GLOBAL TRADE BRIDGE

F S V P

COMPLIANCE PLAN

MOLINOS VALLE DEL CIBAO [BOCEL GALLETAS]

Name of Foreign Supplier

AVIVA SODA CRACKERS | SODA CRACKER PRODUCT-LINE

Name of Product-line

JANUARY 02, 2022 / NOVEMBER 03, 2024

Date of Initial Verification / Re-verification

JANUARY 05, 2026

Date of Plan Expiration

APPROVED | [PENDING REMOVAL FROM RED LIST]

Result of Verification

NUMBER 06

Version

– Confidential –

CONTENT *of* FSVP PLAN

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 *for* USE

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.

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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 Initial and Ongoing Verification Activities and a reviewed and approved copy of the certifying document*(s)* will be included within this FSVP plan.

A food item's 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 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 Initial and Ongoing Verification Activities 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 Initial and Ongoing Verification Activities and 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 consistent with Ongoing Verification Activities.

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*(ies)* 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/ or Initial and/or Ongoing Verification Activities, and a copies of these activity*(ies)* 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: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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: Molinos Valle del Cibao, C. por A.

Product: Soda Crackers

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

Review Start: July 03, 2024 Review End: Nov. 103, 2024

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 imported product falls 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.

Product and supplier are currently listed on the Red List of Import Alert # 99-41. While internally approved, Cassava Bread, supplied by Alimentos Fortuna S.r.l. will not be imported by Global Trade Bridge until our Petition for Removal from the Red List of Import Alert # 99-41 is reviewed and granted by FDA's Division of Northeast Imports, Office of Enforcement and Import Operations, Office of Regulatory Affairs.

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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, Marjorie Balseca (*type name*) certify that I reviewed this FSVP plan on 12/16/24 (*today's date*) and found its contents to be acceptable.

Reviewer's Name: Marjorie Balseca

Reviewer's Signature: Marjorie Balseca

Reviewer's Title: Controller

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

DESIGNATION *of* ROLES & SUMMARY *of* REVIEW

FOREIGN SUPPLIER VERIFICATION PROGRAM IMPORTER

Company Name: Global Trade Bridge Corporation FDA FEI: 3014295479

Physical Address: 60 East Halsey Road DUNS No.: 071148192

City: Parsippany State: New Jersey, 07054 Country: United States

Mailing Address: 30 Wall Street, 8th Floor

City: New York State: New York, 10005-2208 Country: United States

Phone Number: +1 (347) 231-2323 Email Address: lapina@gtbridge.com

Name *of* Representative*(s)*: Mr. Lorenzo Pina Title: Owner

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

Company Name: Molinos Valle del Cibao, C. por A. FDA FFR: 16208278314

Manufacturing Address: Carretera Duarte Km., 1/2 Tramo 5 FDA FEI: 3008721890

City: Santiago-Licey Province/Territory: Santiago, 51000 Country: Dominican Rep.

Office Address: Duarte 5

City: Santo Domingo Province/Territory: Oeste, 02301 Country: Dominican Rep.

Phone Number: +8093370444 Email Address: cpantaleon@grupocel.com

Name *of* Representative*(s)*: Ms. Claudia Pantaleon Title: QA / QC

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

Agent/QI Name: Claudio Innocenti Signature: Claudio Innocenti

Title: Partner & Preventive Controls Qualified Individual. Date: Nov 103, 2024

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**	
Soda Cracker | Ready-To-Eat	☑ Yes ☐ No ☐ *Undetermined*	☑ Yes ☐ No ☐ *Undetermined*	☑ Yes ☐ No ☐ *Undetermined*	Internally Approved. — Awaiting FDA's review and removal from the Red List of Import Alert # 99-41 prior to import.
	☐ FSVP Importer	☐ FSVP Importer	☐ FSVP Importer	
	☐ Disclosure	☐ Disclosure	☐ Disclosure	
	☐ 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: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

REGISTER *of* SUBSTANTIATING DOCUMENTS

HAZARD ANALYSIS

☒ *Requested* ☒ *Required* ☒ *Received* ☒ *Reviewed*

NOTES Molinos Valle del Cibao's HACCP Plan received.
Contains: Food Safety Team Members, Product Specifications, Facility Sanitation, Product Storage and Handling, HACCP Plan/HAZARDS Analysis, Process Preventive Control, Allergen Statement, Environmental Monitoring, etc.

ON-SITE AUDIT REPORT

☒ *Requested* ☒ *Required* ☒ *Received* ☒ *Reviewed*

NOTES Molinos Valle del Cibao's Annual On-site Audit Report received.
Dated: May 26, 2024. Audit Grade: 98.3% out of 100%. Re-audit Due Date: May, 2025.
Reason for Audit: At least one SAHCODHA hazard was identified. Audit report considers FDA food safety regulations and includes a review of the facility's written food safety plan, and its implementation, for the controlled hazard.
Note: Audit was carried out by AGROBIOTEK Labororatorios SRL, under GlobalSTD Standards to confirm that Alimentos Fortuna S.r.l. is in current compliance with FDA's Risk-Based Preventive Controls for Human Food Title 21 CFR Section 117.
Molinos Valle del Cibao's 2021 Costco Onsite audit report received.

SAMPLING OR TESTING RESULTS

☒ *Requested* ☒ *Required* ☒ *Received* ☒ *Reviewed*

NOTES Certificate of Analysis received from supplier.
Dated: July 2022
Tested for: Molds and Yeasts, Total Coliforms, and E.coli.
Laboratory: ALTOL PETROLEUM PRODUCTS SERVICES DOMINICANA, SRL.
Note: Ongoing. If granted removal from Import Alert, per-batch testing results will be acquired, reviewed and approved prior to import, to confirm that product has been effectively processed to control for all FDA identified biological and chemical hazards. This requirement will be transfered to annual results after 4 acceptable batches.

OTHER FOOD SAFETY RECORDS

☒ *Requested* ☒ *Required* ☒ *Received* ☒ *Reviewed*

NOTES Molinos Valle del Cibao's completed Foreign Supplier FSVP Questionnaire received.
Dated: Dec. 03, 2021.
Completed by: Claudia Pantaleon.
Attestation of Conformance, Signed and Dated.
Molinos Valle del Cibao certifies that its facility is responsible for implementing, and has implemented, controls that significantly minimize or prevent all FDA-identified biological, chemical, and/or physical hazards in relation to Soda Crackers.

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: Molinos Valle del Cibao, C. por A.

Product: Soda Crackers

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

Review Start: July 03, 2024 Review End: Nov. 103, 2024

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

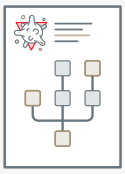
- ☑ if positive results are returned
- ☑ if recall or import refusal occurs
- ☑ if inspection occurs
- ☑ on an annual basis
- ☑ on a per-batch/shipment basis
- ☑ Chemical ☑ Biological
- ☑ *other:* Ber-batch (first 4 batches) Annual thereafter.

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 once every three years or sooner, per above.

unitedsafetyagents.com/documents

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

INITIAL VERIFICATION ACTIVITIES

Summary of Actions Conducted Prior To Initial Approval

To confirm that all and any relevant or identified food safety hazards requiring a control have been significantly minimized or prevented, the below enumerated activities were used to initially verify Soda Crackers ("product" or "imported product"), supplied by Molinos Valle del Cibao (Grupo Bocel) ("supplier" or "foreign supplier"), imported by Global Trade Bridge Corp. ("importer" or "FSVP importer"); by United Safety Agents ("USA", "FSVP qualified individual", "qualified individual", or "QI"):

A review and assessment of Molinos Valle del Cibao's

ON-SITE AUDIT REPORT, Per §1.506(d)(2), a hazard has been identified for which there is a reasonable probability that exposure may result in serious adverse health consequences or death to humans or animals. It is the responsibility of Molinos Valle del Cibao (Grupo Bocel) to control the identified hazards. Thus, an on-site audit of the supplier's facility was commissioned, acquired, assessed, and ruled acceptable. The audit report considers FDA food safety regulations and includes a review of the facility's written food safety plan, and its implementation, for the controlled hazards. Global Trade Bridge will continue to maintain its engagement of a qualified auditor to provide annual onsite audit reports under GlobalSTD Standards, in perpetuity.

RELEVANT FOOD SAFETY RECORDS, including a review of supplier's [1] Hazard Analysis and Critical Control Plan ("HACCP Plan"); and [2] Food Safety Plan. 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 QI were completed.

SAMPLING AND/OR LABORATORY 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 relevant or identified hazards which required and requires 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.

FSVP SUPPLIER QUESTIONNAIRE, including a review and assessment of the supplier's reported [1] critical/process/supply-chain controls for biological, chemical, environmental, allergenic, and physical hazards; [2] facility cleaning and sanitary monitoring information; [3] staff hygiene details; [4] pest control procedures; [5] traceability procedures; [6] release procedures; [7] packaging format; [8] customer complaint handling procedures; and [9] anticipated plans and protocols relating to a potential recall and/or unanticipated food safety-related issue. Per §1.506(d)(1)(ii)(D) and (e)(1)(iv)(B), documentation of each initial 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.

OTHER APPROPRIATE SUPPLIER VERIFICATION ACTIVITIES, including a review of the supplier's [1] implementation records; [2] internal monitoring procedures; and [3] compliance history – including whether the foreign supplier is or was the subject of 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 QI were completed.

NOTE

Per §1.506(d)(3), FSVP importer relied on the determination of appropriate foreign supplier verification activities made by an entity other than the foreign supplier and has reviewed and assessed whether the determination was appropriate. The Importer has documented its review and assessment, including documenting that the determination of appropriate verification activities was made by a FSVP QI. The FSVP importer's attestation of review and assessment can be found on page number nine (9) of this FSVP. USA's certifications and qualifications can be found on page numbers twenty-eight (28) through thirty-six (36) of this FSVP.

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

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

ONGOING VERIFICATION ACTIVITIES

Summary of Ongoing Verification Activities Necessary To Maintain Approval

To confirm that all and any relevant or identified food safety hazards requiring a control, for Soda Crackers, supplied by Molinos Valle del Cibao (Grupo Bocel), continue to be significantly minimized or prevented, 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 and verification activity-specific requirements:

PRIOR TO EACH ENTRY OF PRODUCT INTO THE U.S.

If granted removal from Import Alert, per-batch LABORATORY TESTING RESULTS demonstrating that the incoming product is absent of (or within acceptable levels of) all biological and chemical hazards, will be requested from Molinos Valle del Cibao, C. por A. If results exceed established tolerances, the product will be rejected prior to entering into the United States by importer, or delayed from distribution to the public until corrective actions have been performed and their efficacy verified. Molinos Valle del Cibao, C. por A. has been informed of this ongoing requirement. This requirement may be transfered to annual results after 4 consecutive acceptable batches, bearing USA and Global Trade Bridge Corp.'s assessment at that time.

ANNUALLY OR UPON CHANGE

An updated version of foreign supplier's HACCP PLAN will be required if any change or update occurs. The supplier 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 the supplier's most up-to-date copy.

An updated version of supplier's ON-SITE AUDIT REPORT will be requested on an annual basis. The supplier 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 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. The supplier has been informed of this ongoing requirement and USA will acquire the results from the supplier annually.

Confirmation that supplier's FOOD FACILITY REGISTRATION remains active with FDA will be made annually by USA.

Updated substantiation of supplier'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 REGULATORY COMPLIANCE STANDING will be checked by USA via FDA's Data Dashboard annually – at a minimum – or sooner if USA is made aware of new information.

An updated version of the product's LABELING will be required if any change or update occurs. the supplier has been informed of this ongoing requirement and USA will confirm annually that the label on file remains current. Important 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 the FSVP importer'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 hazard 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 [12] of FSVP.

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

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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
Dec. 05, 2011	IMPORT REFUSAL Product Code: 04AGT05 \SPAGHETTI Refusal Charges: 11 Shipment ID: MU8-0025747-7/1/6/ Note: Product not related.
Dec. 29, 2011	IMPORT REFUSAL Product Code: 03MFT99 \ COOKIE,BISCUIT,W… DOUGH, N.E.C. Refusal Charges: 11 Shipment ID: BHE-0359170-4/4/1/ Note: Three refusals listed.
April 25, 2018.	INSPECTION Inspection Id: 1060730. Project Area: Foodborne Biological Hazards Classification: NAI Note: Full EIN provided by supplier. FSVP Importer should acquire corrective actions from supplier for deficiencies listed on EIN.
June 06, 2024	IMPORT REFUSAL Product Code: Noodles Enriched Refusal Charges: 9 Shipment ID: EWV-1117147-4/31/1 Note: Product not related to Soda Crackers.
	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: Molinos Valle del Cibao, C. por A. FEI: 3008721890 Date: Nov. 103, 2024

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

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

REVISION LOG *for* FSVP PLAN

Version No.	Date *of* Change	Description *of* Revision
		——— FSVP IMPORTER'S REGULATORY HISTORY AND PLAN TIMELINE ———
—	September 11, 2018	FDA INSPECTION Inspection Id: 1066522 Project Area: Foodborne Biological Hazards Classification: VAI
—	December 23, 2020	FDA FSVP RECORDS INSPECTION Inspection Id: 1134232 Project Area: Foodborne Biological Hazards Classification: OAI Short Description: Develop FSVP; Hazard analysis written; Evaluation - performance, risk; Verification activity assurance; Verification activity before import, periodically.
—	March 25, 2021	WARNING LETTER Case Id: 612898 Product Type: Food/Cosmetics
		——————— CORRECTIVE ACTIONS AND PLAN TIMELINE ———————
—	November 05, 2021	Global Trade Bridge Corp. engaged United Safety Agents (USA) to act as its properly designated, third-party qualified individual, as the term is defined under Section 805 of the FD&C Act and 21 CFR §1.503(a).
No. 01	Jan. 02, 2022	Foreign Supplier and product underwent initial FSVP verification. All requisite food safety documents were requested, received, reviewed and added to FSVP. FSVP was created and reflects recent FDA Guidance document(s) and/or regulatory statues.
No. 02	March 12, 2022	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	Jan. 03, 2023	Product and supplier underwent initial FSVP verification.
No. 04	Jan. 04, 2024	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. 05	July 11, 2024	FSVP was updated upon the receipt of Molinos Valle del Cibao, C. por A.'s 2024 on-site audit report results .
No. 06	November 03, 2024	Product and supplier underwent additional FSVP verification procedures.

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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: product baked to a temperature of 100ºC. Controls are validated regularly (monthly) by PCQI. 02. Supplier utilizes laboratory testing of finished product to verify that biological hazards have been effectively controlled. Details: Certificates of Analysis received. Dated: July 2022 Tested for: Molds and Yeasts, Total Coliforms, and E.coli. 03. Per §1.506(d)(2), a hazard has been identified for which there is a reasonable probability that exposure may result in serious adverse health consequences or death to humans or animals. It is the responsibility of Molinos Valle del Cibao (Grupo Bocel) to control the identified hazards. Thus, an on-site audit of the supplier's facility was commissioned, acquired, assessed, and ruled acceptable. 04. All staff undergoes formal food hygiene training. 05. All staff issued protective clothing. 06. All production operatives are required to cover head/facial hair within the processing/manufacturing area. 07. Adequate toilet and hand washing facilities provided. 08. Product is positively released by PCQI.	YES. 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. ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) Category: Baked. Category No.: 1 Subcategory: Bread snacks, Unseasoned. Storage: Shelf-Stable

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: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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 utilizes laboratory testing to verify that product is free from chemical hazards prior to release. 03. Product's formulation closely controlled and monitored by PCQI. ——————NOTE—————— 01. The FDA does not recognize any chemical hazards in reference to this product type. Appendix 1 (Hazards Tables) Category: Baked. Subcategory: Bread snacks, Unseasoned.	YES. 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: Baked. Category No.: 1 Subcategory: Bread snacks, Unseasoned. Storage: Shelf-Stable ——————— ———————

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: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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***†	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) Milk, Wheat, and Soy are present in product B) a documented allergen control program is in use. C) a dedicated process line and a documented cleaning procedure are in place to prevent contamination. D) all employees undergo allergen training and processes have been put in place to reduce the likelihood of cross contact or unintentional introduction of allergens into processing area. ———————NOTE——————— ---------- 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.	YES. 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. ——————— ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) Category: Baked. Category No.: 1 Subcategory: Bread snacks, Unseasoned. Storage: Shelf-Stable ——————— ———————

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 need to reflect allergen labeling for sesame beginning on January 1, 2023.

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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. 03. All product is positively released and hermetically sealed within plastic. 04. Supplier conduct periodic checks of packaging integrity (e.g., upon receipt and prior to use) including for packaged products, ingredients, and equipment components. 05. Supplier reports to also utilizes the following: - Microbiological test to the environment. - Fogging of the environment of areas. - Microbiological test of compressed air. ———————NOTE——————— Product has a very low aW level.	YES. 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: Baked. Category No.: 1 Subcategory: Bread snacks, Unseasoned. Storage: Shelf-Stable ——————— ———————

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.

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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: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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: 3.0 mm. Non Ferrous: 3.0 mm. Stainless Steel: 3.0 mm. 02. Glass and Breakable Plastic Program in use. 03. Supplier sieves incoming ingredients.	YES. 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: Baked. Category No.: 1 Subcategory: Bread snacks, Unseasoned. Storage: Shelf-Stable

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: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

ASSESSMENT *of* FOREIGN SUPPLIER

1.0 FOREIGN SUPPLIER INFORMATION

1.1. Supplier name: Molinos Valle del Cibao, C. por A. 1.2. Supplier country: Dominican Rep.

1.3. Products manufactured/supplied: Soda Crackers

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

Standard: GlobalSTD Standards

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: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

REVIEW *of* GENERAL FOOD SAFETY PROGRAM

Claims Made Against Product

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

Overview *of* Foreign Supplier's Commercial Operation

Molinos Valle del Cibao, C. por A., based in the Dominican Republic, is a leading company in the production and distribution of wheat-based products. Established with a focus on high-quality standards, the company specializes in milling and processing wheat to produce various products, including flour, baking ingredients, and other related goods.

Testing Program & Accreditation

Tests Performed on the Product for Verification
Objective: To verify the suitability of the Process Control, time and temperature control in the ovens and final product. Sample Identification: The temperature in the different zones of the furnaces and control panel is verified; this temperature is validated with a laser thermometer. Samples of finished product are sent to the External Laboratory and the sample is identified with the lot number to which it belongs.

Laboratory: Agrobiotek Laboratorios SRL, Calle Santiago No. 608, Altos, Santo Domingo, D.N. Dominican Republic Analysis Performed: The representative of the Laboratory takes the packed sample to determine the presence of: Salmonella, Escherichia Coli and staphylococcus aureus.

Supplier & Product Allergen Information

Supplier certifies that: A) there are allergens handled on site, B) a documented allergen control program is in use, C) a dedicated process line and a documented cleaning procedure are in place to prevent contamination, D) all employees undergo allergen training and processes have been put in place to reduce the likelihood of cross contact or unintentional introduction of allergens into processing area.

_____

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

Packaging Type & Shipping / Handling Requirements

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

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

REVIEW *of* GENERAL FOOD SAFETY PROGRAM

Supplier GFSI Status & Historical Performance

Supplier appears to be following GMPs and utilizes an established food safety program. Products supplied by this supplier have been verified and are approved for import, bearing FDA's review and determination related to our petition for removal from the Red List of Import Alter 99-41.

Close Supplier Monitoring

If granted removal from Import Alert, per-batch testing results will be acquired, reviewed and approved prior to import, to confirm that product has been effectively processed to control for all FDA identified biological and chemical hazards. This requirement may be transfered to annual results after 4 acceptable batches.

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.

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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.

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

ADDENDUM

FDA REGULATORY COMPLIANCE AND INSIDENT HISTORY

IMPORT REFUSAL
Product Code: 04AGT05 \SPAGHETTI
Refusal Charges: 11
Shipment ID: MU8-0025747-7/1/6/
Note: Product NOT related.

IMPORT REFUSAL
Product Code: 03MFT99 \ COOKIE,BISCUIT,W… DOUGH, N.E.C.
Refusal Charges: 11
Shipment ID: BHE-0359170-4/4/1/
Note: Three refusals listed.

INSPECTION
Inspection Id: 1060730.
Project Area: Foodborne Biological Hazards
Classification: NAI
Note: Full EIN provided by supplier. FSVP Importer should acquire corrective actions from supplier for deficiencies listed on EIN.

CLOSE SUPPLIER MONITORING PROCEDURES

USA recommends that FSVP Importer implement and closely follow appropriate monitoring procedures in an effort to determine that product has been effectively processed to control for all FDA identified biological and chemical hazards.

If granted removal from Import Alert, per-batch LABORATORY TESTING RESULTS demonstrating that the incoming product is absent of (or within acceptable levels of) all biological and chemical hazards, will be requested from Molinos Valle del Cibao, C. por A. If results exceed established tolerances, the product will be rejected prior to entering into the United States by importer, or delayed from distribution to the public until corrective actions have been performed and their efficacy verified. Molinos Valle del Cibao, C. por A. has been informed of this ongoing requirement. This requirement may be transfered to annual results after 4 consecutive acceptable batches, bearing USA and Global Trade Bridge Corp.'s assessment at that time.

These procedures may include per-batch laboratory testing, conducted by an independent third-party laboratory (preferably ISO 17025-accredited for all biological and chemical hazards.

END

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

ADDENDUM

INTENTIONALLY

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Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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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

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AAFCO
Association of American Feed Control Officials

Certificate # 223faa17

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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Foreign Supplier Verification Programs

delivered by Lead Instructor

Bob Bauer

completed on

09/14/2018

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

Gerald 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 # 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: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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Bob Bauer

completed on

05/31/2018

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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

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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

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Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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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

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ILLINOIS INSTITUTE OF TECHNOLOGY

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AFDO

Certificate # 2d697331

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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

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ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti

Certificate # ed6f0b58

AFDO

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Foreign Supplier Verification Programs

delivered by Lead Instructor

tina coil

completed on
06/13/2017

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Institute for Food Safety and Health

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Joseph Corby, Executive Director
Association of Food and Drug Officials

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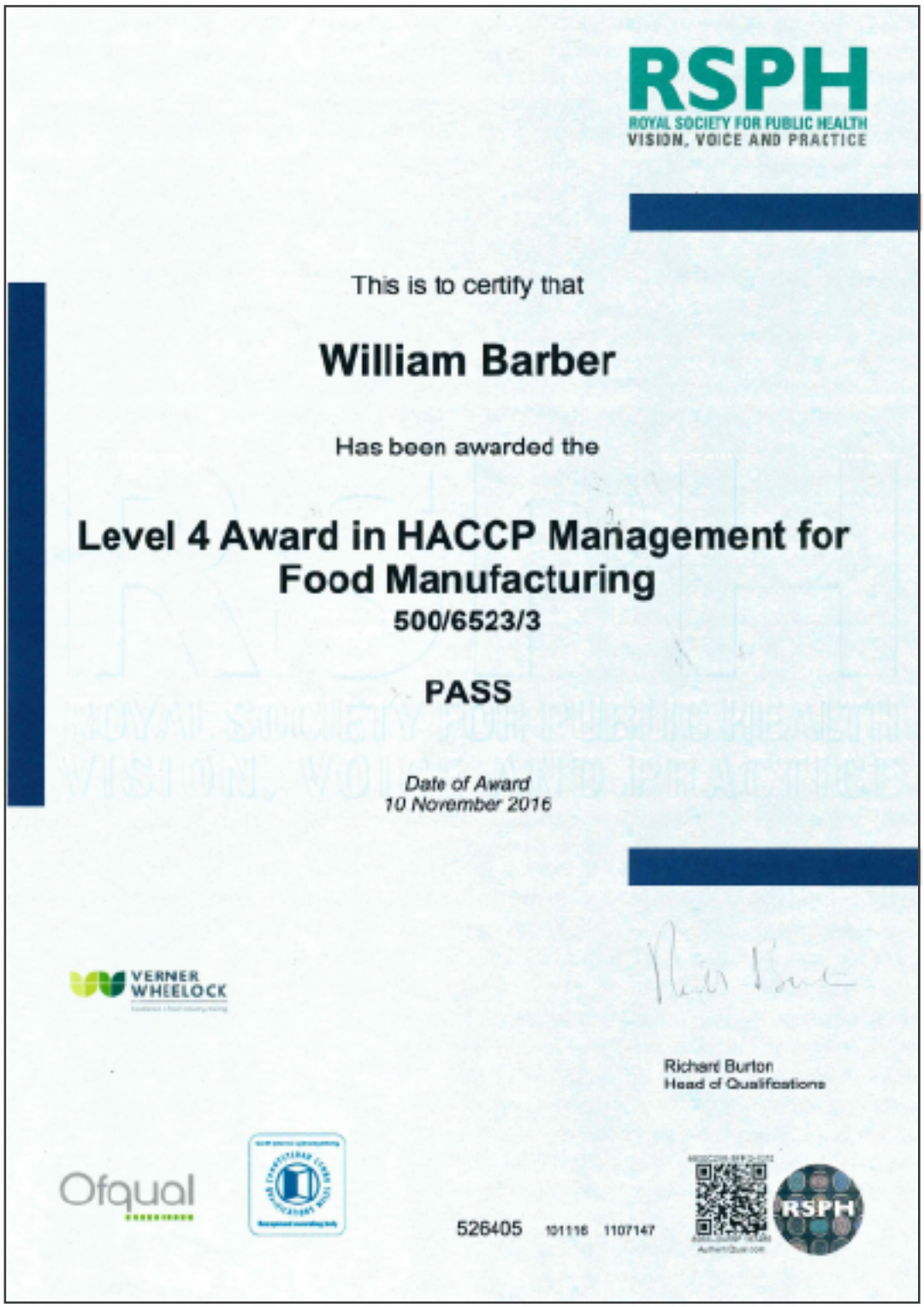
Certificate # 917b0241

AFDO

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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

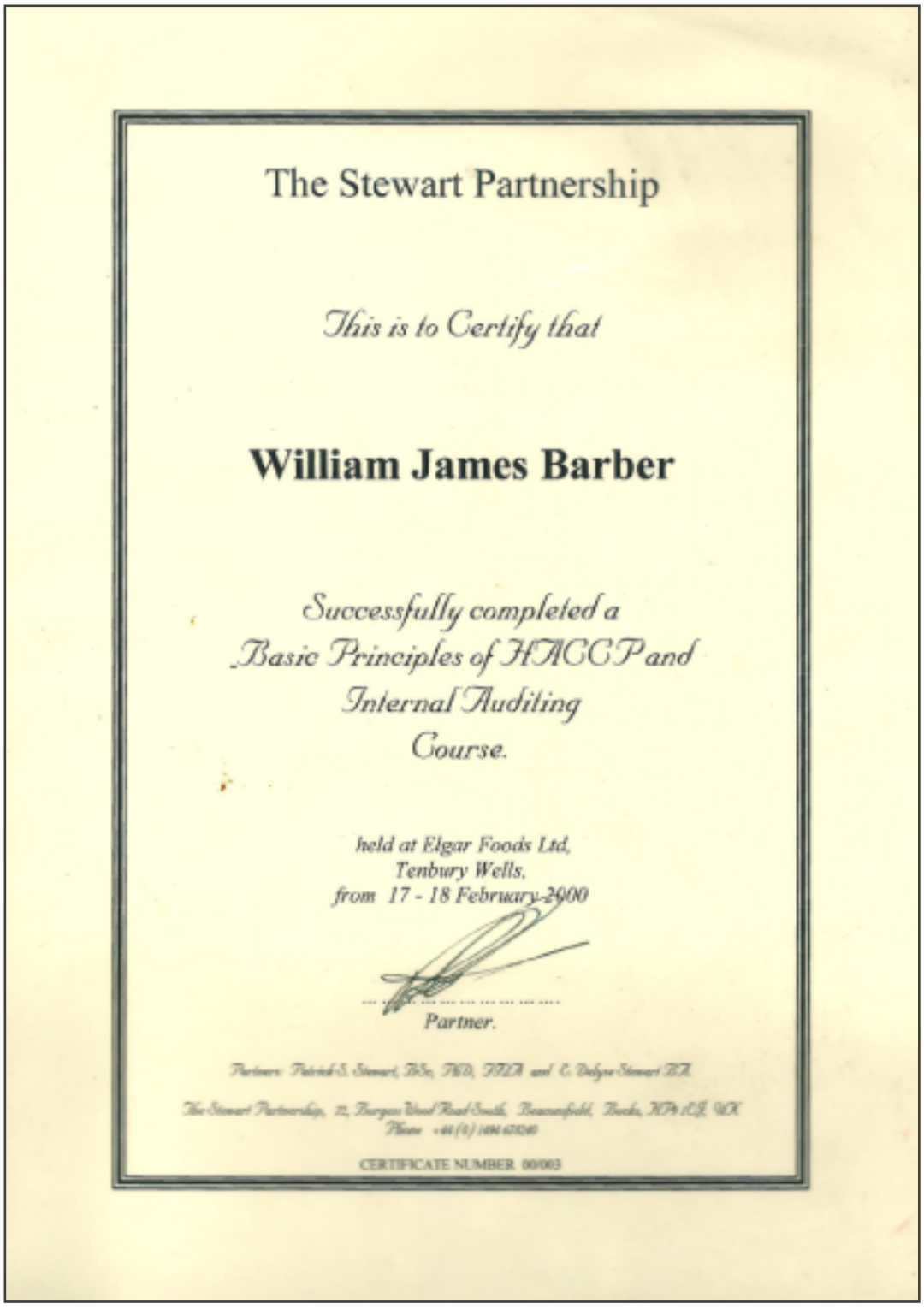
526405 101116 1107147

RSPH

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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. Dalyn Stewart BA

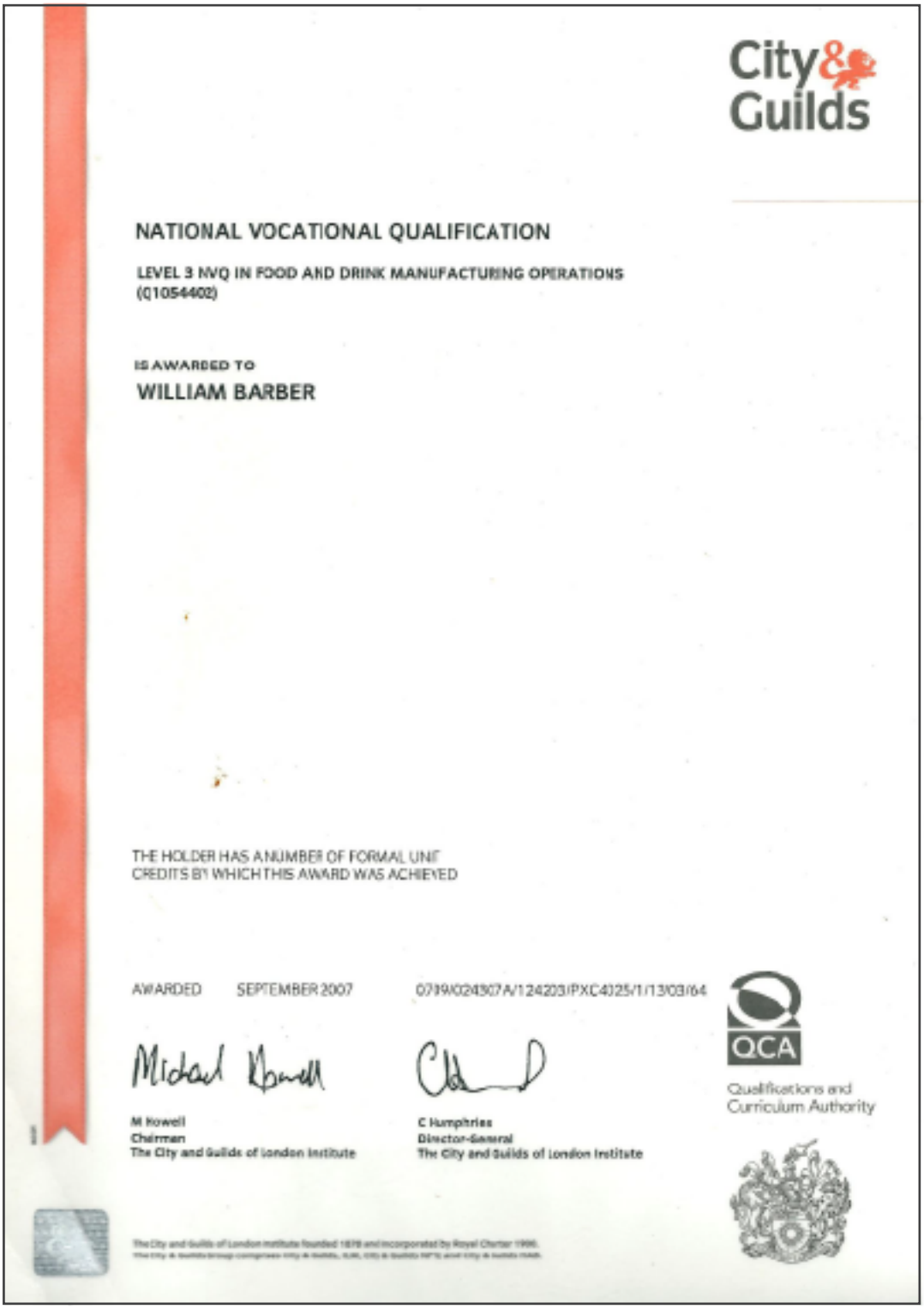
The Stewart Partnership, 22, Burgess Wood Road South, Beaconsfield, Bucks, HP9 1EJ, UK
Phone +44 (0) 1494 672040

CERTIFICATE NUMBER 00/003

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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 0739/024907A/124203/PXC4025/1/13/03/64

M Howell
Chairman
The City and Guilds of London Institute

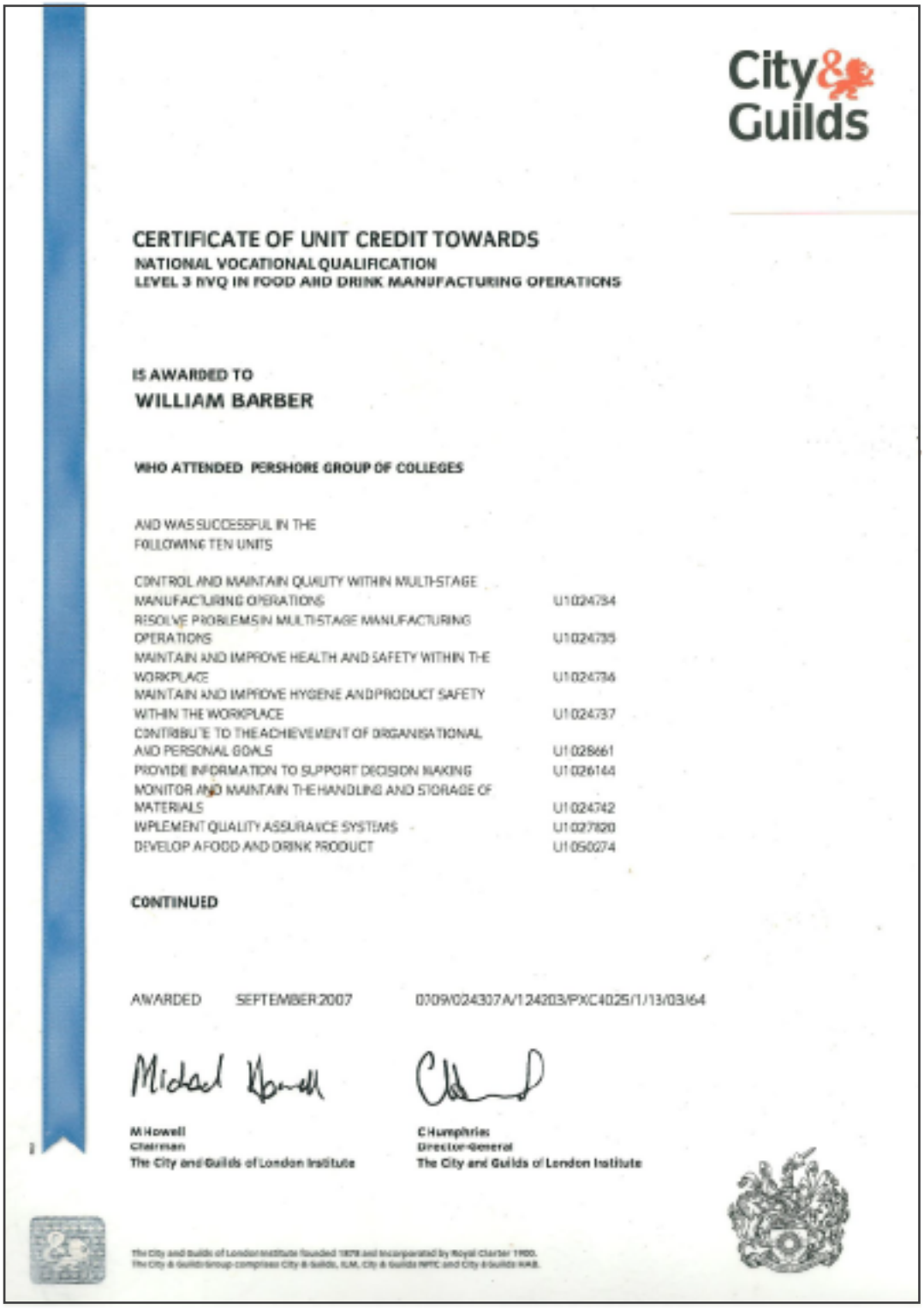
C Humphries
Director-General
The City and Guilds of London Institute

QCA
Qualifications and Curriculum Authority

Supplier: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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: Molinos Valle del Cibao, C. por A. Product: Soda Crackers

Agent(s): Claudio Innocenti (PCQI. Member, USA) Review Start: July 03, 2024 Review End: Nov. 103, 2024

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' PCQI*(s)*.

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.

Control Id
3335fb09

Organización
Bocel Galletas

Plantilla
Controles preventivos

Dirección
Bocel , Santiago de los Caballeros

Fechas
Programado para: 26-06-2024 12:39hs
Última actualización: 26-06-2024 15:07hs
Inicio: 26-06-2024 15:07hs
Finalización: 27-06-2024 21:34hs

Contacto Organización
Email: asiri@grupobocel.com
Teléfono: 809-747-6524

Auditor
Nombre: Mariangel Popa Báez
Email: mpopa@agrobiotek.com
Teléfono: 809-972-4406

Firma del Auditor

Comentario
In general, it is observed that the company is in a position to carry out productive activities. During the audit, some construction activities were observed that did not represent a risk of contamination for the product. Appropriate procedures and records are available to demonstrate compliance with security requirements. However, during the audit some non-conformities were detected that must be addressed, which in general are findings that are easy to solve. In addition, it is highlighted that compliance with safety programs associated with supplier evaluation, product withdrawal, maintenance programs, non-conforming product management and reprocessing is maintained to strengthen the system.

Resumen

	Cantidad	Porcentaje
Conforme	200	93.0%
No Conforme	2	0.9%
Necesita mejora	1	0.5%
No Aplica	12	5.6%

98.3%
APROBADO

Items auditados: 215

Hallazgos: 0

ITEMS AUDITADOS

1) § 117.4. Qualifications of individuals who manufacture, process, pack, or hold food. (Importancia: 5/100 - Puntaje: 100/100)

Puntos: 4.90%

1.1 - b Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must: (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

1.2 - Be a qualified individual as that term is defined in § 117.3—i.e.,

- Conform

Conforme

Importancia: 100/100
Puntaje: 100/100
Puntos: 0.93%

**Comentario: There's a qualified individual:
Crackers - Ana Marlenis Siri Siri Certificate #918ec84c**

1.3 - Receive training in the principles of food hygiene and food safety

- Conform

Conforme

Importancia: 100/100
Puntaje: 100/100
Puntos: 0.93%

Comentario: They carry out annual BPM training. Evidence was observed. They have a 2024 food safety training program PE-CAL-GB-02/RC25 rev 0. It includes training on safety issues: allergen control, plant defense, review of the HACCP plan, Contamination, GMP, among others.

1.4 - Adequate training is offered to new and temporary employees

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.47%

Comentario: There's a format for general induction process, it includes GMP induction. It was signed may 05th, 2024 for Marielis Hernández García. There's a training program for all employees.

1.5 - The training is done in the appropriate language

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.47%

Comentario: Training is given in spanish.

1.6 - At least annually, refresher courses

- Conform

Conforme

Importancia: 100/100
Puntaje: 100/100
Puntos: 0.93%

Comentario: Training is given every year. There is a program that is updated annually.

1.7 - Additional qualifications of supervisory personnel.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.47%

Comentario: There's a training on GMP in June 2024 for supervisory personnel.

1.8 - Records. Records that document training are established and maintained.

- Conform

Conforme

Importancia: 75/100
Puntaje: 100/100
Puntos: 0.70%

Comentario: Records of training for new and old employees were observed. Allergen Control may and june 2024, GMP may 2024 with exit criteria, Food defense may 2024 with exit criteria.

2) § 117.10 Personnel. (Importancia: 8/100 - Puntaje: 92/100)

Puntos: 7.19%

2.1 - § 117.10 Personnel. Observation (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

2.2 - a Disease control.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.87%

Comentario: There is a GMP Program PE-CAL-GB-004 rev. 2. In section 6.8.a. talks about disease control and in 6.8.c mention anual analysis.

2.3 - b Cleanliness. Maintaining adequate personal cleanliness.

Conforme

Importancia: 50/100

- Conform

Puntaje: 100/100
Puntos: 0.87%

Comentario: There is a GMP Program PE-CAL-GB-02 rev. 1. In section 6.9.b. talks about personal hygiene. Staff were observed maintaining proper cleanliness.

2.4 - Good Manufacturing Practices Program (GMP) and Good Personal Hygiene Practices (BPH)

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.87%

Comentario: They have a program of good manufacturing and hygiene practices PE-CAL-GB-004 rev. 2. It includes the requirements for GMP and GHP practices.

2.5 - Wearing outer garments suitable to the operation

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.87%

Comentario: There is a GMP Program PE-CAL-GB-004 rev. 2. In section 6.8.c. talks about uniform.

2.6 - Washing hands

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.87%

Comentario: There are hand washing stations in different areas of the plant. They are observed with all the elements (water, soap, drying paper, etc.). Instructions for hand washing are observed. There is a GMP Program PE-CAL-GB-004 rev. 2. In section 6.8.b. talks about personal hygiene, includes hand washing.

2.7 - Removing all unsecured jewelry and other objects

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.87%

Comentario: There is a GMP Program PE-CAL-GB-004 rev. 2. In section 6.8.b. Hygiene, in includes jewelry removal.

2.8 - Maintaining gloves, if applicate

No Aplica

2.9 - Wearing hair nets

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.87%

Comentario: There is a GMP Program PE-CAL-GB-004 rev. 2. In section 6.8.c. talks about uniform. It includes wearing hair nets.

2.10 - Storing clothing or other personal

Conforme

- Conform

Importancia: 25/100
Puntaje: 100/100
Puntos: 0.44%

2.11 - Separate areas for: eating food, chewing gum, drinking beverages, or using tobacco

Conforme

- Conform

Importancia: 25/100
Puntaje: 100/100
Puntos: 0.44%

Comentario: There's an employee canteen. It was observed clean.

2.12 - c Self-inspection

No Conforme

- Mayor NC

Importancia: 50/100
Puntaje: 25/100
Puntos: 0.22%

Comentario: There's a GMP report. It's carried out monthly. PE-CAL-GB-02/RC12 rev. 1. The inspections carried out from January to May 2024 were observed. The same finding is observed - lack of identification of areas -.

Non-compliance. Although they express that they have addressed the findings in the monthly GMP audit PE-CAL-GB-02/RC12 rev. 1, no actions have been documented. This is a recurring finding.

3) § 117.20. Plant and grounds. (Importancia: 8/100 - Puntaje: 100/100) Puntos: 7.84%

3.1 - a Grounds. The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food.(SP)

Conforme

- Conform

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

3.2 - Properly storing equipment, removing litter and waste, and cutting weeds or grass

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.71%

Comentario: No storing equipment outside, litter and waste well maintain, no weeds or grass within the immediate vicinity of the plant

3.3 - Maintaining roads, yards, and parking lots

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.71%

3.4 - Adequately draining areas

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.71%

3.5 - Operating systems for waste treatment

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.71%

3.6 - Maintenance of Bordered not under the operator's control

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.71%

3.7 - b. Plant construction and design. (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

3.8 - Provide adequate space for such placement of equipment and storage of materials

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.71%

3.9 - Precautions to reduce the potential for allergen cross-contact

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.71%

3.10 - 3. Protect food in installed outdoor bulk vessels by any effective means, including: (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

3.11 - Floors, walls, and ceilings area adequately to be cleaned and kept clean and kept in good repair

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.71%

3.12 - Provide adequate lighting and provide shatter-resistant light bulbs or protected against food contamination in case of glass breakage

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.71%

Comentario: In general the lamps are LED. Some warehouse lamps are not LED but were protected.

Observation: During the inspection they expressed that the non-LED lamps in the warehouse are inspected; however, no evidence was observed that this activity was carried out. The record PE-CAL-GB-04/RC01 does not clearly indicate the warehouse areas. It is focused on the lines.

3.13 - Provide adequate ventilation or control equipment to minimize dust, odors and vapors

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.71%

3.14 - Provide, where necessary, adequate screening or other protection against pests.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.71%

4) § 117.35 Sanitary operations. (Importancia: 8/100 - Puntaje: 100/100) Puntos: 7.84%

4.1 - a General maintenance. Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition.

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.39%

4.2 - b Substances used in cleaning and sanitizing; storage of toxic materials. (SP)

Conforme

- Conform

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

4.3 - Cleaning compounds and sanitizing agents..

Conforme

- Conform

Importancia: 25/100
Puntaje: 100/100
Puntos: 0.20%

Comentario: There is a GMP Program PE-CAL-GB-02 rev. 1. In section 6.6.4. talks about chemical warehouse. The technical data sheet of the chemicals is observed: Easy Foam - Chlorinated alkaline detergent. Final Step 512, Dufome. Sanitizing concentration validation record is observed PE-CAL-GB-02/RC28 rev. 0. from April 2023 to June 2024. They measure each preparation.

4.4 - Identification- Toxic cleaning compounds, Sanitizing agents, and pesticide chemicals

Conforme

- Conform

Importancia: 25/100
Puntaje: 100/100
Puntos: 0.20%

4.5 - c. Pest control. (SP)

Conforme

- Conform

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

4.6 - Exclude pests from areas

Conforme

- Conform

Importancia: 100/100
Puntaje: 100/100
Puntos: 0.78%

4.7 - Use of pesticides

Conforme

- Conform

Importancia: 25/100
Puntaje: 100/100
Puntos: 0.20%

Comentario: There's a list of pecticides used in pest control and a rotation program. The technical data sheet of the pesticide K-Othrine 2.5 EC, Cybor 10 EA and Zapi Ekoset 22 EC was observed. Approval for use in food plants is evident.

4.8 - Documented and specific pest control program

Conforme

- Conform

Importancia: 25/100
Puntaje: 100/100
Puntos: 0.20%

Comentario: There's an Integrated Pest Management Manual. ME-CAL-GB-05 rev. 2. Power Exterminating Services SRL is the company that provides the pest control services. Their permits were observed: Environmental permits No. 0685-08 Exp december 2028. Sanitary permit No. II979-0645 Exp. june 2025. Agriculture permit No. FU-83 Exp june 2027. Insurance policy No. 2629964 Exp december 2024.

The map of external traps is observed.

Observation: include the update date.

4.9 - Management of the exterior to minimize the possibility of pests

Conforme

- Conform

Importancia: 25/100
Puntaje: 100/100
Puntos: 0.20%

4.10 - No evidence of infestation is observed (Ensencial)

Conforme

- Conform

Importancia: 100/100
Puntaje: 100/100
Puntos: 0.78%

4.11 - Pest control devices managed properly

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.39%

4.12 - The doors adjust correctly and prevent the entry of pests into the building

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.39%

4.13 - Adequate records of pest control are maintained

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.39%

4.14 - d. Sanitation of food-contact surfaces.

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

4.15 - Food-contact surfaces used must be in a clean, dry, sanitary condition before use.

- Conform

Conforme

Importancia: 100/100
Puntaje: 100/100
Puntos: 0.78%

4.16 - Equipment and utensils used in a continuous production operation

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.39%

4.17 - Single-service articles

- Conform

Conforme

Importancia: 25/100
Puntaje: 100/100
Puntos: 0.20%

4.18 - Sanitation of non-food-contact surfaces. Non-food-contact surfaces of equipment

- Conform

Conforme

Importancia: 25/100
Puntaje: 100/100
Puntos: 0.20%

4.19 - Storage and handling of cleaned portable equipment and utensils.

- Conform

Conforme

Importancia: 25/100
Puntaje: 100/100
Puntos: 0.20%

4.20 - D1 Sanitation (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

4.21 - They have a Master Cleaning Program (PML)

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.39%

Comentario: There is a hygiene and disinfection manual ME-CAL-GB-04 rev. 1. They have defined SSOPs for cleaning areas. The SSOPs for line 1, 6 and 7 was observed.

4.22 - They have Operative Cleaning Procedures (POES)

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.39%

Comentario: They have defined SSOPs for cleaning areas. The SSOPs for line 1, 6 and 7 was observed.

4.23 - Perform and document pre-operational inspection

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.39%

Comentario: They carry out pre-operational inspections PE-CAL-GB-02/RC17 rev. 1. The record for May and June 2024 was observed.

Observation: review the filling out or writing the record, they are putting no in questions that do not seem to apply.

4.24 - Operational hygiene is efficient

- Conform

Conforme

Importancia: 100/100
Puntaje: 100/100
Puntos: 0.78%

Comentario: They have cleaning and sanitation records PE-CAL-GB-02/RC16 rev. 1. The records from May 2024 are observed.

5) § 117.37 Sanitary facilities and controls. (Importancia: 8/100 - Puntaje: 100/100) Puntos: 7.84%

5.1 - a Water supply.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.84%

Comentario: Water records indicate that the water is potable. Evidence of analysis of water results from May 2024 (RD-LAB-241004). They have a microbiological analysis program: water, finished product and environment.

5.2 - b Plumbing. (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

5.3 - Carry adequate quantities of water to required locations throughout the plant

- Conform

Conforme

Importancia: 25/100
Puntaje: 100/100
Puntos: 0.42%

Comentario: There is a GMP Program PE-CAL-GB-004 rev. 2. In section 6.6.1. talks about water supply which is permanent.

5.4 - Properly convey sewage and liquid disposable waste from the plant

- Conform

Conforme

Importancia: 25/100
Puntaje: 100/100
Puntos: 0.42%

Comentario: There is a GMP Program PE-CAL-GB-02 rev. 1. In section 6.6.2. talks about waste water and solid waste disposal.

5.5 - Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.84%

5.6 - 4. Provide adequate floor drainage

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.84%

5.7 - 5. Provide that there is not backflow from, or cross-connection.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.84%

5.8 - c. Sewage disposal.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.84%

Comentario: There is a GMP Program PE-CAL-GB-02 rev. 1. In section 6.6.2. talks about waste water and solid waste disposal.

5.9 - d. Toilet facilities.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.84%

5.10 - Toilet facilities must be kept clean

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.84%

5.11 - e. Hand-washing facilities.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.84%

5.12 - f. Rubbish and offal disposal.

- Conform

Conforme

Importancia: 15/100
Puntaje: 100/100
Puntos: 0.25%

6) § 117.40 Equipment and utensils. (Importancia: 10/100 - Puntaje: 100/100) Puntos: 9.80%

6.1 - 1. Design - All plant equipment and utensils used in manufacturing, processing, packing, or holding.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 1.15%

6.2 - 2. Equipment and utensils- avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 1.15%

6.3 - 3. Equipment - facilitate the cleaning and maintenance

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 1.15%

Comentario: Reports of corrective maintenance carried out on line 7 no. 35,332; 35,333; 35,335. They have a preventive maintenance control system PE-MANT-GB-02/RC05 rev. 0. Other observed records. PE-MANT-GB-02/ RC03 rev. 0. There is a cleaning validation report after maintenance IT-CAL-GB-12/RC12 rev. 0.

6.4 - 4. Food-contact surfaces must be corrosion-resistant when in contact with food.

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 1.15%

6.5 - 5. Food-contact surfaces must be made of nontoxic materials.

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 1.15%

6.6 - 6. Food-contact surfaces protect food from allergen cross-contact

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 1.15%

6.7 - Surfaces must be smoothly bonded...

Conforme

- Conform

Importancia: 25/100
Puntaje: 100/100
Puntos: 0.58%

6.8 - Holding, conveying, and manufacturing systems - appropriate clean and sanitary condition.

Conforme

- Conform

Importancia: 25/100
Puntaje: 100/100
Puntos: 0.58%

6.9 - Freezer and cold storage indicating temperature-measuring device.

No Aplica

6.10 - Instruments and controls must be accurate and precise.

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 1.15%

Comentario: They have calibration certificates for oven thermometers. Exp jun 2025. TI-19 and TI-16 report were observed.

6.11 - Compressed air must be treated in such a way that food is not contaminated

Conforme

- Conform

Importancia: 25/100
Puntaje: 100/100
Puntos: 0.58%

Comentario: An analysis report of compressed air was observed. No. 12806 Sample 94674 on january 2024. Results in compliance.

7) § 117.80 Processes and controls. (Importancia: 15/100 - Puntaje: 100/100) Puntos: 14.71%

7.1 - a General

Conforme

- Conform

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

7.2 - 1. All operations must be conducted in accordance with adequate sanitation principles.

Conforme

- Conform

Importancia: 15/100
Puntaje: 100/100
Puntos: 0.19%

7.3 - 2. Ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

Conforme

- Conform

Importancia: 15/100
Puntaje: 100/100
Puntos: 0.19%

7.4 - 3. All food that has become contaminated must be rejected...

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100

Puntos: 0.64%

7.5 - b. Control - Raw materials and other ingredients.

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

7.6 - 1. Inspection -Raw materials and other ingredients must be inspected

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

7.7 - 2. Cleaning - Raw materials must be washed or cleaned as necessary to remove soil or other contamination.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

7.8 - 3. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

7.9 - 4. Water may be reused if it does not cause allergen cross-contact or increase the level of contamination of the food."

- Conform

Conforme

Importancia: 15/100
Puntaje: 100/100
Puntos: 0.19%

7.10 - 5. Microbiological Contamination - Raw materials not contain levels of microorganisms

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

7.11 - 6. Aflatoxin - Raw materials and other ingredients susceptible to contamination with aflatoxin

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

7.12 - 7. Pest - Raw materials, other ingredients, susceptible to contamination with pests

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

7.13 - 8. Allergen - Raw materials

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

Comentario: They have an allergen control manual ME-CAL-GB-06 rev. 1 . Section 14.1 includes controls for raw material. They have a record of effectiveness for cleaning by monitoring ATP and Isopado for allergens. PE-CAL-GB-02/RC14 rev. 1.

7.14 - 9. Temperature Control- Frozen raw materials

No Aplica

7.15 - 10. Liquid or dry raw materials received and stored in bulk

No Aplica

7.16 - c. Manufacturing operations. (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

7.17 - 1. Minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

7.18 - 2. Temperatures Control - that will prevent the food from becoming adulterated

No Aplica

7.19 - 3. Process Control - to destroy or prevent the growth of undesirable microorganisms

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100

Puntos: 0.64%

7.20 - 4. Control of Work-in-process and rework

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

Comentario: They have a non-compliant product procedure PG 8.7 rev. 1. Includes the steps to follow in the event of a non-compliant product internally, in process, by the supplier, etc. Daily reprocessing record is observed PE-PRO-GB/RC24 rev. 1. Daily reprocessing record is observed PE-PRO-GB/RC24 rev. 1. Record from June 2024 is observed. They have a mass rework usage limit table PE-PRO-GB-01/RC23 rev. 1.

7.21 - d. Allergen Management Program (Essential) (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

7.22 - 1. Have a documented allergen control program

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

Comentario: Disponen de un manual de control de alérgenos ME-CAL-GB-06 rev. 1

7.23 - 2. The allergenic ingredients are correctly identified, stored and reworked

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

7.24 - 3. Controls to avoid cross-contamination of allergens: production

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

7.25 - 4. The effectiveness of the allergen cleaning procedures is validated and this verification is documented

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

Comentario: They have a record of cleaning effectiveness by monitoring ATP and Isopado for allergens PE-CAL-GB-02/RC14 rev. 1. Includes test type, frequency, measurement and line.

Observation: the frequency and lines indicated in the revised form do not correspond to what is indicated in the preventive control program sampling allergen determination PE-SGC-02/RC26 rev. 1.

7.26 - 5. Documents and products are properly labeled with allergen information

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

Comentario: Included in section 5.7 of the safety manual.

7.27 - e. Control of Foreign Material (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

7.28 - 1. Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

7.29 - 2. Processing containers, ingredients and open products are kept protected

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

7.30 - 3. They have fragile glass and plastic management program

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

Comentario: They have a glass and brittle plastic program PE-CAL-GB-04 rev. 1. They carry out monthly inspection with the PE-CAL-GB-04/RC01 form and the actions are documented in RC 8.7/RC01.

Observation: During the inspection they expressed that the non-LED lamps in the warehouse are inspected; however, no evidence was observed that this activity was carried out. The record PE-CAL-GB-04/RC01 does not clearly indicate the warehouse areas. It is focused on the lines.

Recommendation: Consider conducting an inventory of brittle plastic and glass.

7.31 - 4. Sieves, filters and screens are used, in the cases that apply — **No Aplica**

7.32 - 5. They have metal detectors and they are managed correctly. If necessary — **Conforme**

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

Comentario: The calibration reports of the metal detectors at the beginning of the line (serial 133447) and the end of the line (serial 914490804) are observed as of October 2024.

Observation #1: the values of the standards indicated in the introduction of the certificate of the beginning of the line metal detector do not correspond to the reported values.

Observation #2: It is recommended to reinforce good hygiene practices when handling metal detector verification standards. In addition, consider washing and sanitizing the inspector's hands beforehand, since there is a detector in the packaging area where the product is ready to consume.

7.33 - 6. The blades are controlled and inspected (if used) — **No Aplica**

7.34 - 7. Management of food, raw materials, and other ingredients that are adulterated -Physical — **Conforme**

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

7.35 - 8. Control for Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, — **Conforme**

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.64%

7.36 - 9. Control for Food, such as acid and acidified food — **No Aplica**

7.37 - 10. When ice is used in contact with food. — **No Aplica**

8) § 117.93 Warehousing and distribution. (Importancia: 1/100 - Puntaje: 100/100) — Puntos: 0.98%

8.1 - Storage and transportation of food must be under conditions that will protect — **Conforme**

- Conform

Importancia: 100/100
Puntaje: 100/100
Puntos: 0.98%

Comentario: The warehousing and distribution are under condition that protect against any contamination.

9) § 117.95 Holding and distribution of human food by-products for use as animal food. (Importancia: 1/100 - Puntaje: No Aplica) — Puntos: 0.00%

9.1 - Human food by-products held for distribution as animal food — **No Aplica**

10) § 117.110 Defect action levels. (Importancia: 1/100 - Puntaje: No Aplica) — Puntos: 0.00%

10.1 - 1. Quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible — **No Aplica**

10.2 - 2. The mixing of a food containing defects at levels — **No Aplica**

11) § 117.126 Food safety plan. (Importancia: 5/100 - Puntaje: 100/100) — Puntos: 4.90%

11.1 - a Requirement for a food safety plan. (SP) — **Conforme**

- Conform

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

11.2 - 1. You must prepare, or have prepared, and implement a written food safety plan. — **Conforme**

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.86%

11.3 - 2. The food safety plan must be prepared, by one qualified individuals.

- Conform

Conforme

Importancia: 25/100
Puntaje: 100/100
Puntos: 0.43%

11.4 - b. Contents of a food safety plan. The written food safety plan must include: (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

11.5 - 1. The written hazard analysis as required by § 117.130(a)(2);

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.86%

11.6 - 2. The written preventive controls as required by § 117.135(b);

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.86%

11.7 - 3. The written supply-chain program as required by subpart G of this part;

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.86%

11.8 - 4. The written recall plan as required by § 117.139(a); and

- Conform

Conforme

Importancia: 15/100
Puntaje: 100/100
Puntos: 0.26%

Comentario: PE-CAL-GB-03 rev. 4 Product recall procedure.

11.9 - 5. The written procedures for monitoring the implementation of the preventive controls as required by § 117.145(a);

- Conform

Conforme

Importancia: 15/100
Puntaje: 100/100
Puntos: 0.26%

11.10 - 6. The written corrective action procedures as required by § 117.150(a)(1); and

- Conform

Conforme

Importancia: 15/100
Puntaje: 100/100
Puntos: 0.26%

11.11 - 7. The written verification procedures as required by § 117.165(b).

- Conform

Conforme

Importancia: 15/100
Puntaje: 100/100
Puntos: 0.26%

12) § 117.130 Hazard analysis. (Importancia: 5/100 - Puntaje: 100/100) Puntos: 4.90%

12.1 - a. Requirement for a hazard analysis.

- Conform

Conforme

Importancia: 100/100
Puntaje: 100/100
Puntos: 0.61%

12.2 - 1. Hazard identification. (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

12.3 - i. Biological hazards.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.31%

12.4 - ii. Chemical hazards including radiological

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.31%

12.5 - iii. Physical hazards.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.31%

12.6 - 2. Known or reasonably foreseeable hazards that may be present in the food for any of the following reasons: (SP) **- Conform**	**Conforme** Importancia: 0/100 Puntaje: 100/100 Puntos: 0.00%
12.7 - "(i) The hazard occurs naturally; **- Conform**	**Conforme** Importancia: 50/100 Puntaje: 100/100 Puntos: 0.31%
12.8 - (ii) The hazard may be unintentionally introduced; or **- Conform**	**Conforme** Importancia: 50/100 Puntaje: 100/100 Puntos: 0.31%
12.9 - (iii) The hazard may be intentionally introduced for purposes of economic gain." **- Conform**	**Conforme** Importancia: 50/100 Puntaje: 100/100 Puntos: 0.31%
12.10 - c. Hazard evaluation. (SP) **- Conform**	**Conforme** Importancia: 0/100 Puntaje: 100/100 Puntos: 0.00%
12.11 - i. The hazard analysis must include an evaluation of the hazards **- Conform**	**Conforme** Importancia: 50/100 Puntaje: 100/100 Puntos: 0.31%
12.12 - ii. The hazard evaluation include an evaluation of environmental pathogens **- Conform**	**Conforme** Importancia: 50/100 Puntaje: 100/100 Puntos: 0.31%
12.13 - 3. The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer: **- Conform**	**Conforme** Importancia: 50/100 Puntaje: 100/100 Puntos: 0.31%
12.14 - i. The formulation of the food; **- Conform**	**Conforme** Importancia: 25/100 Puntaje: 100/100 Puntos: 0.15%
12.15 - ii. The condition, function, and design of the facility and equipment; **- Conform**	**Conforme** Importancia: 25/100 Puntaje: 100/100 Puntos: 0.15%
12.16 - iii. Raw materials and other ingredients; **- Conform**	**Conforme** Importancia: 25/100 Puntaje: 100/100 Puntos: 0.15%
12.17 - iv. Transportation practices;" **- Conform**	**Conforme** Importancia: 26/100 Puntaje: 100/100 Puntos: 0.16%
12.18 - v. Manufacturing/ processing procedures; **- Conform**	**Conforme** Importancia: 25/100 Puntaje: 100/100 Puntos: 0.15%
12.19 - (vi) Packaging activities and labeling activities; **- Conform**	**Conforme** Importancia: 25/100 Puntaje: 100/100 Puntos: 0.15%
12.20 - (vii) Storage and distribution; **- Conform**	**Conforme** Importancia: 25/100

Puntaje: 100/100
Puntos: 0.15%

12.21 - (viii) Intended or reasonably foreseeable use; 21 CFR 117.130(c)(2)(v)

- Conform

Conforme
Importancia: 25/100
Puntaje: 100/100
Puntos: 0.15%

12.22 - (ix) Sanitation, including employee hygiene; and

- Conform

Conforme
Importancia: 25/100
Puntaje: 100/100
Puntos: 0.15%

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

- Conform

Conforme
Importancia: 25/100
Puntaje: 100/100
Puntos: 0.15%

13) § 117.135 Preventive controls. (Importancia: 5/100 - Puntaje: 100/100) Puntos: 4.90%

13.1 - 1. You must identify and implement preventive controls, Include: (SP)

- Conform

Conforme
Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

13.2 - (i) Controls at critical control points (CCPs), if there are any CCPs

- Conform

Conforme
Importancia: 50/100
Puntaje: 100/100
Puntos: 0.31%

13.3 - (ii) Controls, other than those at CCPs, that are also appropriate for food safety.

- Conform

Conforme
Importancia: 50/100
Puntaje: 100/100
Puntos: 0.31%

13.4 - b. Preventive controls must be written.

- Conform

Conforme
Importancia: 100/100
Puntaje: 100/100
Puntos: 0.63%

13.5 - c. Preventive controls include, as appropriate to the facility and the food: (SP)

- Conform

Conforme
Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

13.6 - 1. Process controls. Process controls (SP)

- Conform

Conforme
Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

13.7 - (i) Parameters associated with the control of the hazard; and

- Conform

Conforme
Importancia: 50/100
Puntaje: 100/100
Puntos: 0.31%

13.8 - (ii) The maximum or minimum value.

- Conform

Conforme
Importancia: 50/100
Puntaje: 100/100
Puntos: 0.31%

13.9 - 2. Food allergen controls. (SP)

- Conform

Conforme
Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

13.10 - (i) Ensuring protection of food from allergen cross-contact, including during storage, handling, and use;

- Conform

Conforme
Importancia: 50/100
Puntaje: 100/100
Puntos: 0.31%

13.11 - (ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act."

Conforme

- Conform

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.31%

13.12 - 3. Sanitation controls. (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

13.13 - (i) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.31%

13.14 - (ii) Prevention of allergen cross-contact and cross-contamination

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.31%

13.15 - 4. Supply-chain controls. Supply-chain controls include the supply-chain program as required by subpart G of this part.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.31%

13.16 - Annual supplier evaluation

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.31%

13.17 - There is a list of approved providers

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.31%

13.18 - Suppliers are classified based on risk

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.31%

13.19 - An audit is made or a GFSI certificate is requested

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.31%

13.20 - 5. Recall plan. Recall plan as required by § 117.139.

- Conform

Conforme

Importancia: 15/100
Puntaje: 100/100
Puntos: 0.09%

13.21 - 6. Other controls.

- Conform

Conforme

Importancia: 15/100
Puntaje: 100/100
Puntos: 0.09%

14) § 117.139 Recall plan. (Importancia: 3/100 - Puntaje: 90/100) Puntos: 2.65%

14.1 - a. You must establish a written recall plan for the food.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.59%

14.2 - b. The written recall plan must include procedures: (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

14.3 - 1. Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;

- Minor NC

Necesita mejora

Importancia: 50/100
Puntaje: 50/100
Puntos: 0.29%

Comentario: Non compliance: In the withdrawal procedure, they have a list of the positions that are members of the withdrawal team, but their contact information (name, telephone, email) is not included.

14.4 - 2. Notify the public about any hazard presented by the food when appropriate to protect public health;

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.59%

Comentario: They have a product recall notice model.

14.5 - 3. Conduct effectiveness checks to verify that the recall is carried out.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.59%

Comentario: The withdrawal exercise carried out on May 14, 2024 is observed, they recovered 100% of the product. A record of inspection and analysis of raw materials or inputs is observed PE-SGC-02/RC11 rev. 0.

14.6 - 4. Appropriately dispose of recalled food

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.59%

15) § 117.145 Monitoring. (Importancia: 5/100 - Puntaje: 100/100) Puntos: 4.90%

15.1 - a. Written procedures.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 1.23%

15.2 - b. Monitoring. Frequency

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 1.23%

15.3 - c. Records.

- Conform

Conforme

Importancia: 100/100
Puntaje: 100/100
Puntos: 2.45%

16) § 117.150 Corrective actions and corrections. (Importancia: 5/100 - Puntaje: 100/100) Puntos: 4.90%

16.1 - a. Corrective action procedures. (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

16.2 - i. If the presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.49%

16.3 - ii. If the presence of an environmental pathogen

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.49%

16.4 - b. The corrective action procedures must describe the steps to be taken to ensure that: (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

16.5 - i. Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.49%

16.6 - ii. Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.49%

16.7 - iii. All affected food is evaluated for safety.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.49%

16.8 - iv. All affected food is prevented from entering into commerce.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.49%

16.9 - v. A preventive control is not properly implemented and a corrective action procedure has not been established

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.49%

16.10 - vi. A preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.49%

16.11 - vii. A review of records in accordance finds that the records are not complete.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.49%

16.12 - c. Records. All corrective actions must be documented

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.49%

17) § 117.155 Verification. (Importancia: 5/100 - Puntaje: 100/100) Puntos: 4.90%

17.1 - a. Verification activities. Verification activities must include: (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

17.2 - 1. Validation in accordance with § 117.160.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.82%

17.3 - 2. Verification that monitoring

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.82%

17.4 - 3. Verification that appropriate decisions about corrective actions are being made

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.82%

17.5 - 4. Verification of implementation and effectiveness

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.82%

17.6 - 5. Reanalysis in accordance with § 117.170.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.82%

17.7 - b. Documentation. All verification activities conducted in accordance with this section must be documented in records.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.82%

18) § 117.160 Validation. (Importancia: 5/100 - Puntaje: 85/100) Puntos: 4.17%

18.1 - a. You must validate that the preventive controls identified and implemented

- Mayor NC

No Conforme

Importancia: 50/100
Puntaje: 25/100
Puntos: 0.25%

Comentario: Non compliance: Although they have monitoring information for the CCPs, a validation report in compliance with the requirements of this guideline has not been documented.

18.2 - b. The validation of the preventive controls: (SP)

- Conform

Conforme

Importancia: 0/100
Puntaje: 100/100
Puntos: 0.00%

18.3 - 1. Must be performed by a preventive controls qualified individual

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.98%

Comentario: See section 18.1.

18.4 - i. Prior to implementation of the food safety plan or...

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.98%

18.5 - ii. Whenever a change to a control measure or combination of control measures could impact

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.98%

18.6 - iii. Whenever a reanalysis of the food safety plan reveals the need to do so.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.98%

19) § 117.165 Verification of implementation and effectiveness (Importancia: 1/100 - Puntaje: 100/100) Puntos: 0.98%

19.1 - a. Verification activities. You must verify that the preventive controls are consistently implemented...

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.25%

19.2 - 1. Calibration of process monitoring instruments and verification instruments.

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.25%

19.3 - 2. Product testing, for a pathogen (or appropriate indicator organism) or other hazard;

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.25%

Comentario: There's a preventive control taking microbiological samples. It include finished product, includes Salmonella and Staphylococcus. It was observed the report of analysis on Aviva Normal Lot: L7004241 sample 94651.

Observation: A report was observed without including the result of E. coli in the sample Aviva Salted Soda Crackers Lot: SPA 1 158 241 Sample: 100866.

19.4 - 3. Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism...

- Conform

Conforme

Importancia: 50/100
Puntaje: 100/100
Puntos: 0.25%

Comentario: They have a microbiological analysis program: water, finished product and environment, and a preventive control taking microbiological samples. Results were observed on surface analysis on sept 2023, january 2024.

ALCHEM
ALTOL CHEMICAL ENVIRONMENTAL LABORATORY INC.

ALTOL

JOB NO. / LABORATORY REFERENCE NUMBER: RD-LAB-221154

CUSTODY CHAIN NUMBER: 9220

SAMPLING DATE: 07/07/2022

DATE OF DELIVERY OF RESULTS: 11/07/2022

ANALYSIS REPORT

CORRESPONDING TO QUOTATION NUMBER: 14198

MOLINOS VALLE DEL CIBAO, S.A (GALLETAS)

ALTOL PETROLEUM PRODUCTS SERVICE DOMINICANA, SRL.
Calle Pablo Pumarol No.2, Esquina Nicolás Ureña de Mendoza,
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Claudio Innocenti

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ANALYSIS REPORT

CUSTOMER NAME:	MOLINOS VALLE DEL CIBAO, S.A (GALLETAS)	**TIPE OF SAMPLE:**	DIRECT
CONTACT:	SRA. ANA SIRI	**SAMPLING DATE & TIME:**	07/07/2022 10:06
CUSTOMER ADDRESS:	CARRETERA DUARTE KM 5 1/2 SANTIAGO-LICEY SANTIAGO REP. DOM.	**SAMPLES COLLECTED BY:**	VICTOR CANARIO
JOB NO. / LABORATORY REFERENCE NUMBER:	RD-LAB-221154	**RECEPTION DATE & TIME OF SAMPLE**	07/07/2022 16:16
CUSTODY CHAIN NUMBER:	9220	**SAMPLES RECEIVED BY:**	BERNARDO LOPEZ
SAMPLE NUMBER:	73678	**TEMPERATURE RECEPTION:**	8.4º C
SAMPLE MATRIX:	SWABBED SURFACE	**FINAL DATE OF ANALYSIS:**	08/07/2022
SAMPLE DESCRIPTION	**ALEXANDER LORA (LINEA 7)**	**DATE OF DELIVERY OF RESULTS:**	**11/07/2022**

PARAMETER	METHOD	UNITS	MDL	RESULT	PERMISSIBLE LIMITS Min - Max	ANALYST
Total Coliforms.	Swab Contact Method 3.81, Chapter 3.	UFC / Surface	----	< 5	< 10	BL
Escherichia coli.	Swab Contact Method 3.81, Chapter 3.	UFC / Surface	----	< 5	Absence (< 5.0 UFC/Surface)	BL
Final parameters analyzed for this sample	----	---	----	----	----	---

COMMENTS:
"The results for the analyzed and norman parameters thrown by this sample are within the limits recommended by the Technical Guide for the Microbiological Analysis of Surfaces in Contact with Food and Beverages"
Reported values for E.coli (<5 CFU/surface) in analytical operations, these values are indicators of absence.

MDL: Method Detection Limit NS: Not Specified ND: Not Detected LMP: Permitted limit

YESLAIRA PAMELA SOSA RAMIREZ
ANALISTA DE LABORATORIO

BERNARDO LOPEZ
CONTROL DE CALIDAD

SHARON LUGO
GERENTE DE LABORATORIO

ALTOL PETROLEUM PRODUCTS SERVICE DOMINICANA SRL
Santo Domingo
República Dominicana
RNC.: 130-00900-7

ALTOL PETROLEUM PRODUCTS SERVICES DOMINICANA, SRL.

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ANALYSIS REPORT

CUSTOMER NAME:	MOLINOS VALLE DEL CIBAO, S.A (GALLETAS)	**TIPE OF SAMPLE:**	DIRECT
CONTACT:	SRA. ANA SIRI	**SAMPLING DATE & TIME:**	07/07/2022 10:08
CUSTOMER ADDRESS:	CARRETERA DUARTE KM 5 1/2 SANTIAGO-LICEY SANTIAGO REP. DOM.	**SAMPLES COLLECTED BY:**	VICTOR CANARIO
JOB NO. / LABORATORY REFERENCE NUMBER:	RD-LAB-221154	**RECEPTION DATE & TIME OF SAMPLE**	07/07/2022 16:16
CUSTODY CHAIN NUMBER:	9220	**SAMPLES RECEIVED BY:**	BERNARDO LOPEZ
SAMPLE NUMBER:	73682	**TEMPERATURE RECEPTION:**	8.4º C
SAMPLE MATRIX:	SWABBED SURFACE	**FINAL DATE OF ANALYSIS:**	08/07/2022
SAMPLE DESCRIPTION	**JEAN MANUEL TAVERAS (LINEA 7)**	**DATE OF DELIVERY OF RESULTS:**	**11/07/2022**

PARAMETER	METHOD	UNITS	MDL	RESULT	PERMISSIBLE LIMITS Min - Max	ANALYST
Total Coliforms.	Swab Contact Method 3.81, Chapter 3.	UFC / Surface	----	< 5	< 10	BL
Escherichia coli.	Swab Contact Method 3.81, Chapter 3.	UFC / Surface	----	< 5	Absence (< 5.0 UFC/Surface)	BL
Final parameters analyzed for this sample	----	---	----	----	----	---

COMMENTS:
"The results for the analyzed and norman parameters thrown by this sample are within the limits recommended by the Technical Guide for the Microbiological Analysis of Surfaces in Contact with Food and Beverages"
Reported values for E.coli (<5 CFU/surface) in analytical operations, these values are indicators of absence.

MDL: Method Detection Limit NS: Not Specified ND: Not Detected LMP: Permitted limit

YESLAIRA PAMELA SOSA RAMIREZ
ANALISTA DE LABORATORIO

BERNARDO LOPEZ
CONTROL DE CALIDAD

SHARON LUGO
GERENTE DE LABORATORIO

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ANALYSIS REPORT

CUSTOMER NAME:	MOLINOS VALLE DEL CIBAO, S.A (GALLETAS)	**TIPE OF SAMPLE:**	DIRECT
CONTACT:	SRA. ANA SIRI	**SAMPLING DATE & TIME:**	07/07/2022 10:18
CUSTOMER ADDRESS:	CARRETERA DUARTE KM 5 1/2 SANTIAGO-LICEY SANTIAGO REP. DOM.	**SAMPLES COLLECTED BY:**	VICTOR CANARIO
JOB NO. / LABORATORY REFERENCE NUMBER:	RD-LAB-221154	**RECEPTION DATE & TIME OF SAMPLE**	07/07/2022 16:16
CUSTODY CHAIN NUMBER:	9220	**SAMPLES RECEIVED BY:**	BERNARDO LOPEZ
SAMPLE NUMBER:	73683	**TEMPERATURE RECEPTION:**	8.4º C
SAMPLE MATRIX:	SWABBED SURFACE	**FINAL DATE OF ANALYSIS:**	08/07/2022
SAMPLE DESCRIPTION	**LUIS POLANCO (LINEA 2)**	**DATE OF DELIVERY OF RESULTS:**	**11/07/2022**

PARAMETER	METHOD	UNITS	MDL	RESULT	PERMISSIBLE LIMITS Min - Max	ANALYST
Total Coliforms.	Swab Contact Method 3.81, Chapter 3.	UFC / Surface	----	< 5	< 10	BL
Escherichia coli.	Swab Contact Method 3.81, Chapter 3.	UFC / Surface	----	< 5	Absence (< 5.0 UFC/Surface)	BL
Final parameters analyzed for this sample	----	---	----	----	----	---

COMMENTS:
"The results for the analyzed and norman parameters thrown by this sample are within the limits recommended by the Technical Guide for the Microbiological Analysis of Surfaces in Contact with Food and Beverages"
Reported values for E.coli (<5 CFU/surface) in analytical operations, these values are indicators of absence.

MDL: Method Detection Limit NS: Not Specified ND: Not Detected LMP: Permitted limit

YESLAIRA PAMELA SOSA RAMIREZ
ANALISTA DE LABORATORIO

BERNARDO LOPEZ
CONTROL DE CALIDAD

SHARON LUGO
GERENTE DE LABORATORIO

ALTOL PETROLEUM PRODUCTS SERVICES DOMINICANA, SRL.

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www.altolrd.com /ptillero@altolrd.com / laboratorio@altolrd.com

ANALYSIS REPORT

CUSTOMER NAME:	MOLINOS VALLE DEL CIBAO, S.A (GALLETAS)	**TIPE OF SAMPLE:**	DIRECT
CONTACT:	SRA. ANA SIRI	**SAMPLING DATE & TIME:**	07/07/2022 10:22
CUSTOMER ADDRESS:	CARRETERA DUARTE KM 5 1/2 SANTIAGO-LICEY SANTIAGO REP. DOM.	**SAMPLES COLLECTED BY:**	VICTOR CANARIO
JOB NO. / LABORATORY REFERENCE NUMBER:	RD-LAB-221154	**RECEPTION DATE & TIME OF SAMPLE**	07/07/2022 16:16
CUSTODY CHAIN NUMBER:	9220	**SAMPLES RECEIVED BY:**	BERNARDO LOPEZ
SAMPLE NUMBER:	73684	**TEMPERATURE RECEPTION:**	8.4º C
SAMPLE MATRIX:	SWABBED SURFACE	**FINAL DATE OF ANALYSIS:**	08/07/2022
SAMPLE DESCRIPTION	**ALFREDO GUZMAN (LINEA 6)**	**DATE OF DELIVERY OF RESULTS:**	**11/07/2022**

PARAMETER	METHOD	UNITS	MDL	RESULT	PERMISSIBLE LIMITS Min - Max	ANALYST
Total Coliforms.	Swab Contact Method 3.81, Chapter 3.	UFC / Surface	----	< 5	< 10	BL
Escherichia coli.	Swab Contact Method 3.81, Chapter 3.	UFC / Surface	----	< 5	Absence (< 5.0 UFC/Surface)	BL
Final parameters analyzed for this sample	----	---	----	----	----	---

COMMENTS:
"The results for the analyzed and norman parameters thrown by this sample are within the limits recommended by the Technical Guide for the Microbiological Analysis of Surfaces in Contact with Food and Beverages"
Reported values for E.coli (<5 CFU/surface) in analytical operations, these values are indicators of absence.

MDL: Method Detection Limit NS: Not Specified ND: Not Detected LMP: Permitted limit

YESLAIRA PAMELA SOSA RAMIREZ
ANALISTA DE LABORATORIO

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República Dominicana
RNC.: 130-00900-7

ALCHEM
ALTOL CHEMICAL ENVIRONMENTAL LABORATORY INC.

ALTOL

JOB NO. / LABORATORY REFERENCE NUMBER: RD-LAB-221155

CUSTODY CHAIN NUMBER: 9219

SAMPLING DATE: 07/07/2022

DATE OF DELIVERY OF RESULTS: 14/07/2022

ANALYSIS REPORT

CORRESPONDING TO QUOTATION NUMBER: 14454

MOLINOS VALLE DEL CIBAO, S.A (GALLETAS)

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ANALYSIS REPORT

CUSTOMER NAME:	MOLINOS VALLE DEL CIBAO, S.A (GALLETAS)	**TIPE OF SAMPLE:**	DIRECT
CONTACT:	SRA. ANA SIRI	**SAMPLING DATE & TIME:**	07/07/2022 10:54
CUSTOMER ADDRESS:	CARRETERA DUARTE KM 5 1/2 SANTIAGO-LICEY SANTIAGO REP. DOM.	**SAMPLES COLLECTED BY:**	VICTOR CANARIO
JOB NO. / LABORATORY REFERENCE NUMBER:	RD-LAB-221155	**RECEPTION DATE & TIME OF SAMPL**	07/07/2022 16:17
CUSTODY CHAIN NUMBER:	9219	**SAMPLES RECEIVED BY:**	BERNARDO LOPEZ
SAMPLE NUMBER:	73679	**TEMPERATURE RECEPTION:**	N/A
SAMPLE MATRIX:	SOLID, FOOD C / HEAT TREATMENT	**FINAL DATE OF ANALYSIS:**	12/07/2022
SAMPLE DESCRIPTION	**SODA CRACKER AVIVA NORMAL LOTE: L7188221**	**DATE OF DELIVERY OF RESULTS:**	**14/07/2022**

PARAMETER	METHOD	UNITS	MDL	RESULT	PERMISSIBLE LIMITS Min - Max	ANALYST
Aerobic Plate Count	Chromogenic Plate Equiv. AOAC Official Method 966.23 Microbiological Methods	UFC/g	----	4.6E+02	Acceptable from ≥1E+3(*) to ≤5E+3(**)	SL
Total Coliforms	AOAC Official Method 2018.13 / 3M™ Petrifilm™	UFC/g	----	< 10	≤10	BL
Escherichia coli	BS ISO 16649-2:2001. ß-Glucuronidasa Positivo. Pour Plate	Absence/presence/g	----	Absence	---	BL
Staphylococcus aureus	AOAC 2003.07 / 3M™ Petrifilm™ Staph Express	UFC/g	----	< 10	<1E+2	BL
Salmonella spp.	Methods for the Isolation of salmonella spp.	Absence/presence/ 25 g	----	Absence	---	BL
Yeasts and Molds	Spread Plate / Pour Plate, Chapter 18. BAM.	UFC/g	----	< 100	≤5E+2	BL
Final parameters analyzed for this sample	----	---	----	---	---	---

COMMENTS:
"The results obtained by this sample for the parameters analyzed and regulated are satisfactory according to the microbiological limits established by the NORDOM 705 Biscuits - Requirements, which are specified in Table 2 (Microbiological requirements for unfilled biscuits)".
"Satisfactory if it is less than (*) / Unsatisfactory if it is Greater than (**)"

MDL: Method Detection Limit NS: Not Specified ND: Not Detected LMP: Permitted limit

YESLAIRA PAMELA SOSA RAMIREZ
ANALISTA DE LABORATORIO

BERNARDO LOPEZ
CONTROL DE CALIDAD

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ANALYSIS REPORT

CUSTOMER NAME:	MOLINOS VALLE DEL CIBAO, S.A (GALLETAS)	**TIPE OF SAMPLE:**	DIRECT
CONTACT:	SRA. ANA SIRI	**SAMPLING DATE & TIME:**	07/07/2022 10:56
CUSTOMER ADDRESS:	CARRETERA DUARTE KM 5 1/2 SANTIAGO-LICEY SANTIAGO REP. DOM.	**SAMPLES COLLECTED BY:**	VICTOR CANARIO
JOB NO. / LABORATORY REFERENCE NUMBER:	RD-LAB-221155	**RECEPTION DATE & TIME OF SAMPL**	07/07/2022 16:17
CUSTODY CHAIN NUMBER:	9219	**SAMPLES RECEIVED BY:**	BERNARDO LOPEZ
SAMPLE NUMBER:	73680	**TEMPERATURE RECEPTION:**	N/A
SAMPLE MATRIX:	SOLID, FOOD C / HEAT TREATMENT	**FINAL DATE OF ANALYSIS:**	12/07/2022

SAMPLE DESCRIPTION	**PRINCESA CLUB LOTE: L6188221**	**DATE OF DELIVERY OF RESULTS:**	**14/07/2022**

PARAMETER	METHOD	UNITS	MDL	RESULT	PERMISSIBLE LIMITS Min - Max	ANALYST
Aerobic Plate Count	Chromogenic Plate Equiv. AOAC Official Method 966.23 Microbiological Methods	UFC/g	----	2.2E+02	Acceptable from ≥1E+3(*) to ≤5E+3(**)	SL
Total Coliforms	AOAC Official Method 2018.13 / 3M™ Petrifilm™	UFC/g	----	< 10	≤10	BL
Escherichia coli	BS ISO 16649-2:2001. ß-Glucuronidasa Positivo. Pour Plate	Absence/presence/g	----	Absence	---	BL
Staphylococcus aureus	AOAC 2003.07 / 3M™ Petrifilm™ Staph Express	UFC/g	----	< 10	<1E+2	BL
Salmonella spp.	Methods for the Isolation of salmonella spp.	Absence/presence/ 25 g	----	Absence	---	BL
Yeasts and Molds	Spread Plate / Pour Plate, Chapter 18. BAM.	UFC/g	----	< 100	≤5E+2	BL
Final parameters analyzed for this sample	----	---	----	---	---	---

COMMENTS:
"The results obtained by this sample for the parameters analyzed and regulated are satisfactory according to the microbiological limits established by the NORDOM 705 Biscuits - Requirements, which are specified in Table 2 (Microbiological requirements for unfilled biscuits)".
"Satisfactory if it is less than (*) / Unsatisfactory if it is Greater than (**)"

MDL: Method Detection Limit NS: Not Specified ND: Not Detected LMP: Permitted limit

YESLAIRA PAMELA SOSA RAMIREZ
ANALISTA DE LABORATORIO

BERNARDO LOPEZ
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ANALYSIS REPORT

CUSTOMER NAME:	MOLINOS VALLE DEL CIBAO, S.A (GALLETAS)	**TIPE OF SAMPLE:**	DIRECT
CONTACT:	SRA. ANA SIRI	**SAMPLING DATE & TIME:**	07/07/2022 10:58
CUSTOMER ADDRESS:	CARRETERA DUARTE KM 5 1/2 SANTIAGO-LICEY SANTIAGO REP. DOM.	**SAMPLES COLLECTED BY:**	VICTOR CANARIO
JOB NO. / LABORATORY REFERENCE NUMBER:	RD-LAB-221155	**RECEPTION DATE & TIME OF SAMPLE:**	07/07/2022 16:17
CUSTODY CHAIN NUMBER:	9219	**SAMPLES RECEIVED BY:**	BERNARDO LOPEZ
SAMPLE NUMBER:	73681	**TEMPERATURE RECEPTION:**	N/A
SAMPLE MATRIX:	SOLID, FOOD C / HEAT TREATMENT	**FINAL DATE OF ANALYSIS:**	12/07/2022
SAMPLE DESCRIPTION	**WAFER CHOCOLATE LOTE: L4188221**	**DATE OF DELIVERY OF RESULTS:**	**14/07/2022**

PARAMETER	METHOD	UNITS	MDL	RESULT	PERMISSIBLE LIMITS Min - Max	ANALYST
Aerobic Plate Count	Chromogenic Plate Equiv. AOAC Official Method 966.23 Microbiological Methods	UFC/g	----	1.8E+02	Acceptable from ≥1E+3(*) to ≤5E+3(**)	SL
Total Coliforms	AOAC Official Method 2018.13 / 3M™ Petrifilm™	UFC/g	----	< 10	≤10	BL
Escherichia coli	BS ISO 16649-2:2001. ß-Glucuronidasa Positivo. Pour Plate	Absence/presence/g	----	Absence	---	BL
Staphylococcus aureus	AOAC 2003.07 / 3M™ Petrifilm™ Staph Express	UFC/g	----	< 10	<1E+2	BL
Salmonella spp.	Methods for the Isolation of salmonella spp.	Absence/presence/ 25 g	----	Absence	---	BL
Yeasts and Molds	Spread Plate / Pour Plate, Chapter 18. BAM.	UFC/g	----	< 100	≤5E+2	BL
Final parameters analyzed for this sample	----	---	----	----	----	---

COMMENTS:
"The results obtained by this sample for the parameters analyzed and regulated are satisfactory according to the microbiological limits established by the NORDOM 705 Biscuits - Requirements, which are specified in Table 3 (Microbiological requirements for filled biscuits)".
"Satisfactory if it is less than (*) / Unsatisfactory if it is Greater than (**)"

MDL: Method Detection Limit NS: Not Specified ND: Not Detected LMP: Permitted limit

YESLAIRA PAMELA SOSA RAMIREZ
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Santo Domingo
República Dominicana
RNC.: 130-00900-7

ATTESTATION *of* COMPLIANCE

GLOBAL TRADE BRIDGE CORP.

Per Title 21 of the Code of Federal Regulations, §1.501-14; MOLINOS VALLE DEL CIBAO S.A, which maintains a facility at CARRETERA DUARTE KM 5.5 TRAMO SANTIAGO LICEY; is producing CRACKERS AND BISCUITS in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 and 403(w) *(if applicable)* of the Federal Food, Drug, and Cosmetic Act.

FURTHERMORE, MOLINOS VALLE DEL CIBAO S.A certifies that its facility is responsible for implementing, and has implemented, controls that significantly minimize or prevent all FDA-identified biological, chemical, and/or physical hazards in relation to CRACKERS AND BISCUITS.

CERTIFICATION: By entering my name below, I certify that the information I provide on and in connection with this Attestation is true, accurate, and complete to the best of my knowledge. I understand that any false statements or deliberate omissions on this Attestation or any other provided documents may be grounds for disqualification from successful Foreign Supplier Verification Program *(FSVP)* approval or, if discovered after FSVP approval takes place, may result in a product's FSVP approval status being revoked, may result in a product or shipment being rejected from entry into the United States, and/or any consequence prescribed by Title 21 of the Code of Federal Regulations, §1.514.

MOLINOS VALLE DEL CIBAO, S.A. BOCEL GRUPO Santiago, R.D.

Signed

Full Name CHRISTIAN REYNOSO

Title GENERAL MANAGER

Date AUGUST 11, 2022

PG-10.2/RC01 REV.1	MOLINOS VALLE DEL CIBAO SA - COOKIES AND BISCUITS DIVISION QUALITY MANAGEMENT SYSTEM CORRECTIVE ACTION FORM	BOCEL GRUPO

Date:	Julio 2,2024	**Detection method:**	*Auditoría Externa Inocuidad A.- Agrobiotek*	**Order number:**	N/A
Product	N/A	**Department:**	Calidad GB	**Corrective Action No.:**	
Customer	Global Trade C.	**Amount:**	N/A	**Degree of nonconformity**	Menor

Description of Non-Conformity

Comment: There's a GMP report. It's carried out monthly. PE-CAL-GB-02/RC12 rev. 1. The inspections carried out from January to May 2024 were observed. The same finding is observed - lack of identification of areas -. Non-compliance. Although they express that they have addressed the findings in the monthly GMP audit PE-CALGB- 02/RC12 rev. 1, no actions have been documented. This is a common finding.**Spanish**Comment: There is a GMP report. It is done monthly. PE-CAL-GB-02/RC12 rev. 1. Inspections carried out from January to May 2024. The same finding is observed - lack of identification of areas. Non-compliance. Although they state that they have addressed the findings in the monthly GMP audit PE-CAL-GB-02/RC12 rev. 1, no actions have been documented. This is a recurring finding.

Analysis of the Causes

Although appropriate actions were taken, they were not documented on the corresponding form.

Corrective Actions

Actions	Responsible	Start Date	End Date	State
Carry out a corrective action plan corresponding to the monthly BPM results in the corresponding form.	Ana Siri	6/1/24	Continuous	In progress
Follow up on the closure of the proposed corrective actions.	Wilissa Pineda/Jesus Herrera	Continuous		In progress

Responsible: Ana Siri

Start Date:	*1-Jun-24*
End Date:	

Verification of the Effectiveness of the Actions Taken

Responsible: Wilissa Pineda

Start Date:	
State:	
End Date:	

PG-10.2/RC01 REV.1	MOLINOS VALLE DEL CIBAO SA - COOKIES AND BISCUITS DIVISION QUALITY MANAGEMENT SYSTEM CORRECTIVE ACTION FORM	BOCEL GRUPO

Date:	Julio 2,2024	**Detection method:**	*Auditoría Externa Inocuidad A.- Agrobiotek*	**Order number:**	N/A
Product	N/A	**Department:**	Calidad GB	**Corrective Action No.:**	
Customer	Global Trade C.	**Amount:**	N/A	**Degree of nonconformity**	Mejora

Description of Non-Conformity

Comment: Non compliance: In the withdrawal procedure, they have a list of the positions that are members of the withdrawal team, but their contact information (name, telephone, email) is not included. **Spanish**Comment: Non-compliance: In the withdrawal procedure they have a list of the positions that are members of the withdrawal team, but their contact information (name, phone number, email) is not included.

Analysis of the Causes

Previously, Committee member positions were updated, however, it was not known that it was necessary to include personal details in the Retirement Committee Member List such as phone number and address.

Corrective Actions

Actions	Responsible	Start Date	End Date	State
Include in the Product Collection Procedure a form with the names, telephone numbers, addresses and functions of the different members of the Product Collection Committee.	Wilissa Pineda	7/1/24	7/1/24	Ready
Include form in the Product Collection Procedure.	Wilissa Pineda	7/2/24	7/5/24	Ready
Check semi-annually that the information in the Product Collection Committee Member List form is kept up to date.	Wilissa Pineda	Continuous		N/A

Responsible: Wilissa Pineda

Start Date:	*1-Jul-24*
End Date:	

Verification of the Effectiveness of the Actions Taken

Responsible: Jesus Herrera

Start Date:	
State:	
End Date:	

PG-10.2/RC01 REV.1	MOLINOS VALLE DEL CIBAO SA - COOKIES AND BISCUITS DIVISION QUALITY MANAGEMENT SYSTEM CORRECTIVE ACTION FORM	BOCEL GRUPO

Date:	Julio 2,2024	**Detection method:**	*Auditoría Externa Inocuidad A.- Agrobiotek*	**Order number:**	N/A
Product	N/A	**Department:**	Calidad GB	**Corrective Action No.:**	
Customer	Global Trade C.	**Amount:**	N/A	**Degree of nonconformity**	Menor

Description of Non-Conformity

Comment: Non compliance: Although they have monitoring information for the CCPs, a validation report in compliance with the requirements of this guideline has not been documented.**Spanish** Comment: Non-compliance: Although there is CCP monitoring information, a validation report on compliance with the requirements of this guide has not been documented.

Analysis of the Causes

The requirement to have an additional validation exercise in addition to the data collection carried out by the inspectors, as well as the verification of equipment carried out by the company providing calibration services, was unknown.

Corrective Actions

Actions	Responsible	Start Date	End Date	State
Define methodology for the validation exercise.	Ana Siri	7/15/24	7/18/24	Not started
Perform validation exercise to verify compliance with requirements.	Ana Siri	7/22/24	7/26/24	Not started
Establish PCC Validation Instructions and define the frequency of its implementation.	Ana Siri	7/15/24	7/18/24	Not started

Responsible: Ana Siri

Start Date:	*1-Aug-24*
End Date:	

Verification of the Effectiveness of the Actions Taken

Responsible: Wilissa Pineda

Start Date:	
State:	
End Date:	

PG-10.2/RC01 REV.1	MOLINOS VALLE DEL CIBAO SA - COOKIES AND BISCUITS DIVISION QUALITY MANAGEMENT SYSTEM CORRECTIVE ACTION FORM	BOCEL GRUPO

Date:	Julio 2,2024	**Detection method:**	*Auditoría Externa Inocuidad A.- Agrobiotek*	**Order number:**	N/A
Product	N/A	**Department:**	Calidad LDI	**Corrective Action No.:**	
Customer	Global Trade C.	**Amount:**	N/A	**Degree of nonconformity**	Menor

Description of Non-Conformity

Comentario: They have a handwashing inspection checklist PE-CAL-LDI-02/RC02 rev. 0. Record is observed for May and June 2024. Evidence is observed that actions are taken when findings are observed, e.g.: of 06/17/24. Compliance verification form observed for good personal practices PE-CAL-LDI rev. 0. Evidence is observed that actions are taken when findings are observed, e.g.: 06.07.24. Monthly GMP audit verification form PE-CAL-LDI-02/ RC06 is observed. The reports from January to May 2024 are reviewed. Non-compliance. Although they express that they have addressed the findings in the monthly GMP audit PE-CALLDI- 02/RC06, no actions have been documented. This is a recurring finding. Observation: Records of GMP audit observed with some questions without being answered (a check mark): january 24 (5.7.1, 5.9.2) and april 24 (3.7.2). **Español:**Comment: They have a handwashing inspection checklist PE-CAL-LDI-02/RC02 rev. 0. Records are shown for May and June 2024. Evidence is shown that actions are taken when findings are observed, e.g., 06/17/24. Personal Good Practices Observed Compliance Verification Form PE-CAL-LDI rev. 0. Evidence is shown that actions are taken when findings are observed, e.g., 06/07/24. Monthly GMP audit verification form PE-CAL-LDI-02/RC06 is shown. Reports are reviewed from January to May 2024. Non-compliance. While they state that they have addressed the findings in the monthly GMP audit PE-CALLDI-02/RC06, no actions have been documented. This is a recurring finding. Note: BPF audit logs observed with some questions unanswered (one check mark): January 24 (5.7.1, 5.9.2) and April 24 (3.7.2).

Analysis of the Causes

Corrective actions taken after obtaining results below the target were not formalized on a form.

Corrective Actions

Actions	Responsible	Start Date	End Date	State
Carry out corrective action plan corresponding to the results of Monthly BPM	Yohanny Fabian	6/1/24	Continuous	
Follow up on the closure of the proposed corrective actions.	Wilissa Pineda	Continuous		

Responsible: Yohanny Fabian

Start Date:	*1-Jun-24*
End Date:	

Verification of the Effectiveness of the Actions Taken

Responsible: Wilissa Pineda

Start Date:	
State:	
End Date:	

PG-10.2/RC01 REV.1	MOLINOS VALLE DEL CIBAO SA - COOKIES AND BISCUITS DIVISION QUALITY MANAGEMENT SYSTEM CORRECTIVE ACTION FORM	BOCEL GRUPO

Date:	Julio 2,2024	**Detection method:**	*Auditoría Externa Inocuidad A.- Agrobiotek*	**Order number:**	N/A
Product	N/A	**Department:**	Calidad LDI	**Corrective Action No.:**	
Customer	Global Trade C.	**Amount:**	N/A	**Degree of nonconformity**	Mejora

Description of Non-Conformity

Door with broken mesh is observed, they have put up a protective curtain, but it's not a control that completely eliminates the risk of pest entry. During the inspection some open areas were observed. Additionally, it was observed that some doors do not close completely.**Spanish:** A door with a broken mesh was observed. A protective curtain has been installed, but it is not a control that completely eliminates the risk of pest entry. During the inspection, some open areas were observed. In addition, it was observed that some doors do not close completely.

Analysis of the Causes

Not enough financial resources have been allocated to correct infrastructure breakdowns.

Corrective Actions

Actions	Responsible	Start Date	End Date	State
Remove mesh with hole and replace header door	Adonias Mariñez	7/8/24	7/31/24	Not started
Place covers or rubbers that help to hermetically seal the roll-up doors of the office and headboard	Adonias Mariñez	7/8/24	7/31/24	Not started

Responsible: Adonías Mariñez

Start Date:	*8-Jul-24*
End Date:	

Verification of the Effectiveness of the Actions Taken

Responsible: Wilissa Pineda

Start Date:	
State:	
End Date:	

PG-10.2/RC01 REV.1	MOLINOS VALLE DEL CIBAO SA - COOKIES AND BISCUITS DIVISION QUALITY MANAGEMENT SYSTEM CORRECTIVE ACTION FORM	BOCEL GRUPO

Date:	Julio 2,2024	**Detection method:**	*Auditoría Externa Inocuidad A.- Agrobiotek*	**Order number:**	N/A
Product	N/A	**Department:**	Calidad LDI	**Corrective Action No.:**	
Customer	Global Trade C.	**Amount:**	N/A	**Degree of nonconformity**	Menor

Description of Non-Conformity

Some pigeons were observed in the external area of the plant; they were not observed entering the reception or process areas. An insect was observed at the entrance door, without risk of contamination.**Spanish:** Some pigeons were observed in the external area of the plant; they were not observed entering the reception or processing areas. One insect was observed at the entrance door, with no risk of contamination.

Analysis of the Causes

Corrective Actions

Actions	Responsible	Start Date	End Date	State
Evaluate alternatives for physical barriers to prevent pigeons from entering the plant's external corridor. Receive quotes.	Adonias Mariñez/ Jose Arias	7/15/24	8/15/24	
Approve installation project.	Mario/Yanire/Christian Reynoso	9/1/24	10/1/24	
Install physical barriers	External Provider	11/1/24	12/23/24	

Responsible:

Start Date:	
End Date:	

Verification of the Effectiveness of the Actions Taken

Responsible: Wilissa Pineda

Start Date:	
State:	
End Date:	

PG-10.2/RC01 REV.1	MOLINOS VALLE DEL CIBAO SA - COOKIES AND BISCUITS DIVISION QUALITY MANAGEMENT SYSTEM CORRECTIVE ACTION FORM	BOCEL GRUPO

Date:	Julio 2,2024	**Detection method:**	*Auditoría Externa Inocuidad A.- Agrobiotek*	**Order number:**	N/A
Product	N/A	**Department:**	Calidad LDI	**Corrective Action No.:**	
Customer	Global Trade C.	**Amount:**	N/A	**Degree of nonconformity**	Mejora

Description of Non-Conformity

Comentario: There's a corrective and preventive maintenance report. Records were observed of january 2nd (number 02) and 5th (number 20). There's a maintenance anual program PE-MANT-GB-02/GB rev. 0. Observation #1: Strengthen the filling of maintenance records. Some were observed incomplete. Observation #2: There's not an completed preventive maintenance program. It should be finished. Non compliance: There is no documented evidence that equipment is cleaned and disinfected after maintenance activities are performed.
Español: Comment: There is a corrective and preventive maintenance report. Records were observed for January 2 (number 02) and January 5 (number 20). There is an annual maintenance program PE-MANT-GB-02/GB rev. 0. Observation #1: Strengthen the completion of maintenance records. Some were observed to be incomplete. Observation #2: There is no complete preventive maintenance program. It should be completed. Non-compliance: There is no documented evidence that equipment is cleaned and disinfected after maintenance activities are performed.

Analysis of the Causes

Corrective Actions

Actions	Responsible	Start Date	End Date	State
Review organizational structure of the Maintenance Department. Manage 1 mechanical maintenance intern.	Mario Jimenez/Adonias M./Elias Morel/ Christian Reynoso	7/3/24	7/15/24	
Design a preventive maintenance program with mechanical and electrical equipment routines.	Mario Jimenez/Adonias M.	7/3/24	12/15/24	
Design maintenance forms	Vanessa Tineo/Adonias M.	7/3/24	12/15/24	
Establish cleaning activities in the current form in maintenance routines after intervention.	Adonias M.	4/3/24	8/4/24	
Train maintenance personnel in preventive maintenance requirements. External	Mariel Hernandez			

Responsible:

Start Date:	
End Date:	

Verification of the Effectiveness of the Actions Taken

Responsible: Wilissa Pineda

Start Date:	
State:	
End Date:	

PG-10.2/RC01 REV.1	MOLINOS VALLE DEL CIBAO SA - COOKIES AND BISCUITS DIVISION QUALITY MANAGEMENT SYSTEM CORRECTIVE ACTION FORM	BOCEL GRUPO

Date:	Julio 2,2024	**Detection method:**	*Auditoría Externa Inocuidad A.- Agrobiotek*	**Order number:**	N/A
Product	N/A	**Department:**	Calidad LDI	**Corrective Action No.:**	
Customer	Global Trade C.	**Amount:**	N/A	**Degree of nonconformity**	Mejora

Description of Non-Conformity

Comment: Production control procedure PE-LDI-PRO-01 rev. 1 is observed. It mention reprocessing. A report of non-compliant products and supplies since 06/08/24 is observed. Non compliance: During the inspection of the process area, unidentified non-conforming products were observed. Recommendation: Document in detail the reprocessing process and non-conforming product.**Spanish:** Comment: Production control procedure PE-LDI-PRO-01 rev. 1 is observed. It mentions reprocessing. A report of non-conforming products and inputs from 06/08/24 is observed. Non-compliance: During the inspection of the process area, it was observed that the product was not in compliance with the regulations. observed unidentified nonconforming products. Recommendation: Document in detail the reprocessing process and the nonconforming product.

Analysis of the Causes

Corrective Actions

Actions	Responsible	Start Date	End Date	State
Strengthen labeling of non-compliant products between production and quality.	Yohanny Fabian			
Raise awareness among staff about the importance of identifying non-conforming products, products in process, and finished products.	Yohanny Fabian	8/1/24	8/15/24	

Responsible:

Start Date:	
End Date:	

Verification of the Effectiveness of the Actions Taken

Responsible: Wilissa Pineda

Start Date:	
State:	
End Date:	

PG-10.2/RC01 REV.1	MOLINOS VALLE DEL CIBAO SA - COOKIES AND BISCUITS DIVISION QUALITY MANAGEMENT SYSTEM CORRECTIVE ACTION FORM	BOCEL GRUPO

Date:	Julio 2,2024	**Detection method:**	*Auditoría Externa Inocuidad A.-Agrobiotek*	**Order number:**	N/A
Product	N/A	**Department:**	Calidad LDI	**Corrective Action No.:**	
Customer	Global Trade C.	**Amount:**	N/A	**Degree of nonconformity**	Mejora

Description of Non-Conformity

Comentario: They have a glass and brittle plastic program PE-CAL-LDI-03 rev. 0. They carry out monthly inspection with the PE-CAL-LDI-03/RC01 form and the actions in case of an incident are documented. In general the lamps are LED. Some warehouse lamps are not LED but were protected. The hard glass and plastic verification record PECAL- LDI-03/RC01 rev. 0. Records of june 2024 are observed. Non-compliance: Records with non-compliant comments are observed without documented actions. Observation: some are observed without indicating whether it is plastic or glass. Recommendation: Consider conducting an inventory of brittle plastic and glass. **Español:**Comment: They have a brittle glass and plastic program PE-CAL-LDI-03 rev. 0. They carry out a monthly inspection using form PE-CAL-LDI-03/RC01 and the actions taken in the event of an incident are documented. In general, the lamps are LED. Some lamps in the warehouse are not LED but were protected. The hard glass and plastic verification record PECAL- LDI-03/RC01 rev. 0. Records from June 2024 are observed. Non-compliance: Records with non-compliance comments are observed without documented actions. Observation: some are observed without indicating whether it is plastic or glass. Recommendation: consider conducting an inventory of brittle plastic and glass.

Analysis of the Causes

Corrective Actions

Actions	Responsible	Start Date	End Date	State
Modify record by placing inventory of videos and plastics	Sandy Mendoza/ Yohanny Fabian	8/1/24	8/15/24	
Place behind the Glass and Plastic Verification Form and a Corrective Action Form,	Sandy Mendoza/ Yohanny Fabian			

Responsible:

Start Date:	
End Date:	

Verification of the Effectiveness of the Actions Taken

Responsible: Wilissa Pineda

Start Date:	
State:	
End Date:	

PG-10.2/RC01 REV.1	MOLINOS VALLE DEL CIBAO SA - COOKIES AND BISCUITS DIVISION QUALITY MANAGEMENT SYSTEM CORRECTIVE ACTION FORM	BOCEL GRUPO

Date:	Julio 2,2024	**Detection method:**	*Auditoría Externa Inocuidad A.-Agrobiotek*	**Order number:**	N/A
Product	N/A	**Department:**	Calidad LDI	**Corrective Action No.:**	
Customer	Global Trade C.	**Amount:**	N/A	**Degree of nonconformity**	Menor

Description of Non-Conformity

Comentario: They have metal detectors on one of the lines but there is no metal detector on line 2400, which is also used in the production of exported products. They have a monitoring record of critical control points PE-CAL-LDI-01/RC16 rev. 0. They use 3.0 and 3.5 mm standards, it's monitor every hour. Observation: The record does not indicate the acceptance range of the standards used. Review the completion of the question for all the products in the line, some enter yes and others the line number. Non-compliance: line (2400) does not have a metal detector. Note: evidence was observed that they are working to acquire them, e.g. quote, technical sheet, emails. ***Español.*** English: Comment: They have metal detectors on one of the lines but there is no metal detector on line 2400, which is also used in the production of export products. They have a critical control points monitoring record PE-CAL-LDI-01/RC16 rev. 0. They use 3.0 and 3.5 mm standards, which are monitored every hour. Observation: The record does not indicate the acceptance range of the standards used. Check the completion of the question for all the products on the line, some enter yes and others the line number. Non-compliance: Line (2400) does not have a metal detector. Note: Evidence was observed that they are working to acquire them, e.g. quote, technical sheet, emails.

Analysis of the Causes

Corrective Actions

Actions	Responsible	Start Date	End Date	State
Set acceptance range based on the witness used in the CCP Monitoring form.				

Responsible:

Start Date:	
End Date:	

Verification of the Effectiveness of the Actions Taken

Responsible: Wilissa Pineda

Start Date:	
State:	
End Date:	

PG-10.2/RC01 REV.1	MOLINOS VALLE DEL CIBAO SA - COOKIES AND BISCUITS DIVISION QUALITY MANAGEMENT SYSTEM CORRECTIVE ACTION FORM	BOCEL GRUPO

Date:	Julio 2,2024	**Detection method:**	*Auditoría Externa Inocuidad A.-Agrobiotek*	**Order number:**	N/A
Product	N/A	**Department:**	Calidad LDI	**Corrective Action No.:**	
Customer	Global Trade C.	**Amount:**	N/A	**Degree of nonconformity**	Mejora

Description of Non-Conformity

Comment: Non compliance: In the withdrawal procedure, they have a list of the positions that are members of the withdrawal team, but their contact information (name, telephone, email) is not included.***Spanish*** Comentario: Incumplimiento: En el procedimiento de retiro tienen un listado de los cargos que integran el equipo de retiro, pero no se incluye su información de contacto (nombre, teléfono, correo electrónico).

Analysis of the Causes

Corrective Actions

Actions	Responsible	Start Date	End Date	State
Include in the Product Collection Procedure a form with the names, telephone numbers, addresses and functions of the different members of the Product Collection Committee.				

Responsible:

Start Date:	
End Date:	

Verification of the Effectiveness of the Actions Taken

Responsible: Wilissa Pineda

Start Date:	
State:	
End Date:	

Costco Safety & Quality Audit

05/12/2021 08:00:00

Company Information		Audit Information	
Company# - Name	C0362289 - Molinos Valle del Cibao S.A	Audit# - Visit#	2554126 - 2041692
Company Address	Carretera Duarte Km 5.5 Carretera Santiago, Licey, Santiago, Santiago, Dominican Republic, 00954		
Facility # - Name	C0362290 - Molinos Valle Del Cibao S.A.	Audit Type	COSEFGMP - 1.2 - Costco Safety & Quality Audit
		Announced?	No
Facility Address	Carretera Licey Km 5,, Santiago de los Caballeros,,, Santiago, Dominican Republic	Auditor	Ingrid Jeanette Garcia
		Auditor Phone	(502) 55175293
		Auditor Email	ingarcia@nsf.org
Contact	Ms. Wilissa Pineda Gomez	Audit Company	NSF International
Title	Quality Management System Representative	Audit Date(s)	05/12/2021 08:00:00 - 05/12/2021 17:00:00
Phone	809 7476 524		
Fax		Previous Audit Score	97.61%
Email	wpineda@grupobocel.com		

Note: Please refer to the latest Costco Food Safety Expectations Manual for an explanation of audit results and scores.

Score Summary By Category		
Category Name	**Category Points**	**Category Score**
Management Systems	94/95	98.95%
Food Safety Systems	190/190	100.00%
Quality Systems	110/110	100.00%
Grounds, Buildings, Equipment	145/150	96.67%
Pest Control	60/60	100.00%
Employee Practices	45/45	100.00%
Receiving, Storage, and Shipping	75/75	100.00%
Processing	68/70	97.14%
Sanitation	73/75	97.33%
Food Defense	59/60	98.33%
Total Score	919/930	98.82%

Non-Conformance Summary

Note: Below are the non- Conformances found during this audit. Each of these non-conformances needs to be responded to unless the score of the audit is 98% or above. If you have any questions about specific non-conformances, please contact your auditor.

No.	Question/Notes	Answer
Section 3.5 / 3.5.6	A mechanism is established for the collection and evaluation of complaints. All valid complaints are investigated to determine a cause and resolution. Complaints are summarized for trend analysis and identify areas for improvement. *The company has established the complaints procedure "Procedimiento de Quejas y Reclamaciones" where the steps to be follow and the responsibles of the follow up have being assigned. Records of the complaints were observed.* *NC: The company has not implemented a trend analysis of the complaints.*	4.0

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Section 6.2 / 6.2.1	Exterior walls of facility, including troughs and down spouts are in good condition. Plant buildings and roofs are suitable in construction and designed to facilitate maintenance and sanitary operations. There are no roof leaks. *NC: Damaged ceilings with missing pieces were observed in the cleaning area.*	4.0
Section 6.2 / 6.2.2	Floors are in good condition and are constructed with materials that can be cleaned. Walls are in good condition and are constructed with materials that can be cleaned. Ceilings are in good condition and are constructed with materials that can be cleaned. *NC: Damaged floors in production and storage area were observed during the facility tour.*	4.0
Section 6.2 / 6.2.3	All doors and windows that lead to the outside are tightly sealed and/or screened to protect against pest entry. No cracks are present in walls to exterior of facility. All drains protruding on exterior of the buildings are protected and screened where needed. *NC: During the facility tour damaged door gasket in loading area was observed.*	4.0
Section 6.3 / 6.3.2	Equipment is in good repair, and is used for the task it was designed. Seams on food contact surfaces are smooth and free of spot welds. No mold or rust is observed. *NC: Missing screws in the inverted sugar containers were observed during the facility tour.*	4.0
Section 6.3 / 6.3.4	Temporary repairs will not cause contamination issues to products or the environment and do not inhibit sanitation tasks. Any temporary repairs on food contact surfaces are completed using food grade materials. *NC: During the facility tour, one of the water hoses was damaged and with insulating tape as a temporary repair. This hose was used for water used as an ingredient.*	4.0
Section 10.2 / 10.2.10	Screens, sifters, sieves and magnets are inspected and verified on a scheduled basis. All checks are documented. *NC: Staff use blades to open boxes and packages of raw materials and packaging material. An condition control has not been implemented for the blades.*	3.0
Section 11.2 / 11.2.1	Chemicals used for cleaning, sanitizing and processing are properly labeled and approved for a food handling facility. Storage for chemicals is well away from processing and food storage and is locked and secure. The site has an MSDS system that is accessible, organized and current. *NC: During facility tour, in shipping area, a plastic container with liquid inside and with no label were found unattended.* *NC: MSDS of the chlorine used for drains in cleaning area was not available.*	3.0
Section 12.1 / 12.1.2	A multidisciplinary team has assessed the facility and developed a written food defense plan covering all operations. The food defense team meets when reassessments/changes are necessary or at least annually to reassess the plan. The plant has developed a reduction strategy for identified risks. *NC: There was no record available of the last review of the vulnerability analysis performed.*	4.0

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

FRSCHANGE Section 0. Product Changes		
No	**Question/Answer**	
101.0	Are there any changes to the products sold, or the countries sold to, from the facility registration information? If so, please enter the changes in the notes field.	NO
Section Notes :		

Audit Information Section A. Audit Participants-01		
No	**Question/Answer**	
A.1	Audit Participant Name:	Claudia Pantaleón
A.2	Title:	Operation Manager
A.3	Phone:	N/A
A.4	Email:	cpantaleon@grupobocel.com
Section Notes :		

Audit Information Section A. Audit Participants-02		
No	**Question/Answer**	
A.1	Audit Participant Name:	Wilissa Pineda Gomez
A.2	Title:	Quality Management System Representative
A.3	Phone:	+809 7476524
A.4	Email:	wpineda@grupobocel.com
Section Notes :		

Audit Information Section A. Audit Participants-03		
No	**Question/Answer**	
A.1	Audit Participant Name:	Ana Marlenis Siri
A.2	Title:	Quality Assurance Coordinator
A.3	Phone:	N/A
A.4	Email:	asiri@grupobocel.com
Section Notes :		

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Audit Information Section B. Audit Details		
No	**Question/Answer**	
B.1	Number of Hours on Site	8 hours
B.2	Number of Hours with Records	6 hours
B.3	Number of Hours in Facility (Interior/Exterior)	2 hours
B.4	Facility Management Contact (Name, Email, Phone):	Wilissa Pineda
B.5	Facility Food Safety contact (Name, Email, Phone):	wpineda@grupobocel.com
B.6	All findings were agreed with Management as being a true record of the facts observed.	Yes
Section Notes :		

Audit Information Section C. Facility Profile		
No	**Question/Answer**	
C.1	Facility Description	Molinos Valle del Cibao S.A. is a Dominican company, part of Grupo Bocel, located in Santiago, Dominican Republic. Production is sold in Dominican Republic but mainly exported to the US (including Puerto Rico), Jamaica and several Caribbean islands. The cookies and crackers processing facility is 12 years old, and the line for Aviva Soda Crackers is exclusive for this product, with different presentations (4 crackers in a foil packed in plastic pails or cardboard boxes). The cookies and crackers facility has 617 employees in three shifts of production. The site has been certified ISO 9001:2015, Reg # ES-0363/2018 that expires 2021/06/07
C.2	Facility Established	2009
C.3	Facility Square Feet	178,000 square feets
C.4	Number of Employees	617
D.5	Products Produced At This Facility	Crackers, wafers and cupcakes
D.6	% of Facility Production For Costco	0.34% of the production
Section Notes :		

Product Changes Section 1.1. Product Changes		
No	**Question/Answer**	
1.1.1	Are there any changes to the products sold, or the countries sold to, from the facility registration information? If so, please enter the changes in the notes field.	No
Section Notes :		

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Facility Information Section 2.1. Facility Details		
No	**Question/Answer**	
2.1.1	USDA Facility Number (If applicable):	XXXXXXX8314 by Registrar Corp on October 22, 2020
2.1.2	Laboratory Facility Capabilities (Physical, Analytical/Microbiological):	Physical and analytical laboratory. For microbiological analysis an external laboratory is hired.
2.1.3	HACCP Certified? List name and position *Ana Marlenis Siri, Quality Control Coordinator,*	Yes
2.1.4	If Yes where was the class taken? *Received the certified course: USDA Preventive Controls for Human Food for Qualified Individual Course on February 16, 2018.*	Classroom
2.1.5	Certificate Expiration Date(s):	February 2023
Section Notes :		

Facility Information Section 2.2. Facility Allergens Information		
No	**Question/Answer**	
2.2.1	Cereals containing gluten (wheat, rye, barley, oats, spelt, kumat or their hybridized strains) and products thereof *Present in all the facility: gluten*	Yes
2.2.2	Buckwheat and products thereof	No
2.2.3	Fish and products thereof	No
2.2.4	Crustaceans and products thereof	No
2.2.5	Mollusks and products thereof	No
2.2.6	Eggs and products thereof *Eggs are used for other products in different production lines.*	Yes
2.2.7	Peanuts and products thereof	No
2.2.8	Soybeans and products thereof *Soy lecithin is used in several products, not in soda crackers.*	Yes
2.2.9	Milk and products thereof *Milk whey is used in several product, including Aviva Crackers*	Yes
2.2.10	Tree nuts and products thereof	No
2.2.11	Celery and products thereof	No
2.2.12	Lupin and products thereof	No
2.2.13	Mustard and products thereof	No
2.2.14	Sesame seeds and products thereof *Sesame is used for other product type of products.*	Yes
2.2.15	Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO2 *Sulphur dioxide is used in concentrations less than 10 ppm in a special cookie product but it is still handled as an allergen in the facility.*	Yes
Section Notes :		

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Management Systems Section 3.1. Management Policies		
No	**Question/Answer**	
3.1.1	Executive Management (Owner) has a written policy statement that outlines the organization's commitment to produce safe products while meeting all legal and regulatory Requirements. The policy is signed by senior management. The policy is regularly communicated to all employees. Supervisory staff is trained to understand and implement policy statement.	5.0
3.1.2	Executive Management (Owner) demonstrates commitment to make resources available to implement and maintain prerequisite and food safety programs. (In comment section describe specific resources made available to ensure that those responsible for implementing and maintaining prerequisite and food safety programs.)	5.0
3.1.3	Management actively maintains the facility and prioritizes repairs to the facility and equipment based on food safety risk to the product or process.	5.0
Section Notes :		

Management Systems Section 3.2. Organization		
No	**Question/Answer**	
3.2.1	There is a written organization chart showing the management structure of the company. The chart indicates the reporting structure of all individuals responsible for food safety and quality to upper management and links	5.0
3.2.2	Does the facility have a designated Food Safety/Quality Manager that has reports outside of the production hierarchy?	5.0
3.2.3	There are written job descriptions for all key food safety personnel outlining/defining responsibilities. There are provisions made to cover for the absence of key food safety staff.	5.0
Section Notes :		

Management Systems Section 3.3. Written Procedures		
No	**Question/Answer**	
3.3.1	FACILITY HAS WRITTEN FOOD SAFETY PLAN THAT COMPLIES WITH ALL APPLICABLE REGULATIONS AND OUTLINES PROCEDURES, METHODS, AND PRACTICES NECESSARY TO ACHIEVE SET RECOGNIZED STANDARDS. FOOD SAFETY PLAN INCLUDES HAZARD ANALYSIS, PREVENTATIVE CONTROLS, SUPPLY CHAIN PROGRAMS, RECALL PLANS, CORRECTIVE ACTION PROCEDURES, AND VERIFICATION PROCEDURES. *The company has developed the written food safety plan "Plan de Inocuidad Alimentaria para la División de Galletas y Bizcochos" that includes the HACCP Plan for each production line, the traceability and recall procedure, corrective action procedure, training plan and verification procedures.*	5.0
3.3.2	Food Safety Plan is readily available to facility personnel. Facility personnel are trained to understand and implement Food Safety procedures, methods, and practices. Food Safety Plan is reviewed annually or when changes occur to the process to determine the effectiveness of the procedure methods, and practices.	5.0
3.3.3	In the event that the facility has developed their food safety plan using an outside agency, does management have a strategy for implementing and maintaining this plan? *N/A: The Food Safety Plan was not developed by an external agency.*	NA

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Management Systems Section 3.3. Written Procedures		
No	**Question/Answer**	
3.3.4	~If the answer to the previous question is yes, who is responsible for overseeing the implementation of the externally developed Food Safety plan?	N/A: The Food Safety Plan was not developed by an external agency.
3.3.5	A WRITTEN GMP PROGRAM HAS BEEN ESTABLISHED THAT COMPLIES WITH ALL APPLICABLE REGULATIONS AND ADDRESSES EMPLOYEE HYGIENE, PEST CONTROL, SANITATION, AND FACILITY MANAGEMENT. *The company has implemented the GMP Program "PE-CAL-GB-02 Procedimiento de Buenas Prácticas de Manufactura e Higiene". It covers employees health and hygiene, cleaning and sanitation and pest control.*	5.0
Section Notes :		

Management Systems Section 3.4. Regulatory Requirements		
No	**Question/Answer**	
3.4.1	The facility has a written Regulatory Affairs and Inspection program. Program identifies employees responsible to manage the regulatory process. Facility demonstrates compliance to applicable regulatory requirements.	5.0
3.4.2	The Regulatory Affairs and Inspection program specifies that duplicate samples are to be taken when any regulatory samples of product are taken. Product associated with the sampling are held pending regulatory results. Facility maintains records pertaining to any regulatory sampling.	5.0
3.4.3	Products are reviewed for compliance to regulatory requirements for markets to which they are shipped. Records are maintained to support that regulatory reviews have been conducted.	5.0
Section Notes :		

Management Systems Section 3.5. Recalls/Complaints/Crisis Management		
No	**Question/Notes**	**Answer**
3.5.1	The site has an established and documented product recovery (recall) program, including assigned responsibility for managing the program. Program is in compliance with governmental guidelines and includes details on how customers affected by the recovery are to be contacted. The contact lists are updated annually, or as necessary, and include 24/7 contact information for all internal and external contacts necessary to conduct the recovery.	5.0
3.5.2	In the event of a recall the facility has established as part of a self-audit process a procedure or a process to investigate the cause of the failure and identify corrective actions.	5.0
3.5.3	The facility maintains distribution records of the initial point of distribution for all finished food products by specific code date or lot.	5.0

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Management Systems Section 3.5. Recalls/Complaints/Crisis Management		
No	**Question/Notes**	**Answer**
3.5.4	TRACEABILITY EXERCISES ARE CONDUCTED AT LEAST TWICE PER YEAR AND THE SYSTEM IS TESTED FOR BOTH A FINISHED PRODUCT INCIDENT AND AN INGREDIENT SUPPLIER INCIDENT. THE EXERCISE DEMONSTRATES THAT THE COMPANY CAN RECOVER 100% OF THE PRODUCT, INGREDIENT, OR PRIMARY PACKAGING TESTED WITHIN 2 HOURS. *In it´s recall procedure "PE-CAL-GB-03 Procedimiento de Retiro de Productos" the company has established that 2 mock exercises must be conducted per year. Last mock exercise was conducted on June 30, 2020 for 740 Aviva Crackers boxes. It was completed in 41 minutes with 100% efficiency.*	5.0
3.5.5	AN AUDITOR INITIATED TRACEABILITY EXERCISE ON ONE COSTCO ITEM DURING THE AUDIT WILL VERIFY THAT THE FACILITY CAN TRACK AND LOCATE 100% OF THE ASSIGNED ITEM WITHIN 2 HOURS. AUDITOR WILL LIST THE ITEM TESTED AND SUMMARIZE THE RESULTS IN THE COMMENTS. *A traceability exercise was performed during the audit for the product Aviva Crackers lot 809-747-6684 produced in April 26, 2021 for 900 boxes. The exercise was completed in 1 hour 29 minutes with 100% efficiency.*	5.0
3.5.6	A mechanism is established for the collection and evaluation of complaints. All valid complaints are investigated to determine a cause and resolution. Complaints are summarized for trend analysis and identify areas for improvement. *The company has established the complaints procedure "Procedimiento de Quejas y Reclamaciones" where the steps to be follow and the responsibles of the follow up have being assigned. Records of the complaints were observed. NC: The company has not implemented a trend analysis of the complaints.*	4.0*
3.5.7	Facility has a documented crisis management program beyond recalls (i.e. fire, water, power outage, etc.) that includes who is to be notified and the roles and responsibilities of each person.	5.0
Section Notes :		

Food Safety Systems Section 4.1. HACCP		
No	**Question/Answer**	
4.1.1	Facility has a HACCP Team. The HACCP Team is made up of a cross section of staff members and at least on one member of the team is formally HACCP trained. HACCP team meets at least semi-annually and meeting minutes are kept as proof of meeting. Formal HACCP training is performed by a credible agency in a classroom setting and is current (within 5 years). Auditor to verify certificate.	5.0
4.1.2	Employees with HACCP responsibilities have been trained, are aware of basic HACCP elements in their area, and undergo annual refresher training Records of employee training are maintained and include the person responsible for the training, the topic covered, who was trained, and evidence that the training was effective.	5.0
4.1.3	The facility has designed flow charts for all items and all variations of the process or sub-process. The flow chart identifies and describes every step including all inputs and outputs and all interactions between process steps. The charts include rework and recycled pathways, intermediate processes, hand operations, and outsourced or subcontracted work. Auditor to verify accuracy. Flow charts are updated whenever a process has changed. Verification of flow chart accuracy is documented by a date and signature of the verifier.	5.0
4.1.4	A full description of the products is required and must include composition, finished product storage, and distribution. The intended use and consumers must be identified.	5.0
4.1.5	A Hazard Analysis is available and focuses on food safety hazards reasonably likely to occur. This has been completed for each step in the process.	5.0
4.1.6	All Critical Control Points (CCPs) have been identified on the process flow diagram and in the HACCP plan.	5.0
4.1.7	Critical limits that have been scientifically set and validated are specifically listed for each CCP.	5.0
4.1.8	CCPs are being monitored per the plan at regular intervals by person(s) that understand the procedures and the importance. Auditor to verify via employee interview. Monitoring records are maintained and accurately reflect the findings.	5.0
4.1.9	Corrective action procedures have been identified and include all steps needed to identify, quantify, and segregate affected product. Corrective action records are maintained and include documentation on applicable product disposition.	5.0

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Food Safety Systems Section 4.1. HACCP		
No	**Question/Answer**	
4.1.10	CORRECTIVE ACTION PROCEDURES ARE TAKEN WHEN CRITICAL LIMITS ARE NOT MET. The monitoring and/or deviation records review, or direct observation shows that corrective actions were taken when critical limits were not met. *The HACCP plan establishes that when critical limits are not met, corrective action must be taken and recorded. The procedure to follow is: stop the line and retain the product since the last satisfactory inspection until the production and quality assurance team determinate what must be done with product.*	5.0
4.1.11	Procedures for the validation and calibration tasks have been developed. Verification records show compliance with the plan.	5.0
4.1.12	All HACCP records are signed and initialed by the individual performing the task and the individual reviewing the records.	5.0
4.1.13	Reassessments of the HACCP plan are conducted when changes occur but at least annually to ensure plan is still controlling identified hazards. Reassessment team includes at least one person that has been formally trained in HACCP. Results of the reassessment must be documented and maintained in the HACCP plan's historical records.	5.0
4.1.14	The facility has documented procedures for monitoring process control points. Corrective actions are identified and taken when process step is out of control. Monitoring records are maintained and accurately reflect the findings.	5.0
Section Notes :		

Food Safety Systems Section 4.2. Product Contamination		
No	**Question/Answer**	
4.2.1	NO ACTUAL PRODUCT CONTAMINATION IS OBSERVED. *No product contamination was observed during the facility tour.*	5.0
4.2.2	Access to all production areas is restricted. Access between raw and filling/packaging areas is restricted. Where applicable, requirements are in place that that address changing garments and shoes/foot coverings, and also address hand washing.	5.0
4.2.3	Conditions or practices do not exist that may potentially contaminate product, or could lead to product contamination.	5.0
4.2.4	Facility has written procedures and guidelines for the prevention of foreign material contamination. Procedure also documents steps for product safety review in the event that a foreign material prevention device is not working properly.	5.0
4.2.5	The facility is using automated x-ray or metal detection for foreign material control.(Sites without x-ray or metal detection will be evaluated by the Auditor for risk level and discussed by phone with Costco personnel to determine scoring.) There are written procedures on how to calibrate and maintain all metal detectors, X-ray or other foreign material detection equipment, including how to handle product rejected by the detection systems. Foreign material detection device is located as close to final packaging as possible unless a risk assessment determines otherwise. Facility has documented checks at no more than 2 hour intervals to confirm the foreign material detection device is operating correctly. Metal detectors are challenged against Ferrous (iron), Non-Ferrous (non-iron), and Stainless Steel contaminants. X-ray devices are challenged against manufacturer's recommendations i.e. glass, plastic, wood. Auditor to verify by asking plant staff to challenge all devices on site, not just those pertaining to Costco products. All foreign material detection devices have a proper rejection device i.e. belt stops, air-jet etc. Investigation of all rejected product is undertaken to prevent on-going occurrence of metal contamination.	5.0
4.2.5.1	IF A FOREIGN MATERIAL DEVICE WAS NOT PRESENT DURING THE PREVIOUS AUDIT AND HAS BEEN DETERMINED AS REQUIRED, WAS A DEVICE IN PLACE AND FUNCTIONING DURING THIS ANNIVERSARY AUDIT? *NA: During previous audits the facility already had metal detectors.*	NA
4.2.6	A documented glass, ceramic and brittle plastic control program has been established. The program addresses all glass that is to be shielded within the facility, handling of glass, ceramic, and brittle plastic packaging, and clean-up procedures for glass, ceramic, and brittle plastic breakage. A map is used to perform a monthly audit of glass, ceramics, and brittle plastics located in the facility.	5.0

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Food Safety Systems Section 4.2. Product Contamination		
No	**Question/Answer**	
4.2.7	Processing equipment for exposed raw materials, work-in-process, and exposed finished product is not made of wood.	5.0
4.2.8	Only approved food-grade lubricants (oils/grease etc.) are used in product contact zones and they are appropriately stored and labeled.	5.0
4.2.9	Food processing and packaging areas are set up to minimize the risk of cross-contamination, and employee and equipment traffic flows are used that minimize contamination. Auditor to observe during the physical assessment of the facility.	5.0
4.2.10	Raw areas have a negative pressure to adjacent areas. Clean areas have a positive pressure to the exterior. Auditor to observe during the physical assessment of the facility. *NA: The product is not considered as high risk. Positive pressure is not a necessary control measure.*	NA
Section Notes :		

Food Safety Systems Section 4.3. Allergens		
No	**Question/Answer**	
4.3.1	IF ALLERGENS ARE PRESENT, FACILITY HAS A DEVELOPED A WRITTEN ALLERGEN CONTROL PROGRAM PREVENTING CROSS-CONTACT WITH ALLERGENS. PROGRAM MEETS ALL APPLICABLE COUNTY OF ORIGIN AND ALL DESTINATION COUNTRIES' REQUIREMENTS. *Facility has developed and implemented an Allergen Control Program "PE-SGC-02 Control Preventivo de Alérgeno". The allergens present in the facility are: gluten, soy, milk and eggs. An exclusive production line is in place for the Aviva Crackers. Allergens present in this line are gluten and whey (milk).*	5.0
4.3.2	A complete list of ingredients used by the facility that are classified as food allergens has been documented. Ingredients that are allergens are identified as such on all formulation, batch, or raw material production records.	5.0
4.3.3	The Allergen Control Program documents control procedures for all areas of the facility: receiving process, storage separation, clean up procedures for allergenic ingredient spills, utensils and storage controls for containers that contact allergens which include proper allergen labeling when ingredients or products are not in their original containers.	5.0
4.3.4	Allergens are observed to be controlled through production schedules and detailed SSOPs. There are records of changeovers including verification that allergen removal practices took place.	5.0
4.3.5	Documented label reconciliation program of product labels vs. product being packaged. Documented label inspection program of allergenic containing labels at receipt? Obsolete label program that includes disposal / segregation is in place.	5.0
4.3.6	Rework or work-in-process that contains allergens must be labeled to ensure the allergen ingredient is recognized and only used in like allergen containing product.	5.0
4.3.7	Facility has established validated cleaning procedures that directly affect the cross contamination points of allergens.	5.0
4.3.8	Allergen Control Program is updated when there are any changes in ingredients, processing aids, suppliers, products, processes, or labeling.	5.0
4.3.9	Records demonstrating program compliance and corrective actions are maintained.	5.0
Section Notes :		

Food Safety Systems Section 4.4. Food Safety Training		
No	**Question/Answer**	
4.4.1	Facility has a written program for conducting food safety, food defense, GMP, and allergen training.	5.0

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Food Safety Systems Section 4.4. Food Safety Training		
No	**Question/Answer**	
4.4.2	Trainer qualification is defined, assessed and documented. Trainers are qualified and authorized by the facility to administer the training.	5.0
4.4.3	Training is conducted for all new employees, seasonal employees, and contractors prior to them beginning any work in the facility.	5.0
4.4.4	Completion of training is documented as to date(s) given, what topics were covered, who conducted the training and is a part of the employee's permanent records.	5.0
4.4.5	Training effectiveness is measured and documented via some type of assessment (test or quiz, on-the-job observation).	5.0
4.4.6	Refresher training is conducted on a periodic basis or at least annually and records of training are kept.	5.0
Section Notes :		

Quality Systems Section 5.1. QA/QC Program		
No	**Question/Answer**	
5.1.1	A current documented quality program is in place and includes an approval process for changes. The quality program includes a current organization chart and identifies the individual whose job description includes responsibility for overall program management. The program is well organized and records can be easily located during the audit.	5.0
5.1.2	Written standards and specifications are in place for raw and finished food products and packaging materials that come in contact with food.	5.0
5.1.3	If facility is supplying/producing a high risk item a documented finished goods test and hold program is established. Corrective action procedures are written and implemented and include investigations into failures. Results are reviewed and trended on a routine basis to identify areas for continuous improvement and records are maintained. *N/A: The product is not a high risk item.*	NA
5.1.4	Rework procedures for processing and finished product, including allowable amounts, is clearly defined in finished product specifications or other documents.	5.0
5.1.5	Criteria and procedures are established for all hold and release programs, including reconciliation processes for open holds that ensure all holds are closed in a timely manner and none are missing. Identification records and logs of held products are available and current.	5.0
5.1.6	Written procedures exist for all operations that affect quality including sampling plans, net weight programs, in-process and finished quality checks or inspections. Procedures include: methods, frequency of checks, and verification of compliance.	5.0
5.1.7	There is a documented record retention program for both quality and food safety records that describes records to be included, how long they are to be maintained and where the records will be kept. There are secure back-up procedures for electronically retained records.	5.0
5.1.8	Self-audits of the entire facility including equipment are completed monthly, copies are maintained for 1 year and include evidence of corrective action resolutions. The audits are done by a cross functional team to ensure participation and ownership of the program. Personnel from all departments participate.	5.0
5.1.9	The site has a documented program to review existing product labels and the development of new product labels for information, accuracy and regulatory compliance. This includes ensuring compliance for label claims as well (Kosher, Halal, Organic, Gluten-Free, etc.) This program also identifies the frequency of review, responsible persons, function for completing review and the approval process for new label development and label changes. The auditor will verify compliance to the process by reviewing a minimum of one label against specification and include the label name and compliance level in the comments.	5.0
5.1.10	Facility maintains records for all external laboratory testing. Facility utilizes only accredited external laboratories. Records exist to support external laboratory accreditation.	5.0
Section Notes :		

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Quality Systems Section 5.2. Supplier Certification		
No	**Question/Answer**	
5.2.1	An established, documented program for approving domestic and international suppliers of raw materials, ingredients and packaging is in place. The program meets all applicable, current regulatory requirements. Facility has a master list of approved suppliers.	5.0
5.2.2	A written program has been established for approving all co-manufacturers. The program includes a master list of approved comanufacturers and meets all applicable and current regulatory requirements.	5.0
5.2.3	Facility has procedures established that require their suppliers to provide them with a current third-party food safety audit, which includes HACCP, and a product specification sheet (product requirements, labeling and code date information).	5.0
5.2.4	There is a QA inspection program for ongoing monitoring of inbound deliveries of materials that includes examination of incoming materials for evidence of contamination (pest, microbiological, chemical and physical), temperature abuse, damage, quality and condition. Inspection records for the monitoring programs are documented, filed, and include actions and disposition of rejected products.	5.0
5.2.5	Facility has a documented ongoing QA monitoring program to evaluate ingredients, raw materials, packaging and label compliance to specification. There is a predefined system to verify accuracy of the COAs for materials accepted based on COA reports.	5.0
5.2.6	The facility requests or assigns lot numbers / code date for incoming packaged and bulk raw materials as well as incoming packaging materials.	5.0
5.2.7	FINISHED PRODUCTS CAN BE TRACED TO THE LOT NUMBERS OR CODE DATES OF ANY INGREDIENTS, RAW MATERIALS AND REWORK USED. *Lot number for finished product is: 1297181 which is traceable to the line (1), julian day (297), year (18) and shift (1) as well as the packing time.*	5.0
5.2.8	Finished product is traced back through the manufacturing process to the food contact/primary packaging used.	5.0
5.2.9	The procedure for verifying that finished products are ready for distribution (pre-shipment review) is established and being practiced to ensure specification compliance and load condition, including product rotation and shelf life. Records are available for review.There are procedures for outside storage facilities (company or independently owned) for specification compliance and load condition, including product rotation and shelf life. Records are available for review.	5.0
5.2.10	The facility has written established procedures for product returns that determine the food safety and security of the products, including destruction and disposal procedures and/or controls to be applied if they can be used.Code dates of all returned goods and all actions taken on the returned goods must be recorded and tracked from receipt to use or disposal.	5.0
Section Notes :		

Quality Systems Section 5.3. Equipment Calibration		
No	**Question/Answer**	
5.3.1	There is a set schedule for calibrating all equipment (to a national standard) and records of the calibration results and corrective actions are maintained.	5.0
Section Notes :		

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Quality Systems Section 5.4. Good Laboratory Practices (if facility has on-site laboratory)		
No	**Question/Answer**	
5.4.1	Facility has a documented GLP program that includes handling and storage of reagents and samples, established methods for the analyses being conducted, and internal calibration and control procedures. All laboratory supplies (media, chemicals, etc.) must be dated and not out of date range for reliability. There is a documented verification program for internal laboratory proficiency for chemical and microbiological testing. All results are documented and initialed.	5.0
5.4.2	All appropriate laboratory equipment is calibrated as scheduled or as necessary and is functioning properly on a continuing basis. Records of equipment calibration activities are complete and current.	5.0
5.4.3	If the on site laboratory is testing for pathogens, There is a program in place for running positive controls. There are procedures in place for controlling cross contamination between laboratory and manufacturing area. Auditor will comment whether the laboratory is in a separate building or located under the same roof as the production facility. *N/A: Microbiology analysis is performed by an external laboratory.*	NA
Section Notes :		

Grounds, Buildings, Equipment Section 6.1. Grounds		
No	**Question/Answer**	
6.1.1	Roads, yards and parking lots are maintained, clean, free of litter, and in good condition. Grass and weeds are trimmed and maintained to minimize harborage areas for pests and are not within 20 feet of the building. Ornamental landscaping is not next to building and does not allow potential harborage area.	5.0
6.1.2	No standing water or pot holes are observed and plant grounds have adequate drainage. No signs or evidence of previous inadequate drainage.	5.0
6.1.3	Equipment within 20 feet of building does not create a source of potential pest harborage. Pipes within 20 feet of building must be capped on each end.	5.0
6.1.4	All trash containers are covered and are removed from the premises at appropriate intervals. The frequency of service is sufficient to manage waste. The dumpster is on a regular cleaning schedule and is located on a rigid, cleanable surface.	5.0
6.1.5	Loading dock areas are clean and free of debris and spills. Equipment or items stored on the dock should be clean and organized. All Bumpers, levelers and shelters are in good repair and clean.	5.0
Section Notes :		

Grounds, Buildings, Equipment Section 6.2. Plant Facility		
No	**Question/Notes**	**Answer**
6.2.1	Exterior walls of facility, including troughs and down spouts are in good condition. Plant buildings and roofs are suitable in construction and designed to facilitate maintenance and sanitary operations. There are no roof leaks. *NC: Damaged ceilings with missing pieces were observed in the cleaning area.*	4.0*
6.2.2	Floors are in good condition and are constructed with materials that can be cleaned. Walls are in good condition and are constructed with materials that can be cleaned. Ceilings are in good condition and are constructed with materials that can be cleaned. *NC: Damaged floors in production and storage area were observed during the facility tour.*	4.0*

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Grounds, Buildings, Equipment Section 6.2. Plant Facility		
No	**Question/Notes**	**Answer**
6.2.3	All doors and windows that lead to the outside are tightly sealed and/or screened to protect against pest entry. No cracks are present in walls to exterior of facility. All drains protruding on exterior of the buildings are protected and screened where needed. *NC: During the facility tour damaged door gasket in loading area was observed.*	4.0*
6.2.4	Aisles and workspaces are unobstructed and have adequate width to permit employees to perform their duties and protect against contamination.	5.0
6.2.5	The lighting is adequate for the intended purpose and to ensure effective inspection of product and proper equipment sanitation.	5.0
6.2.6	All glass, ceramic, and brittle plastic are shielded or protected from shattering and breakage	5.0
6.2.7	Air handling units are fitted with clean filters. Filters are capable of removing particles 5 microns or larger. (Minimum Efficiency Reporting Value (MERV) of 4 or larger) Air ducts for HVA systems and air make-up units have cleaning and inspection hatches. Adequate ventilation or control equipment is in place to minimize odors and vapors. Fans and other air-blowing equipment are located, operated, and maintained to minimize the potential for contamination of food, equipment or packaging materials. Air traps and filters are inspected and changed on a set schedule. Records of filter inspection and replacement are maintained.	5.0
6.2.8	Hoses and water lines are protected against cross connection or back flow to prevent contamination of potable water.	5.0
6.2.9	Hand sinks are convenient and allow employees to go directly to work station without contamination. Processing area hand sinks are hands free, including water and paper towels. Hand wash stations have warm water (within 15 seconds), liquid soap, hands free towels or suitable drying devices, and waste container. Hand wash signage is posted near the station and in languages appropriate for workers to understand.	5.0
6.2.10	Restrooms, locker rooms and break areas are clean well lit and maintained properly. Equipment, ventilation and drains are functioning properly. Hand wash signage is posted in all of these areas. Waste containers in restrooms are covered. Signs for washing hands are in languages appropriate for workers to understand are posted. Lunches, drinks or foodstuffs of any sort should not be stored in lockers.	5.0
6.2.11	Walkways and ladders that are over exposed product lines are protected to prevent potential contamination. Kick plates with adequate side shielding are installed where needed.	5.0
6.2.12	Facility management conducts a monthly GMP Audit that evaluates the interior and exterior facility conditions.	5.0
Section Notes :		

Grounds, Buildings, Equipment Section 6.3. Equipment		
No	**Question/Notes**	**Answer**
6.3.1	Equipment is designed and made of material that can be easily cleaned and maintained. Equipment is installed to facilitate cleaning and maintenance.	5.0
6.3.2	Equipment is in good repair, and is used for the task it was designed. Seams on food contact surfaces are smooth and free of spot welds. No mold or rust is observed. *NC: Missing screws in the inverted sugar containers were observed during the facility tour.*	4.0*
6.3.3	Pipelines and mixing and holding tanks are free of defects and have smooth seams. Pipelines and mixing and holding tanks are self-draining.	5.0

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Grounds, Buildings, Equipment Section 6.3. Equipment		
No	**Question/Notes**	**Answer**
6.3.4	Temporary repairs will not cause contamination issues to products or the environment and do not inhibit sanitation tasks. Any temporary repairs on food contact surfaces are completed using food grade materials. *NC: During the facility tour, one of the water hoses was damaged and with insulating tape as a temporary repair. This hose was used for water used as an ingredient.*	4.0*
6.3.5	Soiled or broken pallets have a designated storage area and are not used in the facility. Excess pallets are stored away from raw material, in food processing or food storage areas.	5.0
6.3.6	Propane and gas operated lift equipment is not operated in food processing area. Vehicles and batteries are charged and stored in areas separated from food stuffs.	5.0
6.3.7	Transporting equipment (i.e. pallet jacks, fork lifts, carts, and trolleys) is in good repair and is not a source of potential contamination.	5.0
Section Notes :		

Grounds, Buildings, Equipment Section 6.4. Facility Maintenance		
No	**Question/Answer**	
6.4.1	The plant has a written schedule that addresses both equipment and facility maintenance. Records of verification that the tasks are completed and verified in a timely manner are available for review.	5.0
6.4.2	A written system is in place that allows any employee to inform maintenance about work requests. There is a documented process for creating, tracking and completion of maintenance requests and it can be matched to the work orders.	5.0
6.4.3	Documented procedures address how the facility will protect product when breakdowns occur and/or repairs are made in product zones. Procedures describe product disposition when affected by maintenance activities.	5.0
6.4.4	Written guidelines are established to ensure tool and parts control when repairs are taking place during production. The guidelines should include proper placement of tools and parts and should address tools used in raw areas versus finished product areas. A program should be in place that describes how maintenance will handle tools and equipment when repairs are being made during production, including how tools are inventoried and handled in raw vs. finished areas to protect products and avoid potential cross contamination from maintenance activities.	5.0
6.4.5	Procedures are developed that describe the sanitation activities that occur after equipment has undergone repairs, including sanitation responsibility and verification of its completion. Records are kept showing sanitation was completed, as required by procedure.	5.0
6.4.6	The maintenance program ensures that all outside contractors working in food areas are aware of and have signed a copy of the facility GMPs. Documents are available for review.	5.0
Section Notes :		

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Pest Control Section 7.1. Pest Control		
No	**Question/Answer**	
7.1.1	A WRITTEN INTEGRATED PEST CONTROL PROGRAM (IPM) HAS BEEN ESTABLISHED. THE PROGRAM UTILIZES A LICENSED DESIGNATED PEST CONTROL OPERATOR* (PCO) AND INCLUDES SCHEDULED FREQUENCY OF SERVICE, A CURRENT MAP (UPDATED AS NEEDED BUT AT LEAST ANNUALLY) SHOWING THE LOCATION AND TYPE OF ALL PEST CONTROL DEVICES (INTERNAL AND EXTERNAL). THE PROGRAM INCLUDES RESPONSIBILITIES FOR BOTH IN-HOUSE PERSONNEL AND CONTRACTORS. (*Can be an internal PCO or a contracted PCO). *A written pest control program is in place "Manual de Manejo Integrado de Plagas". Fumicosmos SRL, an external PCO was contracted for pest control inspections. Twice a month service and inspections are made. Records are kept and the PCO documentation is complete.*	5.0
7.1.2	The IPM files include documentation of all business licenses, proof of indemnity insurance and certifications for all PCOs in accordance with state/local requirements. The IPM files also include a current list of approved pesticides to be used in the facility. MSDS and sample labels for products used. All pesticides, chemicals and compounds used meet applicable regulations and approvals (EPA, USDA, OSHA, etc.). The IPM files are accurate, up-to-date and complete.	5.0
7.1.3	Service reports, at the frequency described in the IPM, must be up-to-date and available for review. They must show the service performed, types and amounts of chemicals used, EPA or other applicable regulatory registration numbers, the location treated, targeted pests, signs of activity and applicable follow-up actions. Trends in activity must be assessed by the PCO or plant to identify areas of improvement in the pest control program.	5.0
7.1.4	The plant has an adequate number of coded, secured, tamper-resistant exterior pest control stations spaced at appropriate intervals (≈25-50 ft.) around the building's exterior perimeter. Both the device and the bait are securely anchored. The number and location code must correspond with the master identification map. Exterior bait stations are visited at least monthly. PCO must initial and date labels, scan the barcode, or use punch cards on all devices. Labels must be on the inside of devices, unless there is a clear window on top.	5.0
7.1.5	The plant has an adequate number of interior pest control devices. The spacing is at consistent intervals around the interior perimeter of the building area and around interior perimeter of any walled in dry food storage, packaging or cooler areas. Inside of any exterior wall and cooler walls. Devices should be on both sides of all doors leading to the exterior, including dock doors. Interior catch devices and glue boards are monitored at least weekly. PCO must initial and date labels, scan the barcode, or use punch cards on all devices. Labels must be on the inside of devices, unless there is a clear window on top.	5.0
7.1.6	Traps are properly positioned and located to prevent contamination of products, packaging or equipment. Bait is not used inside the facility. All pest control devices are clean and functioning properly (i.e., are properly wound, are free from obstruction, have bait as appropriate, are of sound construction and working as intended) and bait in the stations has a fresh appearance.	5.0
7.1.7	Pests or pest activity are not observed around the interior and exterior perimeters of the facility. Domestic animals are prohibited from the premises.	5.0
7.1.8	THERE IS NO EVIDENCE OF INSECTS, SPIDERS, RODENTS, AMPHIBIANS OR BIRDS ON OR IN ANY FOOD INGREDIENTS, PRODUCTS, OR PACKAGING MATERIALS. *No pest evidence was observed during the facility tour.*	5.0
7.1.9	THERE IS NO EVIDENCE OF DECOMPOSED PESTS ANYWHERE IN THE INTERIOR OF THE FACILITY, INCLUDING IN PEST CONTROL DEVICES. *No pest evidence was observed during the facility tour.*	5.0
7.1.10	High and low voltage insect light traps (ILTs) are located appropriately, so they are effective, will not contaminate exposed product, packaging, or equipment or interfere with plant operations. They should be installed no closer than 10 feet (3 meters) from food contact areas and are placed so they do not attract insects into the facility. Devices are to be maintained and cleaned on a routine basis. A schedule is in place and adhered to for replacing the sticky boards in sticky-type ILTs. Bulbs must be shatter resistant and checked on an annual basis usually at the start of the active season.	5.0
7.1.11	Avicides are to be used on the exterior of the facility only. Avicides must be used according to program and label requirements.	5.0
7.1.12	Pesticides, chemicals and other compounds stored on site for pest control are properly labeled and kept in locked, secured areas segregated from any food storage or processing areas.	5.0
Section Notes :		

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Employee Practices Section 8.1. Employee Practices		
No	**Question/Answer**	
8.1.1	EMPLOYEES WITH OBVIOUS SORES, INFECTED WOUNDS, OR INFECTIOUS ILLNESSES SHALL NOT HAVE DIRECT CONTACT WITH EXPOSED FOOD PRODUCTS OR PRODUCTION / STORAGE AREAS. *No injured or illness employees were observed during the site inspection.*	5.0
8.1.2	Written GMP Program on employee hygiene practices (hand washing, hair restraints, jewelry, gloves, etc.) personal grooming, and the storing of personal items is signed by each employee. GMP program is followed appropriately by all employees. Employees maintain personal cleanliness and use hygienic practices at all times.	5.0
8.1.3	Hygiene rules are clearly displayed at all entrances to production areas (GMP zones). Appropriate signage is available in languages appropriate for employees to understand about the hygiene practices. Visitors are given a copy of the facility GMPs and are asked to read and sign the facility hygiene rules upon entering the facility. Corrective action procedures have been developed for deviations to employee hygiene practices, including use of a discipline policy for infractions to the GMPs as applicable.	5.0
8.1.4	With the exception of a plain wedding band, all jewelry and other objects that might contaminate products like artificial nails and body piercings are not worn. (Medical Alert neck chains are permissible if worn under garments.) Items such as pens, thermometers, etc. are not carried in above-the-waist pockets.	5.0
8.1.5	Hairnets are properly worn in food processing and other designated areas when working around exposed product. All facial hair including a moustache is covered with beard covers.	5.0
8.1.6	Garments are clean, appropriate for the operation and do not contribute to potential product contamination. All garments have snaps not buttons. Garments are not worn in lunchrooms, restrooms, or outside the facility. Employees change smocks or uniforms as necessary when moving through the facility to minimize cross-contamination. Garments are segregated from outside clothing and personal items in changing room.	5.0
8.1.7	Employees are observed properly washing their hands after activities that may have contaminated them. Activities can include, but are not limited to: using the restrooms; after breaks; prior to entering production and product packaging areas; prior to handling product; prior to touching product contact and non-food contact surfaces or after handling garbage.	5.0
8.1.8	Gloves are to be latex free and powder free, they are maintained intact, clean and in good condition. Gloves must be used where there is direct hand contact with ready-to-eat products. "No Bare Hands" policy in place unless exception has been granted by Costco Food Safety. Procedures for the proper handling and usage of gloves have been developed, implemented, and verified where required. Non-disposable rubber gloves must be washed and sanitized frequently, after breaks, and/or after handling potential contaminates. *N/A: No gloves are use for this type of product.*	NA
8.1.9	Eating and chewing gum is prohibited in processing and storage area and is confined to designated areas only. Drinking and the use of tobacco are confined to designated areas outside of the processing and storage areas.	5.0
8.1.10	Locker inspections are on a defined schedule. Lockers are free of food and drink.	5.0
Section Notes :		

Receiving, Storage, and Shipping Section 9.1. Receiving and Shipping		
No	**Question/Answer**	
9.1.1	Inbound and outbound transport vehicles are clean, free of odor, free of pest contamination, and are in sound condition or are rejected. Ingredients or materials shipped in a damaged, dirty, or infested transport vehicle are rejected. The facility maintains a log for rejected transport vehicles that records the reason for the rejection.	5.0

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Receiving, Storage, and Shipping Section 9.1. Receiving and Shipping		
No	**Question/Answer**	
9.1.2	Trailers are able to maintain product temperatures and do not pose as a potential source of contamination. Temperatures and condition are documented. Perishable product transport vehicles must be pre-cooled prior to loading, and documentation of the pre-cooling cycles must be maintained. *N/A: Product is ambient stable therefore documented transport temperature is not used.*	NA
9.1.3	All materials and ingredients are properly identified and labeled and show date of receipt or other marking so that they can be properly rotated through the system (ex: FIFO). For traceability, primary packaging and raw ingredients are identified by code date or lots numbers which are assigned by either the supplier or the facility.	5.0
9.1.4	Products are stored in the appropriate temperature range. Products are not stored in shipping and receiving areas unless controls are in place to eliminate quality, food safety, and/or temperature abuse issues. Perishable products should not be stored on the cool dock.	5.0
9.1.5	Shipping and receiving docks are clean, organized, and free of debris and spills. Equipment stored on the dock is organized and in good repair.	5.0
9.1.6	Temperatures of refrigerated and frozen products are documented at the time of receipt. Temperature monitoring devices are available and in good repair. Auditor verification confirms that devices cover temperature ranges of the products being monitored. *N/A: Product is ambient stable therefore documented transport temperature is not used.*	NA
9.1.7	Procedures for transferring bulk ingredients are designed to protect the product from contamination. Receiving hoses are clean, capped and properly stored off the ground. Connection ports into the building are capped and locked when not in use.	5.0
Section Notes :		

Receiving, Storage, and Shipping Section 9.2. Storage		
No	**Question/Answer**	
9.2.1	An 18 inch perimeter is maintained along all walls to allow for proper cleaning and pest control treatment. All materials are properly stored at an adequate height (6 in or pallet height) off the floor.	5.0
9.2.2	Proper FIFO (first in first out) practices are used for all finished goods.	5.0
9.2.3	All ingredients, including packaging materials, are properly stored, packaged or covered when not in use to prevent contamination. They are stored under appropriate conditions, in good condition, clean, dry, intact, and free from contamination and spoilage. Partially used raw ingredients or packaging material are protected before returning to storage.	5.0
9.2.4	Damaged cases or containers are immediately segregated and repacked or properly destroyed. Items put "on hold" are segregated, identified and protected from contamination. Product on hold is clearly identified and held under appropriate conditions. Hold items are to be documented and stored in a designated area.	5.0
9.2.5	Ingredient containers that are being reused are sanitized or a protective liner is used. Containers from microbiologically sensitive products must be destroyed.	5.0
9.2.6	Dry storage areas are maintained in a clean and sanitary manner and spills are immediately cleaned.	5.0
9.2.7	Restricted chemicals used in processing or as an ingredient are stored in a locked area separate from food and packaging supplies.	5.0
9.2.8	Cooler floors are kept dry and clean with no aged spills. Cooler floors, walls, ceilings, and racking are in good repair.	5.0
9.2.9	There is no sign of condensation issues in coolers. Product stored in coolers shows no signs of having condensation issues. Cooler temperatures are maintained within acceptable ranges. Temperatures are manually checked twice a day or are on continuous recording devices with alarms.	5.0
9.2.10	Freezer floors are kept dry, clean and with no aged spills. Freezer racks, floors, walls, and ceilings are in good repair. *N/A: There are no freezers in the facility.*	NA
9.2.11	Product stored in freezers is in good condition and shows no sign of freeze/thaw conditions. Frozen condensate is not observed in freezer area. Freezer temperatures are maintained below maximum acceptable levels. Temperatures are manually checked twice a day or are on continuous recording devices with alarms. *N/A: There are no freezers in the facility.*	NA

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Receiving, Storage, and Shipping Section 9.2. Storage		
No	**Question/Answer**	
9.2.12	Pallets are in good repair and clean (GMA #1). Pallets stored outside are inspected for evidence of contamination before being used inside the facility.	5.0
Section Notes :		

Processing Section 10.1. Raw Materials		
No	**Question/Answer**	
10.1.1	Recirculated or reused water for rinsing, washing, or conveying food must be monitored through documented procedures that ensure the water does not increase the level of contamination of the food. Monitoring records must be available and meet the testing frequencies of the written program.	5.0
10.1.2	Tempering or thawing is done under controlled conditions (e.g. under refrigeration) and is monitored to insure stated temperature controls are met. Verification checks of compliance with the procedures are completed and documented. Thawing procedures have been developed that assure safety and quality is maintained. *N/A: Tempering or thawing is not required.*	NA
Section Notes :		

Processing Section 10.2. Process Controls		
No	**Question/Notes**	**Answer**
10.2.1	Process control points and limits are observed being monitored, and the results are being recorded per the procedures. Employees interviewed by auditor during the audit understood their monitoring points. Auditor will comment on what was asked and the worker's response.	5.0
10.2.2	Whenever a process control is outside of the established criteria corrective actions are being taken as required. All corrective actions are documented.	5.0
10.2.3	The plant has taken steps to ensure that no equipment or processing operation used has the potential to contribute to the contamination or adulteration of the product with physical, chemical or microbial contaminants.	5.0
10.2.4	The sanitation practices observed do not have the potential to cause product contamination. Hoses are used in such a way that they are not a source of contamination due to water droplets or aerosols (no high pressure)	5.0
10.2.5	Line stoppages (breakdowns or shutdowns) are monitored to ensure down time, temperature fluctuations or other factors do not affect the safety and/or quality of the product. Action procedures are established when product safety or quality are at risk.	5.0
10.2.6	A calibrated thermometer is used in monitoring perishable product processing temperatures. Ingredient and product temperatures are monitored and maintained throughout processing to ensure they are within acceptable ranges.	5.0
10.2.7	Properly labeled and dated covered ingredient containers are covered as required. If a color-coding system is used for labeling ingredient containers, signage on use of the containers and equipment is posted in languages appropriate for employees to understand.	5.0
10.2.8	Glass, ceramic, or brittle plastic raw material packaging is not used in the processing area. Controls have been implemented to address glass, ceramic, or brittle plastic finished product or packaging.	5.0
10.2.9	Ingredients and packaging materials that are staged for processing are kept clean, dry, and free from contamination during processing.	5.0

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Processing Section 10.2. Process Controls		
No	**Question/Notes**	**Answer**
10.2.10	Screens, sifters, sieves and magnets are inspected and verified on a scheduled basis. All checks are documented. *NC: Staff use blades to open boxes and packages of raw materials and packaging material. An condition control has not been implemented for the blades.*	3.0*
10.2.11	Compressed air or gases used in processing, packaging or cleaning are treated in such a way to prevent contamination (e.g. filters). When using compressed air or gases filters are capable of removing particles of 5 microns or larger. Gases that come in contact with product are of suitable purity to protect finished product if not filtered and are routinely monitored. Air traps and filters are inspected and changed on a set schedule. Records of filter inspection and replacement are maintained.	5.0
10.2.12	All floors are observed to be free of standing water.	5.0
10.2.13	Miscellaneous materials (e.g. maintenance tools, gloves rags) are not found on or near processing equipment. Tools used for equipment adjustment are clean and in good repair.	5.0
Section Notes :		

Sanitation Section 11.1. Cleaning and Sanitizing Systems		
No	**Question/Answer**	
11.1.1	A MASTER CLEANING/SANITATION SCHEDULE OF CLEANING AND SANITATION DUTIES (SSOPs) EXISTS. IT LISTS ALL AREAS AND EQUIPMENT TO BE CLEANED (INCLUDING PROCESSING AND NON-PROCESSING AREAS AND EQUIPMENT) AND THE FREQUENCY OF CLEANING. THERE ARE RECORDS AVAILABLE SHOWING THAT THE TASKS WERE COMPLETED AND BY WHOM, INCLUDING VERIFICATION THAT TASKS WERE COMPLETED AS SCHEDULED.	5.0
11.1.2	Sanitation SOPs for all tasks are written and an order of operation followed to prevent recontamination of cleaned surfaces. SOPs include all necessary tear down procedures, responsibility for the task to be performed and/or regulatory content and equipment needed to perform the cleaning and sanitizing. Sanitation SOPs address how equipment is to be cleaned after being out of service.	5.0
11.1.3	All employees with sanitation responsibility undergo annual sanitation training. Records of the training are kept and include the person responsible for the training, the topic covered, who was trained, and evidence that the training was effective. Contract production cleaning and sanitizing companies must maintain SSOP and safe chemical training records at the facility.	5.0
11.1.4	Verification activities that evaluate sanitation procedures and execution take place using defined criteria and occur on an established frequency. Records of findings are maintained and results are reviewed with sanitation employees.	5.0
11.1.5	A daily pre-operational sanitation inspection program with pass/fail criteria is established for all production related areas to evaluate sanitation levels prior to the start of production. Corrective action instructions are written and implemented on areas needing sanitation follow up, when visual inspection indicates failure. Pre-operational records of sanitation inspection program are maintained and available for review.	5.0
11.1.6	An environmental monitoring program that uses rapid methods and /or microbiological swabbing for pathogens and indicator organisms is established and describes when, where and how sampling and swabbing take place. A pass/fail criteria has been identified. Corrective action procedures are written and implemented and include investigations into the cause of the failure. Results are reviewed and trended on a routine basis to identify areas for continuous improvement and records are maintained.	5.0
11.1.7	THE FACILITY WATER IS FROM A POTABLE SOURCE. *Water use in the facility is treated by the company. There is a water potabilization system that includes chlorine addition, temporary storage and later treatment with carbon filters, reverse osmosis and UV light.*	5.0
11.1.8	WATER POTABILITY IS TESTED BY A CERTIFIED LABORATORY ANNUALLY FOR MUNICIPAL WATER SOURCES AND QUARTERLY FOR WELL WATER (SAMPLES ARE DRAWN FROM VARIOUS SITES THROUGHOUT THE FACILITY). RECORDS ARE MAINTAINED. *Water potability is tested monthly by Agrobiotek, an external certified laboratory. Test results confirming potability were reviewed. Results were in conformance.*	5.0
Section Notes :		

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Sanitation Section 11.2. Cleaning Equipment and Chemicals		
No	**Question/Notes**	**Answer**
11.2.1	Chemicals used for cleaning, sanitizing and processing are properly labeled and approved for a food handling facility. Storage for chemicals is well away from processing and food storage and is locked and secure. The site has an MSDS system that is accessible, organized and current. *NC: During facility tour, in shipping area, a plastic container with liquid inside and with no label were found unattended. NC: MSDS of the chlorine used for drains in cleaning area was not available.*	3.0*
11.2.2	Sanitizing solutions in footbaths, hand dips, and drop down stations are in compliance with the facility written programs and is verified by the auditor. Documented testing procedures are in place that routinely verify that chemical concentrations used are in compliance with regulatory requirements and sanitation program requirements.	5.0
11.2.3	Cleaning and sanitizing equipment is designed for intended use and is either color coded or labeled. Color-coding systems require appropriate signage describing the system are posted throughout plant. When not in use all cleaning equipment is stored properly and away from food processing areas.	5.0
Section Notes :		

Sanitation Section 11.3. Cleaning, Sanitation, and Housekeeping Procedures		
No	**Question/Answer**	
11.3.1	Cleanliness is maintained throughout the plant, in all non-processing and non-food contact areas. Spills are continually cleaned up in a timely manner during production.	5.0
11.3.2	Cleanliness is maintained on all food contact surfaces and significant product build up is not observed.	5.0
11.3.3	Pools of water or excessive moisture are not observed on equipment or in processing environment.	5.0
11.3.4	Processing tools such as knives, saws, trimmers are stored properly and are cleaned and sanitized. Blades, scissors and knives used for opening bags of ingredients are in good repair and properly stored, cleaned, and sanitized.	5.0
Section Notes :		

Food Defense Section 12.1. Food Defense Program		
No	**Question/Notes**	**Answer**
12.1.1	FOR COMPANIES THAT MANUFACTURE OR IMPORT PRODUCT TO THE UNITED STATES FACILITY MUST PROVIDE EVIDENCE THAT IT HAS REGISTERED IN ACCORDANCE WITH THE FDA BIO-TERRORISM REGULATION (a letter stating registration is adequate, Auditor does not need to see actual registration number). *The facility Registration Number for exporting to the US is:* *XXXXXXX8314*	Yes*
12.1.2	A multidisciplinary team has assessed the facility and developed a written food defense plan covering all operations. The food defense team meets when reassessments/changes are necessary or at least annually to reassess the plan. The plant has developed a reduction strategy for identified risks. *NC: There was no record available of the last review of the vulnerability analysis performed.*	4.0*

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Food Defense Section 12.1. Food Defense Program		
No	**Question/Notes**	**Answer**
12.1.3	Records are kept to identify previous source and next customer (one up and one down the supply chain). Documents verifying compliance are maintained for the appropriate time based on product shelf life).	5.0
12.1.4	The plan outlines how access is controlled to all areas of the facility. The plan includes an easy ID system for employees having access to open food sources, including food packaging materials and equipment that touches food. The plan address procedures for handling non-employees (contractors, visitors, outside drivers) while visiting the facility. The access plan identifies how critical departments/areas will be physically secured. (e.g., locks, cameras, alarms, etc.)	5.0
12.1.5	The plan identifies the systems and procedures for controlling the integrity of all incoming materials. There are procedures that describe how receiving of raw materials will take place including the matching of seal numbers, evaluation of product integrity and delivery driver identification verification. The plan provides procedures for securing bulk ingredient ports and water handling facilities (system to limit access to only authorized personnel).A procedure for and documentation of 100% inspection of inbound less than full load unsecured deliveries is in place. Procedures for raw materials receiving include matching of seal numbers, evaluation of product integrity ensuring LTL loads are secured with pad lock and delivery driver identification.	5.0
12.1.6	Established procedures are included in the plan to protect the process and product from deliberate contamination. The plan provides for restricting access to documents and software associated with ingredients or finished products (formula, cleaning, etc.) Finished and raw product have tamper evident packaging.	5.0
12.1.7	Procedures are established on how the shipment of finished product is protected from intentional contamination. LTL and outbound trailers controls are in place and documented. A driver identification system is in place.	5.0
12.1.8	The program includes documented procedures on employee management from a defense perspective. The plan provides a protocol to screen prospective employees prior to hiring, including reference checks for all employees and basic felony background checks for all supervisors and above. Procedures are in place to educate employees on how to report suspicious activity (what to report and who to report to).	5.0
Section Notes :		

Food Defense Section 12.2. Food Defense Observations		
No	**Question/Answer**	
12.2.1	The facility is complying with their program on restricting areas of the plant to authorized personnel only, the auditor will confirm compliance. Auditor confirms the site is adhering to procedures to alert personnel regarding restricted areas (signs, locked doors, etc.). Access points are observed as being secured and/or monitored appropriately.	5.0
12.2.2	The plant has made visitors aware of the facility's program and they are observed to be in compliance. The visitor policy is posted or provided to all visitors, contractors and non-employees.	5.0
12.2.3	Inbound/outbound trailers are secured (seals match receiving documents and bills of lading). Records and observations confirm that receiving records and outbound bills of lading are matched against seals and driver identification is verified. Less than full loads are verified that they are handled according to policy. Bulk receiving ports/silos and water handling facilities are secured	5.0
12.2.4	Company sensitive software and documents associated with ingredients and finished products have limited access. All finished product is provided with tamper evident packaging.	5.0
Section Notes :		

Section D. Employee Interviews-01		
No	**Question/Answer**	
D.1	Department	Joan Flores, production staff

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Section D. Employee Interviews-01		
No	**Question/Answer**	
D.2	Shift	1
D.3	The employee demonstrates knowledge and can/is applying the training received (i.e. – Sanitation requirements and checks, Maintenance requirements and checks, Production requirements and checks to include frequencies, Receiving and Storage requirements, Food Defense requirements.)	Yes
Section Notes :		

Assessment Rating System

This rating system describes a food plant's level of compliance with recognized food safety and Good Manufacturing Practices. The point system and definitions are objective guidelines for evaluating the plant's compliance with the assessed standards and are intended to assure consistency in rating.

Comments must be provided for any standard rated lower than 5.

Questions are scored per the matrix, with 5 being the highest rating possible and 0 being the lowest. If isolated issues
for any element are found, an additional one point deduction will be applied to the question's rating *OR* if numerous issues for any element are found, an additional two point deduction will be applied to the question's rating.

Number of elements in question	>3 elements missed	3 elements missed	2 elements missed	1 element missed	All elements fulfilled	
>3	**0**	**2**	**3**	**4**	**5**	**Rating given to question**
3	N/A	**0**	**2**	**4**	**5**	
2	N/A	N/A	**0**	**3**	**5**	
1	N/A	N/A	N/A	**0**	**5**	

Definitions:

Single issue - One observation, occurrence or instance of a specific/same issue or element
Isolated issues - Two observations, occurrences or instances of a specific/same issue or element.
Numerous issues – Three or more observations, occurrences or instances of a specific/same issue or element.

This rating system is an objective guideline. Auditors may use their discretion regarding scoring, considering the severity of food safety issues and numbers of observations of an issue noted.

Each plant will receive a total overall score based on the ratings of the individual standards in the audit form. The minimum acceptable numerical score may vary depending upon the company requiring the audit.

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

Business License

Clause	Question/Notes	Result	Photo Attachment
E.1	Business license has been attached.	Yes	

MINISTERIO DE SALUD PUBLICA

DEPARTAMENTO DE SALUD AMBIENTAL

LICENCIA O PERMISO SANITARIO

PROVINCIA O ÁREA DE SALUD: SANTIAGO AREA 3 EXPIDE EL PRESENTE DOCUMENTO PARA CERTIFICAR QUE LA INFRAESTRUCTURA FÍSICA Y EL ENTORNO DONDE OPERA LA EMPRESA O ESTABLECIMIENTO COMERCIAL: MOLINO VALLE DEL CIBAO, S.A.

LOCALIZADO EN LA PROVINCIA: SANTIAGO DE LOS CABALLEROS

MUNICIPIO: SANTIAGO ZONA O SECTOR: LICEY ALMEDIO

CALLE: KM 5 CARRETERA LICEY NO. REUNEN LAS CONDICIONES SANITARIAS ADECUADAS PARA OPERAR DE ACUERDO CON ASPECTOS ESPECÍFICOS REQUERIDOS POR SALUD AMBIENTAL CONFORME AL MARCO REGULATORIO Y ÁREAS DE SU COMPETENCIA.

ESTE DOCUMENTO NO SUSTITUYE NI REEMPLAZA NINGUN OTRO REQUERIMIENTO DE OTRA DEPENDENCIA O ENTIDAD Y SE EMITE DE ACUERDO CON LA LEY GENERAL DE SALUD 42-01 Y SUS REGLAMENTOS.

INSPECCIONES O EVALUACIONES DE SEGUIMIENTO	
NOMBRE DEL TRABAJADOR AMBIENTAL	FECHA
INGRI NUÑEZ	14/8/2020

REGISTRADO CON EL NUMERO 200-11 FOLIO 20-20 DEL LIBRO DE LAS LICENCIAS O PERMISOS SANITARIOS, EL DÍA 14 DEL MES DE 08 DEL AÑO 2020 CON UNA VIGENCIA DE UN AÑO A PARTIR DE LA FECHA DE EXPEDICIÓN.

VALIDO HASTA EL DIA [illegible] AÑO 2021

DIRECCIÓN PROVINCIAL O DE ÁREA DE SALUD

ADVERTENCIA: ESTE DOCUMENTO PODRÁ SER CANCELADO POR LA AUTORIDAD DE SALUD PÚBLICA, POR INCUMPLIMIENTO DE LA LEY GENERAL DE SALUD, REGLAMENTOS, CUANDO SE ALTERA O MODIFIQUE NEGATIVAMENTE LAS CONDICIONES SANITARIAS QUE DIERON ORIGEN A SU EXPEDICIÓN.

Items in bold are critical Auto-failure questions and could result in an automatic failure if a "0" is scored by auditor.

CERTIFICATE OF TRAINING

is awarded to

Carolina Mueses

in recognition for having successfully completed

Environmental Monitoring in Food Manufacturing Facilities

delivered by the International Food Protection Training Institute

8/4/2021

Alison Bodor, President and CEO
American Frozen Food Institute

IFPTI Certificate #287-5494

Gerald Wojtala, Executive Director
International Food Protection Training Institute

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 of Completion

Carolina Mueses

Has completed

Mastering FSSC 22000 Version 5

11/21/2019

Cynthia Weber
FSSC 22000 Lead Auditor
ISO 22000 Lead Auditor
FSPCA Lead Instructor

Carolina Mueses

Calle Santiago 608. Altos. Gazcue Santo Domingo, DN 10203
Phone: 1-829-539-3645 Fax: 1-809-685-6428 E-Mail: cmueses@agrobiotek.com

General

Birthdate:	December 25, 1964
Nationality:	Dominican Republic
Identity Card:	001-0942907-6

Education

Bachelor of Chemistry. Autonomous University of Santo Domingo. (1982-1987)

Postgraduate in Food Technology. Santo Domingo Institute of Technology (1988)

MSc. Food Science and Technology. San Carlos University of Guatemala. Institute of Nutrition of Central America and Panama. (1989-1991)

Santo Domingo Institute of Technology. Diploma in Quality Engineering (1993)

Courses

- Food Safety Preventive Control Alliance
    - o Preventive Control for Human Food, Dic 2016
    - o Lead instructor Preventive Control for Human Food – 2018
    - o Lead instructor Foreing Supplier Verification Program - 2018
- Food Technology Institute of the University of Chile. 1997
    - The Basic Nutrition Course
    - the Epidemiology Course
    - o Course on Education and Communication in Nutrition and Health
- American Institut of Baking (AIB)
    - the BPM Course
    - o HACCP and Advanced HACCP Course
    - o Food Plant Sanitation Course
    - the Internal Auditor Course FSSC 2200
    - the SQF Internal Auditor Course
    - FSSC 22000-Internal Auditor FSSC 22000
- Organization of American States. 2008
    - o Virtual Tutoring Training

- Internal Auditor ISO:9000-Lead Auditor ISO:9000
- ServSafe Certification

Positions occupied

- **AgroBioTek Dominicana.** General Manager/Consultant or Director of the company — 2001-actual
  - o Consultant in Development of Management Systems Food Safety – DR – Puerto Rico – Center America – Curacao - Venezuela
  - o Auditor of YUM's Brand/Mc Donald/ Fridays o Auditor of Food Safety Management Systems under GFSI standards
  - o Trainer in GMP courses. Health and safety – FSSC 22000, Preventive Controls
- **Dominican Corn Producer.** Quality Assurance Manager — 1994-2001
  - o Laboratory installation
  - o Development of laboratory methods and documentation o Implementation of the ISO Quality Management System 9000
  - o Department Address
- **Kettle Sánchez Industrial.** Director of Research and Development New Products — 1992-1994
  - o Development and implementation of a development project of new products
  - o Responsible for monitoring and controlling plant pests of Pasta and Oats
- **Dairy and Meat Additives Laboratory.** Assistant Production. — 1991-1992
  - o Assistant in Production processes o Responsible for supervising operators
  - o Development of New Product Lines
- **Caribbean Pharmaceutical Industry.** Production Assistant — 1988
  - o Responsible for supervising operators o Responsible for production lines o Organization of procedures and formulations

- **Santo Domingo Institute of Technology.** Project Assistant 1987
  - o Assistant in the “Capacity Research Project”
    Activated Carbon Absorption
  - the laboratory analyst

Publications

- “Popular Education in Health and Nutrition: Bibliographic Review” 1993
  Social Studies Journal, 26 (93), Jul-Sep 1993, p.83-108
- “Quality Control and Flour Fortification” Ecos de Magazine 2000
  Nutrition. Year 1, No.1, Nov. – Dec. 2000. P.4-7
- “Corn in the food history of America” Ahora Magazine. Year 2001
  XL. No. 1192, March 2001, p.87
- “How to properly store food products” Mi Colmado Magazine, year 2. No. 5 Feb 2001. 2001
  P.40-43
- “Importance of Cleaning and Sanitation in the Industry of 2007
  Foods” Bulletin No. 1 Agrobiotek Dominicana. September 2007
- “Health Problems in Food Services in the Republic” 2007
  Dominican Republic” Bulletin No. 1 Agrobiotek Dominicana September 2007
- Safe Food Blogs: http://alimentoseguro.wordpress.com 2007-actual

Research

- “Determination of Bacteriophages in the Main Cheese Factory of the Dominican 1987
  Republic” Thesis to opt for the title of Lcda. in Chemistry at the Autonomous University
  of Santo Domingo. Dominican Republic

- “Diversification of the use of Pigeon Pea (cajanus cajan) for human consumption: 1991
  Thesis to obtain the title of Master in Science and
  Food Technology at the University of San Carlos of Guatemala
- “Framework for Continuing Education in Health and Nutrition” 1991
  Research conducted at the Nutrition Institute of Centro
  America and Panama
- “Popular Education in Health and Nutrition: Bibliographic Review” 1991
  Research carried out at the Nutrition Institute of Centro
  America and Panama

Teaching Experience

- Pontifical Catholic Mother and Teacher University
  - o Professor of the Master's Degree in Food Quality and Safety -
    subject Programs Prerequisites I and II; Preliminary Projects and
    Projects – 2017-2019
- Autonomous University of Santo Domingo.
  - o Professor of instrumental analysis applied to food in the Post-graduate
    course in Instrumentation at the Faculty of
    Sciences - 1999

- Santo Domingo Institute of Technology 1994-2003
  - o Basic Chemistry I and II Teacher
- Pedro Henriquez Ureña National University
  - o Professor of Instrumental Analysis in the Master's Degree in
    Food Technology
- Colegio Dominicano de la Salle. o 1987-1988
  - Chemistry teacher to senior students.
    Baccalaureate
- Autonomous University of Santo Domingo. 1984-1987
  - o Analytical Chemistry Monitor

Professional Development Projects

- “Educational Intervention Project aimed at improving the 1996
  Hygiene practices in the Los Guandules neighborhood of the Domingo Sector
  Wise Man of the City of Santo Domingo
- Rich Pasteurizer 2006
  - or “CIP Efficiency Determination Project for the
    Elimination of milk allergens
  - o Staphylococcus Toxin Determination Project
    aureus in raw milk received at the plant
  - o CIP efficiency determination project using luminometry technique

- Project for the Installation of a Quality Control Laboratory 1997
  Corn Reception
- Silos del Norte. “Evaluation of the technical feasibility of producing frozen eggs” 1997

- National Public Health Laboratory. “Development and development consultancy” 2007

  Implementation of Documentation for the implementation of the ISO 17025 standard”

- Fruticoop. Villa Fundación Project, Bani. “Improving the process of 2007

  Solar drying and development of documentation for the implementation of good manufacturing practices in the fruticoop cooperative

Achievements and Goals

- Santo Domingo Institute of Technology 1999
  - o Award for the best professorial evaluation in the area of Basic and Environmental Sciences
- Autonomous University of Santo Domingo 1987
  - o Graduation with a Bachelor's degree in Chemistry Cum laude

Interests

- Teaching
- Research and development of projects
- Write technological articles
- Social networks as work tools

Experience

- General Manager of AgroBioTek Dominicana. 25 years of experience in the food and beverage sector. quality and food safety management systems.
- Research and development of new products.
- Extensive experience in the area of pest control and development of preventive control systems.
- Creation of the Quality Assurance department. Implementation of the Quality Management system. quality.
- Consultant in the implementation of systems under the GFSI standards: 22000, SQF, BRC among others, in Food, packaging and food service companies
- HACCP Auditor in Dominican Republic/Puerto Rico.
- Consultant in the implementation of Good Hygiene and Food Handling Practice Systems in Kitchens/Restaurants/ Hotels

- Implementation of Quality Systems. Trained in ISO 9000 processes. Certified lead auditor ISO 9000.
- Trainer in Health and Safety courses: HACCP certified by the International Alliance of HACCP, HACCP Auditor, Prerequisite Programs, Withdrawal and Traceability, FSSC 22000
- Professor of Food Technology.
- Internal Auditor FSSC 22000

Société Générale de Surveillance de México S.A. de C.V.
International Certification Services

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México, D.F. a 3 de mayo de 2001.

Maicera Dominicana

At'n. Carolina Mueses de Molina

Asunto: Curso Lead Auditor / Senior Auditor ISO 9000

Estimada Carolina Mueses de Molina:

Con la presente, le estamos enviando su Certificado del Curso de "Lead Auditor/ Senior Auditor", celebrado en Sto. Domingo, en la semana comprendida del 12 al 16 de febrero de 2001. Habiendo obtenido el grado "A" en la evaluación continua y la calificación "77" en el examen.

Nombre del participante	No. De Certificado	Resultado
Carolina Mueses de Molina	01/D503442S/12146	Passed

Extendemos una cordial FELICITACIÓN por los excelentes resultados obtenidos y tenemos la plena confianza y seguridad de que los conceptos y practicas impartidas durante este curso le serán de gran utilidad en el desarrollo de las actividades de implantación de los Sistemas de Calidad.

Es importante informarle que el certificado tiene una validez de 3 años a partir del ultimo día del curso, para propósitos de obtener su registro ante IRCA ó IATCA.

Aprovechamos la ocasión para reiterarle nuestros más distinguidos saludos.

Emitió

Héctor Rodríguez

Vo. Bo.

Ing. Enrique Vargas

FO-03-51A
Rev. 2

SGS Yarsley
International Certification Services

Certificate of Successful Completion

Carolina Mueses de Molina

has successfully completed an
Auditor/Lead Auditor/Senior Auditor Training Course
by passing the written examination and
continuous assessment

held in: *Sto. Domingo, Rep. Dominicana*

on the: *February 12-16, 2001*

Certificate Number: *01/D503442S/12146*

Enrique A. Vargas R.
SGS ICS México
Operations Manager

Course Number IATCA 2461 certificated by the International Register of Certificated Auditors (IRCA) and compliant with the criteria issued by the International Auditor Training and Certification Association (IATCA)

SGS United Kingdom Ltd., Training Services,
Unit 202B, Worle Parkway,
Weston-Super-Mare,
Somerset, BS22 0WA, United Kingdom.
Tel: +44 (0) 1934 522 917

IRCA CERTIFIED TRAINING COURSE

This Course is certificated by the IRCA and satisfies the formal training requirement for individuals seeking certification under the IRCA Auditor Certification Scheme and for this purpose is valid for three years.

IATCA

FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Carolina Mueses

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

FSPCA Preventive Controls for Human Food

delivered by Lead Instructor,

Jim Chance

completed on,

12/02/2016

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 # 021ea761

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CONFIDENTIAL TREATMENT REQUESTED

Claudio Innocenti

FSPCA

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the Food Safety Preventive Controls Alliance course:

Lead Instructor Training for FSPCA Preventive Controls for Human Food

delivered by Lead Instructor

Jenifer Kane

completed on

04/11/2018

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

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ILLINOIS INSTITUTE OF TECHNOLOGY

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Claudio Innocenti

Universidad Autónoma de Santo Domingo

Primada de América

Fundada el 28 de Octubre de 1538

El Consejo Universitario, en virtud de las disposiciones legales vigentes:

Por cuanto **Carolina Nuñez Pérez**

ha cursado en la Facultad de Ciencias

Departamento de Química de esta

Universidad los estudios requeridos y ha sido aprobado en los

exámenes correspondientes.

Por tanto, ha venido en otorgarle y le otorga el título de

Licenciado en Química

Cum Laude

Y para que sea notorio y constante le expide el presente Diploma, firmado y sellado en Santo Domingo, Distrito Nacional, República Dominicana, hoy día 28 de octubre de 1987.

El Rector

El Decano de la Facultad

REGISTRADO BAJO EL No. 5720 FOLIO 1244

DEL LIBRO DE GRADOS Y TITULOS

La Universidad de San Carlos de Guatemala

Por cuanto:

La Señorita

Carolina Mueses Pérez

miembro de la

Facultad de Ciencias Químicas y Farmacia

ha llenado los requisitos que las Leyes Universitarias establecen para optar al Grado Académico de

Maestro (Magister Scientificae) en Ciencias y Tecnología de Alimentos

Por tanto:

le expide el presente Diploma y le concede el derecho de gozar de los honores y preeminencias debidos a su grado.

Dado en la ciudad de Guatemala, a los ocho días del mes de marzo del año de mil novecientos noventa y uno.

Rector

Decano

Secretario de la Universidad

FSPCA

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Lead Instructor Training for FSPCA Foreign Supplier Verification Programs

delivered by Lead Instructor

Hilary Thesmar

completed on

04/13/2018

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Institute for Food Safety and Health

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CONFIDENTIAL TREATMENT REQUESTED

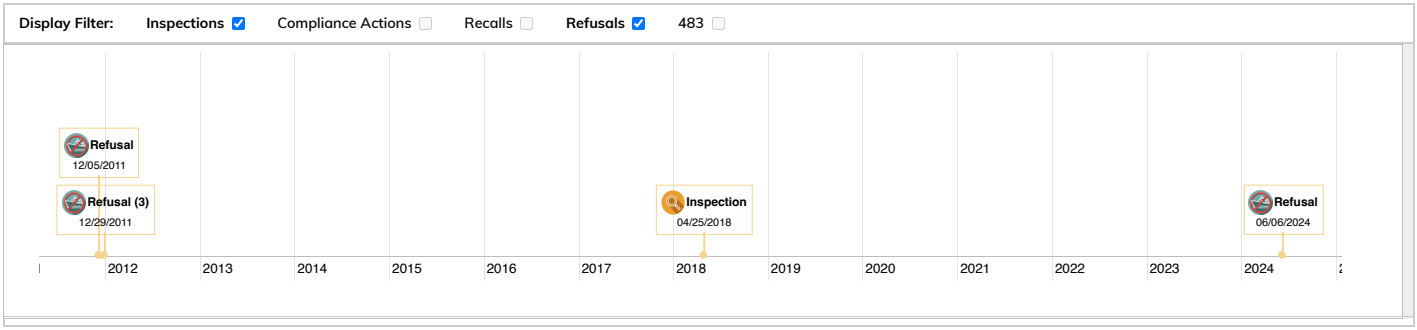
Claudio Innocenti

FEI Number
3008721890

Firm Name
Molinos Valle del Cibao, C. por A.

Firm Address
Carretera Duarte Km., 1/2 Tramo 5
Santiago-Licey
Dominican Republic (the)

FDA Actions Timeline



Documentation Requirements for Global Trade Bridge Corp.

Facility Name: Molinos Valle del Cibao

Product: Aviva Soda Normal Bucket

Facility Location: Carretera Duarte Km 5 1/2 tramo, Santiago, Santiago, Dominican Republic

FSMA International Facility Code: 12123

Date: Dec 03, 2021

1. Facility Food Safety Plan

**Item Information or Product Specification

List of Ingredients :	Wheat Flour, Vegetable Fat, Invert Sugar, Baking soda,enzymes, salt, sugar, milk powder, lecithin, yeast.
Country of Origin of Ingredients:	Wheat Flour: Dominican Republic. Vegetable Fat: Dominican Republic. Invert Sugar : Dominican Republic Baking soda: Germany/China/Italy Enzymes: Germany Salt: Dominican Republic Sugar: Dominican Republic Milk powder: USA/Dominican Republic Lecithin: Argentina/USA/Brazil Yeast: Mexico
Item Label :	The label is attached to the report
Item Packaging Specification :	***Primary Packaging:*** Metallic Polypropylene, printed with brand, product name, weight, nutritional information, ingredients, barcode, sanitary and industrial registration. The production lot number and expiration date are placed with inject. ***Secondary Packaging:*** Folding cardboard (Display), in presentation of 10 and 20 units and printed plastic cubes with brand, product name, weight, nutritional information, ingredients, bar code, sanitary and industrial registration. The production lot number and expiration date. They are placed with inject. ***Tertiary Packaging:*** *Clear* Wrap Shrink. The production lot number and expiration date are placed with inject.
Shelf Life of item:	One year from its elaboration date
	At room temperature

Storage Conditions for Item:	*In a clean and dry place, with a temperature of 30 to32°c.*

Microbiological Specification

Parameters	*Unit*	*Max.*
Total count	*In 25 g*	*< 1 x 10*
Mushrooms and Yeast	*UFC/g*	*< 1x10*
Total coliforms	*UFC/g*	*< 1x10*
Salmonella		*absent*

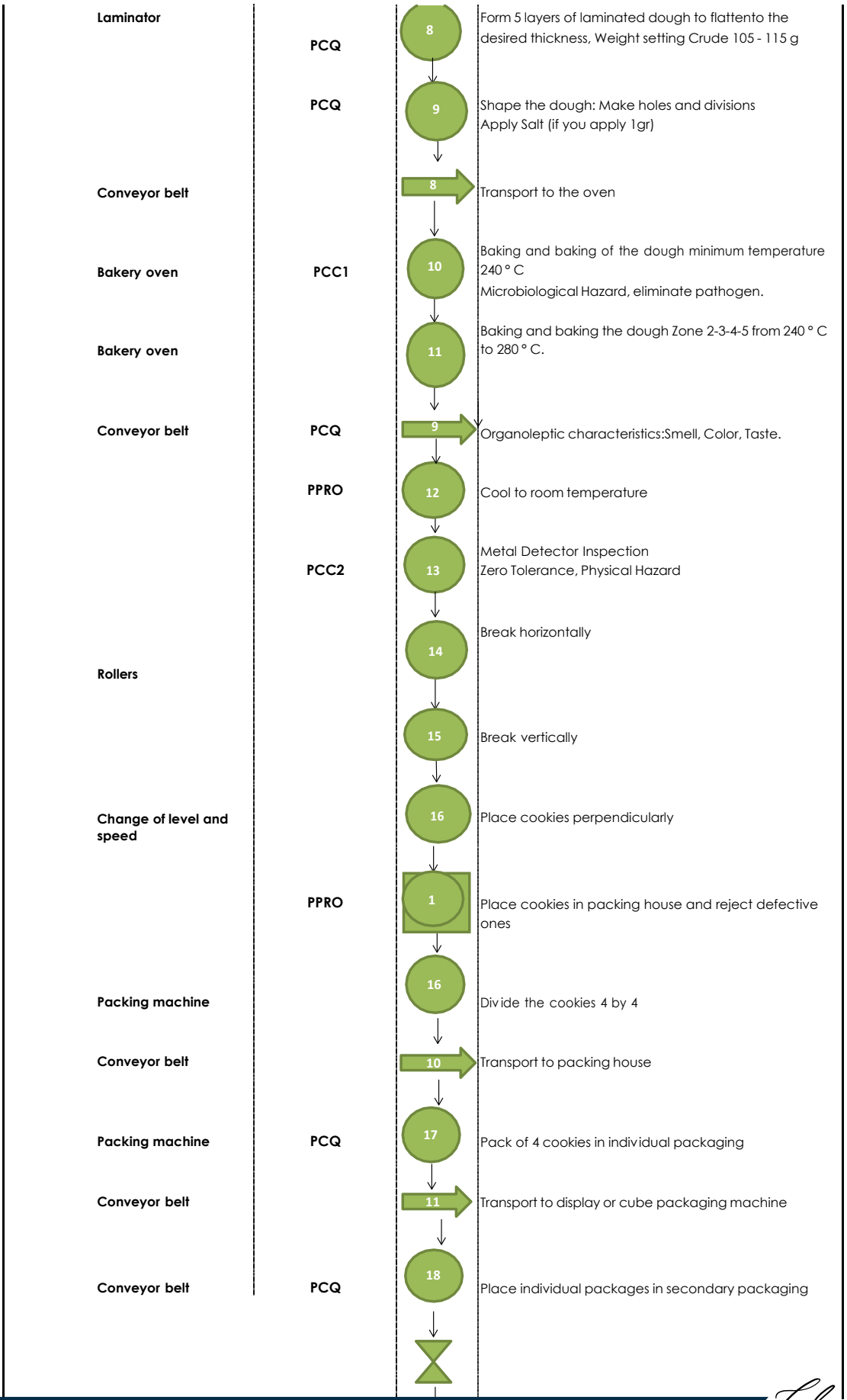
Chemical Specification:

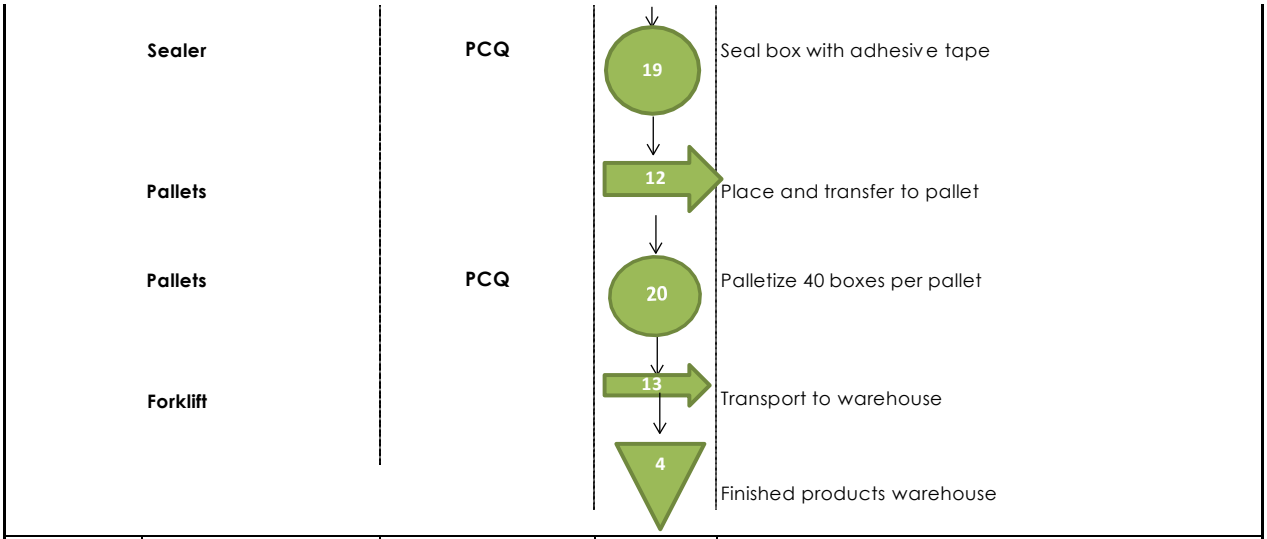
Parameters	U/M	STD	Min.	Max.
pH	-	*7*	*6*	*7.8*
% Humidity	*%*	*3*	*2*	*4*

Manufacturing Variables	
Sponge Mix Time	4 -5 Minutes
Dough Mixing Time	9 -10 minutes
Sponge Amperage	28 -31
Dough Amperage	38-42
Mixing Tempeture	38 -40 °c
Fermentation Time	Sponge: 16 hours
	Dough: 5 hours.
Sponge PH	5.2-6.2
Dough PH	7.0 - 8.0
Cooked Cookie PH	6.8-8.4
% RH	78-83

Flowchart of Process

Equipment	Control Points	Symbol	Description
		1	Raw material warehouse
Forklift / Transpallet		1	Transport to the dosimetry area
	PPR		
Allergen Test/ Luminometer	PCQ	1	Verify cleanliness of the Line. Validate absence of traces of unintended allergens Verify correct use of formula
Scales Containers	PCQ	1	Weigh the ingredients
Transpallet		2	Transport to mixing area
		2	Pour part of the ingredients
Mixer	PCQ	3	Mix the ingredients. Mixed water temperature 15 ° C
Batch Container		3	Transport to the fermentation room
	PPRO	2	Ferment dough room temperature 25-30 ° C 75-85% Relative humidity
Batch Container		4	Transport to mixing areas
PH meter	PCQ	4	Pour remaining ingredients Sponge PH 5.2-6.2
		5	Mix the ingredients
Batch container		5	Transport to the fermentation room
		3	Fermentation
Batch container		6	Transport for head
Mechanical arm		6	Pour into hopper
Blades		7	Section the dough
Metal detector	PPRO	2	Metal detector inspection Zero tolerance
Conveyor belt	PCQ	7	Transport to 2nd hopper Mix Temperature Control 38-48°C


Laminator
PCQ
8
Form 5 layers of laminated dough to flattento the desired thickness, Weight setting Crude 105 - 115 g
PCQ
9
Shape the dough: Make holes and divisions
Apply Salt (if you apply 1gr)
Conveyor belt
8
Transport to the oven
Bakery oven
PCC1
10
Baking and baking of the dough minimum temperature 240 ° C
Microbiological Hazard, eliminate pathogen.
Bakery oven
11
Baking and baking the dough Zone 2-3-4-5 from 240 ° C to 280 ° C.
Conveyor belt
PCQ
9
Organoleptic characteristics:Smell, Color, Taste.
PPRO
12
Cool to room temperature
PCC2
13
Metal Detector Inspection
Zero Tolerance, Physical Hazard
14
Break horizontally
Rollers
15
Break vertically
Change of level and speed
16
Place cookies perpendicularly
PPRO
1
Place cookies in packing house and reject defective ones
Packing machine
16
Divide the cookies 4 by 4
Conveyor belt
10
Transport to packing house
Packing machine
PCQ
17
Pack of 4 cookies in individual packaging
Conveyor belt
11
Transport to display or cube packaging machine
Conveyor belt
PCQ
18
Place individual packages in secondary packaging



Resume	Symbol	Quantity	Time	Distance
Warehouse		4	1260.01	
Inspection		2	1.583+	
Operations		20	31.4+	
Mix		1		
Transport		13		10+

Food Safety Team Members

The Safety team and those responsible for the implementation of thissystem are the following:

1). ***Christian Reynoso, General Manager***. He provides the tools to carry out the operation of the program.
2) ***Elías Morel, Operations Manager***. He is responsible for verifying the operation and effectiveness of the program.
3) ***Ana Marlenis Siri, Quality Coordinator and PCQI***. She is responsible for any changes in the plan and its structure and all documentation related to the program. This person oversees quality inspectors who have the responsibility of monitoring the process.
4) ***Quality Inspectors:*** They are responsible for the execution of the prerequisite programs as well as the control of critical points in the process.
6) ***Support Personnel:*** They are the people responsible for supporting through monitoring all personnel in the areas of production, maintenance, cleaning and sanitation and Purchases so that the program

Pre- Requisite Program

- **Chemical Storage**

Pesticides, disinfectants, cleaning materials or other toxic substances that may pose a health risk are in their original containers, labeled with the indications for use and the measures to follow in the case of poisonings in Spanish. These products are stored in exclusive places for this purpose, away from the areas where food is handled and stored, in locked cabinets.

These products are only distributed and handled by trained personnel.

- **Employee Training**

The training in BPM, Food Safety, Food Defense and Hygiene of the employees of the plant of Molinos Valle del Cibao who have contact with the product is the responsibility of Human Management, is mandatory for the exercise of the activity, and can be provided by specialized personnel of the plant or by external, specialized personnel.

This training includes at least topics related to food contamination, foodborne diseases related to products, General Principles of Hygiene, Good Manufacturing Practices, and Hygiene Programs.

This training is carried out at least every six (06) months or sooner if the administration considers it pertinent and the records thereof are available when required. Food handlers are frequently evaluated in order to ensure the application of training in the work they do.

- **Employee Hygiene and Health Conditions**

It is the responsibility of Human Management of the legal representative of the company and of the administrator, to guarantee the good state of health of the personnel that works inthe establishment in order to avoid that they are a source of contamination of the food they handle.

It is prohibited that personnel suffering from infectious diseases, diarrheal processes, respiratory processes, infected or open wounds, skin infections or sores, have contact with food.

Blood and pharynx tests are performed annually to verify that our employees are free of infection and bacteria that may threaten the safety of our products.

Hygiene

Food handlers maintain rigorous personal hygiene, do not smoke or eat during operations, have their hands with short fingernails (not painted or false), without personal adornments, clean and disinfected before coming into contact with food. Hand hygiene is also done immediately after using the toilet services, after coughing or sneezing, scratching the head or other body part, after handling boxes, containers, packages and other items that may be contaminated and all as many times as necessary. Compliance with GMP in personnel is verified through the registration Form Verification Compliance with Good Personnel Practices PE-CAL-GB-02 / RC05.

Clothing

Food handlers in the production area wear light-colored protective clothing that covers their bodies, they have their hair completely covered, they have appropriate work shoes; in the areas that are required, the manipulators additionally use nasal protection and gloves.
All clothing is washable, kept clean and in good condition, unless disposable, in which case it is only used once.
The cleaning and disinfection operators of the establishments use different colored

- **Pest Control**

Prevention and Control

Cookies and Biscuits Division has a Spraying Program PE-CAL-GB-02 / RC03, applying pest exclusion techniques with respect to the building and facilities to keep the establishment free of rodents and insects See Instruction Control of Insects Internal Areas and External IT-CAL-GB-001.

Prevention measures are applied that prevent the entry of insects and rodents into stores. For any reason, the presence of rodent traps or other control measures that favor the entry of these pests is allowed inside the warehouse and production area.

The use of control measures is strictly within the framework of a Spraying Program PE-CAL-GB-02 / RC03 that does not put food safety at risk and is applied when the preventive measures have been transgressed. Fumigations are carried out inside and outside the plant in the Check List Fumigation PE-CAL-GB-02 / RC13.

For control, the application of rodenticides and insecticides is carried out by contracted company personnel, accompanied by trained maintenance personnel, using only products authorized by the Ministry of Health, being careful not to contaminate food or surfaces where they are manipulated, Rodent Control register PE-CAL-GB-02 /RC11.

The presence of any animal in any area of the establishment is expressly prohibited.

Inspections for the control of vectors and rodents are evidenced in the Insect Control Form Internal and External Area PE-CAL-GB-02 / RC04. The activity of vectors in lamps is recorded in the document Insect Control in Lamps PE-CAL-GB-02 / RC07 and in the register Insect Control PE-CAL-GB-02 / RC13

- **Facility Sanitation**

PE-PRO-GB-01/RC29 Rev.0	MOLINOS VALLE DEL CIBAO S.A- DIVISION GALLETAS Y BIZCOCHOSQUALITY CONTROL DEPARTMENT CLEANING AND SANITIZATION PROGRAM AREA / S: PRODUCTION LINE HEADS							
Activities **Production Lines**	**Responsible(s)**	**Description** **Routine Cleaning**	**Description** **Deep Cleaning**	**Frecuency** **Deep Cleaning**	**Chemical for** **Deep Cleaning**	**Dose** **Deep Cleaning**	**Chemical for** **Sanitize**	**Dose** **Sanitize**
Area conditioning	Operators	Remove residues	Brush / Sanitize		Dufoam/Easy Foam	3%-4%	j512	200ppm
Waste removal from the Area	Operators	Remove residues						
Cleaning floor	Operators	Sweap /Mop	Sweep / Clean with Detergent / Dry / Sanitize		Dufoam	4%	J512	200PPM
Cleaning mixers Lines: 1,2,3,4,6,7	Operators	Remove residues from walls and mixers	Clean with Detergent / Brush / Sanitize		Dufoam/Easy Foam	3%-4%-	j512	200ppm
Cleaning of mass transport tanks	Assistant Operator	Remove residues	Clean with Detergent / Sanitize		Dufoam/Easy Foam	3%-4%-	j512	200ppm
Cleaning of cream transport tanks Lines:2,4	Assistant Operator	Remove residues	Clean with Detergent / Sanitize		Dufoam/Easy Foam	3%-4%-	j512	200ppm
Head Cleaning Lines:1,2,3,4,6 y 7	Assistant Operator	Remove residues	Brush with Detergent / Dry / Sanitize		Dufoam/Easy Foam/J512	3%-4%-	J512	200ppm
Cleaning Molding Area Lines: 1	Operator/Mant.	Remove residues	Brush with Detergent / Dry / Sanitize		Dufoam/Easy Foam	3%-4%	J512	200ppm
Cleaning Ov ens Exterior Lines: 1,2,3,4,6 y 7.	Operator/Mant.	Remove dust-Clean w ith Detergent-Dry-Disinfect	Remove residues w ith a towel		J512	200 PPM	J512	200ppm
Ov en mesh cleaning Lines: 1,2,3,4,6 y 7.	Assistant Operator	Remove residues w ith a towel	Remove residues w ith a towel		J512	200 PPM	J512	200ppm
Cleaning Surfaces Ovens Lines: 1,2,3,4,6 y7.	Assistant Operator	Remove residues w ith a towel	Remove residues w ith a towel		J512	200ppm	J512	200ppm
Cleaning Vibrating Gutters Lines:1,2,3,4,6 y 7.	Packing Assistant	Blow and Disinfect	Remove residues w ith a towel		J512	200ppm	J512	200ppm
Measuring cream cleaning Lines: 2,3,4	Mixers Assistant	Hot water	Disassemble / Hot Water / Clean w ith detergent / Dry / Disinfect		Easy Foam/Dufoam	4%-3%	J512	200ppm
Roll cleaning and cooling canvas Lines:1,2,3,4,6 y 7.	Packing Assistant	Remove residues with a towel-disinfect	Clean w ith Detergent / Dry / Disinfect		Dufoam	4%-		
Cleaning Packing Area Lines: 1,2,3,4,6 y 7	Operator	Sweap /collect	Disassemble / Clean with detergent / Dry / Disinfect		Easy Foam/Dufoam	4%-3%	J512	200PPM
Cleaning Packing conveyers	Packing Assistant	Remove residues w ith a towel	Disarm / Blow / Disinfect / Sanitize		Easy Foam/Dufoam	4%-3%	J512	200ppm
Cleaning Trays Biscuits	Operator	Hot water	Hot Water / Brush with Detergent / Dry		Easy Foam/Dufoam	4%3%		
Cleaning tray washer	Operator	Hot water	Disassemble / Clean Inside		Easy Foam/Dufoam	4%3%m		
Biscuit cleaning dispenser	Assistant Operator	Hot water	Disarm / Clean Interior / Disinfect		Easy Foam/Dufoam	4%-3%	J512	200ppm
Sponge cake cleaning	Assistant Operator	Remove dust-Remove residues	Wash hooks		Easy Foam/Dufoam	4%-3%	J512	200PPM
Cold tower and spiral cleaning	Assistant Operator	Water	Water under pressure / Wall and ceiling cleaning		Easy Foam/Dufoam	4%-3%	J512	200ppm
Tank cleaning	Assistant Operator	Remove waste w ith spatula/Blow w ith air	Remove Waste / Wash - Disinfect		Easy Foam/Dufoam	4%-3%	J512	200ppm
Egg area cleaning	Operator	Remove waste	Water Pressure / Clean Walls-Floor-Ceiling / Disinfect		Easy Foam/Dufoam	4%-3%-	Div osan -K	400PPM
Cleaning inv ert sugar area	Operator	Pick up trash/Organize/Mop	Water Pressure / Clean Walls-Floor-Ceiling / Disinfect		Easy Foam/Dufoam	4%-3%-	J512	200PPM

- **Product Storage and Handling**

Storage of Finished Product

Products already finished in Molinos Valle del Cibao, Biscuits and Biscuits Division, whether or not they contain a cold chain, that do not contain additives for their conservation and whose useful life for consumption does not exceed 48 hours may be sold packaged without Sanitary Registration. A daily inspection of the conditions of the warehouses whose registration is based on the Warehouse Inspection form PE-CAL-GB- 02 / RC18 is carried out.

Any product that requires a cold chain must be kept in refrigeration or freezing conditions as appropriate.

Products that require storage conditions for proper use or consumption, these must be clearly indicated to the consumer in the package.

Packaging Storage

The packages destined for the products must be of exclusive use and of first use, being strictly prohibited the reuse of any container.

The containers constitute a risk for cross contamination of the finished product, so they must be stored properly protected to prevent contamination, in an exclusive place for that purpose, in perfect hygiene and maintenance conditions.

The packaging material used in our products is for food use and exclusive for this purpose, they do not transfer odors or contamination to the food, being subject to verification by the Ministry of Public Health (MSP).

Shipping/ Transportation Practices

The transportation for the distribution of the products made in Molinos Valle del Cibao, Biscuits and Biscuits Division to the establishments of sale is carried out in vehicles of the company destined exclusively for the transport of food and they are in perfect state of conservation and hygiene. See Truck Hygiene and Cleaning Instructions (External Doc.). An inspector verifies the conditions of the transport unit and records the information on the form Transport Units Conditions PE-CAL-GB-02 / RC09.

In the case of products that require a cold chain, the vehicle must be conditioned to the storage temperatures of the finished product.

- **Facility Temperature Monitoring**

The cold chain of the supplies that require it in the room is maintained

For temperature control, the devices have easy-to-read thermometers, placed in a visible place and are checked periodically, keeping a record of the temperatures.

Inputs are stored in such a way that contamination and the transfer of undesirable odors are avoided.

The cold equipment has maintenance and cleaning program that ensures its proper functioning.

2. HACCP Plan/ HAZARDS Analysis

The hazard analysis is the final activity that is carried out in the process of applying the manufacturing program of the process plant and therefore the quality and safety of the processed food product is guaranteed.

The hazard analysis process is undoubtedly the preamble of a series of actions or activities that lead us to ensure that during the manufacturing process the points that represent a food contamination hazard are indicated and controlled, in addition to the established Critical limits and the monitoring that have to be carried out, to ensure that the deviations that occur are controlled in time by means of corrective actions according to each point and that they are duly registered to have control and demonstrate that the deviations were corrected. The Quality inspector monitors the products made, thus ensuring that the product is free of contamination.

The HACCP and / or food safety program is an integral system of analysis, controls, monitoring, records and verification, the latter allows us to evaluate the effectiveness of the manufacturing processes that are carried out during the production of the product,

The following is a summary of the hazard analysis presented in the process lines with the respective identification of the Critical Control Points through the analysis of the process stages, with the justification and the preventive measures taken to eliminate the danger or decrease it.

Ingredient or process step	Potential food safety hazard introduced controlled or increased in this step	Some potential danger to food safety requires significant preventive control	Justification of the decision	Preventive control measures to minimize or prevent hazards	Critical Point
Sugar	Biological N/A	No	Low incidence of reports with presence of microorganisms	Follow-ups to the BPM during the storage process	No
	Physical Strange material	Yes	Incidence reported in the samples taken	Preventive control in the supply chain, control with the supplier Grinding and spraying process, sieving in process	
	Chemical Pesticides Cleaning products Unapproved colors & additives	No	Low incidents of reports about contamination with pesticides and detergents or color changes in this product.	Supplier tracking supplier certification	

Ingredient or process step	Potential food safety hazard introduced controlled or increased in this step	Some potential danger to food safety requires significant preventive control	Justification of the decision	Preventive control measures to minimize or prevent hazards	Critical Point
Wheat	<u>Biological</u> Bacillus cereus Pathogenic *E. coli* Salmonella spp. L. monocytogenes	Yes	Flour can become contaminated in the milling process or the wheat can arrive contaminated from the supplier.	Supplier analysis certificate.	No
	<u>Physical</u> Strange material	No	May contain plastic metal waste, wood	Internal process control sifting metal detector subsequent steps	
	<u>Chemical</u> Pesticides Cleaning products Mycotoxins/Natural toxings	Yes	Flour can become contaminated in the milling process or the wheat can arrive contaminated from the supplier .	Supplier analysis certificate. Control in the supply chain certificates of analysis of the supplier of non-pesticides and non-toxins.	

Ingredient or process step	Potential food safety hazard introduced controlled or increased in this step	Some potential danger to food safety requires significant preventive control	Justification of the decision	Preventive control measures to minimize or prevent hazards	Critical Point
Vegetable Fat	Biological Pathogenic E. coli Salmonella spp. L.monocytogenes	No	No incidence with presence of microorganisms	Application to BPM during the storage process.	No
	Physical Stranger Material	No	Easy visualization of some foreign body. Incidence reported in the samples taken.	Metal detector in process steps, preventive controls in supplier processes.	
	Chemical Unapproved colors and additives	No	No incidence with unapproved colors and aditives	Supplier tracking supplier certification	

Ingredient or process step	Potential food safety hazard introduced controlled or increased in this step	Some potential danger to food safety requires significant preventive control	Justification of the decision	Preventive control measures to minimize or prevent hazards	Critical Point
Ammonium Bicarbonate	Biological N/A	No	No records of positive microbiological results.	Application to BPM during the storage process	No
	Physical N/A	No	No incident log	Metal detector in subsequent steps.	
	Chemical N/A	No	No record of contamination with pesticides and / or detergents.	Supplier tracking supplier certification Visual inspection.	

Ingredient or process step	Potential food safety hazard introduced controlled or increased in this step	Some potential danger to food safety requires significant preventive control	Justification of the decision	Preventive control measures to minimize or prevent hazards	Critical Point
Lecithin	Biological Salmonella spp.	No	No records of positive microbiological results.	Application to BPM during the storage process.	No
	Physical Metal	Yes	By deviation in supplier process	Metal detector in subsequent steps	
	Chemical Allergen	Yes	It is considered an allergen derived from soy.	Statement on allergen control label allergen control program in the process, hygiene and sanitation.	

Ingredient or process step	Potential food safety hazard introduced controlled or increased in this step	Some potential danger to food safety requires significant preventive control	Justification of the decision	Preventive control measures to minimize or prevent hazards	Critical Point
Yeast	Biological Salmonella spp.	No	Low probability	Supplier analysis certificates	No
	Physical N/A	No	Low risk		
	Chemical N/A	No	Low risk	Supplier analysis certificates	

Ingredient or process step	Potential food safety hazard introduced controlled or increased in this step	Some potential danger to food safety requires significant preventive control	Justification of the decision	Preventive control measures to minimize or prevent hazards	Critical Point
Baking Soda	Biological N/A	No	No records of positive microbiological results.	Application to BPM during the storage process.	No
	Physical N/A	No	No incident log.	Metal detector in subsequent steps.	
	Chemical N/A	No	Contamination with pesticides and / or detergents.	Supplier tracking supplier certification Visual inspection.	

Ingredient or process step	Potential food safety hazard introduced controlled or increased in this step	Some potential danger to food safety requires significant preventive control	Justification of the decision	Preventive control measures to minimize or prevent hazards	Critical Point
Salt	Biological N/A	No	Low risk Low severity	Constant monitoring in the storage process supplier analysis sheets	No
	Physical Strange material	Yes	This product is poorly processed so it may contain stones and other foreign materials typical of the nature or origin thereof.	Control in the supply chain, supplier certificates, visit to provider. Internal process control with sieving and metal detector in subsequent steps.	
	Chemical N/A	No	Contamination with pesticides and / or detergents	Supplier tracking supplier certification	

Ingredient or process step	Potential food safety hazard introduced controlled or increased in this step	Some potential danger to food safety requires significant preventive control	Justification of the decision	Preventive control measures to minimize or prevent hazards	Critical Point
Baking of all processes	Biological Aerobic Mesophilic	Yes	Temperature control to eliminate the bacteria present	Baking temperatures control	Yes
	Physical N/A	No			
	Chemical Spillage of cleaning chemicals Allergen	Yes	Although most pathogens must be eliminated with cooking, this is a risk that needs to be controlled in this step, as is the control of allergen contamination in the manufacturing and baking process.	Allergen control program monitoring of GMP	

Ingredient or process step	Potential food safety hazard introduced controlled or increased in this step	Some potential danger to food safety requires significant preventive control	Justification of the decision	Preventive control measures to minimize or prevent hazards	Critical Point
Packing	Biological Aerobic mesophilic E. coli	Yes	Bad handwashing practice and breach of good practices	Use of alcoholated gel training for operating personnel	No
	Physical Wood Metal	Yes	Presence of pests in the area of processes, flies and bees Use of wood in packing room	Monitoring of the fumigation and pest control program. Monitoring of hardwood and hard plastic pallets.	
	Chemical Cleaning material and / or lubricant	Yes	By the presence of chemicals in the area of packaging, alcohol, grease, lubricants	Maintenance and hygiene staff training	

Ingredient or process step	Potential food safety hazard introduced controlled or increased in this step	Some potential danger to food safety requires significant preventive control	Justification of the decision	Preventive control measures to minimize or prevent hazards	Critical Point
Ingredient storage	Biological N/A	No	No records of positive microbiological results	Application to BPM during the storage process.	No
	Physical Presence of flies, bees and other insects	Yes	By incidence in the presence of flies and other pests such as weevils	BPM and SSOP application Follow-up to the pest control program.	
	Chemical N/A	No	Low risk low severity	BPM monitoring and allergen control.	

Ingredient or process step	Potential food safety hazard introduced controlled or increased in this step	Some potential danger to food safety requires significant preventive control	Justification of the decision	Preventive control measures to minimize or prevent hazards	Critical Point
Dough mixer Line 1	Biological N/A	No	Low risk low severity	Application to BPM during the mixing process	No
	Physical Strange material	Yes	Fat may fall from the mixer or a metal	Preventive mixing process control	
	Chemical N/A	No	Low risk low severity	BPM tracking Metal detector BPM monitoring during the mixing process	

Ingredient or process step	Potential food safety hazard introduced controlled or increased in this step	Some potential danger to food safety requires significant preventive control	Justification of the decision	Preventive control measures to minimize or prevent hazards	Critical Point
Water Meter Line 1	Biological Pathogenic E. Coli	Yes	Presence of post process osmosis pseudomonas	Operator Specification Water temperature Maintain the BPM during the process, water analysis	No
	Physical N/A	No	No incident records	Water dosing meter	
	Chemical N/A	No	Low risk low severity		

Ingredient or process step	Potential food safety hazard introduced controlled or increased in this step	Some potential danger to food safety requires significant preventive control	Justification of the decision	Preventive control measures to minimize or prevent hazards	Critical Point
Baler Gag Coil	Biological Pathogenic E. Coli	Yes	Badly sealed	Monitoring of preventive maintenance programs.	No
	Physical N/A	No	No incident records		
	Chemical N/A	No	Low risk low severity	Preventive controls in the supply chain	

Approved Suppliers Of Ingredients That Require Control Applied To The Supply Chain.

Ingredient (which requires a control applied to the supply chain)	Approved Provider	Danger (s) that requires a control applied to the chain of supply	Date approval	Verification Method	Verification Record
Ammonium Bicarbonate **Baking Soda**	Alindus Ativa Multiquímica	Physical and chemical pollutants physical stone metal, wood of the process	3/10/2010 Code1065 05/01/2009 03/01/2010 08/03/2009 Code1020 01/06/2009 Code1024	Supplier analysis sheet, on-site audit	Audit report made to the supplier filed in the suppliers file and quality files
Wheat	MVC	Pathogens vegetative trainers of spores like Salmonella, E. coli pathogen, L. monocytogenes		On-site audit Certificates of analysis provided by the supplier	Audit report made to the supplier filed in the suppliers file and quality files
Lecithin	Alindus ATIVA Multiquímica	Allergen	06/12/2009 Code1009	On-site audit by a qualified individual of the company	Audit report made to the supplier filed in the suppliers file and quality files
Yeast	Espalsa Henry Rodriguez	Biological, Physical Little Incidence	05/10/ 0009 Code 1052	On-site audit Certificates of analysis provided by the supplier	Audit report made to the supplier filed in the suppliers file and quality files
Sugar	Cristóbal Colon Central Romana Central Barahona	Physical danger presence of impurities of the process, metal, stones, wood	03/19/2010 Code 1072 and 1022	Audit log in Situ Certificates of analysis provided by the supplier	Audit report made to the supplier filed in the suppliers

					file and quality files
Salt	Alindus Ativa	Physical danger Process impurities, metal, stone wood	05/05/2009 Code 1021	Audit log in Situ Certificates of analysis provided by the supplier.	Audit report made to the supplier filed in the suppliers file and quality files

- ***Process Preventive Control***

  i. Cooking and Baking

Process Steps	Critical Control Point	Critic Limit	Monitoring				Corrective Action	Records	Verification
			What?	How?	Frecuency	Who?			
Cooking and Baking Aviva Soda Normal	Salmonella, E. Coli, Staphylococcus Aureaus, Total Coliforms	Baking Temperature Zone 1: 270-280°C.	Baking of Aviva Soda Normal	Control panel thermometer and pocket type thermometer inspector quality inspector.	In each dough that is manufactured for the preparation of cookies	Baking Operator	*If nonconformity is detected, the maintenance department should be notified immediately. *Stop the cooking process. *Separate the entire product that has suffered the deviation so as not to pack. * If it is packed remove it to nonconforming products	*Verification record of PCC line 1	Equipment calibration program.
		Baking Temperature Zone 2: 270-290°C						*Record of verification of the proper functioning of the HACCP plan.	Preventive maintenance program.
								*Operational inspection record of auditors.	Records of verification of the operation of the HACCP plan.

Validation Study for Cooking Temperatures

In the guide published by the FDA in the 2011 Fish and Fishery Products Hazards and Controls Guidance Pag. 421 APPENDIX 4: Bacterial Pathogen Growth and Inactivation indicates that:

Salmonella, Escherichia Coli and staphylococcus aureus: easily removed at temperatures above 100 ° C.

Tests Performed on the Product for Verification

Objective: To verify the suitability of the Process Control, time and temperature control in the ovens and final product.

Sample Identification: The temperature in the different zones of the furnaces and control panel is verified; this temperature is validated with a laser thermometer. Samples of finished product are sent to the External Laboratory and the sample is identified with the lot number to which it belongs.

Laboratory: Agrobiotek Laboratorios SRL, Calle Santiago No. 608, Altos, Santo Domingo, D.N. Dominican Republic

Analysis Performed: The representative of the Laboratory takes the packed sample to determine the presence of:

Salmonella, Escherichia Coli and staphylococcus aureus

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Interpretation of Results:

Acceptable Results: Monitoring of temperatures continues.

- Salmonella: Absent / 25 g
- Escherichia Coli: Absent
- Staphylococcus Aureus count: ≤1.00E + 02

Unacceptable Results: A Recall is performed

- Salmonella: Presence / 25g
- Echerichia Coli: Presence / g
- Staphylococcus Aureaus count :> 1.00E + 02

Corrective Measures for Unacceptable Results

- The main cause of the problem is defined.
- The frequency of the analysis is increased.
- Review of the raw material and the process.
- Review of the supply chain program.

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ii. Metal Detector

Process Steps	Critical Control Point	Critic Limit	Monitoring				Corrective Action	Records	Verification
			What?	How?	Frecuency	Who?			
Dough inspections with metal detector	Metal Detection	Metal Absence	Cookie dough line 1	Metal detector running	Every dough	*Operator *Quality Inspector	*If nonconformity is detected, the manufacturing process must be stopped immediately. *Immediately notify the mixing department to check all supplies and equipment that could cause the diversion. *Separate and place a seal retained to all tanks of this production until it is resolved thoroughly. *Decommission mass with defect	PCC Verification Record	Equipment Calibration Program
								Verification record operation of HACCP plan	Preventive Maintenance Program
								Record of auditors operational inspection	

- **Allergen Management and Labeling**

Allergen Preventive Control Procedure

- ***Objective***

Identify the ingredients considered as allergens used in the manufacture of Biscuits and Biscuits of Molinos Valle del Cibao, establishing the correct labeling of products containing allergens and avoiding cross contamination, thus eliminating serious allergic reactions and even life-threatening for our consumers through a program of preventive controls and sanitation of the process lines.

- ***Scope***

To all the ingredients and process lines used in the manufacture of cookies from reception to storage and subsequent addition to the mixture. Determining which allergens are found in our products and how allergen control influences in our practice, to define storage, cleaning and handling requirements of the product in the processes, thus defining the ability of allergen segregation in our processes.

- ***Definitions***:

Allergic reaction: They are sensitivities to substances, called allergens that come into contact with the skin, nose, eyes, respiratory tract and digestive tract. These substances can be inhaled into the lungs, ingested or injected.

Allergen: It is a substance that can cause an allergic reaction in some people; the immune system considers the allergens as "strangers" or "dangerous". As a result, the immune system reacts by making an antibody called IgE to defend against the allergen. This reaction causes allergy symptoms.

The Codex Alimentarius commission has prepared a list of foods and ingredients responsible for the most severe allergic reactions and most cases of food hypersensitivity.

Food allergies: These are adverse reactions caused by an exaggerated immune response due to the ingestion, contact or inhalation of certain foods. These reactions are triggered against proteins or glycoproteins called food allergens that may be part of the food itself or are present in it. The only way to prevent them is to eliminate allergens from the diet of sensitive people.

Main allergens: Eight most common allergens have been identified, which are listed in the U.S. Food and Consumer Protection Labeling Act (FALCPA). As the main "Food Allergens":

- Cereals containing Gluten.
- Crustaceans and byproduct.
- Eggs and egg products.
- Fish and fishery products.
- Peanut Soya and its products.
- Nuts and their derivatives
- Sulfites in concentrations greater than 10mg / kl.

Anaphylaxis: Some people suffering from certain types of allergies (such as food allergies) may have a sudden life-threatening allergic reaction called anaphylaxis.

Cross contamination: The process by which food comes into contactwith foreign substances by passing contamination from a dirty or harmful area to a clean or harmless area.

Standardized operational sanitation procedures (POES): Standardized operational procedures that describe sanitation tasks (establishment hygiene).

- ***Process Description***

Raw Materials

Molinos Valle del Cibao maintains the identification of all allergenic components at the reception of raw materials received from the supplier through the Allergen Declaration Form, in which the receipt of all allergenic components or substances or their derivatives is verified. Declared or added intentionally (as food, additive or aroma, support or solvent of an additive or aroma, technological adjuvant), before entering our facilities.

We have specific sections within our warehouse to avoid cross contamination or unintended use of an allergen as an allergen control strategy.

In the case of the allergen egg used in our biscuit manufacturing process and that, due to its nature after being processed, requires refrigeration, it is stored in a well identified area in a cold room within the dosimetry area with allusive sign and stating that it is placed allergen in cubes and on pallets. With this product, preventive controls are maintained in the reception and processing of the same in a son outside the manufacturing facilities, they are introduced in covered plastic buckets and stored in an area identified as allergenic, the sanitation process of all these utensils, they are sanitized outside the washing room facilities of the other process utensils of the other lines.

- ***Formulations***

With the validation and verification of the formulations we detect which products contain allergens, which we declare in the technical data sheet of each product and on the labels according to Nordon 53.

- ***Facilities, Equipment and Processes.***

In order to avoid cross-contamination, we maintain control over the use of allergen handling equipment and utensils, with an exclusive weighing station for allergenic products and with exclusive use utensils, in the case of weighing blades and In the case of the egg cubes, a stickers type strip with a code and stating that it contains an egg, properly labeled for identification.

We maintain a control of reprocessing operations to avoid reprocessing that may contain allergenic ingredients. Biscuits containing eggs are only reprocessed in cookies containing whey and lecithin are only reprocessed in this product. To avoid any confusion, no cross-product reprocessing has been established, each product is reprocessed in the same family.

- ***Cleaning Process***.

Our cleaning program is based on standardized procedures and sanitizers approved for food processing industries for such purposes; our cleaning program includes washing after each product change in order to avoid possible cross contamination if the previous process used allergenic ingredients or no. This includes cleaning plan washing deep lines and utensils, strict validation of the effectiveness of cleaning by the quality department of the company with the use of luminescence equipment. ATP FOR ALLERGENS

- **Staff Training.**

It is the commitment of the Molinos Valle del Cibao to train new staff as well as the permanent staff on the proper handling of the ingredients and products processed in our facilities and the necessary training to handle the necessary terms on allergen products and the risk of cross contamination by the incorrect use of them. With special emphasis on vulnerable areas such as receiving raw material and heavy ingredients and mixing.

- **Labelled.**

All our product's labels made by us have the declaration of the ingredients included as allergens. Highlighted in size and color as requested by local and international standards such as the FDA, Codex Alimentarius.

- ***Allergenic Ingredients Used In Our Processes:***

In the processes of making cookies and we have identified four raw materials or derivatives as potential allergens:

- Milk
- Egg
- Lecithin (soy)
- Wheat; Flour and wheat bran.

- **Allergen Statement on Labels**

Allergen Control	Hazards	Monitoring					Corrective Action	Verification	Records
		Standard	What?	How?	Frecuency	Who?			
Receipt of Primary Packaging Material	Undeclared Allergens: Milk, wheat, and soy lecithin.	All labels on the primary package of finished products must declare the allergen content in the formula on each list.	The ingredient list and allergen warning match the product.	Visual check of the label verifying that it matches the product formula.	Before shipping to production	Quality Inspector	If the label is incorrect, the reel to the packaging supplier is rejected	Review of verification of labels, corrective actions and verification records within 7 business days.	Allergen checklist, tag allergen check records, corrective action records

- **Radiological Hazards**

No radiological hazards are identified in the process.

- **Hazards Related to Intentional Adulteration**

We are currently working with the food defense plan developed during the current year. We have implemented general mitigation strategies focused on different points where the process or product can be threatened by an act of intentional contamination.

We attach the action plan of those gaps that we still have to close.

ACTION PLAN

Measure # or Process Step	Action Step	Status	Responsibility	Priority
2e. Are all possible access points into the buildings covered, locked, or otherwise secured?		New	Johanny Camilo	High
3a. Does the property have a controlled or guarded entrance for vehicles?		New	Johanny Camilo	
3b. Are all vehicles entering the property identified by decals or other form of company-issued visual identification? This may include forms of permanent identification for employee vehicles, and temporary identification for vehicles belonging to visitors, contract workers, suppliers, and customers.	**Evaluate some type of vehicle identification** **Quote and place purchase order** **Obtain approval from the administration** **Place identification to the**	Planning	Johanny Camilo	High

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	vehicles that enter the installation.			
4d. Does your facility have established emergency procedures, including procedures for responding to an intentional contamination?	**Develop a procedure to respond to acts of intentional contamination** **Disclose procedure to those involved.**	Planning	Johanny Camilo/Wilissa Pineda	High
4f. Is access to production, storage and other sensitive areas restricted to a small number of employees?	**Perform survey of areas that require restricted access** **Quote access restriction signs** **Place purchase order** **Obtain approval from the administration** **Install the access control system.**	In Progress	Johanny Camilo	Medium
4h. Are copies of the facility's site plan and blueprints stored in a secured location at the facility and in an offsite location?	**Collect plans** **Take copy of the plans** **Store the plans in a secondary site**	In Progress	Christian Reynoso/Yudelkis Ceballos	Medium
4i. Are procedures in place to check maintenance closets, personal lockers,	**Write procedure to check maintenance cabinets, personal**	In Progress	Johanny Camilo/Wilissa Pineda	High

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and storage areas for suspicious items or packages?	**lockers and storage areas for suspicious items or packages.** **Get approval of the procedure** **Socialize procedure** **Implement the procedure.**			
13e. Is access to ice-making equipment and ice storage areas restricted?		New		
15b. Is a regular inventory of hazardous materials/chemicals maintained?	**Establish in the food defense procedure periodic review of inventories of chemicals and hazardous materials** **Report to management any discrepancy of inventories to take the measurements of place.**	In Progress	Claudia Pantaleón	High
16d. Do all employees receive training on security procedures and food defense awareness as part of their orientation training?	**Include training in Food defense in the induction of new employees** **Include training in Food defense in the Annual Training Plan for employess who have mor than 2 years working in the organization.**	Complete	Johanny Camilo/Wilissa Pineda	High
16e. Are employees, visitors, and contractors (including construction workers, cleaning crews, and truck drivers) identified in some manner at all times while on the premises?	**Redesign employees's cards, visitors and contractors with different colors** **Place purchase request** **Obtain approval from General**	In Progress	Johanny Camilo	High

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	Management **Implement the use of the cards.**			
16f. Do you control employee and contractor access into the facility during working hours (e.g., coded doors, receptionist on duty, swipe card, etc.)?	**Carry out a survey of all the doors** **Quote and place purchase order of access controls** **Obtain approval from the administration** **Install access controls.**	In Progress	Johanny Camilo	High
16h. Does your facility have a way to limit temporary employees and contractors (including construction workers, cleaning crews, and truck drivers) to areas of the facility relevant to their work?	**Writing a procedure** **Get approval of the procedure** **Socialize procedure with all staff** **Place quotation of the access controls.** **Obtain approval from the administration** **Install access controls that allow restricting entry to unauthorized areas.**	In Progress	Johanny Camilo	
16l. Is there a policy in place that prohibits employees from removing company-provided clothing and protective gear from the premises?		New		
17a. Is there a designated person or team to implement, manage, and update the Food Defense Plan?	**Create the Food Defense team and include it in the procedure.**	New		

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17c. Do you conduct regular food defense exercises to test the effectiveness of your Food Defense Plan?	**Coordinate mocks of the food defense plan that prove the effectiveness of our access controls as well as the vulnerability of access to unauthorized persons and assign responsible** **Include in the Annual Internal Audit Program review of compliance with the Food Defense Plan as well as all its requirements.**	Planning	Wilissa Pineda/Johanny Camilo	Medium
17d. Is the Food Defense Plan reviewed (and revised if necessary) periodically?	**Include in the Food Defense procedure annual review** **Include internal and external audits to the Food Defense Plan in the procedure.**	New		
17g. Are procedures for responding to threats and actual incidents of product contamination detailed in the Food Defense Plan?	**Include into Food Defense procedure how we respond when a threats or an incident is reported in our proccess** **Include all contacts that we have to call during an incident in the Food Defense procedure.**	In Progress	Wilissa Pineda	Medium
17h. Does the Food Defense Plan have procedures to ensure that contaminated or potentially harmful products are held at the facility?		New		

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17i. Does the Food Defense Plan have procedures for safe handling and disposal of contaminated products and decontamination of the facility in accordance with local environmental guidelines and regulations?	**Review the solid waste management procedures verifying that they comply with local environmental guidelines and regulations.**	In Progress	Johanny Camilo	Medium
Manufacturing - 1. Weight the ingredients	**Use electronic access control system to restrict access to location and/or controls (e.g., cipher lock, swipe cards, biometric devices, RFID).** **Use surveillance equipment to monitor locations and operations.**	In Progress	Johanny Camilo	High
Manufacturing - 3. Pour Iingredients	**Conduct periodic checks of packaging integrity (e.g., upon receipt and prior to use) including for packaged products, ingredients, and equipment components** **Use surveillance equipment to monitor locations and operations.**	In Progress	Johanny Camilo	High

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Manufacturing - 6. Feeding Mass at Temperature	**Use personnel (e.g., guards, supervisors, trusted employees) for visual observation at restricted locations and operations** **Use surveillance equipment to monitor locations and operations.**	In Progress	Johanny Camilo	Medium

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Manufacturing - 8. Pour Remaining Ingredients	**Use peer monitoring (e.g., buddy system) during operations or in assigned locations.** **Use surveillance equipment to monitor locations and operations.**	In Progress	Johanny Camilo	Medium
Manufacturing - 15. Form 5 Layers of Dough Rolled to Flatten to Desired Thickness	**Restrict access to equipment and controls to authorized personnel.** **Use surveillance equipment to monitor locations and operations.**	In Progress	Johanny Camilo	Medium
Manufacturing - 16. Shape the Dough	**Restrict access to equipment and controls to authorized personne.** **Use surveillance equipment to monitor locations and operations.**	In Progress	Johanny Camilo	High
Manufacturing - 17. Transport to the Oven	**Restrict access to equipment and controls to authorized personnel.** **Use surveillance equipment to monitor locations and operations.**	In Progress	Johanny Camilo	High
Manufacturing - 19. Cooling	**Restrict access to equipment and controls to authorized personnel.** **Use surveillance equipment to monitor locations and operations**	In Progress	Johanny Camilo	High
Manufacturing - 20. Break Cookie Horizontally	**Restrict access to equipment and controls to authorized personnel.**	In Progress	Johanny Camilo	High

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	Use surveillance equipment to monitor locations and operations.			
Manufacturing - 21. Break Cookie Vertically	**Restrict access to equipment and controls to authorized personnel.** **Use surveillance equipment to monitor locations and operations.**	In Progress	Johanny Camilo	High
Manufacturing - 22. Place Cookie Perpendicularly	**Restrict access to equipment and controls to authorized personnel.** **Use surveillance equipment to monitor locations and operations**	In Progress	Johanny Camilo	High
Manufacturing - 23. Divide from 4 in 4 cookies	**Restrict access to equipment and controls to authorized personnel.** **Use surveillance equipment to monitor locations and operations.**	In Progress	Johanny Camilo	High
Packing - 4. Packing singles packs on displays	**Conduct periodic checks of packaging integrity (e.g., upon receipt and prior to use) including for packaged products, ingredients, and equipment components.** **Use surveillance equipment to monitor locations and operations**	In Progress	Johanny Camilo	High
Packing - 5. Put displays on boxes	**Use personnel (e.g., guards, supervisors, trusted employees) for visual observation at restricted locations and operations**	In Progress	Johanny Camilo	High

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	Use surveillance equipment tomonitor locations and operations.			
Packing - 6. Seal Box with Adhesive Tape	**Conduct periodic checks of packaging integrity (e.g., upon receipt and prior to use) including for packaged products, ingredients, and equipment components.** **Use surveillance equipment to monitor locations and operations**	In Progress	Johanny Camilo	High
Raw Material Reception and Storage - 1. Raw Material Reception	**Maximize visibility of operations,equipment, and locations (e.g., install windows, light adequately, keep area clear of visual obstructions)** **Use surveillance equipment to monitor locations and operations**	In Progress	Johanny Camilo/Yaniré López	High
Raw Material Reception and Storage - 2. Raw Material Storage	**Restrict access to location toauthorized personnel** **Use personnel identification(e.g., color coded uniforms, badges) to restrict access tolocation, equipment, control, andoperations.** **Use surveillance equipment to monitor locations and operations**	In Progress	Johanny Camilo	High

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Raw Material Reception and Storage - 3. Transport raw material to dosimetry	**Use surveillance equipment to monitor locations and operations**	In Progress	Johanny Camilo	High
Warehouse and Dispatch - 1. Warehouse of Finished Products	**Maximize visibility of operations,equipment, and locations (e.g., install windows, light adequately, keep area clear of visual obstructions)** **Use surveillance equipment to monitor locations and operations**	In Progress	Johanny Camilo	High
Warehouse and Dispatch - 2. Dispatch	**Restrict access to transportoperations to authorized personnel** **Use surveillance equipment to monitor locations and operations**	In Progress	Johanny Camilo	High

5. Supplier Qualification Plan

Raw Material / Packaging Materials	Supplier	Presentation	Condition Storage	Danger that Represents	Characteristics to Evaluate	Ranges	Corrective Action for Deviation	Useful Life	Documents Required
Wheat Flour	MVC	45.36 kg bags	Room Temperature	Biological/Phisical/ Allergen	Humidity Absorption Stability	13-13.75 max. 45-58 Greater than 3 in fabulous 1.25 in little princess According to quality certificate from the supplier	Return and / or retain lot to be ev aluated and used in products that apply according to parameters.	3 month	Data sheet *Security sheets *Certificates of Analysis * On-site inspection performed by a qualified individual * Microbiological results not mandat ory in each delivery
Vegetable Fat	Domingo Rijo La Fabril Mercasid	22.62 kg boxes	Room Temperature	Phisical	Acidity Free Iodine Index Peroxide Index Volatile humidity Smell and color	0.010% maximum 48-55 Cg / g. 1.5 max. 0.10 max Characteristic according to quality certificate	Return of the Lot to the Supplier	A year	*Data sheet *Security sheets *Certificates of Analysis * On-site inspection performed by a qualified individual
Sugar	Central Romana Consorcio Azucarero Barahona Cristobal Colón	56.7 kg bags	Room Temperature	Phisical Biological	Ash Humidity Organoleptic	0.00% 0.04% Smell and characteristic color according to quality certificate	If the dev iation is due to high humidity, it is destined for inv erted sugar if it is due to the presence of foreign material to	2 years	*Data sheet *Security sheets *Certificates of Analysis * On-site inspection performed by a qualified individual
Ammonium bicarbonate	Alindus Ativ a Multiquimica	25 kg bags	Room Temperature	Phisical	Appearance Purity	White powder 99% according to quality certificate from the supplier	Return of the Lot to the Supplier	A year	* Technical sheets provided by the manufacturer and certificate of analysis of the received
Lecithin	Alindus Ativ a Multiquimica, Doperco	200kg metal tank	Room Temperature	Biological	Total count Staphylococcus, Salmonella Coliforms, E. coli Peroxide Viscosity	<1x10ufc Absent Absent Max. 1.5 80-120p According to quality certificate	Return of the Lot to the Supplier	A year	* Technical sheets * Inspection Letter *Certificates of Analysis
Yeast	Espalsa Henry Dominguez	9.07kg bags	Room Temperature	Phisical/ Biological	Dry material Protein Phosphorus Peptide E. COLI Coliform Totals Aerobic mesophilic	Min.95% 45.31% 2.35 Máx.10 ufc Máx.100 ufc 600 ufc	Return of the Lot to the Supplier	2 years	* Technical sheets * Inspection Letter made by a certified *Certificates of Analysis
Baking Soda	Alindus, Doperco, Ativ a, Multiquimica	25kg bags	Room Temperature	Phisical	olor and appearanc Odor Substance content	lanco, polv o cristalino sin olor 99% min	Return of the Lot to the Supplier	2 years	* Technical sheets * Inspection Letter *Certificates of Analysis
Salt	ALINDUS- ATIVA, Espalsa	50 kgs bags	Room Temperature	Phisical Presence of impurities Metal, stone Woods Biological	Humidity Sodium chloride Coliforms E.Coli	Less than 0.2% Min.99% <1.00ufc Absent According to quality certificate	Return of the Lot to the Supplier	3 years	* Technical sheets * Inspection Letter made by a certified *Certificates of Analysis
Single Pack Soda Aviva Normal	SIGMAPLAST	700 kg	Room Temperature	Phisical / Presence of impurities	Dimensions /Color and appearance	**Width** 200 **Cutting Distance** 170 **Thickness** 32 **Mat. Printed** BOPPT **Lamination** BOPPM	Return of the Lot to the Supplier	Depends on storage conditions	* Technical sheets * Inspection Letter made by a certified entity
Aviva Cubo Plastico12/1	SIGMAPLAST	3000 unds per p	Room Temperature	Phisical / Presence of impurities	Dimensions /Color and appearance	**Long (mm)** 612 **Wide (mm)** 416 **High (mm)** 417	Return of the Lot to the Supplier	Depends on storage condition	* Technical sheets * Inspection Letter made by a certified entity

Corrugated Cardboard Aviva24/9 26GR.	Smurffit	300 unds	Room Temperature	Phisical / Presence of impurities	Dimensions /Color and appearance	**Long (mm)** 539 **Wide (mm)** 202 **High (mm)** 241	Return of the Lot to the Supplier	Depends on storage condition	* Technical sheets * Inspection Letter made by a certified entity

6. Environmental Monitoring Instructions and Employee Hands.

Goal:

To validate the safety of the process room, hands of employees, Tables of contact with the product, cooling sheets of biscuits and biscuits manufactured by the company.

Scope:

Entire area of the process room, weighing, packaging, production lines, contact tables, cooling tarps, structures in contact with the product or not.

Frequency:

Monthly

Documentation:

Record of results Microbiological tests of external Laboratory.

Responsible:

Quality coordinator

Monitoring Procedure:

The Quality Coordinator proceeds to make the request for microbiological sampling to the purchasing department. This proceeds to pass the request to the accredited laboratory and approved as a supplier for these purposes - Agrobiotek Laboratory and Alton.

The external laboratory analyst proceeds to sample the environment for counting mesophilic aerobes and fungi and yeasts.

In the case of compressed air, the count of Aerobic Mesophils, Salmonella, Fungi and Yeast is measured. (The frequency of this monitoring is quarterly). To sample the lines or surface of contact with the product, the swabs are sampled for the determination of Total, Coliform and Salmonella counts, this process is divided into zone 1 part in direct contact with the product, (tarpaulins, meshes) zone 2 parts where the product does not have direct contact but is very close to the surface where the product passes product and this can be contaminated, (table stands, legs of lines) zone 3 is the furthest part of the contact with the product as the floor and that there is little possibility of contamination.

Hand surface monitoring: 4 to 6 employees are taken at random and hand washing is requested to proceed with the sampling with hyssop to determine Aerobic Mesophiles, Total Coliforms and E. coli.

Corrective actions;
If the results obtained by analysis of the environment sample present some data outside the parameters, it is possible to demonstratecauses that may cause this contamination, performing deep cleaning and sanitizing the environment by sprinkling. Then the sampling is repeated.

In the case of compressed air, if there is a nonconformity, monitoring will be carried out on the surfaces that have been applied or made contact with the air, evaluating the products that have had direct contact with these areas, performing analyzes of Salmonella, and other pathogens that could alter the product.

If there is a deviation in the data of the surface lines in zone 1 and 2, deep cleaning and post-cleaning monitoring are carried out, if the deviation is in zone 1, a Recall of all the product that has been made must be carried out. passed through the line since the last favorable monitoring.

In the case of the surface of the hands of employees with out-of- acceptance results, a new sampling is carried out and if it persists, it refers to the company's health department for clinical analysis.

- **Preventive Water Control Procedure**

Goal

Ensure that the quality of the water used for the production processes of the company is free of any physical / biological contamination that may affect the safety of the products, complying with the legal requirements of national and international standards.

Scope

All the water used in the production processes and cleaning activities in the Bocel group facilities.

Responsibilities:

It is the responsibility of the General Management to provide all the necessary resources to maintain the conditions of the watertreatment system in optimal conditions.

It is the responsibility of the Laboratory Analysts to daily monitor the parameters of all the water points of the company.

It is the responsibility of the Maintenance Coordination to ensure the proper functioning of all equipment that is part of the water treatment system, including the Osmosis System.

- **Description Water Treatment Process**

Drinking Water System has a pretreatment and a Reverse Osmosis system.

The pretreatment is composed of:

- 1 filter feed pump
- 1 sand filter
- 1 activated carbon filter

- Softeners

- Online dosage of sodium hypochlorite The

reverse osmosis system is composed of:

- 1 sand filter

- 1 activated carbon filter

- Softeners

• Requirements Established by the Company

The supply of drinking water is used for the preparation of Biscuitsand Biscuits and the cleaning of the surfaces in contact with the product. Molinos Valle del Cibao has a cistern, pipe network in all areas of the Plant and a water processing unit (drinking water treatment plant), a water storage tank (tank with a capacity of180,000 gallons) as well as a system of Osmosis.

- **Water Supply**

It has water from the sub-soil from a well, to which the national control analyzes are carried out: Chlorides, Surface Tension Agents, Residual Chlorine, Copper, Iron, Magnesium, Calcium, Manganese, Phenolic Compounds, Sulfates, Zinc, Total Hardness, Calcium Hardness, Magnesium Hardness, Phosphate, SST, Barium, Potassium, Sodium, Total Alkalinity, TDS, PH, Color, Turbidity, Odor, Arsenic, Antimony, Cadnium, Cyanide, Fluorides, Hexavalent Chromium, Lead, Nitrates , Nitrites, Mercury, Mesophyll Aerobic Counts, Total Coliforms, Pseudomona, E. Coli, Broken Virus Virus, Parasites.

The water is subjected to a process of purification through sand filter (settler), carbon filter, softeners and ultraviolet lamps. The water is chlorinated, then it is sent to the Cistern, finally going through an Osmosis System before being used in the Production Process of the company.

Drinking water from the company's own network is used in process operations in sufficient quantities and under conditions of adequate temperature and pressure.
A minimum of two residual chlorine analyzes are performed at different locations in the pipes, to ensure an average chlorine concentration of 1.5-3 ppm.
The water pipes are marked according to the color code established by the company, the drinking water has white or gray colored pipes in the case of Osmosis.

The connections and repairs of the network are verified so that there is no possibility of cross contamination between the drinking water and raw water networks.

The environmental and public health permits corresponding to the nature of this company are kept up to date. Every 6 months, analyzes are carried out on water taken directly from the sub / soil toensure that reliable raw water is provided.

Current Controls to Guarantee Water Quality in the Pretreatment System.

Control Point	Analytical Control	Allowed Range
Water Well	Hardness	≤ 10 ppm (part per million)
	Chlorine	1.5 – 3 mg/L.
	UV Lamp	Running lamp
Sand filter	Chlorine	1.5-.3mg/L
Storage tanks	Chlorine	1.5 – 3 mg/L.
Softener 1	Hardness	≤ 10 ppm (part per million)
Softener 2	Hardness	≤ 10 ppm (part per million)
	Chlorine	1.5 – 3 mg/L.
Cistern outlet	Hardness	≤ 10 ppm (part per million)
	Chlorine	1.5 – 3 mg/L.

Current Controls to Guarantee Water Quality in Osmosis System

Control Point	Analytical Control	Maximum Value Allowed
Sand Filter	Hardness	≤ 100 ppm (part per million)
Carbon filter	Hardness	≤ 100 ppm (part per million)
Softeners	Hardness	≤ 1 ppm (part per million)
	Chlorine	≤ 0.5 mg/L.
Osmosis output	Pseudomonas	Absent
	Total Coliforms	Absent
	E. Coli	Absent
	Total Aerobic Mesophilic Count	20 UFC (Colony Forming Units)

Frequency:

The control of residual chlorine and hardness is carried out daily twice a day by the Quality department. The samples analyzed are taken and verified periodically during the process by the operators of the treatment plant, the osmosis system if any nonconformity occurs. Immediately to the operator to adjust the ranges. The microbiological analysis of the water is carried out weekly. The sample is sent to the Garcia and Garcia laboratory, a laboratory approved by the company as a qualified supplier, monthly samples are sent to the Agrobiotek laboratory, accredited laboratory and approved by the company as a provider for these services. The microorganisms that are determined from the sample of water taken are: Microorganisms of Aerobic Mesophilic Count, Total Coliform Count, Total E. coli Count and presence of Pseudomona to eruginosa.

Corrective Measures:

If the chlorine test results show parameters outside the established limits, the following measures should be taken immediately:

- ✓ Stop production immediately
- ✓ Notify maintenance
- ✓ Restore water potability at established levels

In the event that the results of the indicated microbiological analyzes are not satisfactory with respect to the established standards, the Maintenance supervisor will be notified so that the source of contamination is determined and corrected. Together with the Quality and Environment Department for recommendations and adjustments.

All corrective action must be documented on the correspondingrecord sheet.

- Requirements:

The water supply must be sufficient for the different processoperations.
The water that is destined to have direct contact with the eggs or with the surfaces that have contact with the raw material must betreated and of adequate sanitary quality according to the currentnorms of the country (NORDOM).

The supply of pressurized water must be satisfactory for those areasthat require it for food processing, washing equipment and utensils, washing surfaces and for sanitary facilities.

- **Facilities:**

The pipes that carry the drinking water are in optimal maintenance conditions so that they do not become a source of contamination inthe production process. The pipes are measured in a way that ensures they can supply the water flow required by the different process operations.

Process Water Treatment System.

The process begins with the extraction of water from the subsoil by means of submerged pumps, it meets the required protection and safety, the safety controls of this well are managed by the department of environmental and physical security of the company in order to guarantee The integrity of this process.

From this point it passes to the tinacos which send water to the sand filters for the process of elimination of impurities, Carbon filter for the elimination of odors by the softeners where the minerals and solids of a water coming from the subsoil are removed . Required hardness of this point less than 100 ppm.

Then the flow of water is passed through the ultra violet lamp which has a capacity of 100 gallons per minute and with which a preventive control of the elements is changed every year and a preventive maintenance program followed by inspection by the operator of the treatment plant daily ensuring that it is working properly.

In the same flow, chlorine is injected with the purpose of maintaining the microbial stability of water, this concentration of chlorine is measured at this point which should be maintained between 1.5 to 3mg / L. Chlorine, goes to the storage tank or cistern.

After resting the water in the cistern and performing the corresponding analyzes, it passes to the reverse osmosis process where again the water is filtered by sand filters, carbon filters and subjected to the softener process again, the treated water is deposited in water tanks. a plastic material with capacity for xx gallons. According to the process demand by means of pumps It is taken to the ultra violet lamp pipe of the osmosis system which has a capacity of 100 GPM (gallons per minute), at this point it is sought to eliminate the possible pathogenic microorganisms that survived the process of water treatment.

The operators of the pre-treatment and osmosis systems make sure to record all the information in the daily osmosis water control format PE-CAL-GB-02 / R C08

The input water to the plant must meet the hardness parameters of maximum 1ppm hardness, zero residual chlorine, presence of absentpathogenic microorganisms.

- **Monitoring Plan Procedure**

Goal

Ensure compliance with all preventive controls determined in the safety plan.

Scope

Applies to all stages of manufacturing cookies process.

Responsibilities

It is the responsibility of the safety leader, verification of the records or monitoring of preventive controls, as well as implementing the required corrective actions.

Determination of Verification Procedures in the Manufacture of Cookies

This procedure applies to Ingredients that require control applied to the supply chain.

- Cookie Process Control Verification (Cooking)

- Sanitation Verification

- Allergen Control Verification

Verification Records

The Quality Coordinator keeps verification records safeguarded.

Verification Records	***Location***
Cookie Cooking Validation Study	Study included in the Food Safety Plan
Verification of Monitoring and Corrective Measure	Quality Planning Procedure and Quality Objectives
Calibration of monitoring and verification instruments	Procedure Calibration of equipment and instrument calibration.
Product Testing	Laboratory analysis record
Environmental monitoring	Procedure Preventive controls Sanitation. (See Annex)
Supply Chain Program	The procedures include preventive supply chain controls within the food safety plan. The raw material reception record is kept in the laboratory. The Coord. Quality maintains the results of audit providers
Training	It is saved in the Human Management files
Water Control	The records are kept in the laboratory
Allergen control	Allergen Preventive Control Procedure,
	Forms in Annexes

3. On site Audit Results

On May 12, 2021, we received Ingrid Garcia, auditor of the company NSF International who carried out a food safety audit. We only obtained 9 minor nonconformities. In the last 2020 audit, they detected 17 minor non-conformities. Attached the email you can find the audit report. We are working on adapting to all food safety requirements

AgroBioTek AEBT DOMINICANA

Calle Santiago, No. 608. Altos de
Gazcue. Santo Domingo, D. N.,
República Dominicana. 809-221-5751.

Laboratory Analysis Results Report

General Data of the Sample

Sampling Date: 11/11/2021
Reception Date 11/11/2021
Analysis Date: 11/11/2021
Date of Issue: 19/11/2021

Sampling Time: 09:00 am
Reception Time: 04:00 pm
Sample Taken Byr: Deybi del Jesús
Report Code: 21-S-2390

Client Data

Client: Grupo Bocel/Molinos Va le d Gbao Address:
Ave. Duarte Km.5 1/2 Santiago

Phone: 809-583-3286
Location
Galletas

CÓDIGO	NOMBRE	CONDICIÓN/HORA DE INICIO LABORES	PARÁMETROS	RESULTADOS	UNIDADES	LÍMITES PERMITIDOS	NORMA MÉTODO	CONDICIÓN
21-S-2390-1	Lot: 279212	With Heat Treatment	Staphylococcus aureus	Absent	Absence Presence1gr	Presence - Absence	GsR, 07	Ausencia
			E. coli	Absent	Absence Presence/1gr	Presence - Absence	GsR, 04	AAbsent
			HYeast	0.0	UFC/gr	: <= 2.0 x 10²	GsR, 14	Fit
			Total Coliforms	Absent	Presence -Absence/gr	Presence - Absence	GsR, 04	Fit
			Count of microorganisms in sample	80.0	UFC/gr	: < 1.0 x 10³	GsR, 05	Fit

The collection and preservation of the sample were carried out in accordance with "GT-IT-001

Última Línea

Observations

This is a partial result of report 21 S 2390

The results presented apply only to the samples taken and identified on request.

Claudio Innocenti

AgroBioTek AEBT DOMINICANA

Calle Santiago, No. 608. Altos de Gazcue. Santo Domingo, D. N., República Dominicana. 809-221-5751.

ECA. Laboratorio de Ensayo Alcance de Acreditación N° LE-155 Acreditado a partir del 2020.07.29 Alcance disponible en www.eca.or.cr

Laboratory Analysis Results Report

General Data of the Sample

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Reception Date 11/11/2021 — Reception Time: 04:00 pm

Analysis Date: 11/11/2021 — Sample Taken Byr: Oey - del Jesús

Date of Issue: 19/11/2021 — Report Code: 21-S-2390

Client Data

Client: Grupo Bocel/Molinos Va le d Gbao — Phone: 809-583-3286

Address: Ave. Duarte Km.5 1/2 Santiago — Location: Galletas

CÓDIGO	NOMBRE	CONDICIÓN/HORA DE INICIO LABORES	PARÁMETROS	RESULTADOS	LI	LS	UNIDADES	LÍMITES PERMITIDOS	NORMA, MÉTODO	CONDICIÓN
21-S-2390-12	Process Water	Potable	Count aerobic mesophilic microorganisms (*)	0.0	-	-	UFC/ 1mL	<= 2.0 x 10^2	A, 05	Fit
			E. coli(*)	Absent	-	-	100 mL	Presence/ Absence	A, 01	Fit
			Pseudomonas aeruginosa(*)	Absent	-	-	100 mL	Presence/ Absence	A, 26	Fit
			Total de Coliformes(*) < 1.0		0.92	1.08	NMP/100 mL	: <=1.1	A, 01	Fit

The collection and preservation of the sample were carried out in accordance with *GT-IT-001

Last Line

Claudio Innocenti

AgroBioTek
AEBT
NA
Calle Santiago, No. 608. Altos de
Gazcue. Santo Domingo, D. N.,
República Dominicana. 809-221-5751.

Laboratory Analysis Results Report

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Address: Ave. Duarte Km.5 1/2 Santiago

Phone: 809-583-3286
Location: Galletas

CÓDIGO	NOMBRE	CONDICIÓN/HORA DE INICIO LABORES	PARÁMETROS	RESULTADOS	UNIDADES	LÍMITES PERMITIDOS	NORMA, MÉTODO	CONDICIÓN
21-S-2390-5	line 7 carrier canvas	Direct contact with food - In use	Salmonella	Absent	UFC/cm2	Presence - Absent	AI, 48	Absent

The collection and preservation of the sample were carried out in accordance with "GT-IT-001

Last Line

Observations

This is a partial result of report 21 S 2390

The results presentedlapply only to the samples taken and identified on request.

Métodos

Claudio Innocenti

AgroBioTek ABT DOMINICANA

Calle Santiago, No. 608. Altos de
Gazcue. Santo Domingo, D. N.,
República Dominicana. 809-221-5751.

Laboratory Analysis Results Report

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Sample Taken Byr: Dey - del Jesús
Date of Issue: 19/11/2021
Report Code: 21-S-2390

Client Data

Client: Grupo Bocel/Molinos Va le d Gbao
Phone: 809-583-3286
Address: Ave. Duarte Km.5 1/2 Santiago
Location
Galletas

CÓDIGO	NOMBRE	CONDICIÓN/HORAD E INICIO LABORES	PARÁMETROS	RESULTADOS	UNIDADES	LÍMITES PERMITIDOS	NORMA, MÉTODO	CONDICIÓN
21-S-2390-4	Lot: 315213	With heat treatment	Staphylococcus aureus	Absent	/GR	Presence / Absence	GcR, 07	Absent
			E. coli	0.0	UFC/gr	: <= 10.0	GcR, 04	Fit
			Hongos y Levaduras	0.0	UFC/gr	: <= 2.0 x 10^2	GcR, 14	Fit
			Total de Coliformes	0.0	UFC/gr	: <= 10.0	GcR, 04	Fit
			Count aerobic mesophilic microorganisms	40.0	UFC/gr	<= 1.0 x 10^3	GcR, 05	Fit

The collection and preservation of the sample were carried out in accordance with "GT-IT-001

Last Line

Observations

This is a partial result of report 21 S 2390

The results presented apply only to the samples taken and identified on request.

Claudio Innocenti

AgroBioTek
DOMINICANA

Calle Santiago, No. 608. Altos de
Gazcue. Santo Domingo, D. N.,
República Dominicana. 809-221-5751.

Laboratory Analysis Results Report

General Data of the Sample

Sampling date: 11/11/2021
Reception Date 11/11/2021
Analysis Date: 11/11/2021
Date of Issue: 19/11/2021

Sampling Time: 09:00 am
Reception Time: 04:00 pm
Sample Taken Byr: Oey - del Jesús
Report Code: 21-S-2390

Client Data

Client: Grupo Bocel/Molinos Va le d Gbao
Address: Ave. Duarte Km.5 1/2 Santiago

Phone: 809-583-3286
Location: Galletas

CÓDIGO	NOMBRE	CONDICIÓN/HORA DE INICIO LABORES	PARÁMETROS	RESULTADOS	UNIDADES	LÍMITES PERMITIDOS	NORMA, MÉTODO	CONDICIÓN
21-S-2390-3	Lot: 315211	With heat treatment:	Staphylococcus aureus	Absent:	/1gr	Presence - Absence	GsR, 07	Absent:
			E. coli	Absent:	1gr	Presence - Absence	GsR, 04	Absent:
			Fungi-Ycast:	0.0	UFC/gr	Apto: <= 2.0 x 10^2	GsR, 14	Fit:
			Total Coliformes	Ausencia	Ausencia-Presencia/gr	Presencia - Ausencia	GsR, 04	Fit:
			Count: acrobic mesophilic microorganisms	70.0	UFC/gr	Apta: < 1.0 x 10^3	GsR, 05	Fit:

The collection and preservation of the sample were carried out in accordance with "GT-IT-001

Last Line

Observations

This is a partial result of report 21 S 2390

The results presented apply only to the samples taken and identification request.

Claudio Innocenti

5. Recall Plan

- **Recall Procedure**

Goal

The purpose of this procedure is to describe the activities to be carried out in order to collect, in a coordinated and rapid manner, a product from the market that may involve potential damage to the final consumer.

Scope

This procedure is applied to all products produced by the company Molinos Valle del Cibao, Division of Crackers and Biscuits evaluated as dangerous products for public health, which can be found in their own warehouses, in transport or in customer warehouses

References:

Revised Recommended International Code of Practice - general principles of food hygiene CAC / RCP 1-1969, Rev. 3 (1997), Adm. 1 (1999)

Terms and Definition:

Traceability: the ability to follow the history, application or location of a product. It is related to the origin of the materials, the process history and its distribution.

Labeling: the placement of a label or sign with the intention of indicating content, object, destination or address.

Lot: the amount of product produced in essentially equal conditions.

Innocuous: Guarantee that the product will not harm the consumer when it is prepared and / or consumed according to the intended use.

Non-Conforming Product: Product that does not meet the specifications and can be found as raw material, in-process product or finished product. For example: badly sealed, badly labeled, broken bags, presence of contaminants,among others.

Retirement Committee: Is responsible for directing all withdrawals of products from the market

Class I Recall - Retirement situation that corresponds to a serious emergency concerning a product that may have an immediate or long-term effect on human consumers.

Class II Recall - Priority withdrawal situation concerning a product that may be a potential danger to human or animal life or health.

Class III Recall - Retirement situation concerning a product that does not involve threats to health, but that may have serious or extended consequences in the relationship with the client or in the prestige of the company before the public opinion.

External Recall – Recall from the market of a product that has been distributed and that is beyond the direct control of the producer's organization.

Internal Retirement - Recall from the market of a product that is still under the direct control of the producer.

Retention - Retain a product, whether it is on the market, at a point in the process subsequent to manufacturing or at the shipment stage, when there is evidence of a decrease in quality or a labeling error

Responsabilities

The Quality Coordinator is responsible for ensuring compliance and implementation of this procedure.

The Retirement Team is responsible for executing all recalls of products in the market.

The Operations Management reviews and validates the implementation of this procedure, and decides together with the Retirement Team the final destinationof the products collected.

It is the responsibility of the General Manager to approve this procedure and provide necessary resources for its execution.

Development

Preliminary Product Recall Management

When the possibility of having a recall product becomes evident, the Operations Manager and the Quality Control Coordinator are immediately informed.

The Quality Control Coordination is responsible for investigating immediately, if it is a retirement situation of Class I, II, III, or of a minor one.

If the investigation confirms that the product is a risk to the health of the consumers, the coordination of quality control classifies the recall of Class I, II or III and immediately summons the Retirement Committee. From then on the Coordinator of the Committee coordinates all the retreat activities, keeping the rest of the members informed.

The Recall Committee is composed of the following positions:

- ✓ COO
- ✓ Commercial manager
- ✓ Export manager
- ✓ Logistics manager
- ✓ Quality Control Coordinator
- ✓ Accountant
- ✓ Legal Advocate
- ✓ FDA Retreat Coordinator (External Company)

The Committee in Function is defined in register Members of Committee PE-CAL- GB-03 / RC01. The Chairman of the Retirement Committee is appointed.

The Coordinator of the Retirement Committee will carry out contacts with government agencies. When a recall is reported, make sure to record the date and time of the call, and write down the name of the employee who attended.

Product Identification or Lot

Grupo Bocel maintains a codification of all its products before going on sale and through this coding system it is easier to contact an affected lot and expedite the process of withdrawal from the market.

Each production output has a sequence number per line per product with 4 digits, this corresponds to the batch number of the product, each batch

corresponds to a specific production and previously registered. The production date is assigned based on identification of the primary envelope, followed by the process line, the Julian calendar continues, followed by the shift with the expiration date and the manufacturing time. (Military time).

Labeling Finished Products; Physical Lots

Once the process of manufacturing is finished and the packaging process begins, the individual packages are labeled as follows:

SPC	***1***	***352***	***16***	***2***	***Exp. Dec. /17/17***	***21:21***
Wrapping id	Production Line	Julian Day	Year of Manufacture	Turn	Expiration Date	Military time of Manufacture

Multipacks are labeled as follows:

MPA	***2***	***352***	***16***	***2***	***Exp. Dec. /17/17***	***21:21***
Wrapping id	Production Line	Julian Day	Year of Manufacture	Turn	Expiration Date	Military time of Manufacture

The labeling of multipacks is used only with laminate paper, not transparentpaper.

Cookie/cracker dispensers and corrugated materials are labeled as follows:EX:

2	***352***	***16***	***2***	***Exp. Dec. /17/17***
Production Line	Julian Day	Year of Manufacture	Turn	Expiration Date

The packaging operator registers the lot of the multipack and/or dispenser in the Packaging Process Control Form PE-PRO-GB-01/RC10.

When a product collection is presented, the identification codes and the manufacturing dates of the suspect product batch are determined.

The primary packaging, secondary packaging and box are described according to what corresponds.

Recall Products Stages

The batch tracking exercise is carried out, generating Batch Traceability Report available in the company's system, to obtain evidence of the state of all the components used to manufacture the batch of product under study. A report is presented of all the clients to whom the batch of the affected product wassent.

In addition to the Batch Traceability Report, the following activities are carried out in the following stages

Stage 1

Generate Batch Traceability Report. Responsible: Quality Coordinator

- Generate Results of Laboratory of Ingredients and Finished Product. Responsible: Quality Coordinator

- Generate Production Transfer Order History Report. Responsible: Production Digitizer.

- Generate List Report Reported Orders per shift, history to confirm the quantityof product reported. Responsible: Production Digitizer.

• Generate Transfer Report, inventory transaction history report. Responsible: Production Digitizer.

• Generate Production List - Verification of Physical Production Order andprocess controls. Responsible: Production Manager.

Stage 2

• Supply Documents in dispatch related to the affected lot. Responsible:Dispatcher.

• Generate Export Picking List. Responsible: Dispatcher.

• Compare Document Customer Relationship Vs Picking List. Responsible:Quality Coordinator.

• Generate Picking List of loader container. Responsible: Dispatcher.

• Search Container Loading Form

• Compare document Customer Relationship Vs Invoice (Packing List) Responsible: Quality Coordinator.

Stage 3

• Supply Invoice and Commercial Invoice. Responsible: Export Analyst.

Stage 4

• Complete the Product Collection Form. Responsible: Quality Coordinator.

All the information is collected by the Quality Coordination, Production Management, Logistics Management and compared with production orders, laboratory reports, finished product transfers and invoices so that its accuracy can be verified before starting the withdrawal from the market. The Operations Manager analyzes the evidence and provides the conclusions of place together with the Quality Coordinator and the Retirement Committee.

- **Measures to Take**

To corroborate in compiled documents factors that attempt against the innocuousness of the product and therefore the health of our consumers, we proceed in the following way:

1) The Commercial Manager and / or Export Manager immediately informs all the places where the product was issued explaining the reasons for the withdrawal.

2) The Commercial Manager and / or Export Manager orders a "stop to sales". If the product has already reached the hands of consumers, the message is sent via communication means alerting the population not to consume the batch of this product. Through a press release:

3) The FDA Recall Coordinator is informed, which is responsible for the external notification to the appropriate regulatory entities.

4) The Retirement Committee issues instructions on how to handle the external contacts of the company, with clients, agents, media, etc.

5) A press release is issued to inform the public that a product that involves a public health problem is being recalled.

Script For Press Release:

Grupo Bocel company of Molinos Valle del Cibao. Located on the highway Duarte Santiago Licey section KM 51/2 Santiago, public awareness and alert to the population that the lot 1052182 Galletas Aviva expiration date Feb. 21 of the year 2019 is being collected by the company's own initiative, and that it contains metal particles of approximately 0.05mm and is considered a danger to the health of consumers.
Grupo Bocel committed to the health of its consumers ensures that only this aforementioned lot is affected.

- **Collection Efficiency Check to Verify That the Product Is RecalledFrom the Market**

The company ensures that the recovery of its products is progressing satisfactorily in the following ways.

- Daily follow-up to customers through phone calls or email to ensure they are managing to locate and segregate all affected material.

- Physical assistance in the premises of the clients that require it if the collection islocal.

- **Proper Food Provision**

The Quality Coordinator together with the Operations Manager will determine the destination that will be given to the affected product, depending on the danger that it represents for the health of the consumer: by the nature of our products unless it is a Class III recall for cause of printing or labeling all product collection is intended for destruction and in the case of defect of lots, sealing or similar cases will be used as animal feed.

If it is determined that the recall does not affect the health of the client and thatit has been due to a labeling problem, the product will be collected and brought to the product area in poor condition, proceeding to peel it to sell it as animal feed.

In addition If the cause of the collection is due to malpractice in the manufacturing process (non-compliance with GMP) the product is destined for animal feed giving the same previous steps of peeling.

When the cases of collection are of class 1 that can cause a potential damage to the consumer as by salmonella infestation, the presence of metals or any other element harmful to health is proceeded to the destruction of the same by means of incineration which is brought to the in the presence of the collection committee and a representative of the FDA if possible or failing to demonstrate such destruction with images that certify that this product was effectively destroyed.

The reconditioning of products will only be carried out if the deviation or cause of collection is for the tertiary or corrugated packaging, in which it is proceeded to re pack or split as the case of Recall.

- **Corrective Action in Case of Withdrawals**

When a collection occurs due to a deviation in the process or due to salmonella infestation or cross-contamination, whether chemical or physical, it is necessary that the quality coordination together with the Operations Manager proceed to a meeting with all the personnel involved in the production process where the following steps will be evaluated:

- Operation of the safety plan

- Staff training to increase the effectiveness of the implementation of the plan.

- Implement new actions to prevent the problem from recurring.

- Maintain records of the actions taken during the recall.

- After completing the recall, a review meeting is held with the retirement committee

- **Simulation or Retirement Plan**

Every year, a simulation of product collection is carried out in the market, it is called by Quality Coordination, where the members of the product recall committee meet, in the same list of customers is made, a random lot is taken of a product with an imaginary deviation of a contaminated ingredient and that was incorporated into the process or by metal contamination, it is preferred to take as an example a Class I or Class II Recall. This in order to ensure and demonstrate the ability to make a recall if necessary. This information is collected in the Product Collection Form PE-CAL-GB-03 / RC0

6. Product Label/Labeling

See attachments.

7. Qualifications

FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Ana Marlenis Siri

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

FSPCA Preventive Controls for Human Food

delivered by Lead Instructor

Mario Echandi-Bächtold

completed on
07/21/2021

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 # 3fef309c

Claudio Innocenti

8. FDA Registration

2022

CERTIFICATE OF REGISTRATION

This certifies that:

Molinos Valle del Cibao, S.A.
Carretera Duarte KM 5 1/2
Tramo Santiago Licey
Santiago de Los Caballeros, Santiago 51000
Dominican Republic

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

U.S. FDA Registration No.:	**16208278314**
U.S. Agent for FDA Communications:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

This certificate affirms that the above stated facility is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as effective by Registrar Corp as of the date hereof, and Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until December 31, 2022, unless such registration has been terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp
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info@registrarcorp.com • www.registrarcorp.com

David Lennarz
Executive Director
Registrar Corp
Dated: September 2, 2021

Preparado por:	Revisado por Gerencia:	Revisado por SGC:	Aprobado por :	Fecha de Aprobación:
Coordinador de Calidad	Gerente de Operaciones	Representante SGC	Gerente General	4/12/2018

Table of Contents

1. OBJECTIVE

Ensure that the products manufactured in the Bocel Group are free of any type of metal that could harm the health of consumers and comply with national regulations and international standards based in food safety.

2. REACH

This procedure is valid for all products manufactured in Valle del Cibao Mills, Biscuits and Biscuits Division.

3. REFERENCE

- Example of the Food Safety Preventive Controls Manual for Human.
- FDA Guidance on Hazard Analysis

4. TERMS AND DEFINITIONS:

Metals: Chemical elements capable of conducting heat and electricity, that exhibit a characteristic luster and remain in a solid state through room temperature except for mercury.

Nonferrous metals: They are metals that do not contain iron in conditions appreciable**.** The main ones are: aluminum. Copper, lead, gold, nickel, tin, Zinc.

Ferrous metal: They are the most abundant in the earth's crust, they are the metals from iron and its alloys.

5. RESPONSIBILITIES

It is the responsibility of the Quality Coordinator to monitor and guarantee the daily verification according to what is established of the proper functioning of all metal detectors installed in the company.

It is the responsibility of the Quality Inspectors to carry out the daily verifications in each shift according to the provisions of the metal detectors, noting in the records of critical control points for Metal detection and reporting any deviation that is evidenced both to the Quality coordination and to the maintenance department.

It is the responsibility of the Maintenance Manager to give Preventive maintenance to all the metal detection equipment as well as the calibration scheduling of the same in coordination with the Quality coordinator.

The Operations Manager is responsible for providing the necessary resources for the maintenance and replacement of metal detection equipment.

It is the responsibility of the General Manager to provide the necessary resources for the maintenance of Metal Detectors.

6. DEVELOPMENT

6.1 Description of Monitoring, Verification and Validation Activities

The Quality Inspector proceeds according to what is contemplated in the Food Safety Plan to document in the Critical Control Points Monitoring record the constancy of the operation of the metal detector equipment by introducing a bar containing a 7 mm ferrous metal, non-ferrous from 6.5 mm and 7.5 mm stainless steel. . This operation is carried out every hour of production.

In this process the metal detector reacts by removing the mass from the conveyor belt and emitting a sound which is an alert that there is the presence of a metal.

The verification is done by passing through or passing a cylinder with the metals Ferrous, non-ferrous and stainless steel. inside the Metal Detector inside the mass placing it on the Feeding Mat in a vertical position,
the same for the finished product inside the Display.

In this process the metal detector reacts by removing the mass from the conveyor belt and emitting a sound which is an alert that there is the presence of a metal.

The Quality Inspector together with the operator on duty proceeds to remove the cylinder or test object from the mass or secondary packaging, noting on the Monitoring of Critical control points Inspection of Metals PE-SGC-02 / RC15 record sheet that the equipment is working properly.

If this sound is not emitted and the line does not reject the mass or the Display, proceed to stop the process and write down on the report sheet Corrective Actions Form OPG 8.7 / RC0.

This procedure must be performed every hour on all lines with a Metal Detector Installed.

6.2 Taking Corrective Actions in Case of Deviation.

- The Quality Inspector must stop the process immediately
- A held placard is attached to everything produced since the last inspection of the metal detector that has been operating satisfactorily.

- Maintenance is notified for its commissioning, repair and operation of the Metal Detector.

The Quality Inspector makes a non-conformity report for the quantity of product produced in this period before monitoring and all production is destined for confiscation.

Images of rods with Ferrous, NON-Ferrous and Stainless Steel metals to monitor the proper functioning of Metal detectors.

BOCEL GRUPO COPIA NO CONTROLADA

7. RECORDS

Code of document	Document name	Period of Conservation	Responsible)
PE-SGC-02 / RC15	*Critical Control Points Monitoring*	*3 years*	*Coordinator of Quality*
PE-SGC-02 / RC23	*Verification Record of Critical Quality Control Points*	*3 years*	*Coordinator of Quality*

8. ANNEXES

Annex A.- Critical Control Points Monitoring Form

Annex B.- Verification Record Critical Control Points

Annex A

Critical Control Points Monitoring Form

PE-SGC-02/RC15 REV.0	MOLINOS VALLE DEL CIBAO –DIVISION GALLETAS Y BIZCOCHOS DEPARTAMENTO CONTROL DE CALIDAD DGB MONITOREO PUNTOS CRITICOS DE CONTROL	BOCEL

PCC2	Limites Críticos			Monitoreo
	Producto	Rango de Aceptabilidad	Cómo	
Inspección de Metales Línea 1	Todos los productos de Línea 1	Cero Tolerancia	Pasando Metal por el Equipo	Cada Hora

Fecha	Producto	Hora	PCC: Detector de Metales Funcionado SI/NO	Acción Correctiva	Monitoreado por Operador	Verificación Inspector de Calidad

INSPECTOR DE CALIDAD: _____ **COORDINADOR DE CALIDAD**_____

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Annex B

Verification Record at Critical Control Points

PE-SGC-02 / RC23 REV.0	MOLINOS VALLE DEL CIBAO - COOKIES AND BISCUIT DIVISION QUALITY CONTROL DEPARTMENT RECORD VERIFICATION AT CRITICAL CONTROL POINTS				BOCEL GRUPO
Process Step PCC	PCC verification				
	WHO	WHAT	HOUR	WHAT	RESULT
Verified: _____ DATE: _____					

9. CHANGE CONTROL

Rev.	Date	Nature of the change:	Approved by:
0	12/03/2018	Procedure creation	

SUPPLIER QUESTIONNAIRE

for

U.S. IMPORT ENTRY

UNDER FSVP

OVERVIEW *of* REGULATIONS

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

INSTRUCTIONS

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

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

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

Method Two: upload completed questionnaire to USA's **ShareFile**

CONFIDENTIALITY

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

CONTACT

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

GENERAL INFORMATION

Company Name: MOLINOS VALLE DEL CIBAO S.A Today's Date: 11/24/2021

Factory Address: CARRETERA DUARTE KM. 5.5 TRAMO SANTIAGO DOMINICAN REPUBLIC

City: SANTIAGO Province: SANTIAGO Country: DOMINICAN REPUBLIC

Office Address: CARRETERA DUARTE KM. 5.5 TRAMO SANTIAGO DOMINICAN REPUBLIC

City: SANTIAGO Province: SANTIAGO Country: DOMINICAN REPUBLIC

FDA Registration No.: 16208278314 DUNS No.:

FDA Establishment Id.: 12123 Phone No.: 8093370444

QC/QA's Name: CLAUDIA PANTALEON E-mail: CPANTALEON@GRUPOBOCEL.COM

SUPPLIER CLASS

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

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

RESPONSIBILIE *for* HAZARD CONTROLS

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

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

PRODUCTS SUPPLIED

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

No. 01, Product Name: SODA CRACKERS (F-O5) Product Code: 03 F 05

No. 02, Product Name: SALTED CRACKERS (F-06) Product Code: 03 F 06

No. 03, Product Name: CRACKERS (NON FILLED) N.E.C (F-99) Product Code: 03 F 99

No. 04, Product Name: BISCUIT (A-03) Product Code: 03 A03

No. 05, Product Name: COOKIE, BISCUIT, WAFER DOUGH.N.E.C (M-99 Product Code: 03 M 99

No. 06, Product Name: Product Code:

Resources FDA Product Codes and Product Code Builder

Claudio Innocenti

FDA–IDENTIFIED BIOLOGICAL HAZARDS

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

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

Resources  Appendix 1  Description *of* Hazard  Bad Bug Book

CRITICAL CONTROLS *for* BIOLOGICAL HAZARDS

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

- ☒ **Heat**
- ☐ **Chemical**
- ☐ **CGMPs**
- ☐ **Testing**
- ☐ **Other**

DESCRIPTION *of* CRITICAL CONTROLS

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

START:

- Oven cabinet temperature greater than 100 degrees Celsius

Bacteria do not survive temperatures above 65 degrees Celsius

FREQUENCY *of* VALIDATION

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

START:
Monthly

U.S. FDA HAZARD PROFILE

Category Name: Fully Baked Without Filling, No Topping/Frosting
Category Number: 8
Subcategory Name: Cookies
Storage Type: Shelf- Stable

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

FDA–IDENTIFIED CHEMICAL HAZARDS

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

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

Resources  Appendix 1  Description *of* Hazard  Bad Bug Book

CRITICAL CONTROLS *for* CHEMICAL HAZARDS

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

☒ **CGMPs**

☐ **Testing**

☒ **Other**

DESCRIPTION *of* CRITICAL CONTROLS

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

START:

- Microbiological analysis to detect mycotoxins.

- The water is processed through an osmosis system before entering the production process.

- Request for certificates of analysis of the presence of non-pesticides in wheat.

FREQUENCY *of* VALIDATION

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

START: Monthly, except for the certificates of analysis of the presence of non-pesticides in wheat which are requested in each harvest of wheat used in the production of flour.

U.S. FDA HAZARD PROFILE

Category Name: Fully Baked Without Filling, No Topping/Frosting
Category Number: 8
Subcategory Name: Cookies
Storage Type: Shelf- Stable

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

FDA-IDENTIFIED ENVIROMENTAL/PROCESS HAZARDS

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

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

Resources  Appendix 1  Description *of* Hazard  Bad Bug Book

CRITICAL CONTROLS *for* ENVIROMENTAL HAZARDS

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

- ☐ **Heat**
- ☐ **Chemical**
- ☒ **CGMPs**
- ☐ **Testing**
- ☒ **Other**

DESCRIPTION *of* CRITICAL CONTROLS

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

START:

- Microbiological test to the environment.
- Fogging of the environment of areas.
- Microbiological test of compressed air.

FREQUENCY *of* VALIDATION

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

START:

Monthly.

U.S. FDA HAZARD PROFILE

Category Name: Fully Baked Without Filling, No Topping/Frosting
Category Number: 8
Subcategory Name: Cookies
Storage Type: Shelf- Stable

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

FDA-IDENTIFIED PHYSICAL HAZARDS

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

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

Resources  Appendix 1  Description *of* Hazard  Bad Bug Book

CRITICAL CONTROLS *for* PHYSICAL HAZARDS

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

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

DESCRIPTION *of* CRITICAL CONTROLS

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

START:

- Metal detector.

- Sifting of raw materials.

- Glass and plastic control program.

-Visual inspection.

FREQUENCY *of* VALIDATION

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

START:

Monthly. In the case of hourly metal detectors

U.S. FDA HAZARD PROFILE

Category Name: Fully Baked Without Filling, No Topping/Frosting
Category Number: 8
Subcategory Name: Cookies
Storage Type: Shelf- Stable

Metal detection standards

Ferrous: 3 mm

Non-Ferrous: 3 mm

Stainless Steel: 3 mm

Resource U.S. FDA

Hazard Profile – *Appendix 1*

ALLERGEN & CROSS-CONTAMINATION CONTROLS

Component *or* Ingredient	Present in *product?*	Present on *same equipment?*	Present in *same facility?*
Peanuts	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Tree Nuts	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Milk *or* Milk Derivatives	☒ Yes ☐ No	☒ Yes ☐ No	☒ Yes ☐ No
Egg *or* Egg Products	☐ Yes ☒ No	☐ Yes ☒ No	☒ Yes ☐ No
Fish	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Shellfish	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Soy	☒ Yes ☐ No	☒ Yes ☐ No	☒ Yes ☐ No
Gluten	☒ Yes ☐ No	☒ Yes ☐ No	☒ Yes ☐ No
Wheat	☒ Yes ☐ No	☒ Yes ☐ No	☒ Yes ☐ No
Sesame	☐ Yes ☒ No	☒ Yes ☐ No	☒ Yes ☐ No
Celery	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Mustard	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Sulfates	☐ Yes ☒ No	☐ Yes ☒ No	☒ Yes ☐ No
Monosodium Glutamate	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Colorings	☐ Yes ☒ No	☐ Yes ☒ No	☒ Yes ☐ No
Aflatoxins	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
ALL ALLERGENS	☐ **Absent**	☐ **Absent**	☐ **Absent**

DESCRIPTION *of* ALLERGENIC CONTROLS

- Identification and segregation in warehouses and on the production line.
- Weigh ingredients separately.
- Separation of cleaning utensils.
- Area intended for cleaning allergens.
- Declaration of allergens on packaging.

ONSITE AUDITING INFORMATION

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

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

What standard is the GFSI certification? _____

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

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

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

4. Does the site undergo process audits? ☒ Yes ☐ No

CLEANING INFORMATION

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

Does the site have a designated hygiene team? ☒ Yes ☐ No

Are all cleaning staff formally trained? ☒ Yes ☐ No

Do the cleaning schedules include: Chemicals used? ☒ Yes ☐ No

Concentration levels? ☒ Yes ☐ No

Dilution method? ☒ Yes ☐ No

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

- Neutral detergent.
- Chlorinated alkaline detergent.
- Quaternary ammonium.

STAFF HYGIENE INFORMATION

Have all staff undergone formal food hygiene training? ☒ Yes ☐ No

In-house hygiene training? ☒ Yes ☐ No

Accredited hygiene training? ☒ Yes ☐ No

Training level certification obtained: _____

Are staff issued protective clothing? ☒ Yes ☐ No

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

Are adequate toilet and hand washing facilities provided? ☒ Yes ☐ No

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

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

PEST CONTROL

Is a pest control contractor employed? ☑ Yes ☐ No

If yes, please provide: Name of contractor used: FUMICOSMO SRL

Number of yearly visits: 24

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

HACCP & TACCP & VACCP

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

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

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

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

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

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

Are records maintained for all CCPs? ☑ Yes ☐ No

Does the HACCP system include the following:

- Sieving of ingredients? ☑ Yes ☐ No
- Sieving of finished products? ☑ Yes ☐ No
- Glass & hard plastic breakage procedure? ☑ Yes ☐ No
- Metal detection of final product? ☑ Yes ☐ No
- Magnets within the mixing & filling stages? ☐ Yes ☑ No

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

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

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

Please provide details: _____

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

Please provide details: _____

TRACEABILITY

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

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

Claudio Innocenti

RAW MATERIAL

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

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

Are raw materials positively released before use? ☑ Yes ☐ No

Please describe your supplier approval system:

1. The purchasing department coordinates the hygiene inspections of establishments.
2. The quality coordinator performs the inspection.
3. If the facilities meet 85% or more the safety requirements, it can enter the system.

FINISHED / PACKED PRODUCT

Are finished / packed products positively released? ☑ Yes ☐ No

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

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

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

Once a month 3 samples of finished product are sent to an accredited laboratory.

CUSTOMER COMPLAINTS

Does a formal customer complaint procedure exist? ☑ Yes ☐ No

Please describe your customer complaint procedure.

1. The client proceeds to complete the complaint form, filling in all the requested information (batch, find, photo of the product). Send document to sales representative.
2. Form is sent to quality coordinator to initiate investigation.
3. The quality coordinator responds to the customer or sales representative with the complaint response form

RECALL / IMPORT ALERT /FOOD SAFETY ISSUE

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

If yes, please describe fully.

CERTIFICATION

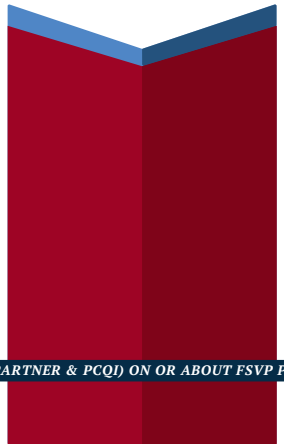
I certify that the information I provided on and in connection with this form is true, accurate and complete. I also understand that any false statements or deliberate omissions on this document or any other document I file with United Safety Agents, LLC may be grounds for disqualification from successful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

CONFIRMATION – REQUIRED

Representative's Name: CLAUDIA PANTALEON

Title: PLANNING DIRECTOR

Today's Date: 12/3/21



ALCHEM
ALTOL CHEMICAL ENVIRONMENTAL LABORATORY INC.

ALTOL

JOB NO:
RD-LAB-210396

CHAIN OF CUSTODY NO:
5658

SAMPLING DATE
02/25/2021

RESULTS ISSUE DATE:
03/04/2021

ANALYSIS REPORT

CORRESPONDING TO THE QUOTE No .: 11781

MOLINOS VALLE DEL CIBAO, SA (GALLETAS)

ALTOL DOMINICANA S.R.L. Empresa Certificada ISO 9001

ALTOL PETROLEUM PRODUCTS SERVICES DOMINICANA, SRL.
Calle Pablo Pumarol No.2, Corner Nicolás Ureña de Mendoza,
Los Prados Sector, Santo Domingo, Dominican Republic TEL:
809-566-5002, MOBILE: 829-659-9872 / 809-390-8240
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Claudio Innocenti

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ANALYSIS REPORT

CLIENT: MOLINOS VALLE DEL CIBAO, SA (GALLETAS)
CONTACT: MS. ANA SIRI
ADDRESS: CARRETERA DUARTE KM 5 1/2 SANTIAGO-LICEY SANTIAGO REP. SUN.
JOB NO: RD-LAB-210396
CHAIN OF CUSTODY No .: 5658
SAMPLE NO .: 50763
SAMPLE MATRIX: SEDIMENTATION ENVIRONMENT

TYPE OF SAMPLE: DIRECT
DATE AND TIME OF SAMPLING: 02/25/2021 11:04
SAMPLE COLLECTED BY: VICTOR CANARIO
DATE AND TIME OF RECEIPT: 02/25/2021 17:00
SAMPLE RECEIVED BY: ALBERT LEAL
RECEPTION TEMPERATURE: DATE 6.2 ° C
OF ANALYSIS: 03/02/2021

SAMPLE DESCRIPTION: LINE 7 AMBIENT
REPORT DATE: 03/04/2021

PARAMETER	METHOD / TECHNIQUE	UNIT	LDM	RESULT	PERMISSIBLE LIMITS Min - Max	ANALYST
Molds and Yeasts (CFU / 30 min)	Sedimentation Methods 3.71, Chapter 3.	CFU / 30 min	-	28	- -	DD

End of parameters for this sample

COMMENTS:

LDM: Limit of Detection Method | NE: Not Specified | ND: Not Detected | LP: Permitted Limit | MIN: Minimum | MAX: Maximum

ALBERT LEAL
LABORATORY ANALYST

DORALIZA GARCIA
QA

SHARON LUGO
LABORATORY MANAGER

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

CONFIDENTIAL TREATMENT REQUESTED

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ANALYSIS REPORT

CLIENT: MOLINOS VALLE DEL CIBAO, SA (GALLETAS)
CONTACT: MS. ANA SIRI
ADDRESS: CARRETERA DUARTE KM 5 1/2 SANTIAGO-LICEY SANTIAGO REP. SUN.
JOB NO: RD-LAB-210396
CHAIN OF CUSTODY No .: 5658
SAMPLE NO .: 50765
SAMPLE MATRIX: SURFACE SWABISHED SURFACE

TYPE OF SAMPLE: DIRECT
DATE AND TIME OF SAMPLING: 02/25/2021 11:10
SAMPLE COLLECTED BY: VICTOR CANARIO
DATE AND TIME OF RECEIPT: 02/25/2021 17:00
SAMPLE RECEIVED BY: ALBERT LEAL
RECEPTION TEMPERATURE: DATE 6.2 ° C
OF ANALYSIS: 02/27/2021

SAMPLE DESCRIPTION: LEIFI LOPEZ (LINE 7)
REPORT DATE: 03/04/2021

PARAMETER	METHOD / TECHNIQUE	UNIT	LDM	RESULT	PERMISSIBLE LIMITS Min - Max	ANALYST
Total Coliforms	Swab Contact Method 3.51, Chapter 3.	CFU / Surface	-	<5	<10	TO THE
E.coli	Swab Contact Method 3.51, Chapter 3.	CFU / Surface	-	<5	Absence (<5.0 CFU / Surface)	TO THE

End of parameters for this sample

COMMENTS:

"The results for the analyzed and Norman parameters produced by this sample are within the limits recommended by The Technical Guide for the Microbiological Analysis of Surfaces in Contact with Food and Beverages"

Values reported for E.coli (<5 CFU / surface) in analytical operations, these values are indicators of absence.

Values indicated with less than (<) express the minimum reading range according to the technique performed without observing growth of colony-forming units on the plate, for the evaluated microorganism.

LDM: Limit of Detection Method | NE: Not Specified | ND: Not Detected | LP: Permitted Limit | MIN: Minimum | MAX: Maximum

ALBERT LEAL
LABORATORY ANALYST

DORALIZA GARCIA
QA

SHARON LUGO
LABORATORY MANAGER

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ANALYSIS REPORT

CLIENT: MOLINOS VALLE DEL CIBAO, SA (GALLETAS)
CONTACT: MS. ANA SIRI
ADDRESS: CARRETERA DUARTE KM 5 1/2 SANTIAGO-LICEY SANTIAGO REP. SUN.
JOB NO: RD-LAB-210396
CHAIN OF CUSTODY No .: 5658
SAMPLE NO .: 50766
SAMPLE MATRIX: SURFACE SWABISHED SURFACE

TYPE OF SAMPLE: DIRECT
DATE AND TIME OF SAMPLING: 02/25/2021 11:12 AM
SAMPLE COLLECTED BY: VICTOR CANARIO
DATE AND TIME OF RECEIPT: 02/25/2021 17:00
SAMPLE RECEIVED BY: ALBERT LEAL
RECEPTION TEMPERATURE: DATE OF ANALYSIS: 6.2 ° C / 02/27/2021

SAMPLE DESCRIPTION: POL GARCIA GARCIA (LINE 7)
REPORT DATE: 03/04/2021

PARAMETER	METHOD / TECHNIQUE	UNIT	LDM	RESULT	PERMISSIBLE LIMITS Min - Max	ANALYST
Total Coliforms	Swab Contact Method 3.51, Chapter 3.	CFU / Surface	-	<5	<10	TO THE
E.coli	Swab Contact Method 3.51, Chapter 3.	CFU / Surface	-	<5	Absence (<5.0 CFU / Surface)	TO THE

End of parameters for this sample

COMMENTS:

"The results for the analyzed and Norman parameters produced by this sample are within the limits recommended by The Technical Guide for the Microbiological Analysis of Surfaces in Contact with Food and Beverages"

Values reported for E.coli (<5 CFU / surface) in analytical operations, these values are indicators of absence.

Values indicated with less than (<) express the minimum reading range according to the technique performed without observing growth of colony-forming units on the plate, for the evaluated microorganism.

LDM: Limit of Detection Method | NE: Not Specified | ND: Not Detected | LP: Permitted Limit | MIN: Minimum | MAX: Maximum

ALBERT LEAL
LABORATORY ANALYST

DORALIZA GARCIA
QA

SHARON LUGO
LABORATORY MANAGER

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

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ANALYSIS REPORT

CLIENT: MOLINOS VALLE DEL CIBAO, SA (GALLETAS)
CONTACT: MS. ANA SIRI
ADDRESS: CARRETERA DUARTE KM 5 1/2 SANTIAGO-LICEY SANTIAGO REP. SUN.
JOB NO: RD-LAB-210396
CHAIN OF CUSTODY No .: 5658
SAMPLE NO .: 50767
SAMPLE MATRIX: SURFACE SWABISHED SURFACE

TYPE OF SAMPLE: DIRECT
DATE AND TIME OF SAMPLING: 02/25/2021 11:14 AM
SAMPLE COLLECTED BY: VICTOR CANARIO
DATE AND TIME OF RECEIPT: 02/25/2021 17:00
SAMPLE RECEIVED BY: ALBERT LEAL
RECEPTION TEMPERATURE: DATE OF ANALYSIS: 6.2 ° C / 02/27/2021

SAMPLE DESCRIPTION: ANGEL PIMENTEL (LINE 7)
REPORT DATE: 03/04/2021

PARAMETER	METHOD / TECHNIQUE	UNIT	LDM	RESULT	PERMISSIBLE LIMITS Min - Max	ANALYST
Total Coliforms	Swab Contact Method 3.51, Chapter 3.	CFU / Surface	-	<5	<10	TO THE
E.coli	Swab Contact Method 3.51, Chapter 3.	CFU / Surface	-	<5	Absence (<5.0 CFU / Surface)	TO THE

End of parameters for this sample

COMMENTS:

"The results for the analyzed and Norman parameters produced by this sample are within the limits recommended by The Technical Guide for the Microbiological Analysis of Surfaces in Contact with Food and Beverages"

Values reported for E.coli (<5 CFU / surface) in analytical operations, these values are indicators of absence.

Values indicated with less than (<) express the minimum reading range according to the technique performed without observing growth of colony-forming units on the plate, for the evaluated microorganism.

LDM: Limit of Detection Method | NE: Not Specified | ND: Not Detected | LP: Permitted Limit | MIN: Minimum | MAX: Maximum

ALBERT LEAL
LABORATORY ANALYST

DORALIZA GARCIA
QA

SHARON LUGO
LABORATORY MANAGER

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ANALYSIS REPORT

CLIENT: MOLINOS VALLE DEL CIBAO, SA (GALLETAS)
CONTACT: MS. ANA SIRI
ADDRESS: CARRETERA DUARTE KM 5 1/2 SANTIAGO-LICEY SANTIAGO REP. SUN.
JOB NO: RD-LAB-210396
CHAIN OF CUSTODY No .: 5658
SAMPLE NO .: 50768
SAMPLE MATRIX: SURFACE SWABISHED SURFACE

TYPE OF SAMPLE: DIRECT
DATE AND TIME OF SAMPLING: 02/25/2021 11:16 AM
SAMPLE COLLECTED BY: VICTOR CANARIO
DATE AND TIME OF RECEIPT: 02/25/2021 17:00
SAMPLE RECEIVED BY: ALBERT LEAL
RECEPTION TEMPERATURE: DATE OF ANALYSIS: 6.2 ° C / 02/27/2021

SAMPLE DESCRIPTION: JUAN ANTONIO VAZQUEZ (LINE 7)
REPORT DATE: 03/04/2021

PARAMETER	METHOD / TECHNIQUE	UNIT	LDM	RESULT	PERMISSIBLE LIMITS Min - Max	ANALYST
Total Coliforms	Swab Contact Method 3.51, Chapter 3.	CFU / Surface	-	<5	<10	TO THE
E.coli	Swab Contact Method 3.51, Chapter 3.	CFU / Surface	-	<5	Absence (<5.0 CFU / Surface)	TO THE

End of parameters for this sample

COMMENTS:

"The results for the analyzed and Norman parameters produced by this sample are within the limits recommended by The Technical Guide for the Microbiological Analysis of Surfaces in Contact with Food and Beverages"

Values reported for E.coli (<5 CFU / surface) in analytical operations, these values are indicators of absence.

Values indicated with less than (<) express the minimum reading range according to the technique performed without observing growth of colony-forming units on the plate, for the evaluated microorganism.

LDM: Limit of Detection Method | NE: Not Specified | ND: Not Detected | LP: Permitted Limit | MIN: Minimum | MAX: Maximum

ALBERT LEAL
LABORATORY ANALYST

DORALIZA GARCIA
QA

SHARON LUGO
LABORATORY MANAGER

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

CONFIDENTIAL TREATMENT REQUESTED

TABLE OF CONTENTS

SUMMARY

(b) (5) [redacted] This modernized cGMP and Preventive Control for Human Food inspection, covered the firm's operations and preventive control plan for Aviva (soda crackers). Draft Guidance Document "Hazard Analysis and Risk- Based Preventive Controls for Human Food: Guidance for Industry" (hazards guide) was utilized as guidance throughout the inspection. This facility manufacturer's various cookies, crackers, cupcakes, and muffins that are sold wholesale.

The current inspection focused on the firm's Food Safety Plan and Preventive Controls, it included review of the firm's Hazard Analysis, Process Controls, Sanitation Controls, Allergen Controls, Supply Chain Controls, and associated records (SOPs, monitoring records, etc.). Manufacturing operations at this facility consist of, six lines, including mixing, ovens, and packaging, the inspection focused on line 1.

No FDA 483, Observational Findings was issued. Several verbal observations were discussed with management. The following verbal items were discussed regarding the Food Safety Plan:

- The preventive control (PC) for baking critical limit was too narrow.

- The preventive control for metal was not fully completed for several months due to the metal detector breaking.
- The plan does not state how the metal verifications are being conducted.
- Corrective actions for preventive controls did not always include what will be done with the product when deviations occur.
- The ingredient hazard analysis, biological pathogens were listed but not the specific pathogens.
- Records had cross offs and white out.
- PCQI was not reviewing all PC records within 7 working days.
- Environmental program currently is collecting one swab per month they are re-evaluating.

The following items were observed in their plant as follows:

- There were belts on line 1 that were damaged. Four belts were replaced prior to close out.
- Area around new cooler area was damaged and a hole in the wall. This was repaired prior to close out.
- There were a few areas on the floor that were damaged.
- There was tape on chairs, equipment, and wires holding a bag up on line 1.
- Mesh screens that are used on the fermentation tubs were damaged and had long strings. Several were fixed prior to close out.

Management agreed with all the verbal observations and promised correction, several items were corrected prior to close out.

There were no refusals and no samples were collected.

ADMINISTRATIVE DATA

Inspected firm:	Molinos Valle del Cibao, C. por A.
Location:	Carretera Duarte Km., 1/2 Tramo 5 Santiago-Licey, Santiago, 51000 Dominican Republic (the)

Phone:	809-337-0444
FAX:	809-736-1318
Mailing address:	Carretera Duarte Km., 1/2 Tramo 5 Santiago-Licey, Norcentral, 51000 Dominican Republic (the)
Dates of inspection:	4/23/2018-4/25/2018
Days in the facility:	3
Participants:	**Rebecca L Mullikin, Investigator**

Credentials were displayed to Christian Reynoso, General Manager, Elias Morel, Operations Manager, Ana Marlenis Siri, Quality Coordinator and PCQI, Clara Abreu, Production Manager and PCQI, and Claudia Pantaleon, Planning Manager.

I discussed the Food Facility Biennial Registration; their registration is current and up to date. I provided the following handouts to management via email; Key Facts about Preventive Controls for Human Food, Final Rule FSMA Final Rule for Mitigation Strategies to Protect Food against Intentional Adulteration, Final Rule on Sanitary Transportation of Human and Animal Food, Final Rule on Preventive Controls for Animal Food, and RFR (Reportable Food Registry).

The top official at this location is Mr. Christian Reynoso, General Manager. Please send the FMD-145 and any post-inspectional correspondence to him at Carretera Durate KM., 1/2 Tramo 5, Santiago-Licey, Santiago, 51000, Dominican Republic.

HISTORY
Bocel Group owns 2 companies within in the group including:

- Molinos Valle del Cibao, C. por A. this location which is a division of cookie and cupcakes. Also part of this group is the division of Flour; this is a flour mill that sells flour throughout the Caribbean Islands and supplies flour to their plants.
- The other group is La Dominicana Industrial which is a pasta plant that is located approximately 2 KM from this plant.
- Distribution Center is located in Santo Doming La Romana.

This location operates 24/7 with 3 shifts. Office hours are 8 am to 6 pm, Monday-Friday.

There are currently 464 employees at Molinos Valle del Cibao, C. por A. Currently at Bocel Group there is approximately 1,208 employees.

Molinos Valle del Cibao, C. por A. is manufacturing in a building that was built specifically for this operation, 9 years ago with all new equipment.

INTERSTATE (I.S.) COMMERCE
Approximately 9% (1,600 tons) of product is sent to the United States of America including Puerto Rico annually. Products are shipped to Grace Kennedy Foods USA, LLC located in Moonachie, NJ and Medley, FL. Products are also shipped to Cherry Valley located in New York, Distrabdora Ferdoc, Puerto Rico, and Global Consumer located in Miami, FL. See **Exhibit 1** for a copy of the last shipment sent to Miami, FL dated 4/12/18.

Molinos Valle del Cibao, C. por A. manufacturers 100% wholesale. Approximately 72% of all their products are manufactured with their own label, the remaining is private label.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)
This firm manufactures a variety of cookies, cupcakes, muffins, and crackers. I reviewed and collected retail label for products shipped into the USA which includes their label Aviva and 3 private labels see **Exhibit 2** for an examples of product labels. A complete list of all products manufactured was collected, see **Exhibit 3**.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED
Mr. Christian Reynoso, General Manager is the most responsible person at this location; his family is part owner of the company. He was present during the opening and close out meeting. He meets with sales, corporate, resources, and weekly operations meetings to stay active in the production portion of the business.

Mr. Elias Morel, Operations Manager, reports to Mr. Reynoso. Mr. Morel is responsible for logistics, production, safety, security, and quality. He has been with the company for 10 years.

Claudia Pantaleon, Planning Manager and my translator has been with the company for over 7 years. She reports directly to Mr. Reynoso. She is responsible for purchasing orders raw material, and production planning.

Clara Abreu, Production manager and PCQI reports to Mr. Morel, she has been with the company for approximately 9 years. She oversees day to day activities in the manufacturing plant.

Ana Siri, Quality Coordinator and PCQI oversee the quality and food safety areas. She reports to Mr. Morel, she has been with the company for approximately a year.

FIRM'S TRAINING PROGRAM
All new employees receive new employee training that includes GMP, security, food defense, health & safety, chemical, and allergen training. On the job training is also conducted. Annual training is

also completed. Refresher training is conducted as needed.

There are six PCQI employees, I reviewed their certificates and training, and found no deficiencies.

I reviewed employee training records and they appeared complete and accurate.

MANUFACTURING/DESIGN OPERATIONS

This nine year old bakery that is manufacturing cookies, crackers, cupcakes, and muffins has six production lines. This inspection focused on the manufacturing of soda crackers, which are manufactured on line 1 to be exported to the United States.

I followed the process of manufacturing starting at the receiving of raw materials in the warehouse. The raw materials are then transported to the dosimetry area from here they are validated and checked for verification of ingredients and allergens per the formulation. Then all the ingredients are weighed out and transported to the mixing area. Ingredients are added, mixed, and water is added at 15°C and mixed. The vessel (vat) is transported to the fermentation room for approximately 16 hours at 25-30°C at 75-85% humidity. In this room there is screen/mesh cover that goes over the top of each vessel. There is a frame for the cover and the mesh is sewn around the frame with a plastic like thread. Some of the covers had holes and long plastic threads hanging from them. Management agreed and started to repair the covers for the vessels, prior to my close out.

After fermentation the vessels are transported to mixing at this time any remaining ingredients are added and a pH measurement is taken. The pH should be around 5.2 to 6.2. The ingredients are mixed again for a goal dough temperature of 38-48°C. The vessels are transported again to the fermentation room for another 5 hours. Then the vessels are transported to the headers where the dough is dumped into the hoper. The dough is cut into small portions and then passes through the metal detector which is PCC1.

The dough is then transported to a second hoper and then the sheeter which forms 5 layers of dough to flatten it to the desired thickness and is adjusted for the raw weight of 110-115 grams. The dough is molded if needed and salt is applied. The dough then travels a series of belts to the oven which is PCC2 with the following critical limits:

- Zone 1 of the oven the dough is baked for a CL (critical limit) of 270-280°C for 3.5 minutes.
- Zone 2 of the oven the dough is baked for a CL of 270-290°C for 3.5 minutes.

There was a belt after the oven near the oil sprayer that was damaged. Management agreed and stated it was ordered and that there were a few other belts that were damaged and were to be replaced as soon as the belts were received. Several belts were replaced prior to my close out. I also observed a lot of tape on equipment and on the legs of chairs. Management agreed that the tape should be removed to assure the area is a cleanable surface.

After the oven organoleptic testing is completed this includes sensory, texture, color, and smell. The crackers then travel on belts to cool to room temperature. The cracker a broke horizontally and then broke vertically. The cracker then enters the positioner perpendicular. They are divided 4 in 4 for

packaging and then are transferred to the packaging area, packaged, boxed, and transported to warehouse. See **Exhibit 4** for a copy of the product flow diagram.

Finish products are taken once per month on all lines for *Salmonella, E. coli*, yeast & mold, and total coliform.

Environmental monitoring is conducted throughout the plant as follows:

- Compressed air is tested monthly for yeast & mold and aerobic bacteria
- Air in the environment is tested monthly for yeast & mold and aerobic bacteria in several areas in the plant.
- Employee's hands for *E. coli* and coliforms monthly.
- One *Salmonella* species environmental swab is be taken per month. (This just started in March of 2018.)

All samples are sent to ABT (Argo Bio Tec Lab) in Santo Domingo, DR. There have been no finish product test results in the past 9 years since this plant has been opened. There have been no positives for any of the above environmental monitoring.

We discussed the possibility of increasing the amount of Salmonella species for environmental swabbing including zone 2 and zone 3 locations. During a walkthrough of the plant I showed management some areas that would be good zone 2 or zone 3 locations to conduct environmental monitoring swabs on. I also showed management the regulations in 21 CFR 117.165 (a)(3) for verification of implantation and effectiveness and 117.165 (b) (3) for more information about environmental monitoring. Management agreed and stated they would look into the regulations and their procedures.

Bocel does have an internal lab that this location uses. They conduct the pH, humidity, moisture, water activity, and the packaging sealing is adequate. They said they are looking into adding a micro lab in the future. I reviewed the lab calibrations, and no issues were noted.

This location has one well. The well water is ran through a reverse osmosis system that includes; sand filter, carbon filter, water softener, UV system, chlorine, cistern (tank), osmosis system (sand – carbon – water), UV (reverse osmosis) to the processing area. Samples are taken daily in different portions of the process. Process samples are taken 3 times a week for micro, coliforms, *E. coli*, and *Pseudomonas aeruginosa.* Preventive maintenance is conducted twice a day checks on the chlorine system.

Management informed me that water is a preventive control step for them as the water is not safe to drink in this area without proper treatment.

Pest control is conducted by an external company weekly for insects, rodents, and flies by XPERTS Pest control. I reviewed records for the past six month and found no major issues.

Hazard Analysis and Preventive

This inspection focused on the firm's food safety plan and preventive controls. I conducted a Hazard Analysis, using the Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry – Draft Guidance for crackers. The firm has conducted a Hazard Analysis and completed a Food Safety Plan and provided it for my review.

HACCP/Food Safety Plan conducted by the firm:
The focus of this inspection was on the Aviva (soda crackers). A product description of this product is a thin salted baked cracker. Processing involves mixing, forming, baking, cooling, and packing with baking as lethality step. Ingredients for this product are: wheat flour, vegetable shortening (palm), inverted sugar, whey (milk), salt, sugar, sodium bicarbonate, yeast, and enzymes (protease & amylase), and water. Intended use: Ready to eat, not intended for persons allergic to wheat or milk. Intended consumers are the general public. Labeling Instructions: Wheat and milk allergen label and storage is ambient storage.

The firm provided me with a process flow diagram, see **Exhibit 4**. Management provided me a copy of their Potential Food Safety Hazards, Process Preventive Controls: Baking PPC and Metal Detection PPC see **Exhibit 5.** Their plan has CCP and PC's at the following steps:

- PCC 1 Baking Oven 1 & Oven 2 - Hazards vegetative pathogens such as: *Salmonella, E. coli, staphylococcus aureus,* and coliforms - Critical limit of zone 1 of 270-280°C for 3.5 minutes and zone 2 of 270-290°C.

- PCC 2 - Metal Detection - hazard metal - Critical limits: zero tolerance.

Allergen Preventive Control:
o Receiving of Raw Ingredients – undeclared allergens

o During packaging of finished product – undeclared allergens – label matches product

o Allergen changeover – cross contact with allergens not in present recipe.

This product only has wheat and whey (milk). Other allergens in the plant are soy, eggs, and sesame seeds.

Supply Chain Preventive Controls Hazard Identification:
Reviewing COA for all incoming products for necessary pathogen or chemical controls is conducted. I reviewed their Supply Chain Preventive Controls Program, no major concerns were noted. Inspections of local suppliers are conducted annually. Approved supplier lists are reviewed continuously when new suppliers are added a detailed review is conducted including samples are taken by QA and a detailed questioner is completed.

I reviewed two COA's for Whey powder received from Mullin's Whey, Inc., Mosinee, WI and for flour that is received from their sister plant. Both COA's were compete and showed the incoming ingredients were free from hazards.

My ingredient hazard analysis for Aviva (soda crackers) is as follows:

- Flour – (wheat/soy) – Biological: *Bacillus cereus, pathogenic E.coli, Salmonella* and *Listeria monocytogenes*. Chemical: mycotoxin & pesticides
- Sugar - Biological: none. Chemical: unapproved colors & additives
- Vegetable Shortening (palm): Biological: *pathogenic E.coli, Salmonella* and *Listeria monocytogenes*. Chemical: none
- Whey (Milk): Biological: *Bacillus cereus, Campylobacter, pathogenic E.coli, Salmonella, Staph aureus,* and *Listeria monocytogenes*.
- Yeast: Biological: *Salmonella* Chemical: none
- Enzymes: Biological: *Salmonella* Chemical: none
- Other ingredients had no hazards and not listed

My hazard analysis for Aviva (soda crackers) (final product) **is as follows:**

- Biological: pathogenic *E.coli, Salmonella, & Staph aureus*
- Chemical: mycotoxin
- Process Related:
    - Bacterial pathogen survival of a lethal treatment - the baking step is identified as a process control.
    - Recontamination with environmental pathogens – environment monitoring is being conducted SOP/protocol was being updated.
    - Undeclared allergens – incorrect label checks
    - Undeclared allergens – cross contact – soy, milk, sesame seeds, and eggs (wheat is in all products) - this is part of their Sanitation Preventive Control.
- Metal – has metal detector as PC.

<u>Record Review</u>
I requested all preventive control and manufacturing records for the following dates: 11/27/17, 12/22/17, 1/24/18, 2/14/18, 3/30/18, and 4/13/18 for Line 1. Their food safety plan was implemented in April 2018. Some of the earlier dates of records requested did not include all the PC information.

When reviewing manufacture records I observed white out was being used and cross offs with no initials, management agreed and promised correction. Their validation of Sanitation pre-op action items were not signed off by who completed the action.

When reviewing the PCC monitoring of baking the critical limit for zone 1 is 270-280°C and zone 2 is 270-290°C. The records I reviewed had the following temperatures for zone 1: 277°C, 265°C, 268°C and zone 2: 263°C, 267°C, and 266°C. Some these temperatures were below their critical limit, which shows they have set their critical limit too narrow. Per their validation of baking it states a 100°C cook temperature must be met. The critical limit temperatures they have set are more for quality reasons not food safety. Management agreed that they need to update their critical limit and if the critical limit is not met corrective actions must be met. These records were also not signed off by PCQI.

There metal detector broke about six months ago, when they contacted the company who they purchased it from and learned they went out of business. They contacted a new company and ordered it from Switzerland. The new metal detector was in place and started verification on 4/23. I reviewed their non-conformance form for this activity of no metal detection. During this time they did run product on the other lines.

Currently the plan for metal detection doesn't say what they are doing. There normal process for checking the function of the metal detector is by placing a pen on the belt. Management agreed and stated they just got new wands and information for the new unit. They will now be testing for the following: Ferrous: 2.5 mm, Non-ferrous: 2.5 mm, and Stainless steel: 3.0 mm. They have updated their metal PCC form.

We also discussed the location of the metal detector. It is currently located after the headers where the dough is dumped into the hoper and then the dough is cut into small portions and then passes through the metal detector which is PCC1. Currently all the equipment is only 9 years old and there is not damage to any of the equipment. We talked about as the equipment gets used more there may be more of a metal hazard. Management agreed and stated they will be moving line 1 and they will reevaluate the location of the metal detector.

Some records were not reviewed by a PCQI within 7 working days. Management agreed and stated they are in process of assuring all PC documents will be signed within 7 working days.

Sanitation Preventive Controls
Cleaning and sanitizing is typically done at the end of each production day. I reviewed the SSOP's they were complete and detailed. ATP's are completed after each deep clean. Allergen test for egg and milk are completed after each use of the allergen to non-allergen use.

All chemicals are received from Diversey, who also provides training. Sanitation is also completed as needed for allergen sequencing. I reviewed SSOP's in detail and no concerns were noted. I did not observe sanitation due to the timing of sanitation schedule. Management stated that they are working on updating their sanitation records. They have a color coded schedule for the frequency of cleaning per their schedule.

Green = daily
Orange = every other day
Yellow = weekly
White = every 2 weeks
Blue = monthly
Gray = as needed

After reviewing their food safety plan and related records I did not have any major concerns. All PC/CCP records/verifications need to be completed within 7 working days. Management agreed

with all of the food safety plan verbal observations and stated they plan to have it updated by June 2018.

MANUFACTURING CODES
Manufacturing codes are applied to all packages. The same code is used for all products. An example of a manufacturing code is as follows:

SPC 1 103 18 3 EXP ABR/13/19

SPC = Single Pack machine C

1 = Line 1

103 = Julian Date

18 = year 2018

3 = third shift

EXP = expiration date

ABR = April

13 = date

19 = year 2019

COMPLAINTS
Management stated that all complaints are handled by export portion of Bocel. Complaints are received then sent to the plant to follow up on, within 48 hours. There had been no injury or illness complaints. I reviewed their Consumer complaint protocol and no concerns were noted.

There were no complaints on file with FDA regarding this firm.

RECALL PROCEDURES
The firm has a recall plan and traceability. They conduct mock recalls annually. All products can be located in less than 5 to 6 hours, however they target goal is for 4 hours. I reviewed the past mock recall documents and it no concerns were noted.

They have not been involved in any recalls.

REFUSALS
No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

A general close out meeting was held with Christian Reynoso, General Manager, Elias Morel, Operations Manager, Ana Marlenis Siri, Quality Coordinator and PCQI, Clara Abreu, Production Manager and PCQI, and Claudia Pantaleon, Planning Manager.

The following additional people were present for the close out meeting: Johaney Camil, Safety Manager, Vanessa Tineo, Internal Audit Cordienater, Yanice Lopez, Audit manager, Johanny Fabian, QC for pasta plant, Rosanny Quezada, QC for flour plant, Cristian Vargas, R &D, Karina Ortiz, Export manager, and Wilissa Pineda, Quality Management Systems.

No FDA 483, Observational Findings was issued. Several verbal observations were discussed with management. The following verbal items were discussed regarding the Food Safety Plan:

- The preventive control (PC) for baking critical limit was too narrow. We discussed that they must be meeting what the critical limit is and if it not met, corrective actions must be completed every time it is out of range. Management agreed and stated the limit they have set is more for quality standards then food safety standards. They promised correction within 2 weeks and stated their plan and records would be updated.

- The preventive control for metal was not fully completed for several months due to the metal detector breaking. During the inspection the new metal detector was in use. We discussed the location of the metal detector. It is currently after mixing dough step. Currently the oven belt is only 9 years old and will be replaced every 10 years. There is a metal risk that could be introduced after the mixing dough step with the sheeter and ovens. Management stated they will be moving the line in the near future and will reevaluate the location of the metal detector.

- The plan does not state how the metal verifications are being conducted. Currently when they are testing to the metal detectors hourly by placing a pen on the line. Management agreed and stated they will update their procedures with using different metal types and sizes.

- Corrective actions for preventive controls did not always include what will be done with the product when deviations occur. Management agreed and promised to update their plans within one month.

- The ingredient hazard analysis, biological pathogens were listed but not the specific

pathogens. Management agreed and updated their hazard analysis.

- Records had cross offs and white out; management agreed and promised correction with retraining of all employees.
- PCQI was not reviewing all PC records within 7 working days. Management agreed and promised to have all PC records reviewed within 7 working days.
- Environmental program currently is collecting one swab per month they are re-evaluating.

The following items were observed in their plant as follows:

- There were belts on line 1 that were damaged. Four belts were replaced prior to close out and more were to be replaced as soon as they were received.
- Area around new cooler area was damaged and a hole in the wall. This was repaired prior to close out.
- There were a few areas on the floor that were damaged. Management agreed and stated that they already identified these areas on their quality walk through and are on a preventive maintenance schedule to be replaced.
- There was tape on chairs, equipment, and wires holding a bag up on line 1. We discussed that all surfaces need to be a cleanable surface. Management agreed and promised correction.
- Mesh screens that are used on the fermentation tubs were damaged and had long strings. Several were fixed prior to close out and I observed several employees continuously working on fixing these screens.

Management agreed with all the verbal observations and promised correction, several items were corrected prior to close out.

EXHIBITS COLLECTED

1 Last shipment to USA, 7 pages
2 Product labels for Soda Crackers, 4 pages
3 Products manufactured per line, 2 pages
4 Process Flow diagram, 3 pages
5 Process Controls, 2 pages
6 PCC records, 3 pages

X Rebecca L Mullikin
Investigator
Signed By: Rebecca L. Mullikin -S
Date Signed: 07-20-2018 10:28:27

Certificado de participación

Quienes suscriben, certifican que:

Suprema Qualitas

Ana Marlenis Siri

Participó en el curso

HACCP - SISTEMA DE INOCUIDAD ALIMENTARIA

el cual tuvo una duración de 16 hora(s)
Del 03/07/2013 al 04/07/2013
Santo Domingo, República Dominicana
Instructor:
Biol. Rocio Salgado

Suprema Qualitas, S.R.L.
Project Manager

Registro: SQ-2358

Suprema Qualitas, S.R.L.
Gerente General

TÜV SÜD
Cert # 10-950-405
ISO 9001:2008
Sistema de Gestión de la Calidad Certificado ISO 9001:2008

5425

Molinos Valle del Cibao, S.A.

Otorga el presente certificado a

ANA MARLENIS SIRI SIRI

Por su participación en

" Curso-Taller Implementación Sistema de H.A.C.C.P "

(10 Horas)

Concedido el día 06 de Diciembre, 2016.

Santiago, República Dominicana.

Nidia Rodríguez

2015-07-00355

BOCEL®

GRUPO

United States
Department of Agriculture

Certificate of Training

This is to certify that

Ana Marlen

Has successfully completed the
USDA Preventive Controls for
Human Food For Qualified
Individual Course

2/16/2018
Date

USDA Foreign Agriculture Service Representative

AENOR

Otorga el presente

CERTIFICADO

A: **Dña. Ana Marlenis SIRI SIRI**

por haber realizado el curso:

EL ESQUEMA DE CERTIFICACIÓN FSSC 22000 v.4.1

De 7 horas de duración, impartido en República Dominicana el 23 de noviembre de 2018

Directora de Formación

AENOR

Susana LOZANO GODOY

República Dominicana, 23 de noviembre de 2018

AENOR

Otorga el presente

CERTIFICADO

A: **Dña. Ana Marlenis SIRI SIRI**

por haber realizado el curso:

LA NORMA ISO 22000 PARA LA GESTIÓN DE LA SEGURIDAD ALIMENTARIA

De 14 horas de duración, impartido en República Dominicana del 21 al 22 de noviembre de 2018

Directora de Formación

AENOR

Susana LOZANO GODOY

República Dominicana, 22 de noviembre de 2018

S2h5

Best before/Consumir antes de
Consommer avant:

Nutrition Facts / Datos de Nutrición
Données de Nutritions

Serv. Size/Tamaño de la Porción/Portion: 1
Package/Paquete/Paquet 1.06 oz (30g)
Serv. per Container/Porciones por Empaque/Teneur 9

Amount per serving/Cantidad por porción/Valeur Nutritive

Calorías/Calories 120

	%(DV)* / %(VD)* / %(VQ)*
Total Fat/Grasa Total/Graisse Totale 2.5g	**3%**
Saturated Fat/Grasa Saturada/ Grasses Saturées 1g	**6%**
Trans Fat/Grasa Trans/Graisse Trans 0g	**0%**
Cholesterol/Colesterol 0mg	**0%**
Sodium/Sodio 330mg	**14%**
Total Carb./Carb. Total/Glucides 23g	**8%**
Dietary Fiber/Fibra Dietética/Fibres Diététique 0g	**0%**
Total Sugars/Azúcares Totales/Sucre totale 1g	
Added Sugars/Azúcares Añadidos/Less than 1g/Menos de 1g	**0%**
Protein/Proteínas/Protéines 3g	
Vitamin/Vitamina/Vitamine D	0%
Calcium/Calcio	0%
Iron/Hierro/Fer	6%
Potasio/Potassium 10mg	0%

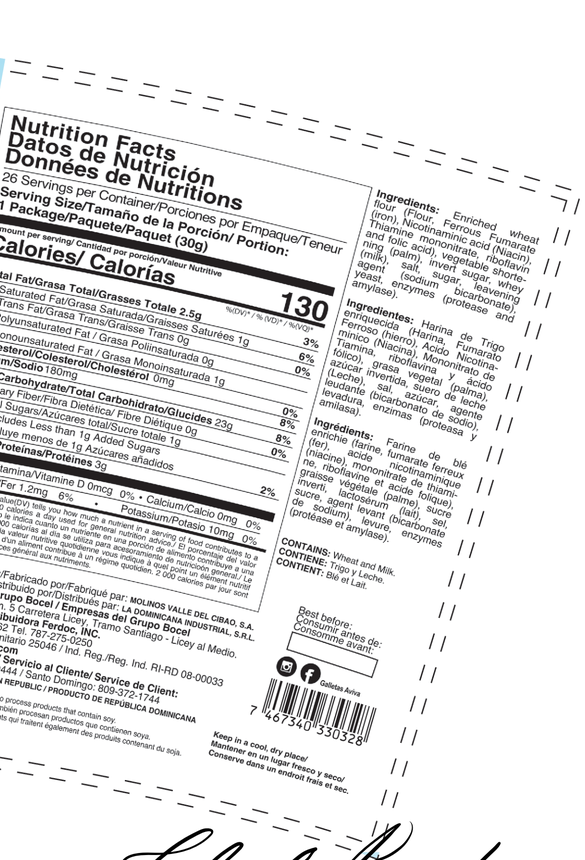
The % Dally value (DV) tells you how much a nutrient in a serving of food contributes to a dally diet. 2000 calories a day is used for general nutrition advice./El porcentaje del valor nutricional diario te dice qué tanto contribuye un nutriente en una porción de alimento a la dieta diaria. Se usan 2,000 calorías al día como base para hacer recomendaciones generales de nutrición./Le pourcentage de la valeur quotidienne (DV) vous indique combien un nutriment dans une portion de nourriture contribue à un régime alimentaire. 2000 calories par jour est utilisé pour des conseils nutritionnels généraux.

643.833mm

321.92mm

321.92mm

185



Nutrition Facts
Datos de Nutrición
Données de Nutritions

26 Servings per Container/Porciones por Empaque/Teneur
Serving Size/Tamaño de la Porción/ Portion:
1 Package/Paquete/Paquet (30g)

Amount per serving/ Cantidad por porción/Valeur Nutritive	%DV* / % (VD)* / %VQ*
Calories/ Calorías	**130**
Total Fat/Grasa Total/Grasses Totale 2.5g	
Saturated Fat/Grasa Saturada/Graisses Saturées 1g	6%
Trans Fat/Grasa Trans/Graisse Trans 0g	
Polyunsaturated Fat / Grasa Poliinsaturada 0g	
Monounsaturated Fat / Grasa Monoinsaturada 1g	
Cholesterol/Colesterol/Cholestérol 0mg	0%
Sodium/Sodio 180mg	8%
Total Carbohydrate/Total Carbohidrato/Glucides 23g	8%
Dietary Fiber/Fibra Dietética/ Fibre Diétique 0g	0%
Total Sugars/Azúcares total/Sucre totale 1g	
Includes Less than 1g Added Sugars	0%
Incluye menos de 1g Azúcares añadidos	
Protein/Proteínas/Protéines 3g	
Vitamin/Vitamina/Vitamine D 0mcg	0%
Iron/Hierro/Fer 1.2mg	6%
Calcium/Calcio 0mg	0%
Potassium/Potasio 10mg	0%

The % Daily Value(DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice./ El porcentaje de valor nutricional diario le indica cuanto un nutriente en una porción de alimento contribuye a una dieta diaria. 2,000 calorías al día se utiliza para consejos generales de nutrición./ La pourcentage de la valeur nutritive quotidienne vous indique à quel point un aliment nutrit dans une portion d'un aliment contribuye à un régime quotidien. 2 000 calories par jour sont utilisées pour l'advies général aux nutriments.

Manufactured by/Fabricado por/Fabriqué par: **MOLINOS VALLE DEL CIBAO, S.A.**
Distributed by/Distribuido por/Distribués par: **LA DOMINICANA INDUSTRIAL, S.R.L.**
Companies of Grupo Bocel / Empresas del Grupo Bocel
Puerto Rico: **Distribuidora Ferdoc, INC.**
Cataño, P. R. 00962 Tel. 787-275-0250
San. Reg./Reg. Sanitario 25046 / Ind. Reg./Reg. Ind. RI-RD 08-00033
www.grupobocel.com
Customer Service/ Servicio al Cliente/ Service de Client:
Santiago: 809-337-0444 / Santo Domingo: 809-372-1744
PRODUCT OF DOMINICAN REPUBLIC / PRODUCTO DE REPUBLICA DOMINICANA

Made on equipments that also process products that contain soya.
Elaborada en equipos que también procesan productos que contienen soya.
Fabriqué dans des équipements qui traitent également des produits contenant du soja.

Ingredients: Enriched wheat flour (Flour, Ferrous Fumarate (Iron), Nicotinamide, Acid (Niacin), Thiamine mononitrate, riboflavin and folic acid), vegetable shortening (palm), invert sugar, leavening agent (sodium bicarbonate), salt, sugar, whey yeast, enzymes (protease and amylase).

Ingredientes: Harina de Trigo enriquecida (Harina, Fumarato Ferroso (hierro) Acido Nicotinamínico (Niacina), Mononitrato de Tiamina, riboflavina y ácido fólico), grasa vegetal y (palma), azúcar invertida, suero de leche (Leche), sal, azúcar, agente leudante (bicarbonato de sodio), levadura, enzimas (proteasa y amilasa).

Ingrédients: Farine de blé enrichie (farine, fumarate ferreux (fer), acide nicotinamique (niacine), mononitrate de thiamine, riboflavine et acide folique), graisse végétale (palme), sucre inverti, lactosérum (lait), sel, sucre, agent levant (bicarbonate de sodium), levure, enzymes (protéase et amylase).

CONTAINS: Wheat and Milk.
CONTIENE: Trigo y Leche.
CONTENT: Blé et Lait.

Best before:
Consumir antes de:
Consomme avant:

Galletas Aviva
7 46734 330328

Keep in a cool, dry place/
Mantener en un lugar fresco y seco/
Conserve dans un endroit frais et sec.

sigmaplast DOMINICANA S.A.

SR. CLIENTE:
Esta Prueba Color Una vez aprobada, es el único elemento válido para el V²B² en máquina. Revísela muy bien. No se aceptarán reclamos posteriores por omisión o descuido.

FECHA: 02/06/2021
PRODUCTO: Cubeta Aviva Soda
CLIENTE: Molinos Valle del Cibao

TIPO DE IMPRESIÓN: FLEXOGRAFÍA — REVERSO / SUPERFICIE
VERSIÓN: 3 — No. REPETICIONES: 4

Nombre | Firma | Fecha

Esta Prueba color una vez aprobada, es el único elemento válido para el V²B² en máquina

Comentarios:

TIPOS DE ENROLLAMIENTO EXTERNOS
TIPOS DE ENROLLAMIENTO INTERNOS
TRABAJO CON CAMBIO
COLORES A CAMBIAR
CYAN MAGENTA AMARILLO NEGRO
FAVOR SIN FAVOR
TRANSP.
Fecha: Tipo Trabajo:
Pre-Prensa
Porcentaje Lectura Código de Barras
de una versión anterior

Claudio Innocenti

Distancia de Corte

170mm ±3mm) - **6.65”(±1/8)**

25.5mm

Ancho de Lamina: 200 mm(±3mm) **7.87”(±1/8)**

149 mm

25.5mm

DIRECCION DE MAQUINA

sigmaplast s.a.

SR. CLIENTE:
Esta Prueba Color Una vez aprobada, es el único elemento válido para el V°B° en máquina.
Revísela muy bien. No se aceptarán reclamos posteriores por omisión o descuido.

FECHA: 17/11/2017
PRODUCTO: Cherry Valey Single 30g
CLIENTE: Molinos Valle del Cibao

MED MECANICAS REVISADO ☐ TEXTOS REVISADO ☐

TIPO DE IMPRESIÓN: FLEXOGRAFÍA REVERSO ☐ SUPERFICIE ☐

VERSIÓN: V1 No. REPETICIONES: 2
RODILLO: 400 No. BLOQUES: 0

Nombre Firma Fecha

Esta Prueba color una vez aprobada, es el único elemento válido para el V°B° en máquina

TIPOS DE ENROLLAMIENTO EXTERNOS

1 2 3 4

TIPOS DE ENROLLAMIENTO INTERNOS

5 6 7 8

Cyan Magenta Amarillo Negro Blanco

BASE SUBSTRATO BOPPT

Comentarios:

Pre-Prensa

Porcentaje Lectura Código de Barras

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

Distancia de Corte
170mm ±3mm) - 6.65"(±1/8)

25.5mm

Ancho de Lamina:
200 mm(±3mm)
7.87"(±1/8)

149 mm

25.5mm

DIRECCION DE MAQUINA

sigmaplast s.a.

SR. CLIENTE:
Esta Prueba Color Una vez aprobada, es el único elemento válido para el V°B° en máquina.
Revísela muy bien. No se aceptarán reclamos posteriores por omisión o descuido.

FECHA: 17/11/2017
PRODUCTO: Cherry Valley Single 30g
CLIENTE: Molinos Valle del Cibao

MED MECANICAS REVISADO ☐ TEXTOS REVISADO ☐

TIPO DE IMPRESIÓN: FLEXOGRAFÍA
REVERSO ☐
SUPERFICIE ☐
VERSIÓN: V1
No. REPETICIONES: 2
RODILLO: 400
No. BLOQUES: 0

TIPOS DE ENROLLAMIENTO EXTERNOS

TIPOS DE ENROLLAMIENTO INTERNOS

Nombre | Firma | Fecha

Esta Prueba color una vez aprobada, es el único elemento válido para el V°B° en máquina

Comentarios:

Fecha: Tipo Trabajo:

Pre-Prensa

Porcentaje Lectura Código de Barras

sigmaplast s.a.

SR. CLIENTE:
Esta Prueba Color Una vez aprobada, es el único elemento válido para el V°B° en máquina. Revísela muy bien. No se aceptarán reclamos posteriores por omisión o descuido.

TIPOS DE ENROLLAMIENTO EXTERNOS

TIPOS DE ENROLLAMIENTO INTERNOS

ROLLO: 37.0" No. BLOQUES: 8

Nombre Firma Fecha

Esta Prueba color una vez aprobada, es el único elemento válido para el V°B° en máquina

Fecha: Tipo Trabajo:

Comentarios:

Pre-Prensa

Porcentaje Lectura Código de Barras

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

150mmx150mm

sigmaplast s.a.

SR. CLIENTE:
Esta Prueba Color Una vez aprobada, es el único elemento válido para el V°B° en máquina. Revísela muy bien. No se aceptarán reclamos posteriores por omisión o descuido.

FECHA: 14 de Nov. del 2017
PRODUCTO: Cherry Valley Tapa
CLIENTE: GRUPO BOCEL

TIPO DE IMPRESIÓN: FLEXOGRAFÍA
REVERSO ☐
SUPERFICIE ☐

MED MECANICAS REVISADO ☐ TEXTOS REVISADO ☐

VERSIÓN: ------- No. REPETICIONES: ------
RODILLO: ------- No. BLOQUES: ------

Nombre Firma Fecha

TIPOS DE ENROLLAMIENTO EXTERNOS

1 2 3 4

TIPOS DE ENROLLAMIENTO INTERNOS

5 6 7 8

CIAN MAGENTA AMARILLO NEGRO

BLANCO

BASE SUBSTRATO

TRANSP

Porcentaje Lectura
Código de Barras

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

Comentarios: _____

Pre-Prensa

FDA U.S. FOOD & DRUG ADMINISTRATION

Date:12/16/2020 10:11:46

Created Date **2018-12-28 15:57:35.0**	Created by **glo40722**
Registration Expiration Date **2022-12-31**	Registration Renewed Date **2020-12-16**
Last Updated **2020-12-16**	Registration Status Reason **Initial registration**

Registration Status
VALID

Is this facility engaged in the manufacturing/processing, packing, or holding of food for human or animal consumption in the United States?

◉Yes ○No

Section 1: Type of Registration

Facility Location: **Domestic Registration**

UPDATE OF REGISTRATION INFORMATION:

Registration Number: **19052126352** Pin No **x939xha3**

Are you the new owner of a previously registered facility?

○Yes ◉No

Previous Owner's Title:

Previous Owner's Name:

Previous Owner's Registration Number:

Section 2: Facility Name/Address Information

Facility Name **Global Trade Bridge**	Telephone Number **001 646 8630888 403**
Facility Name Suffix **Corporation**	Fax Number
Facility Street Address, Line 1 **1435 51st St Bld 1-A**	E-Mail Address **lapina@gtbridge.com**
Facility Street Address, Line 2	Unique Facility Identifier (UFI) **806890633**

City
North Bergen

State/Province/Territory
New Jersey

Zip Code (Postal Code)
07047

Country/Area
UNITED STATES

2021

CERTIFICATE OF REGISTRATION

This certifies that:

La Dominicana Industrial, C. por A.
Carretera Duarte Km 3 1/2
Tramo
Santiago, Santiago 51000
Dominican Republic

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

U.S. FDA Registration No.:	**13802650460**
U.S. Agent for FDA Communications:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

This certificate affirms that the above stated facility is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as effective by Registrar Corp as of the date hereof, and Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until December 31, 2021, unless such registration has been terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

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

David Lanniaz
Executive Director
Registrar Corp
Dated: November 4, 2020

FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Marjorie Balseca

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
12/13/2018

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

IFSH INSTITUTE OF FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Certificate # 9a3dc960

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Search Results

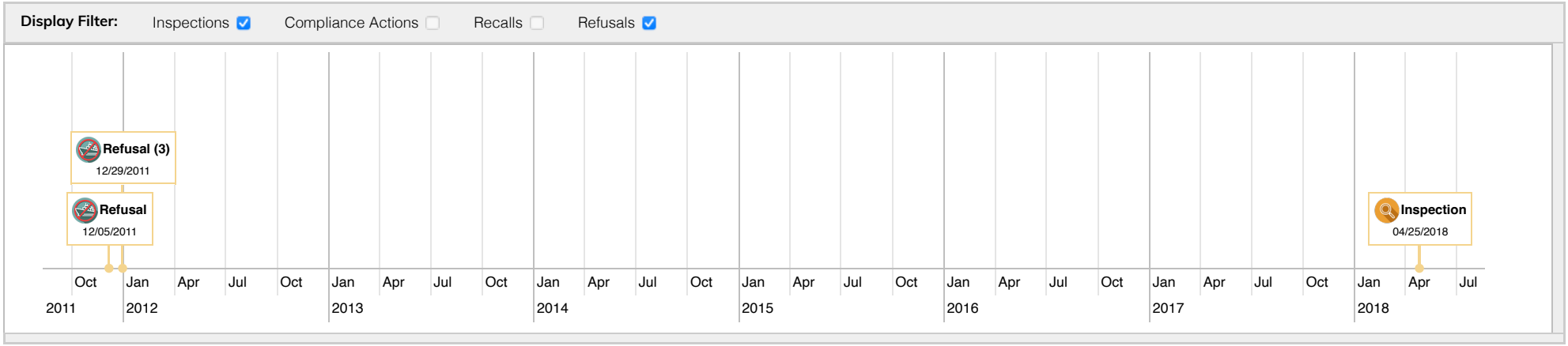
FEI Number	Firm Name	Physical Address	Mailing Address
3008721890	Molinos Valle del Cibao, C. por A.	Carretera Duarte Km., 1/2 Tramo 5, Santiago-Licey, Santiago, 51000, DO	Duarte 5, Santo Domingo Oeste, 02301, DO

FEI Number
3008721890

Firm Name
Molinos Valle del Cibao, C. por A.

Firm Address
Carretera Duarte Km., 1/2 Tramo 5
Santiago-Licey, Santiago 51000
Dominican Republic

FDA Actions Timeline



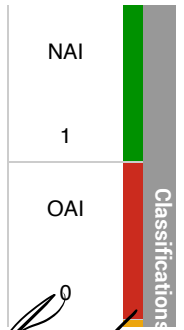
3008721890 – Molinos Valle del Cibao, C. por A.

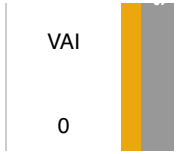
Inspections

Inspections	Classifications
1	1

Inspection Classifications by Fiscal Year
Fiscal Years: 2018 - 2018

Inspection Classifications by Type
Fiscal Years: 2018 - 2018





Inspections Details

Inspection ID	Inspection End Date	Project Area	Product Type	Classification	
1060730	04/25/2018	Foodborne Biological Hazards	Food/Cosmetics	NAI	

3008721890 – Molinos Valle del Cibao, C. por A.

Inspections Citations Details

No data found for the selected firm

3008721890 – Molinos Valle del Cibao, C. por A.

Compliance Actions

Warning Letters	Injunctions	Seizures
0	0	0

Actions by Percentage

Fiscal Years: 2009 - 2022

No data found for the selected firm

Compliance Actions Details

No data found for the selected firm

3008721890 – Molinos Valle del Cibao, C. por A.

Recalls

Recalled Products by Classification
Fiscal Years: 2012 - 2022

No data found for the selected firm

Recall Events by Status
Fiscal Years: 2012 - 2022

No data found for the selected firm

Recalls Details

No data found for the selected firm

3008721890 – Molinos Valle del Cibao, C. por A.

Import Refusals

Refusals by Product Category

Fiscal Years: 2012 - 2012

Import Refusals Details

Product Code and Description	Refused Date	Refusal Charges	Shipment ID
03MFT99 \ COOKIE,BISCUIT,W... DOUGH, N.E.C.	12/29/2011	11	BHE-0359170-4/4/1/
03MFT99 \ COOKIE,BISCUIT,W... DOUGH, N.E.C.	12/29/2011	11	BHE-0359170-4/6/1/
03MFT99 \ COOKIE,BISCUIT,W... DOUGH, N.E.C.	12/29/2011	11	BHE-0359170-4/7/1/
04AGT05 \ SPAGHETTI	12/05/2011	11	MU8-0025747-7/1/6/

3008721890 – Molinos Valle del Cibao, C. por A.

Import Alerts

- Search results are not returned based on an exact match of the firm name. Users should review the search results to determine whether the firm appears in the Import Alert and that the firm's products are allowed into the country.
- Only current/active Import Alerts are displayed. For more information see Import Alerts.

No Import Alerts data found for the selected firm.

3008721890 – Molinos Valle del Cibao, C. por A.

Warning Letters

- The search results below should be reviewed to determine whether the firm is directly or indirectly referenced in the Warning Letter.
- Only Warning Letters issued in the last 5 years are displayed. For more information see Warning Letters.

No Warning Letters data found for the selected firm.

Caveats:

- Certain information in these datasets may not be presented or may have changed since the posting. The datasets are updated weekly and only include final actions. If you need to present more recent or more complete data for official purposes or have questions about obtaining other data, please contact the Division of Freedom of Information about what materials may be available in electronic reading rooms or inquire about other datasets that would satisfy your needs.
- Compliance data provide information on a subset of the actions used by the FDA to bring firms into compliance, specifically data pertaining to Warning Letters, Seizures, and Injunctions. The compliance actions disclosed include only finalized and completed actions and are primarily used in the domestic arena.
- More than one establishment may be associated with one compliance action. The counts provided in this section reflect the number of establishments linked to the compliance action.

- For more information regarding the Center for Tobacco Products (CTP) issued warning letters click here.