UNITED SAFETY AGENTS

FSVP

COMPLIANCE PLAN

GLOBALCONNECT COMPANY

Name of FSVP Importer

SAMIYA CO. S.A.

Name of Foreign Supplier

SWEET PLANTAIN SLICES (FROZEN, PRE-FRIED, READY-TO-COOK)

Name of Product

JANUARY 23, 2020 / JANUARY 25, 2022

Date of Initial Verification / Reverification

JANUARY 24, 2023

Date of FSVP Plan Expiration

VERIFICAITON COMPLETE | APPROVED FOR IMPORT

Result of Verification

NUMBER 03

Version

– Confidential –

– TABLE *of* CONTENTS –

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 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 within 24 hours of FDA's request. Electronic records are considered to be on-site if they are accessible from an on-site location. Records obtained by FDA are subject to the disclosure requirements found under Part 20. **Please contact USA immediately** to report a change in a foreign supplier's processes or status, upon contact by FDA, or with any questions that you may have by email at info@unitedsafetyagents.com, or by telephone at +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

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 on-site 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 on-site 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 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 page eleven, Ongoing Document Requirements found on page twelve, and Ongoing Verification Activities & Frequency of Ongoing Verification Activities found on page fourteen.

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 successful 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: Samiya Co. S.A.

Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

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

Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

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: Samiya Co. S.A.

Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

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

Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

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 Manufac turing Practice Regulation?
- ☐ **§1.512.** What FSVP May I Have If I Am A Very Small Importer or I Am Importing Certain Food from Certain Small Foreign Suppliers?
- ☐ **§1.513.** What FSVP May I Have If I'm Importing Certain Food from A Country with An Officially Recognized Food Safety System?
- ☒ **§1.514.** What Are Some Consequences of Failing to Comply with the Requirements of FSVP?

NOTES & COMMENTS

FSVP 21 CFR §1.500–§1.514

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

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

ATTESTATION of REVIEW & ASSESSMENT

21 C.F.R., §1.506, (d)(3) provides that *"You may rely on a determination of appropriate foreign supplier verification activities . . . made by an entity other than the foreign supplier if you review and assess whether the entity's determination regarding appropriate activities. . . . You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual."* **Please review this FSVP plan in its entirety and document your review below.**

I, Eric Lai certify that I reviewed this FSVP plan on 8/30/22 and found its contents to be acceptable.

Reviewer's Name: Eric Lai

Reviewer's Signature:

Reviewer's Title: Sale Manager

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

DESIGNATION *of* ROLES & SUMMARY *of* REVIEW

FOREIGN SUPPLIER VERIFICATION PROGRAM IMPORTER

Company Name: GlobalConnect Company FDA FEI: N/A

Physical Address: 314-J Merchants Drive DUNS No.: Not Provided

City: Knoxville State: Tennessee, 37912 Country: United States

Mailing Address: P.O. Box 52935

City: Knoxville State: Tennessee Country: United States

Phone Number: +1 (865) 300-3828 Email Address: laimin@hotmail.com

Name *of* Representative*(s)*: Mr. Eric Lai Title: Commercial Rep.

FOREIGN SUPPLIER &/OR MANUFACTURER *as defined by §1.500*

Company Name: Samiya Co. S.A. FDA FFR: 10561005226

Manufacturing Address: Km 19.5 vía a la Costa FDA FEI: 3014976748

City: Guayaquil Province/Territory: Guayas, 090150 Country: Ecuador

Office Address: Km 19.5 vía a la Costa

City: Guayaquil Province/Territory: Guayas, 090150 Country: Ecuador

Phone Number: +593 98 156 1340 Email Address: info@samiya.co

Name *of* Representative*(s)*: Ma. Muñoz Helper Title: Team Coordinator

QUALIFIED INDIVIDUAL*(s)* & AGENT*(s)*

Agent/QI Name: Claudio Innocenti Signature: Claudio Innocenti

Title: Partner & Preventive Controls Qualified Individual. Date: Jan. 25, 2022

Support PCQI: William J. Barber Signature: W. J. Barber

Title: Preventive Controls Qualified Individual.

SUMMARY *of* REVIEW

Details *of* Product(s)	*Is foreign supplier expected to implement controls for*			**Comments**
	Biological Hazards	**Chemical Hazards**	**Physical Hazards**	
Frozen, Pre-Fried Sweet Plantain Slices.	☑ Yes ☐ No ☐ *Undetermined*	☑ Yes ☐ No ☐ *Undetermined*	☑ Yes ☐ No ☐ *Undetermined*	Verified & Approved.
	☐ FSVP Importer	☐ FSVP Importer	☐ FSVP Importer	
Product is in Ready-to-Cook form upon arrival to FSVP Importer.	☐ Disclosure	☐ Disclosure	☐ Disclosure	Products must be cooked prior to consumption.
	☐ Customer	☐ Customer	☐ 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: Samiya Co. S.A.

Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

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

Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

REGISTER *of* SUBSTANTIATING DOCUMENTS

HAZARD ANALYSIS

☑ *Requested* ☑ *Required* ☑ *Received* ☑ *Reviewed*

NOTES Samiya Co. S.A.'s HACCP Matrix received.
Pertinent To: Frozen Sweet Plantains Version: No. SMY-SGIA-R-017 Dated: 2020.

Samiya Co. S.A.'s Food Safety Management System HACCP Plan received.
Pertinent To: Frozen Sweet Plantains Version: No. SMY-AC-M-003 Dated: 2020.
Contains: Company overview, Layout description, HACCP team, Role descriptions of the HACCP team members, Process flowchart: frozen sweet plantains, Hazard analysis, Critical points control, Verification procedure, Verification frequency, Verification records, Lab analysis, etc.

ON-SITE AUDIT

☑ *Requested* ☐ *Required* ☑ *Received* ☑ *Reviewed*

NOTES Samiya Co. S.A.'s Announced PrimusGFS Audit Report received.
Dated: December 17, 2019.
Re-audit Due Date: Not provided.
Audit Grade: 87/100.
Previous Audit Grade: Not provided.
Previous Audit Date: Not provided.
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 Certificates of Analysis received from supplier.
Dated: Vary, but fall within 2021-2022.
Tested for: Quality perimeters, Moisture levels, Staphylococcus aureus, Escherichia coli, Salmonella spp., Aerobic mesophilic, and Total coliforms. Results acceptable.
Laboratory: Analisis de Alimentos y Ambiente Protal.

OTHER FOOD SAFETY RECORDS

☑ *Requested* ☑ *Required* ☑ *Received* ☑ *Reviewed*

NOTES Various other food safety documents provided by Samiya Co. S.A.
Documents include: Process Flow Chart: Pre-Fried, Frozen Sweet Plantains, Customer Claims and Suggestions Management, Supplier Control, Allergen Control, and Integrated Pest Management – as well as several non-English documents.

Training certificates received for Samiya Co. S.A.'s PCQI.
Food Defense and Intentional Adulteration Rule Training certificates 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 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 regulations prior to import.

Supplier: Samiya Co. S.A.

Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

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

Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

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 recomended accord to their individually-marked time interval.

FACILITY FOOD SAFETY 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:*_____

ON-SITE AUDIT RESULTS

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

LABORATORY TESTING RESULTS

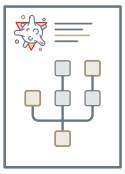
- ☑ if positive results are returned
- ☑ if recall or import refusal occurs
- ☑ if inspection occurs
- ☑ on an annual basis
- ☐ on a per-batch/shipment basis
- ☑ Chemical ☑ Biological
- ☐ *other:*_____

FDA REGISTRATION

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

FACILITY LICENSE

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



RECALL 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:*_____

QUALIFICATIONS

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

IMPLEMENTATION RECORDS

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

FSVP QUESTIONNAIRE

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

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: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

INITIAL VERIFICATION ACTIVITIES

To confirm that all relevant or identified food safety hazards requiring a control have been significantly minimized or prevented, the below enumerated activities were used to initially verify Sweet Plantain Slices (Frozen, Pre-Fried) ("product" or "imported product"), supplied by Samiya Co. S.A. ("supplier" or "foreign supplier"), imported by GlobalConnect Company ("importer" or "FSVP importer"):

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

SAMPLING AND/OR TESTING of the imported product, including the assessment of one or more certificates of analysis – for testing conducted to determine the presence or absence of all relevant or identified hazards requiring a control. Per §1.506(d)(1)(ii)(B) and (e)(1)(ii), documentation of the report or reports, the number of samples tested, the tests conducted, the date(s) on which the tests were conducted and the date(s) of the report(s) of the testing, the results of the testing, information identifying the laboratory or laboratories conducting the testing, and documentation that the review was conducted by a qualified individual (ISO 17025-accreditation requested) were completed.

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

NOTE

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

***Note**: see next page for Ongoing Verification Activities.*

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

ONGOING VERIFICATION ACTIVITIES

To confirm that all relevant or identified food safety hazards requiring a control, for Sweet Plantain Slices (Frozen, Pre-Fried) ("product" or "imported product"), supplied by Samiya Co. S.A. ("supplier" or "foreign supplier"), continue to be significantly minimized or prevented prior to public distribution, up-to-date versions of all documents used during the initial FSVP verification and approval processes will be re-acquired at least once every three years – or sooner, per the following document-specific requirements:

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

An updated version of Samiya Co. S.A.'s HACCP PLAN will be required if any change or update occurs. Samiya Co. S.A. has been informed of this ongoing requirement and USA will confirm annually that the HACCP Plan on file remains current and faithfully illustrates all supply chain controls and/or process/critical control procedures, or acquire and review Samiya Co. S.A.'s most up-to-date copy.

An updated version of Samiya Co. S.A.'s ON-SITE AUDIT REPORT will be requested annually, or if any change or update occurs prior to year's end. Samiya Co. S.A. has been informed of this ongoing request and USA will acquire and review the updated Report from the supplier annually, or sooner if a change has been made.

Updated LABORATORY TESTING RESULTS for all relevant biological and chemical hazards will be required if a positive result is returned, recall or import refusal occurs, facility inspection takes place, or – at minimum – on an annual basis. Samiya Co. S.A. has been informed of this ongoing requirement and USA will acquire the results from the supplier annually.

An updated version of Samiya Co. S.A.'s RECALL PLAN/OTHER RELEVANT FOOD SAFETY RECORDS listed under the Initial Verification Activities will be required if any change or update occurs. Samiya Co. S.A. has been informed of this ongoing requirement and USA will confirm annually that the documents on file remain current and faithfully illustrates all process and procedures, or acquire and review Samiya Co. S.A.'s most up-to-date copy or copies.

Updated substantiation of Samiya Co. S.A.'s QUALIFIED INDIVIDUAL'S CREDENTIALS will be required if any change or update occurs. USA will confirm annually that the certificate(s) on file remain current.

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

An updated version of the product's LABELING will be required if any change or update occurs. Samiya Co. S.A. has been informed of this ongoing requirement and USA will confirm annually that the label on file remains current.

NOTE

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

FREQUENCY *of* VERIFICATION ACTIVITIES

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

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

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

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: Samiya Co. S.A. FEI: 3014976748 Date: Jan. 25, 2022

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

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

REVISION LOG *for* FSVP PLAN

Version No.	Date *of* Change	Description *of* Revision
No. 01	January 22, 2020.	Product and supplier underwent initial FSVP verification.
No. 02	January 23 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.
No. 03	January 25 2022.	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: Samiya Co. S.A.

Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

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

Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

ANALYSIS & DETERMINATION *of* BIOLOGICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☐ ***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.*** ☐ ***Other***	1	3	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. ——— SUPPLIER CONTROL MEASURES ——— 01. Supplier utilizes Heat Application (thermal kill step) to control hazards posed by biological agents. Details: Oil temperature monitoring. CCP Limits: 160°C +/-10°C. SSOP's and GMP's compliance in processing facility, effective application of cleaning and sanitation procedures for utensils and equipment. CCP Corrective action. 1. Stop process. 2. Adjust temperature. 3. Reprocess product that was fried off s et-temperature. 4. Evaluate specs. If compliant, restart process. If not, discard product. 02. Supplier utilizes laboratory testing of finished product to verify that biological hazards have been controlled. Details: Certificates of Analysis received. Dated: Vary, but fall within 2021-2022. Tested for: Quality perimeters, Moisture levels, Staphylococcus aureus, Escherichia coli, Salmonella spp., Aerobic mesophilic, and Total coliforms. Results acceptable. Laboratory: Analisis de Alimentos y Ambiente Protal. 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 processing area. 06. Adequate toilet and hand washing facilities provided. 07. Product is positively released.	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 FDA identified biological hazards. Product is not in Ready-to-Eat form upon arrival to FSVP Importer. Product is frozen [-04ºC] and must be cooked prior to consumption. ——————— ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) Category: Fried. Category No.: 11. Subcategory: Dehydrated Fruit snacks Storage: Frozen ——————— ———————

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)

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

ANALYSIS & DETERMINATION *of* CHEMICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☐ ***Drug residues*** ☐ ***Heavy metals*** ☐ ***Industrial chemicals*** ☐ ***Pesticides*** ☐ ***Mycotoxins/Toxins*** ☐ ***Radiological*** ☐ ***Unapproved colors & additives*** ☐ ***Chemical hazards due to mis-formulation*** ☐ ***Other***	-	-	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. ——— SUPPLIER CONTROL MEASURES ——— 01. Supplier utilizes raw material inspection and approval procedures to control for hazards posed by chemical agents prior to production. 02. Supplier reportedly utilizes frying to control hazards posed by chemical agents. Details: Chemical: dioxine and PCB's formation, trans fats formation, benzo (a) pyrene CCP Preventative Measures. COA required to supplier for every batch, oil exchange program. Verification. Daily revision of TPM monitoring record/tally sheets by HACCP delegate. ——————————NOTE—————————— 01. The FDA does not recognize any chemical hazards in reference to this product type. Appendix 1 (Hazards Tables) Subcategory: Dehydrated Fruit snacks	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 FDA identified chemical hazards. ——————————— ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) Category: Fried. Category No.: 11. Subcategory: Dehydrated Fruit snacks Storage: Frozen —————————— ———————————

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)

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

ANALYSIS & DETERMINATION *of* ALLERGENIC HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☒ ***Undeclared allergens - Incorrect label*** ☒ ***Undeclared allergens - Cross-contact*** **ALLERGENS** ☐ ***Milk*** ☐ ***Eggs*** ☐ ***Fish*** ☐ ***Shellfish*** *(Crustacean)* ☐ ***Tree nuts*** ☐ ***Peanuts*** ☐ ***Wheat*** ☐ ***Soybeans*** ☐ ***Sesame**** ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) Category: Fried. Category No.: 11. Subcategory: Dehydrated Fruit snacks Storage: Frozen	3	3	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. ——— SUPPLIER CONTROL MEASURES ——— 01. Supplier certifies that: A) there are NO major 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. ---------- IMPORTANT ---------- Major deficiency In the storage of bananas, the use of a dirty cardboard box was observed, there is no control for these materials by the auditor, only the fruit suppliers. ———————NOTE——————— ---------- Labeling Requirements ---------- - 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.	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. 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.

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.

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

ANALYSIS & DETERMINATION *of* ENVIRONMENTAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☒ ***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 poor formulation control.*** ☐ ***Bacterial growth and/or toxin formation due to reduced oxygen packaging.*** ☐ ***Other***	1	2	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. ——— SUPPLIER CONTROL MEASURES ——— 01. Hazard posed by recontamination with environmental pathogens is controlled through Current Good Manufacturing Practices. 02. Supplier has implemented a cleaning program and environmental monitoring for microbiological and biological hazards. Supplier utilizes Microbiology control, ATP swabbing on surfaces, product monitoring to control hazards posed by biological agents during several production stages including Packing and Shipping. Details: Cross contamination, improper hygiene habits from workers, improper or lack of sanitation of working surfaces, equipment and utensils. Hazards Identified: Microbiological contamination from pathogens: E. coli, Listeria sp., Salmonella sp. 03. Kill step validation is carried out via TPM monitoring record/tally sheets by HACCP delegate. 04. All product is positively released and hermetically sealed within plastic. 05. Cooking instructions are printed on product's label. Details: "Fry frozen product in frying oil heated to 350 ºF for 4-5 minutes or until caramelized. Slices must be fully covered by oil. Shake basket and do not overload to keep slices separated. Let product drain before serving."	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 FDA identified environmental hazards. ———— HAZARD PROFILE ———— ———— SOURCE ———— Appendix 1 (Hazards Tables) Category: Fried. Category No.: 11. Subcategory: Dehydrated Fruit snacks Storage: Frozen

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)

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

ANALYSIS & DETERMINATION *of* PHYSICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☒ ***Metal*** ☐ ***Glass*** ☐ ***Extraneous Matter*** ☐ ***Plastics*** ☐ ***Stones*** ☐ ***Wood*** ☐ ***Natural Component of Food*** ☐ ***Other***	1	2	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. ——— SUPPLIER CONTROL MEASURES ——— 01. Supplier utilizes an operational and calibrated metal detector to control hazards posed by physical agents. Critical Limits: In-line Metal Detector. Ferrous: 3.5 mm. Non Ferrous: 4.0 mm. Stainless Steel: 4.5 mm. CCP Preventative Measures. Verification of effective performance using test pieces. Performing proper preventive maintenance to equipment. CCP Corrective action. 1. Stop process 2. Calibration verification using test pieces 3. Test product again through conveyor belt 4. Open suspicious bags and find metallic particle 5. If confirmed, discard opened bags. Verification. Daily revision of metal detector monitoring record/tally sheets by HACCP delegate 02. Glass and Breakable Plastic Program in use. 03. Supplier inspects incoming ingredients and finished products. 04. Supplier utilizes raw material inspection and approval procedures.	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. ——————— ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) Category: Fried. Category No.: 11. Subcategory: Dehydrated Fruit snacks Storage: Frozen ——————— ———————

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)

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

ASSESSMENT *of* FOREIGN SUPPLIER

1.0 FOREIGN SUPPLIER INFORMATION

1.1. Supplier name: Samiya Co. S.A. 1.2. Supplier country: Ecuador

1.3. Products manufactured/supplied: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

1.4. Is the supplier certified to a Global Food Safety Standard and audited annually? ☑ Yes ☐ No ☐ N/A

Standard: Audit report outstanding.

2.0 SUPPLIER PROCEDURES, PROCESSES & PRACTICES

2.1. Does supplier follow current GMPs? ☑ Yes ☐ No

2.2. Does the supplier have SOPs in place? ☑ Yes ☐ No ☐ N/A

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

2.4. Does the supplier have a HACCP/PC plan for the product manufactured for the importer? ☑ Yes ☐ No ☐ N/A

2.5. Has the supplier's HACCP/PC plan been reviewed and approved by USA's PCQI? ☑ Yes ☐ No

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

3.0 SUPPLIER PERFORMANCE HISTORY

3.1. 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.*

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

☑ Yes ☐ No *Description:*

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 activitie(s) 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 FSVP** ☑ Yes ☐ No

Supplier: Samiya Co. S.A.

Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

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

Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

REVIEW *of* GENERAL FOOD SAFETY PROGRAM

Claims Made Against Product

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

Product is not in Ready-to-Eat form upon arrival to FSVP Importer. Product is frozen [-04ºC] and must be cooked prior to consumption.

Overview *of* Foreign Supplier's Commercial Operation

Founded in 2007 as a family business. There are 3 freezing tunnels, 2 storage tunnels, packing material warehouse, Chips finished product warehouse, ripening area. 60 workers are reported. No allergens The destination of the product is the United States.

Testing Program & Accreditation

Supplier certifies that testing is conducted. We respectfully request that recent Certificates of Analysis be provided for testing conducted on all FDA-identified biological hazards.

Specification Characteristics:
Aerobic mesophilic, total count: <1x106 CFU per g
Coliforms, total: <1x103 CFU per g
E. coli: <1x102 CFU per g
Molds and yeast: <1x103 CFU per g
Salmonella: absence
Listeria monocytogenes: absence
Staphylococcus aureus: 1x103 CFU per g

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.

IMPORTANT: Samiya Co. S.A.'s December 17, 2019 announced PrimusGFS Audit Report found a major deficiency in the storage of bananas, the use of a dirty cardboard box was observed, there is no control for these materials by the auditor, only the fruit suppliers.

Packaging Type & Shipping / Handling Requirements

Supplier certifies that packaging is accredited for food use. Product is packaged in bag. Bag is placed in box. Label in on box.

Bag (primary packaging): Measures: 12" x 16" Thickness: 0.0025 mm / 3 µm Material: LDPE, white pigmented, printed.
Box (secondary packaging): Measures: 41.1 x 26.0 x 21.0 cm / 16.18" x 10.24" x 8.27" Material: kraft paperboard.

Product must be kept frozen at -4 ºF (-18 ºC). Do not defrost product before use. Unopened bags can be stored in freezer and used for 18 months after production date. Do not thaw and refreeze. Product is shipped in reefer containers at -4 ºF. Frozen conditions must be kept while shipping and handling the product in order to ensure best quality.

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

REVIEW *of* GENERAL FOOD SAFETY PROGRAM

Supplier GFSI Status & Historical Performance

Supplier appears to be following CGMPs and utilizes an established food safety program. Products supplied by this supplier have been verified and are approved for import.

Close Supplier Monitoring

No. 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.

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

We respectfully request:

- corrective actions for Samiya Co. S.A.'s Dec. 17, 2019 announced PrimusGFS Audit Report's Major deficiencies.
- supplier complete and return the provided FSVP Supplier Questionnaire.

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

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.

IMPORTANT

FSVP Importer must verify that all labels comply with FALCPA. We recommend that FSVP Importer develop and utilize SOPs to ensure all labeling is compliant with FALCPA prior to product's distribution.

ADDENDUM

INTENTIONALLY

BLANK PAGE

ADDENDUM

INTENTIONALLY

BLANK PAGE

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Claudio Innocenti

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

Foreign Supplier Verification Programs

delivered by Lead Instructor

Bob Bauer

completed on
05/13/2021

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

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Steve Mandernach, Executive Director
Association of Food and Drug Officials

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti

AFDO

Certificate # 31d8ad94

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Claudio Innocenti

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

FSPCA Preventive Controls for Animal Food

delivered by Lead Instructor

Charles Nolan

completed on
07/09/2020

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

Gerald Wojtala, Executive Director
International Food Protection Training Institute

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

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

AAFCO
Association of American Feed Control Officials

Certificate # 223faa17

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

CLAUDIO INNOCENTI

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

Foreign Supplier Verification Programs

delivered by Lead Instructor

Bob Bauer

completed on

09/14/2018

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

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

Joseph Corby, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # d2e9c287

Produce Safety ALLIANCE

AFDO
ASSOCIATION OF FOOD & DRUG OFFICIALS
SINCE 1896

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

Class Number
NY-180712-GR
Grower ID Number
50447
Training Date and Location
7/12/2018–7/12/2018
Voorheesville, NY

Joseph Corby
Executive Director, AFDO

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

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

CLAUDIO INNOCENTI

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

Foreign Supplier Verification Programs

delivered by Lead Instructor

Bob Bauer

completed on

05/31/2018

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

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Joseph Corby, Executive Director
Association of Food and Drug Officials

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

AFDO

Certificate # d2e9c287

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

CLAUDIO INNOCENTI

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

Foreign Supplier Verification Programs

delivered by Lead Instructor

Bob Bauer

completed on

09/14/2017

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

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Joseph Corby, Executive Director
Association of Food and Drug Officials

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

AFDO

Certificate # d2e9c287

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

CLAUDIO INNOCENTI

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

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
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

AFDO

Certificate # 2d697331

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

QUALIFICATIONS *of* SUPPORTING QI

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

WILLIAM BARBER

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

FSPCA Preventive Controls for Human Food

delivered by Lead Instructor

Mirasol Mohal

completed on
06/05/2019

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

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Steve Mandernach, Executive Director
Association of Food and Drug Officials

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti

Certificate # ed6f0b58

AFDO

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

William Barber

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

Foreign Supplier Verification Programs

delivered by Lead Instructor

tina coil

completed on
06/13/2017

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

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Joseph Corby, Executive Director
Association of Food and Drug Officials

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

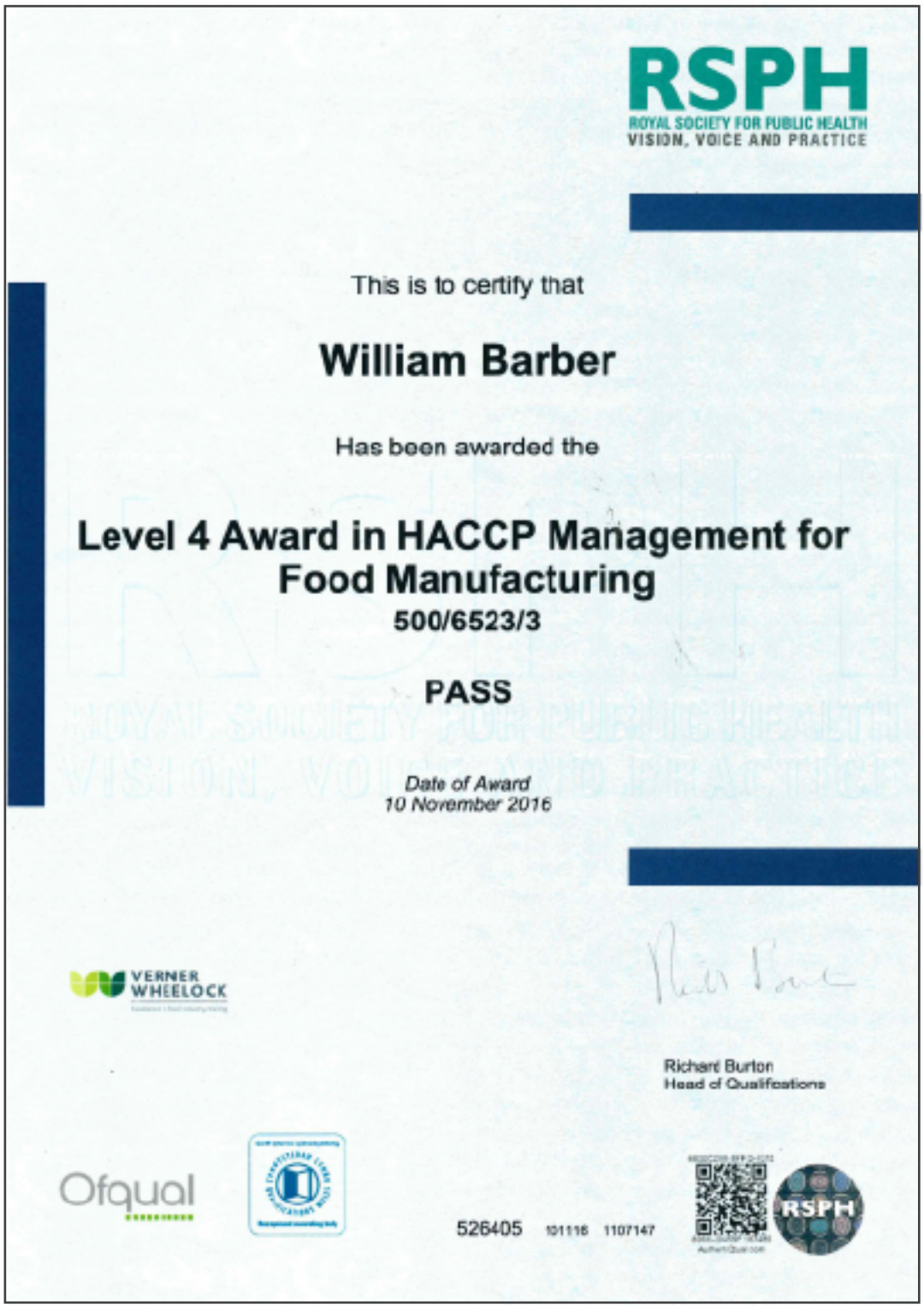
Certificate # 917b0241

AFDO

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

QUALIFICATIONS *of* SUPPORTING QI



RSPH
ROYAL SOCIETY FOR PUBLIC HEALTH
VISION, VOICE AND PRACTICE

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

VERNER WHEELOCK

Richard Burton
Head of Qualifications

Ofqual

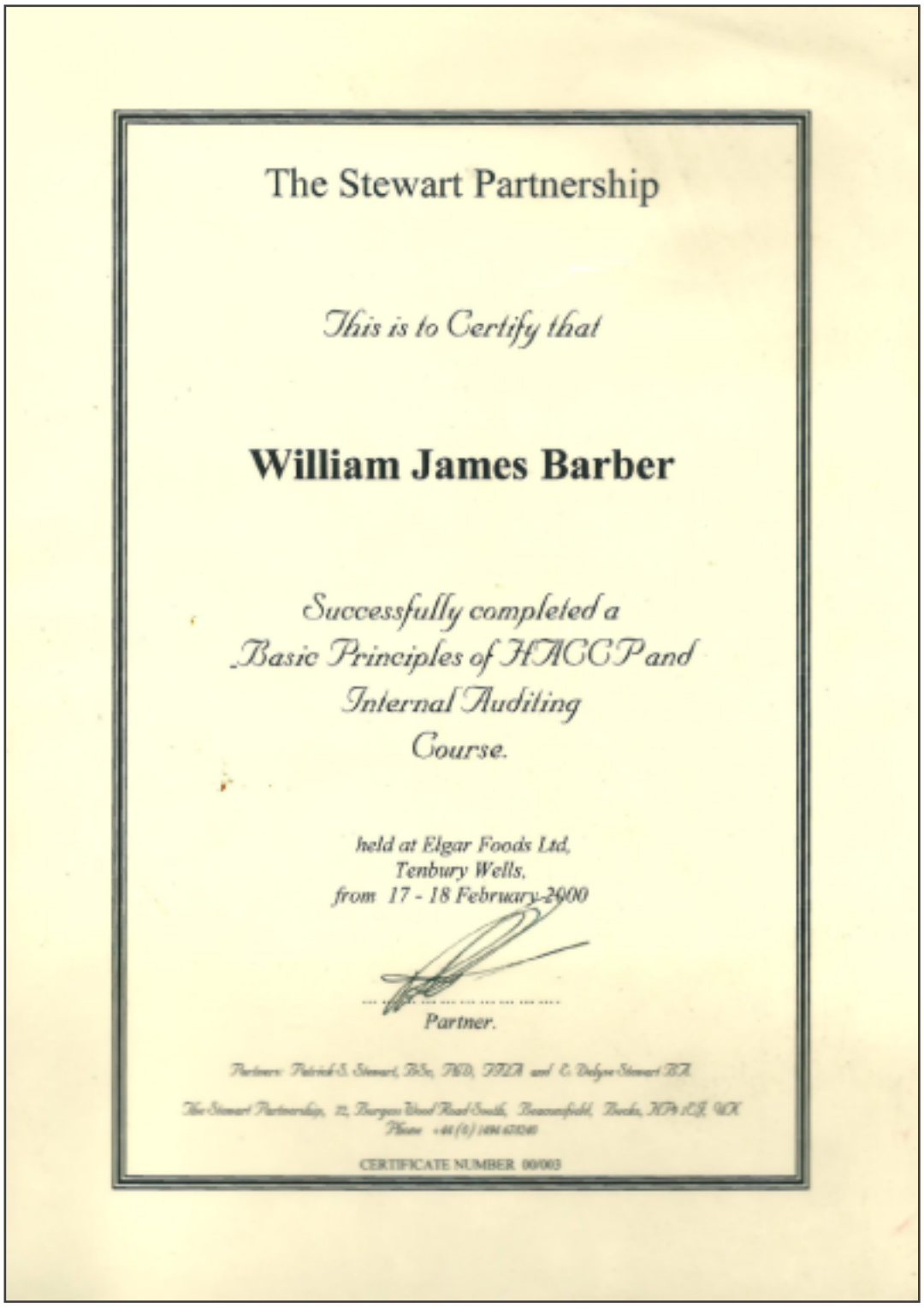
526405 101116 1107147

RSPH

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

QUALIFICATIONS *of* SUPPORTING QI



The Stewart Partnership

This is to Certify that

William James Barber

Successfully completed a
Basic Principles of HACCP and
Internal Auditing
Course.

held at Elgar Foods Ltd,
Tenbury Wells,
from 17 - 18 February 2000

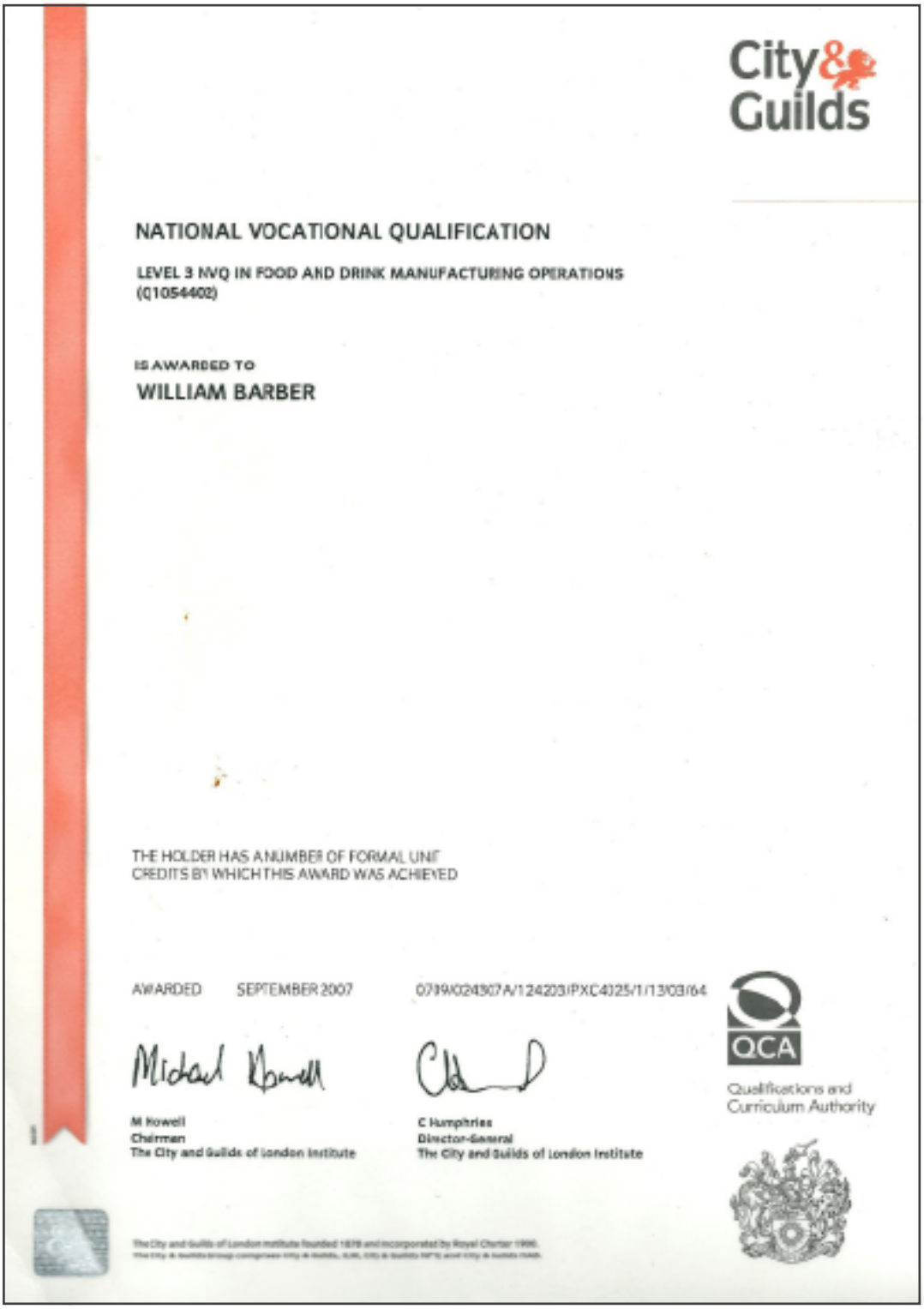
Partner.

Partners: Patrick S. Stewart, BSc, PhD, FIFST and C. Dalyce Stewart BA

The Stewart Partnership, 22, Burgess Wood Road South, Beaconsfield, Bucks, HP9 1EJ, UK
Phone +44 (0) 1494 672040

CERTIFICATE NUMBER 00/003

QUALIFICATIONS *of* SUPPORTING QI



City & Guilds

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 0739/0249/07A/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

QCA
Qualifications and Curriculum Authority

The City and Guilds of London Institute founded 1878 and incorporated by Royal Charter 1900.

QUALIFICATIONS *of* SUPPORTING QI

City & Guilds

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	U1050074

CONTINUED

AWARDED SEPTEMBER 2007 0709/024307/A/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

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 KAB.

Supplier: Samiya Co. S.A. Product: Sweet Plantain Slices (Frozen, Pre-Fried, Ready to Cook)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: Jan. 12, 2022 Review End: Jan. 25, 2022

SUBSTANTIATING DOCUMENTS

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

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

MANUAL

HAZARD ANALYSIS AND CRITICAL CONTROL POINTS

Food Safety Management System

SAMIYAMEALS S.A

Guayaquil – Ecuador

10/10/2020

Table of Contents

1 Mission

To add value to the life of our consumer by offering them carefully crafted natural food products – which are tasty, easy-to-cook and share, versatile and sustainably produced – that will inspire them to invest quality time with their loved ones and experience moments filled with joy, excitement and a big – really big! – load of outstanding tropical flavors.

2 Vision

To be a leading food manufacturing company strongly committed to providing high quality food products, which stay true to their nature, that stands out for promoting holistic well-being through a values-driven culture aimed to achieve sustainable development in our communities and consequently in our planet.

3 Reasons to certify under the HACCP scheme

The international market for food products requires the compliance of a set of standards aimed to safeguard and ensure the food safety of the products being traded, in order to protect consumer health. As a response to this requirement, the HACCP system represents the most important scheme for food safety among the food industry.

SAMIYAMEALS S.A. is strongly committed to implementing the HACCP system throughout its food manufacturing processes to back-up its operations and strengthen our customers' confidence in the safety and security of the food products that are elaborated in our facility. Consequently, this enables us to keep food safety and quality as the top priorities in our processes, as part of all the food products that we manufacture.

4 Objective

To implement the HACCP system (Hazard Analysis and Critical Control Points) for the analysis and control of the processes involved in our production lines.

5 Scope

The guidelines outlined in this manual are applicable to all of the operations and processes involved in the manufacturing of pre-fried and frozen sweet plantains, pre-fried and frozen tostones and ready-to-eat tostones chips, that are carried out at SAMIYAMEALS S.A.'s facility.

6 Reference framework

This document has been written in accordance to valuable information presented in the following literatura written in Spanish:

BRC Global Standards. 2018. *Norma Mundial de Seguridad Alimentaria (Inocuidad de los Alimentos)*. Versión 8. Londres (GB): BRC. 124 p. ISBN 978-1-78490-350-3.

FAO (Food and Agriculture Organization). 2003. *Codex Alimentarius: Principios Generales de Higiene de los Alimentos.* CAC/RCP 1-1969. Roma (IT): Comisión del Codex Alimentarius; FAO. Disponible en el *World Wide Web*: <http://www.fao.org/input/download/standards/23/cxp_001s.pdf>

FSPCA (Food Safety Preventive Controls Alliance). 2016. *Controles Preventivos de Alimentos para Humanos: Manual del Participante*. 1ª Edición. Versión 1.2. Chicago (US): Institute for Food Safety and Health; FDA; FSPCA. Disponible en el *World Wide Web*: <https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food>

Primus Group, Inc. 2019. *PrimusGFS.* Versión 3.1. Santa María (US): Primus Labs; Primus Group Inc. Disponible en el *World Wide Web*: <http://primusgfs.com/documents.aspx>

7 Definitions

Accredited: condition by which a business or supplier is recognized by an authorative body, organization or agency as to be compliant with a known standard.

CCP decisión tree: a sequence of questions used to determine if a control point is a CCP.

Certification: written document that publicly endorses the process by which a recognized certifying organization or agency entitles a company or business to be compliant with a quality or management standard, after having audited it.

Cleaning: the removal of soil, food residues, dirt or grease.

Consumer: end user of the goods produced, who consumes the product.

Contaminant: any chemical substance, biological agent or physical matter unintentionally added to or present in a food product that can harm or affect its safety or quality. Anything that can get into food that is not supposed to be there.

Contamination: the introduction or presence of a contaminant into a food product or the environment surrounding it.

Control measure: any action or activity aimed to prevent, eliminate or reduce a significant hazard.

Control point: any step at which biological, chemical, or physical factors can be controlled.

Control: a management tool within a process that is applied to its activities or developing actions, part of it, in order to guarantee that real operations are being executed as planned, according to reference criteria or limits set for that particular process.

Corrective action: procedures followed when a deviation occurs.

Criterion: a requirement on which a judgement or decision can be based.

Critical Control Point (CCP): a step at which control can be applied and is essential to prevent or reduce a food safety hazard or reduce it to an acceptable level.

Critical limit: a maximum and/or minimal value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.

Cross-contamination: the involuntary transfer of any substance, microorganism, material or ingredient, present on a surface or food product to another that does not have it in its formula, representing a potential risk to the consumer.

Deviation: failure to meet a critical limit or standard.

Disposable: single-use material, aimed to be used or consumed just one time and then discarded.

Food safety team: group of people responsible for developing, implementing, evaluating and verifying that the food safety plan is working as planned.

Food safety: the condition of a food product that ensures it is safe to eat and will not cause any illness or disease, when consumed as intended.

Functionality: a set of food safety or quality traits or characteristics that makes a product suitable to serve its purpose and ensure it's safe to be consumed.

GMP: good manufacturing practice.

HACCP plan: the written document, based on the HACCP principles, that delineates and outlines the procedures to be followed and implemented.

HACCP system: the result of the implementation of the HACCP plan.

HACCP: a systematic approach to the identification, evaluation, and control of food safety hazards.

Hazard analysis: process by which information is collected and analyzed regarding hazards associated to a particular food product in order to decide which of them are significant and must be addressed in the HACCP plan for that food product.

Hazard: a biological, chemical or physical agent that is reasonably likely to cause illness or injury if not controlled.

Monitor: to conduct a planned sequence of observations or measurements to assess if a CCP is under control and to produce an accurate record for future use in verification.

Prerequisite programs: procedures, including Good Manufacturing Practices, that address operational conditions providing the foundation for the HACCP system.

Preventive control: any procedure, action or process that is executed based on a risk analysis, previously performed, aimed to reduce significantly a targeted risk or eliminate its occurrence as to protect the food safety of a product.

Preventive measure: any action implemented aimed to eliminate the fundamental root cause of an identified non-conformity and avoid its reoccurrence.

Probability: the possibility of a hazard to take place or occur.

Re-packing: the process by which a finished product is packed again.

Risk: the level of probability of a hazard to occur.

Sanitation: refers to the activities performed to clean and disinfect tools, utensils, work surfaces, premises and equipment in an effort to eliminate residues that represent potential contamination that could affect the quality of a product.

Severity: the seriousness of the effect or effects of a hazard.

Step: a point, procedure, operation or stage in the food system from primary production to final consumption.

Supplier: a person or establishment that manufactures or processes inputs used in the production process of a receiving facility (processing plant) without having undergone additional processing or processing by a third party affecting its integrity, composition or formula.

Validation: that element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards. Any measure or action aimed to determine the validity of the HACCP plan and that the system is operating as planned.

Verification: any process or action aimed to check that control or preventive measures are being applied as planned.

8 Company overview

SAMIYAMEALS S.A. is a company dedicated to the manufacturing and trading of fruit and vegetable food products.

9 Production lines and trading brands

9.1 Chips line

- Chips, bulk presentation (1 x 2.5 kg case)
- Chips, retail presentation (24 x 142 g; 20 x 150 g; 12 x 350 g case)

9.2 Frozen sweet plantains line

- Maduro 30 lb (6 x 5 lb)
    - SAMIYA
- Maduro 24 lb (4 x 6 lb)
    - Deliciosos
    - Latin Gourmet
    - Casa Tropical
    - Doña Sofía
    - Loty
    - Peña

  - SAMIYA (12 x 2 lb)
  - Maya (12 x 2 lb)
  - Maya (8 x 3 lb)
- Maduro 18 lb (6 x 3 lb)
  - Supreme

9.3 Frozen tostones line

- Regular tostones 18 lb (6 x 3 lb)
  - Supreme
  - Doña Sofía
  - Deliciosos
  - Latin Gourmet
- Regular tostones 25 lb (5 x 5 lb)
  - SAMIYA
- Hawaiian tostones 18 lb (9 x 2 lb)
  - Maya Food Service
  - Maya Retail Resealable Pouch Bag
- Maqueño tostones 18 lb (6 x 3 lb)
  - Maya Retail, Hawaiian Style

10 Layout description

See appendix, layouts.

11 Organizational chart

See appendix, organizational chart.

12 HACCP team

The conformation of the HACCP team, its surrogates and the roles of its members in the implementation of the HACCP plan are described in the following section.

12.1 Members

- **Quality Assurance and Food Safety Management System Coordinator:** is the team's leader.
- **President / CEO:** is the leader's surrogate.

- **Production Coordinator**
- **General Manager**
- **Logistics Coordinator**
- **Quality Technician**
- **Quality Monitor**
- **Production Manager**

12.2 Surrogate members

In case any of the members is not present, the surrogate members will take charge. The list of the surrogate members is presented below:

- **Quality Assurance and Food Safety Management System Coordinator:** surrogated by the President.
- **President:** surrogated by the Quality Technician.
- **Production Coordinator:** surrogated by the Production Manager.
- **General Manager:** surrogated by the President.
- **Logistics Coordinator:** surrogated by the General Manager.
- **Quality Technician:** surrogated by the Quality Monitor.
- **Quality Monitor:** surrogated by the Quality Technician.
- **Production Manager:** surrogated by the Production Coordinator.

12.3 Role descriptions of the HACCP team members

The roles of the HACCP team members are described below. Their responsibilities are, but not exclusive to:

- **Team leader:**

Manage the design, implementation and development of the food safety management system.

Guarantee that the system is compliant to local regulations and standards, as applicable.

Inform about the performance of the HACCP management system.

Summon and direct all HACCP team meetings.

Ensure the continuous training and education of the HACCP team members.

Identify opportunities for continuous improvement.

Carry out the internal verification and validation of the HACCP plan.

Ensure the balance between experience and technical knowledge among the team members.

- **Leader's surrogate and back-up support:**

Surrogate the leader when absent.

Inform about the HACCP system performance.

Participate in an active way in HACCP team meetings.

Identify opportunities for continuous improvement.

Carry out the internal verification and validation of the HACCP plan.

Coordinate active team members' participation within the HACCP team.

- **Responsible members:**

Carry out the internal verification and validation of the HACCP plan.

Ensure the execution and operational maintenance of the HACCP system.

Identify opportunities for continuous improvement.

Promote the guidelines outlined by the food safety management system policy on all organizational levels.

Control and administer the resources needed to maintain the HACCP and food safety system fully operational and going.

Take part in the elaboration and maintenance of the HACCP system.

- **HACCP team support**

In case of any member absent, the Senior Management must determine the surrogates. Depending on the existing needs, the HACCP team may require the support of those who are more knowledgeable or experience in the field according to the topics under consideration. These persons may not necessarily be part of the HACCP or food safety team structure.

13 Technical specs sheets

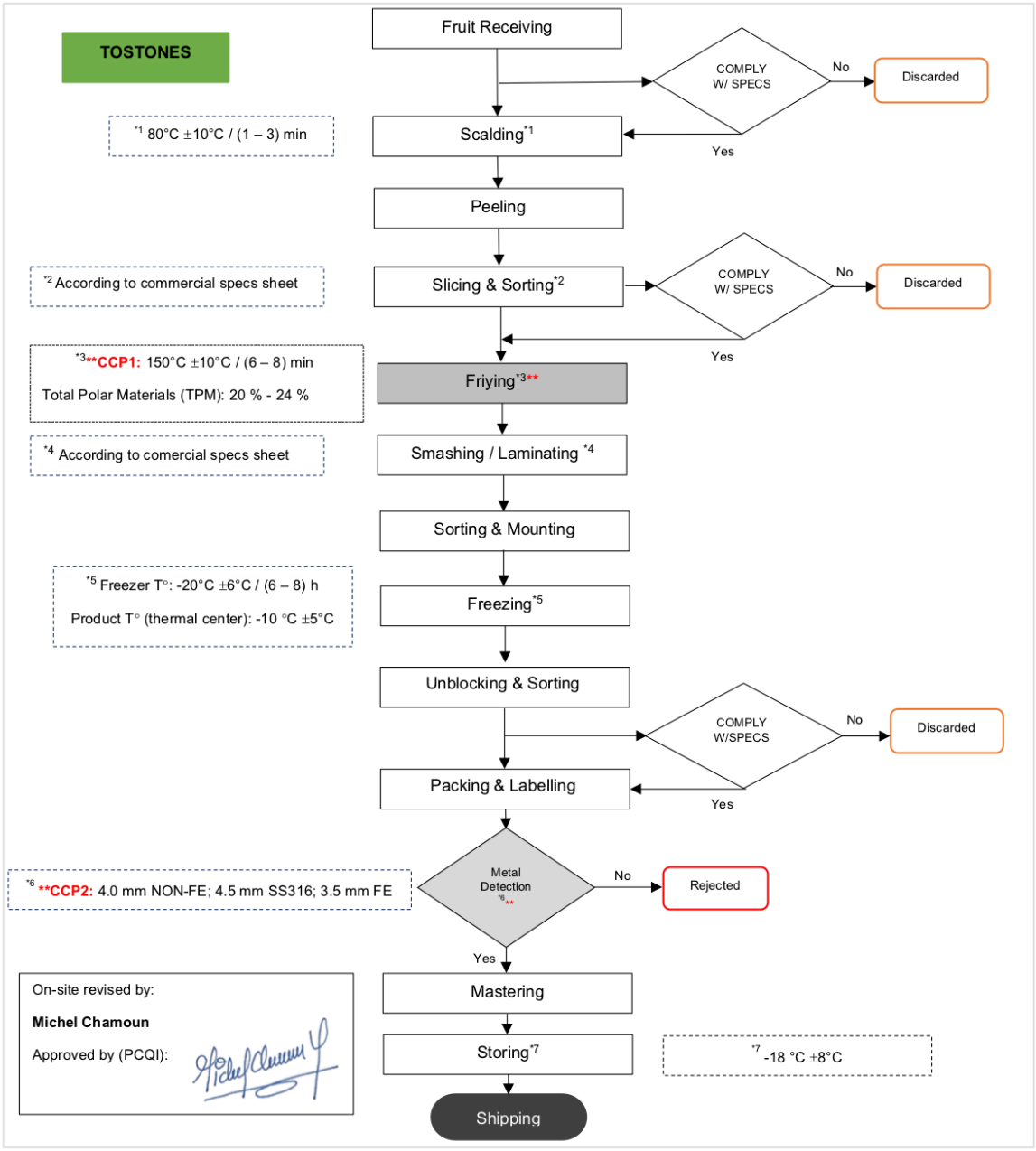
See appendix.

14 Flowcharts

In the following section, the flowcharts are shown for each production process. Each flowchart has been built, verified and validated on-site by the facility's Preventive Controls for Human Food Qualified Individual (PCQI).

14.1 Process flowchart: frozen tostones

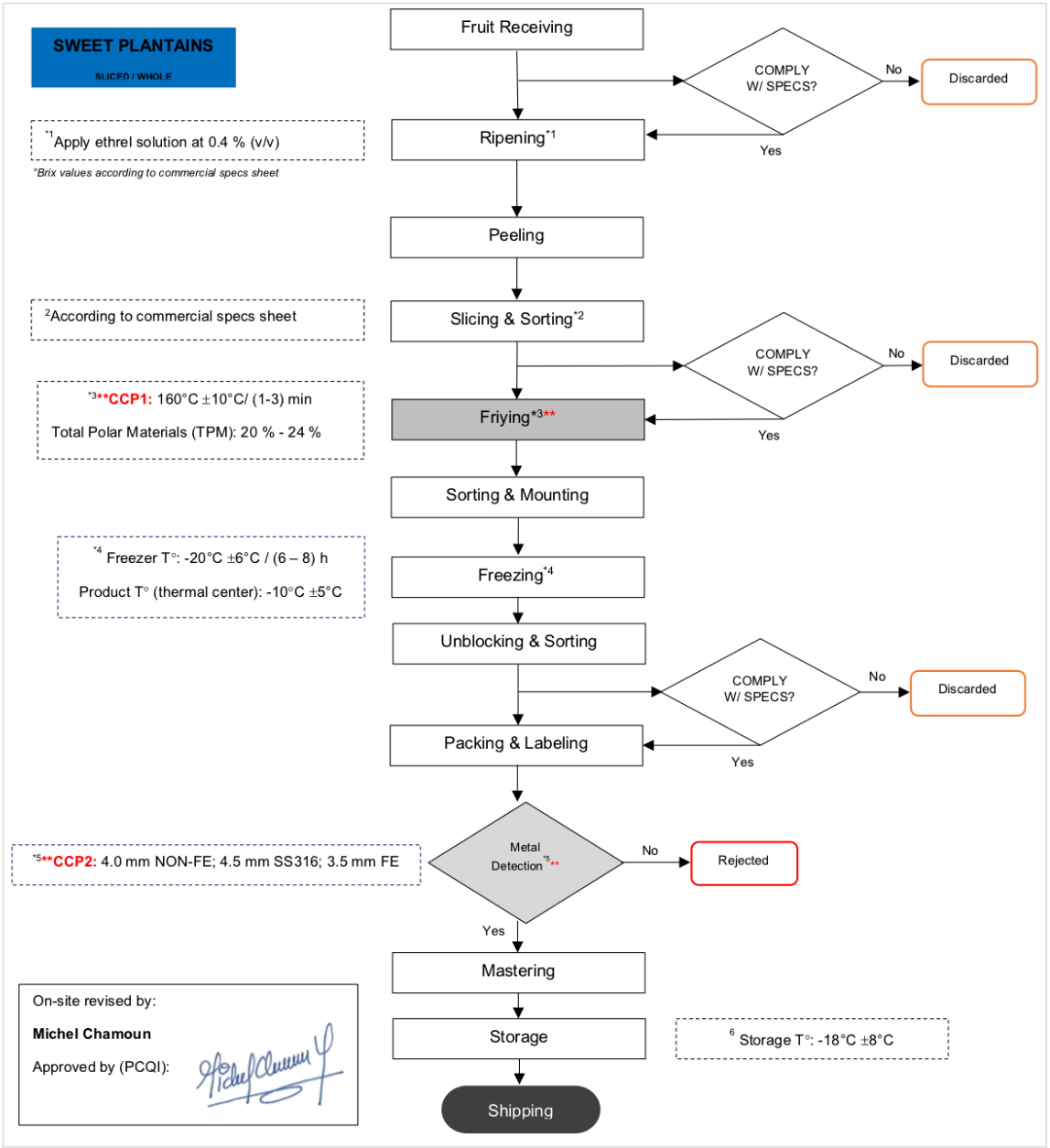
SAMIYA	PROCESS FLOW CHART: PRE-FRIED & FROZEN TOSTONES			
	Code: SMY-PC-E-003	**Version:** 01	Date: 07/25/2019	Page 1 of 1
Created by: Food Safety Date: 07/15/2019	**Revised by:** HACCP Date: 07/17/2019		**Approved by:** CEO Date: 07/25/2019	



SAMIYAMEALS S.A. / km. 19,5 vía a la Costa, Guayaquil-Ecuador

14.2 Process flowchart: frozen sweet plantains

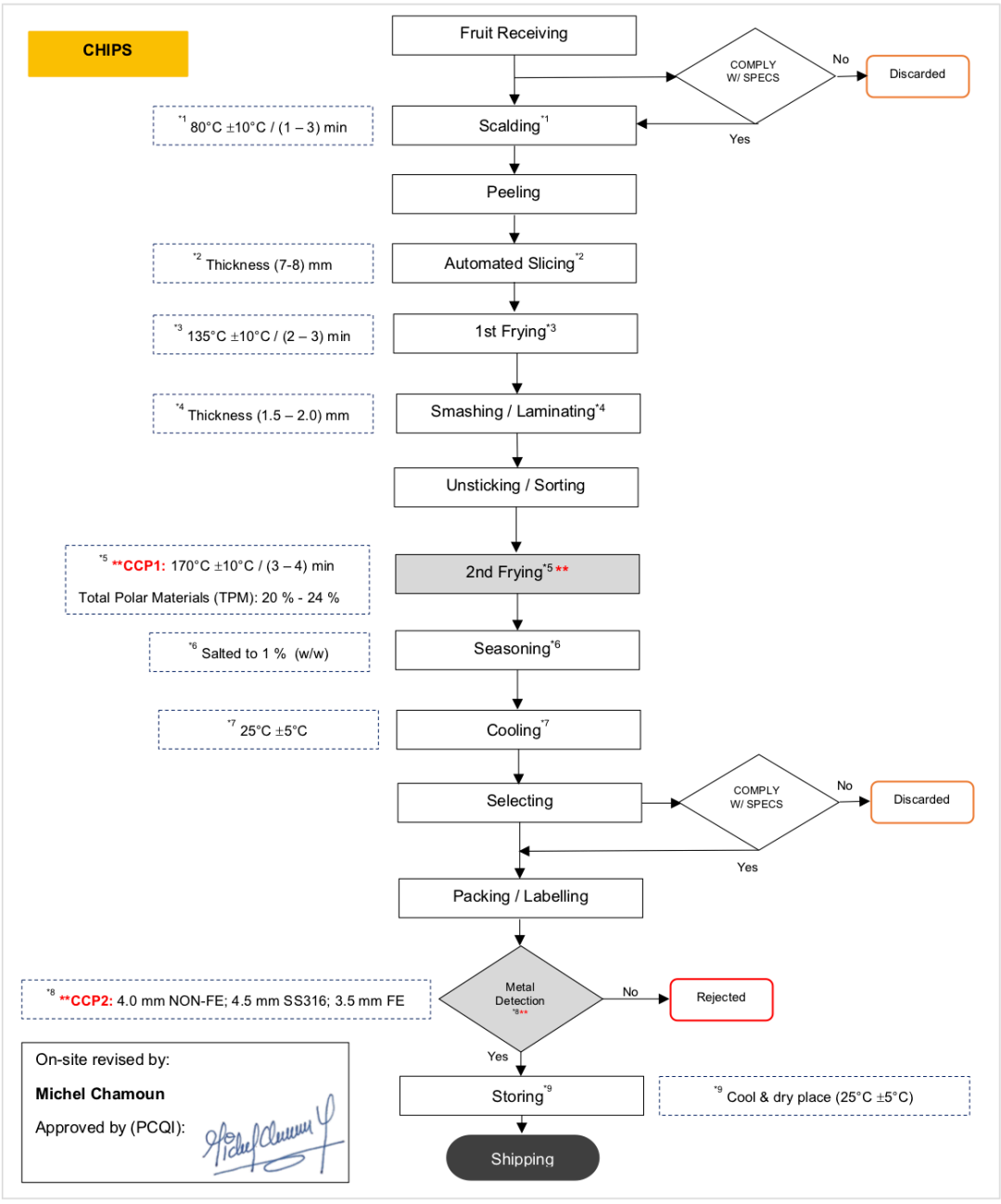
SAMIYA	PROCESS FLOW CHART: PRE-FRIED, FROZEN SWEET PLANTAINS			
	Code: SMY-PC-E-001	**Version:** 01	Date: 07/22/2019	Page 1 of 1
Created by: Food Safety Date: 07/15/2019	**Revised by:** CEO Date: 07/17/2019		**Approved by:** Food Safety Date: 07/22/2019	



SAMIYAMEALS S.A. / km. 19,5 vía a la Costa, Guayaquil-Ecuador

14.3 Process flowchart: ready-to-eat, tostones chips

SAMIYA	PROCESS FLOW CHART: TOSTON CHIPS			
	Code: SMY-PC-E-002	**Version:** 02	Date: 12/16/2019	Page 1 of 1
Created by: Food Safety Date: 07/15/2019	**Revised by:** HACCP Date: 12/16/2019		**Approved by:** CEO Date: 12/16/2019	



SAMIYAMEALS S.A. / km. 19,5 vía a la Costa, Guayaquil-Ecuador

15 Description of flowchart process steps

15.1 Frozen tostones production process

The description for each process step of the manufacturing process to elaborate frozen tostones is presented below:

- **Fruit receiving:** the fruit is received in clean plastic crates or carton boxes. All units presenting variable levels of ripeness or quality defects must be segregated and rejected from processing. This process step involves the receiving of plantains from several farms and is controlled under the “approved suppliers’ program”.
- **Scalding:** the fruit is scalded in water for a time lapse of 1-3 min. Water temperature is at 80 +/- 10°C, with the purpose of deactivating enzymatic processes and proteins and make the peeling process easier.
- **Peeling:** the fruit is hand-peeled, separating the peel from the pulp. The fruit peels are put in plastic containers and then donated to farms for composting and/or animal feed.
- **Slicing and sorting:** the fruit is selected and sliced into cylinders from 2.0-2.5 inches of length. This is a manual operation.
- **Frying:** sliced chunks are fried in non-hydrogenated RSPO certified palm oil at 170 +/- 10°C for 6-8 min.
- **Smashing / Laminating:** fried slices are smashed to form the tostones.
- **Sorting and mounting:** the smashed and toston-shaped units is put on trays to be entered into the freezing rooms.
- **Freezing:** the product is frozen in blast freezers over a period of 6-8 hours, at a set temperature of -20 +/- 10°C.
- **Unblocking and sorting**: product is sorted by size and according to client’s specs.
- **Packing and labeling:** the individually frozen units is packed into bags as fast as possible to avoid defrosting.
- **Metal detector:** the packed product is put through the metal detector, as critical control point, to detect the presence of any metallic particle, ferrous, non-ferrous and stainless steel.
- **Mastering:** the bags are placed into carton boxes and these are palletized to be moved into the cold storage room.
- **Storing:** palletized product is stored in the storage freezer and kept at -18 +/- 8 °C.
- **Shipping:** the product in pallets is put into reefer containers and shipped to its target market. Temperature log tags are located inside the reefer containers to monitor temperature settings.

15.2 Frozen sweet plantains production process

The description of each process step from the manufacturing process for pre fried and frozen sweet plantains is shown below:

- **Fruit receiving:** the fruit is received in plastic crates or carton boxes. Any units presenting deviation in Brix recordings must be segregated and evaluated for processing on a different batch.
- **Ripening:** the fruit is sprayed with Ethrel liquid solution, at 0.4 %, to achieve homogeneous ripening results.
- **Peeling:** the fruit is manually peeled, disposing fruit peels in plastic containers to be donated to local farms to be used in composting or as animal feed.
- **Slicing and sorting:** the fruit is sliced and sorted by size and ripeness, according to client's specs. *When manufacturing whole sweet plantains, fruit is not cut just sorted.
- **Frying:** the slices are fried in non-hydrogenated RSPO certified palm oil at 160 +/- 10°C for 1-3 min.
- **Sorting and mounting:** the pre-fried product is put on trays and freezing carts to be taken into the blast freezers.
- **Freezing:** the product is frozen in blast freezers at -20 +/- 10°C for 6-8 hours.
- **Unblocking and sorting:** the frozen product is unblocked and separated into individual units, as requested by the client and sorted according to clients' specs.
- **Packing and labeling:** the individually frozen units is packed into bags as fast as possible to avoid defrosting.
- **Metal detector:** the packed product is put through the metal detector, as critical control point, to detect the presence of any metallic particle, ferrous, non-ferrous and stainless steel.
- **Mastering:** the bags are placed into carton boxes and these are palletized to be moved into the cold storage room.
- **Storing:** palletized product is stored in the storage freezer and kept at -18 +/- 8 °C.
- **Shipping:** the product in pallets is put into reefer containers and shipped to its target market. Temperature log tags are located inside the reefer containers to monitor temperature settings.

15.3 Ready-to-eat tostones chips production process

The description for each process step involved in the manufacturing of ready-to-eat tostones chips is shown below:

- **Fruit receiving:** the fruit is received in plastic crates or carton boxes. All units presenting deviation in Brix must be segregated and evaluated separately for processing. Quality

screening is performed to identify damaged or defective fruit, due to physical or microbiological factors (fungi, bacteria or insects).

- **Scalding:** the fruit is scalded in water for a time lapse of 1-3 min. Water temperature is at 80 +/- 10°C, with the purpose of deactivating enzymatic processes and proteins and make the peeling process easier.
- **Peeling:** the fruit is hand-peeled, separating the peel from the pulp. The fruit peels are put in plastic containers and then donated to farms for composting and/or animal feed.
- **Automated slicing:** the fruit is sliced in an automated slicer and then sorted according to clients' specs.
- **1st Frying:** slices are fried in non-hydrogenated RSPO certified palm oil at 135 +/- 10°C for 2-3 min.
- **Smashing / Laminating:** fried slices are smashed to give shape to the tostones chips. Thickness depends on clients' specs.
- **Unsticking and sorting:** the laminated product is separated into individual pieces when two or more pieces stick together.
- **2nd Frying:** individual pieces are fried a second time to give them a crisp texture at 170 +/- 10°C for 3-4 min.
- **Seasoning:** fried pieces are pass through a seasoning tumbler to add salt. Percentage varies according to clients' specs, 3 % ($^{w}/_{w}$) maximum.
- **Cooling:** seasoned product is let cool to 25 +/- 5°C in order to guarantee shelf life and sensory traits.
- **Packing and labeling:** product is packed into bags, according to clients' presentation.
- **Metal detector:** the packed product is put through the metal detector, as critical control point, to detect the presence of any metallic particle, ferrous, non-ferrous and stainless steel.
- **Storing:** packed product is stored in the warehouse, over pallets, properly labeled. The warehouse is at room temperature, dry and cool.
- **Shipping:** the product is shipped in dry containers, following clients' specs and shipping requests.

16 Hazard analysis

See HACCP matrix, appendix.

17 Critical points control

See HACCP and PCC's matrix, appendix.

18 Archive of records and tally sheets

The document management system (DMS) constitutes a physical evidence upon which all actions performed in the implementation of the food safety and HACCP system are recorded and documented. The DMS guarantees that written and physical evidence are in existence and available for review, enabling further examinations or inspections of all recorded information throughout the time and during the archive period of time.

19 Records keeping procedure

The responsible HACCP personnel for completing tally sheets and operational records must not, by any means, anticipate the filling-in of information of any record or tally sheet associated to the procedures being monitored. Data entry and recording can only be documented while the on-going monitoring process of the action step or procedure being supervised or monitored.

Any correction or modification to the recorded information or data must not be erased by any means. If needed, the tally sheets or records requiring some type of correction must be corrected by crossing a line over the fragment to be corrected, without erasing information, and the initials of the responsible must be written right next to it. Explanatory notes or foot notes are highly recommended to justify the modification of the record or tally sheet.

Tally sheets and record format must have a standardized presentation. These must be revised on a regular basis to make sure they are filled-in correctly and all information is completed. If a part of the tally sheet or record is intentionally left in blank, then the responsible person must cross a line over it.

HACCP tally sheets and records must include the following data:

- Date and time, written in the document.
- Date and time of data input, if applies, and the signature or initials of the responsible person.
- Data from the process, recorded at the time of supervision.
- Relevant comments or information to the process, recorded while supervising.
- Signature of person who verifies (verifier).

In addition to the above-mentioned requirements, all HACCP records must include the following information to achieve an effective document management system:

- Company name and location.
- Title or name of document, or, document code.
- The criterion for CCP's, such as critical limits (CL's) – applies to monitoring records.
- Corrective actions applied and the responsible of its executions – applies to monitoring records.

20 Verification procedure

The HACCP plan includes verification procedures for CCP's. This is implemented to confirm that the process CCP's are being monitored as planned and stated, but also to verify that corrective actions are being executed and effectively implemented when necessary, in cases where deviations are reported for the CCP's.

The verification is done according to these five steps:

1. HACCP plan revision.
2. CCP's conformity.
3. Confirmation that the procedures for treating irregularities, non-conformities and tally sheets/records are being held or implemented accordingly.
4. Visual inspections of the processes while processing.
5. Verification records.

21 Lab analysis

The company will establish the required lab analysis for the monitoring and control of its operations (consult the microbiology monitoring plan).

22 On-site verification

On-site inspections are executed by a certified Preventive Controls for Human Food Qualified Individual (PCQI) on a monthly basis, with the objective to verify the control and supervision of CP's and CCP's in the manufacturing process.

23 Verification frequency

The verification activities are executed following the frequency below:

Nº	Verification activity	Frequency
1	CCP standard monitoring record	Daily
2	Non-conformities / IrregularitiesI (if exist)	Daily
3	Visual inspections	Daily
4	On-site verifications	Monthly
5	Lab analysis	As indicated by the Microbiology Plan
6	HACCP audits	Semestral

The inspection schedules to verify CCP's will be in accordance to the HACCP team leader criteria. All records of the HACCP document management system will be under the HACCP team leader custody, who will revise them and verify them daily having them signed and approved accordingly.

24 Verification records

The verification record for the HACCP audit will be similar to the one used by PrimusGFS, on its current and most up-to-date version, during the food safety audits performed by them. Frequency will be semestral. With respect to CCP's and lab analysis, tally sheets and records used will be those developed by the company for these purposes, which are shown in the appendix section.

25 Track of changes

Nº	Date approved	Description of change	Responsible
1	July 29, 2019	Creation	Alicia Paz
2	August 21, 2019	Revision	Mariuxi Muñoz
3	November 19, 2019	Approval	Michel Chamoun
4	October 10, 2020	Translation (ENG)	Michel Chamoun

SAMIYA	HACCP MATRIX - FROZEN SWEET PLANTAINS										SMY-SGIA-R-017
	QUALITY ASSURANCE										VERSIÓN:01
PROCESS STEP	**TYPE OF RISK**	**HAZARD**	**CAUSE**	**ARE THERE SIGNIFICANT RISKS TO THE FOOD SAFETY OF THE PRODUCT?**	**PROBABILITY**	**SEVERITY**	**PROBABILITY LEVEL INTREPRETATIO N**	**JUSTIFICATION FOR PROBABILITY LEVEL**	**INDICATE PREVENTIVE MEASURES THAT CAN BE APPLIED TO ELIMINATE THE RISK OR REDUCE IT TO AN ACCEPTABLE LEVEL**	**IS IT NECESSARY TO APPLY A CONTROL MEASURE TO ELIMINATE THE RISK OR REDUCE IT TO AN ACCEPTABLE LEVEL?**	**IS THIS STEP IN THE PROCESS A CCP?**
1. Receiving of Raw Material	**Physical**	Presence of foreign materials (rocks, sticks, leaves, etc.)	Defficiencies in post-harvest management	NO	1	3	Tolerable	The step involves a vehicle inspection process with each delivery	GAP (Good Agricultural Practices) compliance in growers' premises	NO	NO
	Chemical	Pesticide excess residue or presence of banned pesticides	Grower disregards allowed pesticide list for plantain farms, issued by the Ecuadorian and European Standard Cross contamination (crops, vehicle, etc.)	NO	1	1	Trivial	Disregard allowed pesticide list for plantain farms, issued by the Ecuadorian and European Standard Cross contamination (crops, vehicle, etc.)	This step involves supplier control and approval	NO	NO
	Biological	Presence of pathogens: E. coli, Salmonella sp., Listeria sp.	Mishandling of product, cross contamination	NO	1	3	Tolerable	Pathogens represent a hazard to product food safety	GAP (Good Agricultural Practices) compliance in growers' premises	NO	NO
2. Ripening	**Physical**	Presence of foreign materials (rocks, sticks, leaves, etc.)	Defficiencies in post-harvest management	NO	1	3	Tolerable	The step involves a vehicle inspection process with each delivery	GAP (Good Agricultural Practices) compliance in growers' premises, GMP's compliance in facility	NO	NO
	Chemical	Excess of Ethrel solution in produc	Disregard solution concentration while spraying the product	YES	5	5	Moderate	Procedure to control how to prepare the Ethrel solution in place, monitoring of Brix in fruit	Procedure to control how to prepare Ethrel solution and training to personnel	NO	NO
	Biological	Presence of pathogens: E. coli, Salmonella sp., Listeria sp.	Mishandling of product, cross contamination	NO	3	3	Tolerable	Pathogens represent a hazard to product food safety	GAP (Good Agricultural Practices) compliance in growers' premises, control applied in further step - product is pre-cooked	NO	NO
3. Peeling	**Physical**	Rubber or nitrile fragments from gloves or protective gear wore by operators	Foreign objects (rubber or nitriles fragments, pieces from clothing, hair, jewelry parts, etc.)	NO	3	3	Tolerable	Presence of foreign objects can affect product quality	GMP compliance in facility	NO	NO
	Chemical	Pesticide excess residue or presence of banned pesticides	Grower disregards allowed pesticide list for plantain farms, issued by the Ecuadorian and European Standard Cross contamination (crops, vehicle, etc.)	NO	1	1	Trivial	Disregard allowed pesticide list for plantain farms, issued by the Ecuadorian and European Standard Cross contamination (crops, vehicle, etc.)	GAP (Good Agricultural Practices) compliance in growers' premises	NO	NO
	Biological	Microbiological contamination from pathogens: E. coli, Listeria sp., Salmonella sp.	Cross contamination, improper hygiene habits from workers, improper or lack of sanitation of working surfaces, equipment and utensils.	NO	3	3	Tolerable	Pathogens represent a hazard to product food safety	SSOP's and GMP's compliance in processing facility, effective application of cleaning and sanitation procedures for utensils and equipment	NO	NO

4. Slicing and sorting	**Physical**	Foreign objetcs: rubber or nitrile fragments from gloves or protective gear wore by operators, pieces from clothing, hair, plastic parts from broken lamps.	Foreign objects (rubber or nitriles fragments, pieces from clothing, hair, jewelry parts, plastic parts from broken light lamps.)	YES	5	5	Moderate	Presence of foreign objects can affect product quality	SSOP's and GMP's compliance in processing facility, effective application of cleaning and sanitation procedures for utensils and equipment	NO	NO
	Chemical	None	This step does not involve chemical products that pose a risk of this type	NO	1	1	Trivial	N/A	N/A	NO	NO
	Biological	Microbiological contamination from pathogens: E. coli, Listeria sp., Salmonella sp.	Cross contamination, improper hygiene habits from workers, improper or lack of sanitation of working surfaces, equipment and utensils.	YES	5	5	Moderate	Pathogens represent a hazard to product food safety	SSOP's and GMP's compliance in processing facility, effective application of cleaning and sanitation procedures for utensils and equipment. ATP swabbing on gloves, utensils and surfaces	NO	NO
5. Frying	**Physical**	Foreign objetcs: rubber or nitrile fragments from gloves or protective gear wore by operators, pieces from clothing, hair, plastic parts from broken lamps.	Foreign objects (rubber or nitriles fragments from gloves, pieces from clothing, hair, jewelry parts, plastic parts from broken light lamps, parts from broken knives)	YES	5	5	Moderate	Presence of foreign objects can affect product quality	SSOP's and GMP's compliance in processing facility, effective application of cleaning and sanitation procedures for utensils and equipment. A control measure is applied on a further step	NO	NO
	Chemical	Presence of polar compounds in frying oil	Frying temperatures that exceed 170 C can generate polar compounds in oil	YES	5	25	Critical	Long lasting exposure to high levels of polar compounds may cause a health hazard	COA requested to oil supplier with the delivery, procedure for change of oil, tempeature control in frying oil, monitoring of TPM in oil	YES	YES
	Biological	Presence of pathogens: E. coli, Salmonella sp., Listeria sp.	Cross contamination, improper hygiene habits from workers, improper or lack of sanitation of working surfaces, equipment and utensils.	YES	5	25	Critical	Pathogens represent a hazard to product food safety	SSOP's and GMP's compliance in processing facility, effective application of cleaning and sanitation procedures for utensils and equipment.	YES	YES
6. Sorting and mounting	**Physical**	Foreign objetcs: rubber or nitrile fragments from gloves or protective gear wore by operators, pieces from clothing, hair, plastic parts from broken lamps.	Foreign objects (rubber or nitriles fragments from gloves, pieces from clothing, hair, jewelry parts, plastic parts from broken light lamps, parts from broken knives)	YES	5	5	Moderate	Presence of foreign objects can affect product quality and pose a health hazard	Knife control, control on loose parts, SSOP's and GMP's compliance in processing facility, effective application of cleaning and sanitation procedures for utensils and equipment	NO	NO
	Chemical	None	This step does not involve chemical products that pose a risk of this type	NO	1	1	Trivial	N/A	N/A	NO	NO

	Biological	Presence of pathogens: E. coli, Salmonella sp., Listeria sp.	Cross contamination, improper hygiene habits from workers, improper or lack of sanitation of working surfaces, equipment and utensils.	YES	5	9	Moderate	Pathogens represent a hazard to product food safety	Microbiology control, ATP swabbing on surfaces, product monitoring	NO	NO
7. Freezing	**Physical**	Presence of foreign materials (loose parts, broken plastic, etc.)	Residues or broken parts from freezer equipment, plastic crates or freezing plastic sheets	YES	5	5	Moderate	Presence of foreign objects can affect product quality and pose a health hazard	Control on loose parts, SSOP's and GMP's compliance in processing facility, effective application of cleaning and sanitation procedures for utensils and equipment, preventive maintenance	NO	NO
	Chemical	None	This step does not involve chemical products that pose a risk of this type	NO	1	1	Trivial	N/A	N/A	NO	NO
	Biological	Microbiological contamination from pathogens: E. coli, Listeria sp., Salmonella sp.	Cross contamination, improper hygiene habits from workers, improper or lack of sanitation of working surfaces, equipment and utensils.	YES	5	5	Moderate	Pathogens represent a hazard to product food safety	SSOP's and GMP's compliance in processing facility, effective application of cleaning and sanitation procedures for utensils and equipment	NO	NO
8. Unblocking and sorting	**Physical**	Presence of foreign materials (loose parts, broken plastic, etc.)	Residues or broken parts from freezer equipment, plastic crates or freezing plastic sheets	YES	5	5	Moderate	Presence of foreign objects can affect product quality and pose a health hazard	Control on loose parts, SSOP's and GMP's compliance in processing facility, effective application of cleaning and sanitation procedures for utensils and equipment, preventive maintenance	NO	NO
	Chemical	None	This step does not involve chemical products that pose a risk of this type	NO	1	1	Trivial	N/A	N/A	NO	NO
	Biological	Microbiological contamination from pathogens: E. coli, Listeria sp., Salmonella sp.	Cross contamination, improper hygiene habits from workers, improper or lack of sanitation of working surfaces, equipment and utensils.	YES	5	5	Moderate	Pathogens represent a hazard to product food safety	Microbiology control, ATP swabbing on surfaces, product monitoring	NO	NO
9. Packing and labeling	**Physical**	Entrance of foreign objects into packaging	Bag seal is not sealing properly, bag not sealed completely	YES	5	5	Moderate	Presence of foreign objects can affect product quality	SSOP's and GMP's compliance in processing facility, effective application of cleaning and sanitation procedures for utensils and equipment. Preventive maintenance to equipment (sealer). Control of sealed bags	NO	NO
	Chemical	None	This step does not involve chemical products that pose a risk of this type	NO	1	1	Trivial	N/A	N/A	NO	NO

	Biological	Microbiological contamination from pathogens: E. coli, Listeria sp., Salmonella sp.	Cross contamination from equipment, improper GMP's, improper sanitation of facility	SI	5	5	Moderate	Pathogens represent a hazard to product food safety	GMP control, microbiology control, ATP swabbing on surfaces, product monitoring	NO	NO
10. Metal Detection	**Physical**	Presence of metallic parts in product	Metal detector uncalibrated, not detecting metal particles present in finished product	YES	5	25	Critical	Choking hazard, health hazard to consumer	Preventive maintenance perfomed to equipment, routine callibration performed	YES	YES
	Chemical	None	This step does not involve chemical products that pose a risk of this type	NO	1	1	Trivial	N/A	N/A	NO	NO
	Biological	Microbiological contamination from pathogens: E. coli, Listeria sp., Salmonella sp.	Improper sanitation of surfaces, floor, walls and ceiling in packing and storage areas	NO	3	3	Tolerable	Pathogens represent a hazard to product food safety	GMP control, microbiology control, ATP swabbing on surfaces, microbiology release	NO	NO
11. Mastering	**Physical**	Damage of boxes or bags during palletizing activity	Some wooden pallets may have exposed nails or wood chips with cutting edges	NO	3	3	Tolerable	Presence of foreign objects can affect product quality and pose a health hazard	GMP compliance and contro	NO	NO
	Chemical	None	This step does not involve chemical products that pose a risk of this type	NO	1	1	Trivial	N/A	N/A	NO	NO
	Biological	Presence of pathogens: E. coli, Salmonella sp., Listeria sp.	Improper sanitation of surfaces, floor, walls and ceiling in packing and storage areas	YES	3	9	Moderate	Pathogens represent a hazard to product food safety	Microbiology control, COAs of finished product, microbiology release	SI	NO
12. Storing	**Physical**	Detachment of small parts in storage area (broken pieces from glass or plastic material)	Improper preventive maintenance practices	NO	1	3	Tolerable	The possibility of pieces or parts from storage area falling into product	Preventive maintenance perfomed to equipment, GMP's compliance on infrastructure	NO	NO
	Chemical	None	This step does not involve chemical products that pose a risk of this type	NO	1	1	Trivial	N/A	N/A	NO	NO
	Biological	Presence of pathogens: E. coli, Salmonella sp., Listeria sp.	Improper sanitation of surfaces, floor, walls and ceiling in packing and storage areas	YES	3	9	Moderate	Pathogens represent a hazard to product food safety	Microbiology control, COAs of finished product, microbiology release	NO	NO
13. Shipping	**Physical**	Presence of foreign material, not belonging to shipping container	Improper cleaning of container (residues or materials from previous shipments or cargo)	NO	1	3	Tolerable	Presence of foreign matter or objects can represent a contamination risk	GMP's compliance, vehicle inspection prior to loading	NO	NO
	Chemical	None	This step does not involve chemical products that pose a risk of this type	NO	1	1	Trivial	N/A	N/A	NO	NO
	Biological	Microbiological contamination from pathogens: E. coli, Listeria sp., Salmonella sp.	Improper sanitation of surfaces, floor, walls and ceiling in packing and storage areas and shipping container	NO	1	3	Tolerable	Pathogens represent a hazard to product food safety	Microbiology control, COAs of finished product, microbiology release	NO	NO

Risk Evaluation Matrix	
Probability (Frequency)	**Probability of ocurrence in finished product**

Risk Significance	
Probability (Frequency)	**Severity (Consequence)**

Low = 1	**1 (Trivial)**	**3 (Tolerable)**	**5 (Moderate)**
Medium = 3	**3 (Tolerable)**	**9 (Moderate)**	**15 (Important)**
High = 5	**5 (Moderate)**	**15 (Important)**	**25 (Critical)**
Gravity (Consequence)	**Insignificant = 1**	**Moderate = 3**	**Hazardous = 5**

Occurs frequently	High	Hazardous	Severe illness, harmful effects or seizures, both manifest immediately after and involve long term effects that could lead to death (fatal)
May ocurr, it's known to have happened in the past with some frequency	Medium	Moderate	Serious illness, harmful effects or seizures that manifest immediately and may have long term consequences. Not fatal.
Theoretically possible to occurr, but practically very improbable to occurr	Low	Insignificant	Minor illness, harmful effects or seizures, do not manifest immediately or barely manifest, long term effects happen only with extremely high dosis

SOP N°6

CRISIS MANAGEMENT AND PRODUCT RECALL

Food Safety Management System

SAMIYAMEALS S.A

Guayaquil - Ecuador

09/01/2019

Table of contents

1 Objective

Define the mechanisms of action and response for the timely removal and effective recovery of commercial goods produced by SAMIYA, which is deployed in distribution channels, points of sale or in the hands of consumers, as it is considered unfit in quality, safety or legality.

2 Scope

The field of execution described in this procedure applies to all commercial goods produced by SAMIYA that are distributed in the market, in the possession of customers or final consumers.

3 Reference Framework

This document has been prepared based on the information contained in the following documents:

BRC Global Standards. 2018. Global Safety *Standard (Food Safety)*. Version 8. London (GB): BRC. 124 p. ISBN 978-1-78490-350-3.

FAO (Food and Agriculture Organization). 2003. *Codex Alimentarius: General Principlesis Food Hygiene.* CAC/RCP 1-1969. Rome (IT): Codex AlimentariusCommission; Fao. Available on the *World Wide Web*: <http://www.fao.org/input/download/standards/23/cxp_001s.pdf>

FSPCA (Food Safety Preventive Controls Alliance). 2016. *Preventive Food Controls for Humans*:*Participant's Manual*. 1st Edition. Version 1.2. Chicago (US): Institute for Food Safety and Health; FDA; FSPCA. Available on the *World Wide Web*:<https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food>

INEN (Ecuadorian Standardization Institute). 2011. *Labeling of Food Products for Human Consumption*: *NTE INEN 1334-1: 2011. Part 1. I'd like to.* 3rd Review. Quito (EC): Ecuadorian Institute of Standardization. Available on the *World Wide Web*: <shorturl.at/dlpD1>

INEN (Ecuadorian Standardization Institute). 2011. *Labeling of Food Products for Human Consumption*: *NTE INEN 1334-2*:*2011. Part 2. Nutritional labeling. Requirements*. 2a Review. Quito (EC): Ecuadorian Institute of Standardization. Available on the *World Wide Web*: <shorturl.at/bwFM3>

INEN (Ecuadorian Standardization Institute). 2011. Labeling of Food Products for Human Consumption: NTE INEN 1334-3:2011. Part 3. Requirements for Nutrition Statements and Healthy Declarations. 1st Edition. Quito (EC): Ecuadorian Institute of Standardization. Available on the World Wide Web: <shorturl.at/tvxGI>

Primus Group, Inc. 2019. *PrimusGFS.* Version 3.1. Santa Maria (US): Primus Labs; Primus GroupInc. Available on the *World Wide Web*:<http://primusgfs.com/documents.aspx>

4 Definitions

Allergen: a substance or component present in a food capable of inducing a physiological reaction in the body by an immune response in susceptible persons.

Batch code: A combination of characters, numeric or alpha-numeric, that allows you to identify and track a production batch.

Class I withdrawal: when adverse health consequences are likely to be temporary or the likelihood of adverse health consequences is minimal.

Class II withdrawal: when there is a high probability that the health consequences of consumption of the product will be adverse and may lead to death.

Class III withdrawal: when consumption of the product is unlikely to produce adverse health consequences.

Commercial Area: responsible personnel in charge of an account and/or communication with the customer.

Commercial merchandise: finished product that is distributed in points of sale, collection or distribution for sale on the market.

Consumer: end user of the goods produced, who consumes the product.

Customer: natural or legal person (company) to which commercial goods have been sold for distribution or sale.

Destruction: final disposal of the removed product.

Incident: an event that can lead to customers being supplied with products unfit in quality, safety or legality.

Lot – Prepared quantity of a finished product or material on a given production day.

Non-compliance with a legal standard: non-compliance with a quality, safety or customer requirement.

Product recall: all measures aimed at achieving the return by customers, but not of end consumers, of products that are unfit or non-compliant.

Product recovery: all measures aimed at achieving the return of a product,by customers as finalconsumers, as they are considered unfit or non-compliant.

Quarantine: the state in which a finished product or commercial merchandise is located as a section while confirming that it is suitable for its intended use, sale or consumption.

Receiver: for the purposes of this procedure is any member of the company that receives, from the carrier, the communication of an alleged withdrawal incident.

Recovery Simulation: An intentionally mounted procedure to test the effectiveness of the product recall and recall system, being able to evaluate the team's ability to find and track the goods during the recovery exercise.

Reporter: for the purposes of this procedure is any individual who reports or reports on a product suspected of breaching specifications of safety, quality or legality.

Risk: likelihood of a danger occurring.

SGIA: Food Safety Management System.

Supplier: a person or establishment that manufactures or processes inputs used in the production process of a receiving facility (processing plant) without having undergone additional processing or processing by a third party affecting its integrity, composition or formula.

5 Responsibilities: Market Withdrawal Team

They are then presented to the team responsible for executing the recall plan, as well as their coordination area within the team.

Coordinator	Number	Contact
Team	Andrea Chica Alternate: Michel Chamoun	Office: +593 98 156 1340 Mail: recall.leader@samiya.co
Communication	Michel Chamoun Alternate: Margoire Yunes	Mobile (EC): +593 99 318 2772 Mobile (US): +1 805 308 4856 Mail: recall.communicate@samiya.co
Sales	Sebastián Moncayo Alternate: Michel Chamoun	Mobile: +593 99 406 2489 Mail: recall.sales@samiya.co
Logistics	Franco Chamoun Alternate: Sebastián Moncayo	Mobile: +593 99 181 8717 Mail: recall.logistics@samiya.co
Accounting	Sara Defaz Alternate: Nancy Carrazco	Office: +593 98 156 1340 Mail: recall.accounting@samiya.co
Quality	Margoire Yunes Alternate: Andrea Chica	Mobile: +593 99 181 8753 Mail: recall.quality@samiya.co
Receiving	Carlos Pesantes Alternate: Franco Chamoun	Office: +593 98 156 1340 Mail: recall.receiving@samiya.co
Administrative support	Nancy Carrazco	Office: +593 98 156 1340 Mail: recall.support@samiya.co

5.1 Team coordinator

- Convene a committee meeting to the withdrawal team to present the incident with the details and preliminary information lifted.
- Classify the incident according to the appropriate type of withdrawal and open the process of investigation and execution of the response mechanisms.
- Conduct reporting and monitoring of progress in product recall and recovery mechanisms with coordinators in each area.
- Close the incident with the respective closing and reporting results.

5.2 Communication coordinator

- Prepare official communications based on the results of the withdrawal team's investigation, to report the incident to the public, customers, media, health or governmental authorities and raise the respective alarms according to the type of withdrawal that is applicable.
- Maintain the official line of communication with customers and other stakeholders throughout the development of the recall plan.
- Collaborate with the legal advisor to provide the details of the incident and propose legal strategy of protection of the company and care of affected, if applicable.
- Socialize the results of the plan to withdraw and close the incident with the community.

5.3 Sales coordinator

- Perform survey of customers involved in the incident for the exercise of recall and recovery of the product.
- Build database with identified customers to establish immediate contact.
- Determine the amount of product that is in the possession of each customer based on sales records.
- Validate existing inventories of the lots involved in the incident, both in company warehouses and distribution channels.

5.4 Logistics coordinator

- Propose the strategy of withdrawal and recovery of the product based on the information provided by sales.
- Execute with sales the intervention of distribution points and external warehouses to activate quarantine and prevent the spread of the product in more points.
- Manage the means of recovery and recall based on the volumes to be collected.
- Display geographic map of impact points during the retirement exercise and monitor percentage progress of effectiveness.

5.5 Accounting Coordinator

- Perform the survey of invoices committed in the withdrawal incident with their respective quantities, dates and customers.
- Download the invoiced lots from the accounting system and classify them together with the customers who maintain possession of them.
- Display checked versus recovered quantity monitoring file along with receipt coordination.
- Perform the accounting closing of the withdrawal exercise, with the costs of the incident and the credit notes arranged, if applicable.

5.6 Quality coordinator

- Carry out the collection of evidence related to the affectation of the product, whether by safety, quality or legality.
- Examine internal management system records to collect backup information that supports decision-making and findings from the incident investigation process.
- Determine the level of product affectation based on the causes identified for withdrawal.
- Contact external technical advisors or laboratories to support research, if required, and build the reported incident data sheet.

5.7 Receiving coordinator

- Prepare the conditions for receiving the product recovered and recalled in the warehouses.
- Custody the product under quarantine during the time of execution of the incident until its closing time.
- Keep track of recovered and withdrawn quantities for effectiveness reporting along with logistics coordination and sales.
- Ensure adequate storage of the affected product until the incident is closed and the case resolved.

5.8 Administrative support coordinator

- Provide documentary and logistical support to other coordinations.
- Provide resources required by others to achieve the objectives set.

6 Development / Procedures

6.1 Logical sequence of steps in withdrawal exercise

No.	Action	Responsible

1	Contact the company to report suspected incident related to quality, safety or legality, or Disclose complaint or complaint to the Commercial Area, if the carrier is a client (see 1. 1.)	Reporter
1.1.	Proceed with the opening of customer claim case, completing the format ***SMY-SG-P-007 Management of Claims and Customer Suggestions,*** facilitated by the Commercial Area.	Commercial Area
2	Immediately inform the Retirement Team Coordinator to assess the alleged incident, with the evidence attached, and determine whether a retirement exercise should begin.	Receiver
3	Assess the alleged incident and determine whether or not it should proceed. If so, convene the Retirement Team to initiate action and response mechanisms to committee.	Team Coordinator
4	Determine whether the withdrawal is *Class I*, *Class II* or *Class III* (complete matrix of "MARKET **PRORDUCTO REQUIREMENT REQUIREMENT DETERMINATION"** – see Annex 1). Activate response mechanisms as appropriate. Determine with team coordinations: a) Product distribution extension b) Quantity and lots involved c) Product identification d) Customers in possession of lots involved e) Withdrawal, recovery and/or disposal mechanism f) Communication strategy and outreach Fill summary fact sheet **"INFORMATION SHEET OF WITHDRAWAL"** (see annex 2) with case number assigned.	Recall Team
5	Issue, if class I, written notice of direct alert to customers and distributors with the title **"URGENT: PRODUCT WITHDRAWAL NOTICE"** (see Annex 3) and proceed with inspection visit of compliance with measures,if feasible.	Communication Coordinator

6.1 Logical sequence of steps in withdrawal exercise (continued)

6	Ask customers to activate their own contingency measures and deploy their own withdrawal procedure.	Communication/ Sales Coordinators

7	Contact the suppliers involved, in case the cause of the incident is due to raw material or supplies.	Logistics Coordinator
8	Perform product segregation arrangements with customers, collection and transfer of recalled product to quarantine warehouses and physical capacity of recovered quantities.	Sales / Reception / Logistics / Quality Coordinators
9	Perform documentary survey of recovered and unrecovered product, physical inventory check, collection of team coordination reports, compensation measures if necessary.	Retirement Team
10	Perform documentary closure of the incident, submit closing report and archive case.	Retirement Team Coordinator

6.2 Checking the Effectiveness of the Product Withdrawal Program, Class I

For Class I withdrawals, periodic monitoring is established to check the effectiveness of the withdrawal exercise or according to the matrix in Annex 4. Exclusively, for Class I are listed exclusive tasks that are incorporated into the previous section *Logical sequence of steps in the withdrawal exercise.*

No.	Action	Responsible
6.1.	Manage product recall mechanism from customer warehouses, ensuring that the customer applies recovery to their point-of-sale or retail channel.	Sales/Communication Coordinators
8.1.	Lift physical capacity in quarantine hold, verifying that the removed units are complete. Open units must be reported as such.	Reception Coordinator
9.1.	Validate committed batches against a sales invoice, generating a report card for each sales invoice issued.	Accounting Coordinator
9.2.	Assess removaleffectiveness, run cause analysis if there are deficiencies and pose corrective actions. Schedule destruction.	Quality Coordinator
10.1.	Perform final destruction report of the product with evidence.	Team Coordinator

6.3 Market Product Recall Program Simulation

No.	Action	Responsible
1	To train the team involved in the program and check the validity of the plans proposed in this procedure, a biannual frequency drill is	Retreat Team Coordinators

performed in which a fictitious scenario is proposed in collaboration with a volunteer client.

The measure is led by the Retirement Team Coordinator in conjunction with the Commercial Area. The methodology to be followed is an exact replica of what is described in the present proceedings.

7 Corrective actions

If deviations exist in any component of this procedure, the steps of the corrective actions and enhancement procedure with *code SMY-AC-P-012*are carriedout.

8 Internal documents and archiving time

Document	Responsible	Time
SMY-SG-P-007 Customer Claims and Suggestions Management	Quality Assurance Coordinator and Integrated Management Systems	2 years
SMY-SG-E-001 Safety Team		2 years
SMY-SG-P-008 Identification and Traceability Procedure		2 years
SMY-AC-P-012 Pertaining corrective actions and improvement		2 years

9 Annex

Annex 1

DETERMINATION OF NEED FOR PRODUCT RECALL FROM THE MARKET

Incident reported by	Initial measurement	Decisions	Measures
The health authority or control entity considers that the product is causing disease.	Summon the Retirement Team, consult the health authority if I recommend removing the product from the market.	Evaluate the case along with evidence and records to determine whether or not a recall is appropriate: which product to withdraw and in what quantities.	If a withdrawal is not required: Document the evaluation process and strongly support the reasons behind the decision.
News article reporting a problem related to the consumption of a product made by the company.	To convene the Retirement Team to examine internal records related to the product referred to in the news article.		If the incident is classified as appropriate, based on the evaluation by the Retirement Team, then: Activate mechanisms of action Deploy Team Coordination Action Gathering evidence Analyzing evidence Socialize findings and inform the target audience Activate response and recovery mechanisms Having the product Request termination of the withdrawal incident Summon the Team for final analysis Prepare legal strategy, if required
Company Quality Control or customer-supplied information suggests a possible problem.	Convene the Retirement Team to examine the internal records of the product in question.		
The Ministry of Health or the competent entity believes that a product made by the company is causing disease	Summon the Retirement Team, contact the appropriate regulatory entity immediately.		

Annex 2

SAMIYA

[MM/DD/YYYY]

FICHA INFORMATIVA DE RETIRO

CASO #

El siguiente reporte presenta información valiosa referente a un incidente de retiro de producto que SAMIYAMELS S.A. está efectuando.

1. Información de producto

Nombre de producto	
Nº de ítem	
Nº de orden de compra	
Descripción	*Indicar naturaleza del producto, su composición/ingredientes, fecha de elaboración, fecha de vencimiento, presentación de producto y características particulares.*
Marca	
Etiqueta del empaque	
Etiqueta de la caja	
Uso previsto	

2. Código

Código de lote	
Fecha de elaboración	
Fecha de vencimiento	
Código EAN 13 / EAN 14	

SAMIYAMEALS S.A. / km. 19,5 vía a la Costa, Guayaquil - Ecuador
Basado en lineamientos para la industria de la FDA: retiro de productos, incluyendo recuperación y correcciones.

3. Empresa que solicita el retiro

Nombre de la empresa	SAMIYAMEALS S.A.
Dirección	km. 19 y medio vía a la Costa
Ciudad	Guayaquil
Estado/Provincia	Guayas
País	Ecuador
Tipo de industria	Fabricante
Contacto para retiro	Michel Chamoun
Correo para retiro	michel.chamoun@samiya.co

4. Fabricante

Nombre del fabricante	SAMIYAMEALS S.A.
Dirección	km. 19 y medio vía a la Costa
Ciudad	Guayaquil
Registro FDA	10561005226

5. Identificación del responsable del incidente reportado

Nombre de la compañía	
Dirección	
Ciudad	
Estado/Provincia	
País	

6. Razón del incidente de retiro

6.1. Explique por qué el producto que está siendo retirado se considera defectuoso o no conforme:

6.2. Explique cómo el defecto o la no conformidad afecta el desempeño, seguridad o inocuidad del producto:

6.3. En caso de que el retiro se deba a la presencia de un objeto extraño, por favor describa el mismo con profundidad de detalle:

SAMIYAMEALS S.A. / km. 19,5 vía a la Costa, Guayaquil - Ecuador
Basado en lineamientos para la industria de la FDA: retiro de productos, incluyendo recuperación y correcciones.

Claudio Innocenti

6.4. En caso de que el retiro sea por la presencia de un contaminante (desinfectante, aceite mecánico, vapores de aerosol, etc.), explique el nivel de contaminación sufrida en el producto. Facilite la etiqueta del contaminante, así como su ficha técnica y hoja de seguridad:

6.5. En caso de que el retiro sea por un desperfecto de calidad que incumple con especificaciones, por favor facilite la ficha de técnica de especificaciones comerciales y reporte los resultados de los muestreos realizados (adjunte copias):

6.6. En caso de que el retiro se deba a un error de etiquetado, facilite la etiqueta correcta e identifique la etiqueta incorrecta, descripciones y formulaciones:

6.7. Explique cómo ocurrió el incidente o problema y la fecha en que sucedió:

6.8. Explique cómo fue descubierto el problema y la fecha en que fue descubierto:

6.9. Explique si el defecto identificado afecta a todas las unidades solicitadas para el retiro, o si afecta únicamente a una porción de las unidades de los lotes requeridos en el retiro:

6.10. Explique por qué la afectación sólo aplica a los productos o lotes sujetos al retiro:

6.11. Facilite información detallada del registro de reclamos asociados con el producto defectuoso:

Fecha de reclamo	Descripción del reclamo	Código de lote	Evidencia

6.12. Si una agencia gubernamental está involucrada en la solicitud de retiro, por favor identifíquela y facilite la información de contacto del agente responsable o asignado:

7. Análisis de riesgos para la salud

Si aplica, por favor facilite la valoración de riesgos para la salud asociados con el producto defectuoso. Tenga presente que un riesgo para la salud no constituye la única razón para solicitar un retiro de producto del mercado.

8. Volumen de producto bajo retiro

Cantidad total producida	
Fecha de producción	
Cantidad distribuida	
Fecha de distribución	
Cantidades en cuarentena por el fabricante y los distribuidores	

8. Volumen de producto bajo retiro (continuación)

Indique la forma de cuarentena	
Cantidad estimada de remanente en el mercado	En distribuidores, minoristas…
Estado de la mercadería comercializada	En uso, descartada, unidades completas…

9. Patrón de distribución

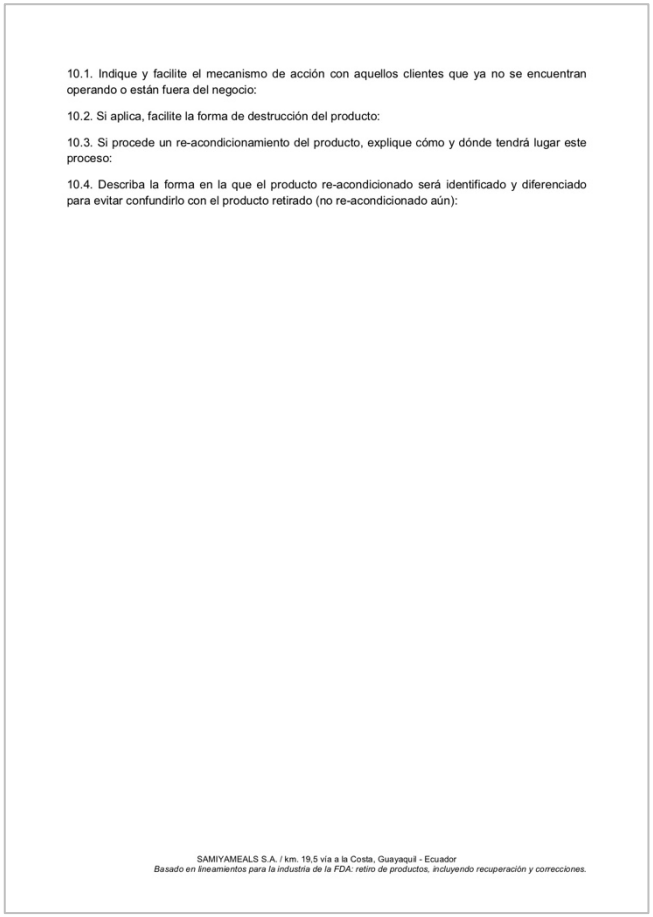
Cantidad de cuentas directas, por tipo	
	Mayoristas/distribuidores:
	Reempacadores:
	Fabricantes:
	Minoristas:
Distribución geográfica del producto:	
Lista general de consignatarios:	
Nombre	**Dirección física**
Ciudad	**Estado**
Contacto para retiros de mercado	**Teléfono de contacto:**
¿Se despachó el producto afectado?	
¿Se vendió el producto afectado?	
¿El producto afectado puede haber sido despachado o vendido?	

9.1. ¿Ha sido el producto vendido a alguna entidad del gobierno federal/nacional, estatal/provincial o local para su consumo en el plan de alimentación escolar? En caso afirmativo, por favor indicar los consignatarios y facilite cantidades vendidas y fechas de despachos:

10. Estrategia de retiro del mercado

Alcance en nivel de retiro	*Indicar: mayorista, distribuidor, minorista, etc…*
Si el alcance de nivel de retiro es para una porción del total de cuentas, justifique por qué:	
Método de notificación	
Canal de notificación	
Mecanismo de recolección	*Indique y describa la forma de recolección de producto*
¿El producto retirado generará escasez en el mercado?	

SAMIYAMEALS S.A. / km. 19,5 vía a la Costa, Guayaquil - Ecuador
Basado en lineamientos para la industria de la FDA: retiro de productos, incluyendo recuperación y correcciones.



10.1. Indique y facilite el mecanismo de acción con aquellos clientes que ya no se encuentran operando o están fuera del negocio:

10.2. Si aplica, facilite la forma de destrucción del producto:

10.3. Si procede un re-acondicionamiento del producto, explique cómo y dónde tendrá lugar este proceso:

10.4. Describa la forma en la que el producto re-acondicionado será identificado y diferenciado para evitar confundirlo con el producto retirado (no re-acondicionado aún):

SAMIYAMEALS S.A. / km. 19,5 vía a la Costa, Guayaquil - Ecuador
Basado en lineamientos para la industria de la FDA: retiro de productos, incluyendo recuperación y correcciones.

Annex 3

SAMIYA

[MM/DD/YYYY]

URGENTE: AVISO DE RETIRO DE PRODUCTO
[PRODUCT NAME]

Nombre del Cliente
Dirección
Ciudad, Estado/Provincia, Código Postal

Estimado Cliente/Distribuidor:

El propósito de esta comunicación es informarle que SAMIYAMEALS S.A. está retirando voluntariamente [INGRESE NOMBRE DEL PRODUCTO]. Nuestra empresa se encuentra retirando este producto del mercado por las siguientes razones:

- Razón 1:
- Razón 2:
- Razón 3:

El siguiente cuadro facilita toda la información necesaria relevante al producto de retiro para su fácil identificación y recuperación.

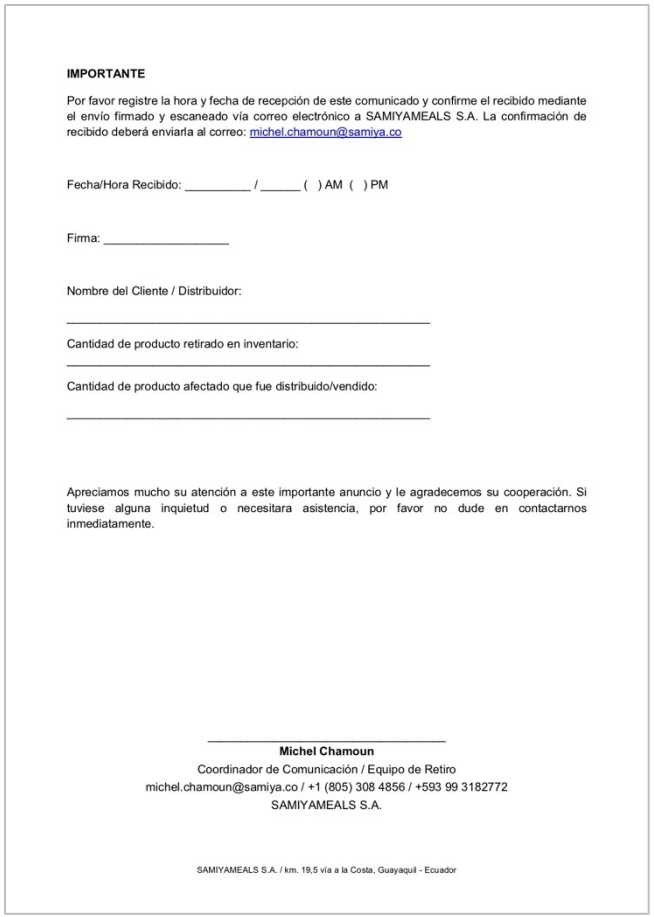
Nombre	Marca	Presentación	Lote	Fecha Elab.	EAN
		Indique tamaño, peso, etc.			

Le solicitamos urgentemente descontinuar la venta/distribución del referido producto INMEDIATAMENTE retirándolo de exhibición y bodegas. Luego de retirarlo, le solicitamos realice un conteo de cantidades en inventario y lo almacene bajo resguardo en lugar separado y seguro. Facilite esta información a nosotros lo antes posible mediante correo electrónico, con las evidencias escaneadas junto con el reporte firmado.

INMEDIATAMENTE tras recibir este aviso, por favor contacte a todas sus cuentas compradoras de este producto e infórmeles de este anuncio de retiro. Facilite a nosotros prueba documentada de este ejercicio de contacto a todas sus cuentas con la fecha de ejecución y el tiempo

SAMIYAMEALS S.A. generará una nota de crédito a beneficio suyo por la cantidad equivalente del producto retirado. Por favor identifique el producto con la palabra "RETIRADO". Lo contactaremos pronto para facilitarle instrucciones sobre cómo manejar este producto y qué hacer con el mismo.

SAMIYAMEALS S.A. / km. 19,5 vía a la Costa, Guayaquil - Ecuador



IMPORTANTE

Por favor registre la hora y fecha de recepción de este comunicado y confirme el recibido mediante el envío firmado y escaneado vía correo electrónico a SAMIYAMEALS S.A. La confirmación de recibido deberá enviarla al correo: michel.chamoun@samiya.co

Fecha/Hora Recibido: _____ / _____ ( ) AM ( ) PM

Firma: _____

Nombre del Cliente / Distribuidor:

_____

Cantidad de producto retirado en inventario:

_____

Cantidad de producto afectado que fue distribuido/vendido:

_____

Apreciamos mucho su atención a este importante anuncio y le agradecemos su cooperación. Si tuviese alguna inquietud o necesitara asistencia, por favor no dude en contactarnos inmediatamente.

_____
Michel Chamoun
Coordinador de Comunicación / Equipo de Retiro
michel.chamoun@samiya.co / +1 (805) 308 4856 / +593 99 3182772
SAMIYAMEALS S.A.

SAMIYAMEALS S.A. / km. 19,5 vía a la Costa, Guayaquil - Ecuador

Claudio Innocenti

Annex 4

CHECKING THE EFFECTIVENESS OF THE RETIRO PROGRAM, CLASS I

Evaluation parameter	a / b	%	Guest reviews
Of the total consignees involved, how many were successfully contacted?			
Of the total number of consignees contacted, how many responded to the alert?			
Of the total number of unresponsive consignees, how many could finally be contacted?			
Of the total lots involved, how many were actually identified on day 1?			
Of the total customers involved, how many were identified on day 1?			
Of the total reported customers, how many were contacted within day 1?			
Of the total consignees involved, how many could be visited and assisted?			
Of the total customers contacted, how many are satisfied with the overall procedure?			
Of the total reported customers, how many followed retention and segregation instructions?			
Of the total kg of compromised product, how many kg were recovered during the incident?			
Key: Where a number of cases meet the question; and, b - total of possible cases; therefore, a/b sets the proportion of events that meet the condition on the universe of the question. Cell % must translate this ratio to percentage ([a/b]*100).			GLOBAL SCORE

Claudio Innocenti

GLOBAL SUPPORT: the sum of "a" divided for the sum of "b" multiplied by 100 will give the overall percentage score. A score of 80% and poor <80% is considered satisfactory.

SOP N°3

ALLERGEN CONTROL

Food Safety Management System

SAMIYAMEALS S.A

Guayaquil – Ecuador

09/01/2019

Table of Contents

1 Objective

To avoid cross-contamination caused by allergens and to ensure an effective management, control and labeling of allergen ingredients in case these are present in our premises or finished product.

2 Scope

The guidelines listed in this procedure apply to all production areas where there are exposed food products or finished products, as well as raw materials and ingredients.

3 Reference Framework

This document has been produced considering valuable information presented in the following literature written in Spanish:

BRC Global Standards. 2018. *Norma Mundial de Seguridad Alimentaria (Inocuidad de los Alimentos)*. Versión 8. Londres (GB): BRC. 124 p. ISBN 978-1-78490-350-3.

FAO (Food and Agriculture Organization). 2003. *Codex Alimentarius: Principios Generales de Higiene de los Alimentos.* CAC/RCP 1-1969. Roma (IT): Comisión del Codex Alimentarius; FAO. Disponible en el *World Wide Web*: <http://www.fao.org/input/download/standards/23/cxp_001s.pdf>

FSPCA (Food Safety Preventive Controls Alliance). 2016. *Controles Preventivos de Alimentos para Humanos: Manual del Participante*. 1ª Edición. Versión 1.2. Chicago (US): Institute for Food Safety and Health; FDA; FSPCA. Disponible en el *World Wide Web*: <https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food>

INEN (Instituto Ecuatoriano de Normalización). 2011. *Rotulado de Productos Alimenticios para Consumo Humano*: *NTE INEN 1334-1: 2011. Parte 1. Requisitos.* 3ª Revisión. Quito (EC): Instituto Ecuatoriano de Normalización. Disponible en el *World Wide Web*: <shorturl.at/dlpD1>

INEN (Instituto Ecuatoriano de Normalización). 2011. *Rotulado de Productos Alimenticios para Consumo Humano*: *NTE INEN 1334-2: 2011. Parte 2. Rotulado Nutricional. Requisitos*. 2ª Revisión. Quito (EC): Instituto Ecuatoriano de Normalización. Disponible en el *World Wide Web*: <shorturl.at/bwFM3>

INEN (Instituto Ecuatoriano de Normalización). 2011. Rotulado de Productos Alimenticios para Consumo Humano: NTE INEN 1334-3: 2011. Parte 3. Requisitos para Declaraciones Nutricionales y Declaraciones Saludables. 1ª Edición. Quito (EC): Instituto Ecuatoriano de Normalización. Disponible en el World Wide Web: <shorturl.at/tvxGI>

Primus Group, Inc. 2019. *PrimusGFS.* Versión 3.1. Santa María (US): Primus Labs; Primus Group Inc. Disponible en el *World Wide Web*: <http://primusgfs.com/documents.aspx>

4 Definitions

Allergen: a substance or food ingredient known to generate a hypersensitivity reaction or immune response in susceptible people after ingesting or being in contact with it. These food products or its derivatives are known as the big eight allergens: milk (dairy), eggs, fish, crustaceans, tree nuts, wheat, peanuts and soybeans (soy).

Control: a management tool within a process that is applied to its activities or developing actions, part of it, in order to guarantee that real operations are being executed as planned, according to reference criteria or limits set for that particular process.

Cross-contamination: the involuntary transfer of any substance, microorganism, material or ingredient, present on a surface or food product to another that does not have it in its formula, representing a potential risk to the consumer.

Disposable: single-use material, aimed to be used or consumed just one time and then discarded.

FSMS: Food Safety Management System.

Preventive control: any procedure, action or process that is executed based on a risk analysis, previously performed, aimed to reduce significantly a targeted risk or eliminate its occurrence as to protect the food safety of a product.

Re packaging: the act by which a finished product is packaged once again.

Sanitation: refers to the activities performed to clean and disinfect tools, utensils, work surfaces, premises and equipment in an effort to eliminate residues that represent potential contamination that could affect the quality of a product.

Supplier: any business or person offering a service to another (client). Business or person that provides a service to another after being hired for that purpose.

Verification: any process or action aimed to check that control or preventive measures are being applied as planned.

5 Responsibilities

In the following, responsible individuals are listed as well as a brief description of their roles within the allergen control program. Roles are listed after each responsible person.

5.1 Quality Assurance and Food Safety Management System Coordination

Also called Quality Coordinator for the purpose of this procedure.

- To verify that the guidelines outlined in this procedure are executed as described.

5.2 Quality Monitor

- To execute monitoring activities as to verify that transport of raw materials and premises are kept allergen-free.

- To validate constantly that all food-contact surfaces in production and storage areas are properly clean.
- To perform visual inspections over production people to ensure uniform and protection gear is being properly used and is kept clean and hygienic.

5.3 Quality Technician

- To create control logs for quality monitors to be used to in data collection, presented to and revised by the Quality Coordinator and then archived in the allergen control folder.
- To elaborate an allergen declaration to be signed by suppliers for packaging materials, raw material and ingredients as a standing commitment to allergen control and avoidance applied to their production and logistics chain.
- To create an allergen identification label to be used whenever an allergen ingredient arrives to the company's premises.

5.4 Food Safety Team

- To run a cause-analysis if the presence of an allergen is confirmed and reported.
- To execute a traceability study as to determine liable people and deviations, if an incident happens.
- To classify the reported incident and generate a case report outlining corrective actions to be implemented.

5.5 HACCP Team

- To provide training to production and warehouse personnel regarding allergen handling and labeling.
- To alert about any reported incident involving an identified allergen localized in the company's premises through written communication addressed to all people in the company.

6 Development

6.1 Risk analysis

Nº	Action	Responsible
1	To execute a risk-based analysis following HACCP principles to determine de presence or absence of allergen-associated risks and to apply preventive controls if needed. The performed risk-based analysis reveals no allergen-associated risks due to the total absence of allergen ingredients or inputs in the company's production process.	Food Safety Team

6.2 Controls applied to the supply chain

Nº	Action	Responsible
1	To require all packaging, raw material and ingredients suppliers to sign the allergen declaration form.	Quality Coordinator
2	To execute visual inspections to all cargo vehicles delivering raw materials, ingredients and packaging material, in search of any visible signs of allergens and record inspection findings in *SMY-AG-R-001 Truck reception*. The inspection frequency is for every delivery. The specific findings for packaging materials are recorded in *SMY-AC-R-001 Monitoring log for inspection of incoming carton boxes* and *SMY-AC-R-002 Monitoring log for inspection of incoming bags*. The targeted allergens for which inspections are held are those recognized by the FDA as the "big eight": peanuts, eggs, soybeans, tree nuts, crustaceans, fish, wheat and milk.	Quality Monitor
3	To check food ingredients and inputs are being properly labeled to verify the effective declaration of allergen components, if existing, according to the information stated in the products' specs provided by the respective supplier.	Receiving Lead / Quality Monitor

6.3 Controls applied to direct distribution chain for finished products

Nº	Action	Responsible
1	To execute an exhaustive inspection of all cargo vehicles responsible for transporting finished product in order to ensure proper cleanliness and hygiene as to avoid any chance of allergen residue existence that could represent a contamination risk. The frequency of inspection is per every cargo vehicle used to transport finished product. If applicable, “unit washing certificate” for reefer containers should be verified upon unit arrival to the company’s premises and before loading. This “unit washing certificate” is handled by logistics supplier carrying the reefer unit.	Shipping Lead

6.4 Preventive measures applied to facility personnel

Nº	Action	Responsible
1	To provide training regarding allergen-associated risks, control measures and proper labeling to production people as to avoid any chance of undesired cross-contamination.	HACCP Team
2	To execute routine inspections over production people as they enter to production areas after lunch, in order to ensure that guidelines to enter production areas are being properly followed as stated in the company’s Food Safety Policy.	Area Lead / Quality Monitor

6.5 Controls applied to allergen ingredients or containing allergen components

Nº	Action	Responsible
1	To properly label any allergen ingredient, if existing, with a special sticker label outlining the product name and explicitly indicating in capital letters “CONTAINS ALLERGEN” followed by the type of allergen present in the product, which could be: peanuts, eggs, soybeans, tree nuts, crustaceans, fish, wheat or milk.	Quality Technician
2	To keep all allergen ingredients properly labeled and identified in a specially designated safeguarded storage area administered exclusively by the Quality Department which is responsible for its release to be used under supervision.	Quality Coordinator

7 Corrective Actions

Currently, there are no identified allergens in any of the company's production processes or premises. If it happens that an allergen ingredient is found present in the company's premises, the Food Safety team is responsible of shutting down all undergoing processes in the production facility and start an investigation right away with Quality Technicians and Quality Monitors. Corrective actions will be determined by this same Food Safety team as soon as enough evidence is collected and research findings are revealed.

If any deviation occurs in any of the components described in this procedure, corrective actions must be applied. For this purpose, the document *SMY-SG-R-010 Request for action* must be completed and corrective actions applied according to its resolution.

8 Internal Documents and Filing Time

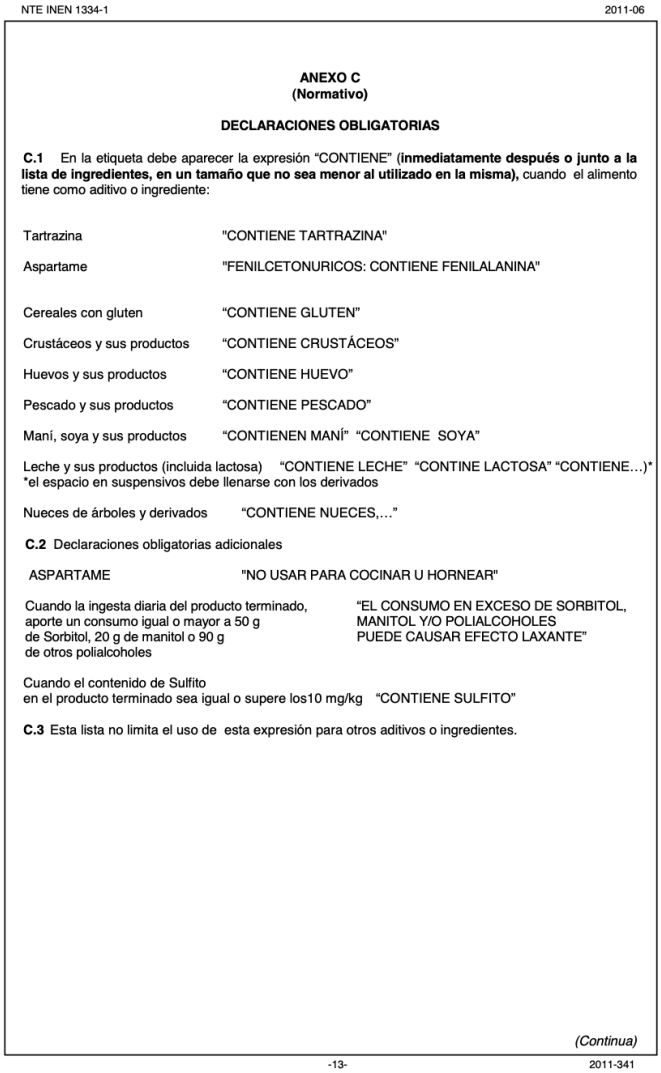
Document	Responsible	Timing
SMY-AG-R-001 Truck Reception	Quality Monitor	2 years
SMY-SG-R-003 GMP's Control Log		2 years
SMY-AC-R-001 Monitoring Log for Inspection of Incoming Carton Boxes		2 years
SMY-AC-R-002 Monitoring Log for Inspection of Incoming Bags		2 years
SMY-AC-N-001 Master Plan for Cleaning and Sanitation	Quality Coordinator / Quality Monitor / Production Coordinator / Area Leads	2 years
SMY-AC-R-027 Pre-Start of Process Cleanliness Inspection Log	Quality Coordinator / Quality Monitor / Production Coordinator / Area Leads	2 years

9 Annex

Annex 1: allergen labeling according to Ecuadorian INEN standard, 3rd revision.

Our product labeling for the local market is done following the guidelines presented on local standards: *NTE INEN 1334-3:2011*, *NTE INEN 1334-2:2011* and *NTE INEN 1334-3:2011-06*.

Regarding allergens, local standard *NTE INEN 1334-3:2011 Tercera revisión. Rotulado de Productos Alimenticios para Consumo Humano. Parte 1. Requisitos; en su Anexo C* states the following:



NTE INEN 1334-1 2011-06

ANEXO C
(Normativo)

DECLARACIONES OBLIGATORIAS

C.1 En la etiqueta debe aparecer la expresión "CONTIENE" (**inmediatamente después o junto a la lista de ingredientes, en un tamaño que no sea menor al utilizado en la misma),** cuando el alimento tiene como aditivo o ingrediente:

Tartrazina	"CONTIENE TARTRAZINA"
Aspartame	"FENILCETONURICOS: CONTIENE FENILALANINA"
Cereales con gluten	"CONTIENE GLUTEN"
Crustáceos y sus productos	"CONTIENE CRUSTÁCEOS"
Huevos y sus productos	"CONTIENE HUEVO"
Pescado y sus productos	"CONTIENE PESCADO"
Maní, soya y sus productos	"CONTIENEN MANÍ" "CONTIENE SOYA"
Leche y sus productos (incluida lactosa) *el espacio en suspensivos debe llenarse con los derivados	"CONTIENE LECHE" "CONTINE LACTOSA" "CONTIENE...)*
Nueces de árboles y derivados	"CONTIENE NUECES,..."

C.2 Declaraciones obligatorias adicionales

ASPARTAME	"NO USAR PARA COCINAR U HORNEAR"
Cuando la ingesta diaria del producto terminado, aporte un consumo igual o mayor a 50 g de Sorbitol, 20 g de manitol o 90 g de otros polialcoholes	"EL CONSUMO EN EXCESO DE SORBITOL, MANITOL Y/O POLIALCOHOLES PUEDE CAUSAR EFECTO LAXANTE"
Cuando el contenido de Sulfito en el producto terminado sea igual o supere los10 mg/kg	"CONTIENE SULFITO"

C.3 Esta lista no limita el uso de esta expresión para otros aditivos o ingredientes.

(Continua)

-13- 2011-341

Figure 1. *Anexo C: Declaraciones obligatorias* from local standard *NTE INEN 1334-3:2011. Rotulado de Productos Alimenticios para Consumo Humano*.

SOP N°7

CUSTOMER CLAIMS AND SUGGESTIONS MANAGEMENT

Food Safety Management System

SAMIYAMEALS S.A

Guayaquil – Ecuador

09/01/2019

Table of Contents

1 Objective

To define the responsive mechanisms and means of communication to attend, process and provide solutions to customer claims, as well as to take into consideration their suggestions for continuous improvement processes.

2 Scope

This procedure applies to the commercial department that manages customer relationships and service which is responsible of ensuring a satisfying purchasing experience.

3 Reference Framework

This document has been produced considering valuable information presented in the following literature written in Spanish:

BRC Global Standards. 2018. *Norma Mundial de Seguridad Alimentaria (Inocuidad de los Alimentos)*. Versión 8. Londres (GB): BRC. 124 p. ISBN 978-1-78490-350-3.

FSPCA (Food Safety Preventive Controls Alliance). 2016. *Controles Preventivos de Alimentos para Humanos: Manual del Participante*. 1ª Edición. Versión 1.2. Chicago (US): Institute for Food Safety and Health; FDA; FSPCA. Disponible en el *World Wide Web*: <https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food>

Primus Group, Inc. 2019. *PrimusGFS.* Versión 3.1. Santa María (US): Primus Labs; Primus Group Inc. Disponible en el *World Wide Web*: <http://primusgfs.com/documents.aspx>

4 Definitions

Case number: code assigned to a posted claim, through a claim treatment (CT), that is composed by the claim number plus the report number plus the document code. E.g. *ITR 002-19 SMY-AC-R-023*. The case number is shared with the customer for follow-up purposes.

Claim treatment (CT): internal document created by the company to approach a claim and investigate it, through the search of evidence and possible solutions. The code for this document is *SMY-AC-R-023*.

Claim treatment report (CTR): internal document created by the company to inform the customer about the findings, resolutions and corrective actions derived from a claim treatment case that has been successfully closed. The code for the CTR template is *SMY-AC-R-035*.

Claim: an assertion of discontentment, spoken or written, expressed by a customer towards a purchased product or service.

Commercial department: sales associates responsible of a customer account.

Consumer: final user of a product. The one who consumes the product.

Customer Claims' Group: private internal group of responsible multidisciplinary people created to attend and speed up the response to customers' claims. The contact email for customers to present

a claim is claims@samiya.co, while the internal group email to notify about a posted claim is reclamos-itr@samiya.co.

Customer: a person or business that has purchased goods (merchandise) from the company for its sale or distribution.

Defective product: any product, raw material, input, ingredient, intermediate or finished product that does not meet the quality or technical specs stated in the product's data sheet. It may include returned product by a customer.

Discontentment: the feeling of dissatisfaction experienced by a customer towards a product or his purchasing experience.

Dismissed claim: a claim that, after being analyzed, has no evidence or supporting background information so it is dismissed or rejected.

Document reception (DR): act by which the company receives requested documentation or evidence from the customer as supporting material for a claim treatment.

Elaboration date: date in which a product was manufactured. It may be abbreviated as "elab." or "fab.".

Expiration date: date in which a product expires. It may be abbreviated as "exp.".

FSMS: Food Safety Management System.

Informal claim: a claim that has been informed by a customer through informal means, without settling a formal or official communication to post the claim.

Lot code: set of characters, numeric or alfa-numeric, that allows to identify and track down a production lot or batch.

Merchandise: commercial goods sold to customers to be offered for sale in the market.

Performance indicators: the synthesis of quantitative or qualitative data that is analyzed to assess satisfaction level or goal achievement in customer service management. For the purpose of this procedure, this data refers to customer expectations, satisfaction level and claims incidence.

Source: for the purpose of this procedure, it refers to the place where a claim comes from or the customer who posts the claim. It may happen that one same client be considered as several sources if more than one point of sale exists under his ownership.

Verification: any process or action aimed to check that control or preventive measures are being applied as planned.

Verified claim: a claim that, after being analyzed through a CT process, has enough supporting evidence or background information to be accepted and acknowledged.

5 Responsibilities

5.1 Commercial Department

May be also called Sales

- To serve as a communication link between the customer and the Company in order to offer the necessary assistance to execute the claim treatment processing or implement customer suggestions.
- To manage the opening and closing of claim treatments along with the customer claims' group and terminating the claim treatment process when official communication is sent to the complaining customer.
- To represent the company after a customer when a claim is posted and claim treatment is in development.

5.2 Quality Assurance and FSMS Coordinator

- To input information into customer claims log and assign case number to posted claims.
- To open and close the claim management process through the creation and completion of a CT document.
- To determine the coordinator or any other person in charge of researching and collecting evidence in a claim treatment according to the area involved in the claim.
- To revise the proposed action plan and present it to the Commercial Department representative.

5.3 Area Coordinators

- To communicate research outcomes to the Quality Department, in case research is being conducted by another coordination, in order to fill in the CTR document.
- To propose an action plan according to the findings and outcomes derived from the research process performed with other coordinators.
- To lead the research process in order to gather supporting evidence.
- To determine the root-cause of the incident by analyzing the claim, according to the area or areas involved.

5.4 Customer Claims' Group

- To call for claims and statistics assessment meetings on a semestral basis in order to analyze root causes and avoid their occurrence or reproduction in the future.

6 Development

6.1 Customer suggestions

Nº	Action	Responsible
1	To receive suggestions from customers and communicate them via email to the corresponding area coordinator according to the field of action of the suggested.	Commercial Department
2	To provide follow-up to the addressed coordinator or team as to verify the execution of the suggestion, as long as it is feasible.	

6.2 Customer claim generation

Nº	Action	Responsible
1	To receive posted claim, in a formal or informal way, through any of the following means: i) Phone call, email or physical note (e.g. letter, memo, etc.). ii) Meeting with customer or follow-up visit. iii) Customer inspection or visit to company premises	Commercial Department
2	To formalize the claim reception via email sent to customer and request graphic evidence and supporting documents for claim.	
3	To inform the Customer Claims Group, via email, about the posted claim in order to open the CT case and attach evidence sent by customer.	

6.3 Claim recording and enabling actions to open a CT process

Nº	Action	Responsible
1	To input shared information regarding the claim, fill in the document *SMY-VT-R-003 Customer Claims List* and request the Commercial Department delegate any missing information for traceability purposes that should be sent by customer.	Quality Assurance and FSMS Coordinator

6.3 Claim recording and enabling actions to open a CT process (continued)

Nº	Action	Responsible
2	To coordinate inspection visit to customer's premises as to verify what is being claimed or request the customer to send over samples to be analyzed. **DR / Important:** if the samples are not received from the customer within the next 2 weeks after being requested, the claim is classified as **dismissed claim**.	Quality Assurance and FSMS Coordinator

6.4 Opening of claim treatment process and creation of CT document

Nº	Action	Responsible
1	To create a CT file and assign case number, considering the following: i) If the claim involves more than one defect, a CT is created for each defect. ii) If several claims are posted from different sources but relating to the same defect, a CT is created for each source posting the claim. iii) If several claims are posted from the same source but these are all related to the same probable cause, then just one CT is created.	Quality Assurance and FSMS Coordinator
2	To indicate the area coordinator that will investigate the case and fill in the CT file, if applicable, and notify the responsible, via email with TR file attached, with copy to the Commercial Department.	

6.5 Claim treatment process, completion and communication of CTR

Nº	Action	Responsible
1	To analyze the claim, conduct investigation for findings and evidence collection, and, fill in document *SMY-AC-R-023* to be sent to the Quality Assurance and FSMS Coordinator.	Area Coordinator
2	To verify reported information and findings in CT.	Quality Assurance and FSMS Coordinator
3	To offer help in assisting corrections or necessary adjustments to presented information in CT, if needed.	
4	To send revised CT to the CEO, or his delegate.	
5	To revise CT and if found compliant, proceed with written approval via email addressed to the Quality Assurance and FSMS Coordinator.	CEO
6	To create CTR file and send it to the Commercial Department following approved CT. **DR / Important:** upon customer request, *Request for Action* files from the customer itself may be used and attached to CTR.	Quality Assurance and FSMS Coordinator
7	To revise and acknowledge reported information in CTR and then communicate the customer via email about CTR resolution where the claim was either classified as **accepted** or **dismissed**. CTR must be attached.	Commercial Department
8	To inform the Customer Claims Group about CTR resolution, leaving the case open until all actions listed in resolution are applied.	

6.6 Execution of derived actions and closing process for CTR

Nº	Action	Responsible
1	To execute the measures stated in CTR resolution, previously informed to the Quality Assurance and FSMS Coordinator, which may be: i) Replace product, generate credit note, product destruction, etc.	Commercial Department
1.1.	To follow guidelines outlined in procedure *SMY-SG-P-006 Recall and crisis management*, if recalling is a listed measure in CTR file.	

6.6 Execution of derived actions and closing process for CTR (continued)

Nº	Action	Responsible
2	To record the executed actions as per CTR resolution in document *SMY-VT-R-003 Customer Claims List*.	Quality Assurance and FSMS Coordinator
3	To verify that listed actions in CTR resolution have been executed as planned. If so, proceed with approval and send to Customer Claims Group the "closed claim treatment process" declaration notice via email.	
4	To communicate the customer via email that the CTR has been closed and archived, signaling the termination of the claim treatment.	Commercial Department
5	To record response dates from Commercial Department to customer in document *SMY-VT-R-003 Customer Claims List* along with relevant observations or comments from the customer that were shared by the Commercial Department.	Quality Assurance and FSMS Coordinator

6.7 Monitoring and effectiveness strengthening actions for claim management

Nº	Action	Responsible
1	To input statistics in "claims data base" to be used as a decision-making tool for improvement measures.	Quality Assurance and FSMS Coordinator
2	To call for a claims' revision and assessment meeting on a semestral basis to promote improvement measures. The outcomes of said meetings should be recorded in document *SMY-SG-R-004 Meeting Minute*.	Customer Claims' Group
3	To request execution of action by filling in the document *SMY-SG-R-019 Request for Action* and then communicate the responsible personnel about action to take in order to implement corrective, preventive or improvement measures accordingly.	Quality Assurance and FSMS Coordinator

7 Corrective actions

If any deviation occurs in any of the components described in this procedure, corrective actions must be applied. For this purpose, the document *SMY-SG-R-010 Request for action* must be completed and corrective actions applied according to its resolution.

8 Internal documents and filing time

Document	Responsible	Timing
SMY-VT-R-003 Customer Claims List	Quality Assurance and FSMS Coordinator	2 years
SMY-AC-R-023 Claim Treatment		2 years
SMY-SG-R-010 Request for Action		2 years
SMY-AC-R-035 Claim Treatment Report		2 years
SMY-SG-P-006 Recall and crisis management procedure		Permanent

9 Annex

Report: 21-09/0089-M001

Client data

Name:	SAMIYAMEALS SA	**Telephone:**	0981561340
Address:	GUAYAS / GUAYAQUIL / TARQUI / SOLAR 88A		

Sample identification / label

Name:	Frozen Hawaiian Patacon	**Sample code:**	21-09/0089-M001
Commercial brand:	Samiya	**Batch:**	1009650-9
Reference rules:	NUTRITIONAL TABLE: CEREALS	**Elaboration date:**	09/10/2021
Container:	LDPE plastic sheath	**Expiration date:**	03/09/2022
Sample preservation:	Freezing -24ºC to -18ºC	**Reception date:**	09/22/2021
Analysis date:	09/22/2021	**Useful life:**	5 months 27 days
Declared net content:	200g		
Presentations:	2lbs; 3lbs; 2.5lbs; 4lbs		
Cond. climatic conditions of the test:	Temperature 22.5 ºC ± 2.5 ºC and Relative Humidity 55% ± 15%		

Physicochemical analysis

Tests carried out	Unit	Result	Requirements	Methods/Ref.
Humidity *	%	60.13	---	ISO1026:1982 *
protein *	%	1.75	---	AOAC 21st 920.87 *
ashes *	%	1.29	---	NTE INEN 401:2013 *
Fat *	%	3.23	---	AOAC 21st 2003.06 *
Unsaturated fatty acids º*	%	2.19	---	PEE-LASA-FQ-47 (AOAC 996.06 - AOAC 963.22) º*
Monounsaturated fatty acids º*	%	1.70	---	PEE-LASA-FQ-47 (AOAC 996.06 - AOAC 963.22) º*
Polyunsaturated fatty acids º*	%	0.49	---	PEE-LASA-FQ-47 (AOAC 996.06 - AOAC 963.22) º*
Saturated fatty acids º*	%	1.04	---	PEE-LASA-FQ-47 (AOAC 996.06 - AOAC 963.22) º*
Trans Fatty Acids*	%	0.00	---	PEE-LASA-FQ-47 (AOAC 996.06 - AOAC 963.22) º*
Cholesterol *	mg/100g	<1.00	---	HPLC UV/VIS (ME02-PG20-PO02-7.2C) *
Sodium *	mg/100g	0.24	---	AOAC 21st 985.35 *

receplab@espol.edu.ec • ventasprotal@espol.edu.ec • cotizacionesprotal@espol.edu.ec
Guayaquil - Ecuador
Campus Gustavo Galindo Velasco • Km 30.5 Via Perimetral – Pbx: (593-4) 2269 733 www.espol.edu.ec

Report: 21-09/0089-M001

Sodium *	%	0.00024	---	Calculation *
Sodium chloride *	%	0.00	---	Selective electrode *
Carbohydrates by difference *	%	33.60	---	Calculation *
Total sugars per investment *	%	1.79	---	Lane & Enyon *

The laboratory discharges responsibility for the information provided by the client that may affect the validity of its results. The results issued apply exclusively to the sample(s) received in the conditions delivered by the client.

The opinions / interpretations / observations, etc. listed below are outside the scope of SAE accreditation.

The results issued correspond exclusively to the sample and the information provided by the client.

The bromatological parameters requested by the client were carried out.

° The subcontracted results are registered in the report INF.LASA-06-10-21-4722.

Subcontracting Laboratory: SAE LEN 06-002.

Note: The reported values of fatty acids are calculated based on the percentage of fat.

Protein = (%N x 6.25)

GENERAL CONSIDERATIONS	
Uncredited Parameters	*
Sub-contracted Parameters	either
In microbiology (according to the method): < 1.0, < 1.1, < 1.8, < 2, < 3, and < 10	**IT IS CONSIDERED ABSENCE**
Maximum conservation of the sample after the study and delivery of results.	**10 DAYS**
Maximum period for reprinting results reports from its issuance.	**5 YEARS**
Maximum term for requesting changes or reviews of the results report, after its delivery. (The request must be technically justified at the discretion of the laboratory).	**6 MONTHS**
Document validity, physical or digital. (Print or PDF)	**ONLY WITH SIGNATURE AUTHORIZED ORIGINAL**
Total or partial reproduction of this document by any means without written permission from Laboratory PROTAL.	**PROHIBITED**

DECISION RULE FOR THE DECLARATION OF CONFORMITY	
The laboratory documents the decision rule with the client before entering the test item and under no circumstances may modifications be made due to suppression of the uncertainty value, change of regulations, change of requirements, etc.	
For this, the following criteria will be considered:	
CRITERION	VALUE TO DECLARE
For parameters that have a maximum compliance requirement, if the measurement result plus the expanded uncertainty does not exceed the maximum requirement.	**YES COMPLIANT**
For parameters that have a maximum requirement of compliance, if the test result plus the expanded uncertainty exceeds the maximum requirement.	**FAILS**
For parameters that have a minimum compliance requirement, if the test result minus the expanded uncertainty exceeds the minimum requirement.	**YES COMPLIANT**
For parameters that have a minimum compliance requirement, if the test result minus the expanded uncertainty is less than the minimum requirement.	**FAILS**

receplab@espol.edu.ec • ventasprotal@espol.edu.ec • cotizacionesprotal@espol.edu.ec
Guayaquil - Ecuador
Campus Gustavo Galindo Velasco • Km 30.5 Via Perimetral – Pbx: (593-4) 2269 733 www.espol.edu.ec

Report: 21-09/0089-M001

Guayaquil, October 08, 2021

Digitally signed by

Dr. Gloria Bajaña Jurado de Pacheco

EXECUTIVE DIRECTOR

receplab@espol.edu.ec • ventasprotal@espol.edu.ec • cotizacionesprotal@espol.edu.ec
Guayaquil - Ecuador
Campus Gustavo Galindo Velasco • Km 30.5 Via Perimetral – Pbx: (593-4) 2269 733 www.espol.edu.ec

Report: 21-09/0089-M002

Client data

Name:	SAMIYAMEALS SA	**Telephone:**	0981561340
Address:	GUAYAS / GUAYAQUIL / TARQUI / SOLAR 88A		

Sample identification / label

Name:	Ripe Cracked Frozen	**Sample code:**	21-09/0089-M002
Commercial brand:	Samiya	**Batch:**	1409646-1
Reference rules:	NUTRITIONAL TABLE: CEREALS	**Elaboration date:**	09/14/2021
Container:	LDPE plastic sheath	**Expiration date:**	03/13/2022
Sample preservation:	Freezing -24ºC to -18ºC	**Reception date:**	09/22/2021
Analysis date:	09/22/2021	**Useful life:**	5 months 27 days
Declared net content:	200g		
Presentations:	2lbs; 3lbs; 4lbs; 5lbs; 6lbs		
Cond. climatic conditions of the test:	Temperature 22.5 ºC ± 2.5 ºC and Relative Humidity 55% ± 15%		

Physicochemical analysis

Tests carried out	Unit	Result	Requirements	Methods/Ref.
Humidity *	%	55.71	---	ISO1026:1982 *
protein *	%	1.24	---	AOAC 21st 920.87 *
ashes *	%	1.09	---	NTE INEN 401:2013 *
Fat *	%	1.18	---	AOAC 21st 2003.06 *
Unsaturated fatty acids º*	%	0.70	---	PEE-LASA-FQ-47 (AOAC 996.06 - AOAC 963.22) º*
Monounsaturated fatty acids º*	%	0.60	---	PEE-LASA-FQ-47 (AOAC 996.06 - AOAC 963.22) º*
Polyunsaturated fatty acids º*	%	0.10	---	PEE-LASA-FQ-47 (AOAC 996.06 - AOAC 963.22) º*
Saturated fatty acids º*	%	0.48	---	PEE-LASA-FQ-47 (AOAC 996.06 - AOAC 963.22) º*
Trans Fatty Acids*	%	0.00	---	PEE-LASA-FQ-47 (AOAC 996.06 - AOAC 963.22) º*
Cholesterol *	mg/100g	<1.00	---	HPLC UV/VIS (ME02-PG20-PO02-7.2C) *
Sodium *	mg/100g	0.24	---	AOAC 21st 985.35 *

receplab@espol.edu.ec • ventasprotal@espol.edu.ec • cotizacionesprotal@espol.edu.ec
Guayaquil - Ecuador
Campus Gustavo Galindo Velasco • Km 30.5 Via Perimetral – Pbx: (593-4) 2269 733 www.espol.edu.ec

Report: 21-09/0089-M002

Sodium *	%	0.00024	---	Calculation *
Sodium chloride *	%	0.00	---	Selective electrode *
Carbohydrates by difference *	%	40.78	---	Calculation *
Total sugars per investment *	%	27.81	---	Lane & Enyon *

The laboratory discharges responsibility for the information provided by the client that may affect the validity of its results. The results issued apply exclusively to the sample(s) received in the conditions delivered by the client.

The opinions / interpretations / observations, etc. listed below are outside the scope of SAE accreditation.

The results issued correspond exclusively to the sample and the information provided by the client.

The bromatological parameters requested by the client were carried out.

° The subcontracted results are registered in the report INF.LASA-06-10-21-4723.

Subcontracting Laboratory: SAE LEN 06-002.

Note: The reported values of fatty acids are calculated based on the percentage of fat.

Protein = (%N x 6.25)

GENERAL CONSIDERATIONS	
Uncredited Parameters	*
Sub-contracted Parameters	either
In microbiology (according to the method): < 1.0, < 1.1, < 1.8, < 2, < 3, and < 10	**IT IS CONSIDERED ABSENCE**
Maximum conservation of the sample after the study and delivery of results.	**10 DAYS**
Maximum period for reprinting results reports from its issuance.	**5 YEARS**
Maximum term for requesting changes or reviews of the results report, after its delivery. (The request must be technically justified at the discretion of the laboratory).	**6 MONTHS**
Document validity, physical or digital. (Print or PDF)	**ONLY WITH SIGNATURE AUTHORIZED ORIGINAL**
Total or partial reproduction of this document by any means without written permission from Laboratory PROTAL.	**PROHIBITED**

DECISION RULE FOR THE DECLARATION OF CONFORMITY	
The laboratory documents the decision rule with the client before entering the test item and under no circumstances may modifications be made due to suppression of the uncertainty value, change of regulations, change of requirements, etc.	
For this, the following criteria will be considered:	
CRITERION	VALUE TO DECLARE
For parameters that have a maximum compliance requirement, if the measurement result plus the expanded uncertainty does not exceed the maximum requirement.	**YES COMPLIANT**
For parameters that have a maximum requirement of compliance, if the test result plus the expanded uncertainty exceeds the maximum requirement.	**FAILS**
For parameters that have a minimum compliance requirement, if the test result minus the expanded uncertainty exceeds the minimum requirement.	**YES COMPLIANT**
For parameters that have a minimum compliance requirement, if the test result minus the expanded uncertainty is less than the minimum requirement.	**FAILS**

receplab@espol.edu.ec • ventasprotal@espol.edu.ec • cotizacionesprotal@espol.edu.ec
Guayaquil - Ecuador
Campus Gustavo Galindo Velasco • Km 30.5 Via Perimetral – Pbx: (593-4) 2269 733
www.espol.edu.ec

Report: 21-09/0089-M002

Guayaquil, October 08, 2021

Digitally signed by

Dr. Gloria Bajaña Jurado de Pacheco

EXECUTIVE DIRECTOR

receplab@espol.edu.ec • ventasprotal@espol.edu.ec • cotizacionesprotal@espol.edu.ec
Guayaquil - Ecuador
Campus Gustavo Galindo Velasco • Km 30.5 Via Perimetral – Pbx: (593-4) 2269 733 www.espol.edu.ec

Report: 21-09/0089-M003

Client data

Name:	SAMIYAMEALS SA	**Telephone:**	0981561340
Address:	GUAYAS / GUAYAQUIL / TARQUI / SOLAR 88A		

Sample identification / label

Name:	Ripe Cracked Frozen	**Sample code:**	21-09/0089-M003
Commercial brand:	Samiya	**Batch:**	1409646-1
Reference rules:	NTS N - MINSA/DIGESA-V.01 . XV.1 Prepared Meals without heat treatment (raw salads, mayonnaise, potato sauce huancaina, ocopa, desserts, juices, others). prepared foods that contain ingredients with and without heat treatment (mixed salads, stuffed avocado, sandwiches, cebiche, desserts, soft drinks, others).	**Elaboration date:**	09/14/2021
Container:	LDPE plastic sheath	**Expiration date:**	03/13/2022
Sample preservation:	Freezing -24ºC to -18ºC	**Reception date:**	09/22/2021
Analysis date:	09/22/2021	**Useful life:**	5 months 27 days
Declared net content:	200g		
Presentations:	2lbs; 3lbs; 4lbs; 5lbs; 6lbs		
Cond. climatic conditions of the test:	Temperature 22.5 ºC ± 2.5 ºC and Relative Humidity 55% ± 15%		

Microbiologic analysis

Tests carried out	Unit	Result	Requirements	Methods/Ref.
Aerobic mesophilic	CFU/g	<10	m: 10^5	AOAC 21st 966.23 (ME03-PG20-PO02-7.2M)
Total coliforms *	CFU/g	<10	m: 10^2	AOAC 21st 991.14 *
Staphylococcus aureus *	CFU/g	<10	m: 10	AOAC 21st 2003:07 *
Escherichia coli*	CFU/g	<10	m: 10	AOAC 21st 991.14 *
Salmonella spp.	Absence/Presence	Absence	m: Absence	AOAC 21st 967.26 (ME20-PG20-PO02-7.2M)

The laboratory discharges responsibility for the information provided by the client that may affect the validity of its results. The results issued apply exclusively to the sample(s) received in the conditions delivered by the client.

receplab@espol.edu.ec • ventasprotal@espol.edu.ec • cotizacionesprotal@espol.edu.ec
Guayaquil - Ecuador
Campus Gustavo Galindo Velasco • Km 30.5 Via Perimetral – Pbx: (593-4) 2269 733
www.espol.edu.ec

Report: 21-09/0089-M003

The opinions / interpretations / observations, etc. listed below are outside the scope of SAE accreditation.

The results issued correspond exclusively to the sample and the information provided by the client.

The analyzed sample DOES meet the microbiological requirements requested by the client for PREPARED FOODS WITHOUT THERMAL TREATMENT, according to the NTS Standard No. - MINSA/DIGESA-V.01. Prepared foods containing ingredients with and without heat treatment XV.1. Processed Foods XV. health standard that Establishes the Microbiological Criteria for Sanitary Quality and Safety for Food and Beverages for Human Consumption. The microbiological results are registered in the internal microbiology workbook, on page 21-04898.

GENERAL CONSIDERATIONS	
Uncredited Parameters	*
Sub-contracted Parameters	either
In microbiology (according to the method): < 1.0, < 1.1, < 1.8, < 2, < 3, and < 10	**IT IS CONSIDERED ABSENCE**
Maximum conservation of the sample after the study and delivery of results.	**10 DAYS**
Maximum period for reprinting results reports from its issuance.	**5 YEARS**
Maximum term for requesting changes or reviews of the results report, after its delivery. (The request must be technically justified at the discretion of the laboratory).	**6 MONTHS**
Document validity, physical or digital. (Print or PDF)	**ONLY WITH SIGNATURE AUTHORIZED ORIGINAL**
Total or partial reproduction of this document by any means without written permission from Laboratory PROTAL.	**PROHIBITED**

DECISION RULE FOR THE DECLARATION OF CONFORMITY	
The laboratory documents the decision rule with the client before entering the test item and under no circumstances may modifications be made due to suppression of the uncertainty value, change of regulations, change of requirements, etc.	
For this, the following criteria will be considered:	
CRITERION	VALUE TO DECLARE
For parameters that have a maximum compliance requirement, if the measurement result plus the expanded uncertainty does not exceed the maximum requirement.	**YES COMPLIANT**
For parameters that have a maximum requirement of compliance, if the test result plus the expanded uncertainty exceeds the maximum requirement.	**FAILS**
For parameters that have a minimum compliance requirement, if the test result minus the expanded uncertainty exceeds the minimum requirement.	**YES COMPLIANT**
For parameters that have a minimum compliance requirement, if the test result minus the expanded uncertainty is less than the minimum requirement.	**FAILS**

receplab@espol.edu.ec • ventasprotal@espol.edu.ec • cotizacionesprotal@espol.edu.ec
Guayaquil - Ecuador
Campus Gustavo Galindo Velasco • Km 30.5 Via Perimetral – Pbx: (593-4) 2269 733
www.espol.edu.ec

Report: 21-09/0089-M003

Guayaquil, October 04, 2021

Digitally signed by

Dr. Gloria Bajaña Jurado de Pacheco

EXECUTIVE DIRECTOR

receplab@espol.edu.ec • ventasprotal@espol.edu.ec • cotizacionesprotal@espol.edu.ec
Guayaquil - Ecuador
Campus Gustavo Galindo Velasco • Km 30.5 Via Perimetral – Pbx: (593-4) 2269 733
www.espol.edu.ec

Report: 21-09/0089-M004

Client data

Name:	SAMIYAMEALS SA	**Telephone:**	0981561340
Address:	GUAYAS / GUAYAQUIL / TARQUI / SOLAR 88A		

Sample identification / label

Name:	Frozen Hawaiian Patacon	**Sample code:**	21-09/0089-M004
Commercial brand:	Samiya	**Batch:**	1009650-9
Reference rules:	NTS N - MINSA/DIGESA-V.01 . XV.1 Prepared Meals without heat treatment (raw salads, mayonnaise, potato sauce huancaina, ocopa, desserts, juices, others). prepared foods that contain ingredients with and without heat treatment (mixed salads, stuffed avocado, sandwiches, cebiche, desserts, soft drinks, others).	**Elaboration date:**	09/10/2021
Container:	LDPE plastic sheath	**Expiration date:**	03/09/2022
Sample preservation:	Freezing -24ºC to -18ºC	**Reception date:**	09/22/2021
Analysis date:	09/22/2021	**Useful life:**	5 months 27 days
Declared net content:	200g		
Presentations:	2lbs; 3lbs; 4lbs; 2.5lbs;		
Cond. climatic conditions of the test:	Temperature 22.5 ºC ± 2.5 ºC and Relative Humidity 55% ± 15%		

Microbiologic analysis

Tests carried out	Unit	Result	Requirements	Methods/Ref.
Aerobic mesophilic	CFU/g	<10	m: 10^5	AOAC 21st 966.23 (ME03-PG20-PO02-7.2M)
Total coliforms *	CFU/g	<10	m: 10^2	AOAC 21st 991.14 *
Staphylococcus aureus *	CFU/g	<10	m: 10	AOAC 21st 2003:07 *
Escherichia coli*	CFU/g	<10	m: 10	AOAC 21st 991.14 *
Salmonella spp.	Absence/Presence	Absence	m: Absence	AOAC 21st 967.26 (ME20-PG20-PO02-7.2M)

The laboratory discharges responsibility for the information provided by the client that may affect the validity of its results. The results issued apply exclusively to the sample(s) received in the conditions delivered by the client.

receplab@espol.edu.ec • ventasprotal@espol.edu.ec • cotizacionesprotal@espol.edu.ec
Guayaquil - Ecuador
Campus Gustavo Galindo Velasco • Km 30.5 Via Perimetral – Pbx: (593-4) 2269 733
www.espol.edu.ec

Report: 21-09/0089-M004

The opinions / interpretations / observations, etc. listed below are outside the scope of SAE accreditation.

The results issued correspond exclusively to the sample and the information provided by the client.

The analyzed sample DOES meet the microbiological requirements requested by the client for PREPARED FOODS WITHOUT THERMAL TREATMENT, according to the NTS Standard No. - MINSA/DIGESA-V.01. Prepared foods containing ingredients with and without heat treatment XV.1. Processed Foods XV. health standard that Establishes the Microbiological Criteria for Sanitary Quality and Safety for Food and Beverages for Human Consumption. The microbiological results are registered in the internal microbiology workbook, on page 21-04899.

GENERAL CONSIDERATIONS	
Uncredited Parameters	*
Sub-contracted Parameters	either
In microbiology (according to the method): < 1.0, < 1.1, < 1.8, < 2, < 3, and < 10	**IT IS CONSIDERED ABSENCE**
Maximum conservation of the sample after the study and delivery of results.	**10 DAYS**
Maximum period for reprinting results reports from its issuance.	**5 YEARS**
Maximum term for requesting changes or reviews of the results report, after its delivery. (The request must be technically justified at the discretion of the laboratory).	**6 MONTHS**
Document validity, physical or digital. (Print or PDF)	**ONLY WITH SIGNATURE AUTHORIZED ORIGINAL**
Total or partial reproduction of this document by any means without written permission from Laboratory PROTAL.	**PROHIBITED**

DECISION RULE FOR THE DECLARATION OF CONFORMITY	
The laboratory documents the decision rule with the client before entering the test item and under no circumstances may modifications be made due to suppression of the uncertainty value, change of regulations, change of requirements, etc.	
For this, the following criteria will be considered:	
CRITERION	VALUE TO DECLARE
For parameters that have a maximum compliance requirement, if the measurement result plus the expanded uncertainty does not exceed the maximum requirement.	**YES COMPLIANT**
For parameters that have a maximum requirement of compliance, if the test result plus the expanded uncertainty exceeds the maximum requirement.	**FAILS**
For parameters that have a minimum compliance requirement, if the test result minus the expanded uncertainty exceeds the minimum requirement.	**YES COMPLIANT**
For parameters that have a minimum compliance requirement, if the test result minus the expanded uncertainty is less than the minimum requirement.	**FAILS**

receplab@espol.edu.ec • ventasprotal@espol.edu.ec • cotizacionesprotal@espol.edu.ec
Guayaquil - Ecuador
Campus Gustavo Galindo Velasco • Km 30.5 Via Perimetral – Pbx: (593-4) 2269 733
www.espol.edu.ec

Report: 21-09/0089-M004

Guayaquil, October 04, 2021

Digitally signed by

Dr. Gloria Bajaña Jurado de Pacheco

EXECUTIVE DIRECTOR

receplab@espol.edu.ec • ventasprotal@espol.edu.ec • cotizacionesprotal@espol.edu.ec
Guayaquil - Ecuador
Campus Gustavo Galindo Velasco • Km 30.5 Via Perimetral – Pbx: (593-4) 2269 733
www.espol.edu.ec

PRIMUSGFS AUDIT NUMBER: **244671**
CB REGISTRATION No.: **PA-PGFS-16706**
AUDIT DATE: **Dec 13, 2021**

Revision 1

CERTIFICATE

Issued to:

ORGANIZATION

SAMIYAMEALS S.A.

KM. 19,5 VIA A LA COSTA, FRENTE AL RECINTO NUEVA ESPERANZA. GUAYAQUIL, GUAYAS 090115, Ecuador

OPERATION

SAMIYAMEALS S.A.
km. 19,5 via a la Costa Guayaquil, Guayas 090115, Ecuador
Operation type: PROCESSING

PRELIMINARY AUDIT SCORE:	CERTIFICATE VALID FROM:	FINAL AUDIT SCORE:
92%	**Jan 24, 2022 To Jan 23, 2023**	**97%**

Primus Auditing Operations certifies that this operation has complied with the applicable requirements of PrimusGFS Version 3.1

See subsequent certificate page(s) for audit executive summary

ANAB
ANSI National Accreditation Board
ACCREDITED
ISO/IEC 17065
PRODUCT CERTIFICATION BODY
#1183
ISO/IEC 17065
Product Certification Body

Primus AuditingOps
Observe. Report.

Primus Auditing Operations | 1265 Furukawa way | Santa Maria
California 93458 United States |
primusgfsqa@primusauditingops.com | 805.623.5563 | 805.352.1364

Authorized by:
President
Javier Sollozo

DOCUMENT REVIEWED AND ASSESSED BY CLAUDIO INNOCENTI (PARTNER & PCQI) ON OR ABOUT FSVP PLAN'S NOTED REVIEW START/END DATES

CONFIDENTIAL TREATMENT REQUESTED

Claudio Innocenti

CERTIFICATE VALID FROM:

Jan 24, 2022 To Jan 23, 2023

AUDIT TYPE:

Announced Audit

AUDIT EXECUTIVE SUMMARY:

Installation audit with operation of the process of ripe plantain and green plantain (patacón) of the company SAMIYAMEALS SA Conventional product, two lines where three processes are worked non-simultaneously: ripe for frozen frying, patacón for frozen frying and chips (frying). The product is received from third parties, for ripening: the product is subjected to maturation with ethylene if necessary, it is peeled (not washed), it is sliced manually, it is fried (PCC1 160+-10ºC/1-3 min and no more than 24% TPM), it is placed in extended trays, frozen for 6-8 h until it has a thermal center of -18ºC, it is emptied to the packaging line, it is packed in bags, they are thermally sealed, they go through a metal detector (PCC2), they are packed in previously coded cardboard boxes with traceability, they are stored cold at -18ºC until they are shipped. In the Patacón process, the green plantain is blanched (80+-10ºC for 1-3 min), peeled, sliced manually, fried (PCC1 150+-10ºC/6-8 min and no more than 24% TPM) , may or may not be pressed at the customer's request, it is spread out on trays, frozen at -20ºC for 6-8 hours until it has a thermal center of -18ºC, it is packed, passed through a metal detector (PCC2) and stored as mature. Chips are blanched, peeled, mechanically cut (7-8 mm thick), fried (150+-10ºC/2-3 min), pressed (1.5-2 mm thick),It is automatically extended in a band that goes on to second frying (PCC1 170+-10ºC/3-4 min and no more than 24% TPM), salt is manually added, it is cooled to room temperature, it is manually packed in bags (laminated or high density), sealed, passed through a metal detector (PCC2), packed in labeled cardboard boxes, stored and shipped. In the three processes the metal detector PCC2 Fe 3.5 mm, Inox316 4.5 mm, NoFe 4 mm. There are 3 freezing tunnels, 2 storage tunnels, a packaging material warehouse, a finished product warehouse for Chips, and a maturation area. 60 workers are reported. allergen free The destination of the product is the United States and Ecuador.

Addendum(s) included in the audit:

Not Applicable

CERTIFICATE VALID FROM:

Jan 24, 2022 To Jan 23, 2023

Product information for each product			
Product Group/Product Name	**Observed Product**	**Seasonality**	**Country of destination for product**
Plantains, Processed (See Scope)	Observed on the day of audit	Year round	Ecuador, United States

THE

FOOD PROTECTION AND DEFENSE INSTITUTE

RECOGNIZES

MICHEL CHAMOUN YUNES

FOR COMPLETING

Food Defense and Intentional Adulteration Rule Training

Training Objectives:

- Define and differentiate food protection, food safety, food defense, and food security
- Explain food defense awareness and preparedness
- Understand Intentional Adulteration Rule requirements
- Acquire knowledge and training to prepare a food defense plan including:
  - Vulnerability Assessment by Key Activity Types*
  - Identification and Explanation of Mitigation Strategies*,
  - Mitigation Strategies Management Components, and
  - Food Defense Plan Reanalysis*

TRAINING COMPLETED ON

February 19, 2020

Jennifer van de Ligt, PhD
Director, Food Protection and Defense Institute

The Food Protection and Defense Institute is an Emeritus U.S. Department of Homeland Security Center of Excellence at the University of Minnesota

*The IA Rule requires that individuals conducting or overseeing these tasks "have successfully completed training for the specific function at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities" (21 CFR 121.4(c)(2)). FPDI works diligently to assure our training program approach, detail, and materials are regularly updated to align with the most current interpretation and guidance for the IA Rule. As such, we believe that our program meets the IA rule training requirement of at least equivalent to the FDA standardized curriculum.

FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

MICHEL CHAMOUN YUNES

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

FSPCA Intentional Adulteration Vulnerability Assessments

delivered by Lead Instructor

Ned Mitenius

completed on

02/20/2020

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

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # dfe6d18b

DOCUMENT REVIEWED AND ASSESSED BY CLAUDIO INNOCENTI (PARTNER & PCQI) ON OR ABOUT FSVP PLAN'S NOTED REVIEW START/END DATES

CONFIDENTIAL TREATMENT REQUESTED

Claudio Innocenti

FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

MICHEL ANTOINE CHAMOUN YUNES

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

FSPCA Preventive Controls for Human Food

delivered by Lead Instructor

Cynthia Vargas

completed on

09/30/2018

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

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # 7e50b26b

DOCUMENT REVIEWED AND ASSESSED BY CLAUDIO INNOCENTI (PARTNER & PCQI) ON OR ABOUT FSVP PLAN'S NOTED REVIEW START/END DATES

CONFIDENTIAL TREATMENT REQUESTED

Claudio Innocenti

FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Margoire Yunes

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

FSPCA Preventive Controls for Human Food

delivered by Lead Instructor

Cynthia Vargas

completed on

07/19/2020

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

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # 7e8d8e91

DOCUMENT REVIEWED AND ASSESSED BY CLAUDIO INNOCENTI (PARTNER & PCQI) ON OR ABOUT FSVP PLAN'S NOTED REVIEW START/END DATES

CONFIDENTIAL TREATMENT REQUESTED

Claudio Innocenti

SAMIYAMEALS S.A., hereby provides the approved list of our company's representatives that may be contacted anytime if an incident, unfortunate event or recall occurs.

Food Safety Contact:	Margoire Yunes
Title:	Food Safety Technician
Food Safety Phone:	+593 99 181 8753
Food Safety Email:	foodsafety@samiya.co

Recall Contact:	Michel Chamoun
Title:	Recall Communication Coordinator
Recall Phone:	+1 805 308 4856 / +593 99 318 2772
Recall Email:	recall@samiya.co

Recall Back-Up Contact:	Franco Chamoun
Title:	Recall Logistics Coordinator
Recall Phone:	+593 99 181 8717
Recall Email:	franco.chamoun@samiya.co

Authorized by:	 Michel Chamoun Yunes
Title:	Chief Executive Officer / PCQI
Date:	01-07-2020

[MM/DD/YYYY]

URGENT: RECALL COMMUNICATION LETTER
[PRODUCT NAME]

Customer Name
Street Address
City, State, Zip Code

Dear Customer/Distributor,

The purpose of this letter is to advise you that "SAMIYAMEALS S.A." is voluntarily recalling [ENTER PRODUCT NAME]. Our company is recalling this product from the market because of (enter list of reasons below by using bullet points):

- Reason 1
- Reason 2
- Reason 3

The following chart provides all the necessary information regarding the product being recalled for fast identification and retrieval.

Product Name	Brand	Presentation	Lot Code	Manufacturing Date	UPC
		Refer to: size, product description, etc.			

We urge you to please discontinue selling/distributing this product IMMEDIATELY by removing them from display and/or warehouse. After removal, please count amount of product in your inventory and store it in a secure place. Provide this information to us as soon as possible via scanned email or digital report, properly signed.

IMMEDIATELY after receiving this notice, please contact all accounts that you sell this product to and inform them of this recall. Please provide proof of contacted accounts with contact date and time.

"SAMIYAMEALS S.A." will issue a credit note under your name for the recalled product. Please mark the product as "RECALLED". We will contact you soon to provide further instructions on what to do with the recalled product.

IMPORTANT

Please record the time and date of reception for this recall communication letter and acknowledge receipt by signing, scanning and emailing this document to "SAMIYAMEALS S.A.". Acknowledgement of receipt must be sent to the following email: michel.chamoun@samiya.co

Date/Time Received: _____ / _____ ( ) AM ( )PM Signature: _____

Name of Customer / Distributor: _____

Amount of Recalled Product in Stock: _____

Amount of Inventory Distributed/Sold: _____

We appreciate your attention to this matter and thank you for your cooperation. Should you have any further question or are in need of any assistance, please do not hesitate to contact us immediately.

_____

Michel Chamoun

Recall Coordinator / SAMIYAMEALS S.A.

michel.chamoun@samiya.co / (805) 308 4856

[MM/DD/YYYY]

RECALL INFORMATION SHEET

CASE NUMBER

The following report presents pertinent information regarding a product recall that "SAMIYAMEALS S.A." is executing.

1. Product information

Product name	
Item No.	
Product order number	
Description	*Indicate nature of the product, its composition/ingredients; manufacture date, expiry date, product presentation or features.*
Product label	
Individual package label	
Case label	
Directions for use	

2. Codes

Lot code	
Manufactured date	
Expiration date	
UPC	

3. Recalling firm

Firm name	SAMIYAMEALS S.A.
Address	km. 19 y medio via a la Costa
City	Guayaquil
State/Province	Guayas
Country	Ecuador
Firm type	Manufacturer
Recall contact name	Michel Chamoun
Recall contact email	michel.chamoun@samiya.co

4. Manufacturer

Manufacturer	SAMIYAMEALS S.A.
Address	km. 19 y medio via a la Costa
City	Guayaquil
FDA Registration	10561005226

5. Identify firm responsible for the violation/problem

Firm name	
Address	
City	
State/Province	
Country	

6. Reason for the recall

6.1. Explain why the product being recalled is defective and/or violative:

6.2. Explain how the defect affects the performance and safety of the product:

6.3. In case the recall is due to the presence of a foreign object, please provide full physical description of the foreign object:

6.4. In case the recall is due to the presence of a contaminant (cleaning fluid, machine oil, paint vapors), explain level of contaminant in the product. Provide labeling and technical spec sheet or Material Safety Data Sheet for the contaminant:

6.5. In case the recall is due to failure of the product to meet product specifications, provide the specifications and report all test results (provide copies of any sample analysis):

6.6. In case the recall is due to a label/ingredient issue, provide and identify the correct and incorrect labels, descriptions and formulations:

6.7. Explain how the problem occurred and the date it occurred:

6.8. Explain how the problem was discovered and the date it was discovered:

6.9. Explain if the problem/defect affects all units subject to recall, or just a portion of the units in the lots subject to recall:

6.10. Explain why this problem affects only those products/lots subject to recall:

6.11. Provide detailed information on complaints associated with the product/problem:

Date of complaint	Description of complaint	Lot code	Evidence

6.12. If a State agency is involved in this recall request, please indicate which and provide contact information.

7. Health hazard assessment

If applies, please provide assessment of the health risk associated with product deficiency. Note that a health hazard is not the only reason for a product to be recalled.

8. Volume of recalled product

Total quantity produced	
Dates produced	
Quantity distributed	
Dates distributed	
Quantity on HOLD by recalling firm and its distribution centers	

8. Volume of recalled product (continued)

Indicate how the product is being quarantined	
Estimate amount remaining in marketplace	Distributor level, retail level…
Status/disposition of marketed product	

9. Distribution pattern

Overall number of direct accounts		
	Wholesalers/distributors:	
	Repackers:	
	Manufacturers:	
	Consumers:	
Geographic areas of distribution		
Product consignee list		

9.1. Was product sold to any federal, state or local agency involved in the *school luch program*? If yes, list the consignees and provide quantity and sale and shipment dates.

10. Recall strategy

Recall extent level	*Indicate: wholesale, retail, etc…*
If recall extent level only extends to a portion of total accounts, please tell why…	
Notification method	
Notification delivery method	
Product return mechanism	*Indicate and describe*
Will recall create a market shortage?	

10.1. Determine and provide your course of action for out-of-business distributors:

10.2. If applicable, provide a method for destruction:

10.3. If the product is to be “reconditioned”, explain how and where the reconditioning will take place:

10.4. Describe how reconditioned product will be identified so it is not confused with recalled (pre-reconditioned) product:

SAMIYA	PRODUCT SPECS SHEET				
	Code	**Created on**	**Version**	**Last updated**	**Page**
	MD009	12/05/2020	02	01/24/2022	1 of 3

SWEET PLANTAIN SLICES, PRE-FRIED & FROZEN, 4 / 6 lb

Description	Product is naturally sweet. It is pre-fried and individually frozen. Made from sliced plantain fruit (*Musa paradisiaca*) that has been grown and harvested in Ecuador's coastal region.
Process	Plantains are sourced from a selective network of farms. Raw material is ripened, peeled, sliced, fried, frozen and packed at our facility, complying with GMP standards. Product is free from additives or preservatives and is cooked in vegetable oil.
Ingredients	Sliced sweet plantains, vegetable oil.

COOKING DIRECTIONS

Fryer: Fry frozen product in frying oil heated to 350 ºF for 4-5 minutes or until caramelized. Slices must be fully covered by oil. Shake basket and do not overload to keep slices separated. Let product drain before serving.

Oven: Preheat oven to 350 ºF. Place frozen product on a baking sheet. Cook for 15-20 minutes or until golden brown.

*Do not defrost product before cooking. Do not thaw and refreeze.

INTENDED USE

Once cooked, product can be served in a wide array of presentations, as an appetizer, side dish or snack.

*Do not consume uncooked. Always follow cooking instructions.

CHARACTERISTICS

Organoleptic	Color: naturally bright yellow, turns golden brown (caramelized) when fried Odor: Fruity smell, characteristic of ripe fried plantain Flavor: Sweet, characteristic of ripe fried plantain Texture: Firm, becomes softer when cooked, characteristic of ripe fried plantain Appearance: Fried ripe plantain	
Physical	Length: 7.00 cm – 9.00 cm / 2.76" to 3.54" Width: 3.00 cm – 4.00 cm / 1.18" to 1.57" Thickness: 1.50 cm – 2.00 cm / 0.59" to 0.79" Consistency: firm	Unit weight: 30 g – 40 g / 1.05 oz – 1.41 oz Units per bag: 70 – 90 Net weight per bag: 6 lb / 2.72 kg
Quality	Uniformity / Off size: ≤10 % Peel on / skin on: 0 % Brix: 27º – 29º Allergens: none	Stains: 0 % Foreign matter: 0 % Gluten: none GMO: none
Chemical	Pesticides: as indicated in the Codex Alimentarius Heavy metals: as indicated in the Codex Alimentarius	
Microbiological	Aerobic mesophilic, total count: <1x10^6 CFU per g Coliforms, total: <1x10^3 CFU per g *E. coli*: <1x10^2 CFU per g	Molds and yeast: <1x10^3 CFU per g *Salmonella*: absence *Listeria monocytogenes*: absence *Staphylococcus aureus*: 1x10^3 CFU per g

PRODUCT PRESENTATION / PACKAGING FEATURES

Net weight per box: 24 lb / 10.89 kg

Gross weight: 25 lb / 11.40 kg

Contents: 4 bags / 6 lb ea

Carton volume: 0.02 m^3 / 0.67 ft^3

Bag (primary packaging)

Measures: 12" x 16"

Thickness: 0.0025 mm / 3 µm

Material: LDPE, white pigmented, printed

Box (secondary packaging)

Measures: 41.1 x 26.0 x 21.0 cm / 16.18" x 10.24" x 8.27"

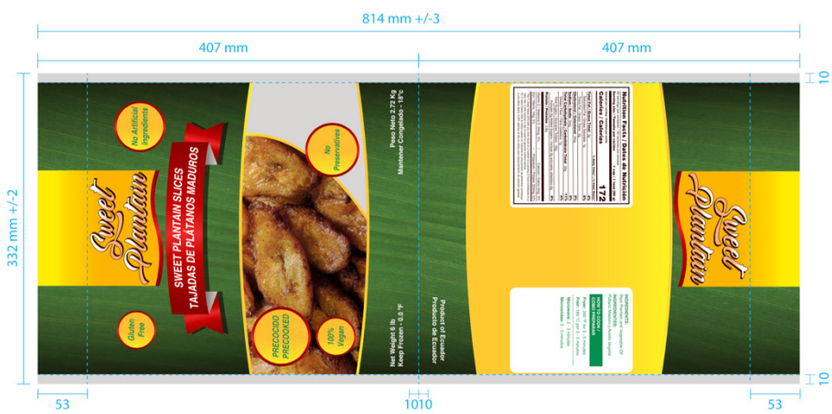
Material: kraft paperboard

Test: 250 Corrugated: C

PRODUCT PRESENTATION / BOX DESIGN

The appearance of the box for *SWEET PLANTAIN SLICES, PRE-FRIED & FROZEN, 4 / 6 lb* is shown in the figure below.

PRODUCT PRESENTATION / BAG DESIGN



STOW

Merchandise is palletized for shipping. The pallet conformation for a 40 ft HC reefer container is as follows:

Base (TI): 10 boxes Layers (HI): 11 rows	Cases per pallet: 110	Pallets per container: 20	Cases per load: 2200

CODING & TRACEABILITY

BAG

Each bag is codified with the following information: production date (FAB), best before date (EXP) and production lot (LOTE). For example:

FAB 23/01/19
EXP 22/07/20
LOTE 2301021-1

BOX

The code that appears on the box consists of an 8-digit number that describes production date, supplier farm and product category such as follows:

2301021-1

23: day of production	01: month of production	021: fruit supplier code	1: sweet plantain slices

STORAGE & SHELF LIFE

Product must be kept frozen at -4 ºF (-18 ºC). Do not defrost product before use. Unopened bags can be stored in freezer and used for 18 months after production date. Do not thaw and refreeze.

DISTRIBUTION, SHIPPING & HANDLING

Product is shipped in reefer containers at -4 ºF. Frozen conditions must be kept while shipping and handling the product in order to ensure best quality.

LEGAL & REGULATORY REQUIREMENTS

FDA facility registration #10561005226

DUNS Number 88-680-1442

GFSI Accredited under PrimusGFS, v.3.1. Primus Audit No. 244671. CB Registration No. PA-PGFS-16706.

NUTRITION FACTS CHART

Nutrition Facts / Datos de Nutrición

30 servings per container / 30 raciones por envase

Serving size / Tamaño por ración: 1 cup / 1 taza (90 g)

Amount per serving / Cantidad por ración

Calories / Calorías **172**

	% Daily Value* / % Valor Diario*
Total Fat / Grasa Total 3g	**4%**
Saturated Fat / Grasa Saturada 1g	**6%**
Trans Fat / Grasa *Trans* 0g	
Cholesterol / Colesterol 0mg	**0%**
Sodium / Sodio 0mg	**0%**
Total Carbohydrate / Carbohidrato Total 33g	**11%**
Dietary Fiber / Fibra Dietética 1g	**4%**
Total Sugars / Azúcares Totales 22g	
Includes 0g Added Sugars / Incluye 0g azúcares añadidos 0g	**0%**
Protein / Proteína 0.8g	

Vitamin D / Vitamina D 0mcg 0% • Calcium / Calcio 0mg 0%

Iron / Hierro 1mg 5% • Potassium / Potasio 350mg 12%

* The % Daily Value (DV) tells you how much of a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.
* El % Valor Diario (VD) le indica cuánto un nutriente en una porción de alimentos contribuye a una dieta diaria. 2,000 calorías al día se utiliza para asesoramiento de nutrición general.

Created by	Revised by	Approved by
Michel Chamoun CEO / PCQI & FDQI	**Andrea Chica** Food Safety Coordinator / PCQI	**Michel Chamoun** CEO / PCQI & FDQI

Revision 1

PRELIMINARY REPORT COMPLETED

Operation Type:Processing
Audit Report Summary

CB Registration No.PA-PGFS-16706-1
PrimusGFS ID #192269
Audited by Primus Auditing Operations

PrimusGFS Version 3.1

Ver en Español

Organization:	**SAMIYAMEALS S.A.** Contact(s): MICHEL CHAMOUN Address: KM 19,5 VIA A LA COSTA, FRENTE AL RECINTO NUEVA ESPERANZA Location: GUAYAQUIL, GUAYAS 090115, Ecuador Phone Number: +593993182772
Operation:	**SAMIYAMEALS S.A.** Contact(s): MICHEL CHAMOUN Location: km. 19,5 via a la Costa Guayaquil, Guayas 090115, Ecuador
Shipper:	SAMIYAMEALS S.A.
Operation Type:	**Processing**
Audit Type:	**Announced Audit**
Audit Scope:	Installation audit with process operation of ripe plantain and green plantain (patacón) of the company SAMIYAMEALS SA Conventional product, two lines where three processes are not simultaneously worked: ripe for frozen fried, fried fried fried and chips (fried). The product is received from third parties, for mature: the product is subjected to maturation with ethylene if necessary, peeled (not washed), sliced manually, passed to frying (PCC1 160 + -10ºC / 1-3 min and not more than 24% TPM), it is placed in trays in an extended way, it is frozen for 6-8 h until it has a thermal center of -18ºC, it is emptied to the packing line, it is packed i n bags, they are thermally sealed, it is they pass through a metal detector (PCC2), they are packed in cardboard boxes previously coded with traceability code, stored cold at -18ºC until being shipped. In the Patacón process, the green banana is scalded (80 + -10ºC for 1-3 min), peeled, sliced manually, fried (PCC1 150 + -10ºC / 6-8 min and no more than 24% TPM) It may or may not be pressed at the customer's request, it is spread in trays, it is frozen at -30ºC for 6-8 h until it has a thermal center at -18ºC, it is packed, it passes through a metal detector (PCC2) and it stores just as mature. For Chips, it is scalded, peeled, mechanically cut (thickness 8 mm), fried (135 + -10ºC / 2-3 min), press (1.5-2 mm droughly), it automatically extends in a band that goes to second frying (PCC1 170 + -10ºC / 3-4 min and no more than 24% TPM), salt is added manually, cooled to room temperature, packed in bags manually (laminated or high density), sealed, passed to metal detector (PCC2), packed in labeled cardboard boxes, stored and shipped. In all three lines the PCC2 metal detector Fe 3.5 mm, Inox 4.5 mm, NFe 4 mm. There are 3 freezing tunnels, 2 storage tunnels, packing material warehouse, Chips finished product warehouse, ripening area. 60 workers are reported. No allergens The destination of the product is the United States.
Date Documentation Review Started:	17 Dec 2019 09:30
Date Documentation Review Finished:	17 Dec 2019 17:00
Total Amount of Time on the Documentation Review:	7.50 Hours
Date Visual Inspection Started:	16 Dec 2019 09:45
Date Visual Inspection Finished:	16 Dec 2019 21:00
Total Amount of Time on Visual Inspection:	11.25 Hours
Addendum(s) included in the audit:	Not Applicable
Product(s) observed during audit:	Plantains Processed (See Scope)
Similar product(s)/process(es) not observed:	None
Product(s) applied for but not observed:	None
Auditor:	Dulce María Rangel Fajardo (Primus Auditing Operations)
Preliminary Audit Score:	**87%**

	Latitude	Longitude	
GPS Coordinates:	2° 11' 37"	80° 3' 8"	Click here to see map

Non-conformance Summary Report

Information related to the audited operation			
Total number of workers for the operation:	60	**Maximum worker number during peak season:**	60
Number of lines in normal production:	2	**Number of lines running during the audit:**	2
Facility Size:	735 Square feet	**Facility Environment Conditions:**	Wet- Recycled Water Use with Product Contact
Allergens:	No		
Temperature Controlled Storage:	Yes	**Was an anti-microbial used in the water/ice?**	Yes
Water Source:	Municipal/District	**Antimicrobial Used:**	**Other:** ácido cítrico
Is cooling equipment used?	Yes	**Cooling Equipment:**	**Other:** Cámara de congelación

Product information for each product			
Product Group/Product Name	**Observed Product**	**Seasonality**	**Country of destination for product**
Plantains, Processed (See Scope)	Observed on the day of audit	Year round	

AUDIT SCORING SUMMARY	Pre-Corrective Action Review	
Food Safety Management System Requirements	**Score:** **Possible Points:** **Percent Score:**	201 224 **89%**
Module 5 - Good Manufacturing Practices Requirements	**Score:** **Possible Points:** **Percent Score:**	1060 1254 **84%**
Module 6 - HACCP System Requirements	**Score:** **Possible Points:** **Percent Score:**	270 270 **100%**
TOTAL	**Score:** **Possible Points:** **Percent Score:**	1531 1748 **87%**

Non-Conformance Summary By Count	Pre-Corrective Action Non-Conformances
Food Safety Management System Requirements	5
Module 5 - Good Manufacturing Practices Requirements	36
Module 6 - HACCP System Requirements	0
TOTAL	**41**

SECTIONS:

Food Safety Management System Requirements	Module 5 - Good Manufacturing Practices Requirements	Module 6 - HACCP System Requirements
Management System	General GMP	Preliminary Steps
Control of Documents and Records	Pest Control	Development of the HACCP Plan
Procedures and Corrective Actions	Storage Areas & Packaging Materials	Execution of the HACCP Plan on the Plant Floor
Internal and External Inspections	Operational Practices	
Release of Items/Product	Worker Practices	
Supplier Monitoring/Control	Equipment	
Traceability and Recall	Equipment Cleaning	
Food Defense	General Cleaning	
	Site	
	Buildings and Grounds	
	Chemical Files	
	Pest Control Documentation	
	Operation Monitoring Records	
	Maintenance & Sanitation Files	
	Worker Documentation	
	Testing	
	Temperature Controlled Storage & Distribution Logs	
	Allergen Control	

FSMS Management System

1.01.01	**Question:** Is there a documented food safety policy detailing the company's commitment to food safety?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. There is a safety policy published on the entry of facilities in view of the staff. SMY-SG-L-002 The company is committed through the implementation of good manufacturing practices. Continuous improvement is established in the document Policy of integrated food safety management systems, Signature: Michel Chamoun and Daniel Cevallos Valarezo, 2019.	

1.01.02	**Question:** Is there an organizational chart showing all management and workers who are involved in food safety related activities and documentation (job descriptions) detailing their food safety responsibilities?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Organizational chart SMY-RH-E-001, president, general manager, quality coordinator and SGIA, administrative coordinator, general coordinator, quality technician, production coordinator, logistics among others. The substitutes are integrated in document SMY-RH-T-001. Description of positions and functions is included.	
1.01.03	**Question:** Is there a food safety committee and are there logs of food safety meetings with topics covered and attendees?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Safety committee conformed MY-SG-E-001 formed by safety and quality control coordinator, president of the company, production coordinator, commercial - general manager, logistics coordinator, quality technician, quality analyst and manager of production. They meet every 08/23/2019 and 11/25/2019.	
1.01.04	**Question:** Is there a training management system in place that shows what types of training are required for various job roles of specific workers, including who has been trained, when they were trained, which trainings they still need to take, and a training schedule?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Training matrix. SMY-RH-R-008 Training Plan V.01 2019. The training matrix includes topics, area, trainer, position, subject, duration, among others. All positions of the company are included.	
1.01.05	**Question:** Is there documented management verification review of the entire food safety management system at least every 12 months, including an evaluation of resources, and are there records of changes made?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. A complete documented verification of the safety administrative system SMY-SG-R-024 is presented where program status, modifications and changes of the last months are reported. The list of resources for the safety program includes training. Master list of documents SMY-SG-R-001 is presented. Budget required for safety year 2019 is presented	
1.01.06	**Question:** Where specific industry guidelines or best practices exist for the crop and/or product, does the operation have a current copy of the document?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. Compliance with the ARCSA resolution of 067-2015 Standard of prosecutors of the Ministry of Public Health of Ecuador, modified in May 2017, is followed. Free GMO 1829/2003 and 1830/2003. INEN 1640: 2012 for reference in counting minerals in oil.	

FSMS Control of Documents and Records

1.02.01	**Question:** Is there a written document control procedure (including document control register/record) describing how documents will be maintained, updated and replaced?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. Document and registration control procedure SMY-SG-P-001. In the procedure it is established that the personnel responsible for the generation of new documents by the incubation committee, declares the relative to obsolete documents. The records are protected for 2 years.	
1.02.02	**Question:** Is there a documented and implemented procedure that requires all records to be stored for a minimum period of 24 months (or greater if legally required) or for at least the shelf life of the product if it is greater than 24 months?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Document and registration control procedure SMY-SG-P-001. The procedure establishes that the records are protected for 2 years.	
1.02.03	**Question:** Are both paper and electronic food safety related documents and records created, edited, stored and handled in a secure manner?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. The company stores the documents in a safety office in folders in order on a shelf. It has controlled access and safety charge. The procedure SMY-SG-P-001 establishes that the records must be filled in ink and without the use of proofreader to validate changes. No crossings were observed in records.	

1.02.04	**Question:** Are records maintained in an organized and retrievable manner?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. Records are stored in folders labeled and sorted. The documents are backed up in a printed folder and electronic system. The records are filled in ink without the use of proofreader and each document is validated with signature by the person in charge of the program. It has full manual backup in computer and printed.	
1.02.05	**Question:** Are all records and test results that can have an impact on the food safety program reviewed and signed off by a person responsible for the food safety program?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. Safety personnel sign monitoring records of PCC1 and PCC2, maintenance records, laboratory reports among others.	

FSMS Procedures and Corrective Actions

1.03.01	**Question:** Is there a written and standardized procedure for creating Standard Operating Procedures (SOPs) and their content?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Document and registration control procedure SMY-SG-P-001. In the procedure the format of new documents is established, responsible for the creation of new procedures is harmless, they are authorized at the management level.	
1.03.02	**Question:** Are the written procedures available to relevant users and is a master copy maintained in a central file?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Copies of procedures were observed in different parts of the company by those in charge of specific areas, for example production, maintenance, cleaning.	
1.03.03	**Question:** Is there a documented corrective action procedure that describes the required processes for handling non-conformances affecting food safety?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Corrective and improvement actions SMY-SG-P-015, root cause identification is indicated by techniques such as 5 because it is ishikawa. SMY-SQ-R-019 action request.	
1.03.04	**Question:** Is there an incident reporting system, also known as a Notice(s) of Unusual Occurrence and Corrective Actions Log (NUOCA) ?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. SMY-AC-R-026 Unusual events, no records are kept.	

FSMS Internal and External Inspections

1.04.01	**Question:** Is there a documented procedure for how internal audits are to be performed at the operations, including frequency and covering all processes impacting food safety and the related documents and records?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Internal audit procedure SMY-SG-P-005. Internal auditing calendar SMY-SG-R-008: three complete audits are performed per year and monthly BPM: 11/20/2019, 10/17/2019, 09/15/2019 performs Maria Auxiliadora Muñoz.	
1.04.02	**Question:** Are there written procedures for handling regulatory inspections?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. Regulatory inspections SMY-SG-P-016, indicates the taking of photos or samples.	

1.04.03	**Question:** Are there records of regulatory inspections and/or contracted inspections, company responses and corrective actions, if any?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A There have been no regulatory audits or contracts with third parties. The score n is affected.	
1.04.04	**Question:** Are there documented calibration and/or accuracy verification procedures for measuring and monitoring devices used in the operations that are related to the safety of the product?	**Possible Points:** 10 **Points Scored:** 7 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency Luminometer is not included in the calibration and / or verification requirements of the SMY-AC-P-009 calibration procedure or in the SMY-AC-001 schedule. Refractometer, vernier, Testo 720 TPM (total polar compounds), red thermometer, water activity meter, deli rule between golds are included.	
1.04.05	**Question:** Are calibration and/or accuracy verification records maintained and are they consistent with the requirements outlined in the SOP(s) for instruments and measuring devices requiring calibration?	**Possible Points:** 5 **Points Scored:** 3 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency The metal detector calibrati on was performed since 05/18/2018 and not annually. Fluke hart scientific LNM-T-201900041D thermometer calibration certificate is presented 04/12/2019, Weight certificate by national metrology laboratory LNM-M-201900184D, 06/14/2019, SMYAC001 refractometer 18/10/2019, detector of metal parts calibration Test sample certificate of conformity LOMA systems 05/18/2018. TPM measurement equipment TESTO 270 08/20/2019 Rivalesa SA Certificate RIV.LC.T.70.19.01A.	

FSMS — Release of Items/Product

1.05.01	**Question:** Is there a written procedure for handling on hold and rejected items?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Non-compliant product procedure SMY-SG-P-012. Indicates as responsible to quality management assurance coordinator, production coordinator and production leader as responsible for the retention or rejection of the product.	
1.05.02	**Question:** Are there records of the handling of on hold and rejected items kept on file?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Non-compliant product claims treatment SMY-AC-R-023. There have been no events indicated by the auditee.	
1.05.03	**Question:** Is there a documented product release procedure available?	**Possible Points:** 5 **Points Scored:** 1 **Score:** Major Deficiency
	Auditor Comments: Major deficiency The SMY-AC-M-002 Quality Manual procedure does not indicate the release of finished product for shipment (microbiology tests, temperatures, quality reviews, humidity, water activity etc).	
1.05.04	**Question:** Are there records of product releases kept on file?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Record of microbiological release of SMY-AC-R-036 product, sample composed of 20 pallets with representativeness based on 1 box per pallet is taken. BMA 5 log / g, Molds and yeasts <10 CFU / g, <10 CFU / g, E. coli absent, Listeria sp absent, Sataphylococcus aureus absent. Number of boxes released, observations and by whom Michel Chamoun performs, product code, product type and date is reported. Free Michel. Transport Review is also presented Control of entrance of unit reefer to plant. SMY-AG-R-009 Transport inspection record. AC temperature reported	
1.05.05	**Question:** Is there a documented procedure for dealing with customer and buyer food safety complaints/feedback along with records and company responses, including corrective actions?	**Possible Points:** 10 **Poi nts Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Customer complaints and suggestions management SMY-SG-P-007. Complaint record SMY-AC-R-035.	

FSMS Supplier Monitoring/Control

1.06.01	**Question:** Is there a list of approved suppliers and service providers?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Product suppliers SMY-AC-E-007, 11 suppliers, updated on 06/12/2019. List of service providers in control of subcontract organizations SMY-AC-P-011 (Rizovacter pest control), Maintenance of Carlos Suquinahua cold and freezing system, oil trap cleaning in Oletnat drainage systems, Post treatment and management discarded fruit oil. Chemical products SMY-SO-R-001 (chemical, biosolutions among others).	
1.06.02	**Question:** Are there current written food safety related specifications for all incoming products, ingredients, materials (including primary packaging), services provided on-site, and outsourced services?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Receipt of packing material SMY-AC-P-004 indicates safety conditions to receive the material, SMY-AC-P-012 Supplier control includes the specification of supplies, materials. Specifications for service providers in SMY-AC-P-011.	
1.06.03	**Question:** Is there a written procedure detailing how suppliers and service providers are evaluated, approved, and include the ongoing verification activities including monitoring? Note that supply chain preventive controls and supply-chain-applied controls are also mentioned in Module 7.	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. SMY-AC-P-012 Supplier control, the supplier evaluation and disposal system is included.	
1.06.04	**Question:** Does the organization have documented evidence to ensure that all incoming products, ingredients, materials, services provided on-site and outsourced service suppliers comply with the approval requirements and that all supplier verification activities (including monitoring) are being followed, as defined in the supplier approval procedure?	**Possible Points:** 15 **Points Scored:** 5 **Score:** Major Deficiency
	Auditor Comments: DM. There is no third party safety certificate for Plastics from Litoral Plastlit SA (BAGS of primary packaging), no third party safety certificates are presented for fruit suppliers. Certificates of palm oil analysis with particularity in peroxide content are presented (peroxide index 1meqO2 / kg, reported in 0.35). Technical data sheets of chlorine-10 10%, of chemicals, foam degreaser, Di Quat 5 (does not indicate whether or not to rinse), Third party certificate in INS-BPM-2017-151 SGCEC Ecuador for palm oil in force at 14 / one	
1.06.05	**Question:** Where food safety related testing is being performed by external laboratory service providers, are these licensed and/or accredited laboratories (e.g., ISO 17025 or equivalent, national and local regulations, etc.)?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Protal Ecuador external laboratory scope is presented before 17025: 2006 in force on 02/13/2024, scope for microbiological SAE-LEN-05-009.	

FSMS Traceability and Recall

1.07.01	**Question:** Is there is a document that indicates how the company product tracking system works, thereby enabling trace back and trace forward to occur in the event of a potential recall issue?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Identification and traceability SMY-SG-P-008. The finished product (laminated bag or standard bag and box) is identified by two digits of production date, two digits per year, three by producer code and the last digit by type of product (regular tostones 8, ripe slices 1, mature whole 2, Hawaiian tostones 9, cassava in pieces 6, tostones chips 7, crotons 3.	
1.07.02	**Question:** Does the organization have a documented recall program including procedures, recall team roles and contact details, external contact listings, requirement for recall effectiveness checks, explanation of different recall classes and handling of recalled product?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. Product recall SMY-SG-P-006, recovery equipment, recovery classes, recovery team role, recovery equipment contact details updated to 01/09/2019 are included.	

1.07.03	**Question:** Is testing of recall procedures (including traceback) performed and documented at least every six months, and the company can demonstrate the ability to trace materials (one step forward, one step back) effectively?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. It is established to carry out two product recovery exercises, an exercise is presented since it is the first audit 12/16/2019 beginning 7:45 am, term 8:40 am, esCenario metal particles in product lot 2510575-9. Considering detection of chemical residues (with the suspicion of being derived from the packaging material used) on pallet 4 of PO221795, product origin (supplier, supplier safety certificate), destination (s), truck and material review record is requested of packaging involved (include batch of packaging material that was used on the day of product packaging	

FSMS — Food Defense

1.08.01	**Question:** Is there a written food fraud vulnerability assessment (FFVA) and protection plan for all types of fraud, including all incoming and outgoing products?	**Possible Points:** 5 **Points Scored:** 1 **Score:** Major Deficiency
	Auditor Comments: Major deficiency No evaluation of the vulnerability of FFVA food fraud for incoming and outgoing products is presented. A vulnerability study focused on biosecurity in the process stages is presented.	
1.08.02	**Question:** Does the company have a documented food defense plan based on the risks associated with the operation?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. SMY-AC-P-007 food defense plan procedure, the evaluation is presented for each plant process diagram in order to protect against malicious intent. Entry protection, personnel training, inventory management among others are indicated.	
1.08.03	**Question:** Are records associated with the food defense plan and its procedures being maintained, including monitoring, corrective action and verification records (where appropriate)?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. SMY-AG-R-001 Reception of trucks v01. Training record SMY-SG-R-005 Biosafety training 09/10/2019 26 attendees. Separate chemical inventory by Jaime Ortega, out of warehouse chemicals, is reported by foam degreasing product, di quat 5, chlorine 10, citric acid. Inventory of palm oil inputs and outputs to production.	
1.08.04	**Question:** Is there a current list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. There is a list of "Emergency telephone numbers" which are located in strategic places such as entrance to the plant and offices.	
1.08.05	**Question:** Are visitors and contractors to the company operations required to adhere to food defense procedures?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. Visitor income is recorded. Badge was given, policies were indicated and registration was requested upon admission.	

GMP — General GMP

5.01.01	**Question:** Is there a designated person responsible for the operation's food safety program?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. There is a safety team made up of PCQI María Auxiliadora Muñoz Vera completed 09/30/2018 certificate 5dd26c4b, PCQI Michel Antonio Chamoun completed 09/30/2018 certificate 7e50b26b and Brian Fajardo. The person in charge of the company's safety program is María Auxiliadora Muñoz.	

5.01.02	**Question:** Are all cleaning and maintenance chemicals (pesticides, sanitizers, detergents, lubricants, etc.) stored securely, safely and are they labeled correctly?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. The chemical storage warehouse is organized, the chemicals are labeled, food grade chemicals are stored separately from non-food chemicals.	
5.01.03	**Question:** Are "food grade" and "non-food grade" chemicals used appropriately, according to the label and stored in a controlled manner?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. The cleaning chemicals used in the operation are food grade or recommended for the food industry, as specified in its technical data sheet. Chemicals in contact with food are food grade.	
5.01.04	**Question:** Are signs supporting GMPs posted appropriately?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. The company has adequate signs in various areas such as hand washing in sinks and bathrooms, the safety and signage regulations that reinforce it.	
5.01.05	**Question:** Are the necessary food defense controls implemented in the operation?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. The company implements necessary biosecurity measures. Closed areas of importance were observed as a warehouse for packing material and access doors.	

GMP Pest Control

5.02.01	**Question:** Are products or ingredients free of pests (e.g. insects,rodents,birds,reptiles, mammals) or any evidence of them? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. There is no presence of pests in the product or evidence of their presence.	
5.02.02	**Question:** Are packaging supplies free of pest (e.g., insects, rodents,birds,reptiles,mammals) or any evidence of them? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. There is no presence of pests or evidence of their presence in the packing material.	
5.02.03	**Question:** Are plant and storage areas free of pest (e.g., insects, rodents,birds,reptiles,mammals) or any evidence of them?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. No insects, birds, rodents or other animals or evidence of their presence were observed.	
5.02.04	**Question:** Is the area outside the facility free of evidence of pest activity?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. No pests were observed outside the facility.	
5.02.05	**Question:** Is there an effective pest control program in place? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. There is a pest control service contract with the external Rizobacter Ecuatoriana C. LTDA, of which ARCSA-2019-22.0-0000195 operating permit and sanitary regulation is in force as of 06/08/2019; contract signed by both parties with annual term validity 12/18/2019. Insurance policy SBS-INSP-205-207 effective as of May 2020. FOR-OP-07 Program.	

5.02.06	**Question:** Are pest control devices located away from exposed raw materials, work-in-progress, ingredients (including water and ice), finished goods and packaging, and poisonous bait traps are not used within the facility?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. The traps are located more than 3 meters away from product and packaging materials. The mechanical traps are found on the banks of the floor without touching the product.	
5.02.07	**Question:** Are pest control devices maintained in a clean and intact condition and marked as monitored (or bar code scanned) on a regular basis?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. All traps reviewed were clean, with monitoring card and match location reported in sketches.	
5.02.08	**Question:** Are interior and exterior building perimeter pest control devices adequate in number and location?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. There are four trapping cords: black light lamps 4, capture stations 2, monitoring station 8, bait station 27. Outdoors they distance one another at a maximum of 25 m and the internal ones, by 12 m. There are traps on both sides of the entrance doors	
5.02.09	**Question:** Are all pest control devices identified by a number or other code (e.g. barcode) ?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. They have a sheet attached to the wall with their number and inside or together there is a card where inspections are recorded. Monitoring records were observed.	
5.02.10	**Question:** Are all pest control devices effective and bait traps secured?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. The traps are attached to the floor and attached to the wall. There is a copy of the trap key. During the audit the traps were opened by staff of the external controller.	

GMP Storage Areas & Packaging Materials

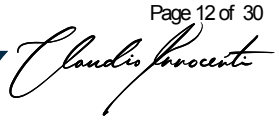
5.03.01	**Question:** Does the facility layout ensure separation of ingredients (including ice), products, and packaging stored to prevent cross contamination (this includes iced product pallets stored above pallets of product without adequate protection as well as any allergen cross contamination issues)?	**Possible Points:** 15 **Points Scored:** 5 **Score:** Major Deficiency
	Auditor Comments: Major deficiency In the storage of bananas, the use of a dirty cardboard box was observed, there is no control for these materials by the auditee, only the fruit suppliers.	
5.03.02	**Question:** Is the storage area completely enclosed?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. The installation is completely closed and insulated by sanitary panels, these are cold storage tunnels at freezing temperatures (-18ºC), packing material is closed.	
5.03.03	**Question:** Is the facility's use restricted to the storage of food products?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. No material that is not a product or its packaging material is stored. Chemicals or tools are stored in designated location.	
5.03.04	**Question:** Are rejected or on hold materials clearly identified and separated from other materials?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Rejected product properly identified (date, quantity, lot, motive and responsible) was observed stored in the upstairs warehouse. The product was rejected since the shelf life is no longer enough to market, it was destined to trade in Guatemala which was canceled.	

5.03.05	**Question:** Are raw products, work in progress, ingredients (including water and ice), finished goods and food contact packaging within accepted tolerances for spoilage and free from adulteration? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. In the operation there were no events with risk of adulteration of product, water, ingredients. The water in the entire operation is handled at a drinking capacity 1 ppm of free chlorine can be read in any monitoring. No risk situations with potential for adulteration were observed.	
5.03.06	**Question:** Are all storage areas clean, especially the racking structures, lights, ceilings, floor areas by the walls and other hard to reach areas?	**Possible Points:** 10 **Points Scored:** 7 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency Lack of cleaning was observed in bag storage, upstairs It was observed in the warehouse of packing material, they climb on the pallets without protection in footwear.	
5.03.07	**Question:** Are materials (commodities, packaging, ingredients, processing aids, work in progress, etc.) properly marked with rotation codes (receipt dates, manufacture dates, etc.)?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. All stored packaging materials and product received are identified with date of entry and lot.	
5.03.08	**Question:** Are materials (commodities, packaging, ingredients, processing aids, work in progress, etc.) rotated using FIFO policy?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Entry and batch of materials is identified as bag and product, therefore the policy of first entries and exits for these materials and the product is correctly applied.	
5.03.09	**Question:** Are storage areas at the appropriate temperatures for the specific products being stored?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Freezing tunnels (-30ºC) and storage tunnels (-18ºC) were observed	

GMP Operational Practices

5.04.01	**Question:** Does the process flow, facility layout, worker control, utensil control, internal vehicle use, etc. ensure that finished (processed) products are not contaminated by raw (unprocessed) products?	**Possible Points:** 15 **Points Scored:** 5 **Score:** Major Deficiency
	Auditor Comments: Major deficiency There is a product crossing in loading and unloading area. In the peeling area it was observed that the plastic boxes with banana are placed on a direct wet floor.	
5.04.02	**Question:** Are all exposed materials (product, packaging, etc.) protected from overhead contamination (e.g. ladders, motors, condensation, lubricants, walkways, loose panels, degrading insulation, etc.)?	**Possible Points:** 15 **Points Scored:** 5 **Score:** Major Deficiency
	Auditor Comments: Major deficiency There is no bearing cover located on the line of sliced ripe banana. The engines over the product do not have a spill tray.	
5.04.03	**Question:** Are production areas completely enclosed?	**Possible Points:** 15 **Points Scored:** 10 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency The operation is not completely closed, open spaces greater than 3 mm were observed in banana peeled area (under door, in roof sheet, on door edges etc).	
5.04.04	**Question:** Are production areas clean and well maintained; especially lights, ducts, fans, floor areas by the walls and equipment, and other hard to reach areas?	**Possible Points:** 15 **Points Scored:** 5 **Score:** Major Deficiency
	Auditor Comments: Major deficiency Lack of cleanliness in pipes and wiring was observed (mainly in a second room, fried and decorated). Floor shores in bare area require deep cleaning or sanitary curve adaptation, cleaning is impossible, black spots are observed on the floor. Peeling area walls require cleaning.	

5.04.05	**Question:** Is all re-work / re-packaging handled correctly?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A Re-packing is not done. The score is not affected.	
5.04.06	**Question:** Are raw ingredients examined before use?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. In the reception area, it is checked whether the product meets the necessary quality, with safety standards. If a product does not meet any of these precepts, it is rejected.	
5.04.07	**Question:** Are finished products coded (carton and unit packaging) for the day of production?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. The bag in which the product is packaged has reference to the storage and distribution conditions during the supply chain depending on your specific needs for each product.	
5.04.08	**Question:** Are foreign material control methods (e.g. metal detectors, metal traps, magnets, visual inspection, x-ray machines, etc.) in place and regularly tested (where relevant) to ensure proper operation?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. It has a unique metal detector through which all the finished product is passed, its correct operation is checked every hour, it was tested during the audit being satisfactory. Fe 3.5 mm, Inox 4.5 mm, NFe 4 mm tests are handled.	
5.04.09	**Question:** Does the facility use the appropriate test strips, test kits or test probes for verifying the concentrations of anti-microbial chemicals (product contact water, terminal sanitizers, dip stations, etc.) being used, are they in operational condition and are they being used correctly?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. Test strips are used to measure citric acid and chlorine at expiration date, the use was verified as appropriate.	
5.04.10	**Question:** Are hand washing stations adequate in number and appropriately located for worker access and monitoring usage?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. The ratio of one sink for every 10 people is met, there are 3 sinks in main income for 60 workers which are divided into two shifts, the same for their entry and exit to breaks, it was verified in audit.	
5.04.11	**Question:** Are hand washing stations in working order, have water of suitable temperature and pressure, adequately stocked (e.g. disposable towels, unscented soap, etc.) and restricted to hand washing purposes only?	**Possible Points:** 15 **Points Scored:** 10 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency There is no hot water in the sink. Handwashing stations work properly, they have handwashing materials such as unscented soap, alcohol gel, blotting paper towels.	
5.04.12	**Question:** Are toilet facilities adequate in number and location and are they adequately stocked (e.g. toilet paper, disposable towels, unscented soap, etc.)?	**Possible Points:** 15 **Points Scored:** 5 **Score:** Major Deficiency
	Auditor Comments: Major deficiency There are two useful bathing stations for men and women, 60 employees. The ratio of 3-4 bathrooms is not met.	
5.04.13	**Question:** Are secondary hand sanitation stations (e.g., touch-free dispensers) adequate in number and location, and are the stations maintained properly?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. There is sanitization based on gel alcohol in operating income. They were assorted, clean and observed to be used properly.	



5.04.14	**Question:** Are foot baths, foamers or dry powdered sanitizing stations adequate in number and location, and are the stations maintained properly?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. A sanitary mat with quaternary ammonium salts of 150-200, monitoring every hour, recording every two hours.	
5.04.15	**Question:** Are single service containers used for their intended purpose only so that potential cross contamination is prevented?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. It was noted that the bags are used only once to pack the product. The bags are placed inside non-reusable cardboard boxes.	
5.04.16	**Question:** Are re-usable containers cleanable or used with a liner and clearly designated for the specific purpose (trash, raw product, finished product, re-work, ice, etc.) such that cross contamination is prevented?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Plastic boxes assigned by color were observed for specific activities, for example green box is for waste. The boxes were clean, control measures were applied for cleaning and proper storage of boxes.	
5.04.17	**Question:** Are devices used to measure, regulate or control temperature, pH, acidity, water activity, and other conditions that affect food safety, working properly and adequately maintained?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. The metal detector which works properly was tested. It has a luminometer, thermometers, Testo 720 TPM measuring equipment and test strips for the determination of quaternary salts, citric acid and chlorine.	

GMP Worker Practices

5.05.01	**Question:** Are workers washing and sanitizing their hands before starting work each day, after using the restroom, after breaks, before putting on gloves and whenever hands may be contaminated?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. It was observed that employees wash their hands after using the bathroom and after touching dirty materials.	
5.05.02	**Question:** Are workers' fingernails clean, short and free of nail polish?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. The workers have short, clean nails without enamel.	
5.05.03	**Question:** Is there no sign of any worker with boils, sores, open wounds or exhibiting signs of foodborne illness working directly or indirectly with food?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. No signs of wounds, sores or burns were observed. Workers indicate that they are not allowed to enter operation if they have open wounds.	
5.05.04	**Question:** Are workers wearing effective hair nets that contain all hair?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Employees use coats that adequately cover their hair. The auditor was also offered a cap upon entering. There is one person at the entrance who checks each person who enters to verify correct use of a coping, hand washing etc.	
5.05.05	**Question:** Is jewelry confined to a plain wedding band and watches are not worn?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. No use of jewelry of any kind is allowed, no one wearing jewelry was observed.	

5.05.06	**Question:** Are all workers wearing protective outer garments suitable for the operation (e.g., appropriate clean clothes, smocks, aprons, sleeves, non-latex gloves)?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. The workers wear work uniforms according to the activity they do, for example, in the peeling area, the workers wear yellow aprons, black gloves, pants, oil green aprons, coats. The uniform is washed in laundry contracted by company.	
5.05.07	**Question:** Do workers remove protective outer garments (e.g., smocks, aprons, sleeves, and gloves) when on break, before using the toilets and when going home at the end of their shift?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Employees remove their uniform when leaving the facility. They don't take anything home. There are hooks on the way out to hang uniform, when you leave work you throw away the disposable and gown is taken to the laundry.	
5.05.08	**Question:** Is there a designated area for workers to leave protective outer garments (e.g., smocks, aprons, sleeves, and gloves) when on break and before using the toilets?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. There are hooks at the exit of the package to leave uniform before leaving the installation. There are lockers in men's and women's locker rooms, only boots are available at that site.	
5.05.09	**Question:** Worker personal items are not being stored in the production or material storage area(s)?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. The personal items of the workers are left in lockers in the dressing room area, there is also space in the dining room for food.	
5.05.10	**Question:** Is smoking, eating, chewing and drinking confined to designated areas, and spitting is prohibited in all areas?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Smoking or eating is not allowed in areas of operation and storage. Water is provided for consumption.	
5.05.11	**Question:** Is fresh potable drinking water readily accessible to workers?	**Possible Points:** 10 **Points Scored:** 3 **Score:** Major Deficiency
	Auditor Comments: Major deficiency Workers share glasses for water consumption, individual containers are not provided by the company.	
5.05.12	**Question:** Are all items removed from garment (shirt, blouse, etc.) top pockets, and unsecured items are not worn (e.g., pens, glasses on top of the head, Bluetooth devices, etc.)?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. During the inspection no personnel events were observed carrying items in top bags.	
5.05.13	**Question:** Are workers issued non-reproducible identification (e.g., badges, company ID cards, etc.)?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Registration and entry through a biometric system, entry is restricted by image of the workers' face, fingerprint. Position, name and data relevant to your position are registered.	
5.05.14	**Question:** Are first aid kits adequately stocked and readily available in the facility, and are blue band aids used?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. The company has a first aid kit which contains the basic material for cures and blue water resistant bands with a metal strip.	

GMP Equipment

5.06.01	**Question:** Are food contact equipment surfaces free of flaking paint, corrosion, rust and other unhygienic materials (e.g., tape, string, cardboard, etc.)?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. No detachments of paint, rust or other inappropriate materials were observed on contact surfaces such as tables, bands, frying tubs etc.	
5.06.02	**Question:** Are non-food contact equipment surfaces free of flaking paint, corrosion, rust and other unhygienic materials (e.g., tape, string, cardboard, etc.)?	**Possible Points:** 10 **Points Scored:** 7 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency Some line engines have paint shedding and tartar formation. The frozen mature packing table base has wear and rust.	
5.06.03	**Question:** Does food contact equipment design, placement, and condition (e.g., smooth surfaces, smooth weld seams, non-toxic materials, corrosion-resistant, no wood or other absorbent materials) facilitate effective cleaning and maintenance?	**Possible Points:** 15 **Points Scored:** 5 **Score:** Major Deficiency
	Auditor Comments: Major deficiency Non-smoothed welds were observed at different points of the operation. Non-continuous welding was observed in some parts of the equipment, which limits cleaning and facilitates the accumulation of waste. Vapor extraction systems placed on fryers are not considered hygienic.	
5.06.04	**Question:** Are thermometers (independent of thermostat probes) present in all coolers and freezers?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. The company has independent thermometers to the thermostat of the cold system. The thermometers are infrared.	
5.06.05	**Question:** Are all thermometers non-glass and non-mercury?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. The thermometers are metal and plastic. They do not contain glass or mercury.	

GMP Equipment Cleaning

5.07.01	**Question:** Are food contact equipment surfaces clean?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. During the audit, the equipment used for the operation of direct contact packing with the product such as bands, hands of workers, selection tables was observed in good clean condition. The plastic boxes are stained, which is congruent with the latex that the banana gives off. A box replacement program is managed based on its degree of deterioration and staining.	
5.07.02	**Question:** Are non-food contact equipment surfaces clean?	**Possible Points:** 10 **Points Scored:** 7 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency Lack of cleaning was observed under fryers.	
5.07.03	**Question:** Are items (totes, bins, etc.) that are used to hold or store product clean?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. During the audit it was observed that the boxes, buckets and containers where the product is placed are kept clean.	
5.07.04	**Question:** During cleaning, are food products and packaging materials protected from contamination?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A The cleaning operation was not observed during the audit. The score is not affected.	

5.07.05	**Question:** Are cooling units, including coils in coolers and freezers, clean and free of aged, dirty ice?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A It was not possible to evaluate the cleanliness of the freezers and diffusers since they are at freezing temperatures and it is not possible to enter for review. The score is not affected.	
5.07.06	**Question:** Are all fan guards dust-free and the ceiling in front of the fans free of excessive black deposits?	**Possible Points:** 5 **Points Scored:** 3 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency Lack of cleanliness was observed in fan guards in packing area.	
5.07.07	**Question:** Is stored equipment that is not used on a daily basis stored in a clean condition with food-contact surfaces protected and/or are they retained on cleaning schedules in some manner, even though they are not in use?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. The auditee comments that the equipment that is had and that is not used daily, is given regular cleaning. All equipment was observed in use during the audit.	
5.07.08	**Question:** Are all utensils, hoses, and other items not being used, stored clean and in a manner to prevent contamination?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. The utensils are marked, the hoses are located in their place raised on the wall, stored clean.	
5.07.09	**Question:** Are maintenance tools that are used in the production and storage areas of the facility clean, sanitary and corrosion free?	**Possible Points:** 3 **Points Scored:** 1 **Score:** Major Deficiency
	Auditor Comments: Major deficiency Dirty tools were observed, there is no classification for tools that can be entered into the operation.	
5.07.10	**Question:** Are excess lubricants and grease removed from the equipment and are lubricant catch pans fitted where needed?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. No excess lubricant or grease was observed in the equipment.	

GMP General Cleaning

5.08.01	**Question:** Are spills cleaned up immediately?	**Possible Points:** 10 **Points Scored:** 7 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency Oil spill was observed on one side of the fryer.	
5.08.02	**Question:** Are waste and garbage frequently removed from production and storage areas?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. The auditee mentions that trash is removed daily from the process unit. Clean facilities were observed during the audit. Garbage is placed outside in a company warehouse that provides the external collection service.	
5.08.03	**Question:** Do floor drains flow in a manner that prevents contamination (e.g., from high to low risk areas, from high risk directly to drain system), are they covered, appear clean, free from odors and are well maintained?	**Possible Points:** 5 **Points Scored:** 1 **Score:** Major Deficiency
	Auditor Comments: Major deficiency In the area of peeling drip (leak) was observed coming from the pipeline that carries condensate waste from the cold system to drains. There is an unsealed strainer in the chip packing area.	

5.08.04	**Question:** Do high level areas, including overhead pipes, ducts, fans, etc., appear clean?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. The upper areas, such as roof and wiring, are observed clean.	
5.08.05	**Question:** Are plastic strip curtains maintained in good condition, kept clean and mounted so that the tips are not touching the floor?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. It was noted that the Hawaiian curtains that are available are in good condition and are kept clean and mounted so that they do not touch the floor.	
5.08.06	**Question:** Does personal protection equipment (PPE) for the sanitation crew meet label requirements of chemicals used, and is it in good condition and stored to prevent cross contamination to raw products, work in progress, ingredients, finished goods or packaging?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. The crew has special protective equipment for handling chemicals and cleaning facilities, protective equipment is stored at the entrance of the facility.	
5.08.07	**Question:** Is cleaning equipment maintained clean and stored properly?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. During the audit it was observed that there is cleaning equipment for each area, classified by color and in the same way it is kept in its place of use to avoid cross contamination. Stored material turned down, without touching the floor, clean.	
5.08.08	**Question:** Is cleaning equipment identified in order to prevent potential cross contamination issues (e.g., production, maintenance, outside, restroom equipment)?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. The immersion tubs of knives and gloves are independent, cleaning material is coded by area, utensils and workers by area.	
5.08.09	**Question:** Are all items used for sanitation appropriate for their designated purpose (e.g., no steel wool, metal bristles, etc.)?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. There are no inappropriate brushes or fibers, they are all plastic bristles.	
5.08.10	**Question:** Are toilet facilities and hand washing stations clean?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. At the time of the audit, toilets and stations for clean handwashing were observed.	
5.08.11	**Question:** Are worker break facilities clean, including microwaves and refrigerators, and no rotting or out of date foodstuffs?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. There is an appropriate dining room with tables and benches for staff. No food is stored overnight.	
5.08.12	**Question:** Is the maintenance shop organized, with equipment and spares stored in a neat and tidy fashion?	**Possible Points:** 5 **Points Scored:** 3 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency The maintenance shop is messy.	
5.08.13	**Question:** Are internal transport vehicles (e.g., forklifts, bobcats, pallet jacks, carts, floor cleaners, etc.), clean, do not emit toxic fumes and are being used in a sanitary manner?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. The forklift is used only outdoors. It is operational, it is used in a sanitary manner. In internal areas no transport equipment is used.	

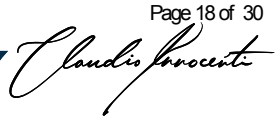
5.08.14	**Question:** Are shipping trucks clean and in good condition?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A Truck loading was not observed during the audit. The score is not affected.	

GMP Site

5.09.01	**Question:** Is there a site plan showing the facility location, adjacent sites, roads, water sources, storm water, wastewater and other relevant features?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Map showing water flow, water-plant flow diagram is presented.	
5.09.02	**Question:** Is there a facility floor plan showing the layout of the building, production areas, storage areas, water sources and fixtures, layout of equipment and traffic flow patterns?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Production flow diagram showing the internal areas and indicating the direction of the operational flow.	

GMP Buildings and Grounds

5.10.01	**Question:** Are all lights in the facility that could potentially contaminate raw materials, work in progress, ingredients (including ice), finished goods, equipment or packaging shielded, coated or otherwise shatter resistant to protect product from contamination in the event of a breakage?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. All clean and protected lamps were observed.	
5.10.02	**Question:** Has the operation eliminated or adequately controlled any potential metal, glass or hard plastic contamination issues?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. During the review there were no risks of potential contamination by metal, glass or plastic. It has plastic film in glass located in windows of material storage area, upper floor.	
5.10.03	**Question:** Has the facility eliminated the use of wooden items or surfaces?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. During the audit, no wooden articles were observed except for the pallets.	
5.10.04	**Question:** Is there adequate lighting in the production and storage areas?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. All areas have adequate lighting.	
5.10.05	**Question:** Is ventilation adequate to control dust, condensation, odors and vapors?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. No condensation events were observed, no odors, dust detected.	
5.10.06	**Question:** Are floor surfaces in good condition, with no standing water, no debris trapping cracks and are they easy to clean?	**Possible Points:** 10 **Points Scored:** 3 **Score:** Major Deficiency
	Auditor Comments: Major deficiency Part of the floor of the operation is worn and porous (example in frying area, decoration area, in front of tunnels etc).	



5.10.07	**Question:** Are the floor drains where they are needed for drainage and cleanup?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. They have grilles distributed strategically throughout the installation.	
5.10.08	**Question:** Are all entry points to the production and storage areas protected to prevent the entry of rodents and birds?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Deficiency given in 5.04.03. The packing doors are pest proof. The entrance of plagues is taken care of avoiding to open these doors and to use only sanitary platforms. There is trapping of insects and baits covering each door inside and outside respectively.	
5.10.09	**Question:** Are dock doors fitted with buffers/shelters to seal against trucks in temperature controlled environments?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. It has a single platform with sealing bearings.	
5.10.10	**Question:** Are dock load levelers and buffers/shelters maintained in good condition, pest proof and debris free?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A There are no load levelers. The score is not affected.	
5.10.11	**Question:** Are exterior walls free of holes to exclude pests, and are pipes, vents, and air ducts designed and protected in order to prevent pest entry (e.g., by using fine mesh)?	**Possible Points:** 5 **Points Scored:** 3 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency The outer walls have holes as part of their design, possible spaces for pest refuge.	
5.10.12	**Question:** Are interior walls and ceilings free of cracks and crevices to prevent pest harborage and allow proper sanitation?	**Possible Points:** 5 **Points Scored:** 1 **Score:** Major Deficiency
	Auditor Comments: Major deficiency In different parts of the installation there are holes or separations that allow the possible storage of insects or dirt: for example on a ceiling in front of a conservation chamber, a roof on a line of sliced ripened (peeled laminate), crawlers detached on the wall next to a chamber, openings under warehouses 1 and 2 among other points.	
5.10.13	**Question:** Is an 18" (46 cm) internal wall perimeter being maintained within the facility, with adequate access to these wall perimeters, thereby allowing inspection and cleaning?	**Possible Points:** 5 **Points Scored:** 3 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency 18 inches or enough space for fruit storage review for ripening are not respected.	
5.10.14	**Question:** Is the exterior area immediately outside the facility, including roads, yards and parking areas, free of litter, weeds and standing water?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. The outside area is clean, without garbage, weeds or standing water.	
5.10.15	**Question:** Are control measures being implemented for the outside storage of equipment, pallets, tires, etc. (i.e. out of the mud, pipe ends capped, stacked to prevent pest harborage, away from the building perimeter)?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. The pallets are stored in a covered area adjacent to the facility, clean and in order. There are no materials stored together with installation.	

5.10.16	**Question:** Are pallets inspected to separate and replace dirty or broken pallets, and broken or dirty pallets are not in use?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. The auditee mentions, the pallets that are used are new or mostly repaired and an inspection is also carried out to verify their status.	
5.10.17	**Question:** Is the area around the dumpster/cull truck/trash area clean?	**Possible Points:** 3 **Points Scored:** 2 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency There is a lack of cleanliness in the garbage container area, there were spilled liquids and a bad smell.	
5.10.18	**Question:** Are outside garbage receptacles and dumpsters kept covered or closed?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. The garbage container is covered with tarpaulin.	
5.10.19	**Question:** Are all water lines protected against back siphonage?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. There are shut-off valves in the water distribution system and it is not considered that there may be a backflow.	
5.10.20	**Question:** Is the on-site laboratory completely enclosed and separated from production and storage areas?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Closed laboratory, in office area, separated from the rest of the operation.	

GMP Chemical Files

5.11.01	**Question:** Are copies of all Safety Data Sheets (detergents, sanitizers, pesticides, etc.) on file and fully accessible at all times with clear indexes?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Data sheets and safety sheets of disinfectants, detergents and soaps used for workers' hands were shown. The file of technical data sheets and safety data sheets are available in the chemical storage room.	
5.11.02	**Question:** Are there copies of specimen labels for chemicals used, where the full label is not immediately accessible (e.g., rodent chemicals, product sanitizers)?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. A copy folder for labels and technical information was shown in the chemical store.	
5.11.03	**Question:** Are there chemical inventory logs for chemicals, including pesticides, fertilizers and cleaning and sanitizing chemicals?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. Separate chemical inventory by Jaime Ortega, exiting warehouse chemicals, is reported by foam degreasing product, di quat 5, chlorine 10, citric acid. Inventory of palm oil inputs and outputs to production.	
5.11.04	**Question:** Are there specific Standard Operating Procedures (SOPs) for the monitoring/testing and changing of recirculated and batch water systems (e.g., dump tanks, flumes, hydrovacuums, hydrocoolers, etc.) and testing of single pass water systems?	**Possible Points:** 10 **Points Scored:** 0 **Score:** Non-Compliance
	Auditor Comments: No. There is no procedure for handling, changing and monitoring recirculated water systems.	

GMP Pest Control Documentation

5.12.01	**Question:** Is there a documented pest control program, detailing the scope of the program, target pests and frequency of checks, including a copy of the contract with the extermination company (if used), Pest Control Operator license(s)/training (if baits are used), and insurance documents?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. There is a pest control service contract with the external Rizobacter Ecuatoriana C. LTDA, of which ARCSA-2019-22.0-0000195 operating permit and sanitary regulation is in force as of 06/08/2019; contract signed by both parties with annual validity ending 12/18/2019. Insurance policy SBS-INSP-205-207 effective as of May 2020. FOR-OP-07 Program.	
5.12.02	**Question:** Is there a schematic drawing/plan of the facility showing numbered locations of all pest monitoring devices (e.g., rodent traps, bait stations, insect light traps, etc.) both inside and outside the facility?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. SAMIYA PLANO DE CORDÓN SANITARIO FOR-AS-42 trapping scheme is presented. Four cords are indicated: black light lamps 4, capture stations 2, monitoring station 8, bait station 27.	
5.12. 03	**Question:** Are service reports created for pest control checks detailing inspection records, application records, and corrective actions of issues noted (in-house and/or contract)?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. The revisions are biweekly, trapping and outdoor sprinkler coverage is covered by a directed cord. Trap review reports are presented in formats with internal work order number. Records of October, November and December were reviewed. The records report the expenditure of input (baits, sheets etc), reported incidence is reported: rodent insects or others. Sprays only outdoors. Last revision 12/15/2019.	

GMP Operation Monitoring Records

5.13.01	**Question:** Are there inspection records for incoming goods (e.g., raw materials, ingredients and packing materials)?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Registration of truck reception SMY-AG-R-001. Truck and product cleaning conditions are reviewed. Review of materials and supplies trucks SMY-AC-R-031.	
5.13.02	**Question:** Are there inspection logs on incoming trailers (and other forms of transport) for rodents and insects, cleanliness, holes and temperature control of the trailer (for food requiring temperature control for safety and/or as required per buyer specifications)?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Registration of truck reception SMY-AG-R-001. Truck and product cleaning conditions are reviewed. Review of materials and supplies trucks SMY-AC-R-031.	
5.13.03	**Question:** Are there records for the necessary process monitoring activities (e.g., pH, water temperature vs. product temperature, metal detection, X-ray, labeling, heating processes, reduction/kill step processes, postharvest pesticides (i.e. fungicides, wax, etc.), control of water activity, drying, etc.), showing, for example, monitoring frequencies, results and where necessary the corrective actions?	**Possible Points:** 10 **Points Scored:** 7 **Score:** Minor Deficiency
	Auditor Comments: Dm. The metal detector does not have the sensitivity to detect the band-aid metal band. Record of temperature monitoring and TPM in oil "Control of PCC1 Medium frying temperature SMY-SG-R-021" is kept, batch, time, band time and frying temperature are reported (mature frozen 160 + -10ºC 1- 3 min, Frozen Potato 150 + -10 ° C 6-8 min, double chip chips 1st 135 + .10 ° C). TPM Frying quality SMY-AC-R-015 at the beginning of the production run must be no more than 24%, the oil change is every one that exceeds 24% of TPM and can be in 5 days as in more SMY-A	
5.13.04	**Question:** Are there records (with corrective actions) that show anti-microbial (e.g., free chlorine, ORP, peroxyacetic acid) strength testing of product contact water and ice solutions prior to start up and throughout the production runs?	**Possible Points:** 10 **Points Scored:** 3 **Score:** Major Deficiency
	Auditor Comments: Major deficiency Citric acid is not monitored in immersion solution of sliced banana for chips (the objective is the antioxidant benefit), There is no record of water potability monitoring in the operation (low concentration free chlorine). The product is not washed, it is not required.	
5.13.05	**Question:** Are there records of visual monitoring and/or testing and changing of recirculated and batch water systems (e.g., dump tanks, flumes, hydrovacuums, hydrocoolers, etc.), for build-up of organic material (turbidity)?	**Possible Points:** 5 **Points Scored:** 3 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency There is no record of turbidity monitoring or, where appropriate, change of recirculated water in the application of antioxidant. The solution is used for immersion of banana in antioxidant solution, the goal is not to sanitize.	

5.13.06	**Question:** Are there records (with corrective actions) that show anti-microbial strength testing of hand/foot/tool dip stations, and are there stock check and replenishment records for gel and spray stations?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. Monitoring of chlorine and quaternary ammonium SMY-AC-R-011, concentration of quaternary salts in sanitary mats of 150 to 200 ppm is reported. Immersion of gloves and knives in free chlorine at 200 ppm. The monitoring is done every hour.	
5.13.07	**Question:** Is there a tool accountability program for knives and similar cutting hand tools used in the production area?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. SMY-SG-R-020 Record of verification of gloves and knives, 12 gloves and 12 knives are delivered, reviewed and reports any observations.	
5.13.08	**Question:** Is there a pre-operation inspection log?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Pre-start inspection record SMY-AC-R-027. Ppm verification record SMY-SG-R-003. Routine infrastructure checklist of plant equipment SMY-AC-R-016.	
5.13.09	**Question:** Has a documented risk assessment been performed to ensure that any food safety hazards relevant to facility location and adjacent land use are identified and controlled?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. There is a current risk review report for the operation and location, fence, trapping, inspection is handled. There is domestic activity to the surroundings and road, September 2019.	
5.13.10	**Question:** Is there a current certificate of inspection (or similar record) for backflow prevention assemblies on water lines into the facility?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. The topographic map of the installation and the water distribution network is presented. Erick Moran Architect 1006-05-600571 University of Guayaquil 09/29/2015.	
5.13.11	**Question:** Is there documented evidence of the internal audits performed, detailing findings and corrective actions?	**Possible Points:** 15 **Points Scored:** 10 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency There is no record of corrective actions derived from all internal audits submitted. Internal auditing calendar SMY-SG-R-008: three complete audits per year are planned for SAIA and HACCP and monthly BPM: 11/20/2019, 10/17/2019, 09/15/2019 carried out by Maria Auxiliadora Muñoz	

GMP Maintenance & Sanitation Files

5.14.01	**Question:** Does the facility have a preventative maintenance program and a documented schedule?	**Possible Points:** 10 **Points Scored:** 3 **Score:** Major Deficiency
	Auditor Comments: Major deficiency There is no preventive maintenance program and a documented schedule for all the services required in the plant, for example a fryer maintenance program is not presented. A schedule of improvements is presented which only reports what is scheduled for November and December.	
5.14.02	**Question:** Are there a logs of maintenance work and repairs and are they signed off when work is completed?	**Possible Points:** 10 **Points Scored:** 3 **Score:** Major Deficiency
	Auditor Comments: Major deficiency There are no records of maintenance of fryers and machinery in general (bands, engines, packing equipment, etc). SMY-MT-R-002 maintenance service is reported for tunnel and cameras. Work order application SMY-MT-R-003.	

5.14.03	**Question:** Are there logs showing that equipment is properly cleaned and sanitized after maintenance and repair work has been completed?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Cleaning in SMY-AC-R-041, cleaning, sanitization and surface release with ATP are reported, criterion <10 URL.	
5.14.04	**Question:** Is there a written cleaning schedule (Master Sanitation Schedule) that shows what and where is to be cleaned and how often?	**Possible Points:** 10 **Points Scored:** 7 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency In the master cleaning program, not all areas and surfaces are included, for example: forklifts, drains. SMY-AC-N-001 cleaning program: floors in general, walls in general, stainless steel tables plastic mandrels, production bands, worktable surfaces, fruit dipping tub, pataconera band (decorated), utensils cleaning, cars, trays, green meshes, garbage cans, fryer. External area: courtyards, bathrooms, dining room, among others are included.	
5.14.05	**Question:** Are there written cleaning and sanitation procedures (Sanitation Standard Operating Procedures) for the facility and all equipment?	**Possible Points:** 10 **Points Scored:** 7 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency There are no procedures / instructions for cleaning external areas. SMY-AC-N-001 cleaning program: floors in general, walls in general, stainless steel tables plastic mandrels, production bands, worktable surfaces, fruit dipping tub, pataconera band (decorated), utensils cleaning, cars, trays, green meshes, garbage cans, fryer.	
5.14.06	**Question:** Are cleaning and sanitation logs on file that show what was done, when and by who?	**Possible Points:** 10 **Points Scored:** 7 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency There is no record of cleaning of external areas. From internal areas, the register does not indicate the cleaning done to fryers, there is a lack of detail for equipment and particularization by specific line.	
5.14.07	**Question:** Are there records showing verification of cleaning and sanitizing chemical concentrations?	**Possible Points:** 5 **Points Scored:** 3 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency No verification of concentration of equipment sanitizing solution in ppm is recorded, only the dilution made is reported. Boot inspection record is presented SMY-AC-R-027	
5.14.08	**Question:** Are there documented procedures and completion records for clean-in-place (CIP) activities (e.g., cleaning re-circulating water systems such as washing flumes, ice injectors, hydrocoolers, ice makers, etc.), where applicable?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A CIP cleaning is not performed. The score is not affected.	
5.14.09	**Question:** Is there a routine program and written procedure to verify sanitation effectiveness using rapid post sanitation checks (e.g., ATP measurements, allergen specific proteins)?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. SMY-AC-I-007 luminometer usage instructions. Cleaning in SMY-AC-R-041, cleaning, sanitization and surface release with ATP are reported, criterion <10 URL.	
5.14.10	**Question:** Are there sanitation logs on file indicating that floor drains are cleaned on a regular basis (minimum daily in wet and fresh-cut production areas)?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. SMY-PC-R-013 cleaning of doors, interior paths and gutters V.01. Daily cleaning if required.	
5.14.11	**Question:** Are there records showing filters in air conditioning, ventilation and air filtration units are regularly cleaned and replaced?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A The air conditioning systems are new, they were installed a week ago. They have not required changing filters, the registration format is presented in white, installation note is presented. The score is not affected.	

5.14.12	**Question:** Are there records showing cooling units are maintenance serviced and cleaned at least every 12 months or more frequently as required?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Service report is presented by Suquinahua Moran Carlos Enrique maintaining cold rooms on several dates, for example 12/09/2019 and 10/21/2019.	
5.14.13	**Question:** Is there a documented glass and brittle plastic management procedure (including company glass and brittle plastic policy, glass breakage procedure and where necessary a glass register)?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Control of brittle material and sharp elements SMY-SG-P-003.	

GMP Worker Documentation

5.15.01	**Question:** Are there records of new worker food safety (GMP) orientation training (with topics covered and attendees) and are all workers required to sign the company's food safety hygiene and health policy?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Training record SMY-SG-R-005 Training 08/27/2019 3 attendees, rapporteur Michel Chamoun, 09/02/2019 2 attendees Speaker María Auxiliadora Muñoz V. HACCP Training 17, 18 and 19 September 2013 based on CODEX. 09/09/2019 29 assistants, 09/11/2019 29 assistants, 09/10/2019 26 assistants, 12/26/2019 management system policies, general policies, BPM, hand washing. Regulation is signed by all workers upon admission.	
5.15.02	**Question:** Are there logs of ongoing worker food safety education training, including topics covered, attendees, etc.?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Training record SMY-SG-R-005 Training 08/27/2019 3 attendees, rapporteur Michel Chamoun, 09/02/2019 2 attendees Speaker María Auxiliadora Muñoz V. HACCP Training 17, 18 and 19 September 2013 based on CODEX. 09/09/2019 29 assistants, 09/11/2019 29 assistants, 09/10/2019 26 assistants, 12/26/2019 management system policies, general policies, BPM, hand washing. Regulation is signed by all workers upon admission.	
5.15.03	**Question:** Is there a documented training program with training logs for the sanitation workers, including best practices and chemical use details?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Training record SMY-SG-R-00 Cleaning of contact surfaces and cleaning chemicals 10/18/2019. 46 attendees, rapporteur Medardo Silva representative of Chemicals.	
5.15.04	**Question:** Are there written and communicated procedures in place that require food handlers to report any cuts or grazes and/or if they are suffering any illnesses that might be a contamination risk to the products being produced, and return to work requirements? (In countries with health privacy/confidentiality laws, e.g. USA, auditors can check procedure/policy but not the actual records).	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Regulation is signed by all workers upon admission, 12/26/2019 management system policies, general policies, BPM, hand washing.	
5.15.05	**Question:** Are there worker food safety non-conformance records and associated corrective actions (including retraining records)?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. Memorandum is raised with non-compliance.	
5.15.06	**Question:** Are visitors and contractors required to sign a log stating that they will comply with the operations' personal hygiene and health requirements?	**Possible Points:** 3 **Points Scored:** 3 **Score:** Total Compliance
	Auditor Comments: Yes. Visitors are given a badge indicating basic policies according to staff regulations.	

GMP Testing

5.16.01	**Question:** Is there a written risk-based, scientifically valid microbiological testing program that may include pathogen testing, and details program design (zonal approach, food contact/non-food contact surfaces, spent sprout irrigation water, test & hold, water, ice, etc.), rationale for organisms tested for, procedures for sampling and testing (surfaces, water, product, ingredients, etc.), timing and frequency of testing, the testing methodology, the lab that performs the tests, and acceptable results/threshold levels for each organism?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. Sampling program. Sample type, area approach, specific surface, laboratory, parameters to be analyzed are included. They are made weekly on contact and non-contact surfaces, Listeria once a month, water once a month, Product per truck load, among others.	
5.16.02	**Question:** Are there records of microbiological test results and does testing meet the program requirements?	**Possible Points:** 15 **Points Scored:** 10 **Score:** Minor Deficiency
	Auditor Comments: Minor deficiency There are no microbiological records made in December. No analysis of Salmonella in the product. SMY-AC-R-038 on surfaces the sampling areas are divided into 1-3 (1 contact), they are made weekly starting on 10/25/2019, cold chamber walls 1 and 2, personnel hands, gloves, knives , drains, fryer, aprons, among others: CT, L. monocytogenes, Staphylococcus aureus absent.	
5.16.03	**Question:** Are there records of microbiological tests on water used in the facility (sampled from within the facility) and does the testing meet the program requirements?	**Possible Points:** 15 **Points Scored:** 0 **Score:** Non-Compliance
	Auditor Comments: No. No water analysis is presented.	
5.16.04	**Question:** Are there records of microbiological tests on ice used in the facility (either produced in-house or purchased) and does testing meet the program requirements?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A Ice is not used. The score is not affected.	
5.16.05	**Question:** Are there records of tests performed on compressed air or other mechanically introduced gases that are used directly on food and food contact surfaces and does testing meet the program requirements?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A No other analyzes are performed. The score is not affected.	
5.16.06	**Question:** Are there records of other tests (e.g., spent sprout irrigation water, product, raw ingredients, etc.) that are performed for any reason (e.g., customer requirements, best practice, regulatory requirements) and does testing meet program requirements?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. In product the analyzes are by shipment (lots in shipment vary, possibly 11 lots in dry season, in wet season they can be 4 lots per truck as they have to supply in greater quantity). Microbiological release record of SMY-AC-R-036 product is presented, sample composed of 20 pallets with representativeness based on 1 box per pallet is taken. BMA 5 log / g, Molds and yeasts <10 CFU / g, <10 CFU / g, E. coli absent, Listeria sp absent, Sataphylococcus aureus absent. Number of boxes released, observations and by whom Michel Chamoun, product code is reported	
5.16.07	**Question:** Are there written risk-based corrective action procedures for when unacceptable test results are received, that describe the steps to be taken, assign responsibility for taking those steps, and steps to ensure the cause is identified (e.g., root cause analysis) and corrected to minimize the potential for product contamination?	**Possible Points:** 10 **Points Scored:** 3 **Score:** Major Deficiency
	Auditor Comments: Major deficiency There is no corrective action procedure to follow in case of inappropriate results in non-contact contact surface analysis.	
5.16.08	**Question:** Are there records of corrective actions taken after unsuitable testing results that describe the steps taken, responsibility for taking those steps, and actions taken to ensure that the cause of contamination has been identified and corrected?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: N / A There are no laboratory reports with inappropriate results. The score is not affected.	
5.16.09	**Question:** Where food safety related testing is being done in-house, is there a laboratory quality assurance manual with validated testing methods and protocols, evidence of training related to sample collection and testing protocols, and relevant records of results?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. A manual of good laboratory practices SMY-AC-M-005 is presented. Michel Chamoun laboratory manager. Manual of environmental monitoring SMY-SG-I-012.	

GMP Temperature Controlled Storage & Distribution Logs

5.17.01	**Question:** Are there records of final product temperature checks for temperature sensitive product?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Temperature control of storage warehouses SMY-AC-R-019. 4 temperature taps are recorded in the product in process both inside the product (for example -11ºC) and in the environment (tunnel -20ºC). In finished product (internal -18 ° C, and chamber environment -18 ° C).	
5.17.02	**Question:** Are there temperature logs for the production area (if refrigerated)?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Registration SMY-AC-R-043 Temperature control of process areas is presented. Temperatures are recorded every hour during the operating day in the areas of: ambient peeling, ambient cutting, frying (the area is hot by the type of operation 48ºC), packing and shipping 9-11ºC.	
5.17.03	**Question:** Are there temperature logs for storage rooms?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Temperature control of storage warehouses SMY-AC-R-019. 4 temperature taps are recorded in the product in process both inside the product (for example -11ºC) and in the environment (tunnel -20ºC). In finished product (internal -18 ° C, and chamber environment -18 ° C).	
5.17.04	**Question:** Is there a documented procedure for checking truck trailer temperature prior to shipping?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Frozen product dispatch SMY-AG-P-017.	
5.17.05	**Question:** Are there records of shipping truck trailer (or other transportation systems) temperature checks, indicating the truck trailer temperature settings and that the truck trailer was pre-cooled prior to loading?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. SMY-AG-R-009 Transportation inspection record. Truck temperature is reported on boarding -20ºC, cleaning review, release firm José Bastidos P. Revenue control of reefer unit to plant where temperature is reported is also recorded.	
5.17.06	**Question:** Is there a documented procedure for reviewing the sanitary condition of truck trailers that will transport the product?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Frozen product dispatch SMY-AG-P-017.	
5.17.07	**Question:** Are there sanitary condition logs for shipping truck trailers (or other transportation systems)?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. SMY-AG-R-009 Transportation inspection record. Truck temperature on boarding is reported -20ºC, cleaning review, release firm José Bastidos P.	

GMP Allergen Control

5.18.01	**Question:** Are there no allergen risks handled or stored within production and storage areas?	**Possible Points:** 0 **Points Scored:** 0 **Score:** Yes
	Auditor Comments: Yes. No allergens are handled in the facility.	
5.18.02	**Question:** Has a documented allergen management plan been developed?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A No allergens are handled in the facility. The score is not affected.	

5.18.03	**Question:** Are there adequate storage controls (e.g., separation, identification, etc.) that ensure that allergens are not contaminating other materials?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A No allergens are handled in the facility. The score is not affected.	
5.18.04	**Question:** Is there a dedicated allergen production line or adequate clean down and production procedures that prevent allergen cross contamination?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A No allergens are handled in the facility. The score is not affected.	
5.18.05	**Question:** Are utensils and work in progress storage containers identified in order to prevent allergen cross contamination?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A No allergens are handled in the facility. The score is not affected.	
5.18.06	**Question:** Does re-work handling take into account the issues associated with allergen containing products?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A No allergens are handled in the facility. The score is not affected.	
5.18.07	**Question:** Are workers trained with respect to allergen risks and the facility allergen cross contamination controls (including hand washing between production runs) and are there records of this allergen training?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A No allergens are handled in the facility. The score is not affected.	
5.18.08	**Question:** Are worker practices adequate and being followed to protect against allergen cross-contact and against contamination of food?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A No allergens are handled in the facility. The score is not affected.	
5.18.09	**Question:** Are all products manufactured on site labeled correctly with respect to allergens?	**Possible Points:** 0 **Points Scored:** 0 **Score:** N/A
	Auditor Comments: N / A No allergens are handled in the facility. The score is not affected.	

HACCP Preliminary Steps

6.01.01	**Question:** Is there a team responsible for the HACCP program at the operation, with a leader assigned, if applicable, for the development, implementation and on-going maintenance of the HACCP system?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. The HACCP team is the same as the MY-SG-E-001 safety committee: safety and quality control coordinator, company president, production coordinator, commercial - general manager, logistics coordinator, quality technician , quality analyst and production manager. They meet every three months, last meetings 08/23/2019 and 11/25/2019.	
6.01.02	**Question:** Is there documented evidence that the HACCP team members have been trained on HACCP principles?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. Team leader: Michel Antonio Chamoun Monday, May 12 and 13, 2015 Costa Rica Carola Boneli in the HACCP Alliance. Training record SMY-SG-R-00 for all staff training was provided in BPM's and HACCP 12/02/2019 speaker María Auxiliadora Muñoz Vera.	

6.01.03	**Question:** Does a product description exist for the products produced?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Shelf life 18 months in freezing conditions, bulk chips one month in environmental conditions, in chips in laminated packaging 1 year. Preferred use is indicated, product characteristics, presentations among others.	
6.01.04	**Question:** Has the process (es) been flow charted in sufficient detail to completely describe the process or product handling/processing steps?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Process flow diagram: Conventional product, two lines where three processes are not simultaneously worked: mature for frozen frying, frozen frying pan and chips (frying). The product is received from third parties, for mature: the product is subjected to maturation with ethylene if necessary, peeled (not washed), sliced manually, passed to frying (PCC1 160 + -10ºC / 1-3 min and not more than 24% TPM), it is placed in trays of extended form, it is frozen for 6-8 h until it has a thermal center of -18ºC, it is emptied to the packing line, it is packed in bags, they are thermally sealed	
6.01.05	**Question:** Is t here documented evidence that the flow chart(s) been verified on-site?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Flowcharts verified on site on December 17, 2019 by Michel Chamoun team leader.	

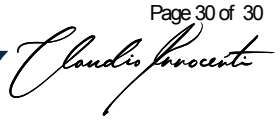
HACCP — Development of the HACCP Plan

6.02.01	**Question:** Has a documented hazard analysis for the processes been conducted, showing the various types of hazards, their likelihood of occurrence, their associated severity and their control measures? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. SMY-AC-T-006 mature frozen. SMY-AC-T-002 Frozen Patacon and SMY-AC-T-005 Chips. Hazards are indicated at each stage of the operation, probability of occurrence, severity, control measure and determination of PCC. "Control of PCC1 Medium frying temperature SMY-SG-R-021", PCC 2 SMY-SG-R- 023 a test is carried out with three parameters every hour: Fe 3.5 mm, Inox 4.5 mm, NFe 4 mm.	
6.02.02	**Question:** Have CCP decisions been made with documented justification and where CCPs are implemented in a specific processing step, have they been developed to control the identified hazard(s)?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. There is support literature for the identified CCPs, the product is ready for consumption and this is the importance of both CCPs. PPC1 Regulation of used frying fats and validity of quick tests for discarding the facts 1998, vOL. 49 Fasciae 3-4. 331-335 MC Dobarganes. Chemical and physical parameters as quality indicators of used frying fats 2000, Eur J. Lipid Sol. Technology 102-2000. PCC2 CPG Sec. 555.425 Foods, Adulteration Involving hard or Sharp Foreign Objects, CAC / GL 69-2008 Determination of tests for heavy metal detectors.	
6.02.03	**Question:** Have critical control point (CCP) processing steps been identified that eliminate or reduce food safety hazards to an acceptable level? Informational gathering. If the answer is YES, continue with the next question. If the answer is NO, the rest of "Module 6 HACCP" is not applicable	**Possible Points:** 0 **Points Scored:** 0 **Score:** Yes
	Auditor Comments: Yes. Mature frozen PCC1 160 + -10ºC 1-3 min, Frozen Patacon 150 + -10ºC 6-8 min, chips fried 2nd 170ºC + -10ºC 3-4 min, all frying points must be at 20-24% TPM at the beginning of the production run. In all three lines the PCC2 metal detector Fe 3.5 mm, Inox 4.5 mm, NFe 4 mm, hourly monitoring.	
6.02.04	**Question:** Have CCP critical control limits been established and supported by relevant validation documentation?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. Mature frozen PCC1 160 + -10ºC 1-3 min, Frozen Patacon 150 + -10ºC 6-8 min, chips fried 2nd 170ºC + -10ºC 3-4 min, all frying points must be at 20-24% TPM at the beginning of the production run. In all three lines the PCC2 metal detector Fe 3.5 mm, Inox 4.5 mm, NFe 4 mm, hourly monitoring. PPC1 Regulation of used frying fats and validity of quick tests for discarding the facts 1998, vOL. 49 Fasciae 3-4. 331-335 MC Dobarganes. Chemical and physical parameters as quality indicators of used frying fats 2000, Eur J. Lipid Sol. Technology 102-2000. PCC2 CPG Sec. 555.425 F	

6.02.05	**Question:** Have monitoring requirements and frequencies been determined and documented for the CCPs?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. Mature frozen PCC1 160 + -10ºC 1-3 min, Frozen Patacon 150 + -10ºC 6-8 min, chips fried 2nd 170ºC + -10ºC 3-4 min, all frying points must be at 20-24% TPM at the beginning of the production run. In all three lines the PCC2 metal detector Fe 3.5 mm, Inox 4.5 mm, NFe 4 mm, hourly monitoring.	
6.02.06	**Question:** Have specific responsibilities been assigned for the monitoring, recording and corrective action implementation of each CCP?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. PCC1 Manager Edwin Zambrano. Head of PCC2 Esther María Hernández Hidalgo.	
6.02.07	**Question:** Have standard operating procedures (SOPs) been created for the monitoring process(es) of the CCPs, which would include how to carry out the monitoring activities?	**Possible Points:** 5 **Points Scored:** 5 **Score:** Total Compliance
	Auditor Comments: Yes. Monitoring, frequencies, records, verifications and corrective actions are indicated in the PCC description and summary table.	
6.02.08	**Question:** Have corrective action procedures been established for the CCPs, including a detailed action plan for operators to follow if the critical control limit(s) of a CCP are not met (loss of control/deviation) and plans to adjust the process back into control?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. HACCP Manual SMY-AC-M-003. The PCC description and summary table shows the monitoring, frequencies, records, verifications and corrective actions. It is mentioned by Esther María Hernández Hidalgo that, due to the absence of detection of detector tests, the product worked since the last satisfactory test will be returned to review again and failing that it will be rejected. PCC1 product rejected, oil change.	
6.02.09	**Question:** Have recording templates (recording forms) been developed for monitoring the CCPs?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. Record of temperature and TPM monitoring in oil "Control of PCC1 Medium frying temperature SMY-SG-R-021" is recorded lot, time, band time and frying temperature (mature frozen 160 + -10ºC) 1-3 min, frozen potato 150 + -10 ° C 6-8 min, chips fried 2nd 170 ° C + -10 ° C 3-4 min, all frying points must be at 20-24% TPM at the start of the production run. In PCC 2 SMY-SG-R-023 metal detector, a test with three parameters is performed every hour: Fe 3.5 mm, Inox 4.5 mm, NFe 4 mm.	
6.02.10	**Question:** Have verification plans and schedules been developed for each CCP?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Verification in HACCP Manual SMY-AC-M-003. Measuring equipment used in both CCP is calibrated: TPM 270 TPM 270 measurement equipment 08/20/2019 Rivalesa SA Certificate RIV.LC.T.70.19.01A. Metal detector calibration of parts Test sample certificate of conformity LOMA systems 05/18/2018. Random PCC checks are performed.	
6.02.11	**Question:** Is the HACCP system verified when operational changes are made and at least once every 12 months?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Internal auditing calendar SMY-SG-R-008: three complete audits are planned for SAIA and HACCP and monthly BPM per year: 11/20/2019, 10/17/2019, 09/15/2019 Maria Auxiliadora Muñoz.	
6.02.12	**Question:** Is there documented evidence that all plant workers have attended a HACCP training, including training for CCP operators?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Training record SMY-SG-R-00. For all staff, training was provided in BPM´s and HACCP 12/02/2019 speaker María Auxiliadora Muñoz Vera,	

HACCP — Execution of the HACCP Plan on the Plant Floor

6.03.01	**Question:** Do all of the documents noted in the HACCP Plan accurately reflect plan requirements for the CCPs?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. The records of both CCPs were reviewed in accordance with the established revision plan, as well as the verification plan.	
6.03.02	**Question:** Are the CCP monitoring activities and frequencies in compliance with the HACCP Plan and CCP SOPs?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. The records of both CCPs were reviewed in accordance with the established revision plan, as well as the verification plan and procedures presented.	
6.03.03	**Question:** Do CCP operators understand basic HACCP principles and their role in monitoring CCPs?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Process operators were interviewed, staff showed knowledge on the subject of HACCP.	
6.03.04	**Question:** Are CCP monitoring records signed off (or initialed) by the operator(s) who are carrying out and recording the CCP check?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. The records of each CCP are signed on each occasion of monitoring by the CCP manager in turn.	
6.03.05	**Question:** Is there a deviation record detailing documented corrective actions when a deviation/loss of control of a CCP occurs (a critical control limit is exceeded)?	**Possible Points:** 15 **Points Scored:** 15 **Score:** Total Compliance
	Auditor Comments: Yes. There have been no corrective actions because there have been no deviations, however, the registry of each CCP has a column for the correction of corrective actions if necessary.	
6.03.06	**Question:** Are the CCP records reviewed and signed off by the quality control supervisor and/or management (second signatory)?	**Possible Points:** 10 **Points Scored:** 10 **Score:** Total Compliance
	Auditor Comments: Yes. Supervisor and safety staff signs the records of each CCP daily as part of the verification.	



814 mm +/-3

407 mm

407 mm

332 mm +/-2

10

10

53

1010

53

MEDIDAS	ANCHO	LARGO	ESPESOR
TEXTOS	CÓDIGO	TABLAS	INFO
COLORES	PANTONES	TRAMAS	
TACA	COLOR	UBICACIÓN	
MATERIAL	TIPO	PIGMENTO	
BOBINADO	COLORCAR NÚMERO FINAL		
IMPRESIÓN	INTERIOR	EXTERIOR	

*GARANTIZAMOS QUE SU PRODUCTO ESTÉ DE ACUERDO CON SUS EXIGENCIAS PARA LO CUAL NECESITAMOS SU COMPROMISO EN LA REVISIÓN DEL ARTE APROBANDO CADA CUADRO.

TARJETA DE IMPRESIÓN

ESTIMADO CLIENTE: SU APROBACION CONFIRMA LO IMPRESO EN ESTA TARJETA, Y POR ENDE SE CONVIERTE EN NUESTRO RESPALDO PARA LA CONTINUACION DEL PROCESO Y UNICO DOCUMENTO DE COMPARACION PARA LA ENTREGA DE LOS CYRELES

MATRIFLEXO S.A. — Planchas Fotopolimeras Digitales — FOR DIS 10 VER. 15 08 17

Para: PLASTIGOMEZ — PUNTUALIDAD GARANTIZADA

CLIENTE: SAMIYAMEALS

PRODUCTO: MADURO SWEET PLANTAINS 6LB

DISEÑADOR: RONNY BATIOJA

COLORES REFERENCIALES:

1.- CYAN
2.- MAGENTA
3.- AMARILLO
5.- PANTONE 355 C
6.- BLANCO
7.- BARNIZ

MEDIDA	407x332	PLANCHA	45
FUELLE/SOLAPA	-	LINEATURA	110 lpi
CILINDRO	340 mm	SELLADO	LATERAL
FIG. ALREDED	1	CARAS IMP.	1

AAMMDD 20190611

ARTE # 95466

ANULA A # NUEVO

OBSERVACIONES: SE CAMBIA TABLA NUTRICIONAL, SE ELIMINA INFORMACION DEL DISTRIBUIDOR

TIPOS DE ENROLLAMIENTO:

MATERIAL DE IMPRESIÓN

ESPECIFICACIÓN	Funda
PIGMENTO	PEBD NATURAL
ESPESOR	64 Micras
LAMINADO	NO

IMPRESORAS: COMEXI, NOVAGRAF

VENTAS	PRODUCCION
CONTROL DE CALIDAD	ELABORACION CLISES

Aprobado: 11-12-2019

Claudio Innocenti

DOCUMENT REVIEWED AND ASSESSED BY CLAUDIO INNOCENTI (PARTNER & PCQI) ON OR ABOUT FSVP PLAN'S NOTED REVIEW START/END DATES

CONFIDENTIAL TREATMENT REQUESTED

DOCUMENTO ELABORADO BAJO SISTEMA DE GESTION ISO 9001:2008

SU FIRMA ES UN COMPROMISO DE RESPONSABILIDAD.

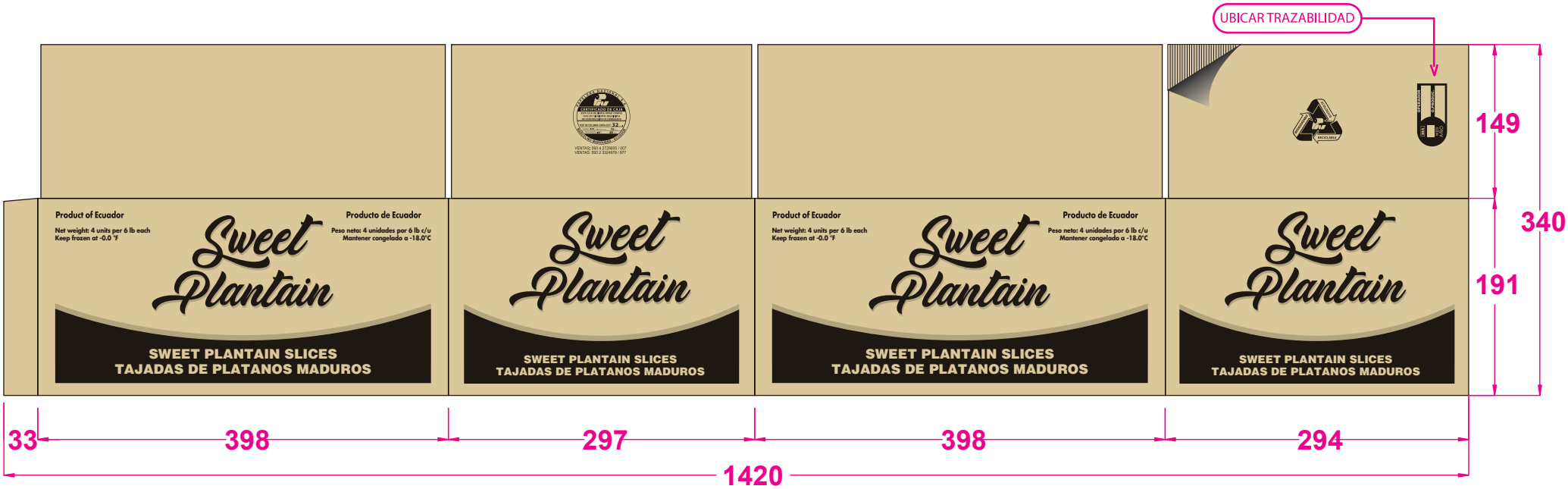
Papelera Nacional S.A. 1961

Cliente: **SAMIYA**

Referencia: **CAJA SWEET PLANTAIN GCC 24 LB**

T/I# **14425**

REEMPLAZA A TDI# **12723**



JEFE DE DISEÑO E ING. DE EMPAQUES:	EJECUTIVO DE NEGOCIOS:	CLIENTE:	Colores de Impresión:
FECHA:	FECHA:	FECHA:	GCMI-90 CUBRIENTE KRAFT

D9	Fecha: 22/10/2021	Medidas Internas:	Largo: 393	Ancho: 292	Alto: 186	Largo de Lamina 1420	Ancho de Lamina 340	Medidas Externas:	Largo: --	Ancho: --	Alto: --																
Mercado	LOCAL ☐	EXPORTACIÓN ☒	Tipo Aleta	NORMAL ☒	PASADO ☐	Aleta Pegada	SI ☒	NO ☐	Recubrimiento:	SI ☒	NO ☐	Material:	KRAFT	ECT	32	TEST	200	ONDA	C	TROQUEL	-	CABIDA	1	PLANO	8918	Máquina	BOBST	Escala: 18%

Observaciones: **REEMPLAZA POR CAMBIO DE MEDIDA Y TEST Y SE UTILIZA CLISÉ EXISTENTE DE TI 12723**

DOCUMENT REVIEWED AND ASSESSED BY CLAUDIO INNOCENTI (PARTNER & PCQI) ON OR ABOUT FSVP PLAN'S NOTED REVIEW START/END DATES

SEÑOR CLIENTE: REVISAR TEXTOS Y COLORES PREVIA APROBACIÓN

CONFIDENTIAL TREATMENT REQUESTED

Claudio Innocenti

G-DIE-F-02 (04:14)

U.S. FOOD & DRUG ADMINISTRATION

FOREIGN SUPPLIER VERIFICATION PROGRAM

—

Recertification Questionnaire Submission

} Foreign Supplier
} **SAMIYAMEALS SA**
} *as of January 25, 2022*

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

START

01) Has SAMIYAMEALS SA's Food Safety Plan or Program been revised in any way?
Response: **Yes**

02) Has SAMIYAMEALS SA's HACCP Plan been revised in any way?
Response: **Yes**

03) Has any change occurred to SAMIYAMEALS SA's product Ingredients?
Response: **No**

04) Has SAMIYAMEALS SA's Allergen Control Procedure been revised in any way?
Response: **Yes**

05) Has any change occurred to SAMIYAMEALS SA's product Labeling?
Response: **No**

06) Has SAMIYAMEALS SA's Onsite Audit report expired or been updated?
Response: **Yes**

07) Has SAMIYAMEALS SA undergone a recall, for any reason?

Response: **No**

08) Has SAMIYAMEALS SA been inspected by the United States Food & Drug Administration?

Response: **No**

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

Response: **No**

10) Has the U.S. FDA issued SAMIYAMEALS SA a Warning Letter in relation to its facility or product(s)?

Response: **No**

11) Does SAMIYAMEALS SA perform laboratory analysis on its product(s)?

Response: **Yes**

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

Response: **No**

13) Has SAMIYAMEALS SA's conformance with FSVP, or its appendant regulations, changed in any way?

Response: **No**

14) Are SAMIYAMEALS SA's products considered to be “Ready To Eat” when leaving its facility?

Response: **Yes**
14a) What hazard(s) remain uncontrolled?
Response: **None.**

15) Would you like to share any additional information?

Response: **Yes**
15a) Additional information:
Response: **Our operation is GFS accredited under the PrimusGFS standard.**

U.S. FOOD & DRUG ADMINISTRATION

FOREIGN SUPPLIER VERIFICATION PROGRAM

—

Recertification Questionnaire Submission

} Foreign Supplier
} **SAMIYAMEALS SA**
} *as of January 25, 2022*

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

Certified by: **MICHEL CHAMOUN YUNES**
Date of Certification: **2022-01-24**
Email Address of Respondent: **MICHEL.CHAMOUN@SAMIYA.CO**

—

END

Search Results

FEI Number	Firm Name	Physical Address	Mailing Address
3014976748	SAMIYA	Km 19.2 Via A La Costa, Guayaquil, Guayas, 090150, EC	Km 19.2 Via A La Costa, Guayaquil, Guayas, 090150, EC

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

3014976748

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: **FDADataDashboard@fda.hhs.gov** (mailto:FDADataDashboard@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)

Import Refusals

FSMA Data Search (index.htm)

Firm/Supplier Evaluation Resources (fser.htm)

LAAF Participants (laaf.htm)

TPP Participants (tpp.htm)

Approved VQIP

Resources

How to Use the Dashboard (../howto.htm)

Glossary (../glossary.htm)

API (../api/index.htm)

Notifications (../notifications.htm

Contact Us (../contact.htm)

(../cd/imprefusals.htm) Importers (vqip.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)
