and attachments	4

Process of checking in the minced hazelnut processing

Assumptions

The grinding process is a continuous closed process that takes place within the milling structure. The phases of this process are carried out by different machines in which the product passes transported by ducts, elevators, augers. The different phases of the system can however be inspected through bushings. It is therefore possible to monitor the efficiency of the processing phases considered critical for the quality and wholesomeness of the final product.

Purpose and field of application

The purpose of this procedure is to keep the following phases under control for the detailed aspects as reported in the risk analysis scheme.

Each process is managed through a form that provides for the recording of the checks carried out, the outcomes and the possible management of non-conformities.

Responsibility

The processing control is performed by RH. The results of the checks are approved by RA. RH assignments include:

- Perform process checks
- Manage and record non-conformities
- Implement corrective measures
- Record the results of the checks
- Archive the registration documents

Operating modes

Each process for making hazelnuts and / or ground hazelnuts involves checking and recording the following phases:

RAW MATERIAL CHECK	Visual inspection of the lot (internal lot) to be milled: <ul style="list-style-type: none"> • <i>Attack and / or proliferation of weeds and / or rodents, moistening, mold growth, germination</i> • <i>Insufficient removal of foreign bodies and undesirable parts</i>
MANUAL SORTING	<ul style="list-style-type: none"> • See procedure
PRE-OPERATIVE SIEVES CHECK	<ul style="list-style-type: none"> • Check the integrity of the sieve meshes • Check the correct positioning and stop of the sieves
POST-OPERATIVE SIEVES CHECK	<ul style="list-style-type: none"> • Check the correct positioning and stop of the sieves • Check the integrity of the sieve meshes

Application

This procedure applies to all the grinding cycles carried out: flour, grain, hazelnut paste.

Acceptability limits, corrective actions

Simultaneously with the monitoring in progress, the person in charge of the procedure must compare the data of the findings with the limit values of acceptability listed below so as to be able to implement, point by point, the corrective actions on the process.

CHECK		NON-COMPLIANCE	CORRECTIVE ACTION
RAW MATERIAL CHECK visual inspection of the lot (lot internal) to be subjected to grinding / refining	Attack and / or proliferation of weeds and / or rodents	Absence of fragments, exuvia, insect residues, rodent hairs	The infested lot must be removed (not suitable for human consumption)
	Moistening, mold growth, germination	Imperceptible	Eliminate the batch, subject to laboratory analysis to exclude mycotoxins, allocate, if within limits, only to animal feed
	Insufficient removal of foreign bodies and undesirable parts	A limited presence of particles, a slight dust is acceptable.	Repeat the cleaning phase
MANUAL SORTING		<ul style="list-style-type: none"> See sorting procedure 	
PRE-OPERATIVE SIEVES CHECK	Check of the integrity of the mesh of the sieves	Damage to the meshes of the sieves Cracks Canvas relaxation	Replace the canvas / sieves
	Check the correct positioning and stop of the sieves	Sieves not firmly in place	Replace the sieves correctly
POST-OPERATIVE SIEVES CHECK	Check of the correct positioning and stop of the sieves	Sieves not firmly in place	Replace the sieves correctly. Resetting the entire lot by repeating the pre- and post-operative checks
	Check of the integrity of the mesh of the sieves	Damage to the sieve meshes Cracks Canvas relaxation	Replace the canvases and resetting the entire lot by repeating the pre and post operative checks

Documentation Archiving

Only non-compliant events are recorded on the Non-Compliance Report.

Normative and bibliographical references

Modules and attachments

/

SELF-CHECK DOCUMENT FOR THE FOOD COMPANY

pursuant to Article 5 EC / EU Reg. No. 852/2004
D.D. 15 October 2012, n. 692

Pre-operative and post-operative control procedure

Cascina Fontane

Società Semplice Agricola

Via Molino 3, 12050 Castino

Laboratorio di Via Alba Cortemilia 50, Diano D'Alba CN

REVISION INDEX: 01

REVISION DATE: 17/02/2020

DISTRIBUTION:

CONTROLLED

NOT CONTROLLED

INDEX

INDEX.....	1
Purpose	2
Field of application.....	2
Responsibility	2
Pre-operation inspection.....	2
Implementation methods.....	2
Frequencies or situations in which it must be implemented.....	2
Monitoring and checks to be carried out	3
Post-operative control.....	3
Implementation methods.....	3
Frequencies or situations in which it must be implemented.....	4
Monitoring and checks to be carried out	4
Estimated limit values, emergency and corrective actions in the event of non-compliance.....	5
Normative and bibliographical references	6
Modules and attachments	6

Purpose

This procedure describes the checks carried out in the goods storage and packaging premises prior to the start of processing, in order to guarantee operations in hygienic and functional conditions, and at the end of the work, including reorganization and cleaning operations, to ascertain the correct execution of cleaning procedures and to verify their effectiveness. It is in fact a fundamental condition to operate in clean and tidy rooms and with a guarantee of efficiency of all the necessary instruments. No less important is to leave the premises in due conditions after work in order to prevent phenomena of bacterial proliferation, attraction of insects and animals and to spread dirt and contamination.

For practical reasons, pre-operational checks are extended to the personnel in charge of the operations that will be carried out.

Field of application

This procedure is applied at the beginning, for the pre-operational phase, and at the end of the operations, for the post-operative phase.

Responsibility

The verification methods indicated in this procedure are approved by the Company Manager. The pre-operational and post-operative verification of the work areas is carried out by expert operators trained during the annual courses or, in the case of changes to the procedure, supported by the Company Manager for a number of verifications necessary for learning.

Pre-operation inspection

Implementation methods

The control includes visual verification activities and practical tests in the storage rooms, including cells, and goods handling areas, recording the results of the control on a specific report, the application of any corrective actions and recording them on the same report or , if necessary, serious NC, on non-compliance report.

Frequencies or situations in which it must be implemented

Pre-operation inspection is carried out before the start of activities in each individual room.

Monitoring and checks to be carried out

The person in charge of the control proceeds as described below:

- ↪ Verify that in the area there are no anomalous odors, that no smells come from the sinks and sink drains, from the machines connected to the water network.
- ↪ Check that the area is in order, there are no materials, waste, abandoned goods, stored goods or wrongly introduced.
- ↪ Check that doors and windows are functional, that the mosquito nets are intact.
- ↪ Check the integrity of windows, lamps, other structures with glass or transparent plastic.
- ↪ Check the cleaning conditions of the area by carefully inspecting the most hidden corners, windowsills, under machines or furnishings.
- ↪ Check the cleanliness conditions of the refrigerated cells by carefully inspecting the most hidden points.
- ↪ Check the functionality of the cells; below is a summary table of the main controls to be implemented on each type of machine and equipment. The table also shows the corrective actions in the event of a defect.
- ↪ Check the water supply. Also check that the water delivered is promptly removed from the discharge demonstrating its functionality and efficiency.
- ↪ Finally, check that the staff in charge of operating in that area have worn the complete uniform of all its parts, that the clothes have been worn correctly, that they are clean and tidy. It also verifies that the staff has discharged jewelry and anything else required by the specific instruction.
- ↪ In the event of non-compliance, note the results of the checks on the non-conformity form.
- ↪ In the case of NC, it applies the corrective actions envisaged and described in the following paragraphs. He then notes the interventions carried out on the same module.
- ↪ In case of serious NC or for which AC has not been foreseen, requires the intervention of RM. In this case the NCs will be managed as described in the procedure concerning the subject.
- ↪ In case of complete compliance or if the implementation of the CAs has brought the conditions to complete compliance, it starts the planned operations.

Post-operative control

Implementation methods

The control includes visual verification activities and practical tests in the rooms in the storage rooms, including cells, and goods handling areas, the recording of the control results on a specific report, the application of

any corrective actions and the recording of the same on the same report or, if necessary, serious NC, on non-conformity report.

Frequencies or situations in which it must be implemented.

The post-operative check is carried out at the end of the work after the cleaning operations have been carried out with the aim of guaranteeing adequate conditions for a new production process.

Monitoring and checks to be carried out.

The person in charge of the control proceeds as described below:

- ↪ Check that there are no abnormal odors in the area, that no smells come from the sink and drain drains.
- ↪ Check that the area is in order, there are no materials, waste, abandoned, stored or incorrectly introduced goods.
- ↪ Check that doors and windows are functional, that the mosquito nets are intact.
- ↪ Check the integrity of windows, lamps, other structures with glass or transparent plastic.
- ↪ Check the cleaning conditions of the area by carefully inspecting the most hidden corners, windowsills, under machines or furnishings.
- ↪ Check the cleanliness of the equipment by carefully inspecting the most hidden points.
- ↪ Check the water supply. It also checks that the water supplied is promptly removed from the drain demonstrating its functionality and efficiency.
- ↪ Write down the results of the checks on the form.
- ↪ In the case of NC, it applies the corrective actions envisaged and described in the following paragraphs. He then notes the interventions carried out on the NC management module.
- ↪ In case of serious NC or for which AC has not been foreseen, it requires the intervention of RH. In this case the NCs will be managed as described in the procedure concerning the subject.
- ↪ In case of complete compliance or if the implementation of the CAs has brought the conditions to complete compliance, start the planned operations.

Estimated limit values, emergency and corrective actions in the event of non-compliance

Check	Acceptability limit	Corrective actions in case of deviation
Abnormal odors in the area	The phenomenon is not acceptable	Carefully inspect the area to detect any source; remove the cause. Repeat the cleaning operations throughout the area.
Abnormal odors from manholes	The phenomenon is not acceptable	Wash ducts, grills and manhole covers with hot water and lance. Disinfect with chlorine. Provide to clear the manhole covers with special chemical products. Repeat the washing operations throughout the area.
Abnormal odors from drains	The phenomenon is not acceptable	Unblock the drain with special chemicals. Repeat the washing operations on the sinks.
Disorder, materials, waste, abandoned, stored or incorrectly introduced goods	The phenomenon is not acceptable	Discard non-conforming material. Repeat the cleaning operations in the area. Admonish the operators in charge of cleaning operations and report them to RH.
Doors and windows	They must be intact, well closed and openable. The springs on the doors must completely close the opening when released.	Request appropriate repairs. Activities cannot be resumed until completion of the work.
Mosquito nets	The mosquito nets must be intact, well fixed, clean and well stretched.	
Stained glass, lamps, other structures with glass or transparent plastic	All glass or plexiglass structures they must be intact.	
Cleaning conditions of the area	The area must be perfectly clean, with no residue or accumulation in the most hidden corners. There must not be incrustations, greasy traces, stains, stagnant water.	Repeat the cleaning operations throughout the area. Warning the operators in charge of cleaning operations and report them to RH
Equipment cleaning conditions	All the equipment present must be perfectly clean, with no residue or accumulation in the most hidden corners. There must not be incrustations, greasy traces, stains, stagnation of water.	Repeat the equipment cleaning operations. Warning the operators in charge of cleaning operations and report them to RH.
Hot water supply	Present and available in a short time	Request appropriate repairs.
Cold water supply	Available with regular and abundant flow	
Functionality and efficiency discharge	Quick and complete water removal	Unblock the drain with special chemicals. Repeat the washing operations on the sinks.

Normative and bibliographical references

Modules and attachments

❖ --

SELF-CHECK DOCUMENT FOR THE FOOD COMPANY
pursuant to Article 5 EC / EU Reg. No. 852/2004
D.D. 15 October 2012, n. 692

Procedure for analytical control

Cascina Fontane

Società Semplice Agricola

Via Molino 3, 12050 Castino

Laboratorio di Via Alba Cortemilia 50, Diano D'Alba CN

REVISION INDEX: 01

REVISION DATE: 17/02/2020

DISTRIBUTION:

CONTROLLED

NOT CONTROLLED

INDEX

INDEX	1
Purpose	2
Field of application	2
Responsibility	2
Operating modes	2
Types of analysis	2
Analysis plan	2
Analytical checks for chemical safety	3
Analytical validation checks	3
Corrective actions to be taken in the event of non-compliance	4
Normative and bibliographical references	4
Modules and attachments	4

Purpose

The analytical controls are mainly oriented towards:

Supplier's initial assessment;

Check on finished products.

Analyzes rarely assume importance and significance in prevention; generally, analysis is used to verify, in retrospect, the proper functioning of the system. The initial assessment of the supplier is subject to a specific procedure.

The analysis on finished products is aimed at verifying:

The application of correct self-control procedures;

The effectiveness of the self-control system.

The self-control system therefore uses the analytical determination exclusively as an act of verification and validation of the system itself.

Field of application

This procedure applies to raw materials and products made by the company.

Responsibility

The organization of the analytical self-control plan is the responsibility of the Self-Control Manager. The sampling and analysis activities are the responsibility of the laboratory in charge.

Operating modes

Types of analysis

Each product has its own specificities that make it impossible to generalize the grid of controls to be performed. However, some key parameters to be used as an index in analytical assessments can be identified.

For regulated products, the minimum grid is that required by law. In the cross-checks on the analyzes presented by the supplier, only some parameters to be used for comparison can be taken into consideration.

Analysis plan

The chemical and microbiological examination program is reviewed annually; frequency and characteristics of the analyzes are established based on:

- Legal obligations;
- Type of products;
- Production quantities;
- Results of previous analysis.

The analysis plan defines exactly the expected frequencies and parameters, the limits of acceptability. The method used is indicated for each analysis.

This procedure will be re-issued only in case of need for changes during the annual review.

Analytical checks for chemical safety

ESSAY	METHOD	PRODUCT	LIMIT VALUES	FREQUENCY
aflatoxins B1, B2, G1, G2	UNI EN 12955:1999 or equivalent	Own hazelnuts	B1 < 5 µg/Kg; TOTAL < 10 µg/Kg Reg. CE 165/2010	2nd YEAR Season start Season end
aflatoxins B1, B2, G1, G2	UNI EN 12955:1999 or equivalent	Purchased hazelnuts	B1 < 8 µg/Kg; TOTAL < 10 µg/Kg Reg. CE 165/2010	2nd YEAR Season start Season end choosing a quantity among the most large or mixed purchases

Analytical checks of hygiene validation

ESSAY	METHOD	PRODUCT	LIMIT VALUES	FREQUENCY
Coliforms at 30 °C	ISO 4832:2006	Hazelnut paste	<1000 UFC/g	Annual
Escherichia coli β-glucuronidase positive at 44 °C	UNI 10980:2002		<100 UFC/g	
Coagulase-positive staphylococci at 37 °C	UNI EN ISO 6888-1:2004		<100 UFC/g	
Coliforms at 30 °C	ISO 4832:2006	Hazelnut grains	<1000 UFC/g	Annual
Escherichia coli β-glucuronidase positive at 44 °C	UNI 10980:2002		<100 UFC/g	
Coagulase-positive staphylococci at 37 °C	UNI EN ISO 6888-1:2004		<100 UFC/g	
Coliforms at 30 °C	ISO 4832:2006	Spreadable cream (1 product per year in rotation)	<1000 UFC/g	Annual
Escherichia coli β-glucuronidase positive at 44 °C	UNI 10980:2002		<100 UFC/g	
Coagulase-positive staphylococci at 37 °C	UNI EN ISO 6888-1:2004		<100 UFC/g	

Corrective actions to be taken in the event of non-compliance

- ✚ Aflatoxins B1, B2, G1, G2 OUT OF LIMITS

STOP THE PRODUCT

- ✚ TEST coliforms at 30 °C OUT OF LIMITS
- ✚ TEST escherichia coli β -glucuronidase positive at 44 °C OUT OF LIMITS
- ✚ TEST coagulase-positive staphylococci at 37 °C OUT OF LIMITS

STOP THE PRODUCT

Normative and bibliographical references

- ❖ EC / EU Regulation No. 1881 of 19/12/2006; Regulation (EC) n. 1881/2006 of the Commission, of December 19, 2006, which defines the maximum levels of some contaminants in food products.
- ❖ EC / EU Regulation 165/2010, with regard to aflatoxins, modifying Regulation (EC) n. 1881/2006 which defines the maximum levels of some contaminants in food products.

Modules and attachments

- ❖ ---

PRODUCTION CHECKS

CHECK		NON-COMPLIANCE	CORRECTIVE ACTION
RAW MATERIAL CHECK visual inspection of the lot (internal lot) to be subjected to grinding / refining	Attack and / or proliferation of weeds and / or rodents	Absence of fragments, exuviae, insect residues, rodent hairs	The infested lot must be removed (not suitable for human consumption)
	Moistening, mold growth, germination	Imperceptible	Eliminate the batch, subject to laboratory analysis to exclude mycotoxins, allocate, if within limits, only to animal feed
	Insufficient removal of foreign bodies and undesirable parts	A limited presence of particles, a slight dust is acceptable	Repeat the cleaning phase
MANUAL SORTING		<ul style="list-style-type: none"> See sorting procedure 	
PRE-OPERATIVE CHECK FOR SIEVES	Verification of the integrity of the mesh sieves	Damage to the mesh sieves Sieves Cracks Canvas relaxation	Replace the canvas / sieves
	Check the correct positioning and stop of the sieves	Sieves not firmly in place	Replace the sieves correctly
POST-OPERATIVE CHECK FOR SIEVES	Verification of the correct positioning and stop of the sieves	Sieves not firmly in place	Replace the sieves correctly. Resetting the entire lot by repeating the pre- and post-operative checks
	Verification of the mesh sieves integrity	Damage to the sieve meshes Cracks Canvas relaxation	Replace the canvases and reset the entire lot by repeating the pre- and post- operative checks



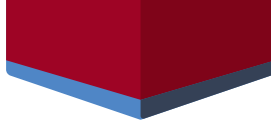
SUPPLIER QUESTIONNAIRE

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: Cascina Fontane SSA Today's Date: 04/28/2021
Factory Address: Via Molino 3
City: Castino Province: CN Country: Italy
Office Address: Via Alba Cortemilia 50
City: Diano D'Alba Province: CN Country: Italy
FDA Registration No.: 10168521158 DUNS No.: _____
FDA Establishment Id.: _____ Phone No.: +393282168587
QC/QA's Name: _____ E-mail: info@cascinafontane.it

SUPPLIER CLASS

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

- | | | | |
|--|--|----------------------------------|--------------------------------------|
| <input checked="" type="checkbox"/> Manufacturer (<i>Raw Material</i>) | <input checked="" type="checkbox"/> Processor | <input type="checkbox"/> Packer | <input type="checkbox"/> Re-Packer |
| <input checked="" 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 checked="" 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? 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.

No. 01, Product Name: PASTE OF NOCCIOLA PIEMONTE PGI Product Code: _____
No. 02, Product Name: _____ Product Code: _____
No. 03, Product Name: _____ Product Code: _____
No. 04, Product Name: _____ Product Code: _____
No. 05, Product Name: _____ Product Code: _____
No. 06, Product Name: _____ Product Code: _____

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 checked="" 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

We send a sample of our product to a laboratory to have it analyzed.

FREQUENCY of VALIDATION

The frequency of the analysis is one time a year, however analyzes can also be carried out in a shorter period of time following a specific request from customers.

U.S. FDA HAZARD PROFILE

Category Name:
Category Number:
Subcategory Name:
Storage Type:

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

Research aflatoxins (B1, B2, G1, G2)

FREQUENCY of VALIDATION

The frequency of the analysis is two times a year, however analyzes can also be carried out in a shorter period of time following a specific request from customers

U. S. FDA HAZARD PROFILE

Category Name:
Category Number:
Subcategory Name:
Storage Type:

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.

- | | |
|---|---|
| <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Recontamination with environmental pathogens. <input checked="" type="checkbox"/> Bacterial growth and/or toxin formation due to lack of time / temperature control. <input checked="" type="checkbox"/> Bacterial growth and/or toxin formation due to reduced oxygen packaging. | <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Bacterial pathogen survival of a lethal treatment. <input checked="" type="checkbox"/> Recontamination due to lack of container integrity. <input checked="" 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

MOCA analysis on packaging to ensure its integrity;
 - Storage and storage of the products at correct temperatures;
 - Consumption of the products within and not beyond the shelf-life,
 - Correct sanitary hygienic practice.

FREQUENCY of VALIDATION

The frequency of the analysis is one time a year, however analyzes can also be carried out in a shorter period of time following a specific request from customers

U. S. FDA HAZARD PROFILE

Category Name:
 Category Number:
 Subcategory Name:
 Storage Type:

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 checked="" type="checkbox"/> Glass | <input checked="" type="checkbox"/> Extraneous Matter | <input checked="" type="checkbox"/> Plastics |
| <input checked="" type="checkbox"/> Stones | <input checked="" 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

The freshly picked hazelnut is placed inside an air cleaner to eliminate foreign materials (stones, plastic, glass, metal).
It is then calibrated and separated from the tastes by a grid.
Once roasted the hazelnut is checked on a sorting tape to verify the quality of the product and to eliminate any foreign materials and shells.
For the preparation of the pasta, the hazelnut is processed inside a mill with a magnet that eliminates any traces of metals and is eventually filtered.

FREQUENCY of VALIDATION

The frequency of the analysis is one time a year, however analyzes can also be carried out in a shorter period of time following a specific request from customers

U.S. FDA HAZARD PROFILE

Category Name:
Category Number:
Subcategory Name:
Storage Type:

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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Milk or Milk Derivatives	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" 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
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: 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: Ambiente Servizi

Number of yearly visits: 4

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: The products are identified with a batch

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.

Following the customer's complaint, we proceed with the evaluation of the actual problem encountered and proceed with the collection of the wrong product and replacement with goods in accordance with its requests.

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: Cristina Boffano

Title: Owner

Today's Date: 04/28/2021



Test Report n. 32378 of the 08/07/2020

Customer

CASCINA FONTANE
Via Guido Cane, 1 - Fraz. Valle Talloria
Diano d'Alba CN 12055

Sample	Description	SURFACE
	Declared denomination	PLASTIC BASKET FOR HAZELNUTS
	Identification # assigned by the laboratory	32378
Container	Description	COLLECTION PAD
Sampling	Performer	CUSTOMER
	Date and time of sampling	03/07/2020 - 15:00
	Method / Procedure	ISO 18593:2018 p.to 7.5.3 (pad)
Delivery	Performer	Customer

Sample receipt date 03/07/2020

Sample acceptance date 03/07/2020

Test	Start	Finish	Method	Result	Unit of measure	Measurement uncertainty	Limit Values
Microorganisms count at 30 °C	03/07/2020	06/07/2020	ISO 18593:2018+ ISO 4833-1:2013	86 estimated	CFU/100cm ²	/	/
Microorganisms count at 30 °C	03/07/2020	06/07/2020	ISO 18593:2018+ ISO 4833-1:2013	0,86 estimated	CFU/cm ²	/	/
Enterobacteriaceae count	03/07/2020	04/07/2020	ISO 18593:2018 + ISO 21528-2:2017	<10	CFU/100cm ²	/	/
Enterobacteriaceae count	03/07/2020	04/07/2020	ISO 18593:2018 + ISO 21528-2:2017	<0,1	CFU/cm ²	/	/

NOTE:

DIREZIONE TECNICA
Dr. Laura Icardi



End of Test Report

The results reported in this test report refer exclusively to the sample subjected to analysis. In the event that the Laboratory is not responsible for the sampling phase, the results refer to the sample as received. This test report cannot be partially reproduced without the written authorization of the Laboratory.

The decision rule for issuing conformity judgments does not envisage taking into account the contribution of measurement uncertainty to the result. The Laboratory issues judgments of conformity on the basis of the limits of the law in force and / or on the basis of the limits agreed with the customer.

L.O.D. = Limit of detection. It is the lowest concentration of analyte that can be detected, but not quantified by the analytical method. L.Q. = Limit of quantification. It is the lowest concentration of analyte that can be quantified by the analytical method. LI = Lower limit LS = Upper limit. The value preceded by the graphic sign "<" (lower) indicates that the result found is lower than the measuring range applied by the laboratory. The value preceded by the graphic sign ">" (greater) indicates that the result found is greater than the measuring range applied by the laboratory.



Test Report n. 32379 of the 08/07/2020

Customer

CASCINA FONTANE
Via Guido Cane, 1 - Fraz. Valle Talloria
Diano d'Alba CN 12055

Sample	Description	SURFACE
	Declared denomination	INTERNAL WALL BATHROOM SINK
	Identification # assigned by the laboratory	32379
Container	Description	COLLECTION PAD
Sampling	Performer	CUSTOMER
	Date and time of sampling	03/07/2020 - 15:00
	Method / Procedure	ISO 18593:2018 p.to 7.5.3 (pad)
Delivery	Performer	Customer

Sample receipt date 03/07/2020

Sample acceptance date 03/07/2020

Test	Start	Finish	Method	Result	Unit of measure	Measurement uncertainty	Limit Values
Microorganisms count at 30 °C	03/07/2020	06/07/2020	ISO 18593:2018+ ISO 4833-1:2013	60 estimated	UFC/100cm ²	/	/
Microorganisms count at 30 °C	03/07/2020	06/07/2020	ISO 18593:2018+ ISO 4833-1:2013	0,60 estimated	UFC/cm ²	/	/
Enterobacteriaceae count	03/07/2020	04/07/2020	ISO 18593:2018 + ISO 21528-2:2017	<10	UFC/100cm ²	/	/
Enterobacteriaceae count	03/07/2020	04/07/2020	ISO 18593:2018 + ISO 21528-2:2017	<0,1	UFC/cm ²	/	/

NOTE:

DIREZIONE TECNICA
Dr. Laura Icardi



End of Test Report

The results reported in this test report refer exclusively to the sample subjected to analysis. In the event that the Laboratory is not responsible for the sampling phase, the results refer to the sample as received. This test report cannot be partially reproduced without the written authorization of the Laboratory.

The decision rule for issuing conformity judgments does not envisage taking into account the contribution of measurement uncertainty to the result. The Laboratory issues judgments of conformity on the basis of the limits of the law in force and / or on the basis of the limits agreed with the customer.

L.O.D. = Limit of detection. It is the lowest concentration of analyte that can be detected, but not quantified by the analytical method. L.Q. = Limit of quantification. It is the lowest concentration of analyte that can be quantified by the analytical method. LI = Lower limit LS = Upper limit. The value preceded by the graphic sign "<" (lower) indicates that the result found is lower than the measuring range applied by the laboratory. The value preceded by the graphic sign ">" (greater) indicates that the result found is greater than the measuring range applied by the laboratory.



Test Report n. 32380 of the 08/07/2020

Customer

CASCINA FONTANE
Via Guido Cane, 1 - Fraz. Valle Talloria
Diano d'Alba CN 12055

Sample	Description	SURFACE
	Declared denomination	PLASTIC BASKET FOR HAZELNUTS
	Identification # assigned by the laboratory	32380
Container	Description	COLLECTION PAD
Sampling	Performer	CUSTOMER
	Date and time of sampling	03/07/2020 - 15:00
	Method / Procedure	ISO 18593:2018 p.to 7.5.3 (pad)
Delivery	Performer	Customer

Sample receipt date 03/07/2020

Sample acceptance date 03/07/2020

Test	Start	Finish	Method	Result	Unit of measure	Measurement uncertainty	Limit Values
Microorganisms count at 30 °C	03/07/2020	06/07/2020	ISO 18593:2018+ ISO 4833-1:2013	95 estimated	UFC/100cm ²	/	/
Microorganisms count at 30 °C	03/07/2020	06/07/2020	ISO 18593:2018+ ISO 4833-1:2013	0,95 estimated	UFC/cm ²	/	/
Enterobacteriaceae count	03/07/2020	04/07/2020	ISO 18593:2018 + ISO 21528-2:2017	<10	UFC/100cm ²	/	/
Enterobacteriaceae count	03/07/2020	04/07/2020	ISO 18593:2018 + ISO 21528-2:2017	<0,1	UFC/cm ²	/	/

NOTE:

DIREZIONE TECNICA
Dr. Laura Icardi



End of Test Report

The results reported in this test report refer exclusively to the sample subjected to analysis. In the event that the Laboratory is not responsible for the sampling phase, the results refer to the sample as received. This test report cannot be partially reproduced without the written authorization of the Laboratory.

The decision rule for issuing conformity judgments does not envisage taking into account the contribution of measurement uncertainty to the result. The Laboratory issues judgments of conformity on the basis of the limits of the law in force and / or on the basis of the limits agreed with the customer.

L.O.D. = Limit of detection. It is the lowest concentration of analyte that can be detected, but not quantified by the analytical method. L.Q. = Limit of quantification. It is the lowest concentration of analyte that can be quantified by the analytical method. LI = Lower limit LS = Upper limit. The value preceded by the graphic sign "<" (lower) indicates that the result found is lower than the measuring range applied by the laboratory. The value preceded by the graphic sign ">" (greater) indicates that the result found is greater than the measuring range applied by the laboratory.



Test Report n. 32381 of the 08/07/2020

Customer

CASCINA FONTANE
Via Guido Cane, 1 - Fraz. Valle Talloria
Diano d'Alba CN 12055

Sample	Description	SEMI-FINISHED PRODUCT
	Declared denomination	HAZELNUT PASTE - LOT: 20/27 - EXPIRY: 6/2021
	Identification # assigned by the laboratory	32381
Container	Description	STERILE JAR
Sampling	Performer	CUSTOMER
Delivery	Performer	Customer
Sample receipt date	03/07/2020	
Sample acceptance date	03/07/2020	

Test	Start	Finish	Method	Result	Unit of measure	Measurement uncertainty	Limit Values
Microorganisms count at 30 °C	03/07/2020	06/07/2020	ISO 4832:2006	<10	UFC/g	/	/
Escherichia coli beta-glucuronidase count positive at 44 °C	03/07/2020	04/07/2020	ISO 16649-2:2001	<10	UFC/g	/	/
Coagulase staphylococci count positive at 37 °C (Staphylococcus aureus and other species)	03/07/2020	04/07/2020	UNI EN ISO 6888-1:2018	<100	UFC/g	/	/

NOTE:

DIREZIONE TECNICA
Dr. Laura Icardi



End of Test Report

The results reported in this test report refer exclusively to the sample subjected to analysis. In the event that the Laboratory is not responsible for the sampling phase, the results refer to the sample as received. This test report cannot be partially reproduced without the written authorization of the Laboratory.
The decision rule for issuing conformity judgments does not envisage taking into account the contribution of measurement uncertainty to the result. The Laboratory issues judgments of conformity on the basis of the limits of the law in force and / or on the basis of the limits agreed with the customer.
L.O.D. = Limit of detection. It is the lowest concentration of analyte that can be detected, but not quantified by the analytical method. L.Q. = Limit of quantification. It is the lowest concentration of analyte that can be quantified by the analytical method. LI = Lower limit LS = Upper limit. The value preceded by the graphic sign "<" (lower) indicates that the result found is lower than the measuring range applied by the laboratory. The value preceded by the graphic sign ">" (greater) indicates that the result found is greater than the measuring range applied by the laboratory.



Test Report n. 32382 of the 08/07/2020

Customer

CASCINA FONTANE
Via Guido Cane, 1 - Fraz. Valle Talloria
Diano d'Alba CN 12055

Sample	Description	SEMI-FINISHED PRODUCT
	Declared denomination	GIANDUJA CREAM - LOT: 20/024 - EXPIRY: 04/2021
	Identification # assigned by the laboratory	32382
Container	Description	STERILE JAR
Sampling	Performer	CUSTOMER
Delivery	Performer	Customer
Sample receipt date	03/07/2020	
Sample acceptance date	03/07/2020	

Test	Start	Finish	Method	Result	Unit of measure	Measurement uncertainty	Limit Values
Microorganisms count at 30 °C	03/07/2020	06/07/2020	ISO 4832:2006	<10	UFC/g	/	/
Escherichia coli beta-glucuronidase count positive at 44 °C	03/07/2020	04/07/2020	ISO 16649-2:2001	<10	UFC/g	/	/
Coagulase staphylococci count positive at 37 °C (Staphylococcus aureus and other species)	03/07/2020	04/07/2020	UNI EN ISO 6888-1:2018	<100	UFC/g	/	/

NOTE:

DIREZIONE TECNICA
Dr. Laura Icardi



End of Test Report

The results reported in this test report refer exclusively to the sample subjected to analysis. In the event that the Laboratory is not responsible for the sampling phase, the results refer to the sample as received. This test report cannot be partially reproduced without the written authorization of the Laboratory.
The decision rule for issuing conformity judgments does not envisage taking into account the contribution of measurement uncertainty to the result. The Laboratory issues judgments of conformity on the basis of the limits of the law in force and / or on the basis of the limits agreed with the customer.
L.O.D. = Limit of detection. It is the lowest concentration of analyte that can be detected, but not quantified by the analytical method. L.Q. = Limit of quantification. It is the lowest concentration of analyte that can be quantified by the analytical method. LI = Lower limit LS = Upper limit. The value preceded by the graphic sign "<" (lower) indicates that the result found is lower than the measuring range applied by the laboratory. The value preceded by the graphic sign ">" (greater) indicates that the result found is greater than the measuring range applied by the laboratory.



Test Report n. 32383 of the 08/07/2020

Customer

CASCINA FONTANE
Via Guido Cane, 1 - Fraz. Valle Talloria
Diano d'Alba CN 12055

Sample	Description	SEMI-FINISHED PRODUCT
	Declared denomination	HAZELNUT FLOUR - LOT: 20/27 - EXPIRY: 06/2021
	Identification # assigned by the laboratory	32383
Container	Description	STERILE BAG
Sampling	Performer	CUSTOMER
Delivery	Performer	Customer
Sample receipt date	03/07/2020	
Sample acceptance date	03/07/2020	

Test	Start	Finish	Method	Result	Unit of measure	Measurement uncertainty	Limit Values
Microorganisms count at 30 °C	03/07/2020	06/07/2020	ISO 4832:2006	<10	UFC/g	/	/
Escherichia coli beta-glucuronidase count positive at 44 °C	03/07/2020	04/07/2020	ISO 16649-2:2001	<10	UFC/g	/	/
Coagulase staphylococci count positive at 37 °C (Staphylococcus aureus and other species)	03/07/2020	04/07/2020	UNI EN ISO 6888-1:2018	<100	UFC/g	/	/

NOTE:

DIREZIONE TECNICA
Dr. Laura Icardi



End of Test Report

The results reported in this test report refer exclusively to the sample subjected to analysis. In the event that the Laboratory is not responsible for the sampling phase, the results refer to the sample as received. This test report cannot be partially reproduced without the written authorization of the Laboratory.

The decision rule for issuing conformity judgments does not envisage taking into account the contribution of measurement uncertainty to the result. The Laboratory issues judgments of conformity on the basis of the limits of the law in force and / or on the basis of the limits agreed with the customer.

L.O.D. = Limit of detection. It is the lowest concentration of analyte that can be detected, but not quantified by the analytical method. L.Q. = Limit of quantification. It is the lowest concentration of analyte that can be quantified by the analytical method. LI = Lower limit LS = Upper limit. The value preceded by the graphic sign "<" (lower) indicates that the result found is lower than the measuring range applied by the laboratory. The value preceded by the graphic sign ">" (greater) indicates that the result found is greater than the measuring range applied by the laboratory.



Test Report n. 32384 of the 08/07/2020

Customer

CASCINA FONTANE
Via Guido Cane, 1 - Fraz. Valle Talloria
Diano d'Alba CN 12055

Sample	Description	SEMI-FINISHED
	Declared denomination	TOASTED HAZELNUTS - LOT: 20/27 - EXPIRY: 06/2021
	Identification # assigned by the laboratory	32384
Container	Description	STERILE BAG
Sampling	Performer	CUSTOMER
Delivery	Performer	Customer

Sample receipt date 03/07/2020

Sample acceptance date 07/07/2020

Test	Start	Finish	Method	Result	Unit of measure	Measurement uncertainty	Limit Values
B1 aflatoxin	07/07/2020	07/07/2020	MIC 04 rev 4 of the 24/02/2020	<L.Q. (L.Q.=0,20)	µg/kg	/	Max 5,0 Reg. CE n. 165/2010
B2 aflatoxin	07/07/2020	07/07/2020	MIC 04 rev 4 of the 24/02/2020	<L.Q. (L.Q.=0,20)	µg/kg	/	/
G1 aflatoxin	07/07/2020	07/07/2020	MIC 04 rev 4 of the 24/02/2020	<L.Q. (L.Q.=0,20)	µg/kg	/	/
G2 aflatoxin	07/07/2020	07/07/2020	MIC 04 rev 4 of the 24/02/2020	<L.Q. (L.Q.=0,20)	µg/kg	/	/
Total aflatoxins (B1, B2, G1, G2) by calculation	07/07/2020	07/07/2020	MIC 04 rev 4 of the 24/02/2020	<0,20	µg/kg	/	Max 10,0 Reg. CE n. 165/2010

NOTE: (1) Limit of quantification L.Q. = 0.20 µg / kg for each. The summation of aflatoxins was calculated with the lower bound approach.

DIREZIONE TECNICA

Dr. Laura Icardi



Fine Rapporto di Prova

The results reported in this test report refer exclusively to the sample subjected to analysis. In the event that the Laboratory is not responsible for the sampling phase, the results refer to the sample as received. This test report cannot be partially reproduced without the written authorization of the Laboratory.

The decision rule for issuing conformity judgments does not envisage taking into account the contribution of measurement uncertainty to the result. The Laboratory issues judgments of conformity on the basis of the limits of the law in force and / or on the basis of the limits agreed with the customer.

L.O.D. = Limit of detection. It is the lowest concentration of analyte that can be detected, but not quantified by the analytical method. L.Q. = Limit of quantification. It is the lowest concentration of analyte that can be quantified by the analytical method. LI = Lower limit LS = Upper limit. The value preceded by the graphic sign "<" (lower) indicates that the result found is lower than the measuring range applied by the laboratory. The value preceded by the graphic sign ">" (greater) indicates that the result found is greater than the measuring range applied by the laboratory.

Barattolo PASTA
17 settembre 2020

Etichetta sopra il tappo
diametro 80mm



Etichetta principale 135x56mm

CAMPIONE GRATUITO NON VENDIBILE

DA CONSUMARSI ENTRO FINE MESE/ANNO

LOTION / BATCH _____

Cascina Fontane

— ATELIER DELLA NOCCIOLA PIEMONTE I.G.P. —

PASTA DI "NOCCIOLA PIEMONTE I.G.P." DELLE LANGHE
PASTE OF "NOCCIOLA PIEMONTE P.G.I." DELLE LANGHE

Peso netto / Net Weigh: _____


INGREDIENTI: 100% NOCCIOLA PIEMONTE I.G.P. TOSTATA / INGREDIENTS: 100% NOCCIOLA PIEMONTE PGI ROASTED
Può contenere tracce di LATTE e SOIA/May contain traces of MILK and SOY

VALORI NUTRIZIONALI MEDI PER 100g / AVERAGE NUTRITIONAL VALUES FOR 100g
Energia/Energy 2766kJ/670 kcal | Grassi 62g di cui saturi/Fats 62g of which saturates 5,5g | Carboidrati/Carbohydrate 11g di cui zuccheri/of which sugars 4,8g | Fibre/Fiber 9,0g | Proteine/Protein 12g | Sale/Salt 0,09g

CONSERVARE IN UN LUOGO FRESCO, ASCIUTTO, LONTANO DA FONTI LUMINOSE. Dopo l'apertura consumare entro pochi giorni.
KEEP IN A COOL, DRY PLACE, AWAY FROM LIGHT SOURCES. After opening consume it within few days.

Una eventuale presenza di olio in superficie è dovuta all'artigianalità e naturalezza del prodotto, mescolare bene prima dell'utilizzo.
A possible oil presence on the surface is due to the craftsmanship and naturalness of the product, mix it well before using.

Certificato da organismo di controllo autorizzato dal MIPAAF



CASCINA FONTANE Società Semplice Agricola
Via Molino, 3 - 12050 Casirio (CN) - ITALIA
www.cascinafontane.it | info@cascinafontane.it

LABORATORIO ARTIGIANALE
Via Alba Cortemilia, 50 - Frazione Ricca
12055 Diano d'Alba (CN) - ITALIA

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

3015549701

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
(<https://www.fda.gov/about-fda/about-website/language-assistance-services#korean>) | Tagalog
(<https://www.fda.gov/about-fda/about-website/language-assistance-services#tagalog>) | Русский
(<https://www.fda.gov/about-fda/about-website/language-assistance-services#russian>) | العربية
(<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
(<https://www.fda.gov/about-fda/about-website/language-assistance-services#french>) | Polski
(<https://www.fda.gov/about-fda/about-website/language-assistance-services#polish>) | Português
(<https://www.fda.gov/about-fda/about-website/language-assistance-services#portuguese>) | Italiano
(<https://www.fda.gov/about-fda/about-website/language-assistance-services#italian>) | Deutsch
(<https://www.fda.gov/about-fda/about-website/language-assistance-services#german>) | 日本語
(<https://www.fda.gov/about-fda/about-website/language-assistance-services#japanese>) | فارسی
(<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/about-website/fda-basics>)

FOIA
(<https://www.fda.gov/about-website/foia>)

No FEAR
(<https://www.fda.gov/about-website/no-fear-act>)

Nondiscrimination
(<https://www.fda.gov/about-website/nondiscrimination-notice>)

Website Policies
(<https://www.fda.gov/about-website/policies>)



Search Results

FEI Number	Firm Name	Physical Address	Mailing Address
3015549701	CASCINA FONTANE	Via Del Molino 3, Castino, Cuneo, 12050, IT	Via Del Molino 3, Castino, Cuneo, 12050, IT

FOREIGN SUPPLIER

F S V P

QUESTIONNAIRE



PRIVILEGED & CONFIDENTIAL



- Confidential -

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: Ecco un Poco LLC Today's Date:
Factory Address: VIA MOLINO 3
City: Los Angeles Province: CUNEO Country: United States
Office Address: VIA GUIDO CANE 1
City: Los Angeles Province: CUNEO Country: United States
FDA Registration No.: 10168521158 Website: CASCINAFONTANE.IT
QC/QA's Name: Title: Commercial Rep.
Phone No.: 00393282168587 Email: INFO@CASCINAFONTANE.IT
TraceGains' Account Name:

SUPPLIER CLASS

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

- Manufacturer (Raw Material) Processor Packer Re-Packer
Manufacturer (Finished Product) Distributor Shipper Warehouse
Importer (US-based) Exporter (Non US-based) Broker Other

PRODUCT CATEGORY

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

- Bakery Beverage Chocolate/Candy Dairy
Dressings/Condiments Egg Food Additives Game Meat
Fruits Vegetables Grains Nuts
Oil Snack Foods Spice Other

PRODUCTS SUPPLIED

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

Product No. 01: PASTE OF HAZELNUT 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.

- Bacillus cereus
- Clostridium botulinum
- C. perfringens
- Brucella spp.
- Campylobacter spp.
- Pathogenic E. coli
- Salmonella spp.
- S. aureus
- L. monocytogenes
- Trichinella spiralis
- Giardia lamblia
- 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

We send a sample of our product to a laboratory to have it analyzed.

FREQUENCY of CONTROL VALIDATION

The frequency of the analysis is one time a year, however analyzes can also be carried out in a shorter period of time following a specific request from customers.

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 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

MOCA analysis on packaging to ensure its integrity;
 - Storage and storage of the products at correct temperatures;
 - Consumption of the products within and not beyond the shelf-life,
 - Correct sanitary hygienic practice.

FREQUENCY of CONTROL VALIDATION

The frequency of the analysis is one time a year, however analyzes can also be carried out in a shorter period of time following a specific request from customers

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

Research aflatoxins (B1, B2, G1, G2)

FREQUENCY of CONTROL VALIDATION

The frequency of the analysis is two times a year, however analyzes can also be carried out in a shorter period of time following a specific request from customers

We respectfully request copies of the following documents, written in English.

Required by 21 CFR 117 / 1.



FOOD SAFETY PLAN

Food Safety Plan identifies hazards requiring a control and a description of preventive control procedures.

- Requested Required
- Received Not in use

- ALLERGEN CONTROLS
- SUPPLIER APPROVAL PROCEDURES
- SANITATION CONTROLS
- PROCESS CONTROLS



PRODUCT DESCRIPTION / SPECS

A general description of the product and processing method, assembly, and family of products included in the category.

- Requested Required
- Received Not in use



HACCP PLAN / HAZARD ANALYSIS

A document which lists all identified process hazards and their corresponding critical control points.

- Requested Required
- Received Not in use



LABELING FILES

May include Product labeling, Individual package label, Case label, Package Inserts, Directions for Use, Promotional Material - *if applicable*.

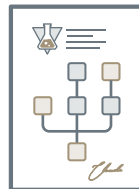
- Requested Required
- Received Not in use (bulk)



ONSITE AUDIT RESULTS

An annual onsite audit of food safety practices conducted by a qualified auditor. Complete audit report required.

- Requested Required
- Received Not in use



RECALL PLAN

Written Recall Plan must include procedures that describe the steps to take and assign responsibility.

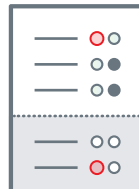
- Requested Required
- Received Not in use



SAMPLING / TESTING RESULTS

Sampling and testing of product for hazards of concern. *This may be done by supplier or receiving facility.*

- Requested Required
- Received Not in use



CORRECTIVE ACTIONS

List of procedures that must be taken if preventive controls are not properly implemented.

- Requested Required
- Received Not in use



SYSTEM RECOGNITION

Government-issued written statement of facility's good compliance with recognized country's food safety authority.

- Requested Required
- Received Not applicable



IMPLEMENTATION RECORDS

Monitoring records, Verification records, Applicable training records, Etc..

- Requested Required
- Received Not in use

ALLERGEN & CROSS CONTAMINATION CONTROLS

Component or Ingredient	Present in product?	Present on same equipment?	Present in same facility?
Product Name: PASTE OF HAZELNUT		Product code:	
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Milk or Milk Derivatives	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input 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
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
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
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
Lupin	<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
Seeds	<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
Grains	<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

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:

Empty text box for listing chemical types used on 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? 1

PEST CONTROL

Is a pest control contractor employed? Yes No

If yes, please provide: Name of contractor used: Ambiente Servizi

Number of yearly visits: Every three months

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: The products are identified with a batch

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.

Following the customer's complaint, we proceed with the evaluation of the actual problem encountered and proceed with the collection of the wrong product and replacement with goods in accordance with its requests.

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: CRISTINA BOFFANO

Title: QA / QC

Today's Date: 12/7/19

INTENTIONALLY LEFT BLANK

Page separates individual foreign supplier-provided food safety documents.





Test Report n. 26356 of 07/05/2019

Customer
CASCINA FONTANE
Via Guido Cane, 1 - Fraz. Valle Talloria
– Frazione Valle Talloria CN 12055

Sample	Description	SEMI-FINISHED
	Declared designation	HAZELNUT PASTA - YEAR 2018
	Identification number assigned by the laboratory	26356
Container	Description	STERILE JAR
Sampling	Performer	CUSTOMER
	Method / procedure variation	/
Delivery	Performer	Customer

Sample receipt date 29/04/2019

Sample acceptance date 29/04/2019

Test	Start	Finish	Method	Result	Unit of measure	Measurement uncertainty	Limit Values
Escherichia coli beta-glucuronidase positive counts at 44 ° C	29/04/2019	30/04/2019	ISO 16649-2:2001	<10	UFC/g	/	/
Coagulase positive staphylococci at 37 ° C (Staphylococcus aureus and other species)	29/04/2019	01/05/2019	UNI EN ISO 6888-1:2018	<100	UFC/g	/	/
Coliforms count at 30 ° C	29/04/2019	30/04/2019	ISO 4832:2006	<10	UFC/g	/	/

NOTE:



TECHNICAL DIR.
Dr. Laura Icardi



End Test Report

Tests marked with * are not covered by accreditation.
The results refer exclusively to the sample subjected to the tests.
This test report cannot be partially reproduced without written authorization from the laboratory.

INTENTIONALLY LEFT BLANK

Page separates individual foreign supplier-provided food safety documents.





Test Report n. 26358 of 07/05/2019

Customer

CASCINA FONTANE
Via Guido Cane, 1 - Fraz. Valle Talloria
– Frazione Valle Talloria CN 12055

Sample	Description	RAW MATERIAL
	Declared designation	HAZELNUT 2018
	Identification number assigned by the laboratory	26358
Container	Description	FOOD BAG
Sampling	Performer	CUSTOMER
	Method / procedure variation	/
Delivery	Performer	

Sample receipt date 29/04/2019

Sample acceptance date 29/04/2019

Test	Start	Finish	Method	Result	Unit of measure	Measurement uncertainty	Limit Values
Aflatoxin B1	03/05/2019	03/05/2019	MIC 04 rev 3 of 30/04/2019	0,44	µg/kg	/	<=5,0 Reg. CE n. 165/2010
Aflatoxin B2	03/05/2019	03/05/2019	MIC 04 rev 3 of 30/04/2019	<0,20	µg/kg	/	/
Aflatoxin G1	03/05/2019	03/05/2019	MIC 04 rev 3 of 30/04/2019	<0,20	µg/kg	/	/
Aflatoxin G2	03/05/2019	03/05/2019	MIC 04 rev 3 of 30/04/2019	<0,20	µg/kg	/	/
Total aflatoxins (B1, B2, G1, G2)	03/05/2019	03/05/2019	MIC 04 rev 3 of 30/04/2019	0,44	µg/kg	/	<=10,0 Reg. CE n. 165/2010

NOTE: (1) Quantification limit L.Q. = 0.20 µg / kg for each. The summation of aflatoxins was calculated with the lower bound approach.



TECHNICAL DIR.
Dr. Laura Icardi



End Test Report

Tests marked with * are not covered by accreditation.
The results refer exclusively to the sample subjected to the tests.
This test report cannot be partially reproduced without written authorization from the laboratory.

INTENTIONALLY LEFT BLANK

Page separates individual foreign supplier-provided food safety documents.



DA CONSUMARSI ENTRO FINE MESE/ANNO / BEST BEFORE
LOTTO N. / BATCH _____



Cascina Fontane

— ATELIER DELLA NOCCIOLA PIEMONTE I.G.P. —

PASTA DI NOCCIOLA PIEMONTE I.G.P. PASTE OF NOCCIOLA PIEMONTE PGI



Peso netto/Net Weight: _____

INGREDIENTI: **100%** NOCCIOLA PIEMONTE I.G.P. *tostata*/INGREDIENTS: **100%** NOCCIOLA PIEMONTE PGI *roasted*

Può contenere tracce di LATTE e SOIA/May contain traces of MILK and SOY

VALORI NUTRIZIONALI MEDI PER 100g/AVERAGE NUTRITIONAL VALUES FOR 100g:

Energia/Energy 2766kJ/670 kcal | Grassi 62g di cui saturi/Fats 62g of which saturates 5,5g | Carboidrati/Carbohydrate 11g di cui zuccheri/of which sugars 4,8g | Fibre/Fiber 9,0g | Proteine/Protein 12g | Sale/Salt 0,09g

CONSERVARE IN UN LUOGO FRESCO, ASCIUTTO, LONTANO DA FONTI LUMINOSE. Dopo l'apertura consumare entro pochi giorni.
KEEP IN A COOL, DRY PLACE, AWAY FROM LIGHT SOURCES. After opening consume it within few days.

Una eventuale presenza di olio in superficie è dovuta all'artigianalità e naturalezza del prodotto, mescolare bene prima dell'utilizzo.

A possible oil presence on the surface is due to the craftsmanship and naturalness of the product, mix it well before using.

Certificato da organismo di controllo autorizzato dal MIPAAFT

ALLERGENI: NOCCIOLA / ALLERGENS: HAZELNUT

CASCINA FONTANE Società Semplice Agricola
Via Molino, 3 - 12050 Castino (CN) - ITALIA
www.cascinafontane.it | info@cascinafontane.it

LABORATORIO ARTIGIANALE
Via Guido Carone, 1 - Frazione Valle Talloria
12055 Diano d'Alba (CN) - ITALIA

INTENTIONALLY LEFT BLANK

Page separates individual foreign supplier-provided food safety documents.



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

Showing 0 to 0 of 0 entries (filtered from 3,119 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 ◀	Response Letter ◀	Closeout Letter ◀

No matching records found

Showing 0 to 0 of 0 entries (filtered from 3,119 total entries)

[Previous](#)

[Next](#)

FDA ISSUED GUIDANCE & REFERENCE DOCUMENTATION



The following documents contain additional information about the FDA's Foreign Supplier Verification Programs and appendant regulations/guidance. Please Note: The FDA is committed to helping ensure that importers can meet the FSVP requirements. In order to facilitate compliance, FDA will provide guidance, outreach, and training.

ADDITIONAL INFORMATION

FSVP Fact Sheet

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM502160.pdf>

Food Safety Preventive Controls Alliance

<http://www.iit.edu/ifsh/alliance/>

Am I subject to FSVP

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472461.pdf>

FSVP Compliance Dates

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm>





Final Rule on Foreign Supplier Verification Programs

The FDA Food Safety Modernization Act of 2011 mandates the creation of a food safety system in which the focus is on preventing contamination rather than primarily reacting to problems after they occur. The FSMA rules include those that require preventive controls for food facilities that manufacture/process, pack, and hold human and animal foods, and establish science-based standards for produce grown on farms. These rules apply to domestic food producers and those in other countries who export to the United States.

The import community will be most impacted by the Foreign Supplier Verification Programs (FSVP) rule, which requires FSVP importers to verify that the food they import meets U.S. safety standards. FSVP importers are required to develop, maintain, and follow an FSVP for each food imported, unless an exemption applies. The goal is to ensure that each food is produced in a manner that provides the same level of public health protection as the preventive controls and produce safety regulations, if applicable, and the food is not adulterated or misbranded with respect to allergen labeling.

Who Is Covered by the FSVP Rule?

The FSVP importer is the U.S. owner or consignee of the food offered for import (i.e., owns the food, has purchased it, or has agreed in writing to purchase it at the time of U.S. entry). If there is no U.S. owner or consignee at time of entry, the FSVP importer is the U.S. agent/representative of the foreign owner/consignee, as confirmed in a signed statement of consent. The key is that there be a FSVP importer in the United States who takes responsibility for meeting the FSVP requirements.

What Will I Have to Do Under the FSVP rule?

Unless exempt, or subject to modified requirements, an FSVP importer may need to perform the following activities:

- Use a qualified individual to develop an FSVP and to perform FSVP activities.
- Perform a hazard analysis that includes identifying known or reasonably foreseeable hazards associated for each type of food and determining whether they require a control.

Potential hazards include:

- biological hazards, including parasites and disease-causing bacteria;
- chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, food decomposition, unapproved additives, food allergens, and (in animal food) nutrient deficiencies or toxicities; and
- physical hazards, such as glass.
- Evaluate risks posed by the food and the performance of the foreign supplier, considering:
 - the hazard analysis for the food;
 - the entity that will be applying hazard controls, such as the foreign supplier or the foreign supplier's ingredient supplier;
 - the foreign supplier's food safety practices and procedures;
 - applicable U.S. food safety regulations and information regarding the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter or import alert; and
 - the foreign supplier's food safety performance history, including results from testing, audit results, and the supplier's record of correcting problems.
- Conduct appropriate supplier verification activities to provide assurance that the hazards requiring a control in the food you import have been significantly minimized or prevented. These activities may include:
 - annual onsite audits (must be performed by a qualified auditor);

- sampling and testing of a food;
- a review of the supplier's relevant food safety records; and/or
- other appropriate activities.
- Take corrective actions (if necessary) and investigate the adequacy of the FSVP (when appropriate).
- Reevaluate the food and foreign supplier every three years or sooner if the FSVP importer becomes aware of new information about the hazards in the food or the foreign supplier's performance.
- Identify the FSVP importer when filing for entry with U.S. Customs and Border Protection using the FSVP importer's name, electronic mailing address, and unique facility identifier (UFI) recognized as acceptable to FDA.
 - The FDA has recognized the [Data Universal Numbering System \(DUNS\) number as an acceptable UFI for FSVP](#). A DUNS number can be obtained by visiting fdadunslookup.com.
 - The FDA has also issued [guidance](#) stating that for FSVP importers temporarily unable to obtain a DUNS number, FDA intends to temporarily allow filers to transmit the value "UNK" (to represent "unknown") in the UFI field. This option will be available beginning May 30, 2017 so that food offered for import can be processed through the Customs and Border Patrol (CBP) Automated Commercial Environment (ACE) system, even if the importer has not yet provided a DUNS number.

FSVP importers can meet key FSVP obligations by relying on analyses, evaluations, and activities performed by other entities in certain circumstances, as long as the FSVP importer reviews and assesses corresponding documentation.

When Would Modified Requirements Apply Under the FSVP Rule?

- Importation of foods that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation under specified circumstances.
- Importation of dietary supplements and dietary supplement components that will be subject to certain provisions of the dietary supplement Current Good Manufacturing Practice regulation under specified circumstances, or other dietary supplements.
- Importation by a very small importer or importer of foods from certain small foreign suppliers.
- Importation of certain food from a foreign supplier in good compliance standing with a food safety system that FDA has officially recognized as comparable or equivalent to that of the United States.

What Foods and Beverages Are Exempt from FSVP?

- Juice and seafood from foreign suppliers that are in compliance with the respective HACCP regulations (21 CFR part 120 or 123) and certain ingredients that are used by the importer in the manufacturing or processing of juice and seafood products in accordance with the respective HACCP regulations.
- Small quantities of food imported for research and evaluation purposes that are not intended for retail sale and are not sold or distributed to the public.
- Small quantities of food imported for personal consumption that are not intended for retail sale and are not sold or distributed to the public.
- Food produced in compliance with FDA's low acid canned food requirements in 21 CFR part 113 (exempt with respect to microbiological hazards controlled by 21 CFR part 113 only), as well as certain ingredients for use in LACF products but only with respect to microbiological hazards).
- Certain alcoholic beverages
- Food that is transshipped through the United States or that is imported for future export and not sold or distributed in the United States.
- Food that is manufactured/processed, raised, or grown in the United States, exported, and returned to the United States without further manufacturing/processing.
- Certain meat, poultry, and egg products

What Are the FSVP Compliance Dates?

The date by which FSVP importers must comply with the FSVP regulations is the latest of the following dates. FDA will inspect FSVP importers to ensure they are in compliance:

- May 30, 2017
- For the importation of food from a supplier that is subject to the preventive controls or produce safety rules, six months after the foreign supplier is required to meet the relevant regulations.
- For an FSVP importer that is itself a manufacturer or processor subject to the supply-chain program provisions in the preventive controls regulations, the date by which it has to comply with those provisions.

For More Information and Further Assistance:

- FSVP Fact Sheet:
<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472890.pdf>
- The FDA has worked with the Food Safety Preventive Controls Alliance (FSPCA) on training and technical assistance programs to facilitate compliance with the FSVP rule:
<http://www.iit.edu/ifsh/alliance/>
- Am I subject to FSVP?
 - <https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472461.pdf>
- FSVP Compliance Dates: <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm>
- Still have questions? Contact the FDA FSMA Food Safety Technical Assistance Network (TAN):
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>
- The FDA is in the process of developing FSVP guidance to help further explain the rule.

INTENTIONALLY LEFT BLANK

Page separates individual foreign supplier-provided food safety documents.



KEY REQUIREMENTS: Final Rule on Foreign Supplier Verification Programs



The FDA FSMA rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals is final, and the first compliance dates begin May 30, 2017.

The final rule requires that importers perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards. This rule is the product of a significant level of outreach by the FDA to industry, consumer groups, the agency's federal, state, local, tribal and international regulatory counterparts, academia and other stakeholders. The FDA first proposed this rule in July 2013.

After input received during the comment period and during numerous engagements that included public meetings, webinars, and listening sessions, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions included providing importers flexibility in determining appropriate verification measures based on food and supplier risks, while acknowledging the greater risk to public health posed by the most serious hazards in foods.

The final rule has elements of both the original and supplemental proposals, with the addition of greater flexibility in meeting certain requirements to better reflect modern supply and distribution chains. For example, importers can meet key FSVP obligations by relying on analyses, evaluations, and activities performed by other entities in certain circumstances, as long as those importers review and assess the corresponding documentation.

The FDA is committed to helping ensure that importers can meet the FSVP requirements. In order to facilitate compliance, FDA will provide guidance, outreach, and training.

1. SCOPE

■ Who is covered by the rule?

- For the purposes of FSVP, an importer is the U.S. owner or consignee of a food offered for import into the United States. If there is no U.S. owner or consignee, the importer is the U.S. agency or representative of the foreign owner of consignee at the time of entry, as confirmed in a signed statement of consent. See [Am I Subject to FSVP? \(PDF: 69KB\)](#) for more information.
- There are exemptions discussed below.

■ What is an FSVP? It is a program that importers covered by the rule must have in place to verify that their foreign suppliers are producing food in a manner that provides the same level of public health protection as the preventive controls or produce safety regulations, as appropriate, and to ensure that the supplier's food is not adulterated and is not misbranded with respect to allergen labeling.

■ Importers are responsible for actions that include (and are explained further below):

- Determining known or reasonably foreseeable hazards with each food
- Evaluating the risk posed by a food, based on the hazard analysis, and the foreign supplier's performance
- Using that evaluation of the risk posed by an imported food and the supplier's performance to approve suppliers and determine appropriate supplier verification activities
- Conducting supplier verification activities
- Conducting corrective actions

■ Importers must establish and follow written procedures to ensure that they import foods only from foreign suppliers approved based on an evaluation of the risk posed by the imported food

and the supplier's performance or, when necessary on a temporary basis, from unapproved suppliers whose foods are subjected to adequate verification activities before being imported.

- Importers are required to develop, maintain, and follow an FSVP for each food brought into the United States and the foreign supplier of that food. If the importer obtains a certain food from a few different suppliers, a separate FSVP would be required for each of those suppliers. Similarly, if the importer obtains many different foods, from a single supplier, a separate FSVP would be required for each food.
- Certain importers that are also manufacturers/processors are deemed in compliance with most FSVP requirements if:
 - they are in compliance with the supply-chain program requirements under the preventive controls rules;
 - they implement preventive controls for the hazards in the food in accordance with the requirements in the preventive controls rules; or
 - they are not required to implement preventive controls under those rules in certain specified circumstances. Examples of such circumstances include when the type of food (e.g., such as coffee beans) could not be consumed without application of a preventive control, or when the customer will be significantly minimizing or preventing identified hazards) and they comply with requirements for disclosures and written assurances.
- The evaluation of the risk posed by the imported food and the supplier's performance must be reevaluated at least every three years, or when new information comes to light about a potential hazard or the foreign supplier's performance.
- Importers are not required to evaluate the food and supplier or conduct supplier verification activities if they receive adequate assurances that a subsequent entity in the distribution chain, such as the importer's customer, is processing the food for food safety in accordance with applicable requirements. FDA has extended the compliance date for obtaining these written assurances for two years. However, as required by the final rule, importers must disclose in documents accompanying the food that the food is not processed to control the identified hazard.

2. HAZARD ANALYSIS

- **What do we mean by 'hazard'?** An importer is required to identify and evaluate—based on experience, illness data, scientific reports and other information—the known or reasonably foreseeable hazards for each type of food it imports to determine if there are any hazards requiring a control. These include:
 - Biological hazards, including parasites and disease-causing bacteria
 - Chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, food decomposition, unapproved food or color additives, and food allergens
 - Physical hazards, such as glass
- They may be hazards reasonably likely to cause illness or injury that occur naturally, are unintentionally introduced, or are intentionally introduced for purposes of economic gain, such as substituting a less costly ingredient.
- The analysis must assess the probability that these hazards will occur in the absence of controls and the severity of the illness or injury that could occur.
- The evaluation would have to consider factors that include the:
 - Formulation of the food
 - Condition, function and design of the establishment and equipment of a typical entity that produces the food
 - Raw materials and other ingredients
 - Transportation practices
 - Harvesting, raising, manufacturing, processing, and packing procedures
 - Packaging and labeling activities
 - Storage and distribution
 - Intended or reasonably foreseeable use
 - Sanitation, including employee hygiene
- An importer can rely on another entity to conduct the hazard analysis, so long as the importer reviews and assesses the relevant documentation.

3. EVALUATION OF FOOD RISK AND SUPPLIER PERFORMANCE

■ What evaluation must be done of the risk posed by an imported food and a supplier's performance?

An importer must evaluate:

- The hazard analysis
- The entity that will be significantly minimizing or preventing the hazards, such as the foreign supplier or the supplier's raw material or ingredient supplier
- A foreign supplier's procedures, processes, and practices related to the safety of food,
- Applicable FDA food safety regulations, and information regarding the foreign supplier's compliance
- The foreign supplier's food safety history, including the responsiveness of the foreign supplier in correcting past problems
- Other factors as necessary, including storage and transportation practices

- The importer can rely on another entity (other than the foreign supplier) to perform the evaluation of risk, so long as the importer reviews and assesses the relevant documentation.

4. SUPPLIER VERIFICATION

- **What supplier verification activities must be conducted?** Based upon the evaluation of risk conducted, the importer must establish and follow written procedures to ensure, in most instances, that it only imports from approved foreign suppliers and must conduct appropriate supplier verification activities.

- Importers have the flexibility to tailor supplier verification activities to unique food risks and supplier characteristics. The options include:
 - Annual on-site audits of the supplier's facility. This is generally required when there is a reasonable probability that exposure to a hazard controlled by the foreign supplier will result in serious adverse health consequences or death to humans or animals (called a SAHCODHA hazard). However, the importer can choose another means of verification provided that the importer documents that the alternate choice is

appropriate and provides adequate assurances that the foreign supplier is producing the food in accordance with applicable U.S. safety standards.

- Sampling and testing
- A review of the supplier's relevant food safety records

- An importer can rely on another entity (other than the foreign supplier) to determine and perform appropriate supplier verification activities, so long as the importer reviews and assesses the relevant documentation.

5. CORRECTIVE ACTIONS

- **What if something goes wrong?** Importers must promptly take appropriate corrective actions if they determine that a foreign supplier has not used processes and procedures that provide the same level of public health protection as required under the produce safety and preventive controls regulations, as applicable, or that the supplier produces food that is adulterated or misbranded with respect to allergen labeling.

- The appropriate corrective measure will depend on the circumstances, but could include discontinuing use of the foreign supplier until the cause of noncompliance, adulteration, or misbranding has been adequately addressed.

6. EXEMPTIONS AND MODIFIED STANDARDS

- The requirements for dietary supplements vary according to a number of factors, including whether the import is a finished product or an ingredient/component.
 - Importers who establish and verify compliance with certain specifications (concerning dietary supplement components and packaging) required under the separate, pre-existing dietary supplement Current Good Manufacturing Practices (CGMP) regulation will not be required to comply with most of the standard FSVP requirements.
 - The same would apply to importers whose customer is required to establish such specifications and verify that they are met, except that the importer would have to obtain written assurance that its customer is complying with those requirements.
 - Importers of other dietary supplements, including finished products, would be required to comply

FDA AT A GLANCE

with most of the standard FSVP requirements (except the hazard analysis requirement), but their verification activities would focus on compliance with the dietary supplement CGMP regulations.

- Modified FSVP requirements are established for very small importers and importers of food from certain small suppliers. (An example of these modified requirements is that certain importers would not have to conduct hazard analyses and would be able to verify their foreign suppliers by obtaining written assurances from their supplier.)

- The definition of very small importer is consistent with the definition of very small business in the preventive controls rules: \$1 million for human food and \$2.5 million for animal food of annual sales (averaged over three year period) combined with the U.S. market value of food that is imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee).
- Importers of certain small foreign suppliers are subject to modified FSVP requirements. Those small suppliers are:
 - Facilities subject to modified requirements under the preventive controls rules because they are qualified facilities
 - Farms that are not covered farms under the produce safety rule because they average \$25,000 or less in annual produce sales or because they meet requirements for a qualified exemption
 - Shell egg producers with fewer than 3,000 laying hens
 - Each of these types of producers is either exempt from their underlying FDA food safety regulations or subject to modified requirements, mostly, and in some cases entirely, because of the size of these firms.

- There are modified requirements for certain foods from a foreign supplier in a country whose food safety system has been recognized as comparable or determined to be the equivalent of the United States' system.

- Additionally, certain categories of imported food are not covered by FSVP. These include:

- Juice, fish, and fishery products subject to and in compliance with FDA's Hazard Analysis and Critical Control Point (HACCP) regulations for those products, and certain ingredients for use in juice and fish and fishery products subject to the HACCP regulations.
- Food for research or evaluation
- Food for personal consumption
- Alcoholic beverages and certain ingredients for use in alcoholic beverages
- Food that is imported for processing and future export
- Low-acid canned foods (LACF), such as canned vegetables, but only with respect to microbiological hazards covered by other regulations, as well as certain ingredients for use in LACF products (but only with respect to microbiological hazards).
- Certain meat, poultry and egg products regulated by the U.S. Department of Agriculture at the time of importation

7. UNIQUE FACILITY IDENTIFIER

- The final FSVP rule requires that an importer provide its name, electronic mail address, and unique facility identifier (UFI) recognized as acceptable by the FDA for each line entry of food product offered for importation into the United States.
- The FDA has recognized the Data Universal Numbering System (DUNS) number as an acceptable UFI for FSVP.
- DUNS numbers, assigned and managed by DUN & Bradstreet, are available free of charge to importers by visiting FDAdunslookup.com.
- The FDA has also issued guidance stating that for FSVP importers temporarily unable to obtain a DUNS number, FDA intends to temporarily allow filers to transmit the value "UNK" (to represent "unknown") in the UFI field. This option will be available beginning May 30, 2017 so that food offered for import can be processed through the Customs and Border Patrol (CBP) Automated Commercial Environment (ACE) system, even if the importer has not yet provided a DUNS number.

COMPLIANCE DATES

The date by which importers must comply with the FSVP regulations is the latest of the following dates:

- 18 months after publication of the final rule;
- For the importation of food from a supplier that is subject to the preventive controls or produce safety rules, six months after the foreign supplier is required to meet the relevant regulations;
- For an importer that is itself a manufacturer or processor subject to the supply-chain program provisions in the preventive controls regulations, the date by which it has to comply with those provisions. A range of compliance dates were established in the preventive controls rules for the supply-chain program provisions, which vary based on the size of the receiving facility and when the receiving facility's supplier is required to comply with the new FSMA regulations.

Read more on Compliance Dates for the FSVP Final Rule and Compliance Date Extensions and Clarifications for FSMA Final Rules at FDA.gov.

ASSISTANCE TO INDUSTRY

The FDA has developed and continues to develop several guidance documents on subjects that include:

- Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA
- Training and Technical Assistance: The FDA has established the FSMA Food Safety Technical Assistance Network, to provide a central source of information to support industry understanding and implementation of FSMA.
- FDA has collaborated with the Food Safety Preventive Controls Alliance (FSPCA) to establish training and technical assistance programs.

ADDITIONAL INFORMATION:

- FSVP Fact Sheet:
<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM502160.pdf>
- Food Safety Preventive Controls Alliance:
<http://www.iit.edu/ifsh/alliance/>
- Am I subject to FSVP?
<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472461.pdf>
- FSVP Compliance Dates
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm>

INTENTIONALLY LEFT BLANK

Page separates individual foreign supplier-provided food safety documents.



Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

21 CFR PART 1--GENERAL ENFORCEMENT REGULATIONS

Subpart L--Foreign Supplier Verification Programs for Food Importers

- 1.500 What definitions apply to this subpart?
1.501 To what foods do the regulations 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 foreign supplier approval and verification must I conduct?
1.506 What foreign supplier verification and related activities must I conduct?
1.507 What requirements apply when I import a 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 FSVP?
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 dietary supplement current good manufacturing practice regulations?
1.512 What FSVP may I have if I am a very small importer or if I am importing certain food from certain small foreign suppliers?
1.513 What FSVP may I have if I am importing certain food from a country with an officially recognized or equivalent food safety system?
1.514 What are some consequences of failing to comply with the requirements of this subpart?

§ 1.500 What definitions apply to this subpart?

The following definitions apply to words and phrases as they are used in this subpart. Other definitions of these terms may apply when they are used in other subparts of this part.

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Audit means the systematic, independent, and documented examination (through observation, investigation, discussions with employees of the audited entity, records review, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

Dietary supplement has the meaning given in section 201(ff) of the Federal Food, Drug, and Cosmetic Act.

Dietary supplement component means any substance intended for use in the manufacture of a dietary supplement, including those that may not appear in the finished batch of the dietary supplement. Dietary supplement components include dietary ingredients (as described in section 201(ff) of the Federal Food, Drug, and Cosmetic Act) and other ingredients.

Environmental pathogen means a pathogen that is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize or prevent the environmental pathogen. Examples of environmental pathogens for the purposes of this subpart include Listeria monocytogenes and Salmonella spp.

Foreign Supplier Verification Programs for Importers of Food for Humans and Animal Rule

but do not include the spores of pathogenic spore formers.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of subpart H of this part.

Farm means farm as defined in § 1.227.

Farm mixed-type facility means an establishment that is a farm but that also conducts activities outside the farm definition that require the establishment to be registered under section 415 of the Federal Food, Drug, and Cosmetic Act.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Foreign supplier means, for an article of food, the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature.

Good compliance standing with a foreign food safety authority means that the foreign supplier--

(1) Appears on the current version of a list, issued by the food safety authority of the country in which the foreign supplier is located and which has regulatory oversight of the supplier, of food producers that are in good compliance standing with the food safety authority; or

(2) Has otherwise been designated by such food safety authority as being in good compliance standing.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Hazard means any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury.

Hazard requiring a control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the probability that the hazard will occur in the absence of controls or measures and the severity of the illness or injury if the hazard were to occur), establish one or more controls or measures to significantly minimize or prevent the hazard in a food and components to manage those controls or measures (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the control or measure and its role in the facility's food safety system.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as

Foreign Supplier Verification Programs for Importers of Food for Humans and Animal Rule

fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Importer means the U.S. owner or consignee of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with a food or the facility in which it is manufactured/processed.

Lot means the food produced during a period of time and identified by an establishment's specific code.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding (of animal food), formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging, pasteurizing, peeling, pelleting (of animal food), rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

Qualified auditor means a person who is a qualified individual as defined in this section and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by § 1.506(e)(1)(i) or § 1.511(c)(5)(i)(A). Examples of potential qualified auditors include:

- (1) A government employee, including a foreign government employee; and
- (2) An audit agent of a certification body that is accredited in accordance with subpart M of this part.

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under this subpart, and can read and understand the language of any records that the person must review in performing this activity. A qualified individual may be, but is not required to be, an employee of the importer. A government employee, including a foreign government employee, may be a qualified

individual.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

Receiving facility means a facility that is subject to subparts C and G of part 117 of this chapter, or subparts C and E of part 507 of this chapter, and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

U.S. owner or consignee means the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

Very small importer means:

(1) With respect to the importation of human food, an importer (including any subsidiaries and affiliates) averaging less than \$1 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of human food combined with the U.S. market value of human food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee); and

(2) With respect to the importation of animal food, an importer (including any subsidiaries and affiliates) averaging less than \$2.5 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of animal food combined with the U.S. market value of animal food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee).

You means a person who is subject to some or all of the requirements in this subpart.

§ 1.501 To what foods do the regulations in this subpart apply?

(a) General. Except as specified otherwise in this section, the requirements in this subpart apply to all food imported or offered for import into the United States and to the importers of such food.

(b) Exemptions for juice and seafood--(1) Importers of certain juice and seafood products. This subpart does not apply with respect to juice, fish, and fishery products that are imported from a foreign supplier that is required to comply with, and is in compliance with, the requirements in part 120 or part 123 of this chapter. If you import juice or fish and fishery products that are subject to part 120 or part 123, respectively, you must comply with the requirements applicable to importers of those products under § 120.14 or § 123.12 of this chapter, respectively.

(2) Certain importers of juice or seafood raw materials or other ingredients subject to part 120 or part 123 of this chapter. This subpart does not apply with respect to any raw materials or other ingredients that you import and use in manufacturing or processing juice subject to part 120 or fish and fishery products subject to part 123, provided that you are in compliance with the requirements in part 120 or part 123 with respect to the juice or fish or fishery product that you manufacture or process from the imported raw materials or other ingredients.

(c) Exemption for food imported for research or evaluation. This subpart does not apply to food that is imported for research or evaluation use, provided that such food:

- (1) Is not intended for retail sale and is not sold or distributed to the public;
- (2) Is labeled with the statement “Food for research or evaluation use”;
- (3) Is imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly

Foreign Supplier Verification Programs for Importers of Food for Humans and Animal Rule

disposed of; and

(4) Is accompanied, when filing entry with U.S. Customs and Border Protection, by an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public.

(d) Exemption for food imported for personal consumption. This subpart does not apply to food that is imported for personal consumption, provided that such food is not intended for retail sale and is not sold or distributed to the public. Food is imported for personal consumption only if it is purchased or otherwise acquired by a person in a small quantity that is consistent with a non-commercial purpose and is not sold or distributed to the public.

(e) Exemption for alcoholic beverages. (1) This subpart does not apply with respect to alcoholic beverages that are imported from a foreign supplier that is a facility that meets the following two conditions:

(i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.), the facility is a foreign facility of a type that, if it were a domestic facility, would require obtaining a permit from, registering with, or obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States; and

(ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act, the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages.

(2) This subpart does not apply with respect to food that is not an alcoholic beverage that is imported from a foreign supplier described in paragraph (e)(1) of this section, provided such food:

(i) Is in prepackaged form that prevents any direct human contact with such food; and

(ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(3) This subpart does not apply with respect to raw materials and other ingredients that are imported for use in alcoholic beverages provided that:

(i) The imported raw materials and other ingredients are used in the manufacturing/processing, packing, or holding of alcoholic beverages;

(ii) Such manufacturing/processing, packing, or holding is performed by the importer;

(iii) The importer is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act; and

(iv) The importer is exempt from the regulations in part 117 of this chapter in accordance with § 117.5(i) of this chapter.

(f) Inapplicability to food that is transshipped or imported for processing and export.

This subpart does not apply to food:

(1) That is transshipped through the United States to another country and is not sold or distributed to the public in the United States; or

(2) That is imported for processing and future export and that is not sold or distributed to the public in the United States.

(g) Inapplicability to U.S. food returned. This subpart does not apply to food that is manufactured/processed, raised, or grown in the United States, exported, and returned to the United States without further manufacturing/processing in a foreign country.

(h) Inapplicability to certain meat, poultry, and egg products. This subpart does not apply with respect to:

(1) Meat food products that at the time of importation are subject to the requirements of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.);

Foreign Supplier Verification Programs for Importers of Food for Humans and Animal Rule

(2) Poultry products that at the time of importation are subject to the requirements of the USDA under the Poultry Products Inspection Act (21 U.S.C. 451 et seq.); and

(3) Egg products that at the time of importation are subject to the requirements of the USDA under the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

§ 1.502 What foreign supplier verification program (FSVP) must I have?

(a) General. Except as specified in paragraph (b) of this section, for each food you import, you must develop, maintain, and follow an FSVP that provides adequate assurances that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the Federal Food, Drug, and Cosmetic Act.

(b) Low-acid canned foods--(1) Importers of low-acid canned foods not subject to further manufacturing or processing. With respect to those microbiological hazards that are controlled by part 113 of this chapter, if you import a thermally processed low-acid food packaged in a hermetically sealed container (low-acid canned food), you must verify and document that the food was produced in accordance with part 113. With respect to all matters that are not controlled by part 113, you must have an FSVP as specified in paragraph (a) of this section.

(2) Certain importers of raw materials or other ingredients subject to part 113 of this chapter. With respect to microbiological hazards that are controlled by part 113, you are not required to comply with the requirements of this subpart for raw materials or other ingredients that you import and use in the manufacturing or processing of low-acid canned food provided that you are in compliance with part 113 with respect to the low-acid canned food that you manufacture or process from the imported raw materials or other ingredients. With respect to all hazards other than microbiological hazards that are controlled by part 113, you must have an FSVP as specified in paragraph (a) of this section for the imported raw materials and other ingredients that you use in the manufacture or processing of low-acid canned foods.

(c) Importers subject to section 418 of the Federal Food, Drug, and Cosmetic Act. You are deemed to be in compliance with the requirements of this subpart for a food you import, except for the requirements in § 1.509, if you are a receiving facility as defined in § 117.3 or § 507.3 of this chapter and you are in compliance with the following requirements of part 117 or part 507 of this chapter, as applicable:

(1) You implement preventive controls for the hazards in the food in accordance with § 117.135 or § 507.34 of this chapter;

(2) You are not required to implement a preventive control under § 117.136 or § 507.36 of this chapter with respect to the food; or

(3) You have established and implemented a risk-based supply-chain program in compliance with subpart G of part 117 or subpart E of part 507 of this chapter with respect to the food.

§ 1.503 Who must develop my FSVP and perform FSVP activities?

(a) Qualified individual. A qualified individual must develop your FSVP and perform each of the activities required under this subpart. A qualified individual must have the education, training, or experience (or a combination thereof) necessary to perform their assigned activities and must be able to read and understand the language of any records that must be

reviewed in performing an activity.

(b) Qualified auditor. A qualified auditor must conduct any audit conducted in accordance with § 1.506(e)(1)(i) or § 1.511(c)(5)(i)(A). A qualified auditor must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

§ 1.504 What hazard analysis must I conduct?

(a) Requirement for a hazard analysis. Except as specified in paragraph (d) of this section, you must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food you import to determine whether there are any hazards requiring a control. Your hazard analysis must be written regardless of its outcome.

(b) Hazard identification. (1) Your analysis of the known or reasonably foreseeable hazards in each food must include the following types of hazards:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, food allergens, and (in animal food) nutrient deficiencies or toxicities; and

(iii) Physical hazards (such as stones, glass, and metal fragments).

(2) Your analysis must include known or reasonably foreseeable hazards that may be present in a food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c) Hazard evaluation. (1) Your hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the probability that the hazard will occur in the absence of controls and the severity of the illness or injury if the hazard were to occur.

(2) The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment before packaging and the packaged food does not receive a treatment or otherwise include a control or measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

(3) Your hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

(i) The formulation of the food;

(ii) The condition, function, and design of the establishment and equipment of a typical entity that manufactures/processes, grows, harvests, or raises this type of food;

(iii) Raw materials and other ingredients;

(iv) Transportation practices;

(v) Harvesting, raising, manufacturing, processing, and packing procedures;

(vi) Packaging and labeling activities;

(vii) Storage and distribution;

(viii) Intended or reasonably foreseeable use;

(ix) Sanitation, including employee hygiene; and

(x) Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of natural toxins).

(d) Review of another entity's hazard analysis. If another entity (including your foreign

supplier) has, using a qualified individual, analyzed the known or reasonably foreseeable hazards for the food to determine whether there are any hazards requiring a control, you may meet your requirement to determine whether there are any hazards requiring a control in a food by reviewing and assessing the hazard analysis conducted by that entity. You must document your review and assessment of that hazard analysis, including documenting that the hazard analysis was conducted by a qualified individual.

(e) Hazards in raw agricultural commodities that are fruits or vegetables. If you are importing a raw agricultural commodity that is a fruit or vegetable that is “covered produce” as defined in § 112.3 of this chapter, you are not required to determine whether there are any biological hazards requiring a control in such food because the biological hazards in such fruits or vegetables require a control and compliance with the requirements in part 112 of this chapter significantly minimizes or prevents the biological hazards. However, you must determine whether there are any other types of hazards requiring a control in such food.

(f) No hazards requiring a control. If you evaluate the known and reasonably foreseeable hazards in a food and determine that there are no hazards requiring a control, you are not required to conduct an evaluation for foreign supplier approval and verification under § 1.505 and you are not required to conduct foreign supplier verification activities under § 1.506. This paragraph (f) does not apply if the food is a raw agricultural commodity that is a fruit or vegetable that is “covered produce” as defined in § 112.3 of this chapter.

§ 1.505 What evaluation for foreign supplier approval and verification must I conduct?

(a) Evaluation of a foreign supplier’s performance and the risk posed by a food. (1) Except as specified in paragraphs (d) and (e) of this section, in approving your foreign suppliers and determining the appropriate supplier verification activities that must be conducted for a foreign supplier of a type of food you import, you must consider the following:

(i) The hazard analysis of the food conducted in accordance with § 1.504, including the nature of the hazard requiring a control.

(ii) The entity or entities that will be significantly minimizing or preventing the hazards requiring a control or verifying that such hazards have been significantly minimized or prevented, such as the foreign supplier, the foreign supplier’s raw material or other ingredient supplier, or another entity in your supply chain.

(iii) Foreign supplier performance, including:

(A) The foreign supplier’s procedures, processes, and practices related to the safety of the food;

(B) Applicable FDA food safety regulations and information relevant to the foreign supplier’s compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety (or, when applicable, the relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and information relevant to the supplier’s compliance with those laws and regulations); and

(C) The foreign supplier’s food safety history, including available information about results from testing foods for hazards, audit results relating to the safety of the food, and responsiveness of the foreign supplier in correcting problems.

(iv) Any other factors as appropriate and necessary, such as storage and transportation practices.

(2) You must document the evaluation you conduct under paragraph (a)(1) of this section.

(b) Approval of foreign suppliers. You must approve your foreign suppliers on the basis

Foreign Supplier Verification Programs for Importers of Food for Humans and Animal Rule

of the evaluation that you conducted under paragraph (a) of this section or that you review and assess under paragraph (d) of this section, and document your approval.

(c) Reevaluation of a foreign supplier's performance and the risk posed by a food. (1) Except as specified in paragraph (d) of this section, you must promptly reevaluate the concerns associated with the factors in paragraph (a)(1) of this section when you become aware of new information about these factors, and the reevaluation must be documented. If you determine that the concerns associated with importing a food from a foreign supplier have changed, you must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier and whether the supplier verification activities conducted under § 1.506 or § 1.511(c) need to be changed.

(2) If at the end of any 3-year period you have not reevaluated the concerns associated with the factors in paragraph (a)(1) of this section in accordance with paragraph (c)(1) of this section, you must reevaluate those concerns and take other appropriate actions, if necessary, in accordance with paragraph (c)(1). You must document your reevaluation and any subsequent actions you take in accordance with paragraph (c)(1).

(d) Review of another entity's evaluation or reevaluation of a foreign supplier's performance and the risk posed by a food. If an entity other than the foreign supplier has, using a qualified individual, performed the evaluation described in paragraph (a) of this section or the reevaluation described in paragraph (c) of this section, you may meet the requirements of the applicable paragraph by reviewing and assessing the evaluation or reevaluation conducted by that entity. You must document your review and assessment, including documenting that the evaluation or reevaluation was conducted by a qualified individual.

(e) Inapplicability to certain circumstances. You are not required to conduct an evaluation under this section or to conduct foreign supplier verification activities under § 1.506 if one of the circumstances described in § 1.507 applies to your importation of a food and you are in compliance with that section.

§ 1.506 What foreign supplier verification and related activities must I conduct?

(a) Use of approved foreign suppliers. (1) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers you have approved based on the evaluation conducted under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). You must document your use of these procedures.

(2) You may rely on an entity other than your foreign supplier to establish the procedures and perform and document the activities required under paragraph (a)(1) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

(b) Foreign supplier verification procedures. You must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to the foods you import.

(c) Requirement of supplier verification. The foreign supplier verification activities must provide assurance that the hazards requiring a control in the food you import have been significantly minimized or prevented.

(d) Determination of appropriate foreign supplier verification activities--(1)(i) General. Except as provided in paragraphs (d)(2) and (3) of this section, before importing a food from a foreign supplier, you must determine and document which verification activity or activities listed in paragraphs (d)(1)(ii)(A) through (D) of this section, as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the food you obtain from the foreign supplier is produced in accordance with paragraph (c) of this section.

Foreign Supplier Verification Programs for Importers of Food for Humans and Animal Rule

Verification activities must address the entity or entities that are significantly minimizing or preventing the hazards or verifying that the hazards have been significantly minimized or prevented (e.g., when an entity other than the grower of produce subject to part 112 of this chapter harvests or packs the produce and significantly minimizes or prevents the hazard or verifies that the hazard has been significantly minimized or prevented, or when the foreign supplier's raw material supplier significantly minimizes or prevents a hazard). The determination of appropriate supplier verification activities must be based on the evaluation of the food and foreign supplier conducted under § 1.505.

(ii) Appropriate verification activities. The following are appropriate supplier verification activities:

- (A) Onsite audits as specified in paragraph (e)(1)(i) of this section;
- (B) Sampling and testing of a food as specified in paragraph (e)(1)(ii) of this section;
- (C) Review of the foreign supplier's relevant food safety records as specified in paragraph (e)(1)(iii) of this section; and
- (D) Other appropriate supplier verification activities as specified in paragraph (e)(1)(iv) of this section.

(2) Verification activities for certain serious hazards. When a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, you must conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless you make an adequate written determination that, instead of such initial and annual onsite auditing, other supplier verification activities listed in paragraph (d)(1)(ii) of this section and/or less frequent onsite auditing are appropriate to provide adequate assurances that the foreign supplier is producing the food in accordance with paragraph (c) of this section, based on the determination made under § 1.505.

(3) Reliance on a determination by another entity. You may rely on a determination of appropriate foreign supplier verification activities in accordance with paragraph (d)(1) or (2) of this section made by an entity other than the foreign supplier if you review and assess whether the entity's determination regarding appropriate activities (including the frequency with which such activities must be conducted) is appropriate. You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual.

(e) Performance of foreign supplier verification activities--(1) Verification activities. Except as provided in paragraph (e)(2) of this section, based on the determination made in accordance with paragraph (d) of this section, you must conduct (and document) or obtain documentation of one or more of the supplier verification activities listed in paragraphs (e)(1)(i) through (iv) of this section for each foreign supplier before importing the food and periodically thereafter.

(i) Onsite audit of the foreign supplier. (A) An onsite audit of a foreign supplier must be performed by a qualified auditor.

(B) If the food is subject to one or more FDA food safety regulations, an onsite audit of the foreign supplier must consider such regulations and include a review of the supplier's written food safety plan, if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(C) If the onsite audit is conducted solely to meet the requirements of paragraph (e) of this section by an audit agent of a certification body that is accredited in accordance with subpart M of this part, the audit is not subject to the requirements in that subpart.

Foreign Supplier Verification Programs for Importers of Food for Humans and Animal Rule

(D) You must retain documentation of each onsite audit, including the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor.

(E) The following inspection results may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date by which the onsite audit would have been required to be conducted:

(1) The written results of an appropriate inspection of the foreign supplier for compliance with applicable FDA food safety regulations conducted by FDA, representatives of other Federal Agencies (such as the USDA), or representatives of State, local, tribal, or territorial agencies; or

(2) The written results of an inspection of the foreign supplier by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the food that is the subject of the onsite audit is within the scope of the official recognition or equivalence determination, and the foreign supplier is in, and under the regulatory oversight of, such country.

(ii) Sampling and testing of the food. You must retain documentation of each sampling and testing of a food, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the date(s) on which the test(s) were conducted and the date of the report of the testing, the results of the testing, any corrective actions taken in response to detection of hazards, information identifying the laboratory conducting the testing, and documentation that the testing was conducted by a qualified individual.

(iii) Review of the foreign supplier's relevant food safety records. You must retain documentation of each record review, including the date(s) of review, the general nature of the records reviewed, the conclusions of the review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

(iv) Other appropriate activity. (A) You may conduct (and document) or obtain documentation of other supplier verification activities that are appropriate based on foreign supplier performance and the risk associated with the food.

(B) You must retain documentation of each activity conducted in accordance with paragraph (e)(1)(iv) of this section, 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 qualified individual.

(2) Reliance upon performance of activities by other entities. (i) Except as specified in paragraph (e)(2)(ii) of this section, you may rely on supplier verification activities conducted in accordance with paragraph (e)(1) of this section by another entity provided that you review and assess the results of these activities in accordance with paragraph (e)(3) of this section.

(ii) You may not rely on the foreign supplier itself or employees of the foreign supplier to perform supplier verification activities, except with respect to sampling and testing of food in accordance with paragraph (e)(1)(ii) of this section.

(3) Review of results of verification activities. You must promptly review and assess the results of the verification activities that you conduct or obtain documentation of under paragraph (e)(1) of this section, or that are conducted by other entities in accordance with paragraph (e)(2) of this section. You must document your review and assessment of the results of verification activities. If the results do not provide adequate assurances that the hazards requiring a control in the food you obtain from the foreign supplier have been significantly minimized or prevented,

you must take appropriate action in accordance with § 1.508(a). You are not required to retain documentation of supplier verification activities conducted by other entities, provided that you can obtain the documentation and make it available to FDA in accordance with § 1.510(b).

(4) Independence of qualified individuals conducting verification activities. There must not be any financial conflicts of interests that influence the results of the verification activities set forth in paragraph (e)(1) of this section, and payment must not be related to the results of the activity.

§ 1.507 What requirements apply when I import a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation?

(a) Circumstances. You are not required to conduct an evaluation of a food and foreign supplier under § 1.505 or supplier verification activities under § 1.506 when you identify a hazard requiring a control (identified hazard) in a food and any of the following circumstances apply:

(1) You determine and document that the type of food (e.g., raw agricultural commodities such as cocoa beans and coffee beans) could not be consumed without application of an appropriate control;

(2) You rely on your 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 this chapter to ensure that the identified hazard will be significantly minimized or prevented and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance, 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;

(3) You rely on your customer who is not 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 this chapter to provide assurance it is manufacturing, processing, or preparing the food in accordance with the applicable food safety requirements and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements;

(4) You rely on your customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of paragraph (c) of this section, that your customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(B) Will only sell the food to another entity that agrees, in writing, it will:

(1) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity 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 this chapter) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based

preventive controls in subpart C of part 117 or subpart C of part 507); or

(2) Obtain a similar written assurance from the entity's customer, subject to the requirements of paragraph (c) of this section, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate; or

(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food you distribute and you document your implementation of that system.

(b) Written assurances. Any written assurances required under this section must contain the following:

(1) Effective date;

(2) Printed names and signatures of authorized officials; and

(3) The assurance specified in the applicable paragraph.

(c) Provision of assurances. The customer or other subsequent entity in the distribution chain for a food that provides a written assurance under paragraph (a)(2), (3), or (4) of this section must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 1.508 What corrective actions must I take under my FSVP?

(a) You must promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic Act. This determination could be based on a review of consumer, customer, or other complaints related to food safety, the verification activities conducted under § 1.506 or § 1.511(c), a reevaluation of the risks posed by the food and the foreign supplier's performance conducted under § 1.505(c) or (d), or any other relevant information you obtain. The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph.

(b) If you determine, by means other than the verification activities conducted under § 1.506 or § 1.511(c) or a reevaluation conducted under § 1.505(c) or (d), that a foreign supplier of food that you import does not produce food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic Act, you must promptly investigate to determine whether your FSVP is adequate and, when appropriate, modify your FSVP. You must document any investigations, corrective actions, and changes to your FSVP that you undertake in accordance with this paragraph.

(c) This section does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

§ 1.509 How must the importer be identified at entry?

(a) You must ensure that, for each line entry of food product offered for importation into the United States, your name, electronic mail address, and unique facility identifier recognized as acceptable by FDA, identifying you as the importer of the food, are provided electronically when filing entry with U.S. Customs and Border Protection.

(b) Before an article of food is imported or offered for import into the United States, the foreign owner or consignee of the food (if there is no U.S. owner or consignee) must designate a U.S. agent or representative as the importer of the food for the purposes of the definition of “importer” in § 1.500.

§ 1.510 How must I maintain records of my FSVP?

(a) General requirements for records. (1) You must keep records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.

(2) You must sign and date records concerning your FSVP upon initial completion and upon any modification of the FSVP.

(3) All records must be legible and stored to prevent deterioration or loss.

(b) Record availability. (1) You must make all records required under this subpart available promptly to an authorized FDA representative, upon request, for inspection and copying. Upon FDA request, you must provide within a reasonable time an English translation of records maintained in a language other than English.

(2) Offsite storage of records, including records maintained by other entities in accordance with § 1.504, § 1.505, or § 1.506, is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(3) If requested in writing by FDA, you must send records to the Agency electronically, or through another means that delivers the records promptly, rather than making the records available for review at your place of business.

(c) Record retention. (1) Except as specified in paragraph (c)(2) of this section, you must retain records referenced in this subpart until at least 2 years after you created or obtained the records.

(2) You must retain records that relate to your processes and procedures, including the results of evaluations and determinations you conduct, for at least 2 years after their use is discontinued (e.g., because you no longer import a particular food, you no longer use a particular foreign supplier, you have reevaluated the risks associated with a food and the foreign supplier, or you have changed your supplier verification activities for a particular food and foreign supplier).

(d) Electronic records. Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.

(e) Use of existing records. (1) You do not need to duplicate existing records you have (e.g., records that you maintain to comply with other Federal, State, or local regulations) if they contain all of the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart.

(2) You do not need to maintain the information required by this subpart in one set of records. If existing records you have contain some of the required information, you may maintain any new information required by this subpart either separately or combined with the existing records.

(f) Public disclosure. Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter.

§ 1.511 What FSVP must I have if I am importing a food subject to certain dietary

supplement current good manufacturing practice regulations?

(a) Importers subject to certain dietary supplement current good manufacturing regulations. If you are required to establish specifications under § 111.70(b) or (d) of this chapter with respect to a food that is a dietary supplement or dietary supplement component you import for further manufacturing, processing, or packaging as a dietary supplement, and you are in compliance with the requirements in §§ 111.73 and 111.75 of this chapter applicable to determining whether the specifications you established are met for such food, then for that food you must comply with the requirements in §§ 1.503 and 1.509, but you are not required to comply with the requirements in § 1.502, §§ 1.504 through 1.508, or § 1.510. This requirement does not limit your obligations with respect to part 111 of this chapter or any other laws enforced by FDA.

(b) Importers whose customer is subject to certain dietary supplement current good manufacturing practice regulations. If your customer is required to establish specifications under § 111.70(b) or (d) of this chapter with respect to a food that is a dietary supplement or dietary supplement component you import for further manufacturing, processing, or packaging as a dietary supplement, your customer is in compliance with the requirements of §§ 111.73 and 111.75 of this chapter applicable to determining whether the specifications it established are met for such food, and you annually obtain from your customer written assurance that it is in compliance with those requirements, then for that food you must comply with the requirements in §§ 1.503, 1.509, and 1.510, but you are not required to comply with the requirements in § 1.502 or §§ 1.504 through 1.508.

(c) Other importers of dietary supplements--(1) General. If the food you import is a dietary supplement and neither paragraph (a) or (b) of this section is applicable, you must comply with paragraph (c) of this section and the requirements in §§ 1.503, 1.505(a)(1)(ii) through (iv), (a)(2), and (b) through (d), and 1.508 through 1.510, but you are not required to comply with the requirements in §§ 1.504, 1.505(a)(1)(i), 1.506, and 1.507. This requirement does not limit your obligations with respect to part 111 of this chapter or any other laws enforced by FDA.

(2) Use of approved foreign suppliers. (i) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers that you have approved based on the evaluation conducted under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). You must document your use of these procedures.

(ii) You may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under paragraph (c)(2)(i) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

(3) Foreign supplier verification procedures. You must establish and follow adequate written procedures for ensuring that appropriate foreign supplier verification activities are conducted with respect to the foods you import.

(4) Determination of appropriate foreign supplier verification activities--(i) General. Except as provided in paragraph (c)(4)(iii) of this section, before importing a dietary supplement from a foreign supplier, you must determine and document which verification activity or activities listed in paragraphs (c)(4)(ii)(A) through (D) of this section, as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the foreign supplier is producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111 of this chapter. This determination must be based on the evaluation conducted under § 1.505.

Foreign Supplier Verification Programs for Importers of Food for Humans and Animal Rule

(ii) Appropriate verification activities. The following are appropriate supplier verification activities:

- (A) Onsite audits as specified in paragraph (c)(5)(i)(A) of this section;
- (B) Sampling and testing of a food as specified in paragraph (c)(5)(i)(B) of this section;
- (C) Review of the foreign supplier's relevant food safety records as specified in paragraph (c)(5)(i)(C) of this section; and
- (D) Other appropriate supplier verification activities as specified in paragraph (c)(5)(i)(D) of this section.

(iii) Reliance upon determination by other entity. You may rely on a determination of appropriate foreign supplier verification activities in accordance with paragraph (c)(4)(i) of this section made by an entity other than the foreign supplier if you review and assess whether the entity's determination regarding appropriate activities (including the frequency with which such activities must be conducted) is appropriate based on the evaluation conducted in accordance with § 1.505. You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual.

(5) Performance of foreign supplier verification activities. (i) Except as provided in paragraph (c)(5)(ii) of this section, for each dietary supplement you import under paragraph (c) of this section, you must conduct (and document) or obtain documentation of one or more of the verification activities listed in paragraphs (c)(5)(i)(A) through (D) of this section before importing the dietary supplement and periodically thereafter.

(A) Onsite auditing. You conduct (and document) or obtain documentation of a periodic onsite audit of your foreign supplier.

(1) An onsite audit of a foreign supplier must be performed by a qualified auditor.

(2) The onsite audit must consider the applicable requirements of part 111 of this chapter and include a review of the foreign supplier's written food safety plan, if any, and its implementation (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(3) If the onsite audit is conducted solely to meet the requirements of paragraph (c)(5) of this section by an audit agent of a certification body that is accredited in accordance with subpart M of this part, the audit is not subject to the requirements in that subpart.

(4) You must retain documentation of each onsite audit, including the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor.

(5) The following inspection results may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date by which the onsite audit would have been required to be conducted:

(i) The written results of appropriate inspection of the foreign supplier for compliance with the applicable requirements in part 111 of this chapter conducted by FDA, representatives of other Federal Agencies (such as the USDA), or representatives of State, local, tribal, or territorial agencies; or

(ii) The written results of an inspection by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the food that is the subject of the onsite audit is within the scope of the official recognition or equivalence determination, and the foreign supplier is in, and under the regulatory oversight of, such country.

(B) Sampling and testing of the food. You must retain documentation of each sampling and testing of a dietary supplement, including identification of the food tested (including lot

Foreign Supplier Verification Programs for Importers of Food for Humans and Animal Rule

number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the date(s) on which the test(s) were conducted and the date of the report of the testing, the results of the testing, any corrective actions taken in response to detection of hazards, information identifying the laboratory conducting the testing, and documentation that the testing was conducted by a qualified individual.

(C) Review of the foreign supplier's food safety records. You must retain documentation of each record review, including the date(s) of review, the general nature of the records reviewed, the conclusions of the review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

(D) Other appropriate activity. (1) You may conduct (and document) or obtain documentation of other supplier verification activities that are appropriate based on foreign supplier performance and the risk associated with the food.

(2) You must retain documentation of each activity conducted in accordance with paragraph (c)(5)(i)(D)(1) of this section, 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 qualified individual.

(ii) Reliance upon performance of activities by other entities. (A) Except as specified in paragraph (c)(5)(ii)(B) of this section, you may rely on supplier verification activities conducted in accordance with paragraph (c)(5)(i) by another entity provided that you review and assess the results of these activities in accordance with paragraph (c)(5)(iii) of this section.

(B) You may not rely on the foreign supplier or employees of the foreign supplier to perform supplier verification activities, except with respect to sampling and testing of food in accordance with paragraph (c)(5)(i)(B) of this section.

(iii) Review of results of verification activities. You must promptly review and assess the results of the verification activities that you conduct or obtain documentation of under paragraph (c)(5)(i) of this section, or that are conducted by other entities in accordance with paragraph (c)(5)(ii) of this section. You must document your review and assessment of the results of verification activities. If the results show that the foreign supplier is not producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111 of this chapter, you must take appropriate action in accordance with § 1.508(a). You are not required to retain documentation of supplier verification activities conducted by other entities, provided that you can obtain the documentation and make it available to FDA in accordance with § 1.510(b).

(iv) Independence of qualified individuals conducting verification activities. There must not be any financial conflicts of interest that influence the results of the verification activities set forth in paragraph (c)(5)(i) of this section, and payment must not be related to the results of the activity.

§ 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?

(a) Eligibility. This section applies only if:

(1) You are a very small importer; or

(2) You are importing certain food from certain small foreign suppliers as follows:

(i) The foreign supplier is a qualified facility as defined by § 117.3 or § 507.3 of this chapter;

(ii) You are importing produce from a foreign supplier that is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a) of this

chapter, or in accordance with §§ 112.4(b) and 112.5 of this chapter; or

(iii) You are importing shell eggs from a foreign supplier that is not subject to the requirements of part 118 of this chapter because it has fewer than 3,000 laying hens.

(b) Applicable requirements--(1) Documentation of eligibility--(i) Very small importer status. (A) If you are a very small importer and you choose to comply with the requirements in this section, you must document that you meet the definition of very small importer in § 1.500 with respect to human food and/or animal food before initially importing food as a very small importer and thereafter on an annual basis by December 31 of each calendar year.

(B) For the purpose of determining whether you satisfy the definition of very small importer with respect to human food and/or animal food for a given calendar year, the relevant 3-year period of sales (and U.S. market value of human or animal food, as appropriate) is the period ending 1 year before the calendar year for which you intend to import food as a very small importer. The baseline year for calculating the adjustment for inflation is 2011. If you conduct any food sales in currency other than U.S. dollars, you must use the relevant currency exchange rate in effect on December 31 of the year in which sales occurred to calculate the value of these sales.

(ii) Small foreign supplier status. If you are a importing food from a small foreign supplier as specified in paragraph (a)(2) of this section and you choose to comply with the requirements in this section, you must obtain written assurance that your foreign supplier meets the criteria in paragraph (a)(2)(i), (ii), or (iii) of this section before first approving the supplier for an applicable calendar year and thereafter on an annual basis by December 31 of each calendar year, for the following calendar year.

(2) Additional requirements. If this section applies and you choose to comply with the requirements in paragraph (b) of this section, you also are required to comply with the requirements in §§ 1.502, 1.503, and 1.509, but you are not required to comply with the requirements in §§ 1.504 through 1.508 or § 1.510.

(3) Foreign supplier verification activities. (i) If you are a very small importer, for each food you import, you must obtain written assurance, before importing the food and at least every 2 years thereafter, that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 and 403(w) (if applicable) of the Federal Food, Drug, and Cosmetic Act.

(ii) If your foreign supplier is a qualified facility as defined by § 117.3 or § 507.3 of this chapter and you choose to comply with the requirements in this section, you must obtain written assurance before importing the food and at least every 2 years thereafter that the foreign supplier is producing the food in compliance with applicable FDA food safety regulations (or, when applicable, the relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States). The written assurance must include either:

(A) A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food; or

(B) A statement that the supplier is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

(iii) If your foreign supplier is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a) of this chapter, or in accordance with §§ 112.4(b) and 112.5 of this chapter, and you choose to comply with the requirements in this section, you must obtain written assurance before importing the produce and at least every 2

Foreign Supplier Verification Programs for Importers of Food for Humans and Animal Rule

years thereafter that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(iv) If your foreign supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has fewer than 3,000 laying hens and you choose to comply with the requirements in this section, you must obtain written assurance before importing the shell eggs and at least every 2 years thereafter that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States).

(4) Corrective actions. You must promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food consistent with the assurance provided in accordance with § 1.512(b)(3)(i) through (iv). The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph (b)(4). This paragraph (b)(4) does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

(5) Records--(i) General requirements for records. (A) You must keep records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.

(B) You must sign and date records concerning your FSVP upon initial completion and upon any modification of the FSVP.

(C) All records must be legible and stored to prevent deterioration or loss.

(ii) Availability. (A) You must make all records required under this subpart available promptly to an authorized FDA representative, upon request, for inspection and copying. Upon FDA request, you must provide within a reasonable time an English translation of records maintained in a language other than English.

(B) Offsite storage of records, including records retained by other entities in accordance with paragraph (c) of this section, is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(C) If requested in writing by FDA, you must send records to the Agency electronically or through another means that delivers the records promptly, rather than making the records available for review at your place of business.

(iii) Record retention. (A) Except as specified in paragraph (b)(5)(iii)(B) or (C) of this section, you must retain records required under this subpart for a period of at least 2 years after you created or obtained the records.

(B) If you are subject to paragraph (c) of this section, you must retain records that relate to your processes and procedures, including the results of evaluations of foreign suppliers and procedures to ensure the use of approved suppliers, for at least 2 years after their use is discontinued (e.g., because you have reevaluated a foreign supplier's compliance history or changed your procedures to ensure the use of approved suppliers).

(C) You must retain for at least 3 years records that you rely on during the 3-year period preceding the applicable calendar year to support your status as a very small importer.

(iv) Electronic records. Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the

Foreign Supplier Verification Programs for Importers of Food for Humans and Animal Rule

requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.

(v) Use of existing records. (A) You do not need to duplicate existing records you have (e.g., records that you maintain to comply with other Federal, State, or local regulations) if they contain all of the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart.

(B) You do not need to maintain the information required by this subpart in one set of records. If existing records you have contain some of the required information, you may maintain any new information required by this subpart either separately or combined with the existing records.

(vi) Public disclosure. Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter.

(c) Requirements for importers of food from certain small foreign suppliers. The following additional requirements apply if you are importing food from certain small foreign suppliers as specified in paragraph (a)(2) of this section and you are not a very small importer:

(1) Evaluation of foreign supplier compliance history--(i) Initial evaluation. In approving your foreign suppliers, you must evaluate the applicable FDA food safety regulations and information relevant to the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation. You may also consider other factors relevant to a foreign supplier's performance, including those specified in § 1.505(a)(1)(iii)(A) and (C).

(ii) Reevaluation of foreign supplier compliance history. (A) Except as specified in paragraph (c)(1)(iii) of this section, you must promptly reevaluate the concerns associated with the foreign supplier's compliance history when you become aware of new information about the matters in paragraph (c)(1)(i) of this section, and the reevaluation must be documented. If you determine that the concerns associated with importing a food from a foreign supplier have changed, you must promptly determine (and document) whether it is appropriate to continue to import the food from the foreign supplier.

(B) If at the end of any 3-year period you have not reevaluated the concerns associated with the foreign supplier's compliance history in accordance with paragraph (c)(1)(ii)(A) of this section, you must reevaluate those concerns and take other appropriate actions, if necessary, in accordance with paragraph (c)(1)(ii)(A). You must document your reevaluation and any subsequent actions you take in accordance with paragraph (c)(1)(ii)(A).

(iii) Review of another entity's evaluation or reevaluation of foreign supplier compliance history. If an entity other than the foreign supplier has, using a qualified individual, performed the evaluation described in paragraph (c)(1)(i) of this section or the reevaluation described in paragraph (c)(1)(ii), you may meet the requirements of the applicable paragraph by reviewing and assessing the evaluation or reevaluation conducted by that entity. You must document your review and assessment, including documenting that the evaluation or reevaluation was conducted by a qualified individual.

(2) Approval of foreign supplier. You must approve your foreign suppliers on the basis of the evaluation you conducted under paragraph (c)(1)(i) of this section or that you review and assess under paragraph (c)(1)(iii) of this section, and document your approval.

(3) Use of approved foreign suppliers. (i) You must establish and follow written procedures to ensure that you import foods only from foreign suppliers you have approved based on the evaluation conducted under paragraph (c)(1)(i) of this section (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before importing the food). You must document your use of

these procedures.

(ii) You may rely on an entity other than the foreign supplier to establish the procedures and perform and document the activities required under paragraph (c)(3)(i) of this section provided that you review and assess that entity's documentation of the procedures and activities, and you document your review and assessment.

§ 1.513 What FSVP may I have if I am importing certain food from a country with an officially recognized or equivalent food safety system?

(a) General. (1) If you meet the conditions and requirements of paragraph (b) of this section for a food of the type specified in paragraph (a)(2) of this section that you are importing, then you are not required to comply with the requirements in §§ 1.504 through 1.508. You would still be required to comply with the requirements in §§ 1.503, 1.509, and 1.510.

(2) This section applies to food that is not intended for further manufacturing/processing, including packaged food products and raw agricultural commodities that will not be commercially processed further before consumption.

(b) Conditions and requirements. (1) Before importing a food from the foreign supplier and annually thereafter, you must document that the foreign supplier is in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and that the food is within the scope of that official recognition or equivalency determination.

(2) Before importing a food from the foreign supplier, you must determine and document whether the foreign supplier of the food is in good compliance standing with the food safety authority of the country in which the foreign supplier is located. You must continue to monitor whether the foreign supplier is in good compliance standing and promptly review any information obtained. If the information indicates that food safety hazards associated with the food are not being significantly minimized or prevented, you must take prompt corrective action. The appropriate corrective action will depend on the circumstances but could include discontinuing use of the foreign supplier. You must document any corrective actions that you undertake in accordance with this paragraph (b)(2).

§ 1.514 What are some consequences of failing to comply with the requirements of this subpart?

(a) Refusal of admission. An article of food is subject to refusal of admission under section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act if it appears that the importer of that food fails to comply with this subpart with respect to that food. If there is no U.S. owner or consignee of an article of food at the time the food is offered for entry into the United States, the article of food may not be imported into the United States unless the foreign owner or consignee has appropriately designated a U.S. agent or representative as the importer in accordance with § 1.500.

(b) Prohibited act. The importation or offering for importation into the United States of an article of food without the importer having an FSVP that meets the requirements of section 805 of the Federal Food, Drug, and Cosmetic Act, including the requirements of this subpart, is prohibited under section 301(zz) of the Federal Food, Drug, and Cosmetic Act.

PART 11--ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

3. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321-393; 42 U.S.C. 262.

4. In § 11.1, add and reserve paragraph (h) and (k) and add paragraph (l) to read as follows:

§ 11.1 Scope.

Foreign Supplier Verification Programs for Importers of Food for Humans and Animal Rule

* * * * *

(1) This part does not apply to records required to be established or maintained by subpart L of part 1 of this chapter. Records that satisfy the requirements of subpart L of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

PART 111--CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS

5. The authority citation for 21 CFR part 111 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 371, 374, 381, 393; 42 U.S.C. 264.

6. In § 111.5, add a sentence after the existing sentence to read as follows:

§ 111.5 Do other statutory provisions and regulations apply?

* * * For importers of dietary supplements and dietary supplement components, the regulation on foreign supplier verification programs can be found in subpart L of part 1 of this chapter.

Dated: October 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-28158 Filed: 11/13/2015 8:45 am; Publication Date: 11/27/2015]

INTENTIONALLY LEFT BLANK

Page separates individual foreign supplier-provided food safety documents.



Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting [your question](#) at <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>.

Appendix 1: Potential Hazards for Foods and Processes

Appendix Organization

This appendix contains information on the potential biological, chemical, and physical hazards that are food-related and process related. The potential hazard information presented covers the following 17 food (including ingredients and raw materials) categories:

- Bakery
- Beverage
- Chocolate and Candy
- Dairy
- Dressings and Condiments
- Egg
- Food Additives
- Fruits and Vegetables
- Game Meat
- Grains
- Multi-Component Foods (such as a refrigerated entrée or a sandwich)
- Nuts
- Oil

¹ This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration. [Underlined text in yellow highlights represents a correction from the draft Appendix 1 that we issued for public comment in August 2016.](#)

***Contains Non-binding Recommendations
Draft-Not for Implementation***

- Snack Foods
- Soups
- Spice
- Sweeteners

To help you to identify food-related and process-related hazards for the food categories listed above, this appendix contains three series of tables:

- **Tables 1A** through **1Q** contain information that you should consider for potential food-related biological hazards.
- **Tables 2A** through **2Q** contain information that you should consider for potential food-related chemical hazards.
- **Tables 3A** through **3Q** contain information that you should consider for potential process-related biological, chemical and physical hazards.

How to Use the Tables in Appendix 1

Information provided in each table is organized to describe:

- Food Categories
- Food Subcategories
- Hazards
- Example Products

Potential hazards that you should consider for each food subcategory are indicated by an “X” in the column for the hazard being assessed.

The tables in Appendix 1 encompass more than 200 pages. To reduce the printed size of this document (which includes all of the available chapters in this guidance), we have not included those tables. To access the tables in Appendix 1, see the separate Appendix 1 (complete with tables).

List of Tables

Biological Hazards Tables

- Table 1A: Information that you should consider for potential ingredient or other food-related biological hazards for Bakery Items
- Table 1B: Information that you should consider for potential ingredient or other food-related biological hazards for Beverage Items
- Table 1C: Information that you should consider for potential ingredient or other food-related biological hazards for Food Additives
- Table 1D: Information that you should consider for potential ingredient or other food-related biological hazards for Chocolate and Candy
- Table 1E: Information that you should consider for potential ingredient or other food-related biological hazards for Dairy
- Table 1F: Information that you should consider for potential ingredient or other food-related biological hazards for Dressings, Condiments, and Dips
- Table 1G: Information that you should consider for potential ingredient or other food-related biological hazards for Egg and Egg Products
- Table 1H: Information that you should consider for potential ingredient or other food-related biological hazards for Fruits and Vegetables
- Table 1I: Information that you should consider for potential ingredient or other food-related biological hazards for Game Meat Products
- Tables 1J: Information that you should consider for potential ingredient or other food-related biological hazards for Grains, Beans and Grain Products
- Table 1K: Information that you should consider for potential ingredient or other food-related biological hazards for Multi-Component Foods
- Table 1L: Information that you should consider for potential ingredient or other food-related biological hazards for Nuts and Seeds
- Table 1M: Information that you should consider for potential ingredient or other food-related biological hazards for Oils and Oils Products
- Table 1N: Information that you should consider for potential ingredient or other food-related biological hazards for Snack Foods
- Table 1O: Information that you should consider for potential ingredient or other food-related biological hazards for Soups and Sauces
- Table 1P: Information that you should consider for potential ingredient or other food-related biological hazards for Spices and Herbs

***Contains Non-binding Recommendations
Draft-Not for Implementation***

Table 1Q: Information that you should consider for potential ingredient or other food-related biological hazards for Food Sweeteners (Nutritive and Non-Nutritive)

Chemical Hazards Tables

Table 2A: Information that you should consider for potential ingredient or other food-related chemical hazards for Bakery Items

Table 2B: Information that you should consider for potential ingredient or other food-related chemical hazards for Beverage Items

Table 2C: Information that you should consider for potential ingredient or other food-related chemical hazards for Food Additives

Table 2D: Information that you should consider for potential ingredient or other food-related chemical hazards for Chocolate and Candy

Table 2E: Information that you should consider for potential ingredient or other food-related chemical hazards for Dairy

Table 2F: Information that you should consider for potential ingredient or other food-related chemical hazards for Dressings, Condiments, and Dips

Table 2G: Information that you should consider for potential ingredient or other food-related chemical hazards for Egg and Egg Products

Table 2H: Information that you should consider for potential ingredient or other food-related chemical hazards for Fruits and Vegetables

Table 2I: Information that you should consider for potential ingredient or other food-related chemical hazards for Game Meat Products

Tables 2J: Information that you should consider for potential ingredient or other food-related chemical hazards for Grains, Beans and Grain Products

Table 2K: Information that you should consider for potential ingredient or other food-related chemical hazards for Multi-Component Foods

Table 2L: Information that you should consider for potential ingredient or other food-related chemical hazards for Nuts and Seeds

Table 2M: Information that you should consider for potential ingredient or other food-related chemical hazards for Oils and Oils Products

Table 2N: Information that you should consider for potential ingredient or other food-related chemical hazards for Snack Foods

Table 2O: Information that you should consider for potential ingredient or other food-related chemical hazards for Soups and Sauces

Table 2P: Information that you should consider for potential ingredient or other food-related chemical hazards for Spices and Herbs

Table 2Q: Information that you should consider for potential ingredient or other food-related chemical hazards for Food Sweeteners (Nutritive and Non-Nutritive)

***Contains Non-binding Recommendations
Draft-Not for Implementation***

Process Hazards Tables

- Table 3A: Information that you should consider for potential process-related biological, chemical, and physical hazards for Bakery Items
- Table 3B: Information that you should consider for potential process-related biological, chemical, and physical hazards for Beverage Items
- Table 3C: Information that you should consider for potential process-related biological, chemical, and physical hazards for Food Additives
- Table 3D: Information that you should consider for potential process-related biological, chemical, and physical hazards for Chocolate and Candy
- Table 3E: Information that you should consider for potential process-related biological, chemical, and physical hazards for Dairy
- Table 3F: Information you should consider for potential process-related biological, chemical, and physical hazards for Dressings, Condiments, and Dips
- Table 3G: Information that you should consider for potential process-related biological, chemical, and physical hazards for Egg and Egg Products
- Table 3H: Information that you should consider for potential process-related biological, chemical, and physical hazards for Fruits and Vegetables
- Table 3I: Information that you should consider for potential process-related biological, chemical, and physical hazards for Game Meats
- Table 3J: Information that you should consider for potential process-related biological, chemical, and physical hazards for Grains, Beans and Grain Products
- Table 3K: Information that you should consider for potential process-related biological, chemical, and physical hazards for Multi-Component Foods
- Table 3L: Information that you should consider for potential process-related biological, chemical, and physical hazards for Nuts and Seeds
- Table 3M: Information that you should consider for potential process-related biological, chemical, and physical hazards for Oils and Oils Products
- Table 3N: Information that you should consider for potential process-related biological, chemical, and physical hazards for Snack Foods
- Table 3O: Information that you should consider for potential process-related biological, chemical, and physical hazards for Soups and Sauces
- Table 3P: Information that you should consider for potential process-related biological, chemical, and physical hazards for Spices and Herbs
- Table 3Q: Information that you should consider for potential process-related biological, chemical, and physical hazards for Food Sweeteners (Nutritive and Non-Nutritive)

*Contains Non-binding Recommendations
Draft-Not for Implementation*

Biological Hazards Tables

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 1A: Information that you should consider for potential ingredient or other food-related biological hazards for Bakery Items

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Unbaked Bakery Items - Ready-To-Bake (RTB)	1a	Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust	Refrigerated						X	X	X					Buttermilk biscuits, Cinnamon rolls, Croissants, Pizza Crust, Chocolate Chip Cookie Dough, Puff Pastry, Phyllo
Unbaked Bakery Items - Ready-To-Bake (RTB)	1b	Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust	Frozen						X	X	X					Buttermilk biscuits, Cinnamon rolls, Croissants, Pizza Crust, Chocolate Chip Cookie Dough, Puff Pastry, Phyllo
Unbaked Bakery Items - Ready-To-Bake (RTB)	2a	Parbaked/ParBoiled Bread, Biscuits, Rolls, Pizza/Pie Crust	Refrigerated						X	X	X					Artisan breads, Bagels, Biscuits, Rolls, Croissant, Pizza Crust
Unbaked Bakery Items - Ready-To-Bake (RTB)	2b	Parbaked/ParBoiled Bread, Biscuits, Rolls, Pizza/Pie Crust	Frozen						X	X	X					Artisan breads, Bagels, Biscuits, Rolls, Croissant, Pizza Crust
Unbaked Bakery Items - Ready-To-Bake (RTB)	3	Liquid Batter	Refrigerated						X	X	X					Pancake batter, Brownie batter, Waffle batter, and Doughnut batter

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Unbaked Bakery Items - Ready-To-Bake (RTB)	4	Fruit pies/cobblers	Frozen						X	X	X		X			Apple/Cherry/Peach Cobbler; Apple, Cherry/Mixed Berries/etc. Pies
Unbaked Bakery Items - Ready-To-Bake (RTB)	5	Custard pies	Frozen						X	X	X		X			Pumpkin and Sweet Potato Pies
Fully-Baked Without Filling, No Topping/Frosting	6	Bread, Whole/Pre-sliced	Shelf-Stable, Refrigerated or Frozen						X	X						Breads (e.g., White, Wheat, Rye, Oat Bran, Pumpernickel), Cheese Breads, Raisin Breads; Cornbread, Plain or Flavored Biscuits, Bagels, Rolls, Croissants, Pita Bread, Pumpkin Bread
Fully-Baked Without Filling, No Topping/Frosting	7a	Cakes/Muffins/Brownies/ Doughnut	Shelf-Stable						X	X						Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Without Filling, No Topping/Frosting	7b	Cakes/Muffins/Brownies/ Doughnut	Refrigerated						X	X						Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Fully-Baked Without Filling, No Topping/Frosting	7c	Cakes/Muffins/Brownies/ Doughnut	Frozen						X	X						Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Without Filling, No Topping/Frosting	8	Cookies	Shelf-Stable						X	X			X			Chocolate Chip, Peanut Butter, Biscotti, Lemon, Butter Cookies, Brownies, Wafers, Oatmeal Cookies, Fruit, Cream or Chocolate-Filled Crisps/Bars, Wafers
Fully-Baked Without Filling, No Topping/Frosting	9a	Other Pastry Products	Refrigerated						X	X	X		X			French Toast, Blueberry Pancakes, Waffles
Fully-Baked Without Filling, No Topping/Frosting	9b	Other Pastry Products	Frozen						X	X	X		X			French Toast, Blueberry Pancakes, Waffles
Fully-Baked Including Fillings, No Topping/Frosting	10	Bread, Whole/Pre-sliced	Shelf-Stable, Refrigerated or Frozen						X	X						Cheese Breads, Raisin Breads; Cornbread, Flavored Biscuits, Chocolate Croissants, Pumpkin Bread, Banana Nut Bread

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Fully-Baked Including Fillings, No Topping/Frosting	11a	Cakes/Muffins/Brownies/ Doughnut	Shelf-Stable		X				X	X						Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Including Fillings, No Topping/Frosting	11b	Cakes/Muffins/Brownies/ Doughnut	Refrigerated		X				X	X						Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Including Fillings, No Topping/Frosting	11c	Cakes/Muffins/Brownies/ Doughnut	Frozen						X	X						Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Including Fillings, No Topping/Frosting	12a	Fruit Pies/Cobblers	Shelf-Stable						X	X	X		X			Various Fruit Pies (Apple/Cherry/Blueberry, Rhubarb, Mixed Berry/etc.)
Fully-Baked Including Fillings, No Topping/Frosting	12b	Fruit Pies/Cobblers	Refrigerated						X	X	X		X			Various Fruit Pies (Apple/Cherry/Blueberry, Rhubarb, Mixed Berry/etc.)
Fully-Baked Including Fillings, No Topping/Frosting	12c	Fruit Pies/Cobblers	Frozen						X	X	X		X			Various Fruit Pies (Apple/Cherry/Blueberry, Rhubarb, Mixed Berry/etc.)

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Fully-Baked Including Fillings, No Topping/Frosting	13a	Custard/Crème Pie	Shelf-Stable						X	X	X		X			Pumpkin/Sweet Potato, Lemon Pie, Key Lime Pie; Coconut Custard
Fully-Baked Including Fillings, No Topping/Frosting	13b	Custard/Crème Pie	Refrigerated						X	X	X		X			Pumpkin/Sweet Potato, Lemon Pie, Key Lime Pie; Coconut Custard
Fully-Baked Including Fillings, No Topping/Frosting	13c	Custard/Crème Pie	Frozen						X	X	X		X			Pumpkin/Sweet Potato, Lemon Pie, Key Lime Pie; Coconut Custard
Fully-Baked Including Fillings, No Topping/Frosting	14	Cookies	Shelf-Stable						X	X			X			Chocolate Chip, Peanut Butter, Biscotti, Lemon, Butter Cookies, Brownies, Wafers, Oatmeal Cookies, Fruit, Cream or Chocolate-Filled Crisps/Bars, Wafers
Fully-Baked Including Fillings, No Topping/Frosting	15a	Other Pastry Products	Refrigerated						X	X	X		X			French Toast, Blueberry Pancakes, Waffles

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Fully-Baked Including Fillings, No Topping/Frosting	15b	Other Pastry Products	Frozen						X	X	X		X			French Toast, Blueberry Pancakes, Waffles
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	16	Bread, Whole/Pre-sliced	Shelf-Stable, Refrigerated or Frozen						X	X	X		X			Bread with Drizzles/Frosting, Seeds/Nuts on Top,
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	17a	Cakes/Muffins/Brownies/ Doughnut	Shelf-Stable		X				X	X	X		X			Cakes/Muffin/Cheesecakes with Frosting and Topping (cream, nuts, confectionery and dried fruits, etc.); Black Forest Torte
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	17b	Cakes/Muffins/Brownies/ Doughnut	Refrigerated		X				X	X	X		X			Cakes/Muffin/Cheesecakes with Frosting and Topping (cream, nuts, confectionery and dried fruits, etc.); Black Forest Torte

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	17c	Cakes/Muffins/Brownies/ Doughnut	Frozen						X	X	X		X			Cakes/Muffin/Cheesecakes with Frosting and Topping (cream, nuts, confectionery and dried fruits, etc.); Black Forest Torte
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	18a	Fruit Pies/Cobblers	Shelf-Stable						X	X	X		X			Fruit Pies/Cobblers with Drizzles and Cream Topping
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	18b	Fruit Pies/Cobblers	Refrigerated						X	X	X		X			Fruit Pies/Cobblers with Drizzles and Cream Topping
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	18c	Fruit Pies/Cobblers	Frozen						X	X	X		X			Fruit Pies/Cobblers with Drizzles and Cream Topping
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	19a	Custard/Crème Pie	Shelf-Stable						X	X	X		X			Pumpkin and Sweet Potato Pies with Whipped Cream, Key Lime Pie, Coconut Custard Pie, Fruit Topped Cheesecake

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	19b	Custard/Crème Pie	Refrigerated						X	X	X		X			Pumpkin and Sweet Potato Pies with Whipped Cream, Key Lime Pie, Coconut Custard Pie, Fruit Topped Cheesecake
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	19c	Custard/Crème Pie	Frozen						X	X	X		X			Pumpkin and Sweet Potato Pies with Whipped Cream, Key Lime Pie, Coconut Custard Pie, Fruit Topped Cheesecake
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	20	Cookies	Shelf-Stable						X	X	X		X			Cream-Filled Sandwich Cookies
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	21a	Other Pastry Products	Refrigerated						X	X	X		X			Danishes, Éclair, Cream Puffs, Cannoli, Doughnuts, Toaster Pastries, Apple Turnovers, Baklava with Additions after Baking

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	21b	Other Pastry Products	Frozen						X	X	X		X			Danishes, Éclair, Cream Puffs, Cannoli, Doughnuts, Toaster Pastries, Apple Turnovers, Baklava with Additions after Baking
Assembled Cream Pies	22a	Custard/Crème Pie	Refrigerated						X	X	X		X			French Silk, Chocolate Cream Pie, Coconut Cream Pie, Peanut Butter Pie, Meringue Pies
Assembled Cream Pies	22b	Custard/Crème Pie	Frozen						X	X	X		X			French Silk, Chocolate Cream Pie, Coconut Cream Pie, Peanut Butter Pie, Meringue Pies
Other Bakery Products	23a	Tortillas, Soft Shell/Hard Shell	Shelf Stable						X	X						Soft (Corn, Wheat), Hard Type, Baked, Fried
Other Bakery Products	23b	Tortillas, Soft Shell/Hard Shell	Refrigerated						X	X	X					Soft (Corn, Wheat), ParBaked

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Other Bakery Products	24	Dry Mixes	Shelf Stable						X	X						Pancake Batter Mixes, Flour Mixes, Cookie Mixes, Cake Mixes, Brownie Mixes, Bread Crumbs, Cornmeal, Biscuits, Breeding Mix, Pie Crust Mix
Other Bakery Products	25	Ice Cream Cones	Shelf Stable						X	X						Sugar cones, regular cone
Other Bakery Products	26	Croutons/Bread Crumbs Unseasoned	Shelf Stable						X	X						Unseasoned
Other Bakery Products	27	Croutons/Bread Crumbs, Seasoned	Shelf Stable						X	X						Seasoned

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 1B: Information that you should consider for potential ingredient or other food-related biological hazards for Beverage Items

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Ready-to-Drink	1	Carbonated	Shelf-Stable													Cola, Root beer, Ginger ale, Fruit-Flavored Soda (Carbonated), Tonic Water, Sparkling Beverages(non-alcoholic)
Ready-to-Drink	2	Bottled Water	Shelf-Stable						X							Mineral Water, Spring Water, Water with Fruit Flavors, Sparkling Water, Distilled Water, Carbonated Water
Ready-to-Drink	3	Coffee, plain	Shelf-Stable													Iced Coffee, Regular and Decaffeinated Coffees
Ready-to-Drink	4a	Coffee, Flavored	Shelf-Stable							X						Lattes, Mocha, Café Vanilla, Cappuccino, Hazelnut Coffee
Ready-to-Drink	4b	Coffee, Flavored	Refrigerated							X						Lattes, Mocha, Café Vanilla, Cappuccino, Hazelnut Coffee

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Ready-to-Drink	5a	Chocolate/Cocoa	Shelf-Stable							X						Non-dairy chocolate/ cocoa flavored drinks
Ready-to-Drink	5b	Chocolate/Cocoa	Refrigerated							X						Non-dairy chocolate/ cocoa flavored drinks
Ready-to-Drink	6a	Tea, Plain	Shelf-Stable													Sweet Tea, Iced Tea, Regular and Decaffeinated Teas, Low Calorie Tea
Ready-to-Drink	6b	Tea, Plain	Refrigerated													Sweet Tea, Iced Tea, Regular and Decaffeinated Teas, Low Calorie Tea
Ready-to-Drink	7a	Tea, Flavored	Shelf-Stable													Flavored Teas (Fruit, Botanicals), Tea Blends, Regular and Decaffeinated, Regular and Low Calorie

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Ready-to-Drink	7b	Tea, Flavored	Refrigerated	X	X				X	X			X			Flavored Teas (Fruit, Botanicals), Tea Blends, Regular and Decaffeinated, Regular and Low Calorie
Ready-to-Drink	8a	Juice-Based	Shelf-Stable						X	X						Fruit Drinks with Some Juice Content (not 100% juice)
Ready-to-Drink	8b	Juice-Based	Refrigerated						X	X						Fruit Drinks with Some Juice Content (not 100% juice)
Ready-to-Drink	9a	Other Flavored	Shelf-Stable							X						Fruit Flavored Drink, Fruit Punch, Raspberry Lemonade
Ready-to-Drink	9b	Other Flavored	Refrigerated							X						Fruit Flavored Drink, Fruit Punch, Raspberry Lemonade

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Ready-to-Drink	10a	Drinks with Supplements	Shelf-Stable							X						Caffeinated Energy Beverages, Sports Drinks, Vitamin Waters, Drinks with Herbal Infusions
Ready-to-Drink	10b	Drinks with Supplements	Refrigerated							X						Caffeinated Energy Beverages, Sports Drinks, Vitamin Waters, Drinks with Herbal Infusions
Ready-to-Drink	11	Milk Substitute	Refrigerated	X					X	X						Rice milk, Soy milk, Almond Milk, Non-Dairy Liquid Creamer
Coffee Beans/Tea Leaves	12	Coffee, Plain	Shelf-Stable													Whole Roasted Coffee Beans, Ground Coffee, Single Serve Coffee Containers
Coffee Beans/Tea Leaves	13	Coffee, Flavored	Shelf-Stable							X						Hazelnut Coffee, Vanilla Coffee, Single Serve Coffee Containers

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Coffee Beans/Tea Leaves	14	Tea, Loose Leaf and Bagged, Tea Substitutes	Shelf-Stable	X		X			X	X			X			Black Tea, Green Tea, Oolong Tea, Chai Tea, Tea With Blends of Fruits, Botanicals, Grains, etc., Tea Substitute (Chamomile, Rose Hip, Mint, Sassafras, and Barley), Single Serve Tea Containers
Powdered Beverages	15	Instant Coffee	Shelf-Stable													Instant Coffee, Coffee Substitute (Chicory Root Powder, Roast Cereal)
Powdered Beverages	16	Cocoa/Chocolate	Shelf-Stable							X						Breakfast Cocoa, Chocolate Dairy Mix, Cocoa Dairy Mix, Cappuccino Mix
Powdered Beverages	17	Powdered drink and flavoring mixes	Shelf-Stable							X						Flavoring powder, Grape, Orange, Lemon-Lime

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Powdered Beverages	18	Instant Tea	Shelf-Stable							X						Lemon-flavored powdered tea
Powdered Beverages	19	Coffee Creamer - Non-Dairy	Shelf-Stable							X						Non Dairy Coffee Creamer
Liquid Beverage Mixes	20	Base mix, Concentrated	Shelf-Stable													Cola Base, Root beer Base, Flavored Drink Syrups, Tea Concentrates, Coffee Concentrates
Liquid Beverage Mixes	21	Dairy-based mixes	Shelf-Stable							X						Breakfast Cocoa, Chocolate Dairy Mix, Cocoa Dairy Mix, Cappuccino Mix
Liquid Beverage Mixes	22	Mixes intended for alcoholic beverages	Shelf-Stable							X						Mohito Mix, Bloody Mary Mix, Margarita Mix, Cocktail Mix, Pina Colada Mix

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 1C: Information that you should consider for potential ingredient or other food-related biological hazards for Food Additives

Category	#	Subcategory	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Emulsifiers	1	Emulsifiers							X						Soy Lecithin, Egg Lecithin, Mono- and Diglycerides, Polysorbates, Sorbitan Monostearate
Stabilizers and Thickeners	2	Firming Agents													Calcium Chloride, Calcium Lactate
Stabilizers and Thickeners	3	Humectants													Glycerin, Sorbitol
Stabilizers and Thickeners	4	Leavening Agents													Baking Soda, Monocalcium Phosphate, Calcium Carbonate
Stabilizers and Thickeners	5	Stabilizers, Thickeners, Binders, Texturizers							X						Gelatin, Pectin, Carrageenan, Modified Starches, Acacia Gum, Guar Gum, Xanthan Gum, Whey Protein, Soy Protein, High Activity Dried Yeast
Stabilizers and Thickeners	6	Dough Strengtheners and Conditioner													Ammonium sulfate, Azodicarbonamide, and L-cysteine
Stabilizers and Thickeners	7	Anti-caking Agents													Calcium Silicate, Iron Ammonium Citrate, Silicon Dioxide
Enzymes	8	Enzymes							X						Lactase, Papain, Chymosin

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Enzymes	9	Starch/Sugar Liquefaction							X						Amylases
Enzymes	10	Bakery							X						Xylanase, Lipases, Amylases, Proteases
Enzymes	11	Dairy							X						Rennet
Colors	12	Certified Colors													FD&C Blue Nos. 1 and 2, FD&C Green No. 3, FD&C Red Nos. 3 and 40, FD&C Yellow No. 5 (tartrazine), No. 6, Orange B, Citrus Red No. 2
Colors	13	Natural Colors													Annatto Extract, Caramel, Beta-Carotene, Grape Skin Extract, Cochineal Extract, Chlorophyllin, Betanin, Carmine, Paprika Oleoresin, Caramel color, Saffron
Flavors	14	Liquid: Oil-Based													Sesame oil, Fruit oils, Almond oil, Cinnamon oil, Anise oil, Spearmint oil, Peppermint oil, Ginger oil
Flavors	15	Liquid: Water-Based													Various
Flavors	16	Liquid: Alcohol-Based													Various

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Flavors	17	Liquid: Glycol-Based													Various
Flavors	18	Powdered: Natural Flavor							X						Vanilla Powder, Butter powder, Jasmine, Cinnamon, Orange blossom, Key Lime
Flavors	19	Artificial: Synthetic							X						Cinnamon Raisin Flavor, Marshmallow Flavor, Watermelon Flavor, Strawberry Flavor, Grape Flavor, Cherry Flavor, Imitation Almond Extract, Imitation Coconut Extract
Flavors	20	Other: Flavor Enhancer							X						Monosodium Glutamate, Autolyzed Yeast Extract, Hydrolyzed Vegetable Proteins, Disodium Guanylate, Inosinate
Flavors	21	Flavor Paste								X					Vanilla Bean Paste
Other Chemical Ingredients	22	Processing Chemicals													Potassium Hydroxide, Potassium Bicarbonate, Potassium Chloride, Hydrochloric Acid, Sodium Hydroxide, Ferrous Sulfate, Magnesium Sulfate, Mineral Oil

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Other Chemical Ingredients	2 3	Organic Acids													Acetic Acid, Citric Acid, Lactic Acid, Fumaric Acid
Other Chemical Ingredients	2 4	Additives													Antioxidants, Vitamin Blends, Butylated Hydroxy Toluene (BHT), d-alpha-tocopherol acetate (TOCO)
Other Chemical Ingredients	2 5	Antimicrobials and Preservatives													Nisiplin, Lauric Arginate, Potassium Sorbate
Other Chemical Ingredients	2 6	Processing Aid Gases													Nitrogen, Carbon Dioxide

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 1D: Information that you should consider for potential ingredient or other food-related biological hazards for Chocolate and Candy

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Chocolate Industrial Products	1	Chocolate/Cocoa Products For Baking (Including Bulk Solid and Bulk Liquid)	Shelf-Stable							X						Bittersweet Chocolate, Semi-sweet Chocolate, Unsweetened Chocolate, Milk Chocolate, Chocolate Chips, Chocolate Morsels, Cocoa Powder, White Chocolate
Chocolate Industrial Products	2	Other Products for Baking (Including Bulk Solid and Bulk Liquid)	Shelf-Stable							X						Butterscotch Morsels, Peanut Butter Morsels
Chocolate Industrial Products	3	Chocolate Coating for Enrobing (Including Bulk Solid and Bulk Liquid)	Shelf-Stable							X						Compound Coatings, White Chocolate
Chocolate and Confectionery Products	4	Chocolate Confections	Shelf-Stable							X			X			Milk Chocolate Bar, Dark/white Chocolate Bar, Fudge, bonbons

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Chocolate and Confectionery Products	5	Chocolate Confections - With Inclusions	Shelf-Stable							X			X			Chocolate Covered Nuts (e.g., Almonds, Pecans, Macadamia Nuts), Chocolate Candy Bar with Nuts, Chocolate Covered Raisins, Chocolate Covered Cherry, Chocolate with coconut, Chocolate with crisped rice, Fruit and Nut Chocolate Bar, Fudge with nuts, Chocolate Covered Biscuit, Chocolate Covered Caramel , Chocolate Covered Mints, Chocolate Covered Nougat or English Toffee

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Chocolate and Confectionery Products	6	Sugar Confections	Shelf-Stable							X			X			Mint, Rock Candy, Lollipop, Lemon Drops, Caramel Candy Bar, Gummy gel Candies, Fruit Chews, Soft Toffee, Licorice Candy, Marshmallow, Soft jellied Candy, Soft Caramel Squares, Gel Cups Candy, Creams, Pastes, Pastilles
Chocolate and Confectionery Products	7	Sugar Confections with inclusions	Shelf-Stable							X			X			Nut brittles (Peanut Brittle, Almond Brittle), Nut Clusters, Candy with fruit pieces
Chocolate and Confectionery Products	8	Sugar Confections Specialties (w/o Chocolate)	Shelf-Stable							X	X		X			Caramel/Candied Apple, Candy Coated Popcorn, Cereal Confection, Marzipan, Coconut Roll, Cake Decoration, Peanut butter fudge, Cotton Candy

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Toppings/Frosting	9	Toppings and Frosting (Non Fruit/Nut)	Shelf-Stable							X			X			Butterscotch Topping, Caramel Topping, Vanilla Frosting, Sour Cream Frosting, Chocolate Flavored Syrup (Hot Fudge)

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 1E: Information that you should consider for potential ingredient or other food-related biological hazards for Dairy

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Dairy - Dry Powders	1	Dry milk products	Shelf-Stable	X					X	X	X		X			Dried Milk, Whey Powder, Instant Nonfat Dry Milk, Whey Protein Powder
Dairy - Milk and Butter	2	Butter products	Refrigerated	X					X	X	X		X			Butter, Butter Spreads, Unsalted Butter Blends
Dairy - Milk and Butter	3	Pasteurized Milk and cream products	Refrigerated	X				X	X	X	X		X			Fluid White Milk, Flavored Milks, Buttermilk, Creams (Heavy, Light, Whipping), Goat Milk, Sheep Milk
Dairy - Milk and Butter	4	Cultured milk products	Refrigerated							X						Sour cream, Plain/Flavored Yogurt
Dairy, Milk and Milk Products Shelf-Stable	5	Ultra-High Temperature Dairy Products	Shelf-Stable	X				X	X	X	X		X			Dairy Creamer, UHT Milk

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Dairy, Milk and Milk Products Shelf-Stable	6	Stabilized Liquid Milk Products	Shelf-Stable	X				X	X	X	X		X			Evaporated Milk, Sweetened Condensed Milk
Dairy - Milk, Frozen	7	Ice cream, regular and low fat (no inclusions)	Frozen						X	X	X					Vanilla, Chocolate, Strawberry, Coconut
Dairy - Milk, Frozen	8	Ice cream, regular and low fat with inclusions	Frozen						X	X	X					Butter Pecan, Mint Chocolate Chip, Fudge Ripple, Rocky Road, Cherry Vanilla, Black Raspberry, Peppermint Cookie
Dairy - Milk, Frozen	9	Sherbets	Frozen						X	X	X					All Flavors

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Dairy - Milk, Frozen	10	Frozen Novelty Items	Frozen						X	X	X					Milk Shakes, Ice Cream Cakes, Ice Cream Sandwiches, Chocolate Covered Ice Cream Bar, Chocolate/Nut Topped Ice Cream Desserts, Frozen Yogurt
Dairy - Cheese and Cheese Products - Whole	11a	Cheese (not soft)	Shelf-Stable						X	X	X		X			Hard Cheese, Cheddar Cheese, Parmesan Cheese, Asiago Cheese
Dairy - Cheese and Cheese Products - Whole	11b	Cheese (not soft)	Refrigerated						X	X	X		X			Hard Cheese, Cheddar Cheese, Parmesan Cheese, Asiago Cheese

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Dairy - Cheese and Cheese Products - Whole	12	Semi-soft cheese	Refrigerated						X	X	X		X			Blue, Monterey, Muenster, Provolone, Oaxaca, Stilton, Colby, Monterey Jack, Mozzarella, Edam, Gouda
Dairy - Cheese and Cheese Products - Whole	13	Soft, ripened cheese	Refrigerated		X				X	X	X	X	X			Brie, Camembert, Grayson, Cheese Curd
Dairy - Cheese and Cheese Products - Whole	14	Soft, unripened cheese/ fresh cheese	Refrigerated		X				X	X	X		X			Cottage Cheese, Cream Cheese, Ricotta, Queso Fresco, Cheese Curd, Goat Cheese
Dairy - Cheese and Cheese Products - Sliced, Shredded, or Grated	15a	Cheese (not soft)	Shelf-Stable						X	X	X		X			Hard Cheese, Cheddar Cheese, Parmesan Cheese, Asiago Cheese

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Dairy - Cheese and Cheese Products - Sliced, Shredded, or Grated	15b	Cheese (not soft)	Refrigerated						X	X	X		X			Hard Cheese, Cheddar Cheese, Parmesan Cheese, Asiago Cheese
Dairy - Cheese and Cheese Products - Sliced, Shredded, or Grated	16	Semi-soft cheese	Refrigerated						X	X	X		X			Monterey, Muenster, Provolone, Oaxaca, Colby, Monterey Jack, Mozzarella

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 1F: Information that you should consider for potential ingredient or other food-related biological hazards for Dressings, Condiments, and Dips

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Condiments	1a	Mayonnaise	Shelf-Stable						X	X			X			Mayonnaise (Regular and Lite), Chipotle Mayonnaise, Mayonnaise, Wasabi Mayonnaise, Sweet Chili Mayonnaise
Condiments	1b	Mayonnaise	Refrigerated						X	X	X		X			Mayonnaise (Regular and Lite), Chipotle Mayonnaise, Mayonnaise, Wasabi Mayonnaise, Sweet Chili Mayonnaise
Condiments	2a	Mustard	Shelf-Stable						X	X	X					Yellow, Spicy, Sriracha Mustard, Garlic and Oregano Mustard
Condiments	2b	Mustard	Refrigerated						X	X	X					Yellow, Spicy, Sriracha Mustard, Garlic and Oregano Mustard
Condiments	3	Ketchup	Shelf-Stable						X	X	X					Tomato Ketchup
Condiments	4	Vinegar	Shelf-Stable													Balsamic, Apple Cider, Wine Vinegar, Grape Vinegar

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Condiments	5	Other Condiments	Shelf-Stable							X						Soy Sauce, Worcestershire Sauce, Horseradish Sauce, Steak Sauce, Tabasco Sauce
Salad Dressings	6a	Dressings, salad (prepared)	Shelf-Stable							X	X					Berries and Balsamic, Ranch, Spinach Vinaigrette, Caesar, Blue Cheese Vinaigrette, Sesame Dressing, Yogurt-based salad dressings
Salad Dressings	6b	Dressings, salad (prepared)	Refrigerated	X ¹	X ¹				X	X	X					Berries and Balsamic, Ranch, Spinach Vinaigrette, Caesar, Blue Cheese Vinaigrette, Sesame Dressing, Yogurt-based salad dressings
Salad Dressings	7	Dry mixes		X	X	X			X	X			X			Dried mixes to be added to oil, water, and vinegar
Dips	8a	Dips and spreads	Shelf-Stable	X			X	X	X	X	X		X			Guacamole, Salsa, Dairy-based Dips and Spreads, Bean Dips, Vegetable Dips, Taco Dip, cheese spreads, parmesan and asiago dip, 7 layer dip

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Dips	8b	Dips and spreads	Refrigerated	X	X ²		X	X	X	X	X		X			Guacamole, Salsa, Dairy-based Dips and Spreads, Bean Dips, Vegetable Dips, Taco Dip, cheese spreads, parmesan and asiago dip, 7 layer dip
Dips	9	Dips and spreads, dry	Shelf-Stable	X	X	X			X	X			X			Dry Dips, Dry Dairy-based Dips and Spreads (e.g., Vegetable Dip Seasoning, Toasted Onion Dip Mix)

¹This hazard may be considered for cold--filled products of this type.

²Consideration should be given to an enhanced risk from *C. botulinum* for products that are in a reduced oxygen environment.

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 1G: Information that you should consider for potential ingredient or other food-related biological hazards for Egg and Egg Products

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Shell Eggs	1	Shell Eggs Raw	Refrigerated							X	X					Shell Eggs, Raw
Shell Eggs	2	Shell Eggs: Pasteurized in Shell	Refrigerated							X	X					Pasteurized in Shell Eggs
Further Processed Egg Products	3	Eggs Hard Boiled: In shell	Refrigerated							X	X					Hard Boiled Eggs in Shell
Further Processed Egg Products	4	Eggs Hard Boiled: Shelled	Refrigerated		X					X	X		X			Hard Boiled Eggs Shelled
Further Processed Egg Products	5a	Cooked Egg Products, Ready-to-Eat (RTE) and Not Ready-to-Eat (NRTE)	Refrigerated	X	X				X	X	X		X			Omelets, Egg Patties, Scrambled Eggs
Further Processed Egg Products	5b	Cooked Egg Products, Ready-to-Eat (RTE) and Not Ready-to-Eat (NRTE)	Frozen	X					X	X	X		X			Omelets, Egg Patties, Scrambled Eggs
Imitation Egg Products	6a	Imitation Egg products and Egg Substitutes	Shelf-stable							X						Soy-based products; vegetable and grain-based products

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Imitation Egg Products	6b	Imitation Egg products and Egg Substitutes	Refrigerated	X						X	X					Southwest Flavored Imitation Egg Product (Liquid), Florentine Imitation Egg Product (Liquid), Imitation Omelets, Imitation Egg Patties, Imitation Scrambled Eggs
Imitation Egg Products	6c	Imitation Egg products and Egg Substitutes	Frozen	X						X	X					Imitation Omelets, Egg Patties, Scrambled Eggs

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 1H: Information that you should consider for potential ingredient or other food-related biological hazards for Fruits and Vegetables

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	<i>Cyclospora</i>	Example Products
Fresh Cut	1	Fresh cut vegetables	Refrigerated		X ¹				X	X	X	X	X	X			Leafy Greens (Single and Mixed Greens), Shredded Carrots, Avocado Chunks, Leafy green salad blends, Diced Onions, Cut Tomatoes, Sliced Mushrooms
Fresh Cut	2	Fresh cut fruits	Refrigerated						X	X	X	X					Mixed Fruit Salad; Packaged Single Fruits, Cut Melon, Apple Slices, Cut Pineapple, Cut Mango
Frozen	3	Vegetables Ready-to-Eat (RTE)	Frozen						X	X	X						Broccoli, Carrots, Corn-sweet, Cauliflower, Garlic, Kale, Peas, Snow peas, Spinach
Frozen	4	Vegetables, Not Ready-to-Eat (NRTE)	Frozen						X	X	X						Eggplants, Okra, Potatoes, Sweet potatoes, Winter squash
Frozen	5	Fruits	Frozen						X	X	X					X	Raspberries, Melon, Blueberries, Sliced Strawberries, Tropical Fruit Blend, Mangoes, Pineapple

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	<i>Cyclospora</i>	Example Products
Refrigerated	6	Prepared Fruit Products Ready-to-Eat (RTE)	Refrigerated	X					X	X	X		X				Cherry Mixed Fruit in Juice, Diced Peaches, Diced Pears, Red Grapefruit
Dried / Dehydrated	7	Dried Fruits	Shelf-Stable	X					X	X	X		X				Raisins, Cranberries, Papaya, Pineapple, Mango, Blends
Dried / Dehydrated	8	Dehydrated Vegetables	Shelf-Stable	X					X	X	X		X				Peas, Celery, Onions, Carrots, Tomatoes, Green Beans, Wasabi Peas
Further Processed	9	Acidified Vegetables	Shelf-Stable		X					X	X		X				Pickled Cucumbers, Pickled Beets, Cocktail Onions, Pickled Turnips, Hearts of Palm, Capers, Roasted Peppers, Roasted Tomatoes, Salsas
Further Processed	9a	Acidified Vegetables	Refrigerated		X					X	X		X				Pickled Cucumbers, Pickled Beets, Cocktail Onions, Pickled Turnips, Hearts of Palm, Capers, Roasted Peppers, Roasted Tomatoes, Salsas
Further Processed	11a	Fermented Vegetables	Shelf-Stable		X				X	X	X						Sauerkraut, Pickles, Kimchi

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	<i>Cyclospora</i>	Example Products
Further Processed	11b	Fermented Vegetables	Refrigerated		X				X	X	X						Sauerkraut, Pickles, Kimchi
Further Processed	12a	Infused Oils	Shelf-Stable		X ¹												Garlic in Oil, Chili Pepper Oil, Lemon Oil, Sun Dried Tomatoes in Oil
Further Processed	12b	Infused Oils	Refrigerated		X ¹												Garlic in Oil, Chili Pepper Oil, Lemon Oil, Sun Dried Tomatoes in Oil
Further Processed	13	Other Processed Fruits	Shelf-Stable		X						X						Jams, Jellies, Chutneys
Further Processed	14a	Acid Pureed Fruits and Vegetables	Shelf-Stable							X	X						Applesauce, Flavored Applesauce, Tomato Paste, Tomato Puree, Apricot Puree
Further Processed	14b	Acid Pureed Fruits and Vegetables	Refrigerated							X	X						Applesauce, Flavored Applesauce, Tomato Paste, Tomato Puree, Apricot Puree

¹Consideration should be given to an enhanced risk from *C. botulinum* for products that are in a reduced oxygen environment.

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 11: Information that you should consider for potential ingredient or other food-related biological hazards for Game Meat Products

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Raw Game Meat	1	Not Ground Game Meat	Refrigerated & Frozen					X	X	X					X	Bison Steak, Deer Shoulder, Alligator Steak, Bear, Antelope, Caribou, Elk, Moose, Reindeer, Wild Boar, Snake, Rabbit, Squirrel, Beaver, and Birds (Pheasant, Grouse, Quail, Wild Turkey, Wild geese)
Raw Game Meat	2	Ground Game Meat	Refrigerated & Frozen					X	X	X					X	Ground Venison, Ground Rabbit, Ground Alligator
Game Meat Products	3a	Processed Game Meat Products	Shelf-Stable			X		X	X	X			X		X	Buffalo Jerky, Alligator Jerky, Venison Salami, Ostrich Stick

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Game Meat Products	3b	Processed Game Meat Products	Refrigerated			X		X	X	X	X		X		X	Bison Sausages, Venison Patties, Wild Boar Meatballs, Bison Meatloaf, Buffalo Jerky, Kangaroo Jerky, Bison Frankfurters, Venison Salami, Ostrich Stick
Game Meat Products	3c	Processed Game Meat Products	Frozen			X		X	X	X	X		X		X	Bison Sausages, Venison Patties, Wild Boar Meatballs, Bison Meatloaf, Buffalo Jerky, Kangaroo Jerky, Bison Frankfurters, Venison Salami, Ostrich Stick

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Tables 1J: Information that you should consider for potential ingredient or other food-related biological hazards for Grains, Beans and Grain Products

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Grains	1	Raw grains	Shelf-Stable	X					X							Wheat, Rye, Sorghum, Oats, Barley, Triticale, Buckwheat, Corn, Soy, Rice, Teff, Amaranth, Millet, Quinoa
Grains	2	Heat-treated grains	Shelf-Stable							X						Toasted oats, Puffed rice

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Beans	3	Single component whole, dried	Shelf-Stable	X	X	X			X	X						Soybean, Kidney, Haricot, Lima, Pinto, Navy, Azuki, Mung, Black Gram, Scarlet Runner, Ricebean, Moth, Tepary; Horse, Broad, Field; Garden Pea; Chickpea; Cowpea/Black-eyed Pea; Pigeon Pea; Lentil; Bambara Groundnut; Vetch; Lupins; Lablab/hyacinth, Jack, Sword, Winged Bean, Velvet Bean, Yam Bean

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Beans	4	Single component bean/pea/corn: paste	Shelf-Stable	X	X	X			X	X	X					Bean paste, Tahini, Hummus
Beans	5a	Single Component Cooked Beans - no sauce	Refrigerated	X	X	X				X	X					Lima beans, Black-eyed peas, Lentils, Chickpeas, Kidney Beans, Peas, Edamame
Beans	5b	Single Component Cooked Beans - no sauce	Frozen NRTE	X		X				X	X					Lima beans, Black-eyed peas, Lentils, Chickpeas, Kidney Beans, Peas, Edamame
Beans	5c	Single Component Cooked Beans - no sauce	Frozen RTE	X		X				X	X					Lima beans, Black-eyed peas, Lentils, Chickpeas, Kidney Beans, Peas, Edamame

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Milled Grain Products	6	Flour	Shelf-Stable	X					X	X	X					Wheat, Oats, Barley, Rye, Buckwheat, Millet, Amaranth, Quinoa, Soy
Milled Grain Products	7	Rice and rice products	Shelf-Stable	X						X						White or Brown Rice, Sticky/sweet Rice, Basmati Rice, Jasmine Rice, Arborio rice, Rice-based noodles
Milled Grain Products	8	Seed or bean: Pulse	Shelf-Stable	X												Garbanzo (Gram), Soy, Lentil, Sesame
Milled Grain Products	9	Malt	Shelf-Stable							X						Malted Barley
Milled Grain Products	10	Corn	Shelf-Stable							X						Cornmeal, Corn Flour
Other Milled Products	11	Root flours	Shelf-Stable	X						X						Potato, Cassava

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Other Milled Products	12	Starch products	Shelf-Stable	X						X						Cornstarch, Potato Starch, Wheat Starch
Grain-based Cereal Products	13a	Cereal Products without Inclusions: Ready-to-Eat	Shelf-Stable	X						X			X			Dry Cereals
Grain-based Cereal Products	13b	Cereal Products with Inclusions: Ready-to-Eat	Shelf-Stable	X						X			X			Granola with Raisins and Nuts, Cereals with Marshmallows, Nuts, Chocolate, Confectionary Bits
Grain-based Cereal Products	14	Breakfast food: Not Ready-to-Eat	Shelf-Stable	X						X			X			Oatmeal, Farina, Oat Bran, Cream of Wheat, Grits
Grain-based Cereal Products	15	Cereal products, N.E. C.	Shelf-Stable	X						X			X			Cereal Bars and Other Nutrition Bars (Baked)
Pasta Products	16a	Unfilled Pasta (not ready to eat)	Refrigerated	X	X					X	X		X			Spaghetti, Linguini, Rotini

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Pasta Products	16b	Unfilled Pasta (not ready to eat)	Frozen	X	X					X	X		X			Spaghetti, Linguini, Rotini
Pasta Products	17a	Filled Par-Boiled Pasta (not ready to eat)	Refrigerated	X	X				X	X	X		X			Mushroom Ravioli, Cheese Tortellini
Pasta Products	17b	Filled Par-Boiled Pasta (not ready to eat)	Frozen	X	X				X	X	X		X			Mushroom Ravioli, Cheese Tortellini
Pasta Products	18	Dried pasta (not ready-to-eat)	Shelf-Stable	X						X			X			Spaghetti, Egg Noodles

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 1K: Information that you should consider for potential ingredient or other food-related biological hazards for Multi-Component Foods

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
	1a	Entrees	Refrigerated	X	X ¹				X	X	X		X			Vegetarian Lasagna, Pizza, Cheese Enchiladas, Bean Burritos; Tandoori Vegetables, Vegetable Stew, Baked Ziti, Teriyaki Bowl, Vegetable Pot Pie, Meat Analogue Chili
	1b	Entrees	Frozen Ready-to-Eat (RTE)	X					X	X	X		X			Vegetarian Lasagna, Pizza, Cheese Enchiladas, Bean Burritos; Tandoori Vegetables, Vegetable Stew, Baked Ziti, Teriyaki Bowl, Vegetable Pot Pie, Meat Analogue Chili

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
	1c	Entrees	Frozen NOT Ready-to-Eat (NRTE)	X					X	X	X		X			Vegetarian Lasagna, Pizza, Cheese Enchiladas, Bean Burritos; Tandoori Vegetables, Vegetable Stew, Baked Ziti, Teriyaki Bowl, Vegetable Pot Pie, Meat Analogue Chili

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
	2a	Side Dishes	Refrigerated	X	X¹				X	X	X		X			Macaroni and Cheese, Cheese and Broccoli Stuffed Baked Potatoes, Creamed Spinach, Broccoli and Rice Casserole, Potatoes Au Gratin, Green Bean Casserole, Corn with Butter Sauce, Mixed Vegetables with Teriyaki Sauce, French Fries, Hash Browned Potatoes, Potato Pancakes, Garlic Mashed Potatoes, Mashed Cinnamon Sweet Potatoes

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
	2b	Side Dishes	Frozen Ready-to-Eat (RTE)	X					X	X	X		X			Macaroni and Cheese, Cheese and Broccoli Stuffed Baked Potatoes, Creamed Spinach, Broccoli and Rice Casserole, Potatoes Au Gratin, Green Bean Casserole, Corn with Butter Sauce, Mixed Vegetables with Teriyaki Sauce, French Fries, Hash Browned Potatoes, Potato Pancakes, Garlic Mashed Potatoes, Mashed Cinnamon Sweet Potatoes

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
	2c	Side Dishes	Frozen NOT Ready-to-Eat (NRTE)	X					X	X	X		X			Macaroni and Cheese, Cheese and Broccoli Stuffed Baked Potatoes, Creamed Spinach, Broccoli and Rice Casserole, Potatoes Au Gratin, Green Bean Casserole, Corn with Butter Sauce, Mixed Vegetables with Teriyaki Sauce, French Fries, Hash Browned Potatoes, Potato Pancakes, Garlic Mashed Potatoes, Mashed Cinnamon Sweet Potatoes
	3	Deli Salads	Refrigerated	X	X¹				X	X	X		X			Three Bean Salad, Redskin Potato Salad, Egg Salad, Pasta Salad, Crunchy Broccoli Salad, Cole Slaw

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
	4a	Lunch Dishes	Refrigerated	X	X ¹				X	X	X		X			Peanut Butter and Jam Sandwich, Black Bean Burger, Croissant Sandwiches, Spinach Feta Sandwiches, Soy Meat Alternative Sandwiches
	4b	Lunch Dishes	Frozen Ready-to-Eat (RTE)	X					X	X	X		X			Peanut Butter and Jam Sandwich, Black Bean Burger, Croissant Sandwiches, Spinach Feta Sandwiches, Soy Meat Alternative Sandwiches
	4c	Lunch Dishes	Frozen NOT Ready-to-Eat (NRTE)	X					X	X	X		X			Peanut Butter and Jam Sandwich, Black Bean Burger, Croissant Sandwiches, Spinach Feta Sandwiches, Soy Meat Alternative Sandwiches

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
	5a	Appetizers and Hors d'Oeuvres	Refrigerated	X	X ¹				X	X	X		X			Mozzarella Sticks, Cheese Stuffed Jalapenos, Toasted Ravioli, Vegetable Egg Rolls, Cream Cheese Wontons, Stuffed Potato Skins
	5b	Appetizers and Hors d'Oeuvres	Frozen Ready-to-Eat (RTE)	X					X	X	X		X			Mozzarella Sticks, Cheese Stuffed Jalapenos, Toasted Ravioli, Vegetable Egg Rolls, Cream Cheese Wontons, Stuffed Potato Skins
	5c	Appetizers and Hors d'Oeuvres	Frozen NOT Ready-to-Eat (NRTE)	X					X	X	X		X			Mozzarella Sticks, Cheese Stuffed Jalapenos, Toasted Ravioli, Vegetable Egg Rolls, Cream Cheese Wontons, Stuffed Potato Skins

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
	6a	Breakfast Items	Refrigerated	X	X				X	X	X		X			Tofu Scramble, Egg and Cheese Breakfast Wrap, Spinach Feta Quiche, Egg, Sausage and Cheese Biscuits
	6b	Breakfast Items	Frozen Ready-to-Eat (RTE)	X					X	X	X		X			Tofu Scramble, Egg and Cheese Breakfast Wrap, Spinach Feta Quiche, Egg, Sausage and Cheese Biscuits
	6c	Breakfast Items	Frozen NOT Ready-to-Eat (NRTE)	X					X	X	X		X			Tofu Scramble, Egg and Cheese Breakfast Wrap, Spinach Feta Quiche, Egg, Sausage and Cheese Biscuits
	7	Meals (Entrees, Breakfast Items) Dehydrated	Shelf-Stable	X	X	X			X	X	X		X			Lentil Stew, Vegetarian Chili, Pasta Alfredo, Pasta Primavera, Tortilla Soup, Southwestern Scrambled Eggs, Biscuits and Gravy, Breakfast Skillet,

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
	8	Side Dishes	Shelf-Stable	X	X	X			X	X	X		X			Macaroni and Cheese, Potatoes Au Gratin, Seasoned Stuffing Mix, Seasoned Grain Blends, Flavored Rice

¹Consideration should be given to an enhanced risk from *C. botulinum* for products that are in a reduced oxygen environment.

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 1L: Information that you should consider for potential ingredient or other food-related biological hazards for Nuts and Seeds

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Nuts	1	Groundnuts, Raw: In-shell	Shelf-Stable							X						Peanuts
Nuts	2	Groundnuts, Raw: Shelled	Shelf-Stable							X						Peanuts
Nuts	3	Groundnuts, Roasted: In-shell, Unseasoned	Shelf-Stable							X						Dry Roasted Peanuts (unsalted)
Nuts	4	Groundnuts, Roasted: Shelled, Unseasoned	Shelf-Stable							X						Roasted Peanuts (unsalted)
Nuts	5	Groundnuts, Roasted: In-shell, Seasoned	Shelf-Stable							X						Salted Peanuts, Barbecue Peanuts, Hickory Smoke Peanuts
Nuts	6	Groundnuts, roasted: Shelled, Seasoned	Shelf-Stable							X						Honey Mustard Peanuts, Sweet Maui Onion Peanuts, Cocoa Peanuts

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Nuts	7	Tree Nuts, Raw: In-Shell	Shelf-Stable						X	X						Almonds, Brazil Nuts, Cashews, Chestnuts, Filbert/Hazelnuts, Macadamias, Pecans, Pine Nuts, Pistachios, Walnuts, Betel Nut, Gingko, Lotus Nuts, Coconuts
Nuts	8	Tree Nuts, Raw: Shelled	Shelf-Stable						X	X						Almonds, Brazil Nuts, Cashews, Chestnuts, Filbert/Hazelnuts, Macadamias, Pecans, Pine Nuts, Pistachios, Walnuts, Betel Nut, Gingko, Lotus Nuts

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Nuts	9	Tree nuts, roasted: In-shell unseasoned	Shelf-Stable						X	X						Almonds, Brazil Nuts, Cashews, Chestnuts, Filbert/Hazelnuts, Macadamias, Pecans, Pine Nuts, Pistachios, Walnuts, Betel Nut, Gingko, Lotus Nuts
Nuts	10	Tree nuts, roasted: Shelled, unseasoned	Shelf-Stable						X	X						Almonds, Brazil Nuts, Cashews, Chestnuts, Filbert/Hazelnuts, Macadamias, Pecans, Pine Nuts, Pistachios, Walnuts, Betel Nut, Gingko, Lotus Nuts

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Nuts	11	Tree nuts, roasted: In-shell Seasoned	Shelf-Stable						X	X						Salted Macadamia Nuts, Spicy Jalapeno Pistachios, Lemon and Lime Pistachios,
Nuts	12	Tree nuts, roasted: Shelled, Seasoned	Shelf-Stable						X	X						Spicy Almonds, Hickory Smoked Almonds, Hot Chili Pepper Roasted Pistachios, Cinnamon and Sugar Walnuts, Cocoa Coated Almonds
Edible Seeds	13	In-Shell, Raw	Shelf-Stable							X						Pumpkin, Sunflower, Melon
Edible Seeds	14	Shelled, Raw	Shelf-Stable							X						Pumpkin, Sunflower, Melon
Edible Seeds	15	In-Shell, Roasted, Unseasoned	Shelf-Stable							X						Pumpkin, Sunflower, Melon

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Edible Seeds	16	Shelled/No Shell , Roasted, Unseasoned	Shelf-Stable							X						Pumpkin, Sunflower, Melon, Hemp, Sesame, Flaxseed/Linseed
Edible Seeds	17	In-Shell, Roasted, Seasoned	Shelf-Stable							X						Cajun Spiced Pumpkin Seeds, Salted Pumpkin Seeds, Barbecue Sunflower Seeds, Dill Sunflowers Seeds, Ranch Sunflower Seeds
Edible Seeds	18	Shelled/No Shell , Roasted, Seasoned	Shelf-Stable							X						Cinnamon and Sugar Pumpkin Seeds, Tomato Italiano Pumpkin Seeds, Sea Salted Pumpkin Seeds
Nut and Seed Butters	19a	Butters	Shelf-Stable							X						Peanut Butter, Almond Butter, Cashew Butter, Hazelnut Butter

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Nut and Seed Butters	19b	Butters	Refrigerated							X	X					Peanut Butter, Almond Butter, Cashew Butter, Hazelnut Butter
Other Nut and Seed Products	20	Single-component Pastes	Shelf-Stable							X						Peanut Paste, Lotus Seed Paste, Sesame Seed Paste/Tahini, Pistachio Paste, Pumpkin Seed Paste/Pipian
Other Nut and Seed Products	21	Nut Flours	Shelf-Stable							X						Coconut Flour, Almond Flour, Pistachio Flour, Pumpkin Seed Flour
Other Nut and Seed Products	22	Coconut Products	Shelf-Stable							X						Shredded Coconut, Coconut Flakes, Toasted Coconut

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 1M: Information that you should consider for potential ingredient or other food-related biological hazards for Oils and Oils Products

Category	#	Subcategory	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Oil Products	1	Cooking Oils													Corn, Soy Bean, Peanut, Safflower, Sesame, Cotton Seed, Canola, Olive, Sunflower, Blends
Oil Products	2	Margarines and other spreads						X	X	X					Oleomargarine
Oil Products	3	Shortening						X	X	X					Vegetable, Imitation/Substitute Vegetable Shortening

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 1N: Information that you should consider for potential ingredient or other food-related biological hazards for Snack Foods

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Baked	1	Bread snacks, Unseasoned	Shelf-Stable						X	X						Breadsticks, Mini Toast, Poori, Crostini, Pretzels, Crackers
Baked	2	Bread snacks, Seasoned	Shelf-Stable						X	X						Honey Mustard Pretzels, Garlic Bagel Chips, Cinnamon Mini Toast, Garlic and Herb Crackers
Baked	3	Bread Snacks with Filling, Unseasoned	Shelf-Stable						X	X						Peanut Butter Pretzels, Cheese Pretzels
Baked	4	Bread Snacks with Filling, Seasoned	Shelf-Stable						X	X						Italian Cheese Pretzels, Buffalo Bleu Cheese Baked Snacks, Pepperoni Pizza Baked Snacks, Salsa Tortilla Baked Snacks
Baked	5	Grain snacks Unseasoned	Shelf-Stable						X	X						Puffed Rice Snacks, Wheat Crackers, Rice Crackers, Whole Grain Crackers
Baked	6	Grain Snacks Seasoned	Shelf-Stable						X	X						Cheddar Cheese Rice Cakes, Caramel Corn Cakes

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Fried	7	Chips, Puffs, Crisps, Unseasoned	Shelf-Stable							X						Potato Chips, Corn Chips, Cheese Puffs, Lentil Chips, Sweet Potato Chips, Mixed Root Vegetable Crisps, Tortilla Chips,
Fried	8	Chips, Puffs, Crisps, Seasoned	Shelf-Stable							X						Sour Cream and Onion Potato Chips, Barbecue Potato Chips, Sriracha Tortilla Chips
Fried	9	Bread snacks Unseasoned	Shelf-Stable							X						Bagel Chips, Pita Chips
Fried	10	Bread snacks Seasoned	Shelf-Stable							X						Garlic Pita Crisps, Everything Bagel Chips
Fried	11	Dehydrated Fruit snacks	Shelf-Stable							X						Plantain Chips, Banana Chips, Durian Chips, Jackfruit Chips, Apple Chips, Pineapple Chips
Fried	12	Grain Snacks Unseasoned	Shelf-Stable							X						Barley Grain Snack, Millet Grain Snack, Rice Grain Snacks, Multigrain Chips, Popped Popcorn
Fried	13	Grain Snacks Seasoned	Shelf-Stable							X						White Cheddar Popcorn, Harvest Cheddar Multigrain Chips, French Onion Multi-Grain Chips

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Cold Pressed	14	Snack Food Bars	Shelf-Stable						X	X						Granola Bars, Cranberry Almond Bars, Fruit and Nut Bars, Coated Bars
Other	15	Snack Blends	Shelf-Stable							X			X			Trail mix; Yogurt Covered Raisins, Coated Nuts
Other	16a	Pudding and gelatin products	Shelf-Stable	X	X				X	X	X					Flavored Gelatin Snacks, Chocolate Pudding, Tapioca Pudding, Vanilla Pudding
Other	16b	Pudding and gelatin products	Refrigerated	X	X ¹				X	X	X					Flavored Gelatin Snacks, Chocolate Pudding, Tapioca Pudding, Vanilla Pudding
Other	17	Non-Dairy Frozen Desserts	Frozen							X	X					Ice Pops, Fruit Pops, Soy Milk Frozen Desserts, Sorbet

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 10: Information that you should consider for potential ingredient or other food-related biological hazards for Soups and Sauces

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Soups, Sauces, Gravies	1	Dry Mixes, Powder	Shelf-stable	X	X	X				X						Noodle Soup, French Onion Soup, Bouillon Cubes, Bullion Powder, Brown Soup Base, Hollandaise Sauce, Turkey Gravy, Béarnaise Sauce, Beef Gravy
Soups, Sauces, Gravies	2	Base, paste	Shelf-Stable	X	X	X				X						Chicken Base, Beef Base, Vegetable Base, Seafood Base, Turkey Base

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Soups, Sauces, Gravies	3a	Ready-to-Eat (RTE), Full Strength Liquid	Refrigerated	X	X¹	X				X	X					Beef-based Soup, Stew, Chili, Chicken Soup, French Onion Soup, Mushroom Soup, Turkey Soup, Potato Soup, Chicken Broth, Consommé, Peanut Sauce, Stir-Fry Sauce, Black Bean Sauce, Chili Sauce, Tandoori Sauce, Tomato Sauce, Broccoli and Cheese Soup, Tortilla Soup, Vegetarian Vegetable Soup, Tartar Sauce, Barbecue Sauce

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Soups, Sauces, Gravies	3b	Ready-to-Eat (RTE), Full Strength Liquid	Frozen	X	X	X				X	X					Beef-based Soup, Stew, Chili, Chicken Soup, French Onion Soup, Mushroom Soup, Turkey Soup, Potato Soup, Chicken Broth, Consommé, Peanut Sauce, Stir-Fry Sauce, Black Bean Sauce, Chili Sauce, Tandoori Sauce, Tomato Sauce, Broccoli and Cheese Soup, Tortilla Soup, Vegetarian Vegetable Soup, Tartar Sauce, Barbecue Sauce

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Soups, Sauces, Gravies	4a	Condensed (Concentrated), Liquid	Refrigerated	X	X¹	X				X	X					Beef-based Soup, Stew, Chili, Chicken Soup, French Onion Soup, Mushroom Soup, Turkey Soup, Potato Soup, Chicken Broth, Consommé, Peanut Sauce, Stir-Fry Sauce, Black Bean Sauce, Chili Sauce, Tandoori Sauce, Tomato Sauce, Broccoli and Cheese Soup, Tortilla Soup, Vegetarian Vegetable Soup, Tartar Sauce, Barbecue Sauce

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Soups, Sauces, Gravies	4b	Condensed (Concentrated), Liquid	Frozen	X	X	X				X	X					Beef-based Soup, Stew, Chili, Chicken Soup, French Onion Soup, Mushroom Soup, Turkey Soup, Potato Soup, Chicken Broth, Consommé, Peanut Sauce, Stir-Fry Sauce, Black Bean Sauce, Chili Sauce, Tandoori Sauce, Tomato Sauce, Broccoli and Cheese Soup, Tortilla Soup, Vegetarian Vegetable Soup, Tartar Sauce, Barbecue Sauce

¹Consideration should be given to an enhanced risk from *C. botulinum* for products that are in a reduced oxygen environment.

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 1P: Information that you should consider for potential ingredient or other food-related biological hazards for Spices and Herbs

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Untreated, Raw Herbs and Spices	1	Dried, ground or cracked	Shelf-Stable	X	X	X			X	X						Cinnamon, Turmeric, Paprika, Pepper (Black, White, Red), Cayenne Powder, Cumin, Coriander, Mustard, Fenugreek, Horseradish, Fennel Seeds, Caraway, All-spice, Nutmeg, Ginger, Garlic (Minced or Powder), Onion (Minced or Powder), Celery Seed
Untreated, Raw Herbs and Spices	2	Dried, whole	Shelf-Stable	X	X	X			X	X						Cinnamon, Cardamom, Fenugreek, Cloves, Nutmeg, Cumin, Anise, fennel Seeds, Caraway, Chili Peppers, Saffron, Peppercorns (Black or White), Coriander, Basil, Varieties of Chili Peppers

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Untreated, Raw Herbs and Spices	3	Dried herbs	Shelf-Stable	X	X	X			X	X						Basil, Oregano, Thyme, Sage, Parsley, Bay Leaf, Dill, Rosemary, Cilantro, Mint, Kaffir Lime, Chives, Peppermint
Treated Herbs and Spices	4	Irradiated	Shelf-Stable	X	X	X			X	X						Various
Treated Herbs and Spices	5	Chemically Treated (EtOH, PPO)	Shelf-Stable	X	X	X			X	X						Various
Treated Herbs and Spices	6	Steam Pasteurization	Shelf-Stable	X	X	X			X	X						Various
Seasonings	7a	Pastes	Shelf-Stable	X	X	X			X	X						Basil Paste, Garlic Paste, Jerk Seasoning Paste
Seasonings	7b	Pastes	Refrigerated	X	X ¹	X			X	X						Basil Paste, Garlic Paste, Jerk Seasoning Paste
Seasonings	8	Essential Oils	Shelf-Stable													Basil, Cinnamon, Clove, Ginger, Lemongrass

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Seasonings	9	Spice and seasoning mixtures, Dry Blends	Shelf-Stable	X	X	X			X	X						Taco Mix, Chili Powder, Curry Powder, Multi-Spice Mix, Adobo Seasoning, Garam Masala, Berebere, Oriental Five-Spice, Crab Snack & Dip Seasoning, Meat Coatings and Rubs, Seafood Seasonings, Scampi Seasoning, Powdered Seasonings, Popcorn Seasonings
Seasonings	10	Spice and seasoning mixtures, Liquid	Shelf-Stable	X	X	X			X	X						Fajita Seasoning Sauce, Kung Pao Seasoning Sauce

¹Consideration should be given to an enhanced risk from *C. botulinum* for products that are in a reduced oxygen environment.

Contains Non-binding Recommendations
Draft-Not for Implementation

Table 1Q: Information that you should consider for potential ingredient or other food-related biological hazards for Food Sweeteners (Nutritive and Non-Nutritive)

Category	#	Subcategory	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Food Sweeteners (Nutritive and Non-Nutritive)	1	Sugars (Dry)													Brown Sugar (Sucrose), Beet Sugar(Sucrose), Invert Sugar, Maple Sugar, Malt Sugar (Maltose), Grape Sugar (Fructose), Corn Syrup Solids, Corn Sugar (Dextrose), Cane Sugar (Sucrose), Milk Sugar, Date sugar, Palm Sugar
Food Sweeteners (Nutritive and Non-Nutritive)	2	Syrup/Molasses (Liquid)													Sorghum Syrup, Maple Syrup, High Fructose Corn Syrup, Molasses, Pancake and Waffle Syrup, Simple Syrup, Liquid Sucrose, Agave Syrup, Rice Syrup
Food Sweeteners (Nutritive and Non-Nutritive)	3	Honey (Liquid)		X											Comb Honey, Strained Honey, Whipped Honey
Food Sweeteners (Nutritive and Non-Nutritive)	4	Imitation Syrup/Molasses (Liquid)		X											Imitation Maple Syrup, Imitation Honey

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Food Sweeteners (Nutritive and Non-Nutritive)	5	Food Sweeteners (Nutr) N.E.C.													Nutritive Sugar Substitutes, Sorbitol, Xylitol, Isomalt, Tagatose, Maltitol, Lactitol
Food Sweeteners (Nutritive and Non-Nutritive)	6	Food Sweeteners (Non-nutr)													Aspartame, Saccharin, Acesulfame K, Neotame, Stevia, Sucralose

*Contains Non-binding Recommendations
Draft-Not for Implementation*

Chemical Hazards Tables

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 2A: Information that you should consider for potential ingredient or other food-related chemical hazards for Bakery Items

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Unbaked Bakery Items - Ready-To-Bake (RTB)	1a	Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust	Refrigerated					X				Buttermilk biscuits, Cinnamon rolls, Croissants, Pizza Crust, Chocolate Chip Cookie Dough, Puff Pastry, Phyllo
Unbaked Bakery Items - Ready-To-Bake (RTB)	1b	Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust	Frozen					X				Buttermilk biscuits, Cinnamon rolls, Croissants, Pizza Crust, Chocolate Chip Cookie Dough, Puff Pastry, Phyllo
Unbaked Bakery Items - Ready-To-Bake (RTB)	2a	Parbaked/ParBoiled Bread, Biscuits, Rolls, Pizza/Pie Crust	Refrigerated					X				Artisan breads, Bagels, Biscuits, Rolls, Croissant, Pizza Crust
Unbaked Bakery Items - Ready-To-Bake (RTB)	2b	Parbaked/ParBoiled Bread, Biscuits, Rolls, Pizza/Pie Crust	Frozen					X				Artisan breads, Bagels, Biscuits, Rolls, Croissant, Pizza Crust
Unbaked Bakery Items - Ready-To-Bake (RTB)	3	Liquid Batter	Refrigerated									Pancake batter, Brownie batter, Waffle batter, and Doughnut batter

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Unbaked Bakery Items - Ready-To-Bake (RTB)	4	Fruit pies/cobblers	Frozen					X				Apple/Cherry/Peach Cobbler; Apple, Cherry/ Mixed Berries/etc. Pies
Unbaked Bakery Items - Ready-To-Bake (RTB)	5	Custard pies	Frozen					X				Pumpkin and Sweet Potato Pies
Fully-Baked Without Filling, No Topping/Frosting	6	Bread, Whole/Pre-sliced	Shelf-Stable, Refrigerated or Frozen					X				Breads (e.g., White, Wheat, Rye, Oat Bran, Pumpernickel), Cheese Breads, Raisin Breads; Cornbread, Plain or Flavored Biscuits, Bagels, Rolls, Croissants, Pita Bread, Pumpkin Bread
Fully-Baked Without Filling, No Topping/Frosting	7a	Cakes/Muffins/Brownies/ Doughnut	Shelf-Stable					X				Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Without Filling, No Topping/Frosting	7b	Cakes/Muffins/Brownies/ Doughnut	Refrigerated					X				Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Fully-Baked Without Filling, No Topping/Frosting	7c	Cakes/Muffins/Brownies/Doughnut	Frozen					X				Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Without Filling, No Topping/Frosting	8	Cookies	Shelf-Stable					X				Chocolate Chip, Peanut Butter, Biscotti, Lemon, Butter Cookies, Brownies, Wafers, Oatmeal Cookies, Fruit, Cream or Chocolate-Filled Crisps/Bars, Wafers
Fully-Baked Without Filling, No Topping/Frosting	9a	Other Pastry Products	Refrigerated					X				French Toast, Blueberry Pancakes, Waffles
Fully-Baked Without Filling, No Topping/Frosting	9b	Other Pastry Products	Frozen					X				French Toast, Blueberry Pancakes, Waffles

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Fully-Baked Including Fillings, No Topping/Frosting	10	Bread, Whole/Pre-sliced	Shelf-Stable, Refrigerated or Frozen					X				Cheese Breads, Raisin Breads; Cornbread, Flavored Biscuits, Chocolate Croissants, Pumpkin Bread, Banana Nut Bread
Fully-Baked Including Fillings, No Topping/Frosting	11a	Cakes/Muffins/Brownies/Doughnut	Shelf-Stable					X				Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Including Fillings, No Topping/Frosting	11b	Cakes/Muffins/Brownies/Doughnut	Refrigerated					X				Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Including Fillings, No Topping/Frosting	11c	Cakes/Muffins/Brownies/Doughnut	Frozen					X				Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Fully-Baked Including Fillings, No Topping/Frosting	12a	Fruit Pies/Cobblers	Shelf-Stable					X				Various Fruit Pies (Apple/Cherry/Blueberry, Rhubarb, Mixed Berry/etc.)
Fully-Baked Including Fillings, No Topping/Frosting	12b	Fruit Pies/Cobblers	Refrigerated					X				Various Fruit Pies (Apple/Cherry/Blueberry, Rhubarb, Mixed Berry/etc.)
Fully-Baked Including Fillings, No Topping/Frosting	12c	Fruit Pies/Cobblers	Frozen					X				Various Fruit Pies (Apple/Cherry/Blueberry, Rhubarb, Mixed Berry/etc.)
Fully-Baked Including Fillings, No Topping/Frosting	13a	Custard/Crème Pie	Shelf-Stable					X				Pumpkin/Sweet Potato, Lemon Pie, Key Lime Pie; Coconut Custard
Fully-Baked Including Fillings, No Topping/Frosting	13b	Custard/Crème Pie	Refrigerated					X				Pumpkin/Sweet Potato, Lemon Pie, Key Lime Pie; Coconut Custard

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Fully-Baked Including Fillings, No Topping/Frosting	13c	Custard/Crème Pie	Frozen					X				Pumpkin/Sweet Potato, Lemon Pie, Key Lime Pie; Coconut Custard
Fully-Baked Including Fillings, No Topping/Frosting	14	Cookies	Shelf-Stable					X				Chocolate Chip, Peanut Butter, Biscotti, Lemon, Butter Cookies, Brownies, Wafers, Oatmeal Cookies, Fruit, Cream or Chocolate-Filled Crisps/Bars, Wafers
Fully-Baked Including Fillings, No Topping/Frosting	15a	Other Pastry Products	Refrigerated					X				French Toast, Blueberry Pancakes, Waffles
Fully-Baked Including Fillings, No Topping/Frosting	15b	Other Pastry Products	Frozen					X				French Toast, Blueberry Pancakes, Waffles

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	16	Bread, Whole/Pre-sliced	Shelf-Stable, Refrigerated or Frozen					X		X		Bread with Drizzles/Frosting, Seeds/Nuts on Top,
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	17a	Cakes/Muffins/Brownies/Doughnut	Shelf-Stable					X		X		Cakes/Muffin/Cheesecakes with Frosting and Topping (cream, nuts, confectionery and dried fruits, etc.); Black Forest Torte
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	17b	Cakes/Muffins/Brownies/Doughnut	Refrigerated					X		X		Cakes/Muffin/Cheesecakes with Frosting and Topping (cream, nuts, confectionery and dried fruits, etc.); Black Forest Torte
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	17c	Cakes/Muffins/Brownies/Doughnut	Frozen					X		X		Cakes/Muffin/Cheesecakes with Frosting and Topping (cream, nuts, confectionery and dried fruits, etc.); Black Forest Torte

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	18a	Fruit Pies/Cobblers	Shelf-Stable					X		X		Fruit Pies/Cobblers with Drizzles and Cream Topping
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	18b	Fruit Pies/Cobblers	Refrigerated					X		X		Fruit Pies/Cobblers with Drizzles and Cream Topping
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	18c	Fruit Pies/Cobblers	Frozen					X		X		Fruit Pies/Cobblers with Drizzles and Cream Topping
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	19a	Custard/Crème Pie	Shelf-Stable					X		X		Pumpkin and Sweet Potato Pies with Whipped Cream, Key Lime Pie, Coconut Custard Pie, Fruit Topped Cheesecake
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	19b	Custard/Crème Pie	Refrigerated					X		X		Pumpkin and Sweet Potato Pies with Whipped Cream, Key Lime Pie, Coconut Custard Pie, Fruit Topped Cheesecake

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	19c	Custard/Crème Pie	Frozen					X		X		Pumpkin and Sweet Potato Pies with Whipped Cream, Key Lime Pie, Coconut Custard Pie, Fruit Topped Cheesecake
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	20	Cookies	Shelf-Stable					X		X		Cream-Filled Sandwich Cookies
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	21a	Other Pastry Products	Refrigerated					X		X		Danishes, Éclair, Cream Puffs, Cannoli, Doughnuts, Toaster Pastries, Apple Turnovers, Baklava with Additions after Baking
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	21b	Other Pastry Products	Frozen					X		X		Danishes, Éclair, Cream Puffs, Cannoli, Doughnuts, Toaster Pastries, Apple Turnovers, Baklava with Additions after Baking
Assembled Cream Pies	22a	Custard/Crème Pie	Refrigerated					X		X		French Silk, Chocolate Cream Pie, Coconut Cream Pie, Peanut Butter Pie, Meringue Pies

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Assembled Cream Pies	22b	Custard/Crème Pie	Frozen					X		X		French Silk, Chocolate Cream Pie, Coconut Cream Pie, Peanut Butter Pie, Meringue Pies
Other Bakery Products	23a	Tortillas, Soft Shell/Hard Shell	Shelf Stable					X				Soft (Corn, Wheat), Hard Type, Baked, Fried
Other Bakery Products	23b	Tortillas, Soft Shell/Hard Shell	Refrigerated					X				Soft (Corn, Wheat), ParBaked
Other Bakery Products	24	Dry Mixes	Shelf Stable					X		X		Pancake Batter Mixes, Flour Mixes, Cookie Mixes, Cake Mixes, Brownie Mixes, Bread Crumbs, Cornmeal, Biscuits, Breeding Mix, Pie Crust Mix
Other Bakery Products	25	Ice Cream Cones	Shelf Stable					X				Sugar cones, regular cone
Other Bakery Products	26	Croutons/Bread Crumbs Unseasoned	Shelf Stable					X				Unseasoned

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Other Bakery Products	27	Croutons/Bread Crumbs, Seasoned	Shelf Stable					X		X		Seasoned

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 2B: Information that you should consider for potential ingredient or other food-related chemical hazards for Beverage Items

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Ready-to-Drink	1	Carbonated	Shelf-Stable				X			X		Cola, Root beer, Ginger ale, Fruit-Flavored Soda (Carbonated), Tonic Water, Sparkling Beverages(non-alcoholic)
Ready-to-Drink	2	Bottled Water	Shelf-Stable		X	X				X		Mineral Water, Spring Water, Water with Fruit Flavors, Sparkling Water, Distilled Water, Carbonated Water
Ready-to-Drink	3	Coffee, plain	Shelf-Stable				X	X				Iced Coffee, Regular and Decaffeinated Coffees
Ready-to-Drink	4a	Coffee, Flavored	Shelf-Stable							X		Lattes, Mocha, Café Vanilla, Cappuccino, Hazelnut Coffee
Ready-to-Drink	4b	Coffee, Flavored	Refrigerated							X		Lattes, Mocha, Café Vanilla, Cappuccino, Hazelnut Coffee
Ready-to-Drink	5a	Chocolate/Cocoa	Shelf-Stable									Non-dairy chocolate/ cocoa flavored drinks

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Ready-to-Drink	5b	Chocolate/Cocoa	Refrigerated									Non-dairy chocolate/ cocoa flavored drinks
Ready-to-Drink	6a	Tea, Plain	Shelf-Stable							X		Sweet Tea, Iced Tea, Regular and Decaffeinated Teas, Low Calorie Tea
Ready-to-Drink	6b	Tea, Plain	Refrigerated							X		Sweet Tea, Iced Tea, Regular and Decaffeinated Teas, Low Calorie Tea
Ready-to-Drink	7a	Tea, Flavored	Shelf-Stable							X		Flavored Teas (Fruit, Botanicals), Tea Blends, Regular and Decaffeinated, Regular and Low Calorie
Ready-to-Drink	7b	Tea, Flavored	Refrigerated							X		Flavored Teas (Fruit, Botanicals), Tea Blends, Regular and Decaffeinated, Regular and Low Calorie
Ready-to-Drink	8a	Juice-Based	Shelf-Stable							X		Fruit Drinks with Some Juice Content (not 100% juice)
Ready-to-Drink	8b	Juice-Based	Refrigerated							X		Fruit Drinks with Some Juice Content (not 100% juice)

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Ready-to-Drink	9a	Other Flavored	Shelf-Stable							X		Fruit Flavored Drink, Fruit Punch, Raspberry Lemonade
Ready-to-Drink	9b	Other Flavored	Refrigerated							X		Fruit Flavored Drink, Fruit Punch, Raspberry Lemonade
Ready-to-Drink	10a	Drinks with Supplements	Shelf-Stable							X		Caffeinated Energy Beverages, Sports Drinks, Vitamin Waters, Drinks with Herbal Infusions
Ready-to-Drink	10b	Drinks with Supplements	Refrigerated							X		Caffeinated Energy Beverages, Sports Drinks, Vitamin Waters, Drinks with Herbal Infusions
Ready-to-Drink	11	Milk Substitute	Refrigerated									Rice milk, Soy milk, Almond Milk, Non-Dairy Liquid Creamer
Coffee Beans/Tea Leaves	12	Coffee, Plain	Shelf-Stable					X				Whole Roasted Coffee Beans, Ground Coffee, Single Serve Coffee Containers
Coffee Beans/Tea Leaves	13	Coffee, Flavored	Shelf-Stable					X		X		Hazelnut Coffee, Vanilla Coffee, Single Serve Coffee Containers

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Coffee Beans/Tea Leaves	14	Tea, Loose Leaf and Bagged, Tea Substitutes	Shelf-Stable					X				Black Tea, Green Tea, Oolong Tea, Chai Tea, Tea With Blends of Fruits, Botanicals, Grains, etc., Tea Substitute (Chamomile, Rose Hip, Mint, Sassafras, and Barley), Single Serve Tea Containers
Powdered Beverages	15	Instant Coffee	Shelf-Stable									Instant Coffee, Coffee Substitute (Chicory Root Powder, Roast Cereal)
Powdered Beverages	16	Cocoa/Chocolate	Shelf-Stable							X		Breakfast Cocoa, Chocolate Dairy Mix, Cocoa Dairy Mix, Cappuccino Mix
Powdered Beverages	17	Powdered drink and flavoring mixes	Shelf-Stable							X		Flavoring powder, Grape, Orange, Lemon-Lime
Powdered Beverages	18	Instant Tea	Shelf-Stable							X		Lemon-flavored powdered tea
Powdered Beverages	19	Coffee Creamer - Non-Dairy	Shelf-Stable									Non Dairy Coffee Creamer

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Liquid Beverage Mixes	20	Base mix, Concentrated	Shelf-Stable							X		Cola Base, Root beer Base, Flavored Drink Syrups, Tea Concentrates, Coffee Concentrates
Liquid Beverage Mixes	21	Dairy-based mixes	Shelf-Stable							X		Breakfast Cocoa, Chocolate Dairy Mix, Cocoa Dairy Mix, Cappuccino Mix
Liquid Beverage Mixes	22	Mixes intended for alcoholic beverages	Shelf-Stable							X		Mohito Mix, Bloody Mary Mix, Margarita Mix, Cocktail Mix, Pina Colada Mix

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 2C: Information that you should consider for potential ingredient or other food-related chemical hazards for Food Additives

Category	#	Subcategory	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Emulsifiers	1	Emulsifiers									Soy Lecithin, Egg Lecithin, Mono- and Diglycerides, Polysorbates, Sorbitan Monostearate
Stabilizers and Thickeners	2	Firming Agents									Calcium Chloride, Calcium Lactate
Stabilizers and Thickeners	3	Humectants									Glycerin, Sorbitol
Stabilizers and Thickeners	4	Leavening Agents									Baking Soda, Monocalcium Phosphate, Calcium Carbonate
Stabilizers and Thickeners	5	Stabilizers, Thickeners, Binders, Texturizers									Gelatin, Pectin, Carrageenan, Modified Starches, Acacia Gum, Guar Gum, Xanthan Gum, Whey Protein, Soy Protein, High Activity Dried Yeast

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Stabilizers and Thickeners	6	Dough Strengtheners and Conditioner									Ammonium sulfate, Azodicarbonamide, and L-cysteine
Stabilizers and Thickeners	7	Anti-caking Agents									Calcium Silicate, Iron Ammonium Citrate, Silicon Dioxide
Enzymes	8	Enzymes									Lactase, Papain, Chymosin
Enzymes	9	Starch/Sugar Liquefaction									Amylases
Enzymes	10	Bakery									Xylanase, Lipases, Amylases, Proteases
Enzymes	11	Dairy									Rennet
Colors	12	Certified Colors									FD&C Blue Nos. 1 and 2, FD&C Green No. 3, FD&C Red Nos. 3 and 40, FD&C Yellow No. 5 (tartrazine), No. 6, Orange B, Citrus Red No. 2

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Colors	13	Natural Colors							X		Annatto Extract, Caramel, Beta-Carotene, Grape Skin Extract, Cochineal Extract, Chlorophyllin, Betanin, Carmine, Paprika Oleoresin, Caramel color, Saffron
Flavors	14	Liquid: Oil-Based									Sesame oil, Fruit oils, Almond oil, Cinnamon oil, Anise oil, Spearmint oil, Peppermint oil, Ginger oil
Flavors	15	Liquid: Water-Based									Various
Flavors	16	Liquid: Alcohol-Based									Various
Flavors	17	Liquid: Glycol-Based									Various
Flavors	18	Powdered: Natural Flavor							X		Vanilla Powder, Butter powder, Jasmine, Cinnamon, Orange blossom, Key Lime

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Flavors	19	Artificial: Synthetic							X		Cinnamon Raisin Flavor, Marshmallow Flavor, Watermelon Flavor, Strawberry Flavor, Grape Flavor, Cherry Flavor, Imitation Almond Extract, Imitation Coconut Extract
Flavors	20	Other: Flavor Enhancer							X		Monosodium Glutamate, Autolyzed Yeast Extract, Hydrolyzed Vegetable Proteins, Disodium Guanylate, Inosinate
Flavors	21	Flavor Paste									Vanilla Bean Paste
Other Chemical Ingredients	22	Processing Chemicals									Potassium Hydroxide, Potassium Bicarbonate, Potassium Chloride, Hydrochloric Acid, Sodium Hydroxide, Ferrous Sulfate, Magnesium Sulfate, Mineral Oil

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Other Chemical Ingredients	23	Organic Acids									Acetic Acid, Citric Acid, Lactic Acid, Fumaric Acid
Other Chemical Ingredients	24	Additives									Antioxidants, Vitamin Blends, Butylated Hydroxy Toluene (BHT), d-alpha-tocopherol acetate (TOCO)
Other Chemical Ingredients	25	Antimicrobials and Preservatives									Nisiplin, Lauric Arginate, Potassium Sorbate
Other Chemical Ingredients	26	Processing Aid Gases				X					Nitrogen, Carbon Dioxide

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 2D: Information that you should consider for potential ingredient or other food-related chemical hazards for Chocolate and Candy

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Chocolate Industrial Products	1	Chocolate/Cocoa Products For Baking (Including Bulk Solid and Bulk Liquid)	Shelf-Stable			X		X		X		Bittersweet Chocolate, Semi-sweet Chocolate, Unsweetened Chocolate, Milk Chocolate, Chocolate Chips, Chocolate Morsels, Cocoa Powder, White Chocolate
Chocolate Industrial Products	2	Other Products for Baking (Including Bulk Solid and Bulk Liquid)	Shelf-Stable					X		X		Butterscotch Morsels, Peanut Butter Morsels
Chocolate Industrial Products	3	Chocolate Coating for Enrobing (Including Bulk Solid and Bulk Liquid)	Shelf-Stable							X		Compound Coatings, White Chocolate
Chocolate and Confectionery Products	4	Chocolate Confections	Shelf-Stable			X				X		Milk Chocolate Bar, Dark/white Chocolate Bar, Fudge, bonbons

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Chocolate and Confectionery Products	5	Chocolate Confections - With Inclusions	Shelf-Stable					X		X		Chocolate Covered Nuts (e.g., Almonds, Pecans, Macadamia Nuts), Chocolate Candy Bar with Nuts, Chocolate Covered Raisins, Chocolate Covered Cherry, Chocolate with coconut, Chocolate with crisped rice, Fruit and Nut Chocolate Bar, Fudge with nuts, Chocolate Covered Biscuit, Chocolate Covered Caramel , Chocolate Covered Mints, Chocolate Covered Nougat or English Toffee
Chocolate and Confectionery Products	6	Sugar Confections	Shelf-Stable			X				X		Mint, Rock Candy, Lollipop, Lemon Drops, Caramel Candy Bar, Gummy gel Candies, Fruit Chews, Soft Toffee, Licorice Candy, Marshmallow, Soft jellied Candy, Soft Caramel Squares, Gel Cups Candy, Creams, Pastes, Pastilles

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Chocolate and Confectionery Products	7	Sugar Confections with inclusions	Shelf-Stable					X		X		Nut brittles (Peanut Brittle, Almond Brittle), Nut Clusters, Candy with fruit pieces
Chocolate and Confectionery Products	8	Sugar Confections Specialties (w/o Chocolate)	Shelf-Stable							X		Caramel/Candied Apple, Candy Coated Popcorn, Cereal Confection, Marzipan, Coconut Roll, Cake Decoration, Peanut butter fudge, Cotton Candy
Chocolate and Confectionery Products						X						Mexican style candy
Toppings/Frosting	9	Toppings and Frosting (Non Fruit/Nut)	Shelf-Stable							X		Butterscotch Topping, Caramel Topping, Vanilla Frosting, Sour Cream Frosting, Chocolate Flavored Syrup (Hot Fudge)

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 2E: Information that you should consider for potential ingredient or other food-related chemical hazards for Dairy

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Dairy - Dry Powders	1	Dry milk products	Shelf-Stable									Dried Milk, Whey Powder, Instant Nonfat Dry Milk, Whey Protein Powder
Dairy - Milk and Butter	2	Butter products	Refrigerated									Butter, Butter Spreads, Unsalted Butter Blends
Dairy - Milk and Butter	3	Pasteurized Milk and cream products	Refrigerated		X	X	X					Fluid White Milk, Flavored Milks, Buttermilk, Creams (Heavy, Light, Whipping), Goat Milk, Sheep Milk
Dairy - Milk and Butter	4	Cultured milk products	Refrigerated					X				Sour cream, Plain/Flavored Yogurt
Dairy, Milk and Milk Products Shelf-Stable	5	Ultra-High Temperature Dairy Products	Shelf-Stable		X	X	X					Dairy Creamer, UHT Milk
Dairy, Milk and Milk Products Shelf-Stable	6	Stabilized Liquid Milk Products	Shelf-Stable							X		Evaporated Milk, Sweetened Condensed Milk

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Dairy - Milk, Frozen	7	Ice cream, regular and low fat (no inclusions)	Frozen				X	X		X		Vanilla, Chocolate, Strawberry, Coconut
Dairy - Milk, Frozen	8	Ice cream, regular and low fat with inclusions	Frozen				X	X		X		Butter Pecan, Mint Chocolate Chip, Fudge Ripple, Rocky Road, Cherry Vanilla, Black Raspberry, Peppermint Cookie
Dairy - Milk, Frozen	9	Sherbets	Frozen							X		All Flavors
Dairy - Milk, Frozen	10	Frozen Novelty Items	Frozen				X	X		X		Milk Shakes, Ice Cream Cakes, Ice Cream Sandwiches, Chocolate Covered Ice Cream Bar, Chocolate/Nut Topped Ice Cream Desserts, Frozen Yogurt
Dairy - Cheese and Cheese Products - Whole	11a	Cheese (not soft)	Shelf-Stable									Hard Cheese, Cheddar Cheese, Parmesan Cheese, Asiago Cheese

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Dairy - Cheese and Cheese Products - Whole	11b	Cheese (not soft)	Refrigerated									Hard Cheese, Cheddar Cheese, Parmesan Cheese, Asiago Cheese
Dairy - Cheese and Cheese Products - Whole	12	Semi-soft cheese	Refrigerated									Blue, Monterey, Muenster, Provolone, Oaxaca, Stilton, Colby, Monterey Jack, Mozzarella, Edam, Gouda
Dairy - Cheese and Cheese Products - Whole	13	Soft, ripened cheese	Refrigerated									Brie, Camembert, Grayson, Cheese Curd
Dairy - Cheese and Cheese Products - Whole	14	Soft, unripened cheese/ fresh cheese	Refrigerated									Cottage Cheese, Cream Cheese, Ricotta, Queso Fresco, Cheese Curd, Goat Cheese
Dairy - Cheese and Cheese Products - Sliced, Shredded, or Grated	15a	Cheese (not soft)	Shelf-Stable									Hard Cheese, Cheddar Cheese, Parmesan Cheese, Asiago Cheese

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Dairy - Cheese and Cheese Products - Sliced, Shredded, or Grated	15b	Cheese (not soft)	Refrigerated									Hard Cheese, Cheddar Cheese, Parmesan Cheese, Asiago Cheese
Dairy - Cheese and Cheese Products - Sliced, Shredded, or Grated	16	Semi-soft cheese	Refrigerated									Monterey, Muenster, Provolone, Oaxaca, Colby, Monterey Jack, Mozzarella

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 2F: Information that you should consider for potential ingredient or other food-related chemical hazards for Dressings, Condiments, and Dips

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Condiments	1a	Mayonnaise	Shelf-Stable									Mayonnaise (Regular and Lite), Chipotle Mayonnaise, Mayonnaise, Wasabi Mayonnaise, Sweet Chili Mayonnaise
Condiments	1b	Mayonnaise	Refrigerated									Mayonnaise (Regular and Lite), Chipotle Mayonnaise, Mayonnaise, Wasabi Mayonnaise, Sweet Chili Mayonnaise
Condiments	2a	Mustard	Shelf-Stable									Yellow, Spicy, Sriracha Mustard, Garlic and Oregano Mustard
Condiments	2b	Mustard	Refrigerated									Yellow, Spicy, Sriracha Mustard, Garlic and Oregano Mustard
Condiments	3	Ketchup	Shelf-Stable									Tomato Ketchup
Condiments	4	Vinegar	Shelf-Stable									Balsamic, Apple Cider, Wine Vinegar, Grape Vinegar
Condiments	5	Other Condiments	Shelf-Stable							X		Soy Sauce, Worcestershire Sauce, Horseradish Sauce, Steak Sauce, Tabasco Sauce

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Salad Dressings	6a	Dressings, salad (prepared)	Shelf-Stable							X		Berries and Balsamic, Ranch, Spinach Vinaigrette, Caesar, Blue Cheese Vinaigrette, Sesame Dressing, Yogurt-based salad dressings
Salad Dressings	6b	Dressings, salad (prepared)	Refrigerated							X		Berries and Balsamic, Ranch, Spinach Vinaigrette, Caesar, Blue Cheese Vinaigrette, Sesame Dressing, Yogurt-based salad dressings
Salad Dressings	7	Dry mixes								X		Dried mixes to be added to oil, water, and vinegar
Dips	8a	Dips and spreads	Shelf-Stable						X	X		Guacamole, Salsa, Dairy-based Dips and Spreads, Bean Dips, Vegetable Dips, Taco Dip, cheese spreads, parmesan and asiago dip, 7 layer dip
Dips	8b	Dips and spreads	Refrigerated						X	X		Guacamole, Salsa, Dairy-based Dips and Spreads, Bean Dips, Vegetable Dips, Taco Dip, cheese spreads, parmesan and asiago dip, 7 layer dip

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Dips	9	Dips and spreads, dry	Shelf-Stable						X	X		Dry Dips, Dry Dairy-based Dips and Spreads (e.g., Vegetable Dip Seasoning, Toasted Onion Dip Mix)

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 2G: Information that you should consider for potential ingredient or other food-related chemical hazards for Egg and Egg Products

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Product
Shell Eggs	1	Shell Eggs Raw	Refrigerated									Shell Eggs, Raw
Shell Eggs	2	Shell Eggs: Pasteurized in Shell	Refrigerated									Pasteurized in Shell Eggs
Further Processed Egg Products	3	Eggs Hard Boiled: In shell	Refrigerated									Hard Boiled Eggs in Shell
Further Processed Egg Products	4	Eggs Hard Boiled: Shelled	Refrigerated									Hard Boiled Eggs Shelled
Further Processed Egg Products	5a	Cooked Egg Products, Ready-to-Eat (RTE) and Not Ready-to-Eat (NRTE)	Refrigerated							X		Omelets, Egg Patties, Scrambled Eggs
Further Processed Egg Products	5b	Cooked Egg Products, Ready-to-Eat (RTE) and Not Ready-to-Eat (NRTE)	Frozen							X		Omelets, Egg Patties, Scrambled Eggs

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Product
Imitation Egg Products	6a	Imitation Egg products and Egg Substitutes	Shelf-stable							X		Soy-based products; vegetable and grain-based products
Imitation Egg Products	6b	Imitation Egg products and Egg Substitutes	Refrigerated							X		Southwest Flavored Imitation Egg Product (Liquid), Florentine Imitation Egg Product (Liquid), Imitation Omelets, Imitation Egg Patties, Imitation Scrambled Eggs
Imitation Egg Products	6c	Imitation Egg products and Egg Substitutes	Frozen							X		Imitation Omelets, Egg Patties, Scrambled Eggs

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 2H: Information that you should consider for potential ingredient or other food-related chemical hazards for Fruits and Vegetables

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Fresh Cut	1	Fresh cut vegetables	Refrigerated						X			Leafy Greens (Single and Mixed Greens), Shredded Carrots, Avocado Chunks, Leafy green salad blends, Diced Onions, Cut Tomatoes, Sliced Mushrooms
Fresh Cut	2	Fresh cut fruits	Refrigerated					X	X			Mixed Fruit Salad; Packaged Single Fruits, Cut Melon, Apple Slices, Cut Pineapple, Cut Mango
Frozen	3	Vegetables Ready-to-Eat (RTE)	Frozen						X			Broccoli, Carrots, Corn-sweet, Cauliflower, Garlic, Kale, Peas, Snow peas, Spinach
Frozen	4	Vegetables, Not Ready-to-Eat (NRTE)	Frozen						X			Eggplants, Okra, Potatoes, Sweet potatoes, Winter squash

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Frozen	5	Fruits	Frozen						X			Raspberries, Melon, Blueberries, Sliced Strawberries, Tropical Fruit Blend, Mangoes, Pineapple
Refrigerated	6	Prepared Fruit Products Ready-to-Eat (RTE)	Refrigerated						X			Cherry Mixed Fruit in Juice, Diced Peaches, Diced Pears, Red Grapefruit
Dried / Dehydrated	7	Dried Fruits	Shelf-Stable					X	X			Raisins, Cranberries, Papaya, Pineapple, Mango, Blends
Dried / Dehydrated	8	Dehydrated Vegetables	Shelf-Stable						X			Peas, Celery, Onions, Carrots, Tomatoes, Green Beans, Wasabi Peas
Further Processed	9	Acidified Vegetables	Shelf-Stable									Pickled Cucumbers, Pickled Beets, Cocktail Onions, Pickled Turnips, Hearts of Palm, Capers, Roasted Peppers, Roasted Tomatoes, Salsas

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Further Processed	9a	Acidified Vegetables	Refrigerated									Pickled Cucumbers, Pickled Beets, Cocktail Onions, Pickled Turnips, Hearts of Palm, Capers, Roasted Peppers, Roasted Tomatoes, Salsas
Further Processed	11a	Fermented Vegetables	Shelf-Stable									Sauerkraut, Pickles, Kimchi
Further Processed	11b	Fermented Vegetables	Refrigerated									Sauerkraut, Pickles, Kimchi
Further Processed	12a	Infused Oils	Shelf-Stable									Garlic in Oil, Chili Pepper Oil, Lemon Oil, Sun Dried Tomatoes in Oil
Further Processed	12b	Infused Oils	Refrigerated									Garlic in Oil, Chili Pepper Oil, Lemon Oil, Sun Dried Tomatoes in Oil
Further Processed	13	Other Processed Fruits	Shelf-Stable					X				Jams, Jellies, Chutneys

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Further Processed	14a	Acid Pureed Fruits and Vegetables	Shelf-Stable									Applesauce, Flavored Applesauce, Tomato Paste, Tomato Puree, Apricot Puree
Further Processed	14b	Acid Pureed Fruits and Vegetables	Refrigerated									Applesauce, Flavored Applesauce, Tomato Paste, Tomato Puree, Apricot Puree

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 2I: Information that you should consider for potential ingredient or other food-related chemical hazards for Game Meat Products

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Raw Game Meat	1	Not Ground Game Meat	Refrigerated & Frozen			X						Bison Steak, Deer Shoulder, Alligator Steak, Bear, Antelope, Caribou, Elk, Moose, Reindeer, Wild Boar, Snake, Rabbit, Squirrel, Beaver, and Birds (Pheasant, Grouse, Quail, Wild Turkey, Wild geese)
Raw Game Meat	2	Ground Game Meat	Refrigerated & Frozen			X						Ground Venison, Ground Rabbit, Ground Alligator
Game Meat Products	3a	Processed Game Meat Products	Shelf-Stable			X	X			X		Buffalo Jerky, Alligator Jerky, Venison Salami, Ostrich Stick
Game Meat Products	3b	Processed Game Meat Products	Refrigerated			X	X			X		Bison Sausages, Venison Patties, Wild Boar Meatballs, Bison Meatloaf, Buffalo Jerky, Kangaroo Jerky, Bison Frankfurters, Venison Salami, Ostrich Stick

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Game Meat Products	3c	Processed Game Meat Products	Frozen			X	X			X	Bison Sausages, Venison Patties, Wild Boar Meatballs, Bison Meatloaf, Buffalo Jerky, Kangaroo Jerky, Bison Frankfurters, Venison Salami, Ostrich Stick
--------------------	----	------------------------------	--------	--	--	---	---	--	--	---	--

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Tables 2J: Information that you should consider for potential ingredient or other food-related chemical hazards for Grains, Beans and Grain Products

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Grains	1	Raw grains	Shelf-Stable					X	X			Wheat, Rye, Sorghum, Oats, Barley, Triticale, Buckwheat, Corn, Soy, Rice, Teff, Amaranth, Millet, Quinoa
Grains	2	Heat-treated grains	Shelf-Stable									Toasted oats, Puffed rice
Beans	3	Single component whole, dried	Shelf-Stable					X				Soybean, Kidney, Haricot, Lima, Pinto, Navy, Azuki, Mung, Black Gram, Scarlet Runner, Ricebean, Moth, Tepary; Horse, Broad, Field; Garden Pea; Chickpea; Cowpea/Black-eyed Pea; Pigeon Pea; Lentil; Bambara Groundnut; Vetch; Lupins; Lablab/hyacinth, Jack, Sword, Winged Bean, Velvet Bean, Yam Bean
Beans	4	Single component bean/pea/corn: paste	Shelf-Stable									Bean paste, Tahini, Hummus

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Beans	5a	Single Component Cooked Beans - no sauce	Refrigerated									Lima beans, Black-eyed peas, Lentils, Chickpeas, Kidney Beans, Peas, Edamame
Beans	5b	Single Component Cooked Beans - no sauce	Frozen NRTE									Lima beans, Black-eyed peas, Lentils, Chickpeas, Kidney Beans, Peas, Edamame
Beans	5c	Single Component Cooked Beans - no sauce	Frozen RTE									Lima beans, Black-eyed peas, Lentils, Chickpeas, Kidney Beans, Peas, Edamame
Milled Grain Products	6	Flour	Shelf-Stable					X	X			Wheat, Oats, Barley, Rye, Buckwheat, Millet, Amaranth, Quinoa, Soy
Milled Grain Products	7	Rice and rice products	Shelf-Stable			X						White or Brown Rice, Sticky/sweet Rice, Basmati Rice, Jasmine Rice, Arborio rice, Rice-based noodles
Milled Grain Products	8	Seed or bean: Pulse	Shelf-Stable					X				Garbanzo (Gram), Soy, Lentil, Sesame
Milled Grain Products	9	Malt	Shelf-Stable									Malted Barley
Milled Grain Products	10	Corn	Shelf-Stable					X	X			Cornmeal, Corn Flour
Other Milled Products	11	Root flours	Shelf-Stable									Potato, Cassava
Other Milled Products	12	Starch products	Shelf-Stable							X		Cornstarch, Potato Starch, Wheat Starch

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Grain-based Cereal Products	13a	Cereal Products without Inclusions: Ready-to-Eat	Shelf-Stable					X	X			Dry Cereals
Grain-based Cereal Products	13b	Cereal Products with Inclusions: Ready-to-Eat	Shelf-Stable					X	X			Granola with Raisins and Nuts, Cereals with Marshmallows, Nuts, Chocolate, Confectionary Bits
Grain-based Cereal Products	14	Breakfast food: Not Ready-to-Eat	Shelf-Stable					X	X			Oatmeal, Farina, Oat Bran, Cream of Wheat, Grits
Grain-based Cereal Products	15	Cereal products, N.E. C.	Shelf-Stable					X	X			Cereal Bars and Other Nutrition Bars (Baked)
Pasta Products	16a	Unfilled Pasta (not ready to eat)	Refrigerated					X				Spaghetti, Linguini, Rotini
Pasta Products	16b	Unfilled Pasta (not ready to eat)	Frozen					X				Spaghetti, Linguini, Rotini
Pasta Products	17a	Filled Par-Boiled Pasta (not ready to eat)	Refrigerated						X			Mushroom Ravioli, Cheese Tortellini
Pasta Products	17b	Filled Par-Boiled Pasta (not ready to eat)	Frozen						X			Mushroom Ravioli, Cheese Tortellini
Pasta Products	18	Dried pasta (not ready-to-eat)	Shelf-Stable					X				Spaghetti, Egg Noodles

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 2K: Information that you should consider for potential ingredient or other food-related chemical hazards for Multi-Component Foods

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
	1a	Entrees	Refrigerated						X			Vegetarian Lasagna, Pizza, Cheese Enchiladas, Bean Burritos; Tandoori Vegetables, Vegetable Stew, Baked Ziti, Teriyaki Bowl, Vegetable Pot Pie, Meat Analogue Chili
	1b	Entrees	Frozen Ready-to-Eat (RTE)						X			Vegetarian Lasagna, Pizza, Cheese Enchiladas, Bean Burritos; Tandoori Vegetables, Vegetable Stew, Baked Ziti, Teriyaki Bowl, Vegetable Pot Pie, Meat Analogue Chili
	1c	Entrees	Frozen NOT Ready-to-Eat (NRTE)						X			Vegetarian Lasagna, Pizza, Cheese Enchiladas, Bean Burritos; Tandoori Vegetables, Vegetable Stew, Baked Ziti, Teriyaki Bowl, Vegetable Pot Pie, Meat Analogue Chili

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
	2a	Side Dishes	Refrigerated						X	X		Macaroni and Cheese, Cheese and Broccoli Stuffed Baked Potatoes, Creamed Spinach, Broccoli and Rice Casserole, Potatoes Au Gratin, Green Bean Casserole, Corn with Butter Sauce, Mixed Vegetables with Teriyaki Sauce, French Fries, Hash Browned Potatoes, Potato Pancakes, Garlic Mashed Potatoes, Mashed Cinnamon Sweet Potatoes
	2b	Side Dishes	Frozen Ready-to-Eat (RTE)						X	X		Macaroni and Cheese, Cheese and Broccoli Stuffed Baked Potatoes, Creamed Spinach, Broccoli and Rice Casserole, Potatoes Au Gratin, Green Bean Casserole, Corn with Butter Sauce, Mixed Vegetables with Teriyaki Sauce, French Fries, Hash Browned Potatoes, Potato Pancakes, Garlic Mashed Potatoes, Mashed Cinnamon Sweet Potatoes

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
	2c	Side Dishes	Frozen NOT Ready-to-Eat (NRTE)						X	X		Macaroni and Cheese, Cheese and Broccoli Stuffed Baked Potatoes, Creamed Spinach, Broccoli and Rice Casserole, Potatoes Au Gratin, Green Bean Casserole, Corn with Butter Sauce, Mixed Vegetables with Teriyaki Sauce, French Fries, Hash Browned Potatoes, Potato Pancakes, Garlic Mashed Potatoes, Mashed Cinnamon Sweet Potatoes
	3	Deli Salads	Refrigerated									Three Bean Salad, Redskin Potato Salad, Egg Salad, Pasta Salad, Crunchy Broccoli Salad, Cole Slaw
	4a	Lunch Dishes	Refrigerated					X				Peanut Butter and Jam Sandwich, Black Bean Burger, Croissant Sandwiches, Spinach Feta Sandwiches, Soy Meat Alternative Sandwiches

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
	4b	Lunch Dishes	Frozen Ready-to-Eat (RTE)					X				Peanut Butter and Jam Sandwich, Black Bean Burger, Croissant Sandwiches, Spinach Feta Sandwiches, Soy Meat Alternative Sandwiches
	4c	Lunch Dishes	Frozen NOT Ready-to-Eat (NRTE)					X				Peanut Butter and Jam Sandwich, Black Bean Burger, Croissant Sandwiches, Spinach Feta Sandwiches, Soy Meat Alternative Sandwiches
	5a	Appetizers and Hors d'Oeuvres	Refrigerated						X	X		Mozzarella Sticks, Cheese Stuffed Jalapenos, Toasted Ravioli, Vegetable Egg Rolls, Cream Cheese Wontons, Stuffed Potato Skins
	5b	Appetizers and Hors d'Oeuvres	Frozen Ready-to-Eat (RTE)						X	X		Mozzarella Sticks, Cheese Stuffed Jalapenos, Toasted Ravioli, Vegetable Egg Rolls, Cream Cheese Wontons, Stuffed Potato Skins

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
	5c	Appetizers and Hors d'Oeuvres	Frozen NOT Ready-to-Eat (NRTE)						X	X		Mozzarella Sticks, Cheese Stuffed Jalapenos, Toasted Ravioli, Vegetable Egg Rolls, Cream Cheese Wontons, Stuffed Potato Skins
	6a	Breakfast Items	Refrigerated							X		Tofu Scramble, Egg and Cheese Breakfast Wrap, Spinach Feta Quiche, Egg, Sausage and Cheese Biscuits
	6b	Breakfast Items	Frozen Ready-to-Eat (RTE)							X		Tofu Scramble, Egg and Cheese Breakfast Wrap, Spinach Feta Quiche, Egg, Sausage and Cheese Biscuits
	6c	Breakfast Items	Frozen NOT Ready-to-Eat (NRTE)							X		Tofu Scramble, Egg and Cheese Breakfast Wrap, Spinach Feta Quiche, Egg, Sausage and Cheese Biscuits
	7	Meals (Entrees, Breakfast Items) Dehydrated	Shelf-Stable							X		Lentil Stew, Vegetarian Chili, Pasta Alfredo, Pasta Primavera, Tortilla Soup, Southwestern Scrambled Eggs, Biscuits and Gravy, Breakfast Skillet,

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
	8	Side Dishes	Shelf-Stable							X		Macaroni and Cheese, Potatoes Au Gratin, Seasoned Stuffing Mix, Seasoned Grain Blends, Flavored Rice

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 2L: Information that you should consider for potential ingredient or other food-related chemical hazards for Nuts and Seeds

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Nuts	1	Groundnuts, Raw: In-shell	Shelf-Stable					X				Peanuts
Nuts	2	Groundnuts, Raw: Shelled	Shelf-Stable					X				Peanuts
Nuts	3	Groundnuts, Roasted: In-shell, Unseasoned	Shelf-Stable									Dry Roasted Peanuts (unsalted)
Nuts	4	Groundnuts, Roasted: Shelled, Unseasoned	Shelf-Stable									Roasted Peanuts (unsalted)
Nuts	5	Groundnuts, Roasted: In-shell, Seasoned	Shelf-Stable							X		Salted Peanuts, Barbecue Peanuts, Hickory Smoke Peanuts
Nuts	6	Groundnuts, roasted: Shelled, Seasoned	Shelf-Stable							X		Honey Mustard Peanuts, Sweet Maui Onion Peanuts, Cocoa Peanuts
Nuts	7	Tree Nuts, Raw: In-Shell	Shelf-Stable					X				Almonds, Brazil Nuts, Cashews, Chestnuts, Filbert/Hazelnuts, Macadamias, Pecans, Pine Nuts, Pistachios, Walnuts, Betel Nut, Gingko, Lotus Nuts, Coconuts

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Nuts	8	Tree Nuts, Raw: Shelled	Shelf-Stable					X				Almonds, Brazil Nuts, Cashews, Chestnuts, Filbert/Hazelnuts, Macadamias, Pecans, Pine Nuts, Pistachios, Walnuts, Betel Nut, Gingko, Lotus Nuts
Nuts	9	Tree nuts, roasted: In-shell unseasoned	Shelf-Stable									Almonds, Brazil Nuts, Cashews, Chestnuts, Filbert/Hazelnuts, Macadamias, Pecans, Pine Nuts, Pistachios, Walnuts, Betel Nut, Gingko, Lotus Nuts
Nuts	10	Tree nuts, roasted: Shelled, unseasoned	Shelf-Stable									Almonds, Brazil Nuts, Cashews, Chestnuts, Filbert/Hazelnuts, Macadamias, Pecans, Pine Nuts, Pistachios, Walnuts, Betel Nut, Gingko, Lotus Nuts
Nuts	11	Tree nuts, roasted: In-shell Seasoned	Shelf-Stable							X		Salted Macadamia Nuts, Spicy Jalapeno Pistachios, Lemon and Lime Pistachios,

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Nuts	12	Tree nuts, roasted: Shelled, Seasoned	Shelf-Stable							X		Spicy Almonds, Hickory Smoked Almonds, Hot Chili Pepper Roasted Pistachios, Cinnamon and Sugar Walnuts, Cocoa Coated Almonds
Edible Seeds	13	In-Shell, Raw	Shelf-Stable									Pumpkin, Sunflower, Melon
Edible Seeds	14	Shelled, Raw	Shelf-Stable									Pumpkin, Sunflower, Melon
Edible Seeds	15	In-Shell, Roasted, Unseasoned	Shelf-Stable									Pumpkin, Sunflower, Melon
Edible Seeds	16	Shelled/No Shell , Roasted, Unseasoned	Shelf-Stable									Pumpkin, Sunflower, Melon, Hemp, Sesame, Flaxseed/Linseed
Edible Seeds	17	In-Shell, Roasted, Seasoned	Shelf-Stable							X		Cajun Spiced Pumpkin Seeds, Salted Pumpkin Seeds, Barbecue Sunflower Seeds, Dill Sunflowers Seeds, Ranch Sunflower Seeds
Edible Seeds	18	Shelled/No Shell , Roasted, Seasoned	Shelf-Stable							X		Cinnamon and Sugar Pumpkin Seeds, Tomato Italiano Pumpkin Seeds, Sea Salted Pumpkin Seeds

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Nut and Seed Butters	19a	Butters	Shelf-Stable					X				Peanut Butter, Almond Butter, Cashew Butter, Hazelnut Butter
Nut and Seed Butters	19b	Butters	Refrigerated					X				Peanut Butter, Almond Butter, Cashew Butter, Hazelnut Butter
Other Nut and Seed Products	20	Single-component Pastes	Shelf-Stable					X				Peanut Paste, Lotus Seed Paste, Sesame Seed Paste/Tahini, Pistachio Paste, Pumpkin Seed Paste/Pipian
Other Nut and Seed Products	21	Nut Flours	Shelf-Stable					X				Coconut Flour, Almond Flour, Pistachio Flour, Pumpkin Seed Flour
Other Nut and Seed Products	22	Coconut Products	Shelf-Stable									Shredded Coconut, Coconut Flakes, Toasted Coconut

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 2M: Information that you should consider for potential ingredient or other food-related chemical hazards for Oils and Oils Products

Category	#	Subcategory	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Oil Products	1	Cooking Oils					X				Corn, Soy Bean, Peanut, Safflower, Sesame, Cotton Seed, Canola, Olive, Sunflower, Blends
Oil Products	2	Margarines and other spreads							X		Oleomargarine
Oil Products	3	Shortening									Vegetable, Imitation/Substitute Vegetable Shortening

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 2N: Information that you should consider for potential ingredient or other food-related chemical hazards for Snack Foods

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Baked	1	Bread snacks, Unseasoned	Shelf-Stable									Breadsticks, Mini Toast, Poori, Crostini, Pretzels, Crackers
Baked	2	Bread snacks, Seasoned	Shelf-Stable							X		Honey Mustard Pretzels, Garlic Bagel Chips, Cinnamon Mini Toast, Garlic and Herb Crackers
Baked	3	Bread Snacks with Filling, Unseasoned	Shelf-Stable									Peanut Butter Pretzels, Cheese Pretzels
Baked	4	Bread Snacks with Filling, Seasoned	Shelf-Stable							X		Italian Cheese Pretzels, Buffalo Bleu Cheese Baked Snacks, Pepperoni Pizza Baked Snacks, Salsa Tortilla Baked Snacks
Baked	5	Grain snacks Unseasoned	Shelf-Stable			X		X				Puffed Rice Snacks, Wheat Crackers, Rice Crackers, Whole Grain Crackers
Baked	6	Grain Snacks Seasoned	Shelf-Stable			X		X		X		Cheddar Cheese Rice Cakes, Caramel Corn Cakes

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Fried	7	Chips, Puffs, Crisps, Unseasoned	Shelf-Stable					X				Potato Chips, Corn Chips, Cheese Puffs, Lentil Chips, Sweet Potato Chips, Mixed Root Vegetable Crisps, Tortilla Chips,
Fried	8	Chips, Puffs, Crisps, Seasoned	Shelf-Stable					X		X		Sour Cream and Onion Potato Chips, Barbecue Potato Chips, Sriracha Tortilla Chips
Fried	9	Bread snacks Unseasoned	Shelf-Stable									Bagel Chips, Pita Chips
Fried	10	Bread snacks Seasoned	Shelf-Stable							X		Garlic Pita Crisps, Everything Bagel Chips
Fried	11	Dehydrated Fruit snacks	Shelf-Stable									Plantain Chips, Banana Chips, Durian Chips, Jackfruit Chips, Apple Chips, Pineapple Chips
Fried	12	Grain Snacks Unseasoned	Shelf-Stable					X				Barley Grain Snack, Millet Grain Snack, Rice Grain Snacks, Multigrain Chips, Popped Popcorn
Fried	13	Grain Snacks Seasoned	Shelf-Stable					X		X		White Cheddar Popcorn, Harvest Cheddar Multigrain Chips, French Onion Multi-Grain Chips

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Cold Pressed	14	Snack Food Bars	Shelf-Stable					X		X		Granola Bars, Cranberry Almond Bars, Fruit and Nut Bars, Coated Bars
Other	15	Snack Blends	Shelf-Stable					X		X		Trail mix; Yogurt Covered Raisins, Coated Nuts
Other	16a	Pudding and gelatin products	Shelf-Stable							X		Flavored Gelatin Snacks, Chocolate Pudding, Tapioca Pudding, Vanilla Pudding
Other	16b	Pudding and gelatin products	Refrigerated							X		Flavored Gelatin Snacks, Chocolate Pudding, Tapioca Pudding, Vanilla Pudding
Other	17	Non-Dairy Frozen Desserts	Frozen							X		Ice Pops, Fruit Pops, Soy Milk Frozen Desserts, Sorbet

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 20: Information that you should consider for potential ingredient or other food-related chemical hazards for Soups and Sauces

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Soups, Sauces, Gravies	1	Dry Mixes, Powder	Shelf-stable					X	X	X		Noodle Soup, French Onion Soup, Bouillon Cubes, Bullion Powder, Brown Soup Base, Hollandaise Sauce, Turkey Gravy, Béarnaise Sauce, Beef Gravy
Soups, Sauces, Gravies	2	Base, paste	Shelf-Stable							X		Chicken Base, Beef Base, Vegetable Base, Seafood Base, Turkey Base
Soups, Sauces, Gravies	3a	Ready-to-Eat (RTE), Full Strength Liquid	Refrigerated							X		Beef-based Soup, Stew, Chili, Chicken Soup, French Onion Soup, Mushroom Soup, Turkey Soup, Potato Soup, Chicken Broth, Consommé, Peanut Sauce, Stir-Fry Sauce, Black Bean Sauce, Chili Sauce, Tandoori Sauce, Tomato Sauce, Broccoli and Cheese Soup, Tortilla Soup, Vegetarian Vegetable Soup, Tartar Sauce, Barbecue Sauce

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Soups, Sauces, Gravies	3b	Ready-to-Eat (RTE), Full Strength Liquid	Frozen							X		Beef-based Soup, Stew, Chili, Chicken Soup, French Onion Soup, Mushroom Soup, Turkey Soup, Potato Soup, Chicken Broth, Consommé, Peanut Sauce, Stir-Fry Sauce, Black Bean Sauce, Chili Sauce, Tandoori Sauce, Tomato Sauce, Broccoli and Cheese Soup, Tortilla Soup, Vegetarian Vegetable Soup, Tartar Sauce, Barbecue Sauce
Soups, Sauces, Gravies	4a	Condensed (Concentrated), Liquid	Refrigerated							X		Beef-based Soup, Stew, Chili, Chicken Soup, French Onion Soup, Mushroom Soup, Turkey Soup, Potato Soup, Chicken Broth, Consommé, Peanut Sauce, Stir-Fry Sauce, Black Bean Sauce, Chili Sauce, Tandoori Sauce, Tomato Sauce, Broccoli and Cheese Soup, Tortilla Soup, Vegetarian Vegetable Soup, Tartar Sauce, Barbecue Sauce

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Soups, Sauces, Gravies	4b	Condensed (Concentrated), Liquid	Frozen							X		Beef-based Soup, Stew, Chili, Chicken Soup, French Onion Soup, Mushroom Soup, Turkey Soup, Potato Soup, Chicken Broth, Consommé, Peanut Sauce, Stir-Fry Sauce, Black Bean Sauce, Chili Sauce, Tandoori Sauce, Tomato Sauce, Broccoli and Cheese Soup, Tortilla Soup, Vegetarian Vegetable Soup, Tartar Sauce, Barbecue Sauce

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 2P: Information that you should consider for potential ingredient or other food-related chemical hazards for Spices and Herbs

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Untreated, Raw Herbs and Spices	1	Dried, ground or cracked	Shelf-Stable			X		X		X		Cinnamon, Turmeric, Paprika, Pepper (Black, White, Red), Cayenne Powder, Cumin, Coriander, Mustard, Fenugreek, Horseradish, Fennel Seeds, Caraway, All-spice, Nutmeg, Ginger, Garlic (Minced or Powder), Onion (Minced or Powder), Celery Seed
Untreated, Raw Herbs and Spices	2	Dried, whole	Shelf-Stable						X			Cinnamon, Cardamom, Fenugreek, Cloves, Nutmeg, Cumin, Anise, fennel Seeds, Caraway, Chili Peppers, Saffron, Peppercorns (Black or White), Coriander, Basil, Varieties of Chili Peppers
Untreated, Raw Herbs and Spices	3	Dried herbs	Shelf-Stable									Basil, Oregano, Thyme, Sage, Parsley, Bay Leaf, Dill, Rosemary, Cilantro, Mint, Kaffir Lime, Chives, Peppermint

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Treated Herbs and Spices	4	Irradiated	Shelf-Stable									Various
Treated Herbs and Spices	5	Chemically Treated (EtOH, PPO)	Shelf-Stable							X		Various
Treated Herbs and Spices	6	Steam Pasteurization	Shelf-Stable									Various
Seasonings	7a	Pastes	Shelf-Stable							X		Basil Paste, Garlic Paste, Jerk Seasoning Paste
Seasonings	7b	Pastes	Refrigerated							X		Basil Paste, Garlic Paste, Jerk Seasoning Paste
Seasonings	8	Essential Oils	Shelf-Stable									Basil, Cinnamon, Clove, Ginger, Lemongrass
Seasonings	9	Spice and seasoning mixtures, Dry Blends	Shelf-Stable					X		X		Taco Mix, Chili Powder, Curry Powder, Multi-Spice Mix, Adobo Seasoning, Garam Masala, Berebere, Oriental Five-Spice, Crab Snack & Dip Seasoning, Meat Coatings and Rubs, Seafood Seasonings, Scampi Seasoning, Powdered Seasonings, Popcorn Seasonings

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Seasonings	10	Spice and seasoning mixtures, Liquid	Shelf-Stable							X		Fajita Seasoning Sauce, Kung Pao Seasoning Sauce

Table 2Q: Information that you should consider for potential ingredient or other food-related chemical hazards for Food Sweeteners (Nutritive and Non-Nutritive)

Category	#	Subcategory	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
----------	---	-------------	----------------------	---------------	--------------	----------------------	---------------------------	------------	-------------------------------	--------------	------------------

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Food Sweeteners (Nutritive and Non-Nutritive)	1	Sugars (Dry)							X		Brown Sugar (Sucrose), Beet Sugar(Sucrose), Invert Sugar, Maple Sugar, Malt Sugar (Maltose), Grape Sugar (Fructose), Corn Syrup Solids, Corn Sugar (Dextrose), Cane Sugar (Sucrose), Milk Sugar, Date sugar, Palm Sugar
Food Sweeteners (Nutritive and Non-Nutritive)	2	Syrup/Molasses (Liquid)							X		Sorghum Syrup, Maple Syrup, High Fructose Corn Syrup, Molasses, Pancake and Waffle Syrup, Simple Syrup, Liquid Sucrose, Agave Syrup, Rice Syrup
Food Sweeteners (Nutritive and Non-Nutritive)	3	Honey (Liquid)		X				X			Comb Honey, Strained Honey, Whipped Honey
Food Sweeteners (Nutritive and Non-Nutritive)	4	Imitation Syrup/Molasses (Liquid)							X		Imitation Maple Syrup, Imitation Honey
Food Sweeteners (Nutritive and Non-Nutritive)	5	Food Sweeteners (Nutr) N.E.C.							X		Nutritive Sugar Substitutes, Sorbitol, Xylitol, Isomalt, Tagatose, Maltitol, Lactitol

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Undeclared allergens	Drug residues	Heavy metals	Industrial chemicals	Mycotoxins/Natural toxins	Pesticides	Unapproved colors & additives	Radiological	Example Products
Food Sweeteners (Nutritive and Non-Nutritive)	6	Food Sweeteners (Non-nutr)							X		Aspartame, Saccharin, Acesulfame K, Neotame, Stevia, Sucralose

*Contains Non-binding Recommendations
Draft-Not for Implementation*

Process Hazards Tables

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 3A: Information that you should consider for potential process-related biological, chemical, and physical hazards for Bakery Items

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	formation due to poor formulation control	formation due to reduced oxygen packaging	recontamination with environmental pathogens	recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Unbaked Bakery Items - Ready-To-Bake (RTB)	1a	Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust	Refrigerated		X			X		X	X	X	X		Buttermilk biscuits, Cinnamon rolls, Croissants, Pizza Crust, Chocolate Chip Cookie Dough, Puff Pastry, Phyllo
Unbaked Bakery Items - Ready-To-Bake (RTB)	1b	Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust	Frozen		X			X		X	X	X	X		Buttermilk biscuits, Cinnamon rolls, Croissants, Pizza Crust, Chocolate Chip Cookie Dough, Puff Pastry, Phyllo
Unbaked Bakery Items - Ready-To-Bake (RTB)	2a	Parbaked/ParBoiled Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust	Refrigerated		X			X		X	X	X	X		Artisan breads, Bagels, Biscuits, Rolls, Croissant, Pizza Crust

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	formation due to poor formulation control	formation due to reduced oxygen packaging	recontamination w/ environmental pathogens	recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Unbaked Bakery Items - Ready-To-Bake (RTB)	2b	Parbaked/ParBoiled Bread, Biscuits, Rolls, Cookie Dough, Pizza/Pie Crust	Frozen		X			X		X	X	X	X		Artisan breads, Bagels, Biscuits, Rolls, Croissant, Pizza Crust
Unbaked Bakery Items - Ready-To-Bake (RTB)	3	Liquid Batter	Refrigerated		X	X		X		X	X	X	X		Pancake batter, Brownie batter, Waffle batter, and Doughnut batter
Unbaked Bakery Items - Ready-To-Bake (RTB)	4	Fruit pies/cobblers	Frozen		X	X		X		X	X	X	X		Apple/Cherry/Peach Cobbler; Apple, Cherry/ Mixed Berries/etc. Pies
Unbaked Bakery Items - Ready-To-Bake (RTB)	5	Custard pies	Frozen		X	X		X		X	X	X	X		Pumpkin and Sweet Potato Pies

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	formation due to poor formulation control	formation due to reduced oxygen packaging	recontamination w/ environmental pathogens	recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Fully-Baked Without Filling, No Topping/Frosting	6	Bread, Whole/Pre-sliced	Shelf-Stable, Refrigerated or Frozen	X				X		X	X	X	X		Breads (e.g., White, Wheat, Rye, Oat Bran, Pumpernickel), Cheese Breads, Raisin Breads; Cornbread, Plain or Flavored Biscuits, Bagels, Rolls, Croissants, Pita Bread, Pumpkin Bread
Fully-Baked Without Filling, No Topping/Frosting	7a	Cakes/Muffins/Brownies/ Doughnut	Shelf-Stable	X				X		X	X	X	X		Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Without Filling, No Topping/Frosting	7b	Cakes/Muffins/Brownies/ Doughnut	Refrigerated	X				X		X	X	X	X		Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Without Filling, No Topping/Frosting	7c	Cakes/Muffins/Brownies/ Doughnut	Frozen	X				X		X	X	X	X		Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	formation due to poor formulation control	formation due to reduced oxygen packaging	recontamination with environmental pathogens	recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Fully-Baked Without Filling, No Topping/Frosting	8	Cookies	Shelf-Stable	X				X		X	X	X	X		Chocolate Chip, Peanut Butter, Biscotti, Lemon, Butter Cookies, Brownies, Wafers, Oatmeal Cookies, Fruit, Cream or Chocolate-Filled Crisps/Bars, Wafers
Fully-Baked Without Filling, No Topping/Frosting	9a	Other Pastry Products	Refrigerated	X	X	X		X		X	X	X	X		French Toast, Blueberry Pancakes, Waffles
Fully-Baked Without Filling, No Topping/Frosting	9b	Other Pastry Products	Frozen	X	X	X		X		X	X	X	X		French Toast, Blueberry Pancakes, Waffles
Fully-Baked Including Fillings, No Topping/Frosting	10	Bread, Whole/Pre-sliced	Shelf-Stable, Refrigerated or Frozen	X		X		X		X	X	X	X		Cheese Breads, Raisin Breads; Cornbread, Flavored Biscuits, Chocolate Croissants, Pumpkin Bread, Banana Nut Bread

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	formation due to poor formulation control	formation due to reduced oxygen packaging	recontamination with environmental pathogens	recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Fully-Baked Including Fillings, No Topping/Frosting	11a	Cakes/Muffins/Brownies/ Doughnut	Shelf-Stable	X				X		X	X	X	X		Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Including Fillings, No Topping/Frosting	11b	Cakes/Muffins/Brownies/ Doughnut	Refrigerated	X		X		X		X	X	X	X		Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Including Fillings, No Topping/Frosting	11c	Cakes/Muffins/Brownies/ Doughnut	Frozen	X		X		X		X	X	X	X		Chocolate, Vanilla, Yellow, Marble, Sponge Cake, Pound Cake, Cheesecakes
Fully-Baked Including Fillings, No Topping/Frosting	12a	Fruit Pies/Cobblers	Shelf-Stable	X				X		X	X	X	X		Various Fruit Pies (Apple/Cherry/Blueberry, Rhubarb, Mixed Berry/etc.)
Fully-Baked Including Fillings, No Topping/Frosting	12b	Fruit Pies/Cobblers	Refrigerated	X	X			X		X	X	X	X		Various Fruit Pies (Apple/Cherry/Blueberry, Rhubarb, Mixed Berry/etc.)

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	formation due to poor formulation control	formation due to reduced oxygen packaging	recontamination with environmental pathogens	recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Fully-Baked Including Fillings, No Topping/Frosting	12c	Fruit Pies/Cobblers	Frozen	X	X			X		X	X	X	X		Various Fruit Pies (Apple/Cherry/Blueberry, Rhubarb, Mixed Berry/etc.)
Fully-Baked Including Fillings, No Topping/Frosting	13a	Custard/Crème Pie	Shelf-Stable	X	X	X		X		X	X	X	X		Pumpkin/Sweet Potato, Lemon Pie, Key Lime Pie; Coconut Custard
Fully-Baked Including Fillings, No Topping/Frosting	13b	Custard/Crème Pie	Refrigerated	X	X	X		X		X	X	X	X		Pumpkin/Sweet Potato, Lemon Pie, Key Lime Pie; Coconut Custard
Fully-Baked Including Fillings, No Topping/Frosting	13c	Custard/Crème Pie	Frozen	X	X	X		X		X	X	X	X		Pumpkin/Sweet Potato, Lemon Pie, Key Lime Pie; Coconut Custard

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	formation due to poor formulation control	formation due to reduced oxygen packaging	recontamination with environmental pathogens	recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Fully-Baked Including Fillings, No Topping/Frosting	14	Cookies	Shelf-Stable	X				X		X	X	X	X		Chocolate Chip, Peanut Butter, Biscotti, Lemon, Butter Cookies, Brownies, Wafers, Oatmeal Cookies, Fruit, Cream or Chocolate-Filled Crisps/Bars, Wafers
Fully-Baked Including Fillings, No Topping/Frosting	15a	Other Pastry Products	Refrigerated	X	X	X		X		X	X	X	X		French Toast, Blueberry Pancakes, Waffles
Fully-Baked Including Fillings, No Topping/Frosting	15b	Other Pastry Products	Frozen	X	X	X		X		X	X	X	X		French Toast, Blueberry Pancakes, Waffles
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	16	Bread, Whole/Pre-sliced	Shelf-Stable, Refrigerated or Frozen	X	X	X		X		X	X	X	X		Bread with Drizzles/Frosting

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	formation due to poor formulation control	formation due to reduced oxygen packaging	recontamination with environmental pathogens	recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	17a	Cakes/Muffins/Brownies/ Doughnut	Shelf-Stable	X		X		X		X	X	X	X		Cakes/Muffin/Cheesecakes with Frosting and Topping (cream, nuts, confectionery and dried fruits, etc.); Black Forest Torte
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	17b	Cakes/Muffins/Brownies/ Doughnut	Refrigerated	X	X	X		X		X	X	X	X		Cakes/Muffin/Cheesecakes with Frosting and Topping (cream, nuts, confectionery and dried fruits, etc.); Black Forest Torte
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	17c	Cakes/Muffins/Brownies/ Doughnut	Frozen	X	X	X		X		X	X	X	X		Cakes/Muffin/Cheesecakes with Frosting and Topping (cream, nuts, confectionery and dried fruits, etc.); Black Forest Torte
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	18a	Fruit Pies/Cobblers	Shelf-Stable	X		X		X		X	X	X	X		Fruit Pies/Cobblers with Drizzles and Cream Topping

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	formation due to poor formulation control	formation due to reduced oxygen packaging	recontamination with environmental pathogens	recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	18b	Fruit Pies/Cobblers	Refrigerated	X	X	X		X		X	X	X	X		Fruit Pies/Cobblers with Drizzles and Cream Topping
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	18c	Fruit Pies/Cobblers	Frozen	X	X	X		X		X	X	X	X		Fruit Pies/Cobblers with Drizzles and Cream Topping
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	19a	Custard/Crème Pie	Shelf-Stable	X	X	X		X		X	X	X	X		Pumpkin and Sweet Potato Pies, Key Lime Pie, Coconut Custard Pie, Fruit Topped Cheesecake
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	19b	Custard/Crème Pie	Refrigerated	X	X	X		X		X	X	X	X		Pumpkin and Sweet Potato Pies, Key Lime Pie, Coconut Custard Pie, Fruit Topped Cheesecake
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	19c	Custard/Crème Pie	Frozen	X	X	X		X		X	X	X	X		Pumpkin and Sweet Potato Pies, Key Lime Pie, Coconut Custard Pie, Fruit Topped Cheesecake

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	formation due to poor formulation control	formation due to reduced oxygen packaging	recontamination w/ environmental pathogens	recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	20	Cookies	Shelf-Stable	X		X		X		X	X	X	X		Cream-Filled Sandwich Cookies
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	21a	Other Pastry Products	Refrigerated	X	X	X		X		X	X	X	X		Danishes, Éclair, Cream Puffs, Cannoli, Doughnuts, Toaster Pastries, Apple Turnovers, Baklava with Additions after Baking
Fully-Baked with Post Bake Added Filling, Frosting and/or Topping	21b	Other Pastry Products	Frozen	X	X	X		X		X	X	X	X		Danishes, Éclair, Cream Puffs, Cannoli, Doughnuts, Toaster Pastries, Apple Turnovers, Baklava with Additions after Baking
Assembled Cream Pies	22a	Custard/Crème Pie	Refrigerated	X	X	X		X		X	X	X	X		French Silk, Chocolate Cream Pie, Coconut Cream Pie, Peanut Butter Pie, Meringue Pies

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	formation due to poor formulation control	formation due to reduced oxygen packaging	recontamination w/ environmental pathogens	recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Assembled Cream Pies	22b	Custard/Crème Pie	Frozen	X	X	X		X		X	X	X	X		French Silk, Chocolate Cream Pie, Coconut Cream Pie, Peanut Butter Pie, Meringue Pies
Other Bakery Products	23a	Tortillas, Soft Shell/Hard Shell	Shelf Stable	X				X		X	X	X	X		Soft (Corn, Wheat), Hard Type, Baked, Fried
Other Bakery Products	23b	Tortillas, Soft Shell/Hard Shell	Refrigerated	X	X			X		X	X	X	X		Soft (Corn, Wheat), ParBaked
Other Bakery Products	24	Dry Mixes	Shelf Stable					X		X	X	X	X		Pancake Batter Mixes, Flour Mixes, Cookie Mixes, Cake Mixes, Brownie Mixes, Bread Crumbs, Cornmeal, Biscuits, Breading Mix, Pie Crust Mix
Other Bakery Products	25	Ice Cream Cones	Shelf Stable					X		X	X	X	X		Sugar cones, regular cone
Other Bakery Products	26	Croutons/Bread Crumbs	Shelf Stable					X		X	X	X	X		Unseasoned
Other Bakery Products	27	Croutons/Bread Crumbs	Shelf Stable					X		X	X	X	X		Seasoned

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 3B: Information that you should consider for potential process-related biological, chemical, and physical hazards for Beverage Items

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Ready-to-Drink	1	Carbonated	Shelf-Stable						X			X	X	X	Cola, Root beer, Ginger ale, Fruit-Flavored Soda (Carbonated), Tonic Water, Sparkling Beverages(non-alcoholic)
Ready-to-Drink	2	Bottled Water	Shelf-Stable	X				X	X			X	X	X	Mineral Water, Spring Water, Water with Fruit Flavors, Sparkling Water, Distilled Water, Carbonated Water

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Ready-to-Drink	3	Coffee, plain	Shelf-Stable						X						Iced Coffee, Regular and Decaffeinated Coffees
Ready-to-Drink	4a	Coffee, Flavored	Shelf-Stable	X		X		X	X	X	X	X	X	X	Lattes, Mocha, Café Vanilla, Cappuccino, Hazelnut Coffee
Ready-to-Drink	4b	Coffee, Flavored	Refrigerated	X	X	X		X	X	X	X	X	X	X	Lattes, Mocha, Café Vanilla, Cappuccino, Hazelnut Coffee
Ready-to-Drink	5a	Chocolate/Cocoa	Shelf-Stable	X		X		X	X	X	X	X	X	X	Non-dairy chocolate/cocoa flavored drinks
Ready-to-Drink	5b	Chocolate/Cocoa	Refrigerated	X	X	X		X	X	X	X	X	X	X	Non-dairy chocolate/cocoa flavored drinks

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Ready-to-Drink	6a	Tea, Plain	Shelf-Stable	X		X		X	X			X	X	X	Sweet Tea, Iced Tea, Regular and Decaffeinated Teas, Low Calorie Tea
Ready-to-Drink	6b	Tea, Plain	Refrigerated		X	X		X	X			X	X	X	Sweet Tea, Iced Tea, Regular and Decaffeinated Teas, Low Calorie Tea
Ready-to-Drink	7a	Tea, Flavored	Shelf-Stable	X		X		X	X	X	X	X	X	X	Flavored Teas (Fruit, Botanicals), Tea Blends, Regular and Decaffeinated, Regular and Low Calorie

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Ready-to-Drink	7b	Tea, Flavored	Refrigerated		X	X		X	X	X	X	X	X	X	Flavored Teas (Fruit, Botanicals), Tea Blends, Regular and Decaffeinated, Regular and Low Calorie
Ready-to-Drink	8a	Juice-Based	Shelf-Stable	X		X		X	X			X	X	X	Fruit Drinks with Some Juice Content (not 100% juice)
Ready-to-Drink	8b	Juice-Based	Refrigerated		X	X		X	X			X	X	X	Fruit Drinks with Some Juice Content (not 100% juice)
Ready-to-Drink	9a	Other Flavored	Shelf-Stable	X		X		X	X			X	X	X	Fruit Flavored Drink, Fruit Punch, Lemonade

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Ready-to-Drink	9b	Other Flavored	Refrigerated		X	X		X	X			X	X	X	Fruit Flavored Drink, Fruit Punch, Lemonade
Ready-to-Drink	10 a	Drinks with Supplements	Shelf-Stable	X		X		X	X			X	X	X	Caffeinated Energy Beverages, Sports Drinks, Vitamin Waters, Drinks with Herbal Infusions
Ready-to-Drink	10 b	Drinks with Supplements	Refrigerated		X			X	X			X	X	X	Caffeinated Energy Beverages, Sports Drinks, Vitamin Waters, Drinks with Herbal Infusions
Ready-to-Drink	11	Milk Substitute	Refrigerated	X	X			X	X	X	X	X	X	X	Rice milk, Soy milk, Almond Milk

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Coffee Beans/Tea Leaves	12	Coffee, Plain	Shelf-Stable												Whole Roasted Coffee Beans, Ground Coffee, Single Serve Coffee Containers
Coffee Beans/Tea Leaves	13	Coffee, Flavored	Shelf-Stable					X							Hazelnut Coffee, Vanilla Coffee, Single Serve Coffee Containers

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Coffee Beans/Tea Leaves	14	Tea, Loose Leaf and Bagged, Tea Substitutes	Shelf-Stable					X				X			Black Tea, Green Tea, Oolong Tea, Chai Tea, Tea With Blends of Fruits, Botanicals, Grains, etc., Tea Substitute (Chamomile, Rose Hip, Mint, Sassafras, and Barley), Single Serve Tea Containers
Powdered Beverages	15	Instant Coffee	Shelf-Stable												Instant Coffee, Coffee Substitute (Chicory Root Powder, Roast Cereal)

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Powdered Beverages	16	Cocoa/Chocolate	Shelf-Stable					X		X	X				Breakfast Cocoa, Chocolate Dairy Mix, Cocoa Dairy Mix, Cappuccino Mix
Powdered Beverages	17	Powdered drink and flavoring mixes	Shelf-Stable					X		X	X				Flavoring powder, Grape, Orange, Lemon-Lime
Powdered Beverages	18	Instant Tea	Shelf-Stable					X		X	X				Lemon-flavored powdered tea
Powdered Beverages	19	Coffee Creamer - Non-Dairy	Shelf-Stable					X		X	X				Non Dairy Coffee Creamer

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Liquid Beverage Mixes	20	Base mix, Concentrated	Shelf-Stable												Cola Base, Root beer Base, Flavored Drink Syrups, Tea Concentrates, Coffee Concentrates
Liquid Beverage Mixes	21	Dairy-based mixes	Shelf-Stable	X		X		X	X	X	X	X	X		Breakfast Cocoa, Chocolate Dairy Mix, Cocoa Dairy Mix, Cappuccino Mix
Liquid Beverage Mixes	22	Mixes intended for alcoholic beverages	Shelf-Stable			X		X	X	X	X	X	X	X	Mohito Mix, Bloody Mary Mix, Margarita Mix, Cocktail Mix, Pina Colada Mix

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 3C: Information that you should consider for potential process-related biological, chemical, and physical hazards for Food Additives

Category	#	Subcategory	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Emulsifiers	1	Emulsifiers												Soy Lecithin, Egg Lecithin, Mono- and Diglycerides, Polysorbates, Sorbitan Monostearate
Stabilizers and Thickeners	2	Firming Agents												Calcium Chloride, Calcium Lactate
Stabilizers and Thickeners	3	Humectants												Glycerin, Sorbitol
Stabilizers and Thickeners	4	Leavening Agents												Baking Soda, Monocalcium Phosphate, Calcium Carbonate
Stabilizers and Thickeners	5	Stabilizers, Thickeners, Binders, Texturizers												Gelatin, Pectin, Carrageenan, Modified Starches, Acacia Gum, Guar Gum, Xanthan Gum, Whey Protein, Soy Protein, High Activity Dried Yeast
Stabilizers and Thickeners	6	Dough Strengtheners and Conditioner												Ammonium sulfate, Azodicarbonamide, and L-cysteine

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Stabilizers and Thickeners	7	Anti-caking Agents												Calcium Silicate, Iron Ammonium Citrate, Silicon Dioxide
Enzymes	8	Enzymes												Lactase, Papain, Chymosin
Enzymes	9	Starch/Sugar Liquefaction												Amylases
Enzymes	10	Bakery												Xylanase, Lipases, Amylases, Proteases
Enzymes	11	Dairy												Rennet
Colors	12	Certified Colors												FD&C Blue Nos. 1 and 2, FD&C Green No. 3, FD&C Red Nos. 3 and 40, FD&C Yellow No. 5 (tartrazine), No. 6, Orange B, Citrus Red No. 2
Colors	13	Natural Colors												Annatto Extract, Caramel, Beta-Carotene, Grape Skin Extract, Cochineal Extract, Chlorophyllin, Betanin, Carmine, Paprika Oleoresin, Caramel color, Saffron

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Flavors	14	Liquid: Oil-Based												Sesame oil, Fruit oils, Almond oil, Cinnamon oil, Anise oil, Spearmint oil, Peppermint oil, Ginger oil
Flavors	15	Liquid: Water-Based												Various
Flavors	16	Liquid: Alcohol-Based												Various
Flavors	17	Liquid: Glycol-Based												Various
Flavors	18	Powdered: Natural Flavor							X					Vanilla Powder, Butter powder, Jasmine, Cinnamon, Orange blossom, Key Lime
Flavors	19	Artificial: Synthetic												Cinnamon Raisin Flavor, Marshmallow Flavor, Watermelon Flavor, Strawberry Flavor, Grape Flavor, Cherry Flavor, Imitation Almond Extract, Imitation Coconut Extract
Flavors	20	Other: Flavor Enhancer							X					Monosodium Glutamate, Autolyzed Yeast Extract, Hydrolyzed Vegetable Proteins, Disodium Guanylate, Inosinate

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Flavors	21	Flavor Pother: Paste								X				Vanilla Bean Paste
Other Chemical Ingredients	22	Processing Chemicals												Potassium Hydroxide, Potassium Bicarbonate, Potassium Chloride, Hydrochloric Acid, Sodium Hydroxide, Ferrous Sulfate, Magnesium Sulfate, Mineral Oil
Other Chemical Ingredients	23	Organic Acids												Acetic Acid, Citric Acid, Lactic Acid, Fumaric Acid
Other Chemical Ingredients	24	Additives												Antioxidants, Vitamin Blends, Butylated Hydroxy Toluene (BHT), d-alpha-tocopherol acetate (TOCO)
Other Chemical Ingredients	25	Antimicrobials and Preservatives												Nisiplin, Lauric Arginate, Potassium Sorbate
Other Chemical Ingredients	26	Processing Aid Gases												Nitrogen, Carbon Dioxide

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 3D: Information that you should consider for potential process-related biological, chemical, and physical hazards for Chocolate and Candy

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Chocolate Industrial Products	1	Chocolate/Cocoa Products For Baking (Including Bulk Solid and Bulk Liquid)	Shelf-Stable	X				X		X	X	X	X		Bittersweet Chocolate, Semi-sweet Chocolate, Unsweetened Chocolate, Milk Chocolate, Chocolate Chips, Chocolate Morsels, Cocoa Powder, White Chocolate
Chocolate Industrial Products	2	Other Products for Baking (Including Bulk Solid and Bulk Liquid)	Shelf-Stable	X				X		X	X	X	X		Butterscotch Morsels, Peanut Butter Morsels

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Chocolate Industrial Products	3	Chocolate Coating for Enrobing (Including Bulk Solid and Bulk Liquid)	Shelf-Stable	X				X		X	X	X	X		Compound Coatings, White Chocolate
Chocolate and Confectionery Products	4	Chocolate Confections	Shelf-Stable	X				X		X	X	X	X		Milk Chocolate Bar, Dark/white Chocolate Bar, Fudge, bonbons

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Chocolate and Confectionery Products	5	Chocolate Confections - With Inclusions	Shelf-Stable	X				X		X	X	X	X		Chocolate Covered Nuts (e.g., Almonds, Pecans, Macadamia Nuts), Chocolate Candy Bar with Nuts, Chocolate Covered Raisins, Chocolate Covered Cherry, Chocolate with coconut, Chocolate with crisped rice, Fruit and Nut Chocolate Bar, Fudge with nuts, Chocolate Covered Biscuit, Chocolate Covered Caramel , Chocolate Covered Mints, Chocolate Covered Nougat or English Toffee

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Chocolate and Confectionery Products	6	Sugar Confections	Shelf-Stable			X		X		X	X	X	X		Mint, Rock Candy, Lollipop, Lemon Drops, Caramel Candy Bar, Gummy gel Candies, Fruit Chews, Soft Toffee, Licorice Candy, Marshmallow, Soft Jellied Candy, Soft Caramel Squares, Gel Cups Candy, Creams, Pastes, Pastilles

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Chocolate and Confectionery Products	7	Sugar Confections with inclusions	Shelf-Stable			X		X		X	X	X	X		Nut brittles (Peanut Brittle, Almond Brittle), Nut Clusters, Candy with fruit pieces
Chocolate and Confectionery Products	8	Sugar Confections Specialties (w/o Chocolate)	Shelf-Stable			X		X		X	X	X	X		Caramel/Candied Apple, Candy Coated Popcorn, Cereal Confection, Marzipan, Coconut Roll, Cake Decoration, Peanut butter fudge, Cotton Candy

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Toppings/Frosting	9	Toppings and Frosting (Non Fruit/Nut)	Shelf-Stable			X				X	X	X	X		Butterscotch Topping, Caramel Topping, Vanilla Frosting, Sour Cream Frosting, Chocolate Flavored Syrup (Hot Fudge)

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 3E: Information that you should consider for potential process-related biological, chemical, and physical hazards for Dairy

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal Glass (when product packed in glass)	Example Products
Dairy - Dry Powders	1	Dry milk products	Shelf-Stable	X				X					X	Dried Milk, Whey Powder, Instant Nonfat Dry Milk, Whey Protein Powder
Dairy - Milk and Butter	2	Butter products	Refrigerated	X	X			X		X	X		X	Butter, Butter Spreads, Unsalted Butter Blends
Dairy - Milk and Butter	3	Pasteurized Milk and cream products	Refrigerated	X	X			X		X	X		X	Fluid White Milk, Flavored Milks, Buttermilk, Creams (Heavy, Light, Whipping), Goat Milk, Sheep Milk
Dairy - Milk and Butter	4	Cultured milk products	Refrigerated	X	X			X		X	X		X	Sour cream, Plain/Flavored Yogurt
Dairy, Milk and Milk Products Shelf-Stable	5	Ultra-High Temperature Liquid Dairy Products	Shelf-Stable	X				X	X	X	X		X	Dairy Creamer, UHT Milk, Flavored Creamers

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal Glass (when product packed in glass)	Example Products
Dairy, Milk and Milk Products Shelf-Stable	6	Stabilized Liquid Milk Products	Shelf-Stable	X				X	X				X	Evaporated Milk, Sweetened Condensed Milk
Dairy - Milk, Frozen	7	Ice cream, regular and low fat (no inclusions)	Frozen	X	X			X		X	X	X	X	Vanilla, Chocolate, Strawberry, Coconut
Dairy - Milk, Frozen	8	Ice cream, regular and low fat with inclusions	Frozen	X	X			X		X	X	X	X	Butter Pecan, Mint Chocolate Chip, Fudge Ripple, Rocky Road, Cherry Vanilla, Black Raspberry, Peppermint Cookie
Dairy - Milk, Frozen	9	Sherbets	Frozen	X	X			X		X	X	X	X	All Flavors , Pineapple, Raspberry, Orange

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal Glass (when product packed in glass)	Example Products
Dairy - Milk, Frozen	10	Frozen Novelty Items	Frozen	X	X			X		X	X	X	X	Milk Shakes, Ice Cream Cakes, Ice Cream Sandwiches, Chocolate Covered Ice Cream Bar, Chocolate/Nut Topped Ice Cream Desserts, Frozen Yogurt
Dairy - Cheese and Cheese Products - Whole	11 a	Cheese (not soft)	Shelf-Stable	X				X		X	X		X	Hard Cheese, Cheddar Cheese, Parmesan Cheese, Asiago Cheese
Dairy - Cheese and Cheese Products - Whole	11 b	Cheese (not soft)	Refrigerated	X	X			X		X	X		X	Hard Cheese, Cheddar Cheese, Parmesan Cheese, Asiago Cheese

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal Glass (when product packed in glass)	Example Products
Dairy - Cheese and Cheese Products - Whole	12	Semi-soft cheese	Refrigerated	X	X			X		X	X		X	Blue, Monterey, Muenster, Provolone, Oaxaca, Stilton, Colby, Monterey Jack, Mozzarella, Edam, Gouda
Dairy - Cheese and Cheese Products - Whole	13	Soft, ripened cheese	Refrigerated	X	X			X		X	X		X	Brie, Camembert, Grayson, Cheese Curd
Dairy - Cheese and Cheese Products - Whole	14	Soft, unripened cheese/ fresh cheese	Refrigerated	X	X			X		X	X		X	Cottage Cheese, Cream Cheese, Ricotta, Queso Fresco, Cheese Curd, Goat Cheese
Dairy - Cheese and Cheese Products - Sliced, Shredded, or Grated	15 a	Cheese (not soft)	Shelf-Stable	X	X		X	X					X	Hard Cheese, Cheddar Cheese, Parmesan Cheese, Asiago Cheese

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal Glass (when product packed in glass)	Example Products
Dairy - Cheese and Cheese Products - Sliced, Shredded, or Grated	15 b	Cheese (not soft)	Refrigerated	X	X		X	X					X	Hard Cheese, Cheddar Cheese, Parmesan Cheese, Asiago Cheese
Dairy - Cheese and Cheese Products - Sliced, Shredded, or Grated	16	Semi-soft cheese	Refrigerated	X	X		X	X					X	Monterey, Muenster, Provolone, Oaxaca, Colby, Monterey Jack, Mozzarella

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 3F: Information you should consider for potential process-related biological, chemical, and physical hazards for Dressings, Condiments, and Dips

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Condiments	1a	Mayonnaise	Shelf-Stable			X			X	X	X		X	X	Mayonnaise (Regular and Lite), Chipotle Mayonnaise, Mayonnaise, Wasabi Mayonnaise, Sweet Chili Mayonnaise
Condiments	1b	Mayonnaise	Refrigerated		X	X		X	X	X	X		X	X	Mayonnaise (Regular and Lite), Chipotle Mayonnaise, Mayonnaise, Wasabi Mayonnaise, Sweet Chili Mayonnaise

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Condiments	2a	Mustard	Shelf-Stable						X				X	X	Yellow, Spicy, Sriracha Mustard, Garlic and Oregano Mustard
Condiments	2b	Mustard	Refrigerated					X	X				X	X	Yellow, Spicy, Sriracha Mustard, Garlic and Oregano Mustard
Condiments	3	Ketchup	Shelf-Stable			X			X				X	X	Tomato Ketchup
Condiments	4	Vinegar	Shelf-Stable											X	Balsamic, Apple Cider, Wine Vinegar, Grape Vinegar
Condiments	5	Other Condiments	Shelf-Stable	X		X			X	X	X	X	X	X	Soy Sauce, Worcestershire Sauce, Horseradish Sauce, Steak Sauce, Tabasco Sauce

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Salad Dressings	6a	Dressings, salad (prepared)	Shelf-Stable	X		X		X	X	X	X	X	X	X	Berries and Balsamic, Ranch, Spinach Vinaigrette, Caesar, Blue Cheese Vinaigrette, Sesame Dressing, Yogurt-based salad dressings
Salad Dressings	6b	Dressings, salad (prepared)	Refrigerated	X ¹	X ¹	X		X	X	X	X	X	X	X	Berries and Balsamic, Ranch, Spinach Vinaigrette, Caesar, Blue Cheese Vinaigrette, Sesame Dressing, Yogurt-based salad dressings
Salad Dressings	7	Dry mixes	Shelf-Stable					X		X	X		X		Dried mixes to be added to oil, water, and vinegar

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Dips	8a	Dips and spreads	Shelf-Stable	X		X		X	X	X	X	X	X	X	Guacamole, Salsa, Dairy-based Dips and Spreads, Bean Dips, Vegetable Dips, Taco Dip, cheese spreads, parmesan and asiago dip, 7 layer dip
Dips	8b	Dips and spreads	Refrigerated	X	X	X	X	X	X	X	X	X	X	X	Guacamole, Salsa, Dairy-based Dips and Spreads, Bean Dips, Vegetable Dips, Taco Dip, cheese spreads, parmesan and asiago dip, 7 layer dip

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Dips	9	Dips and spreads, dry	Shelf-Stable					X		X	X		X		Dry Dips, Dry Dairy-based Dips and Spreads (e.g., Vegetable Dip Seasoning, Toasted Onion Dip Mix)

¹This hazard may be considered for cold-filled products of this type.

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 3G: Information that you should consider for potential process-related biological, chemical, and physical hazards for Egg and Egg Products

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal Glass (when product packed in glass)	Example Products
Shell Eggs	1	Shell Eggs Raw	Refrigerated		X									Shell Eggs, Raw
Shell Eggs	2	Shell Eggs: Pasteurized in Shell	Refrigerated	X	X									Pasteurized in Shell Eggs
Further Processed Egg Products	3	Eggs Hard Boiled: In shell	Refrigerated	X	X									Hard Boiled Eggs in Shell
Further Processed Egg Products	4	Eggs Hard Boiled: Shelled	Refrigerated	X	X		X	X						Hard Boiled Eggs Shelled
Further Processed Egg Products	5a	Cooked Egg Products, Ready-to-Eat (RTE) and Not Ready-to-Eat (NRTE)	Refrigerated	X	X		X	X		X	X		X	Omelets, Egg Patties, Scrambled Eggs

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Further Processed Egg Products	5b	Cooked Egg Products, Ready-to-Eat (RTE) and Not Ready-to-Eat (NRTE)	Frozen	X	X			X		X	X		X		Omelets, Egg Patties, Scrambled Eggs
Imitation Egg Products	6a	Imitation Egg products and Egg Substitutes	Shelf-stable	X				X		X	X		X		Soy-based products; vegetable and grain-based products
Imitation Egg Products	6b	Imitation Egg products and Egg Substitutes	Refrigerated	X				X		X	X		X		Southwest Flavored Imitation Egg Product (Liquid), Florentine Imitation Egg Product (Liquid), Imitation Omelets, Imitation Egg Patties, Imitation Scrambled Eggs
Imitation Egg Products	6c	Imitation Egg products and Egg Substitutes	Frozen	X				X		X	X		X		Imitation Omelets, Egg Patties, Scrambled Eggs

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 3H: Information that you should consider for potential process-related biological, chemical, and physical hazards for Fruits and Vegetables

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Fresh Cut	1	Fresh cut vegetables	Refrigerated		X		X	X					X		Leafy Greens (Single and Mixed Greens), Shredded Carrots, Avocado Chunks, Leafy green salad blends, Diced Onions, Cut Tomatoes, Sliced Mushrooms
Fresh Cut	2	Fresh cut fruits	Refrigerated		X			X					X		Mixed Fruit Salad; Packaged Single Fruits, Cut Melon, Apple Slices, Cut Pineapple, Cut Mango
Frozen	3	Vegetables Ready-to-Eat (RTE)	Frozen	X	X			X					X		Broccoli, Carrots, Corn-sweet, Cauliflower, Garlic, Kale, Peas, Snow peas, Spinach
Frozen	4	Vegetables, Not Ready-to-Eat (NRTE)	Frozen		X			X					X		Eggplants, Okra, Potatoes, Sweet potatoes, Winter squash

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Frozen	5	Fruits	Frozen		X			X					X		Raspberries, Melon, Blueberries, Sliced Strawberries, Tropical Fruit Blend, Mangoes, Pineapple
Refrigerated	6	Prepared Fruit Products Ready-to-Eat (RTE)	Refrigerated		X	X		X	X			X	X		Cinnamon Apples, Cherry Mixed Fruit in Juice, Diced Peaches, Diced Pears, Red Grapefruit
Dried / Dehydrated	7	Dried Fruits	Shelf-Stable			X		X		X	X	X	X		Raisins, Cranberries, Papaya, Pineapple, Mango, Blends
Dried / Dehydrated	8	Dehydrated Vegetables	Shelf-Stable			X		X		X	X	X	X		Peas, Celery, Onions, Carrots, Tomatoes, Green Beans, Wasabi Peas
Further Processed	9	Acidified Vegetables	Shelf-Stable			X		X	X			X	X	X	Pickled Cucumbers, Pickled Beets, Cocktail Onions, Pickled Turnips, Hearts of Palm, Capers, Roasted Peppers, Roasted Tomatoes, Salsa

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Further Processed	9a	Acidified Vegetables	Refrigerated		X	X		X	X			X	X	X	Pickled Cucumbers, Pickled Beets, Cocktail Onions, Pickled Turnips, Hearts of Palm, Capers, Roasted Peppers, Roasted Tomatoes, Salsa
Further Processed	11a	Fermented Vegetables	Shelf-Stable			X		X	X			X	X	X	Sauerkraut, Pickles, Kimchi
Further Processed	11b	Fermented Vegetables	Refrigerated		X	X		X	X			X	X	X	Sauerkraut, Pickles, Kimchi
Further Processed	12a	Infused Oils	Shelf-Stable			X							X	X	Garlic in Oil, Chili Pepper Oil, Lemon Oil, Sun Dried Tomatoes in Oil
Further Processed	12b	Infused Oils	Refrigerated		X	X							X	X	Garlic in Oil, Chili Pepper Oil, Lemon Oil, Sun Dried Tomatoes in Oil
Further Processed	13	Other Processed Fruits	Shelf-Stable	X		X		X					X	X	Jams, Jellies, Chutneys

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Further Processed	14a	Acid Fruits and Vegetables	Shelf-Stable			X		X	X				X	X	Applesauce, Flavored Applesauce, Tomato Paste, Tomato Puree, Apricot Puree
Further Processed	14b	Acid Fruits and Vegetables	Refrigerated		X	X		X	X				X	X	Applesauce, Flavored Applesauce, Tomato Paste, Tomato Puree, Apricot Puree

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 3I: Information that you should consider for potential process-related biological, chemical, and physical hazards for Game Meats

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Raw Game Meat	1	Not Ground Game Meat	Refrigerated & Frozen		X			X					X		Bison Steak, Deer Shoulder, Alligator Steak, Bear, Antelope, Caribou, Elk, Moose, Reindeer, Wild Boar, Snake, Rabbit, Squirrel, Beaver, and Birds (Pheasant, Grouse, Quail, Wild Turkey, Wild geese).
Raw Game Meat	2	Ground Game Meat	Refrigerated & Frozen		X			X					X		Ground Venison, Ground Rabbit, Ground Alligator
Game Meat Products	3a	Processed Game Meat Products	Shelf-Stable	X		X		X	X	X	X	X	X		Buffalo Jerky, Alligator Jerky, Venison Salami, Ostrich Stick

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Game Meat Products	3b	Processed Game Meat Products	Refrigerated	X	X	X	X	X	X	X	X	X	X		Bison Sausages, Venison Patties, Wild Boar Meatballs, Bison Meatloaf, Buffalo Jerky, Kangaroo Jerky, Bison Frankfurters, Venison Salami, Ostrich Stick
Game Meat Products	3c	Processed Game Meat Products	Frozen	X	X	X		X	X	X	X	X	X		Bison Sausages, Venison Patties, Wild Boar Meatballs, Bison Meatloaf, Buffalo Jerky, Kangaroo Jerky, Bison Frankfurters, Venison Salami, Ostrich Stick

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 3J: Information that you should consider for potential process-related biological, chemical, and physical hazards for Grains, Beans and Grain Products

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Example Products
Grains	1	Raw grains	Shelf-Stable					X				X	X	Wheat, Rye, Sorghum, Oats, Barley, Triticale, Buckwheat, Corn, Soy, Rice, Teff, Amaranth, Millet, Quinoa
Grains	2	Heat-treated grains	Shelf-Stable	X				X				X		Toasted oats, Puffed rice

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Example Products
Beans	3	Single component whole, dried	Shelf-Stable		X			X					X	Soybean, Kidney, Haricot, Lima, Pinto, Navy, Azuki, Mung, Black Gram, Scarlet Runner, Ricebean, Moth, Tepary; Horse, Broad, Field; Garden Pea; Chickpea; Cowpea/Black-eyed Pea; Pigeon Pea; Lentil; Bambara Groundnut; Vetch; Lupins; Lablab/hyacinth, Jack, Sword, Winged Bean, Velvet Bean, Yam Bean
Beans	4	Single component bean/pea/corn dried: paste	Shelf-Stable			X		X					X	Bean paste, Tahini, Hummus

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Example Products
Beans	5a	Single Component Cooked Beans - no sauce	Refrigerated	X	X			X					X	Lima beans, Black-eyed peas, Lentils, Chickpeas, Kidney Beans, Peas, Edamame
Beans	5b	Single Component Cooked Beans - no sauce	Frozen NRTE	X	X			X					X	Lima beans, Black-eyed peas, Lentils, Chickpeas, Kidney Beans, Peas, Edamame
Beans	5c	Single Component Cooked Beans - no sauce	Frozen RTE	X	X			X					X	Lima beans, Black-eyed peas, Lentils, Chickpeas, Kidney Beans, Peas, Edamame

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Example Products
Milled Grain Products	6	Flour	Shelf-Stable						X			X	X	Wheat, Oats, Barley, Rye, Buckwheat, Millet, Amaranth, Quinoa, Soy
Milled Grain Products	7	Rice and rice products	Shelf-Stable		X				X				X	White or Brown Rice, Sticky/sweet Rice, Basmati Rice, Jasmine Rice, Arborio rice, Rice-based noodles
Milled Grain Products	8	Seed or bean: Pulse	Shelf-Stable						X				X	Garbanzo (Gram), Soy, Lentil, Sesame
Milled Grain Products	9	Malt	Shelf-Stable						X			X	X	Malted Barley
Milled Grain Products	10	Corn	Shelf-Stable						X			X	X	Cornmeal, Corn Flour
Other Milled Products	11	Root flours	Shelf-Stable						X				X	Potato, Cassava

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Example Products
Other Milled Products	12	Starch products	Shelf-Stable					X					X	Cornstarch, Potato Starch, Wheat Starch
Grain-based Cereal Products	13a	Cereal Products without Inclusions: Ready-to-Eat	Shelf-Stable		X			X		X	X	X	X	Dry Cereals
Grain-based Cereal Products	13b	Cereal Products with Inclusions: Ready-to-Eat	Shelf-Stable		X			X		X	X	X	X	Granola with Raisins and Nuts, Cereals with Marshmallows, Nuts, Chocolate, Confectionary Bits
Grain-based Cereal Products	14	Breakfast food: Not Ready-to-Eat	Shelf-Stable					X		X	X	X	X	Oatmeal, Farina, Oat Bran, Cream of Wheat, Grits
Grain-based Cereal Products	15	Cereal products, N.E. C.	Shelf-Stable	X				X		X	X	X	X	Cereal Bars and Other Nutrition Bars (Baked)
Pasta Products	16a	Unfilled Pasta (not ready to eat)	Refrigerated	X	X		X	X		X	X		X	Spaghetti, Linguini, Rotini
Pasta Products	16b	Unfilled Pasta (not ready to eat)	Frozen	X	X			X		X	X		X	Spaghetti, Linguini, Rotini

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Example Products
Pasta Products	17a	Filled Par-Boiled Pasta (not ready to eat)	Refrigerated	X	X		X	X		X	X	X	X	Mushroom Ravioli, Cheese Tortellini
Pasta Products	17b	Filled Par-Boiled Pasta (not ready to eat)	Frozen	X	X			X		X	X	X	X	Mushroom Ravioli, Cheese Tortellini
Pasta Products	18	Dried pasta (not ready-to-eat)	Shelf-Stable	X						X	X		X	Spaghetti, Egg Noodles

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 3K: Information that you should consider for potential process-related biological, chemical, and physical hazards for Multi-Component Foods

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Multi - component foods	1a	Entrees	Refrigerated	X	X		X	X	X	X	X	X	X		Vegetarian Lasagna, Pizza, Cheese Enchiladas, Bean Burritos; Tandoori Vegetables, Vegetable Stew, Baked Ziti, Teriyaki Bowl, Vegetable Pot Pie, Meat Analogue Chili
Multi - component foods	1b	Entrees	Frozen Ready-to-Eat (RTE)	X	X			X		X	X	X	X		Vegetarian Lasagna, Pizza, Cheese Enchiladas, Bean Burritos; Tandoori Vegetables, Vegetable Stew, Baked Ziti, Teriyaki Bowl, Vegetable Pot Pie, Meat Analogue Chili

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Multi - component foods	1c	Entrees	Frozen NOT Ready-to-Eat (NRTE)	X	X			X		X	X	X	X		Vegetarian Lasagna, Pizza, Cheese Enchiladas, Bean Burritos; Tandoori Vegetables, Vegetable Stew, Baked Ziti, Teriyaki Bowl, Vegetable Pot Pie, Meat Analogue Chili

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Multi - component foods	2a	Side Dishes	Refrigerated	X	X		X	X	X	X	X	X	X		Macaroni and Cheese, Cheese and Broccoli Stuffed Baked Potatoes, Creamed Spinach, Broccoli and Rice Casserole, Potatoes Au Gratin, Green Bean Casserole, Corn with Butter Sauce, Mixed Vegetables with Teriyaki Sauce, French Fries, Hash Browned Potatoes, Potato Pancakes, Garlic Mashed Potatoes, Mashed Cinnamon Sweet Potatoes

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Multi-component foods	2b	Side Dishes	Frozen Ready-to-Eat (RTE)	X	X			X		X	X	X	X		Macaroni and Cheese, Cheese and Broccoli Stuffed Baked Potatoes, Creamed Spinach, Broccoli and Rice Casserole, Potatoes Au Gratin, Green Bean Casserole, Corn with Butter Sauce, Mixed Vegetables with Teriyaki Sauce, French Fries, Hash Browned Potatoes, Potato Pancakes, Garlic Mashed Potatoes, Mashed Cinnamon Sweet Potatoes

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Multi - component foods	2c	Side Dishes	Frozen NOT Ready-to-Eat (NRTE)		X			X		X	X	X	X		Macaroni and Cheese, Cheese and Broccoli Stuffed Baked Potatoes, Creamed Spinach, Broccoli and Rice Casserole, Potatoes Au Gratin, Green Bean Casserole, Corn with Butter Sauce, Mixed Vegetables with Teriyaki Sauce, French Fries, Hash Browned Potatoes, Potato Pancakes, Garlic Mashed Potatoes, Mashed Cinnamon Sweet Potatoes
Multi - component foods	3	Deli Salads	Refrigerated	X	X	X	X	X	X	X	X	X	X		Three Bean Salad, Redskin Potato Salad, Egg Salad, Pasta Salad, Crunchy Broccoli Salad, Cole Slaw

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Multi - component foods	4a	Lunch Dishes	Refrigerated	X	X		X	X	X	X	X	X	X		Peanut Butter and Jam Sandwich, Black Bean Burger, Croissant Sandwiches, Spinach Feta Sandwiches, Soy Meat Alternative Sandwiches
Multi - component foods	4b	Lunch Dishes	Frozen Ready-to-Eat (RTE)	X	X			X		X	X	X	X		Peanut Butter and Jam Sandwich, Black Bean Burger, Croissant Sandwiches, Spinach Feta Sandwiches, Soy Meat Alternative Sandwiches
Multi - component foods	4c	Lunch Dishes	Frozen NOT Ready-to-Eat (NRTE)		X			X		X	X	X	X		Peanut Butter and Jam Sandwich, Black Bean Burger, Croissant Sandwiches, Spinach Feta Sandwiches, Soy Meat Alternative Sandwiches

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Multi - component foods	5a	Appetizers and Hors d'Oeuvres	Refrigerated	X	X		X	X	X	X	X	X	X		Mozzarella Sticks, Cheese Stuffed Jalapenos, Toasted Ravioli, Vegetable Egg Rolls, Cream Cheese Wontons, Stuffed Potato Skins
Multi - component foods	5b	Appetizers and Hors d'Oeuvres	Frozen Ready-to-Eat (RTE)	X	X			X		X	X	X	X		Mozzarella Sticks, Cheese Stuffed Jalapenos, Toasted Ravioli, Vegetable Egg Rolls, Cream Cheese Wontons, Stuffed Potato Skins
Multi - component foods	5c	Appetizers and Hors d'Oeuvres	Frozen NOT Ready-to-Eat (NRTE)		X			X		X	X	X	X		Mozzarella Sticks, Cheese Stuffed Jalapenos, Toasted Ravioli, Vegetable Egg Rolls, Cream Cheese Wontons, Stuffed Potato Skins

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Multi - component foods	6a	Breakfast Items	Refrigerated	X	X		X	X	X	X	X	X	X		Tofu Scramble, Egg and Cheese Breakfast Wrap, Spinach Feta Quiche, Egg, Sausage and Cheese Biscuits
Multi - component foods	6b	Breakfast Items	Frozen Ready-to-Eat (RTE)	X	X			X		X	X	X	X		Tofu Scramble, Egg and Cheese Breakfast Wrap, Spinach Feta Quiche, Egg, Sausage and Cheese Biscuits
Multi - component foods	6c	Breakfast Items	Frozen NOT Ready-to-Eat (NRTE)		X			X		X	X	X	X		Tofu Scramble, Egg and Cheese Breakfast Wrap, Spinach Feta Quiche, Egg, Sausage and Cheese Biscuits
Multi - component foods	7	Meals (Entrees, Breakfast Items) Dehydrated	Shelf-Stable	X				X		X	X	X	X		Lentil Stew, Vegetarian Chili, Pasta Alfredo, Pasta Primavera, Tortilla Soup, Southwestern Scrambled Eggs, Biscuits and Gravy, Breakfast Skillet,

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Multi - component foods	8	Side Dishes	Shelf-Stable	X				X		X	X	X	X		Macaroni and Cheese, Potatoes Au Gratin, Seasoned Stuffing Mix, Seasoned Grain Blends, Stuffing Mix, Flavored Rice

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 3L: Information that you should consider for potential process-related biological, chemical, and physical hazards for Nuts and Seeds

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Nuts	1	Groundnuts, Raw: In-shell	Shelf-Stable					X		X	X	X	X		Peanuts
Nuts	2	Groundnuts, Raw: Shelled	Shelf-Stable					X		X	X	X	X		Peanuts
Nuts	3	Groundnuts, Roasted: In-shell, Unseasoned	Shelf-Stable	X				X		X	X	X	X	X	Dry Roasted Peanuts (unsalted)
Nuts	4	Groundnuts, Roasted: Shelled, Unseasoned	Shelf-Stable	X				X		X	X	X	X	X	Roasted Peanuts (unsalted)
Nuts	5	Groundnuts, Roasted: In-shell, Seasoned	Shelf-Stable	X				X		X	X	X	X	X	Salted Peanuts, Barbecue Peanuts, Hickory Smoke Peanuts
Nuts	6	Groundnuts, roasted: Shelled, Seasoned	Shelf-Stable	X				X		X	X	X	X	X	Honey Mustard Peanuts, Sweet Maui Onion Peanuts, Cocoa Peanuts

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Nuts	7	Tree Nuts, Raw: In-Shell	Shelf-Stable							X	X	X	X		Almonds, Brazil Nuts, Cashews, Chestnuts, Filbert/Hazelnuts, Macadamias, Pecans, Pine Nuts, Pistachios, Walnuts, Betel Nut, Gingko, Lotus Nuts, Coconuts
Nuts	8	Tree Nuts, Raw: Shelled	Shelf-Stable							X	X	X	X		Almonds, Brazil Nuts, Cashews, Chestnuts, Filbert/Hazelnuts, Macadamias, Pecans, Pine Nuts, Pistachios, Walnuts, Betel Nut, Gingko, Lotus Nuts
Nuts	9	Tree nuts, roasted: In-shell unseasoned	Shelf-Stable	X						X	X	X	X	X	Almonds, Brazil Nuts, Cashews, Chestnuts, Filbert/Hazelnuts, Macadamias, Pecans, Pine Nuts, Pistachios, Walnuts, Betel Nut, Gingko, Lotus Nuts

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Nuts	10	Tree nuts, roasted: Shelled, unseasoned	Shelf-Stable	X						X	X	X	X	X	Almonds, Brazil Nuts, Cashews, Chestnuts, Filbert/Hazelnuts, Macadamias, Pecans, Pine Nuts, Pistachios, Walnuts, Betel Nut, Ginkgo, Lotus Nuts
Nuts	11	Tree nuts, roasted: In-shell Seasoned	Shelf-Stable	X						X	X	X	X	X	Salted Macadamia Nuts, Spicy Jalapeno Pistachios, Lemon and Lime Pistachios,
Nuts	12	Tree nuts, roasted: Shelled, Seasoned	Shelf-Stable	X						X	X	X	X	X	Spicy Almonds, Hickory Smoked Almonds, Hot Chili Pepper Roasted Pistachios, Cinnamon and Sugar Walnuts, Cocoa Coated Almonds
Edible Seeds	13	In-Shell, Raw	Shelf-Stable							X			X	X	Pumpkin, Sunflower, Melon
Edible Seeds	14	Shelled, Raw	Shelf-Stable							X			X	X	Pumpkin, Sunflower, Melon

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Edible Seeds	15	In-Shell, Roasted, Unseasoned	Shelf-Stable	X				X		X	X		X	X	Pumpkin, Sunflower, Melon
Edible Seeds	16	Shelled/No Shell , Roasted, Unseasoned	Shelf-Stable	X				X		X	X		X	X	Pumpkin, Sunflower, Melon, Hemp, Sesame, Flaxseed/Linseed
Edible Seeds	17	In-Shell, Roasted, Seasoned	Shelf-Stable	X				X		X	X		X	X	Cajun Spiced Pumpkin Seeds, Salted Pumpkin Seeds, Barbecue Sunflower Seeds, Dill Sunflowers Seeds, Ranch Sunflower Seeds
Edible Seeds	18	Shelled/No Shell , Roasted, Seasoned	Shelf-Stable	X				X		X	X		X	X	Cinnamon and Sugar Pumpkin Seeds, Tomato Italiano Pumpkin Seeds, Sea Salted Pumpkin Seeds

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Nut and Seed Butters	19a	Butters	Shelf-Stable	X				X		X	X	X	X	X	Peanut Butter, Almond Butter, Cashew Butter, Hazelnut Butter
Nut and Seed Butters	19b	Butters	Refrigerated	X	X			X		X	X	X	X	X	Peanut Butter, Almond Butter, Cashew Butter, Hazelnut Butter
Other Nut and Seed Products	20	Single-component Pastes	Shelf-Stable	X				X		X	X	X	X		Peanut Paste, Lotus Seed Paste, Sesame Seed Paste/Tahini, Pistachio Paste, Pumpkin Seed Paste/Pipian
Other Nut and Seed Products	21	Nut Flours	Shelf-Stable					X		X	X	X	X		Coconut Flour, Almond Flour, Pistachio Flour, Pumpkin Seed Flour

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Other Nut and Seed Products	22	Coconut Products	Shelf-Stable					X					X		Shredded Coconut, Coconut Flakes, Toasted Coconut

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 3M: Information that you should consider for potential process-related biological, chemical, and physical hazards for Oils and Oils Products

Category	#	Subcategory	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Oil Products	1	Cooking Oils							X	X			X	Corn, Soy Bean, Peanut, Safflower, Sesame, Cotton Seed, Canola, Olive, Sunflower, Blends
Oil Products	2	Margarines and other spreads		X	X		X		X	X		X		Oleomargarine
Oil Products	3	Shortening		X	X		X		X	X		X		Vegetable, Imitation/Substitute Vegetable Shortening

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 3N: Information that you should consider for potential process-related biological, chemical, and physical hazards for Snack Foods

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Baked	1	Bread snacks, Unseasoned	Shelf-Stable	X				X		X	X	X	X		Breadsticks, Mini Toast, Poori, Crostini, Pretzels, Crackers
Baked	2	Bread snacks, Seasoned	Shelf-Stable	X				X		X	X	X	X		Honey Mustard Pretzels, Garlic Bagel Chips, Cinnamon Mini Toast, Garlic and Herb Crackers
Baked	3	Bread Snacks with Filling, Unseasoned	Shelf-Stable	X				X		X	X	X	X		Peanut Butter Pretzels, Cheese Pretzels

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Baked	4	Bread Snacks with Filling, Seasoned	Shelf-Stable	X				X		X	X	X	X		Italian Cheese Pretzels, Buffalo Bleu Cheese Baked Snacks, Pepperoni Pizza Baked Snacks, Salsa Tortilla Baked Snacks
Baked	5	Grain snacks Unseasoned	Shelf-Stable	X				X		X	X	X	X		Puffed Rice Snacks, Wheat Crackers, Rice Crackers, Whole Grain Crackers

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Baked	6	Grain Snacks Seasoned	Shelf-Stable	X				X		X	X	X	X		Cheddar Cheese Rice Cakes, Caramel Corn Cakes
Fried	7	Chips, Puffs, Crisps, Unseasoned	Shelf-Stable	X				X		X	X	X	X		Potato Chips, Corn Chips, Cheese Puffs, Lentil Chips, Sweet Potato Chips, Mixed Root Vegetable Crisps, Tortilla Chips, Corn Chips, Cheese Curls

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Fried	8	Chips, Puffs, Crisps, Seasoned	Shelf-Stable	X				X		X	X	X	X		Sour Cream and Onion Potato Chips, Barbecue Potato Chips, Sriracha Tortilla Chips
Fried	9	Bread snacks Unseasoned	Shelf-Stable	X				X		X	X	X	X		Bagel Chips, Pita Chips
Fried	10	Bread snacks Seasoned	Shelf-Stable	X				X		X	X	X	X		Garlic Pita Crisps, Everything Bagel Chips
Fried	11	Dehydrated Fruit snacks	Shelf-Stable	X				X		X	X	X	X		Plantain Chips, Banana Chips, Durian Chips, Jackfruit Chips, Apple Chips, Pineapple Chips

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Fried	12	Grain Snacks Unseasoned	Shelf-Stable	X				X		X	X	X	X		Barley Grain Snack, Millet Grain Snack, Rice Grain Snacks, Multigrain Chips, Popped Popcorn
Fried	13	Grain Snacks Seasoned	Shelf-Stable	X				X		X	X	X	X		White Cheddar Popcorn, Harvest Cheddar Multigrain Chips, French Onion Multi-Grain Chips

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Cold Pressed	14	Snack Food Bars	Shelf-Stable					X		X	X	X	X		Granola Bars, Cranberry Almond Bars, Fruit and Nut Bars, Coated Bars
Other	15	Snack Blends	Shelf-Stable					X		X	X	X	X		Trail mix; Ethnic Mexican Wheat Snack, Yogurt Covered Raisins, Coated Nuts
Other	16 a	Pudding and gelatin products	Shelf-Stable	X			X		X	X	X	X	X		Flavored Gelatin Snacks, Chocolate Pudding, Tapioca Pudding, Vanilla Pudding

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Other	16 b	Pudding and gelatin products	Refrigerated		X	X	X		X	X	X	X	X		Flavored Gelatin Snacks, Chocolate Pudding, Tapioca Pudding, Vanilla Pudding
Other	17	Non-Dairy Frozen Desserts	Frozen					X		X	X	X	X		Ice Pops, Fruit Pops, Soy Milk Frozen Desserts, Sorbet

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 30: Information that you should consider for potential process-related biological, chemical, and physical hazards for Soups and Sauces

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Soups, Sauces, Gravies	1	Dry Mixes, Powder	Shelf-stable	X				X		X	X	X	X	X	Noodle Soup, French Onion Soup, Bouillon Cubes, Bullion Powder, Brown Soup Base, Hollandaise Sauce, Turkey Gravy, Béarnaise Sauce, Beef Gravy
Soups, Sauces, Gravies	2	Base, paste	Shelf-Stable	X		X		X		X	X	X	X		Chicken Base, Beef Base, Vegetable Base, Seafood Base, Turkey Base

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Soups, Sauces, Gravies	3a	Ready-to-Eat (RTE), Full Strength Liquid	Refrigerated	X	X		X	X	X	X	X	X	X	X	Beef-based Soup, Stew, Chili, Chicken Soup, French Onion Soup, Mushroom Soup, Turkey Soup, Potato Soup, Chicken Broth, Consommé, Peanut Sauce, Stir-Fry Sauce, Black Bean Sauce, Chili Sauce, Tandoori Sauce, Tomato Sauce, Broccoli and Cheese Soup, Tortilla Soup, Vegetarian Vegetable Soup, Tartar Sauce, Barbecue Sauce

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Soups, Sauces, Gravies	3b	Ready-to-Eat (RTE), Full Strength Liquid	Frozen	X	X			X		X	X	X	X		Beef-based Soup, Stew, Chili, Chicken Soup, French Onion Soup, Mushroom Soup, Turkey Soup, Potato Soup, Chicken Broth, Consommé, Peanut Sauce, Stir-Fry Sauce, Black Bean Sauce, Chili Sauce, Tandoori Sauce, Tomato Sauce, Broccoli and Cheese Soup, Tortilla Soup, Vegetarian Vegetable Soup, Tartar Sauce, Barbecue Sauce

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Soups, Sauces, Gravies	4a	Condensed (Concentrated), Liquid	Refrigerated	X	X	X	X	X	X	X	X	X	X		Beef-based Soup, Stew, Chili, Chicken Soup, French Onion Soup, Mushroom Soup, Turkey Soup, Potato Soup, Chicken Broth, Consommé, Peanut Sauce, Stir-Fry Sauce, Black Bean Sauce, Chili Sauce, Tandoori Sauce, Tomato Sauce, Broccoli and Cheese Soup, Tortilla Soup, Vegetarian Vegetable Soup, Tartar Sauce, Barbecue Sauce

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Soups, Sauces, Gravies	4b	Condensed (Concentrated), Liquid	Frozen	X	X	X		X		X	X	X	X		Beef-based Soup, Stew, Chili, Chicken Soup, French Onion Soup, Mushroom Soup, Turkey Soup, Potato Soup, Chicken Broth, Consommé, Peanut Sauce, Stir-Fry Sauce, Black Bean Sauce, Chili Sauce, Tandoori Sauce, Tomato Sauce, Broccoli and Cheese Soup, Tortilla Soup, Vegetarian Vegetable Soup, Tartar Sauce, Barbecue Sauce

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 3P: Information that you should consider for potential process-related biological, chemical, and physical hazards for Spices and Herbs

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Untreated, Raw Herbs and Spices	1	Dried, ground or cracked	Shelf-Stable					X					X	X	Cinnamon, Turmeric, Paprika, Pepper (Black, White, Red), Cayenne Powder, Cumin, Coriander, Mustard, Fenugreek, Horseradish, Fennel Seeds, Caraway, Allspice, Nutmeg, Ginger, Garlic (Minced or Powder), Onion (Minced or Powder), Celery Seed
Untreated, Raw Herbs and Spices	2	Dried, whole	Shelf-Stable					X					X	X	Cinnamon, Cardamom, Fenugreek, Cloves, Nutmeg, Cumin, Anise, fennel Seeds, Caraway, Chili Peppers, Saffron, Peppercorns (Black or White), Coriander, Basil, Varieties of Chili Peppers

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Untreated, Raw Herbs and Spices	3	Dried herbs	Shelf-Stable					X					X	X	Basil, Oregano, Thyme, Sage, Parsley, Bay Leaf, Dill, Rosemary, Cilantro, Mint, Kaffir Lime, Chives, Peppermint
Treated Herbs and Spices	4	Irradiated	Shelf-Stable	X				X					X	X	Various, as above
Treated Herbs and Spices	5	Chemically Treated (EtOH, PPO)	Shelf-Stable	X				X					X	X	Various, as above
Treated Herbs and Spices	6	Steam Pasteurization	Shelf-Stable	X				X					X	X	Various, as above
Seasonings and Blends	7a	Pastes	Shelf-Stable			X	X	X	X	X	X	X	X	X	Basil Paste, Garlic Paste, Jerk Seasoning Paste
Seasonings and Blends	7b	Pastes	Refrigerated		X	X	X	X	X	X	X	X	X	X	Basil Paste, Garlic Paste, Jerk Seasoning Paste
Seasonings and Blends	8	Essential Oils	Shelf-Stable												Basil, Cinnamon, Clove, Ginger, Lemongrass

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Storage Conditions	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Seasonings and Blends	9	Spice and seasoning mixtures, Dry Blends	Shelf-Stable	X				X		X	X	X	X	X	Taco Mix, Chili Powder, Curry Powder, Multi-Spice Mix, Adobo Seasoning, Garam Masala, Berebere, Oriental Five-Spice, Crab Snack & Dip Seasoning, Meat Coatings and Rubs, Seafood Seasonings, Scampi Seasoning, Powdered Seasonings, Popcorn Seasonings
Seasonings and Blends	10	Spice and seasoning mixtures, Liquid	Shelf-Stable			X		X		X	X	X	X	X	Fajita Seasoning Sauce, Kung Pao Seasoning Sauce

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Table 3Q: Information that you should consider for potential process-related biological, chemical, and physical hazards for Food Sweeteners (Nutritive and Non-Nutritive)

Category	#	Subcategory	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to mis-formulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Food Sweeteners (Nutritive and Non-Nutritive)	1	Sugars (Dry)												Brown Sugar (Sucrose), Beet Sugar(Sucrose), Invert Sugar, Maple Sugar, Malt Sugar (Maltose), Grape Sugar (Fructose), Corn Syrup Solids, Corn Sugar (Dextrose), Cane Sugar (Sucrose), Milk Sugar, Date sugar, Palm Sugar
Food Sweeteners (Nutritive and Non-Nutritive)	2	Syrup/Molasses (Liquid)												Sorghum Syrup, Maple Syrup, High Fructose Corn Syrup, Molasses, Pancake and Waffle Syrup, Simple Syrup, Liquid Sucrose, Agave Syrup, Rice Syrup
Food Sweeteners (Nutritive and Non-Nutritive)	3	Honey (Liquid)									X	X	X	Comb Honey, Strained Honey, Whipped Honey, Molasses

**Contains Non-binding Recommendations
Draft-Not for Implementation**

Category	#	Subcategory	Bacterial pathogen survival of a lethal treatment	Bacterial growth and/or toxin formation due to lack of time/temperature control	Bacterial growth and/or toxin formation due to poor formulation control	Bacterial growth and/or toxin formation due to reduced oxygen packaging	Recontamination with environmental pathogens	Recontamination due to lack of container integrity	Undeclared allergens - Incorrect label	Undeclared allergens - cross-contact	Chemical hazards due to misformulation (e.g. sulfites, yellow #5)	Metal	Glass (when product packed in glass)	Example Products
Food Sweeteners (Nutritive and Non-Nutritive)	4	Imitation Syrup/Molasses (Liquid)			X							X	X	Imitation Maple Syrup, Imitation Honey
Food Sweeteners (Nutritive and Non-Nutritive)	5	Food Sweeteners (Nutr) N.E.C.												Nutritive Sugar Substitutes, Sorbitol, Xylitol, Isomalt, Tagatose, Maltitol, Lactitol
Food Sweeteners (Nutritive and Non-Nutritive)	6	Food Sweeteners (Non-nutr)												Aspartame, Saccharin, Acesulfame K, Neotame, Stevia, Sucralose