UNITED SAFETY AGENTS

FSVP

COMPLIANCE PLAN

AVA JANE'S KITCHEN LLC

Name of FSVP Importer

FLEUR DE SEL, S.A. DE C.V.

Name of Foreign Supplier

COLIMA SEA SALT | 100% NATURAL | NOT COLORED

Name of Product

JULY 23, 2018 / SEPTEMBER 18, 2021

Date of Initial Verification / Reverification

SEPTEMBER 18, 2024 (SO LONG AS NO CHANGE IS RECORDED)

Date of FSVP Plan Expiration

VERIFICAITON COMPLETE | APPROVED FOR IMPORT

Status of Review

NUMBER TWO

Version

– Confidential –

TABLE *of* CONTENTS

OVERVIEW *of* FSVP PLAN

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

INSTRUCTIONS

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

TERMS & DEFINITIONS

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

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

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

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

RULES *of* USE

FOREIGN SUPPLIER VERIFICATION PROCEDURES

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

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

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

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

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

Continued onto next page.

FOREIGN SUPPLIER VERIFICATION PROCEDURES

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

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

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

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

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

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

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

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FOREIGN SUPPLIER VERIFICATION PROCEDURES

Continued from previous page.

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

FREQUENCY *of* VERIFICATION PROCEDURES

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

USE *of* APPROVED SUPPLIERS ONLY

Food and/or food-related products should only be imported from foreign suppliers that have been verified to the standards of FSVP. Prior to importation, all steps necessary to 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: Fleur De Sel, S.A. De C.V.

Product: Colima Sea Salt | 100% Natural | Not Colored

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

Review Start: July 01, 2021 Review End: Sept. 18, 2021

UNITED STATES CODE *of* FEDERAL REGULATIONS

The following are or may be applicable to this product/supplier, FSVP Importer should confirm & comply independently.

- ☑ **101.** §101.1–101.108. Food Labeling.
- ☐ **106.** §106.1–106.160. Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, & Notifications.
- ☐ **110.** §110.3–110.110. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food.
- ☐ **111.** §111.1–111.610. Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.
- ☐ **112.** §112.1–112.213. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.
- ☐ **113.** §113.3–113.100. Thermally Processed Low-Acid Foods Pkged in Hermetically Sealed Containers.
- ☐ **114.** §114.3–114.100. Acidified Foods.
- ☑ **117.** §117.1–117.475. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.
- ☐ **120.** §120.1–120.25. Hazard Analysis and Critical Control Point (HACCP) Systems.
- ☐ **121.** §121.1–121.401. Mitigation Strategies to Protect Food Against Intentional Adulteration.
- ☐ **123.** §123.3–123.28. Fish and Fishery Products.
- ☐ **129.** §129.1–129.80. Processing/Bottle Drinking Water.
- ☐ **131.** §131.3–131.206. Milk and Cream.
- ☐ **133.** §133.3–133.196. Cheeses & Related Products.
- ☐ **135.** §135.3–135.160. Frozen Desserts.
- ☐ **136.** §136.3–136.180. Bakery Products.
- ☐ **137.** §137.105–137.350. Cereal Flours.
- ☐ **139.** §139.110–139.180. Macaroni & Noodle Products.
- ☐ **145.** §145.3–145.190. Canned Fruits.
- ☐ **146.** §146.3–146.187. Canned Fruit Juices.
- ☐ **150.** §150.110–150.160. Fruit Butters, Jellies, Preserves, and Related Products.
- ☐ **152.** §152.126. Fruit Pies.
- ☐ **155.** §155.3–155.201. Canned Vegetables.
- ☐ **156.** §156.3–156.145. Vegetable Juices.
- ☐ **158.** §158.3–158.170. Frozen Vegetables.
- ☐ **160.** §160.100–160.190. Eggs and Egg Products.
- ☐ **161.** §161.30–161.190. Fish and Shellfish.
- ☐ **163.** §163.5–163.155. Cacao Products.
- ☐ **164.** §164.110–164.150. Tree Nut and Peanut Products.
- ☐ **165.** §165.3–165.110. Beverages.
- ☐ **166.** §166.40–166.110. Margarine.
- ☐ **168.** §168.110–168.180. Sweeteners and Table Sirups.
- ☐ **169.** §169.3–169.182. Food Dressings and Flavorings.
- ☑ **170.** §170.3–170.285. Food Additives.
- ☐ **179.** §179.21–179.45. Irradiation in the Production, Processing and Handling of Food.
- ☐ **190.** §190.6. Dietary Supplements.
- ☐ **501.** §501.1–501.110. Animal Food Labeling.
- ☐ **507.** §507.1–507.215. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.
- ☐ **570.** §570.3–570.280. Food Additives.
- ☐ **579.** §579.12–579.40. Irradiation in the Production, Processing, & Handling of Animal & Pet Food.

Note: List is not exhaustive. Other regulations may be applicable.

Supplier: Fleur De Sel, S.A. De C.V.

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

Review Start: July 01, 2021 Review End: Sept. 18, 2021

21 C.F.R. §1.500–§1.514

The following section(s) of the FSVP regulation is/are or may be particularly relevant to this product/supplier.

- ☒ **§1.500.** What Definitions Apply to This Subpart?
- ☒ **§1.501.** To What Foods Do the Requirements in This Subpart Apply?
- ☒ **§1.502.** What Foreign Supplier Verification Program *(FSVP)* Must I Have?
- ☒ **§1.503.** Who Must Develop My FSVP and Perform FSVP Activities?
- ☒ **§1.504.** What Hazard Analysis Must I Conduct?
- ☒ **§1.505.** What Evaluation for F. Supplier Approval & Verification Must I Conduct?
- ☒ **§1.506.** What Foreign Supplier Verification and Related Activities Must I Conduct?
- ☐ **§1.507.** What Requirements Apply When I Import Food That Cannot Be Consumed Without the Hazards Being Controlled or for Which the Hazards Are Controlled After Importation?
- ☒ **§1.508.** What Corrective Actions Must I Take Under My Foreign Supplier Verification Program?
- ☒ **§1.509.** How Must the Importer Be Identified at Entry?
- ☒ **§1.510.** How Must I Maintain Records of My FSVP?
- ☐ **§1.511.** What FSVP Must I Have If I Am Importing A Food Subject to Certain Requirements in the Dietary Supplement Current Good Manufac turing Practice Regulation?
- ☒ **§1.512.** What FSVP May I Have If I Am A Very Small Importer or I Am Importing Certain Food from Certain Small Foreign Suppliers?
- ☐ **§1.513.** What FSVP May I Have If I'm Importing Certain Food from A Country with An Officially Recognized Food Safety System?
- ☒ **§1.514.** What Are Some Consequences of Failing to Comply with the Requirements of FSVP?

NOTES & COMMENTS

FSVP 21 CFR §1.500–§1.514

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

Supplier: Fleur De Sel, S.A. De C.V. Product: Colima Sea Salt | 100% Natural | Not Colored

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 01, 2021 Review End: Sept. 18, 2021

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, _____ certify that I reviewed this FSVP plan on _____ and found
type name *today's date*

its contents to be acceptable.

Reviewer's Name: _____

Reviewer's Signature: _____

Reviewer's Title: _____

Supplier: Fleur De Sel, S.A. De C.V. Product: Colima Sea Salt | 100% Natural | Not Colored

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 01, 2021 Review End: Sept. 18, 2021

DESIGNATION *of* ROLES & SUMMARY *of* REVIEW

FOREIGN SUPPLIER VERIFICATION PROGRAM IMPORTER

Company Name: Ava Jane's Kitchen, LLC FDA FEI: 13836148690

Physical Address: 1809 W Frankford Road, No. 160 DUNS No.: 08-031-2669

City: Carrollton State: Texas, 75007-4645 Country: United States

Mailing Address: P.O. Box 297

City: Bend State: Oregon, 97709 Country: United States

Phone Number: +1-206-331-4524 Email Address: michele@avajaneskitchen.com

Name *of* Representative*(s)*: Ms. Michele Sayko Title: Commercial Rep.

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

Company Name: Fleur De Sel, S.A. De C.V. (Previously: Solysal DE Colima S.P.R. De R.L.) FDA FFR: 16441296972

Manufacturing Address: Adolfo López Mateos No. 40 FDA FEI: 3014274322

City: El Toreo, Cuauhtémoc, 28500 Province/Territory: Colima Country: Mexico

Office Address: Adolfo López Mateos No. 40

City: El Toreo, Cuauhtémoc, 28500 Province/Territory: Colima Country: Mexico

Phone Number: +52 1 312 155 2763 Email Address: patysolysal01@sgmail.com

Name *of* Representative*(s)*: Ms. Patricia Solis Montero Title: Owner

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

Agent/QI Name: Claudio Innocenti Signature: Claudio Innocenti

Title: Partner & Preventive Controls Qualified Individual. Date: Sept. 18, 2021

Agent/QI Name: William J. Barber Signature: W. J. Barber

Title: Preventive Controls Qualified Individual. Date: Sept. 18, 2021

SUMMARY *of* REVIEW

Details *of* Product(s)	*Is foreign supplier expected to implement controls for*			**Comments**
	Biological Hazards	**Chemical Hazards**	**Physical Hazards**	
Sea Salt Natural | Not Colored	☑ Yes ☐ No ☐ *Undetermined*	☑ Yes ☐ No ☐ *Undetermined*	☑ Yes ☐ No ☐ *Undetermined*	Verified & Approved. — See Addendum.
	☐ 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: Fleur De Sel, S.A. De C.V.

Product: Colima Sea Salt | 100% Natural | Not Colored

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

Review Start: July 01, 2021 Review End: Sept. 18, 2021

REGISTER *of* SUBSTANTIATING DOCUMENTS

HAZARD ANALYSIS

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

NOTES Fleur De Sel's HACCP Plan received.
Dated: Not Dated.
Contains: Organization Chart; Training And Functions Of The HACCP Team; Product Description; General Flow Of The Process For Sea Salt; Hazard Analysis And Preventive Measures; Determination Of Critical Control Points; Establishment Of The HACCP Control Table; Verification Procedure; Consumer Complaint Procedure; and Recall Procedure Of Non-Conforming Product.
Fleur De Sel's Recall Plan received.

ON-SITE AUDIT

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

NOTES Note: No substantiating information provided by the supplier.

SAMPLING OR TESTING RESULTS

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

NOTES Certificate of Analysis received from supplier.
Dated: November 10, 2020. Tested for: Purity and Humidity.
Laboratory: Desu Operadora SA De CV.
Certificate of Analysis received from supplier.
Dated: November 10, 2020. Tested for: Heavy Metals.
Laboratory: Desu Operadora SA De CV.
Note: We respectfully request that recent certificate(s) of analysis be provided for testing conducted to determine that product has been effectively processed to control for all FDA identified biological and chemical hazards (preferably by an ISO 17025-accredited laboratory).

OTHER FOOD SAFETY RECORDS

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

NOTES Completed Foreign Supplier FSVP Questionnaire received.
Dated: July 15, 2021.
Completed by: Paulina Eileen Nava Solís.
Note: Supplier was slow in responding to all requests, including the request for their completion of the Questionnaire.
Corporate Name Change Attestation received.
Dated: July 15, 2021.
Note: Fleur De Sel, S.A. De C.V.'s previous business name "Solysal DE Colima"

PRODUCT LABELING

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

NOTES Product Label received. Label clearly identifies no 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: Fleur De Sel, S.A. De C.V.

Product: Colima Sea Salt | 100% Natural | Not Colored

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

Review Start: July 01, 2021 Review End: Sept. 18, 2021

VERIFICATION FREQUENCY *for* UPDATED DOCUMENTS

21 C.F.R., §1.505, §1.506, and §1.510 require that all FSVP records be updated and maintained. Depending on USA's review and determination of the supplier's compliance history and food safety program, receipt of the following food safety documents are recomended accord to their individually-marked time interval.

FACILITY FOOD SAFETY PLAN

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

HACCP PLAN / HARPC PLAN

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

ON-SITE AUDIT RESULTS

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

LABORATORY TESTING RESULTS

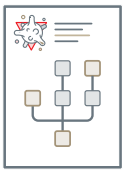
- ☑ if positive results are returned
- ☑ if recall or import refusal occurs
- ☑ if inspection occurs
- ☑ on an annual basis
- ☐ on a per-batch/shipment basis
- ☑ Chemical ☑ Biological
- ☐ *other:*

FDA REGISTRATION

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

FACILITY LICENSE

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



RECALL PLAN

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

PRODUCT LABEL

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

QUALIFICATIONS

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

IMPLEMENTATION RECORDS

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

FSVP QUESTIONNAIRE

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

NOTES

All documents used for FSVP verification and approval must be re-acquired at least one every three years or sooner, per above.

unitedsafetyagents.com/documents

Supplier: Fleur De Sel, S.A. De C.V. Product: Colima Sea Salt | 100% Natural | Not Colored

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 01, 2021 Review End: Sept. 18, 2021

FDA COMPLIANCE ACTIONS & REGULATORY HISTORY

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

RESULTS *of* EVALUATION

Date *of* Action	Description *of* Action
NOTE:	Search was conducted using Fleur De Sel, S.A. De C.V.'s previous business name "Solysal DE Colima"
Note Applicable	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: Fleur De Sel, S.A. De C.V. FEI: 3014274322 Date: Sept. 18, 2021

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

Supplier: Fleur De Sel, S.A. De C.V.

Product: Colima Sea Salt | 100% Natural | Not Colored

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

Review Start: July 01, 2021 Review End: Sept. 18, 2021

REVISION LOG *for* FSVP PLAN

Version No.	Date *of* Change	Description *of* Revision
No. 01	July 23, 2018	Product and supplier underwent initial FSVP verification. Note: No chance reported until re-verification.
No. 02	Sept. 18, 2021	Foreign Supplier and product underwent annual verification. Additional and/or updated food safety documents were requested, received, and added to FSVP. FSVP content and format was updated to reflect recent FDA Guidance document(s) and/or regulatory statues that became applicable since initial verification, or previous reverification.

Supplier: Fleur De Sel, S.A. De C.V. Product: Colima Sea Salt | 100% Natural | Not Colored

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 01, 2021 Review End: Sept. 18, 2021

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***	–	–	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 ——— ———NOTE——— 01. There are no FDA-identified biological hazards in reference to sea salt. Extremely low microbiological hazards due to the fact that Sea Salt is approximately 99.9% Sodium Chloride. 02. Supplier utilizes laboratory testing of finished product to verify that biological contaminates have been effectively controlled through low aW. Details: Certificate of Analysis received. Dated: November 10, 2020. Tested for: Purity and Humidity. Laboratory: Desu Operadora SA De CV. 03. All staff undergoes formal food hygiene training. 04. All staff issued protective clothing. 05. All production operatives are required to cover head/facial hair within the processing/manufacturing area. 06. Adequate toilet and hand washing facilities provided. 07. Product is positively released. 08 Supplier reports to utilize fumigation with "natural pyrethrins" every three months to help control for the presence of biological hazards. Note: No substantiation received.	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. USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified biological hazards. ——— ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) ——— ———

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: Fleur De Sel, S.A. De C.V. Product: Colima Sea Salt | 100% Natural | Not Colored

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 01, 2021 Review End: Sept. 18, 2021

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***	>1	2	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/release. Details: Certificate of Analysis received. Dated: November 10, 2020. Tested for: Heavy Metals. Laboratory: Desu Operadora SA De CV. 02. Supplier utilizes laboratory testing to verify that product is free from chemical hazards prior to release. 03. Supplier utilizes special water selection procedures to minimize the risk of chemical hazards at intake. Details: To avoid chemical contamination of the salt, a careful water extraction process is used to form the salt. Generally, the wells to extract water are 2 meters long, while we make wells that are at least 10 meters deep. As mentioned above, tests are done every semester to control the purity of the salt and rule out the presence of microplastics, lead, and ferrous particles. ———————NOTE——————— USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified chemical hazards – specifically, microplastics.	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. USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified chemical hazards. ——————— ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) ———————

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: Fleur De Sel, S.A. De C.V.

Product: Colima Sea Salt | 100% Natural | Not Colored

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

Review Start: July 01, 2021 Review End: Sept. 18, 2021

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) there are NO allergens handled on site. B) a documented allergen control program is in use. C) a dedicated process line and a documented cleaning procedure are in place to prevent contamination. D) all employees undergo allergen training and processes have been put in place to reduce the likelihood of cross contact or unintentional introduction of allergens into processing area. ———NOTE——— ---------- Labeling Requirements ---------- - Food Allergen Labeling and Consumer Protection Act - ---------- - Nutritional information (not appliance to bulk). - Name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5). - Quantity of contents (21 CFR 101.7). - Statement of identity (21 CFR 101.3). - Presence of artificial flavoring, artificial coloring, or chemical preservative (21 CFR 101.22). - Ingredient statement if the product has two or more ingredients (21 CFR 101.4). - Presence of major food allergens (21 U.S.C. 343(w)). - Percent juice (21 CFR 101.30), when applicable.	Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control the hazard posed by allergenic adulteration. Note: USA's assessment of product(s) labeling is restricted to a label(s)' allergen disclosure statement and should not be interpreted to meant that the label(s) meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food Allergen Labeling and Consumer Protection Act (FALCPA), or any other applicable section of 21 CFR Part 101. USA recommends that FSVP Importer independently confirm that product label(s) is in compliance with all applicable regulations prior to import. _____ ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix 1 (Hazards Tables) _____ _____

Legend *for* Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.

C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.

P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

Probability (*P.*): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))

Severity (*S.*): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))

P. & S. Assessment Scale: **1** - Low, **2** - Moderate, **3** - High, **S** - Serious adverse health consequences or death.

Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

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

*Per Food Allergy Safety, Treatment, Education and Research Act, food packages will need to reflect allergen labeling for sesame beginning on January 1, 2023.

Supplier: Fleur De Sel, S.A. De C.V. Product: Colima Sea Salt | 100% Natural | Not Colored

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 01, 2021 Review End: Sept. 18, 2021

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***	–	–	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 ——— ——————————— ———————NOTE——————— 01. There are no FDA-identified biological hazards in reference to sea salt. Extremely low microbiological hazards due to the fact that Sea Salt is approximately 99.9% Sodium Chloride. ——————————— 02. Supplier utilizes laboratory testing of finished product to verify that biological contaminates have been effectively controlled through low aW. Details: Certificate of Analysis received. Dated: November 10, 2020. Tested for: Purity and Humidity. Laboratory: Desu Operadora SA De CV. 03. Hazard posed by recontamination with environmental pathogens is controlled through Current Good Manufacturing Practices. 04. Supplier has implemented a cleaning program and environmental monitoring for microbiological and biological hazards. 05. All product is positively released and hermetically sealed within plastic.	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) ——————————— ———————————

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: Fleur De Sel, S.A. De C.V. Product: Colima Sea Salt | 100% Natural | Not Colored

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 01, 2021 Review End: Sept. 18, 2021

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 laboratory testing of finished product to verify that physical contaminates have been effectively controlled. Details: Certificate of Analysis received. Dated: November 10, 2020. Tested for: Purity and Humidity. Laboratory: Desu Operadora SA De CV. 02. Supplier utilizes special water selection procedures to minimize the risk of microplastics at intake. Details: To avoid chemical contamination of the salt, a careful water extraction process is used to form the salt. Generally, the wells to extract water are 2 meters long, while we make wells that are at least 10 meters deep. As mentioned above, tests are done every semester to control the purity of the salt and rule out the presence of microplastics, lead, and ferrous particles. ———NOTE——— USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified chemical hazards – specifically, microplastics.	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) ——— ———

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: Fleur De Sel, S.A. De C.V. Product: Colima Sea Salt | 100% Natural | Not Colored

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 01, 2021 Review End: Sept. 18, 2021

ASSESSMENT *of* FOREIGN SUPPLIER

1.0 FOREIGN SUPPLIER INFORMATION

1.1. Supplier name: Fleur De Sel, S.A. De C.V.

1.2. Supplier address: Adolfo Lopez Mateos 40el Toreo, Cuauhtemoc, Colima Me, MX

1.3. Products manufactured/supplied: Sea Salt.

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

GFSI Standard:

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

1.6. Has the supplier provided specifications? ☒ Yes ☐ No

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

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

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

2.0 SUPPLIER PROCEDURES, PROCESSES & PRACTICES

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

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

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

3.0 SUPPLIER PERFORMANCE HISTORY

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

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

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

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

☐ Yes ☒ No ☐ N/A *Description:* *No, Import Alert & Warning Letter search-results, which were conducted on – or about – the Review End date, have been attached to this FSVP Plan.*

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

Description: *No, as of this FSVP Plan's Review End date, USA has no knowledge of any recall undertaken by supplier.*

Continued onto next page.

Supplier: Fleur De Sel, S.A. De C.V. Product: Colima Sea Salt | 100% Natural | Not Colored

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 01, 2021 Review End: Sept. 18, 2021

ASSESSMENT *of* FOREIGN SUPPLIER

3.0 SUPPLIER PERFORMANCE HISTORY *(Continued)*

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

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

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

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

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

☐Yes ☒No *Description:* *Supplier has been less then forthcoming regarding our requests.*

4.0 SUPPLIER APPROVAL

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

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

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

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

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

Comments: *Supplier has been verified and their products have been approved for importation.*

Additional Recommendations:

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

Supplier: Fleur De Sel, S.A. De C.V.

Product: Colima Sea Salt | 100% Natural | Not Colored

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

Review Start: July 01, 2021 Review End: Sept. 18, 2021

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

Small Mexican producer of Colima Sea Salt | 100% Natural | Not Colored.

Testing Program & Accreditation

Supplier appears to use a third party testing facility.

Certificate of Analysis received from supplier.
Dated: November 10, 2020. Tested for: Purity and Humidity. Laboratory: Desu Operadora SA De CV.
Certificate of Analysis received from supplier.
Dated: November 10, 2020. Tested for: Heavy Metals. Laboratory: Desu Operadora SA De CV.

Note: We respectfully request that recent certificate(s) of analysis be provided for testing conducted to determine that product has been effectively processed to control for all FDA identified biological and chemical hazards (preferably by an ISO 17025-accredited laboratory).

Supplier & Product Allergen Information

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

Note: USA's assessment of product(s) labeling is restricted to a label(s)' allergen disclosure statement and should not be interpreted to 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.

Product should be stored in a dry, covered area with controlled humidity under 75%.

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Review Start: July 01, 2021 Review End: Sept. 18, 2021

REVIEW *of* GENERAL FOOD SAFETY PROGRAM

Supplier GFSI Status & Historical Performance

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

Close Supplier Monitoring

No. Supplier/product will be re-assessed and re-verified to the standards of the Foreign Supplier Verification Program on an annual basis, or sooner if necessary.

General Comments & Verification Timeline

Fleur De Sel, S.A. De C.V. has not been responsive to our requests for information and documents. Upon review, Fleur De Sel, S.A. De C.V.'s processes, procedures, and certifications provide the minimum adequate assurance that appropriate controls have been put in place for all FDA-identified hazards.

Products supplied by this supplier have been approved for import, under close monitoring procedures by FSVP Importer.

All documents used for FSVP verification and approval must be re-acquired at least one every three years or sooner, per above.

NOTE

We respectfully request that recent certificate(s) of analysis be provided for testing conducted to determine that product has been effectively processed to control for all FDA identified biological, chemical, and environmental hazards (preferably by an ISO 17025-accredited laboratory).

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

Supplier: Fleur De Sel, S.A. De C.V. Product: Colima Sea Salt | 100% Natural | Not Colored

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 01, 2021 Review End: Sept. 18, 2021

ADDENDUM

NOTE

Labeling Requirements

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

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

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

Food Allergen Labeling and Consumer Protection Act

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

Supplier: Fleur De Sel, S.A. De C.V. Product: Colima Sea Salt | 100% Natural | Not Colored

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 01, 2021 Review End: Sept. 18, 2021

ADDENDUM

Guidance for Industry: Colored Sea Salt

U.S. Department of Health and Human Services Food and Drug Administration
Center for Food Safety and Applied Nutrition September 2015

Under section 201(t) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(t)), a color additive is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction to another substance) of imparting color thereto.2 When substances such as charcoal and red clay are added to sea salt, these substances meet the statutory definition of a color additive under the FD&C Act because these substances impart color to the salt.

Section 721(a) of the FD&C Act (21 U.S.C. 379e(a)) defines conditions under which a color additive is deemed unsafe. A color additive used in or on a food will be deemed unsafe unless: (1) there is a regulation listing such color additive; (2) the regulation allows that particular use; and (3) the color additive and its use conform to the regulation. Neither charcoal nor red clay is listed for safe use by FDA under section 721(a) of the FD&C Act. In addition, charcoal and red clay are not otherwise exempt from such listing. Furthermore, neither charcoal nor red clay is listed in FDA's regulations for use in coloring food, including sea salt (see section 721(b) of the FD&C Act (21 U.S.C. 379e(b)).3 Therefore, any food that contains these color additives is adulterated under section 402(c) of the FD&C Act (21 U.S.C. 342(c)). The introduction or delivery for introduction into interstate commerce of any food that is adulterated is a prohibited act.4 FDA can take enforcement action against an adulterated food product, consistent with our priorities and resources.

Manufacturers of sea salt that intend to add color additives that are not currently approved for food use to their products, such as charcoal or red clay, must first obtain approval for the use of these substances through the color additive petition process. Color additive petitions must be submitted to FDA's Office of Food Additive Safety, HFS-200, 5001 Campus Drive, College Park, MD 20740. The information required for color additive petitions is outlined in 21 CFR 71.1. There are guidance documents available on our website that address the administrative, chemistry, toxicological, and environmental information that should be included in support of a color additive petition.

NOTE: Product is natural and not colored.

ADDENDUM

INTENTIONALLY

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Supplier: Fleur De Sel, S.A. De C.V. Product: Colima Sea Salt | 100% Natural | Not Colored

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 01, 2021 Review End: Sept. 18, 2021

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

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Charles Nolan

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07/09/2020

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Gerald Wojtala, Executive Director
International Food Protection Training Institute

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

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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: Fleur De Sel, S.A. De C.V. Product: Colima Sea Salt | 100% Natural | Not Colored

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Bob Bauer

completed on

05/31/2018

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Institute for Food Safety and Health

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International Food Protection Training Institute

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completed on

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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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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

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

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Joseph Corby, Executive Director
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WILLIAM BARBER

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

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delivered by Lead Instructor

Mirasol Mohal

completed on
06/05/2019

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Institute for Food Safety and Health

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tina coil

completed on
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Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Joseph Corby, Executive Director
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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

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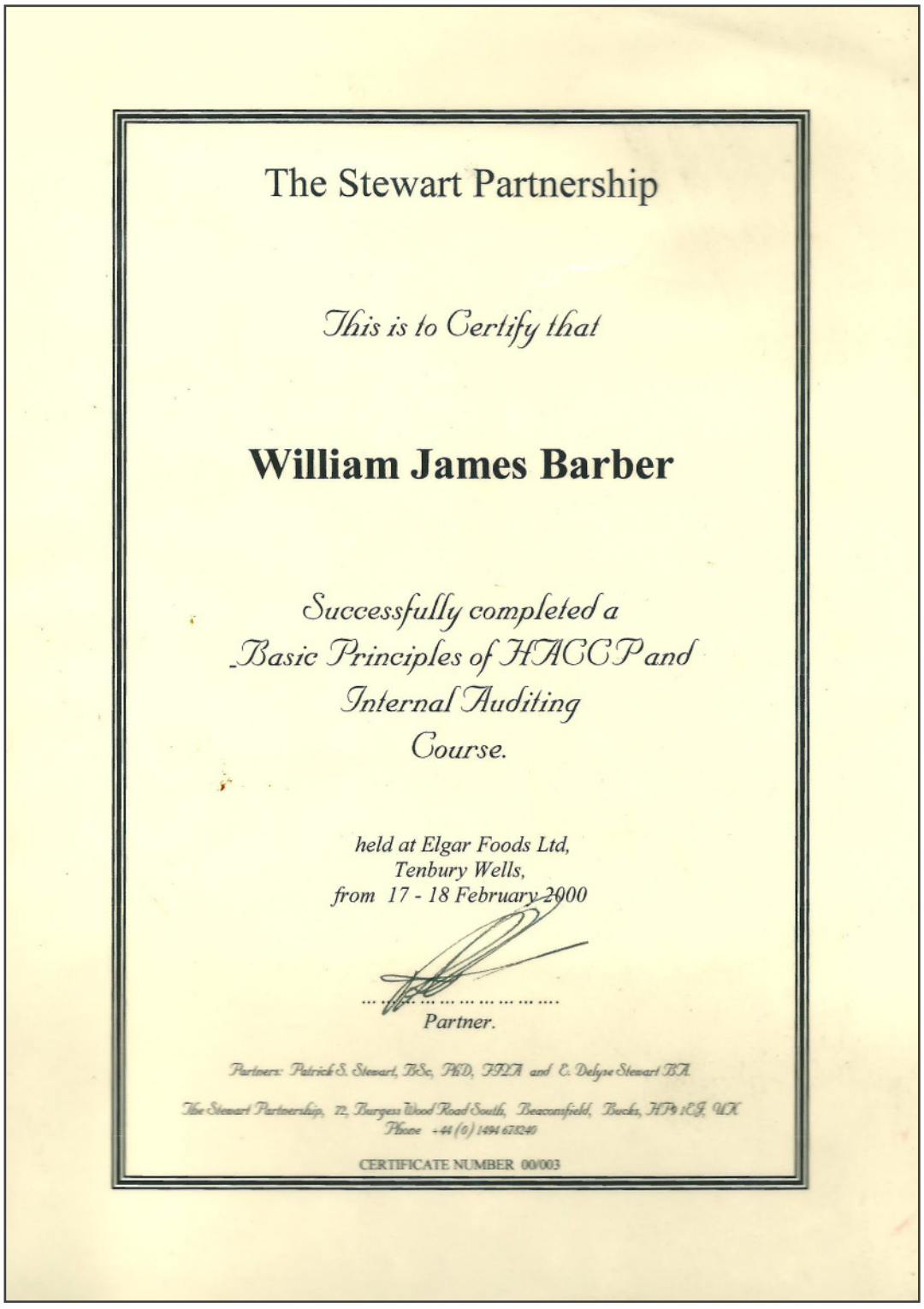

The Stewart Partnership

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 E. Delyse Stewart BA

The Stewart Partnership, 72, Burgess Wood Road South, Beaconsfield, Bucks, HP9 1EJ, UK
Phone +44 (0) 1494 678240

CERTIFICATE NUMBER 00/003

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CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

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

M Howell
Chairman
The City and Guilds of London Institute

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

QCA
Qualifications and Curriculum Authority

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

Supplier: Fleur De Sel, S.A. De C.V. Product: Colima Sea Salt | 100% Natural | Not Colored

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: July 01, 2021 Review End: Sept. 18, 2021

CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

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	U1050274

CONTINUED

AWARDED SEPTEMBER 2007 0709/024307A/124203/PXC4025/1/13/03/64

M Howell
Chairman
The City and Guilds of London Institute

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

R01

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SUBSTANTIATING DOCUMENTS

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

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

CHANGE *of* CORPORATE NAME

Per Title 21 of the United States Code of Federal Regulations, Chapter I, Subchapter A, Part 1, Subpart L, §1.500-§1.514; SOLYSAL DE COLIMA, S.P.R. DE R.L. (current corporate name), which maintains an office or manufacturing facility at ADOLFO LOPEZ MATEOS 40, COL. EL TOREO, 28500, CUAUHTEMOC, C (full address); has, or soon will, change or otherwise alter its corporate name or designation. This change will take effect on 07/15/2021 (date of change), and will result in SOLYSAL DE COLIMA, S.P.R. DE R.L. (current corporate name)'s corporate name being changed to the following: FLEUR DE SEL, S.A. DE C.V. (NEW corporate name).

This change will not affect or otherwise alter the address of the company's office or manufacturing facility. Additionally, this change will not affect or otherwise alter the company's current 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, nor its ability to produce product in compliance with sections 402 and 403(w) *(if applicable)* of the Federal Food, Drug, and Cosmetic Act.

FURTHERMORE, I PAULINA EILEEN NAVA SOLIS (name of individual), hereby certify that this information is true, accurate, and complete to the best of my knowledge and understand that any false statements or deliberate omissions may be grounds for disqualification from successful Foreign Supplier Verification Program *(FSVP)* approval or, if discovered after FSVP approval takes place, can result in the revocation or termination of United Safety Agent LCC's FSVP Agent coverage of previously approved products, and may result in a product or shipment being rejected from entry into the United States.

Signed _____

Name PAULINA EILEEN NAVA SOLIS

Title LEGAL REPRESENTATIVA

Date 07/15/2021

PLANHACCP

SEA SALT

Content

I. INTRODUCTION

The HACCP system, which is scientifically based and systematic in nature, makes it possible to identify specific hazards and measures for their control in order to guarantee food safety.

It is a tool for assessing hazards and establishing control systems that focus on prevention rather than relying primarily on end-product testing. Every HACCP system is susceptible to changes that may result from advances in equipment design, manufacturing procedures, or the technology sector.

The HACCP system, developed in the 60s by the Pillsbury company in conjunction with NASA and the laboratories of the US Navy, turns out to be a tool that allows not only to identify and assess hazards, but also to establish systems control systems focused on prevention, instead of relying on inspection and testing of final products.

HACCP SYSTEM PREREQUISITES

Before applying the HACCP System, the company must have the following prerequisites in place:

The application of Good Manufacturing Practices and Standardized Sanitation Operating Procedures
Knowledge and commitment to the application of the HACCP System by the management and staff of the company.
Constant training at all levels.
An adequate information flow system and a product recall management system.

For an adequate implementation of the HACCP system, commitment and work on the part of the organization is essential, as well as a systemic and multidisciplinary approach. The HACCP system and its implementation is compatible with integrated management systems, quality management systems, such as the ISO 9000, 22000 series, among others.

DEFINITIONS

HACCP
It is the system that allows to identify, evaluate and control hazards that are significant for food safety.

HACCP plan
It is the document built according to the principles of HACCP, to ensure the control of hazards that are significant for food safety, in the considered segment of the agri-food chain.

Dangers
Biological, chemical or physical agents present in a food or the condition in which it is found, which can cause an adverse effect on health.

Hazard identification
Process of collecting and evaluating information on the hazards and the conditions that lead to their appearance, in order to decide which of them are significant for food safety, and which should be addressed in the HACCP plan.

Risk Analysis
It is the analysis of the probability of occurrence, the severity or severity and the detectability of the identified hazards.

Control
Take the necessary actions (laboratory analysis, measurement, inspection, etc. of certain characteristics of the product) to ensure and maintain compliance with the rules and criteria established in the HACCP system.

Critical Control Point (CCP)
Stage of the process where the application of a control measure is essential to prevent, eliminate, or reduce, within acceptable limits, a hazard.

Critical Limit (CL)
It turns out to be the criterion that determines the acceptance or rejection of something. They are minimum and / or maximum values of microbiological, chemical or physical parameters, that is, of hazards, that must be controlled in a CCP.

Preventive action
Action taken to prevent or eliminate hazards that put food safety at risk.

Deviation
It is the withdrawal of the LC, which translates into the loss of control of the corresponding PCC and an inadequate execution of preventive measures.

Corrective action
Action to take when CCP monitoring results indicate loss of process control. In other words, it is carried out when a PCC exceeds the LC, in order to return it to the preset parameters.

Monitoring
Planned sequence of observations or parameter control measurements, to ensure that the CCP is under control.

Validation
Verification that the elements of the HACCP plan are effective.

check
Application of methods, procedures, tests and other evaluations, in addition to surveillance, to verify compliance with the HACCP plan.

Flowchart
Representation of the sequence of stages and operations of the product elaboration process.

Schematic plan of the establishment
Graphic representation of the establishment that reflects the distribution of the different environments, the flow of the product, the process and the personnel.

Record
Document that provides objective evidence of actions carried out or results achieved.

Food recall from the market
Measure to manage a risk detected by the manufacturer, complaints from different sectors of the community, actions initiated by the health authorities or an adverse result of an official sample collected in routine inspection, with the aim of immobilizing the food involved to prevent it from reach the consumer and effectively and efficiently recover the full amount of the risk product from the market, including those that are in the possession of consumers, if deemed necessary.

HACCP APPLICATION SEQUENCE

Following are the stages that must be contemplated for the application of the HACCP System, according to FAO, which involve the previous stages and the 7 principles of HACCP.

The HACCP Plan must be signed and dated by the person in charge of the HACCP team and the highest manager of the company. The signature will mean that the HACCP Plan has been approved by the company for its implementation.

Logical sequence for the implementation of the HACCP System

1. Training of the HACCP team
2. Product description
3. Determination of use
4. Elaboration of the flow diagram
5. On-site verification of flow chart
6. Identification of potential hazards and analysis of risks associated with each stage of the process, and determination of control measures (Principle 1)
7. Determination of CCPs (Principle 2)
8. Establishment of LCs for each CCP (Principle 3)
9. Establishment of a monitoring system for each CCP (Principle 4)
10. Establishment of corrective actions (Principle 5)
11. Establish verification procedures (Principle 6)
12. Establishment of a documentation and records system (Principle 7)

PREVIOUS STAGES OF THE HACCP SYSTEM

To carry out the implementation of the principles of the HACCP system, one must:

1. Training of the HACCP team

The organization must build and consolidate a multidisciplinary team that possesses the appropriate competencies, which can be made up of both company personnel and external personnel. It would be advisable for said team to be made up of people from different areas and competencies such as those related to quality assurance, production and maintenance, cleaning, laboratory, marketing, administration and finances, among others; since the team must determine priorities, collect and evaluate data and build information, as well as identify and analyze hazards to determine the Critical Control Points (CCP). For this, it is also important that team members receive adequate training to facilitate the implementation and maintenance of the system.

2. Product description

The product must be described in detail. Therefore, said description must consider aspects such as intrinsic characteristics such as its physical / chemical structure, composition, treatments / processes such as cooking, pasteurization, sterilization, smoking, brining, among others.), As well as its packaging, useful life, storage conditions and distribution and marketing system.

3. Determination of feed use

It is evident that in every society, there are vulnerable groups in the population, which is why the use, in the conditions and quantities, that said groups (users or final consumers) will give to that food, must be taken into account, in a way that to rationalize the actions of the organization.

4. Elaboration of the flow diagram

The preparation of the flow chart that includes all the stages of the process, should be carried out with awareness, detail and knowledge, which is why it must be carried out by the large HACCP team.

This construction will allow an effective identification of the potentialities of contamination, on the basis of which, the actions regarding the control methods to be implemented and even the potential, if there are any, process modifications can be visualized. Likewise, a schematic plan of the establishment must be drawn up.

5. On-site verification of flow chart

This previous stage of the HACCP plan must be approached by the HACCP team, which must compare the "real" flow diagram "made" with the process itself during all its stages, as well as the current scheme of the plant.

This pertinent verification has the value of confirming that stages of the particular process of that organization have been considered and which are the movements of the employees, of the raw materials and intermediate and final products and to study if they are correct.

Subsequently, and following the logical framework of the HACCP system, its 7 (Seven) principles are applied.

6. Identification of potential hazards and analysis of risks associated with each stage of the process, and determination of control measures (Principle 1)

This activity must be carried out by the HACCP team, which must list all the hazards that can be anticipated in each of all the stages of the scope / scope foreseen for HACCP. That is, if HACCP will be implemented from the reception of raw material, yes or yes, an evaluation of suppliers should be carried out (over time, if necessary as on several occasions, a development of suppliers should be carried out to make them compatible with HACCP), then it will go through the elaboration and distribution until the final use of the product.

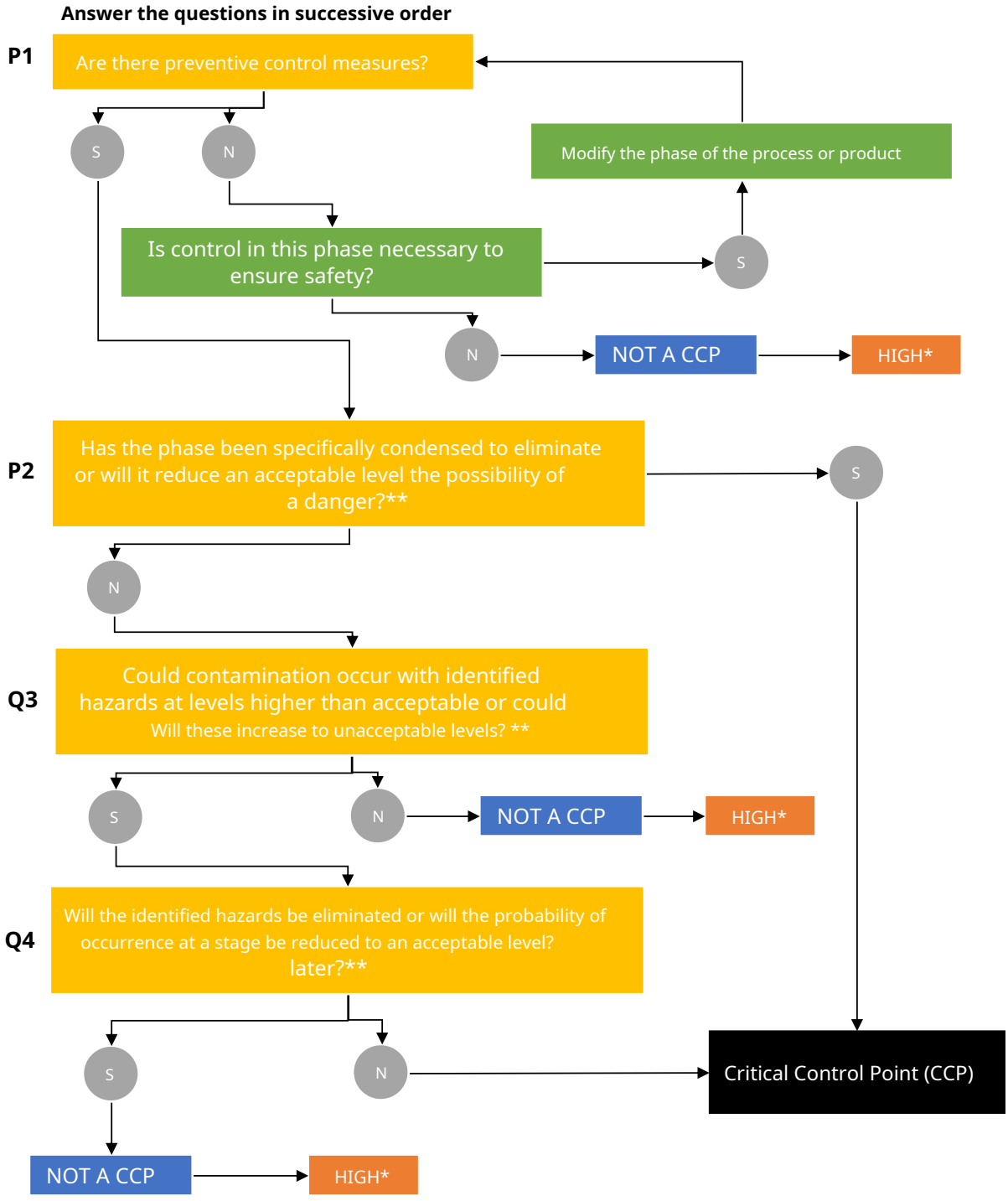
In the identification of the hazard, in its evaluation and in the subsequent operations of design and application of the HACCP System, the ingredients, the food manufacturing practices, the role of the manufacturing processes in the control of the hazards must be taken into account. , the likely end use of the product, the consumer groups for which the product is intended, and epidemiological data related to food safety.

It is important to note that the hazard analysis must be carried out on each new product (of course bearing in mind information from the previous one), therefore, when there are changes in raw materials, inputs, etc., proportion in the formulation, methods of preparation, process, packaging, distribution and / or use of food. Likewise, the control measures that can be applied in relation to each identified hazard must be analyzed.

7. Determination of Critical Control Points -PCC- (Principle 2)

To comply with this principle, it is essential to use a decision tree to determine it or the CCPs in that HACCP system. Here is an example of a decision tree, which may not be applicable to all situations, so eventually other approaches may be used. To apply it properly, it is essential that staff are trained in the application of the decision tree.

In the case of identifying a hazard at a stage in which control is essential to maintain safety and there is no control measure that can be adopted in that part of the process or in any other, the process or product, in that stage / operation It must be modified, or at any earlier or later stage, to include a control measure.



*** Proceed to the next danger** *** * Acceptable levels need to be defined**

8. Establishment of LC Critical Limits for each CCP (Principle 3)

It is necessary for each CCP to define the Critical Limits (CL), that is, the "sender" where the CCP must "transit". Therefore, the LC must be specified and validated for each CCP, and state whether the criteria are acceptable or not and determine whether or not an operation is generating safe products.

Eventually, although rare, more than one LC must be established for any particular stage. In general, the criteria used are quantifications of time, temperature, humidity, pH, aw, free chlorine, and sensory parameters such as taste, smell, texture, color, among others. If these parameters are kept within the established boundaries, it is possible to confirm the safety of the food.

9. Establishment of a monitoring system for each CCP (Principle 4)

The monitoring, that is, the monitoring of the set of measurements of a PCC, is related to its LC and even operating limit (limit narrower than the LC itself). Now, monitoring must have the ability to generate information with enough time to carry out the necessary adjustment actions and thus keep the process under control, preventing the evaluated parameter (s) from not exceeding the LC.

Likewise, it is evident that the adjustments to the process must be made before the occurrence of the deviation, therefore, the data obtained from the monitoring / surveillance system must be evaluated by a competent person, designated for said function (such responsibility must be specified in HACCP manual). It is also worth mentioning that if the monitoring is not continuous, the measurement frequency must be sufficient to guarantee that the CCP is controlled.

These monitoring systems are fast since the determinations are from online processes and therefore, usually, long times are not available for long analyzes. In general, although not always, physicochemical rather than microbiological analysis is chosen because the speed of the determination and even with some, the microbial load of the food or surfaces, etc. can be inferred.

All records and documentation associated with the monitoring of CCP surveillance must be signed by the person / s who carry out said controls and by the person in charge / supervisor of the area.

10. Establishment of corrective actions (Principle 5)

Depending on the deviations that may occur, specific corrective measures must be formulated for each of the CCPs in the system, in order to ensure that it is controlled again.

The predetermined or adopted measures (due to unforeseen eventuality), must contemplate an adequate system for eliminating the compromised product, as well as the procedures for deviations and elimination of the products, must be documented in the HACCP records.

11. Establish verification procedures (Principle 6)

These procedures are intended to determine if the HACCP system is working properly. Verification methods, procedures and tests may be used, in particular by random sampling and the corresponding analysis (s).

This principle of verification must be carried out by personnel other than those in charge of monitoring and corrective measures. In the event that some of the verification activities cannot be carried out in the company, they may be carried out by external experts or qualified third parties as appropriate, always recording everything concerning said action.

12. Establishment of a documentation and records system (Principle 7)

For any implementation, if not non-existent, it is essential to have an effective documentation and records system, a requirement that of course also applies to the entire HACCP system.

For example, it should be documented:

- Hazard analysis.
- Deviations and the corresponding corrective measures.
- Determination of Critical Control Points (CCP).
- Determination of Critical Limits (CL).
- Modifications made to the HACCP system.

All the records and data collected must be kept by the manufacturer, at least for a minimum period, equal to the useful life of the product, although longer periods are suggested.

II. OBJECTIVE

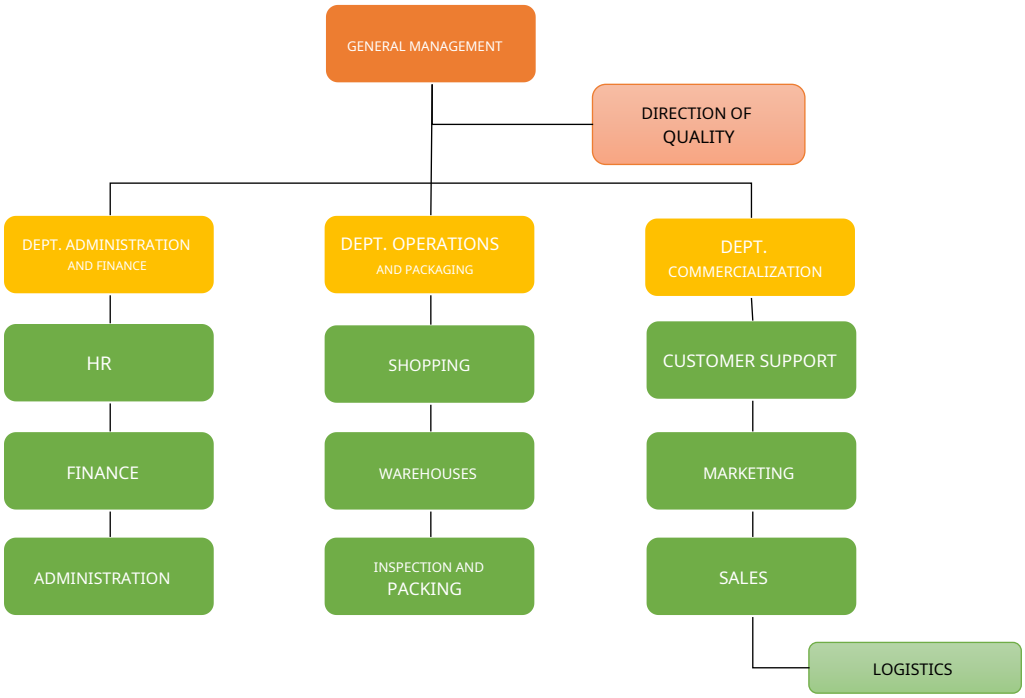
This document is intended to identify hazards related to the safety of the vehicle. consumer to ensure safety and contribute to the quality of sea salt.

The HACCP plan has the following benefits:

- Fosters a preventive culture
- It is compatible with the application of quality and environmental management systems, among others.
- Allows all collaborators to participate in the production of safe products.
- It allows demonstrating that food safety is managed effectively, also facilitating inspection by regulatory bodies.
- Promotes international trade by increasing confidence in food safety.
- Offers the means to solve problems related to safety, avoiding their repetition.
- Meets the regulatory requirements of most countries.
- Applicable to the entire food chain. In addition, it adapts to the size and type of company, due to its flexibility.
- Eliminate unnecessary controls.

III. ORGANIZATION CHART

Below is the organization chart of the company:



FUNCTION LIST

Some of the functions of each area are listed below:

GENERAL MANAGEMENT:

- Manage the activities of the organization establishing tasks, objectives and priorities. Develop,
- implement, coordinate, review, evaluate and improve the procedures and policies of the company.
- Monitor and supervise the progress of projects, objectives, costs and time frames.
- Collaborate with the Sales and Accounting departments to discuss strategies and achieve financial objectives.
- Supervise the performance of the members of each department.
- Cultivate labor relations with employees and third parties.
- Solve conflicts to ensure the proper functioning of the organization.

QUALITY MANAGEMENT

- Plan and establish the procedures, standards and quality specifications of the company.
- Review customer requirements and ensure they are met.
- Work with the purchasing department to establish the quality requirements of external suppliers.
- Establish quality standards, as well as health and safety.
- Ensure that manufacturing or production processes comply with international and national standards.
- Define quality procedures in conjunction with operational personnel.
- Establish and maintain controls and documentation procedures.

ADMINISTRATION AND FINANCE:

HR

- Recruitment and staff selection.
- Hiring.
- Payroll.
- Payment of worker-employer
- fees. Internal regulations.
- Benefits.

ACCOUNTING

- Monthly and annual statements.
- Income statements.
- Balance sheets.
- Procedures before SAT.

ADMINISTRATION

- Billing.
- Receipt of payments.
- Payment to suppliers.
- Formats (sales, purchases, assistance, etc.)
- Databases (customers, suppliers, shipments, etc.)
- Digital inventory.
- Creation of document, trades, etc.

OPERATIONS AND PACKAGING

SHOPPING

- Request for quotes from suppliers and potential suppliers.
- Input purchases.
- Relationship and negotiation with suppliers.
- Credit applications with suppliers.
- Verification of compliance with specifications in the purchase.

WAREHOUSES

- Reception of raw materials.
- Receipt of supplies.
- Warehouse of purchases received.
- Registration of inputs and outputs of raw materials and supplies.
- Management and organization of supplies.
- Quality verification of raw materials and inputs received.

INSPECTION AND PACKAGING

- Salt inspection
- Salt packaging
- Weighing and sealing packages with sea salt
- Labeling of packaging and packaging
- material. Cleaning of work areas.
- Daily logs

COMMERCIALIZATION

CUSTOMER SUPPORT

- Receiving Calls.
- Reply to emails. Quotes.
-
- Relationship with distributors.
- Search for customers and sales
- channels. Direct customer service.

MARKETING

- Digital advertising.
- Management of social networks.
- Creation, maintenance and updating of web page.
- Digital document designs.
- Photography and product image design.

SALES

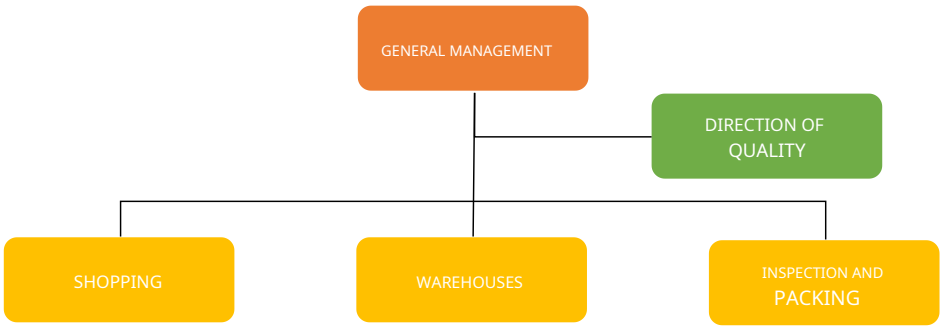
- Set goals
- Develop strategies
- Promote the company
- Follow up with clients
- Instruct logistics about the shipping conditions.

LOGISTICS

- Quote with parcel services. Order
- shipping schedule. Distribution of
- orders.

IV. TRAINING AND FUNCTIONS OF THE HACCP TEAM

The HACCP team is made up of personnel involved with the elaboration of the product, an interdisciplinary group which will meet to elaborate, implement, review after each audit and annually, the plan to establish improvement proposals in it.



MANAGING DIRECTOR

He is in charge of establishing and disseminating the safety / quality policy in the company, in addition to assigning the necessary resources to prepare, implement and improve the plan. In addition to reviewing the HACCP plan annually with the other team members.

QUALITY MANAGEMENT

He is the one who directs the HACCP plan, supervising the critical control points, records, corrective actions to guarantee the correct operation of the HACCP Plan. It is also the one that communicates to the General Director of the operation of the plan.

He is the one who represents before the management the compliance of the system, develops and carries out the increase of competencies of the plant personnel, which may include theoretical training, practices, skills and attitudes, among others.

INSPECTION AND PACKAGING

He is in charge of directing the product process and planning daily tasks. Collaborate with the Quality Director as the relationship between the two is important to obtain safe products. Also, as a member of the HACCP team, you should review the plan annually with the other members.

SHOPPING

It is responsible for making purchases and selecting suppliers, eventually part of these decisions can be made based on the information provided by the heads of other areas, in pursuit of obtaining a better product, reducing costs, adapting to regulations , etc. He also participates in the annual review of the HACCP plan with the other members.

WAREHOUSES

Supervise and coordinate the inspection, reception, batch identification and storage of supplies, raw materials, packaging material, products in process, finished products, as well as their supply to the Production Area.

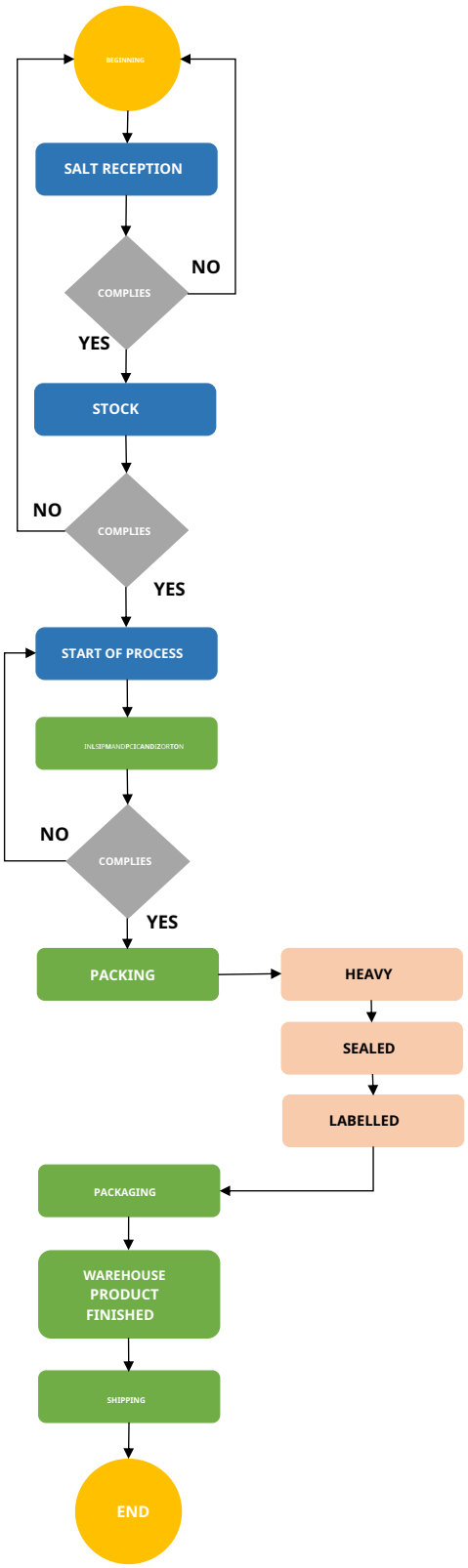
V. PRODUCT DESCRIPTION

PRODUCT NAME	Sea salt
USE OF THE END PRODUCT	Seasoning / additive
SHELF LIFE	10 years
PRESENTATION	8 oz. (227 gr)
CONSUMER EXHIBITION	Humidity <65%
CONDITIONS	Pgeneral public

	AGENT	LIMIT	REF. ANALYTICS
FEATURES MICROBIOLOGICAL	Total coliforms	<3.0	CCAYAC-M-004/11
	Mushrooms	<10	NOM-111-SSA1-1994
	Yeasts	<10	NOM-111-SSA1-1994
	Salmonella	Absent in 25 gr.	NOM-114-SSA1-1994
	S. aureus	<100	NOM-115-SSA1-1994
	E. coli	13.0	CCAYAC-M-004/11
	Listeria monocytogenes	Absent in 25 gr.	Internal PCR method real time

<10 CFU / g = Not detectable
<3.0 MPN / g = Not detectable
<100 CFU / g = Not detectable

SAW. GENERAL FLOW OF THE PROCESS FOR SEA SALT



DESCRIPTION OF THE STAGES establish the limits of control temperature black points

1. SALT RECEPTION

The truck arrives at the facilities, places it at the entrance of raw materials and supplies and unloads the salt in 50-kilo sacks of raffia. The purchasing department receives, opens the bags and checks that they meet the specifications. Once the delivery is authorized and registered, it tells the warehouse to be in charge of emptying the bags in the corresponding area. If the salt does not meet the specifications, then it does not enter the facility.

2. WAREHOUSE

The warehouse department receives the salt that meets the purchasing specifications and deposits it within the warehouse. Once the salt has been placed in its respective area, the batch is registered and the laboratory sample is taken and the microbiological, instrumental, heavy metals and foreign matter analyzes are carried out. If the laboratory results are out of range, the salt is removed from the store and discarded, the store must be thoroughly cleaned.

3. INSPECTION

If the laboratory results are favorable, the batch can be released for the next stage. Here the inspection process begins, at this stage an inspection of the salt is carried out in groups of 40 kg each and all impurities are removed by means of a manual process. Later it is stored in plastic boxes of 40 to 45 kg. and is stored in another area within the warehouse to avoid contamination.

In order for the salt to pass to the next stage of the process, it must be ensured that it does not exceed the limit of 7 points for each pound.

* Point - grains of different coloration

4. PACKAGING

Packaging will only receive the salt that is inside the boxes stored for inspection. Once the box is selected, it is entered into the packaging area and placed next to the work table. The filling of the bags is done manually, by two operators, with a measured container. Once filled, they go to the weighing stage.

5. HEAVY

Two people receive the bags and place them one by one on the scales to check the weight. According to the initial weight of each bag, they manually adjust by removing or adding grams of salt until reaching 227 gr. (80z.) The weight must be exact to pass the product to the sealing area.

6. SEALING

Once the bags are weighed, the sealing personnel are in charge of closing and sealing them, cleaning any grain of salt that may be in the closure of the bag or outside of it. Sealing is by band heat sealer.

7. LABELING

Labeling personnel must ensure that the bag is completely clean, with no residue that could affect the placement of the label. As a security seal, the label with the brand and characteristics of the product is placed on the heat seal. Subsequently, the bag is sealed with batch and expiration date with a heat batch coding machine.

8. PACKAGING

Only sealed and labeled bags are packed in double corrugated cardboard boxes. The content of each box must be 75 bags each. The box is sealed and placed on the pallet. Each pallet carries 40 boxes. The cardboard box is labeled with 3 labels: one with the sender's data, another with the receiver's data and the third with the product code.

9. FINISHED PRODUCT WAREHOUSE

Complete pallets are placed in the finished product warehouse area and entered into inventory. This area is free of pollutants and close to the loading area, since they will not last long while waiting for collection by the parcel or logistics team.

10. SHIPPING

Once the purchase order is completed, the collection is coordinated with customs and a truck from a national parcel is hired. Certified pallets are purchased one week in advance.

On the day of shipment, the pallets are reassembled on top of the truck with the new certified pallet, corner and plastic wrap to protect the boxes, sheets are placed with the pallet number and the content.

The necessary documentation is carried out: invoice, parking list, boarding certificate. The driver is given one set of documents, one for filing, and they are mailed to customs.

VII. HAZARD ANALYSIS AND PREVENTIVE MEASURES

1. Criteria applied to determine the effect of the hazard

Value	Scope	Criterion
Low	SECURITY	No disease
Half	SECURITY	Mild sickness
High	SECURITY	Illness without permanent disability
Very high	SECURITY	Permanent disability or loss of life

2. Ratings for probability of occurrence of the hazard

Value	Probability	Meaning
4	Frequent	More than twice a year
3	Probable	No more than 1 to 2 times every 2 or 3 years No
2	Occasional	more than 1 or 2 times every 5 years
1	Remote	Very unlikely, but it can happen sometime

3. Criteria for determining a significant hazard Is it a significant hazard?

EFFECT	PROBABILITY			
	4	3	2	1
	Frequent	Probable	Occasional	Remote
Very high	YES	YES	YES	YES
High	YES	YES	NO	NO
Half	NO	NO	NO	NO
Low	NO	NO	NO	NO

HAZARD ANALYSIS AND PREVENTIVE MEASURES

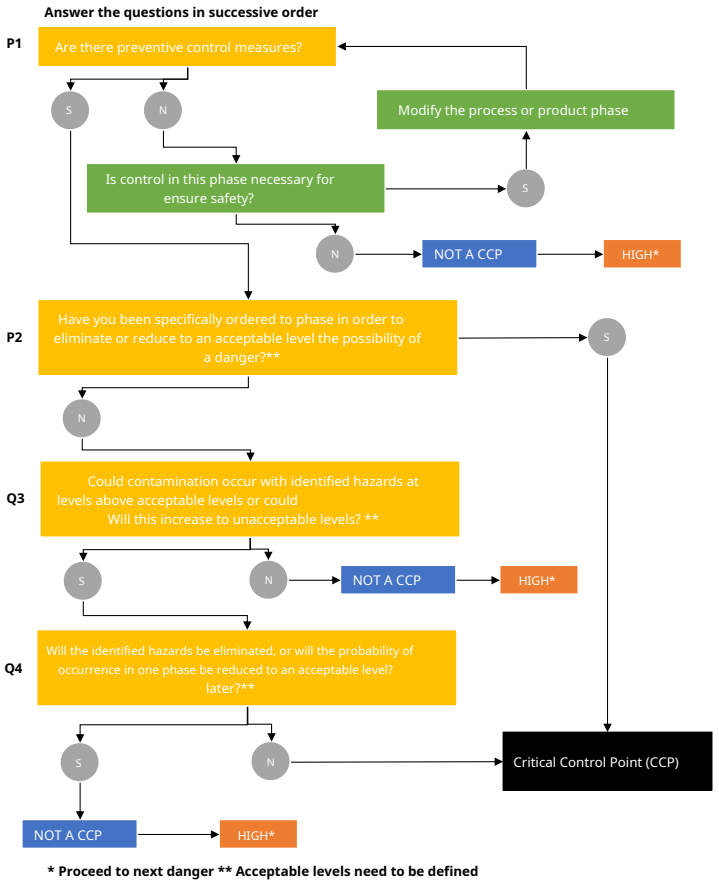
STAGE OF PROCESS	DANGERS POTENTIALS	PROBABILITY AND RISK	DANGER SIGNIFICANT	JUSTIFY YOUR DECISION	PREVENTIVE AND CONTROL MEASURES DANGERS
Receiving raw material **(Salt)**	**PHYSICAL:** Coloration	Probability: Remote Risk: Low	NO	The change in the color of the salt can mean natural contamination.	The salt that arrives at the facilities with characteristics different from those established in the eligibility criteria is rejected and does not enter the warehouse.
	CHEMICAL: No				
	BIOLOGICAL: No				
Stock	**PHYSICAL:**				
	CHEMICAL: Heavy metals	Probability: Remote Risk: Very high	YES	Depending on the water used in the process, the grain of salt could have a high concentration of lead. (*Lead is not found as an object, it is a proper component of salt)	Laboratory analysis to rule out heavy metals upon receipt of each batch of salt.
	BIOLOGICAL: L. monocytogenes Pathogenic E. coli Salmonella spp. S.aureus. Pathogens environmental	Probability: Remote Risk: Very high	YES	Because the salt comes from an outdoor process with natural equipment.	Laboratory analysis to rule out microbiological hazards upon receipt of each batch of salt. To go to the next stage, the laboratory results must be favorable (Do not exceed the limits)
Inspection	**PHYSICAL:** Strange objects	Probability: Probable Risk: High	YES	Natural / environmental objects: Salt has natural components of another color (black grains). Unnatural objects: Operator objects that could get mixed up with the product. (sequin, diamond, earring etc)	Inspection is carried out to remove the grains of different coloration and any foreign objects. Operators must wear gloves, face masks and a cap. In addition, if an operator has symptoms of illness, he cannot enter the facilities.

	CHEMICAL: No **BIOLOGICAL:** No				
Packing	**PHYSICAL:** No **CHEMICAL:** No **BIOLOGICAL:** Contamination by illness of a operator	Probability: Remote Risk: Low	NO	A disease could be transmitted through the product or packaging	Operators must wear gloves, face masks and a cap. Before entering your area, they follow the hygiene regulations. In addition, if an operator presents symptoms of illness, he cannot enter the installations.
Packaging	**PHYSICAL:** No **CHEMICAL:** No **BIOLOGICAL:** No				
Warehouse product finished	**PHYSICAL:** No **CHEMICAL:** No **BIOLOGICAL:** No				
Shipment	**PHYSICAL:** No **CHEMICAL:** No **BIOLOGICAL:** No				

VIII. DETERMINATION OF CRITICAL CONTROL POINTS

PROCESS STAGE	IDENTIFIED HAZARD	P1	P2	Q3	Q4	PCC
Reception of Raw Material	PHYSICAL	YES	NO	YES	YES	NO
Stock	PHYSICAL, CHEMICAL AND BIOLOGICAL	YES	YES	-	-	YES
Inspection	PHYSICAL	YES	YES	-	-	YES
Packing	BIOLOGICAL	YES	NO	NO	-	NO
Packaging						
Product warehouse finished						
Shipment						

DECISION TREE TO IDENTIFY CCP



The identification of critical control points was carried out with the decision tree, determining two critical control points (CCP)

1. WAREHOUSE 2. INSPECTION

IX. ESTABLISHING THE HACCP CONTROL CHART

After establishing the critical control points, the HACCP control table was prepared, where the critical limits for each stage are established. monitoring, corrective actions and records to be used in each CCP.

CRITICAL POINT OF CONTROL	DANGERS SIGNIFICANT	CRITICAL LIMITS	THAT	EXCUSE ME	FREQUENCY	WHO	ACTIONS CORRECTIVE	RECORDS	CHECK
Stock	Heavy metals Dangers microbiological	<2 Absent in 25 gr <3.0 Absent in 25 gr <100	Lead L. monocytogenes Pathogenic E. coli Salmonella spp. S.aureus.	Realizar analysis from laboratory	Test each lot (2 lots by year)	Address Quality and Stock	If the product exceeds limits must backing out totally of warehouse and clean any residue.	File and analysis logs microbiological Register of return to vendors	Analysis of laboratory Assessment supplier

CRITICAL POINT OF CONTROL	DANGERS SIGNIFICANT	CRITICAL LIMITS	THAT	EXCUSE ME	FREQUENCY	WHO	ACTIONS CORRECTIVE	RECORDS	CHECK
Inspection	Pollution by objects strangers	The product must be totally free of strange objects	Grains of different coloring, others objects.	Remove carefully the strange object of product following the rules mandatory of safety and hygiene	Every time start the process of inspection	Address quality e Inspection	For objects natural: If the presence of a Strange object must retire directly. For objects no natural: You must withdraw from the process all come out I know find 15 cm around the area contaminated.	Register of operators in the process Object registration strangers and protocol extraction Claim record consumer	Daily review from compliance of regulations Audits internal and drills Review by HACCP team

X. VERIFICATION PROCEDURE

Verification procedures have been established to ensure that the HACCP System works properly and is effective. The following are listed as verification activities:

VERIFICATION ACTIVITIES	FREQUENCY	RESPONSIBLE
1. Review the HACCP plan	Annual	HACCP team
2. Verification of Flowchart	Annual	HACCP team
3. Validation of the CCPs	Annual	HACCP team
4. Evaluation of supplier	Annual	Quality
5. Review of compliance regulations	Daily	Quality
6. Security drills	Monthly	Management
7. Internal Audit	Annual	Management
8. Review of corrective action records.	Monthly	Quality
9. Review of customer claims records	Monthly	Quality
10. Microbiological tests	Every time a batch arrives	Accredited laboratory

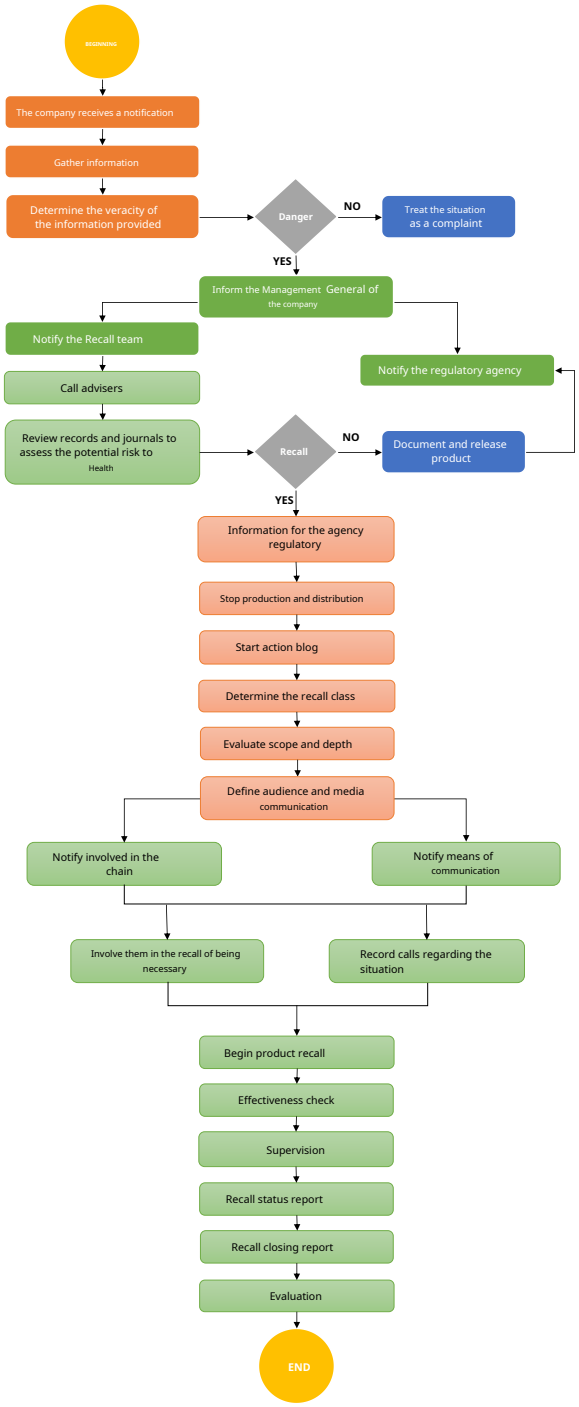
RECORDS:
HACCP Record 01: Microbiological analysis records
HACCP Record 02: Return to suppliers record
HACCP Record 03: Record of operators in process
HACCP Record 04: Foreign Object Record and Extraction Protocol
HACCP Record 05: Customer Complaints
HACCP Record 06: Corrective Actions HACCP
Record 07: HACCP Team Meeting Minutes

XI. CONSUMER COMPLAINT PROCEDURE

1. All consumer complaints will be directed to the Customer Service Department and the latter will communicate the complaint to the Quality Director.
2. The Quality Director will record the complaints in the HACCP 05 Record.
3. The Quality Director will investigate the causes of the complaint and whether it is legitimate.
4. The Quality Director will inform the General Director in writing of the complaint and its cause.
5. The Director General will be in charge of determining whether the complaint has been legitimate or not and the action to be taken.
6. All consumer complaint records are on file in the Quality Director's office.

REGISTRATION
HACCP Record 05: Customer Complaints

XII. RECALL D PROCEDURE E PRODUCT NON-CONFORMING



REGISTRATION

HACCP Record 08: Traceability

HACCP Registration 09: Withdrawal of non-compliant product

XIII. RECORDS

The HACCP plan records shown below will be kept on file in the Quality Director's office for two years, then discarded.

HACCP Record 01: Records of Microbiological Analysis and Heavy Metals for Salt

Limits

AGENT	LIMIT
Total coliforms	<3.0
Mushrooms	<10
Yeasts	<10
Salmonella	Absent in 25 gr.
S. aureus	<100
E. coli	13.0
Listeria monocytogenes	Absent in 25 gr.
Lead	<2

DATE	LOT	SUPPLIER	KIND OF ANALYSIS	LABORATORY	RESULTS	OBSERVATIONS

HACCP Record 02: Record of Return to Suppliers

DATE DETECTION	LOT	SUPPLIER	REASONS FOR RETURN	DATE RETURN	NAME OF WHO RECEIVES

HACCP Register 03: Register of operators in process

AREA / PROCESS:

DATE	NAME	HOUR INITIAL	FINAL HOUR	FIRM

HACCP Record 04: Foreign Object Record and Extraction Protocol

Foreign Object Limits: The finished and packaged product ready for human consumption must not contain foreign matter.

DATE	LOT / BOX	KIND OF OBJECT	AMOUNT FROM OBJECTS	OPERATOR THAT REPORT	DESCRIPTION OF THE PROTOCOL OF EXTRACTION	QTY FROM PRODUCT DISPOSED

HACCP Record 05: Customer Complaints

DATE	CUSTOMER	PRODUCT	INSTEAD OF PURCHASE	REASON FOR CLAIM	RESOLUTION

HACCP Record 06: Corrective Actions

DATE	HOUR	STAGE PROCESS	DEVIATION	CORRECTIVE ACTION	OBERVATIONS

HACCP record 07: Minutes of the HACCP team meeting

DATE_____
HOUR_____

RECORD NUMBER _____

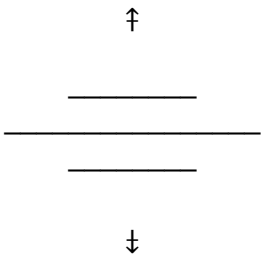
In the meeting held by the HACCP Team of the company Fleur de Sel SA de CV, the following points were concluded:

_____
_____
_____
_____

General management Quality Manager

HACCP Record 08: Traceability

DATE	START TIME AND FINAL	PRODUCT	AMOUNT	CODE	OBERVATIONS



RECALL PLAN

SEA SALT

Content

I. INTRODUCTION

Sanitary measures in international markets have led the food industry to have technical alarms during its marketing processes; one of the strategies used by some states to regulate alarms is Recall.

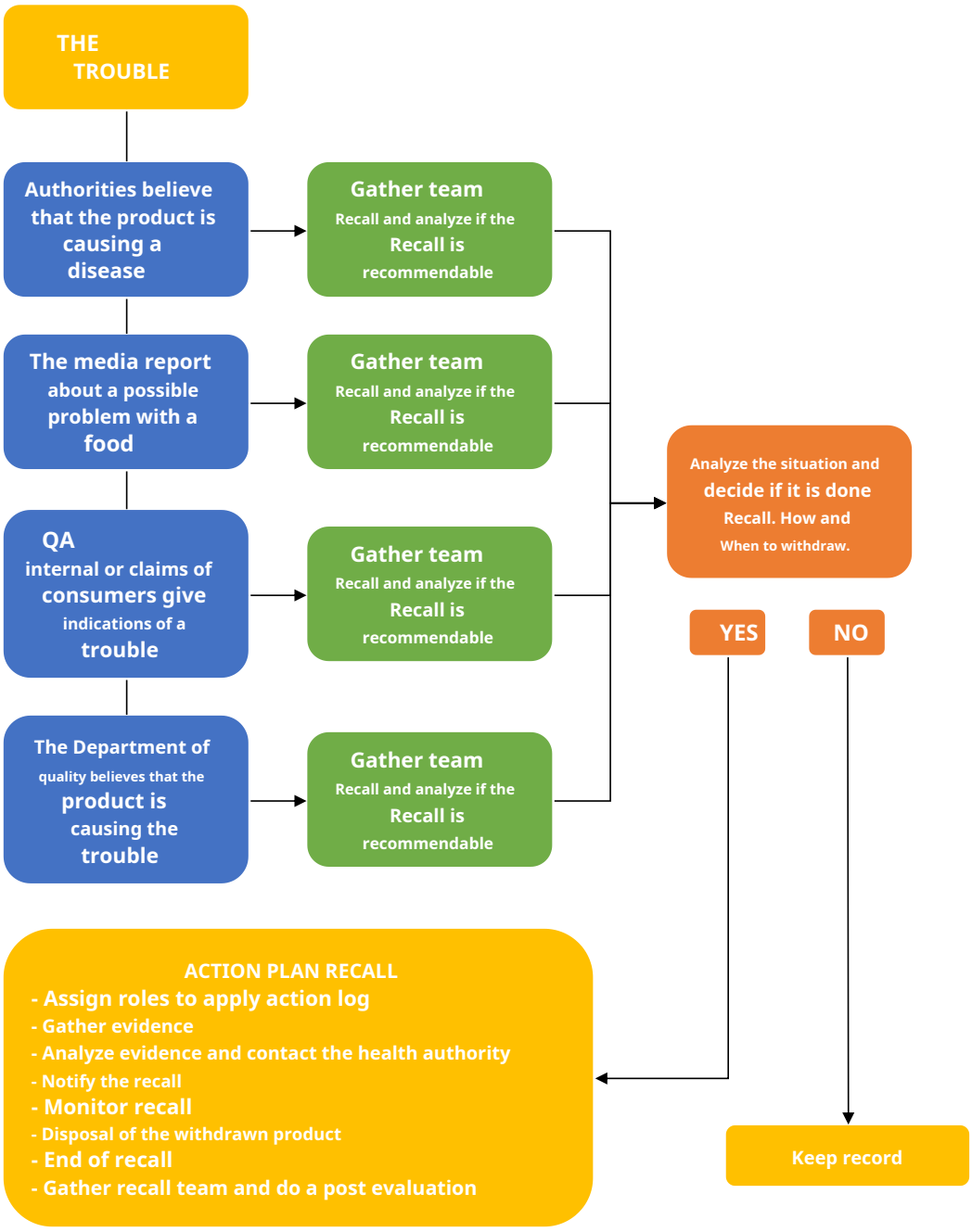
This process, which consists of the withdrawal of products from the market, prevents negative impacts on the health of the population and on the reputation of the food sector industry since it guarantees the safety and quality of the food that reaches the consumer.

The action of this strategy requires a traceability program, which implies the ability to know the history of a product, its distribution channel and its target market; To achieve this purpose, the support and collaboration of the consumer and other institutional and commercial actors such as large supermarkets is required.

This document seeks to contextualize the procedures and routes of action of the Recall.

II. RECALL FLOW CHART

The Schematic below from "The Food Recall Manual" from the University of Florida will give you a quick overview of the flow that takes place during a recall. Each of the links contained in the diagram will be reviewed on the following pages.



III. WHO IS THE MANUAL AIMED AT?

The content of this manual is focused on the entire company, which includes from production, reception, warehouse, inspection, packaging, packaging, storage and distribution to the sale of products, in order to protect the health and nutrition of the company. population and guarantee the supply of healthy and safe products.

IV. WHAT IS A RECALL?

A Recall is a procedure carried out by a company, which consists of withdrawing a product from the market, when it is suspected or certain that it violates current food laws or that the quality standards established by the company for said product are violated. market.

Its objective is to protect the health and nutrition of the population and guarantee the supply of healthy and safe products. Not every product recall is a recall itself, there are other alternatives to recall, here is the difference between its alternatives and recall:

Recall: It consists of withdrawing a product from the market, because it is not innocuous, because it is adulterated, contaminated or badly labeled, or that the health authority considers as an offender of the law.

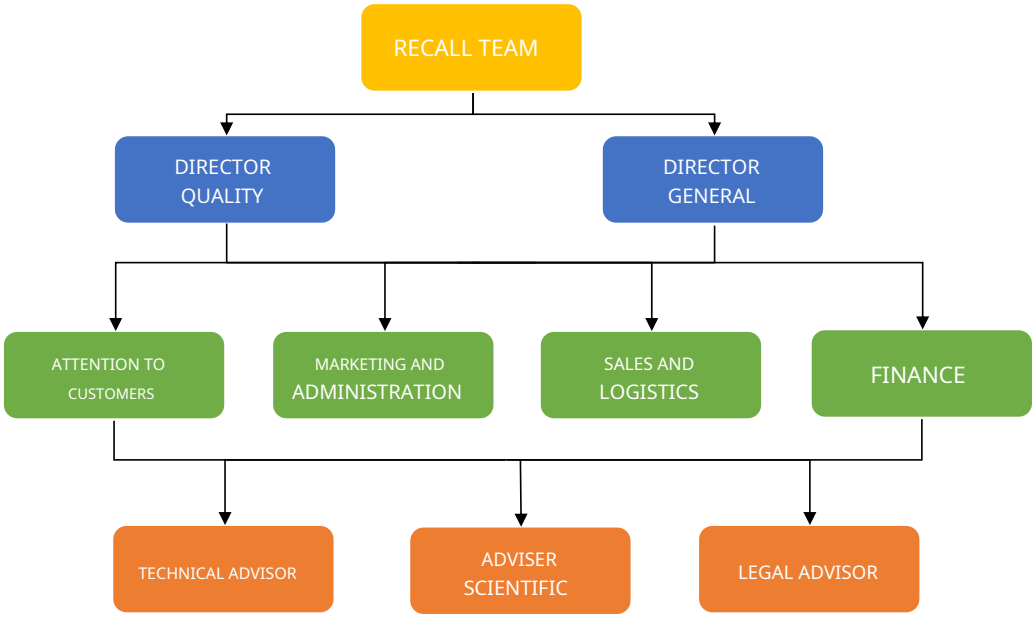
Product or market recovery: It is about the removal of the product once it is being distributed when it violates a law at a lower technical level (does not pose a health risk), or if it does not meet the technical specifications or quality standards of the producer. It does not include products that have been contaminated or adulterated.

Stock recovery: Removal of the product from potential distribution before it leaves the direct control of the producer, that is, even when it is in their warehouse or that of the distributor, but has not been released for sale to the consumer.

V. RECALL IN THE COMPANY

A. THE RECALL TEAM

The Recall team is presented below, being a small company, there are people who fulfill various roles in the team, but are familiar with all aspects of the production process, its suppliers and customers. There are external experts who are helpful in specific areas for which there are no internal competencies.

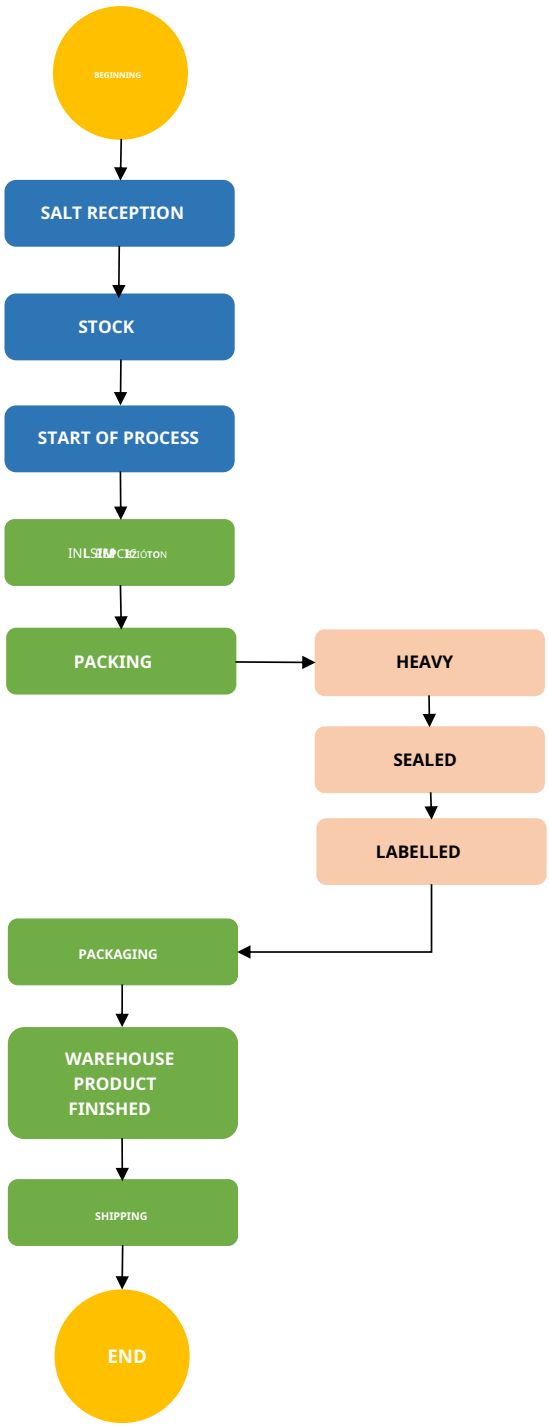


THE RECALL TEAM HAS THE FOLLOWING RESPONSIBILITIES:

Develop the procedures that are necessary to operate a good recall program. This includes a written Recall Plan.
Review existing operational procedures and recommend changes to minimize the likelihood of recall or make it easier if necessary.
Generate a list of potential quality and / or safety problems that could affect your products.
Establish response and action guidelines for all potential problems that could generate a crisis.
Respond to any product quality problem that may require its removal, including handling all information related to the issue, whether internal or external.
Manage communication with health authorities, senior management of the company and the media.
Direct the actions of recall and / or crisis management when it occurs and until the situation is resolved.
Evaluate the effectiveness of the plan and propose improvement actions in order to prevent similar incidents or improve its effectiveness if it is repeated.

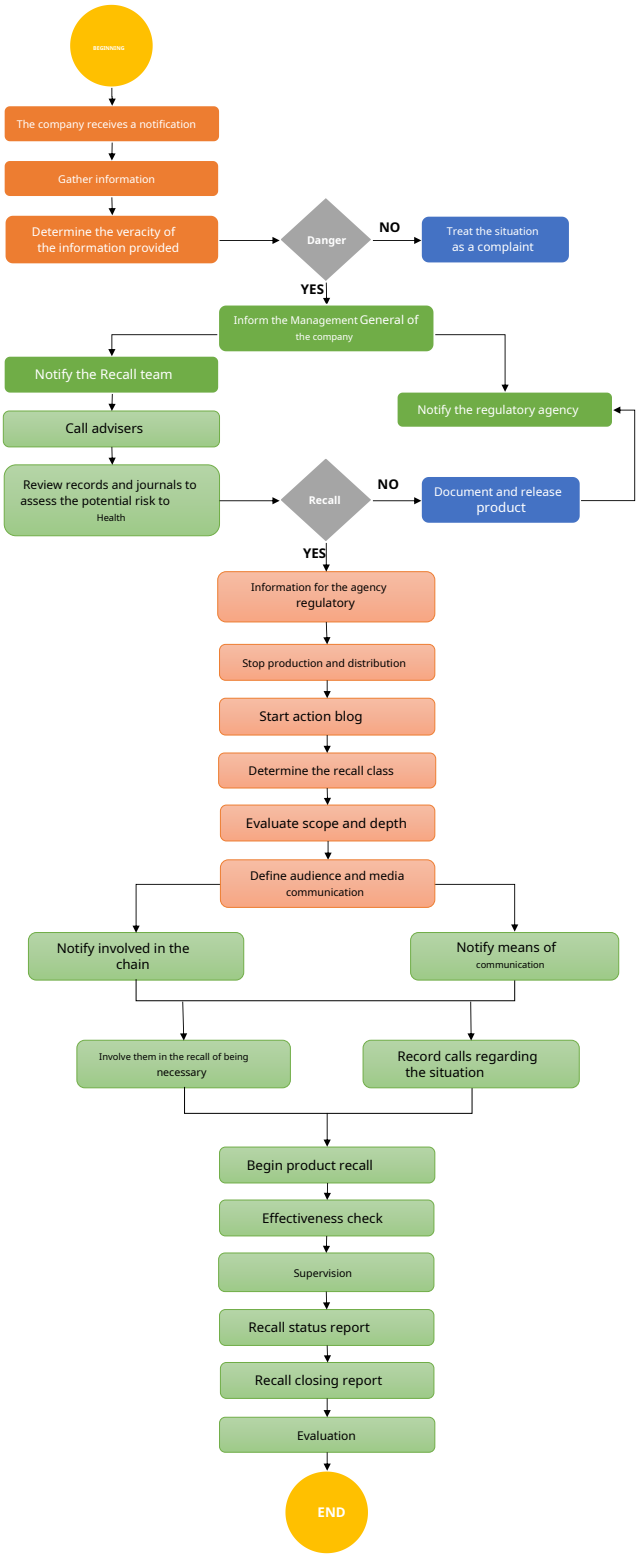
B. IDENTIFY AREAS WITH POTENTIAL PROBLEMS

The process flow was reviewed from the entry of raw materials until the product is shipped in order to detect areas in which a threat may occur according to the points established by the Recall Team.



POINT TO EVALUATE	YES	NO	OBSERVATIONS
1. Unauthorized persons have easy access to the facilities, through keyless doors, accesses, vehicles, etc.?		X	The facilities do not allow the entry of cars or unauthorized personnel, at all times the Doors are closed and there is a regulation to receive visitors
2. Do employees have unnecessary access to a critical part of the process?		X	Each employee knows the activities they must carry out without interfering with the activities of their other colleagues, even though some must carry out more than one activity, they know the protocols and regulations to follow to avoid cross contamination.
3. Can a person enter, store or move unauthorized material within your facilities?		X	There is only one entry to the facilities for materials, the warehouse of everything that is not raw material, is carried out at the end of the process / activities of the day.
4. Is there an adequate inspection of access control for vendors and suppliers?		X	There is a single entrance for merchandise from suppliers, operators do not enter the facilities, everything is received and accommodated by company personnel. For sellers there is a delivery access to one side of warehouses, there they receive the products without entering the facilities.
5. Is there an inspection process for incoming raw materials and inputs?	X		It is checked that it complies with the requested specifications, in case of not complying, the product is not received or stored in the warehouse, it is immediately returned to the supplier. The same is true if the initial inspection passes but the lab results are not favorable.
6. Are the received batches encoded?	X		The traceability process begins when each batch is received, so that each product can be easily identified.
8. Is there a warehouse rotation system?	X		The FIFO system is used, even when the product has a long expiration date, it is necessary for the traceability system to be this way.
9. Is the batch code visible to the customer?	X		
10. Does the label comply with the country's legislation?	X		According to the type of client, the label has the necessary information to comply with the legislation of each country.
11. Is there a record for each stage of the process?	X		Each record is important for the quality standards and traceability of the product, the person in charge of each area is responsible for each record.
12. Are the records duly filled out and kept to avoid their later alteration?	X		The records are kept in the office of the General Directorate, which is locked and can only be entered by the Director and Administration.
13. Does the computer system have antivirus?	X		
14. Is the information in records regularly backed up?	X		Every month a backup of the records is made for each process, this activity is carried out by Administration
15. Are laboratory analyzes carried out with certified companies?	X		
16. Are there responsible for monitoring the safety of the process?	X		The HACCP team is responsible for these activities
17. Are the legal and psychological backgrounds of all employees checked?	X		They are reviewed by Human Resources before approving an employee's entry
18. Each employee has a company identification?		X	Being a small company, the employees know each other and are aware of the activities that each one can carry out.
19. Is there a record of who accesses confidential documents?		X	At the moment General Management and Administration are the only people with authorization to access these documents.
20. Is there a process for employees to report unusual activities?	X		Any employee can report a suspicious or unusual activity directly to the General Directorate, this in order that the information is not distorted from one person to another.

SAW. DECISIONS TREE



1. RECEIPT OF NOTIFICATION

Notification that the product is causing damage or has a defect may be made by one of the following parties:

Sanitary Authority
If the information comes from the health authority, you should pay attention to the statements. The information from it could be generated in a routine inspection, by a consumer complaint or as a result of the permanent surveillance program on the final product.

The maximum background information on the process or findings that linked the product to a particular problem or disease must be requested.

Clients and / or consumers

If the information comes from a customer and / or consumer who has called or written to make a claim, as much information as possible should be collected. This should be documented initially as a complaint or grievance. To follow up, a complaint sheet will be given to the client / consumer.

Media

Customers or consumers, in some cases, turn to the media to make complaints, this in order to discredit the company or make the largest number of people find out and react quickly.

For this type of notification, the media must be contacted to request the data of the person or persons who made the claim, in such a way that as much information as possible can be obtained.

Quality internal team

During the process or routine inspections, the quality team can detect a defect either in the product or in the process, which generates a health hazard. If so, you must immediately report the situation to the General Directorate to avoid intermediaries in the communication.

2. GATHER INFORMATION

This is one of the most important parts to determine the danger of a situation, that is why the R1 Format was designed to collect information. This format is used when the information it is external to the company.

FORMAT R1 - Information Record								
DATE:		HOUR:		ATTENDS:				
REPORTING PERSON								
FULL NAME								
TELEPHONE				MOBILE				
ADDRESS								
PRODUCT								
KIND OF PRODUCT				DUE DATE				
DESCRIPTION OF CONTAINED				CODE				
PACKAGING (GR, KG)								
PROBLEM DETECTED								
UNPLEASANT TASTE		DESCRIPTION						
UNPLEASANT SMELL		DESCRIPTION						
ALLERGIC REACTION		DESCRIPTION						
STRANGE OBJECT		DESCRIPTION						
DEFECT IN THE PACKAGING		DESCRIPTION						
OTHER		DESCRIPTION						
PURCHASE								
DATE OF PURCHASE				SHOP PLACE				
HOW WAS THE PRODUCT STORED?								
HOW WAS IT PREPARED OR USED?								
DATE CONSUMED AMOUNT			PLACE WHERE IT WAS CONSUMED					
CONSUMED								
AFFECTED PERSON								
NUMBER OF PEOPLE AFFECTED								
NAMES OF AFFECTED PERSONS								
1				AGE		TUTOR		
2				AGE		TUTOR		
3				AGE		TUTOR		
ADDRESS AND CONTACT OF THE AFFECTED PERSONS								
1						TELEPHONE		
2						TELEPHONE		
3						TELEPHONE		
ILLNESS ALLERGIES OF AFFECTED PEOPLE								
1								
2								
3								
SYMPTOMS PRESENTED								
1						DATE		HOUR
2						DATE		HOUR
3						DATE		HOUR
TYPES OF FOODS EARNED PREVIOUSLY								
1								
2								
3								
HAVE YOU CONSULTED A DOCTOR ABOUT THIS PROBLEM?								
NAME		DATE		DIAGNOSIS				
NAME		DATE		DIAGNOSIS				
NAME		DATE		DIAGNOSIS				
HAVE THE PRODUCT BEEN INGESTED BEFORE? 1			HAVE YOU TOLD SOMEONE ELSE ABOUT THIS SITUATION?				DO YOU STILL KEEP ANY PRODUCT?	
2								
3								
DO YOU HAVE THE ORIGINAL PACKAGING?		CAN WE SEND SOMEONE TO COLLECT THE PRODUCT AND ANALYZE IT?						
	ADDRESS							
	ADDRESS							
	ADDRESS							
IS THERE SPECIFICALLY SOMETHING YOU REQUEST THAT WE CONSIDER DOING?								

3. DETERMINE THE TRUTH OF THE INFORMATION PROVIDED

External Information

This information is provided by people or companies, organizations outside the company such as customers, consumers, wholesalers or retailers.

In this case, the information received must be evaluated and determine if the information provided corresponds to the type of product, that is, if there is such a presentation, if it is marketed or distributed in that way, that similar reports are found in the history. All to validate the information and ensure that you do not participate in a deception or act of discredit.

Internal information

This information is provided by the company's own team. In this case, the information, being direct, is considered true and automatically goes to the health hazard evaluation.

4. DANGER

At this point, the risk assessment is carried out, if the information provided indicates that there is a potential or current danger to the health of those who handle or consume the product.

5. TREAT THE SITUATION AS A COMPLAINT

If when analyzing the information there is no health hazard, then the information will be treated as a complaint and will be resolved as outlined in the complaint procedure in the HACCP plan.

Consumer complaint procedure

1. All consumer complaints will be directed to the Customer Service Department and the latter will communicate the complaint to the Quality Director.
2. The Quality Director will record the complaints in the HACCP 05 Record.
3. The Quality Director will investigate the causes of the complaint and whether it is legitimate.
4. The Quality Director will inform the General Director in writing of the complaint and its cause.
5. The Director General will be in charge of determining whether the complaint has been legitimate or not and the action to be taken.
6. All consumer complaint records are on file in the Quality Director's office.

HACCP REGISTER 05					
DATE	CUSTOMER	PRODUCT	INSTEAD OF PURCHASE	REASON FOR CLAIM	RESOLUTION

6. INFORM THE GENERAL MANAGEMENT OF THE COMPANY

If when analyzing the information there is a real danger to health, then the General Directorate must be notified immediately since it will be the one that directs the actions from this point.

7. NOTIFY THE RECALL TEAM

The General Directorate must immediately summon the Recall team, preferably and given the characteristics of the company, the ideal is for it to be physically.

8. NOTIFY THE REGULATORY AGENCY

The General Directorate must notify its agent of what is happening so that, in the event of a recall, the due processes are initiated. At this point, the details of the danger have not yet been officially passed since there is still no decision to recall or not.

9. CALL ADVISORS

Depending on the type of danger, its origin and the capacity to respond to it, the advisors will be called to make the recall decision.

10. ASSESS POTENTIAL HEALTH RISK

At this point, the entire Recall team must review the information, audits, processes, records and logs that are related to the product that has generated the risk situation. In this way, it will be determined whether the risk can be reduced or eradicated with other control actions or the recall should be carried out immediately.

eleven. RECALL

Here you must answer the **question Should a recall be done as a first step?**

12. DOCUMENT AND RELEASE THE PRODUCT

If the Recall team decides to proceed with another control measure, then the situation should only be documented for internal records and release the product from preventive observation (monitoring).

Likewise, the Regulatory Agency must be notified of the decision taken and the reasons for it.

13. FILLING OUT THE FORMAT FOR THE REGULATORY AGENCY

SIMULTANEOUS ACTIVITY - GENERAL MANAGEMENT

If the team decides to start a recall, they begin a series of activities simultaneously. One of them is to gather the following information and send it officially to the Regulatory Agency notifying Recall's decision.

INFORMATION NEEDED FOR THE SECRETARIAT OF HEALTH

The identity of the product including original label and expiration or expiration date, the container size (s)

Product data sheet, product form, codes, batch numbers and any other information that identifies it.

The reason for the recall, the date, and the circumstances under which the problem was discovered.

An assessment of the risk associated with the problem.

Period during which the product was produced and the quantity that was produced.

The total amount of product (by package size and box size) that is estimated to be found in the distribution channels.

Distribution information such as number of direct accounts (retail and wholesale). In some cases, you will be asked for names, addresses, and phone numbers.

A copy of any communication that has been or will be sent in connection with the recall.

The proposed strategy for performing the recall, including measures to correct the problem and what is intended to be done with the recalled product.

The name and telephone number of a person from the company who will make contact between it and the health authority.

Written, in which it is stated that the plan itself is not an admission of any kind of fault or negligence.

14. STOP PRODUCTION AND DISTRIBUTION

SIMULTANEOUS ACTIVITY - SALES AND QUALITY

Once the recall has been detected, it is necessary to stop production and carry out an inspection of all control points by the HACCP team. Sales should be responsible for calling all distributors to stop the logistics system until the existing risk is controlled.

fifteen.

START ACTION LOG

SIMULTANEOUS ACTIVITY - ADMINISTRATION AND MARKETING

You should start with the log of actions to control the recall process and ensure that it is comply 100%.

INFORMATION COLLECTION ACTIONS

ACTIONS	ON MARCH	FINISHED	I DONT KNOW PERFORMED
Identify the product			
Establish its ingredients			
Suppliers of ingredients			
Container size			
Product Codes			
Product on market			
Product in the cellar			
Product in transfer			

ACTIONS TO DECIDE WHETHER A RECALL IS MADE

THE DECISION TO MAKE A RECALL	ON MARCH	Finished	I DONT KNOW PERFORMED
Notify the recall team of the problem			
Communicate the problem to managers of each			
department Check if any rule is violated			
The managers send their records			
Make a decision to:	Perform a stock recall Perform a		
	market recall		
	Make a recall		
Inform the health authority if the decision is internal Prepare			
public statement.			

IMMEDIATE ACTIONS

ACTIONS	ON MARCH	Finished	I DONT KNOW PERFORMED
An internal investigation is initiated to detect source and			
cause Stop product production			
The product in the warehouse is safe			
Inform all departments that have contact with clients of the information that must be provided			

CLASSIFICATION AND DEPTH OF RECALL

ACTIONS	ON GOING	FINISHED	I DONT KNOW PERFORMED
Recall classification			
Recall number assigned by the health			
authority Recall depth			
Update the team the classification and depth of the recall			

NOTICE TO EXTERNAL GROUPS

ACTIONS	ON GOING	FINISHED	I DONT KNOW PERFORMED
Notify distributors			
Notify retailers			
Notify institutions Notify			
end consumer Send press			
release			
Instruct sales and logistics representatives about the recall			
Information for Sales Representatives to Give to Retailers			

PRODUCT DISPOSAL

ACTIONS	ON GOING	FINISHED	I DONT KNOW PERFORMED
The health authority and the company agree on the collection and disposal of the product			
Decisions are made regarding refund or product exchange policies			
Inform wholesalers of product disposition			
Inform retailers of product disposition			
Sales representatives help customers comply with recall			
Customer service is instructed on refund policy. Warehouse			
ready to receive the product			
Isolation or disposal of the product			

EFFECTIVENESS CHECK

ACTIONS	ON GOING	FINISHED	I DONT KNOW PERFORMED
Effectiveness check levels are established			
Effectiveness checks begin			
The end date is set Review the			
effectiveness checks Prepare a			
summary			

CLOSING THE RECALL

ACTIONS	ON GOING	FINISHED	I DONT KNOW PERFORMED
The team takes over the recall review			
The recall officially concludes			
Notify the health authority that the recall has been completed			
The team receives written confirmation from the health authority of the end of the recall			
Announce (and thank you if necessary) to customers of the successful completion of the recall			
Update the website, notify the media if necessary			

16. DETERMINE THE CLASS OF THE RECALL

SIMULTANEOUS ACTIVITY - ADVISORS AND GENERAL MANAGEMENT

Depending on the risk, incidence or effect that a certain contaminated, adulterated, or mislabeled product entails on the health of the population, the recall can be divided into different classes.

CLASS 1	This is a health hazard situation where there is a reasonable probability that use of the product will cause serious adverse health consequences or death.
CLASS 2	This is a situation that presents a health hazard where there is a remote probability that the use of the product will cause adverse health consequences.
CLASS 3	This is a situation where the use of the product will not cause adverse health consequences

17. ASSESS SCOPE AND DEPTH

SIM ACTIVITY ULTANEA - SALES AND LOGISTICS

The second big question, in relation to the recall, refers exactly to the scope of the affected products. According to the information provided, the traceability of the product or products with risk should be monitored and decide if the recall will be carried out to:

Lots in particular.
Products made between certain production dates.
Products that contain a certain ingredient.
Products with labeling or packaging error.

Once the size is established, the exact location of the product to be removed must be found.

Can we find them locally, nationally or internationally?
Are they in the warehouse of a wholesaler / distributor?
On supermarket / retail shelves?
Is it being used for direct consumption (restaurants / schools)?

By answering the following questions we can then specify the depth of the recall:

Wholesaler Level
Institutional level
Retail Level
Consumer level

18. DEFINE AUDIENCE AND MEANS OF COMMUNICATION

SIMULTANEOUS ACTIVITY - MARKETING

Depending on the type and depth of the recall, the audience to which the recall will be communicated will be chosen first, in addition to the health authority (regulatory agency) and subsequently the means by which the information will be delivered to them.

HEARING AND THE MEDIA

Kind of Audience	Mark X	MEDIA								
		E-mail	Radio	TV	Newspaper	Telephone	Facebook	Instagram	Twitter	WhatsApp
Workers										
Consumers										
Providers										
Wholesalers										
Dealers										
Retailers										
Industries										

19. NOTIFICATIONS

Once the audience and the means of communication have been defined, the notification of the recall must be initiated in writing, mainly to 2 parties:

1. Involved in the distribution chain
2. Media

Before making the notifications, finances and the general management must decide whether the cost of the product will be returned to the person who returns it or it will be exchanged for a new product. This decision will depend on what those involved in the chain consider.

RECALL NOTIFICATION LETTER FOR ITEM 1

Date
Company name Company
contact Contact telephone
number
E-mail
Web address

SUBJECT: PRODUCT RECALL _____

Addressee:

The purpose of this letter is to confirm our conversation that (Company Name) is recalling product _____, due to (Specify Reason for Recall). (Describe the product, including name, brand, code, size and type of packaging, number of the establishment, etc.)

We ask that you review your inventory records, separate and retain the product listed above. If you have dispatched part of this product, please contact your customers and request that they retrieve the product and return it to you. Once you have recalled all of the product, please contact us. We will arrange for the product to be removed and transported to our facilities. We kindly ask you not to destroy the product. We will credit your account for the returned products.

Your immediate action will be of great help to (Company Name) in this operation. If you have any questions, please do not hesitate to contact Customer Service at (Company Name) at (Telephone Number) and (Email). Thanks for your cooperation.

Sincerely
_____ Name
and Position of the Company Official

PRESS RELEASE FOR ITEM 2

[City], [Company] recalls [Product] that may contain _____.

[City], [Date], [Company], is voluntarily recalling approximately [number of kilos] of [product] because the product may contain _____. Consumption can cause _____.

(Specific information on how to identify the product. For example, type of container [plastic / metal / glass], size or appearance of the product, brand of the product, establishment number and location on the packaging, flavors, codes and expiration date, etc.).

The product was distributed to [List of places where the product was distributed and how it reached the consumer. For example, through retailers, mail order, direct delivery].

[Brief explanation of what is known about the problem, such as how it was revealed and what is known about the source].

Due to the potential danger, [company name] we encourage consumers who have purchased these products not to eat them but to return them to where they were purchased.

[Information on what consumers should do with the product and where they can obtain additional information].

Consumers with recall inquiries can contact [company name and title or division], [phone number], or the customer service hotline [toll free number].

Media with inquiries can contact [name and title] at [phone number].

twenty. INVOLVE IN THE RECALL

In some cases, as stated in the Recall notification letter, the entire chain will have to be involved in order to achieve a successful recall. This in order to recover most or all of the product. In some cases, the direct customer is a Wholesaler, the notification will be made to him, but he will be the one who notifies as many retailers as possible and these to their customers.

In the same way, to support this activity, the notification will be made through the media.

twenty-one. CALL LOG

The customer service area will open a toll-free hotline for anyone who provides or requests information about the recall. Marketing should also be aware of social networks.

Before making the notifications and publications, these two areas must agree on the information and instructions that will be provided to those who communicate.

22. START OF PRODUCT WITHDRAWAL

Once the location of the product has been identified and focused on a point according to the depth of the recall, it is up to the Logistics team to organize and execute the recall.

In extreme cases, in which for some reason, the company's logistics team cannot reach the withdrawal points, an official statement will be sent to those involved, detailing the data and contacts of the collection company that will recall at that location.

At the same time, the Recall team together with the health authority will evaluate, according to the characteristics of the hazard (Class) what will be done with the recalled product.

Donation

If the problem is related to the labeling and the product does not present any type of health risk, the company may choose to donate the recovered products to non-profit organizations, accredited and authorized to receive them.

In this case, it must be ensured that the non-profit group provides written documentation that indicates that it understands the terms of the recall and that it accepts the product anyway.

Reconditioning

Although most of the time the health authority decides by the destruction of the product, there is the possibility that the defect in the product does not cause a health risk. If the company carries out a reconditioning, it must ensure that it complies with the quality, safety and legality standards established by the health authority.

Destruction

If the product represents an actual or potential health hazard, it should ideally be stored in one place to be destroyed. The destruction method must comply with all regulations regarding the disposal of toxic material and / or landfill. The recall team is in charge of compiling a list of landfills and disposal services.

The entire destruction process must be documented through a log and photographic or video evidence. In the same way, a receipt with address, date and method used must be requested from the sanitary landfill or any company / site in charge of the disposal. An official of the health authority must also supervise this process

If the product is located in several different locations, with the approval of the health authority, a third party can be hired to carry out and document the destruction.

The aforementioned disposal measures are for cases in which the product cannot be thrown directly into the company's landfill. However, if the product does not have toxic implications and throwing it away does not pose a health hazard, it can be disposed of like any other type of waste, in the company's garbage cans. Everything must be recorded.

2. 3. EFFECTIVENESS CHECK

The effectiveness checks verify that the consignees have received the recall notification and that they have taken the corresponding actions. Customer service must carry out this activity through telephone calls.

EFFECTIVENESS CHECK

First, make sure you are talking to the right person, someone who can handle the recall or, failing that, has the authority to designate someone to take care of it.

Date _____ Company name_____ Company contact _____ Telephone _____ E-mail _____

Good morning / Good afternoon: My name is (name of the person), I am calling you on behalf of (company that makes the recall) in relation to the recall of (date) of our product (brand, type, product code, code of the date). The reason for my call is to conduct a brief Recall Effectiveness Check with your company to ensure that we are doing everything possible to comply with FDA regulations.

I'm going to have to ask you several questions:

1. Has your company received notification from (recall company) that the above-mentioned product was being recalled?

BUT_____

2. Has your company received a shipment with the product that is the object of the recall? (if the answer is NO, then "Thank you very much for your time, we are done")

3.

BUT_____

4. Do you have any recall items in your current inventory?

5.

BUT_____

6. If your answer to question Nº3 is YES, do you plan to return the recall product to (recall company) as requested?

YES_____ Please indicate quantities and the estimated return date.
_____ NO____
Please explain your intentions.
_____

7. Have you received reports of illness related to the product being recall?

YES_____ Please include details.
_____
_____ NO ____

8. Did you ship the recall product to other distributors, retailers, or consignees?

BUT_____

9. If your answer to question Nº6 was YES, did you send your consignee a recall notice?

BUT_____

10. If your answer to question Nº7 was YES, did your consignee have any product subject to recall in their possession?

11. YES_____ NO_____No question _____

Thanks for your cooperation

_____

Signature and title of the person responsible for the check

24. SUPERVISION

Logistics, quality, administration and general direction will be in charge of supervising the recall, with the advice of the health authority.

25. RECALL STATUS REPORT

To report the status of the recall to any department, media, health authority, involved in the chain, etc. the following format must be filled out. The administration area will be in charge of gathering the information.

RECALL STATUS REPORT

Date _____ Product brand _____ Product code_____ Health authority contact_____ Telephone _____ E-mail address _____

Estimated _____:

Next, (company name) presents the following Recall Status Report in relation to the product indicated above.

1. Notification

to. Total number of consignees identified_____
b. Number of notified consignees_____
c. Means of notification:
_____
_____

2. Consignee response

to. Total number of consignees who responded _____
b. Total number of consignees who did not respond_____
c. Total quantity of products in recall available_____
d. Number / quantity of returned products _____
1. Consignee 1_____
2. Consignee 2_____
3. Consignee 3_____
4. Consignee 4_____
5. Consignee 5_____

3. Effectiveness checks

to. Total number required_____
b. Total number completed_____
c. End date _____

4. Estimated end date for the end of the recall _____

Please let us know if you require additional information.

Sincerely
_____ _____ Signature
and title

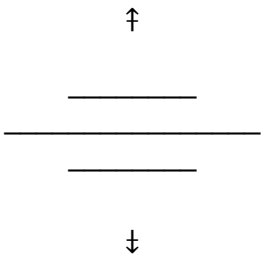
26. RECALL CLOSURE REPORT

The health authority will terminate a recall when it determines that all reasonable efforts have been made and the product has been recalled in accordance with the recall strategy. At that time everyone involved will be notified / thanked.

Each member of the recall team must deliver a complete report of their activities to the General Management, so that through marketing, an official publication is issued in all the company's media.

27. EVALUATION

After the recall, it is important to hold a meeting with the entire team to evaluate the decisions made, correct and, where appropriate, modify the recall plan, so that better tools are available for the prompt resolution of these situations. The main evaluation tool is the action log.



RESULTS REPORT

SOLYSAL DE COLIMA SPR DE RL

ADOLFO LÓPEZ MATEOS N°40 THE BULLFIGHTING
28500 CUAUHTÉMOC COLIMA

FROMSOR ORPANDRTODORRTO SA FROM CV

Report Preparation Date:	02/12/2021
Sample Receipt Date:	02/02/2021
Date of analysis:	02/02/2021
Sample Number	01330/21
Lot Number:	122020
Report Number:	01330
Presentation:	POLYETHYLENE BAG
Sample Identification:	

SEA SALT

SAMPLE TAKEN BY THE INTERESTED PARTY FOR THEIR CONTROL

MICROBIOLOGIC ANALYSIS

ANALYSIS	RESULTS	UNITS	U ±	LIMITS	REF. ANALYTICS
Aerobic mesophilic bacteria	80 •	CFU / g	0.33%	-	NOM-092-SSA1-1994 A
Total Coliforms	< 3.0	MPN / g	-	-	CCAYAC-M-004/11 A
Mushrooms	< 10	CFU / g	-	-	NOM-111-SSA1-1994 A
Yeasts	< 10	CFU / g	-	-	NOM-111-SSA1-1994 A
Salmonella	Absent in 25g	Does not apply	-	-	NOM-114-SSA1-1994 A
S. *aureus*	< 100	CFU / g	-	-	NOM-115-SSA1-1994 A
E. coli	< 3.0	MPN / g	-	-	CCAYAC-M-004/11 A

OBSERVATIONS:
4 Accredited trial • Contracted trial U =% relative uncertainty considering a confidence level of 95% and a coverage factor of K = 2
Aerobic mesophilic bacteria incubated at 35°C for 48h in Aqar standard account
Honqos v yeasts incubated at 25° C for 5 days in Aqar potato dextrose acidified
• Estimated value
<10 CFU / q = Not detectable
<3.0 MPN / q = Not detectable
<100 CFU / q = Not detectable

R/Sandoval - .you

L. Q. Roxana Sandoval Aguirre
Head of Area
Authorized signatory

RESULTS REPORTC).S

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DESU OPERADORA SA DE CV

SOLYSAL DE COLIMA SPR DE RL

ADOLFO LÓPEZ MATEOS N◦40
THE TOREO
28500 CUAUHTÉMOC COLIMA

Report Preparation Date:	02/11/2021
Sample Receipt Date:	02/02/2021
Date of analysis:	02/02/2021
Sample Number	01330/21
Lot Number:	122020
Report Number:	01330
Presentation:	POLYETHYLENE BAG
Sample Identification:	

SEA SALT

SAMPLE TAKEN BY THE INTERESTED PARTY FOR THEIR CONTROL

PCR

ANALYSIS	RESULTS	UNITS	U ±	LIMITS	REF. ANALYTICS
Listeria monocytogenes	Absent in 25g	Does not apply	-	-	Internal method Real Time PCR

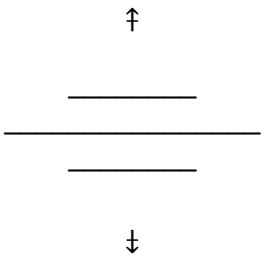
OBSERVATIONS:
• Accredited trial • Contracted trial U =% relative uncertainty considering a confidence level of 95% and a coverage factor of K = 2

'F)\,,.

·------DC[" Roxana Sandoval Aguirre
Head of area
Signatario Autoriza...

DESU Operadora SA de CV
Av. Washington No. 1920 Col Moderna
CP 44190 Guadalajara, Jalisco
Tel: 3312040154
www.laboratoriociaj.com.mx

Laboratorio acreditado



Laboratory CJ.AJ
Chamber of the Industrito Alimandnj ticiatolisco

RESULTS REPORT

SOYSAL DE COLIMA SPR DE RL

ADOLFO LÓPEZ MATEOS N◦40
ELTOREO
28500 QUAHTÉMOCCOLIMA

Report Preparation Date:	05/27/2020
Sample receipt date:	05/20/2020
Date of analysis	05/22/2020
Sample Number:	06827/20
Lot Number:	SYS-001-A / 2020
Report Number:	06827
Presentation:	POLYETHYLENE BAG
Sample Identification:	**SALT**

SAMPLE TAKEN BY THE INTERESTED PARTY FOR THEIR CONTROL

PHYSICOCHEMICAL ANALYSIS

ANALYSIS	RESULTS	REF. ANALYTICS
Foreign matter	Absence of ferrous, non-ferrous and stainless steel particles, as well as absence of plastic material and micro plastics in 50g	AOAC 945.80

OBSERVATIONS:
1,,. Accredited trial • Outsourced testing

THIS DOCUMENT ONLY ENDORSES THE ANALYZED SAMPLE
IT MAY NOT BE PHOTOCOPYED IN PART OR COMPLETELY WITHOUT THE WRITTEN AUTHORIZATION OF THE HEAD OF THE TEST LABORATORY
SHOULD NOT CONTAIN ERASES OR AMENDMENTS

Q.F.B. Clara A. Suárez Rincón
Directora
Signatario Autorizado

RESULTS REPORT

Ltobortotorrio J.AJ
Chamber of the Industrito Alimandnticia from Jaliscor

SOLYSALDE COLIMA SPR DE RL

ADOLFO LÓPEZ MATEOS N◦40
THE TOREO
28500 CUAUHTÉMOCCOLIMA

Report Preparation Date:	05/27/2020
Sample Receipt Date:	05/20/2020
Date of analysis:	05/26/2020
Sample Number	06827/20
Lot Number:	SYS-001-A / 2020
Report Number:	06827
Presentation:	POLYETHYLENE BAG
Sample Identification:	

SALT

SAMPLE TAKEN BY THE INTERESTED PARTY FOR THEIR CONTROL

PHYSICOCHEMICAL ANALYSIS

ANALYSIS	RESULTS	UNITS	U ±	LIMITS	REF. ANALYTICS
Sodium chloride	90.75 *	%	-	-	NOM-040-SSA1-1993

OBSERVATIONS:
.t. Accredited trial • Contracted trial U =% relative uncertainty considering a confidence level of 95% and a coverage factor of K = 2
* Determination carried out on a dry basis

Q.F.B. Clara A. Suarez Rincón
Directora
Signatario Autorizado

DESU OPERADORA S.A. DE C.V.
Av. Washington 1920, Col. Moderna, C.P. 44190
Guadalajara, Jalisco
Tel. (33) 1204 0154, (33) 1955 3155

Laboratorio acreditado

RESULTS REPORT

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SOLYSAL DE COLIMA SPR DE RL

ADOLFO LÓPEZ MATEO $ N◦40
THE TOREO
28500 CUAUHTÉMOC COLIMA

Report Preparation Date:	05/27/2020
Sample Receipt Date:	05/20/2020
Date of analysis:	05/26/2020
Sample Number	06827/20
Lot Number:	SYS-001-A / 2020
Report Number:	06827
Presentation:	POLYETHYLENE BAG
Sample Identification:	

SALT

SAMPLE TAKEN BY THE INTERESTED PARTY FOR THEIR CONTROL

INSTRUMENTAL ANALYSIS

ANALYSIS	RESULTS	UNITS	U ±	LIMITS	REF. ANALYTICS
Lead	<0.5	mg / kg	-	<2	NOM-117-SSA1-1994

OBSERVATIONS:
.to. Accredited trial • Contracted trial U =% relative uncertainty considering a confidence level of 95% and a coverage factor of K = 2
Maximum permissible limits in the modification of NOM-040-SSA1-1993 Products and services. Iodized salt and iodized fluoridated salt. Sanitary specifications.

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Signatario Autorizado

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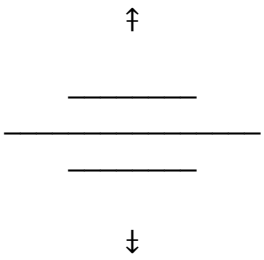
Av. Washington 1920, Col. Moderna, C.P. 44190
Guadalajara, Jalisco
Tel: (33) 1204 0154, (33) 1955 3155



RESULTS REPORT

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SOLYSAL DE COLIMA SPR DE RL

ADOLFO LÓPEZ MATEOS N°40
THE TOREO
28500 CUAUHTÉMOC COLIMA

Report Preparation Date: Sample	11/10/2020
Receipt Date:	11/03/2020
Date of analysis:	11/04/2020
Sample Number	16386/20
Lot Number:	S / L
Report Number:	16386
Presentation:	POLYETHYLENE BAG
Sample Identification:	

SEA SALT

SAMPLE TAKEN BY THE INTERESTED PARTY FOR YOUR CONTROL

PHYSICOCHEMICAL ANALYSIS

ANALYSIS	RESULTS	UNITS	U ±	LIMITS	REF. ANALYTICS
Sodium chloride	91.16 *	%	-	-	NOM-040-SSA1-1993
Humidity	10.71	g / 1009	0.14%	-	NOM-116-SSA1-1994 .i.
Potassium iodate	0.00	mg / kg	-	-	NOM-040-SSA1-1993

OBSERVATIONS:
• Accredited trial • Contracted trial U =% relative uncertainty considering a confidence level of 95% and a coverage factor of K = 2
• Determination carried out on a dry basis

QF B. Clara A. Suarez Corner
Director
Authorized signatory

RESULTS REPORT

Ltoboratorio QIAJ
Camera of Ito Industry TOlimandnticia of Jtolisco

SOLYSAL DE COLIMA SPR DE RL

ADOLFO LÓPEZ MATEOS N◦40
THE TOREO
28500 CUAUHTÉMOC COLIMA

Report Preparation Date:	11/10/2020
Sample Receipt Date:	11/03/2020
Date of analysis:	11/04/2020
Sample Number	16386/20
Lot Number:	S / L
Report Number:	16386
Presentation:	POLYETHYLENE BAG
Sample Identification:	

SEA SALT

SAMPLE TAKEN BY THE INTERESTED PARTY FOR THEIR CONTROL

INSTRUMENTAL ANALYSIS

ANALYSIS	RESULTS	UNITS	U ±	LIMITS	REF. ANALYTICS
Calcium	2 939.59	mg / 100g	-	-	AOAC Official Methods 985.35
Potassium	441.06	mg / 100g	-	-	AOAC Official Methods 985.35
Magnesium	1 114.40	mg / 100g	-	-	AOAC Official Methods 985.35
Iron	0.69	mg / 100g	-	-	NOM-117-SSA1-1994
Sodium	31,472.57	mg / 100g	1.84%	-	Atomic absorption (flame) ..,

OR VACrIandORdN
TOANDS ANANORI ac itANDdsor: • Contracted trial U =% relative uncertainty considering a confidence level of 95% and a coverage factor of K = 2
ASodium: Internal method MP-AA-01 determination of sodium in food by atomic absorption (flame)

Q.F.B. Clara A. Suarez Rincón
Dyrectora
Authorized signatory

Laboratory !AJ
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RESULTS REPORT

SOLYSAL DE COLIMA SPR DE RL

ADOLFO LóPEZ MATEOS N◦40
ELTOREO
28500 CUAHTÉMOC COLIMA

Report Preparation Date:	11/10/2020
Sample receipt date:	11/03/2020
Date of analysis	11/10/2020
Sample Number: Lot	16386/20
Number:	S / L
Report Number:	16386/20
Presentation:	POLYETHYLENE BAG
Sample Identification:	**SEA SALT**

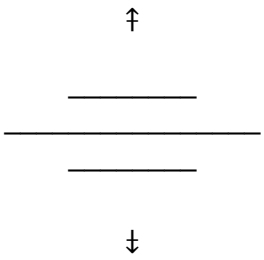
SAMPLE TAKEN BY THE INTERESTED PARTY FOR THEIR CONTROL

PHYSICOCHEMICAL ANALYSIS

ANALYSIS	RESULTS	REF. ANALYTICS
OBSERVATIONS:	Absence of ferrous, non-ferrous and stainless steel particles, as well as absence of plastic material, micro plastics. Presence of particles of black color (impurities) visible on the stereoscope in an SX field. Free of insect fragments, hairs and rodent excreta in 50g.	AOAC 945.80

OBSERVATIONS:
Á Accredited trial • Outsourced testing

Q.F.B. Clara A. Suárez Rincón
Directora
Signatario Autorizado



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REQUIRED 21 CFR, §1.503 requires that all documents be written in a language understandable to the FSVP QI. The original document(s) were written in a language other than English but have since been translated in an effort to meet FDA requirements. An individual that is fluent in both English and the document's original language must confirm that the translation has been accurately performed.

Translated text accurately reflects original message

☑ Agree ☐ Disagree

☐ Agree – *with suggested edits*

Name Paulina Eileen Nava Solís

Date 09/06/2021

L A Y O U T
"F l o u r d e s e l"

PLANTA DE DISTRIBUCION
ESC 1:100

REVISIONES				
FECHA	No.	DESCRIPCION	REVISO	APROBO
08-09-21	A	PARA COMENTARIOS Y/O APROBACION	SIACEP	

SIACEP
AV. JOSE ANTONIO DIAZ 408, COL. PLACETAS ESTADIO
COLIMA, COL. C.P. 28050
TEL.: (312) 314-85-58
www.siacep.com.mx

L A Y O U T

PLANTA DISTRIBUCION

DIBUJO:	JUAN P. CERVANTES JANSSEN	FECHA:	ACOT: INDICADA	ESC.=	SIN
REVISO:	JUAN P. CERVANTES JANSSEN	DIBUJO No.:		# PAG. 1/1	REV. B
APROBO:	J. ALBERTO PERALTA C.				

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: FLEUR DE SEL, S.A. DE C.V. Today's Date: 07/15/2021

Factory Address: LOPEZ MATEOS 40

City: CUAUHTEMOC Province: COLIMA Country: MEXICO

Office Address: LOPEZ MATEOS 40

City: CUAUHTEMOC Province: COLIMA Country: MEXICO

FDA Registration No.: 16441296972 DUNS No.: FSE180612H80

FDA Establishment Id.: Phone No.:

QC/QA's Name: E-mail: PATYSOLYSAL01@GMAIL.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: Sea Salt Product Code:

No. 02, Product Name: Product Code:

No. 03, Product Name: Product Code:

No. 04, Product Name: Product Code:

No. 05, Product Name: Product Code:

No. 06, Product Name: Product Code:

Resources FDA Product Codes and Product Code Builder

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

To control biological hazards, sea salt is prevented from having contact with pests or pollutants that can prevent bacteria from the salt. For this, fumigations are carried out every three months with organic products, using natural pyrethrins. Physical controls such as rodent bait traps and mosquito netting are also used in sales.
Every semester, chemical analyzes are carried out in the CIAJ laboratory (Chamber of the Food Industry of Jalisco) where bacteriological, microplastic, lead and ferrous particles are analyzed on a salt sample.

FREQUENCY *of* VALIDATION

Every three months and every six months.

U.S. FDA HAZARD PROFILE

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

Resource U.S. FDA Product Category Hazard Profiles – *Appendix 1*

FDA–IDENTIFIED CHEMICAL HAZARDS

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

☐ Drug residues	☒ Heavy metals	☐ Industrial chemicals	☒ Pesticides
☐ Mycotoxins/Toxins	☐ Radiological	☐ Unapproved colors & additives	☐ Other

Resources  Appendix 1  Description *of* Hazard  Bad Bug Book

CRITICAL CONTROLS *for* CHEMICAL HAZARDS

Select and describe the method(s) by which Chemical Hazard(s) are controlled. *Please be as detailed as possible.*

☐ **CGMPs**

☒ **Testing**

☐ **Other**

DESCRIPTION *of* CRITICAL CONTROLS

To avoid chemical contamination of the salt, a careful water extraction process is used to form the salt. Generally, the wells to extract water are 2 meters long, while we make wells that are at least 10 meters deep.

As mentioned above, tests are done every semester to control the purity of the salt and rule out the presence of microplastics, lead, and ferrous particles.

FREQUENCY *of* VALIDATION

Every six months.

U.S. FDA HAZARD PROFILE

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

Resource U.S. FDA Product Category Hazard Profiles – *Appendix 1*

FDA-IDENTIFIED 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

To avoid contamination by environmental factors, salt is always stored in greenhouses that do not allow contact with external physical agents. We also take care of the hygiene of our workers with cleaning and protection measures: cap, gloves, face mask, clothing protector and shoe covers. We do not allow the use of accessories inside the facilities or cellular devices or other electronic equipment as they represent a source of contamination.
The packaging area, as well as the materials used, are sanitized every day, before and after the working day.

FREQUENCY *of* VALIDATION

Ever day.

U.S. FDA HAZARD PROFILE

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

Resource U.S. FDA Product Category Hazard Profiles – *Appendix 1*

FDA–IDENTIFIED PHYSICAL HAZARDS

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

- ☐ 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

Our product is not associated with any of the above elements.

FREQUENCY *of* VALIDATION

U.S. FDA HAZARD PROFILE

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

Metal detection standards

Ferrous: _____ mm

Non-Ferrous: _____ mm

Stainless Steel: _____ mm

Resource U.S. FDA Hazard Profile – *Appendix 1*

Claudio Innocenti

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

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

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:

Organic cleaners and detergents.

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? 6

PEST CONTROL

Is a pest control contractor employed? ☑ Yes ☐ No

If yes, please provide: Name of contractor used: Fumigaciones gallo

Number of yearly visits: 4

If no, by what means is pest prevention carried out? _____

HACCP & TACCP & VACCP

Does a fully documented and audited HACCP system exist for the site? ☐ Yes ☐ No

Has a hazard analysis study been completed for each site operation? ☑ Yes ☐ No

Does the business have a trained & certified in-house HACCP team? ☐ Yes ☐ No

If yes, please provide copies of current & relevant HACCP training certificates.

Does the business outsource the HACCP management to a certificated consultant? ☐ Yes ☐ No

If yes, please provide copies of current & relevant HACCP training certificates.

Are records maintained for all CCPs? ☑ Yes ☐ No

Does the HACCP system include the following:

- Sieving of ingredients? ☐ Yes ☐ No
- Sieving of finished products? ☐ Yes ☐ No
- Glass & hard plastic breakage procedure? ☐ Yes ☐ No
- Metal detection of final product? ☐ Yes ☐ No
- Magnets within the mixing & filling stages? ☐ Yes ☐ No

Do you use blue metal detectable plasters in the manufacturing/processing areas? ☐ Yes ☐ No

Please detail any other prevention systems used on-site: _____

Has a full threat assessment of your supply chain been conducted & tested? ☐ Yes ☐ No

Please provide details: _____

Has a full product vulnerability assessment within the supply chain been conducted & tested? ☐ Yes ☐ No

Please provide details: _____

TRACEABILITY

Does full traceability exist for all products supplied to your customer base? ☐ Yes ☐ No

If yes, please give details of traceability codes on the final packaging: _____

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:

When the raw material is received, the person in charge of warehouse control is responsible for verifying that all the product is in good condition. If the product does not meet the physical and hygienic characteristics, it is rejected and returned to the supplier.

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:

There is a person responsible for monitoring the quality of the product, he constantly reviews the final product for evaluation. Each bag that is packaged has an identification color on the bottom to detect who packaged it. In addition, every semester salt analyzes are made.

CUSTOMER COMPLAINTS

Does a formal customer complaint procedure exist? ☑ Yes ☐ No

Please describe your customer complaint procedure.

At the workplace, we have a complaint box, where customers can write suggestions or comments. In the same way, in social networks and on the website you can contact us to answer your comments.

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.

Claudio Innocenti

CERTIFICATION

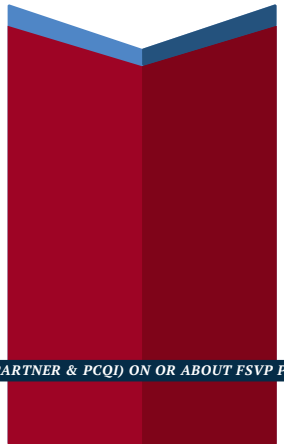
I certify that the information I provided on and in connection with this form is true, accurate and complete. I also understand that any false statements or deliberate omissions on this document or any other document I file with United Safety Agents, LLC may be grounds for disqualification from successful 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: Paulina Eileen Nava Solís

Title: Legal representative

Today's Date: 07/15/2021



AVA JANE'S KITCHEN

FOOD • FAMILY • LOVE

COLIMA

SEA SALT

100% NATURAL UNREFINED SEA SALT

8 OZ (227G)

100% ALL-NATURAL SEA SALT FROM COLIMA MEXICO

Ava Jane's Colima Sea Salt is harvested from La Laguna de Cuyutlán in Colima, Mexico, the same place the Aztecs traded for their salt over 500 years ago. This salt is unique in that it does not come from sea water. Rainwater soaks through the dry lagoon bed, earth's natural filter, dissolving essential minerals as it goes. It is then drawn to the surface into shallow ponds by Salineros (traditional salt farmers) then allowed to evaporate in the hot Mexican sun. This process protects the environment and local wildlife. With your purchase, you are supporting this "small salt economy" of Salineros, their families and their way of salt harvesting. Please enjoy every last, delightful crystal in this bag. And when you're nearly done, we hope to send you another one.

Nutrition Facts

227 servings per container

Serving size **1/4 tsp (1g)**

Amount per serving

Calories **0**

	% DV*
Total Fat 0	**0%**
Sodium 310mg	**13%**
Total Carbohydrate 0g	**0%**
Protein 0g	

Not a significant source of cholesterol, dietary fiber, total sugars, added sugars, vitamin D, calcium, iron, and potassium

* %DV = %Daily Value

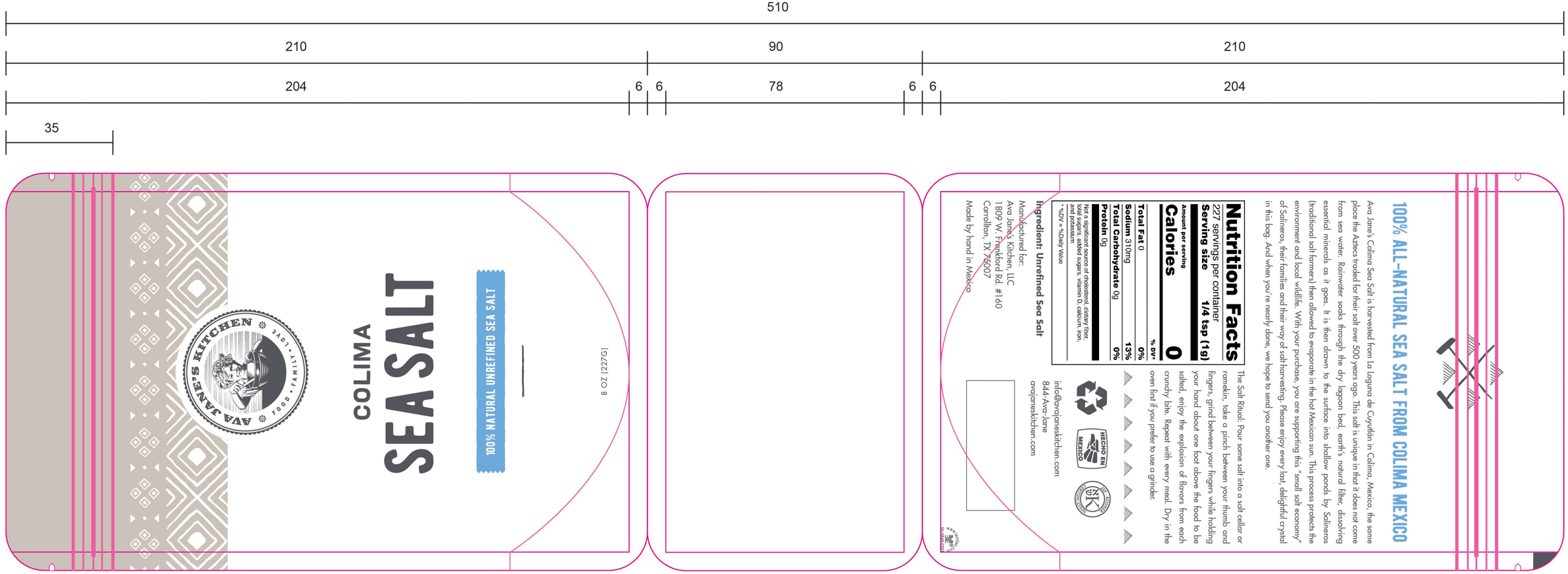
Ingredient: Unrefined Sea Salt

Manufactured for:
Ava Jane's Kitchen, LLC
1809 W. Frankford Rd. #160
Carrollton, TX 75007

Made by hand in Mexico

The Salt Ritual: Pour some salt into a salt cellar or ramekin, take a pinch between your thumb and fingers, grind between your fingers while holding your hand about one foot above the food to be salted, enjoy the explosion of flavors from each crunchy bite. Repeat with every meal. Dry in the oven first if you prefer to use a grinder.

info@avajaneskitchen.com
844-Ava-Jane
avajaneskitchen.com



OD 171648-13 PRODUCTO ▼	TIPO DE EMPAQUE ▸ STAND UP POUCHE	Colores	Materiales
BOLSA COLIMA SEA SALT	SELLO BASE MEDIO CIRCULO; FOTOCELDA ▸ 10 X 6; ACCESORIOS ▸ MUESCA, ZIPPER	FTE/REV: 1. NEGRO 2. CIAN 3. MAGENTA 4. AMARILLO 5. BLANCO 6. 7. 8. 9. — FUELLE: 1. BLANCO 2. 3. 4. 5. 6. 7. 8. 9.	FTE/REV: PET MATE PE NAT 400 — FUELLE: PET MATE PE NAT 400
Cliente ▸ AVA JANE´S KITCHEN LLC			Modo de Impresión: REVERSO

▼ IMPORTANTE ▼

Lamitec — Impresión realizada por el Departamento de Producción Gráfica de Laminaciones Técnicas para Empaques, S.A. de C.V.

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▼ NOTAS ▼

Acotaciones en milímetros

1 - El dibujo de la estructura, muesca y zipper NO se imprimen solo indican su posición

2 -

3 -

Impresión de Dummy ▸ 25 MAYO 2021

APROBACION

26/5/2021
Fecha de Vo.Bo.
Nombre y Firma de Vo.Bo.

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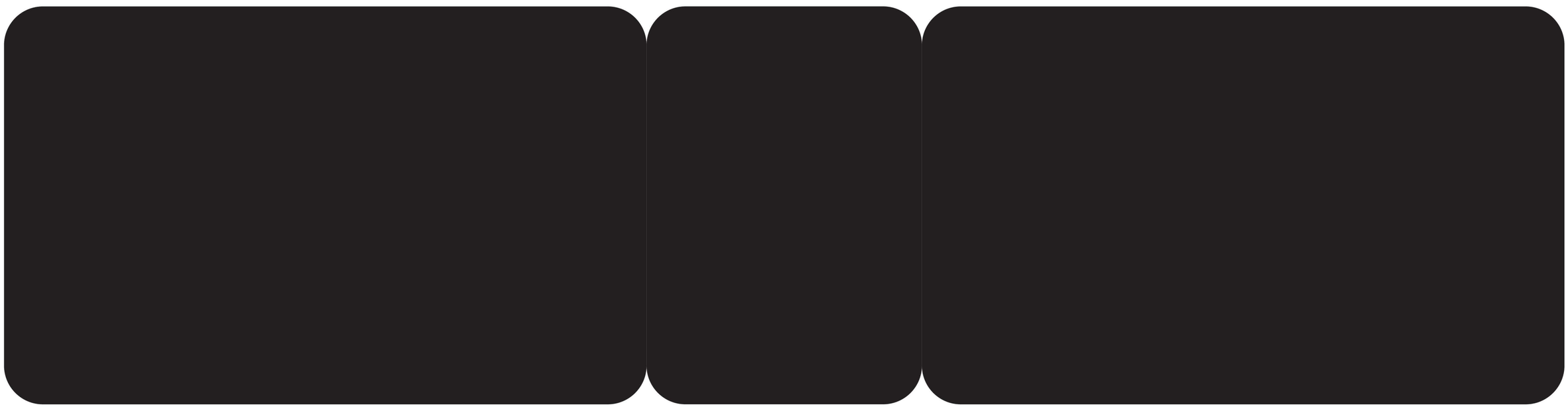
Su uso se limita para observar textos y demás elementos integrantes de Diseño con colores aproximados."



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

CONFIDENTIAL TREATMENT REQUESTED

26/5/2021
Claudio Innocenti
Nombre y Firma de Vo.Bo.

ZONAS CON BASE BLANCA

Guidance for Industry: Colored Sea Salt

Additional copies are available from:
Office of Food Additive Safety, HFS-200
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(Tel) 240-402-1200

http://www.fda.gov/ForIndustry/ColorAdditives/GuidanceComplianceRegulatoryInformation/ucm153033.htm

You may submit written comments regarding this guidance at any time. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the title of the guidance document.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
September2015

Table of Contents

Guidance for Industry: Colored Sea Salt[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This guidance document is intended for manufacturers of colored sea salt products. This document describes the regulatory requirements for the use of color additives to color sea salt.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Discussion

Colored sea salt products containing added charcoal or red clay are sometimes referred to as "Hawaiian Sea Salt." These colored sea salt products are being marketed to consumers and industry for food use in the United States.

Under section 201(t) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(t)), a color additive is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction to another substance) of imparting color thereto.[2] When substances such as charcoal and red clay are added to sea salt, these substances meet the statutory definition of a color additive under the FD&C Act because these substances impart color to the salt.

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[1] This guidance has been prepared by the Office of Food Additive Safety, Division of Petition Review in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] See also 21 CFR 70.3(f).

Section 721(a) of the FD&C Act (21 U.S.C. 379e(a)) defines conditions under which a color additive is deemed unsafe. A color additive used in or on a food will be deemed unsafe unless: (1) there is a regulation listing such color additive; (2) the regulation allows that particular use; and (3) the color additive and its use conform to the regulation. Neither charcoal nor red clay is listed for safe use by FDA under section 721(a) of the FD&C Act. In addition, charcoal and red clay are not otherwise exempt from such listing. Furthermore, neither charcoal nor red clay is listed in FDA's regulations for use in coloring food, including sea salt (see section 721(b) of the FD&C Act (21 U.S.C. 379e(b)).[3] Therefore, any food that contains these color additives is adulterated under section 402(c) of the FD&C Act (21 U.S.C. 342(c)). The introduction or delivery for introduction into interstate commerce of any food that is adulterated is a prohibited act.[4] FDA can take enforcement action against an adulterated food product, consistent with our priorities and resources.

Manufacturers of sea salt that intend to add color additives that are not currently approved for food use to their products, such as charcoal or red clay, must first obtain approval for the use of these substances through the color additive petition process. Color additive petitions must be submitted to FDA's Office of Food Additive Safety, HFS-200, 5001 Campus Drive, College Park, MD 20740. The information required for color additive petitions is outlined in 21 CFR 71.1. There are guidance documents available on our website that address the administrative, chemistry, toxicological, and environmental information that should be included in support of a color additive petition.[5]

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[3] Charcoal was provisionally listed as a color additive for use in food in 1960, but because no evidence was submitted that scientific investigations were under way to establish safety, the provisional listing was terminated by FDA in 1964 (see 29 FR 17089; December 15, 1964).

[4] Section 301(a) of the FD&C Act (21 U.S.C. 331(a)).

[5] **http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/default.htm**.

Leibnitz No. 1 Piso 1, Col. Anzures, C.P. 11590, México, D.F.

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Sociedad Internacional de Gestión y Evaluación SIGE, S.C.

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Certificado No. 2014CRE-319
Emisión del certificado: 09 de Mayo de 2014
Vigente al: 08 de Mayo de 2017
1a. Emisión: 09 de Mayo de 2014

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FORCSG-P01.07.02

3	XXXXXXXXX	XXXXXXXXX	XXXXXXXXX	XXXXXXXXX	XXXXXXXXX

Análisis a realizar

Observaciones

Estos datos deberán estar justificados en el apartado de observaciones

Medidas de Seguridad (Marque con una X)		
1. Se aplica medida de seguridad	SI	X
2. Aseguramiento de productos u objetos	SI	X
2.1 Número de folio de los sellos de aseguramiento	SI	X
3. Suspensión de trabajos o servicios		
3.1 Numero de folio de los sellos de suspensión	SI	X
4. Reubicación de sellos		
4.1 Número de folio de sello(s) reubicado(s)	SI	X
5. Se anexa documentación		
5.1 Número de anexos: XXXXX	Describir: XXXXXX	

Leído lo anterior, se hace saber al interesado el derecho que tiene de manifestar lo que a sus intereses convenga en relación con los hechos contenidos en el acta, o bien, por escrito hacer uso de tal derecho dentro del término de cinco días hábiles a partir del día siguiente de la presente diligencia. En uso de la palabra el C. Zoila Patricia Solis Montero hace constar que recibió original de la orden de visita objeto de la presente acta y que identificó plenamente al(los) verificador(es) para tal efecto, y con relación a los hechos que se asientan en la misma manifiesta lo siguiente

Previa lectura del acta de verificación ante todos los participantes, visto el contenido de la misma y sabedores de los delitos en que incurren los falsos declarantes ante la autoridad administrativa, la presente diligencia se cierra siendo las 13 horas con 00 minutos del día 09, mes Agosto de 2021, firmando los que en ella participan para todos los efectos legales a que haya lugar, dejándose copia de todo lo actuado consistente en 04 hojas en poder del C. Zoila Patricia Solis Montero

ATIENDE LA VISITA	TESTIGO	TESTIGO
Zoila Patricia Solis Montero Nombre y firma	Araceli Osorio Galindo Nombre y firma	XXXXXXXXXXXXXX Nombre y firma
VERIFICADOR SANITARIO	VERIFICADOR SANITARIO	VERIFICADOR SANITARIO
QFB. Arnoldo Hinojosa Puga Nombre y firma	XXXXXXXXXXXXXX Nombre y firma	XXXXXXXXXXXXXX Nombre y firma

3. CONTROL DE AGUA	
42. Cuenta con registros diarios del monitoreo de cloro residual libre y periódicos de análisis de organismos coliformes fecales y totales en el agua que entra en contacto directo con materias primas, productos, superficies en contacto con los mismos y envases primarios	0
43. El vapor utilizado en superficies que están en contacto directo con materias primas y productos no contiene sustancias que puedan representar un riesgo para la salud o contaminar el producto	---
4. LIMPIEZA Y DESINFECCIÓN	
44. Cuenta con programas y registros o bitacoras de limpieza y desinfección de las instalaciones, equipos, utensilios y transportes	2
5. MATERIAS PRIMAS	
45. Cuenta con especificaciones o criterios, registros, reportes o certificados de calidad para la aceptación o rechazo de materias primas y de envase y/o empaque	2
6. FABRICACIÓN	
46. Cuenta con procedimiento o método de fabricación en donde se indique: ingredientes, cantidades, orden de adición, controles aplicables y descripción de las condiciones en que se llevan a cabo las fases de producción y registro del control de las etapas (tiempos, temperatura, presión, pH, línea de producción, entre otros)	2
47. Cuenta con documentación que demuestre la evaluación del producto terminado para su aceptación y liberación y un sistema de lotificación que permite su trazabilidad	2
7. ALMACENAMIENTO Y DISTRIBUCIÓN	
48. Cuenta con registro de entradas y salidas indicando producto, lote, cantidad y fecha	2
49. Cuenta con registros de temperatura de los equipos de refrigeración y/o congelación durante el almacenamiento y transporte del producto	---
8. RECHAZOS (PRODUCTOS FUERA DE ESPECIFICACIONES)	
50. Cuenta con procedimientos y registros para el manejo del producto que no cumple especificaciones	2
9. EQUIPO E INSTRUMENTOS PARA EL CONTROL DE LAS FASES DE PRODUCCIÓN	
51. Cuenta con programa y registros de mantenimiento de equipos y calibración de instrumentos para el control de las fases de producción (balanzas, termómetros, manómetros, etc.)	2
10. LIMPIEZA	
52. Cuenta con procedimientos específicos de limpieza para instalaciones, equipos y transporte	2
11. RETIRO DE PRODUCTO	
53. Cuenta con un plan para retirar del mercado cualquier lote de un producto que represente un peligro para la salud del consumidor y registros de los retiros realizados	2
54. Cuenta con evidencia documental de la notificación a la Secretaría de Salud de cualquier anomalía sanitaria detectada en el producto que represente un riesgo potencial para la salud	2
12. HACCP	
55. Cuenta con el análisis de los peligros relacionados con materias primas, producto y proceso	---

OBSERVACIONES GENERALES

Me presente en el domicilio señalado en la orden de verificación donde después de identificarme con credencial vigente y entregar original de la orden, se procede a realizar un recorrido por las instalaciones, usando bata, cofia, cubre boca calzado antiderrapante, lámpara y kit de cloro, encontrando las siguientes observaciones: 1.- Hay paredes con desprendimiento de pintura en la parte exterior e interior di área de envasado. 2.- Hay una ventana del área de envasado de sal que no tiene protección. 3.- Hay equipos que se encuentran oxidados. 5.- El agua no es potable se realizó la determinación de cloro libre residual y resulto menos de 0.2 ppm. 25.- El agua no es posible. 26.- No se garantiza la potabilidad del agua. 27.- Hay equipos en desuso que se encuentran sucios con presencia de polvo y basura. 40.- No se han capacitado en el último año. 42.- No cuentan con registros de coro libre residual ni análisis de organismos coliformes fecales y totales. Se anexa cuestionario anexo al acta de verificación para establecimientos que producen y/o envasan sal para consumo humano. Al momento de la visita solo habia una persona que firmo como testigo. Se informa lo anterior para lo que proceda.

RECOLECCIÓN DE MUESTRA

Se toma muestra de producto SI ( ) NO ☒

De conformidad con el artículo 401 bis de la Ley General de Salud, la toma de muestras podrá realizarse en cualquiera de las etapas del proceso, pero deberán tomarse del mismo lote, producción o recipiente, procediéndose a identificar las muestras con etiquetas, y en su caso en envases cerrados y sellados.

Se realiza el muestreo del producto por triplicado: SI ( ) NO ☒

Una muestra se deja en poder de la persona con quien se entiende la diligencia para su análisis particular.
Otra muestra queda en poder de la misma persona, pero a disposición de la autoridad sanitaria y tendrá el carácter de muestra testigo.
La última, como muestra oficial.

☒ Se envía por la autoridad sanitaria al laboratorio autorizado y habilitado para su análisis oficial. **Si o No**

☒ Se deja en poder del interesado para ser enviada por su cuenta y costo a un laboratorio tercero autorizado para su análisis correspondiente y el resultado será remitido a la autoridad sanitaria que ordenó el muestreo. **Si o No**

El depositario de la muestra testigo será responsable solidario con el titular, si no conserva la muestra citada.

El procedimiento de muestreo no impide que la Secretaría de Salud dicte y ejecute las medidas de seguridad sanitarias que procedan, en cuyo caso se asentará en el acta de verificación las que se hubieren ejecutado y los productos que comprenda.

Se toma la muestra por triplicado de los siguientes productos:

Número de muestra / Nombre del producto	Marca	Lote	Fecha de caducidad o consumo preferente	Cantidad / Presentación
1. XXXXXXXXX	XXXXXXXXX	XXXXXXXXX	XXXXXXXXX	XXXXXXXXX
2. XXXXXXXXX	XXXXXXXXX	XXXXXXXXX	XXXXXXXXX	XXXXXXXXX

9.	La ventilación evita el calor, condensación de vapor, acumulación de humo y polvo	2
10.	La iluminación permite llevar a cabo la realización de las operaciones de manera higiénica y en las áreas donde los productos se encuentren sin envasar, los focos y lámparas están protegidos o son de material que impide su astillamiento	2
11.	Las estaciones de lavado o desinfección de manos son accesibles al área de producción y cuentan con agua, jabón o detergente, desinfectante, dispositivo de secado por aire caliente o toallas desechables y/o bote con tapa oscilante o de acción de pedal	2
IV.	ALMACENAMIENTO	
12.	Los agentes de limpieza, químicos y sustancias tóxicas, se encuentran almacenados en un área especifica, separada y delimitado de las áreas de almacenamiento y manipulación de materias primas y/o producto	2
13.	Las materias primas y/o productos se colocan en mesas, estibas, tarimas, anaqueles, entrepaños, estructura o cualquier superficie limpia y en condiciones que evite su contaminación	2
14.	Las materias primas y productos están rotulados de tal manera que permita identificar su naturaleza y aplicar un sistema de Primeras Entradas Primeras Salidas	2
15.	Los envases y recipientes en contacto directo con la materia prima y productos se almacenan protegidos de polvo, lluvia, fauna nociva y materia extraña	—
V.	CONTROL DE OPERACIONES	
16.	Los equipos de refrigeración mantienen una temperatura máxima de 7 °C (45°F) y los de congelación una temperatura que permite la congelación del producto	2
17.	Se evita la contaminación cruzada entre la materia prima, producto en elaboración y producto terminado	2
18.	Se monitorea y supervisa la aplicación de procedimientos y controles de operación	2
19.	Se aplican controles que evitan el uso de materias primas en las que puedan existir peligros que no logren reducirse a niveles seguros por los procedimientos normales de inspección, clasificación o elaboración	—
VI.	MATERIAS PRIMAS	
20.	Se inspeccionan o clasifican las materias primas e insumos antes de la producción o elaboración	2
21.	Ausencia de materias primas que puedan representar un riesgo a la salud al utilizarse en la elaboración del producto	2
VII.	CONTROL DE ENVASADO	
22.	El envase primario es inocuo y se encuentra limpio, en buen estado y de ser el caso desinfectado antes de su uso	2
23.	Los recipientes y envases vacíos que contuvieron medicamentos, plaguicidas, agentes de limpieza, agentes de desinfección o cualquier sustancia tóxica no son reutilizados	2
24.	Las condiciones del envasado son tales que se evita la contaminación del producto	2
VIII.	AGUA EN CONTACTO CON LOS ALIMENTOS	
25.	El agua que está en contacto con materias primas, productos, superficies, envases y la de fabricación de hielo es potable	0
26.	Se practica alguna medida y/o método que garantice la potabilidad del agua	0
IX.	MANTENIMIENTO Y LIMPIEZA	
27.	El equipo y utensilios se encuentran en buenas condiciones de funcionamiento, limpios y desinfectados	1
28.	Los lubricantes utilizados en equipos o partes que están en contacto directo con materias primas, envase primario, producto en proceso o terminado sin envasar son de grado alimenticio	—
29.	Los agentes de limpieza y desinfección para equipos y utensilios se utilizan de acuerdo a las instrucciones del fabricante o procedimientos internos garantizando su efectividad	2
X.	CONTROL DE PLAGAS	
30.	Los drenajes cuentan con protección para evitar la entrada de plagas provenientes del alcantarillado o áreas externas	2
31.	Existen dispositivos en buenas condiciones y localizados adecuadamente para el control de insectos y roedores (cebos, trampas, etc.)	2
32.	En las áreas de proceso no hay evidencia de plagas o fauna nociva	2
XI.	MANEJO DE RESIDUOS	
33.	Los residuos (basura, desechos o desperdicios) generados durante la producción o elaboración son retirados de las áreas cada vez que es necesario o por lo menos una vez al día y se colocan en recipientes identificados y con tapa	2
XII.	SALUD E HIGIENE DEL PERSONAL	
34.	El personal que trabaja en producción o elaboración no presenta signos como: los frecuente, secreción nasal, diarrea, vómito, fiebre, ictericia o heridas en áreas corporales que entran en contacto directo con las materias primas o productos y se presenta aseado al área de trabajo, con ropa y calzado limpios e integros y no existe evidencia de que come, bebe, fuma, masca, escupe, tose y/o estornuda	2
35.	El personal de las áreas de producción o elaboración, o que se encuentra en contacto directo con materias primas, envases primarios o productos, se lava las manos al inicio de las labores y cada vez que sea necesario de acuerdo a lo siguiente: a) Se enjuaga las manos con agua y aplica jabón o detergente. b) Se frota vigorosamente la superficie de las manos y entre los dedos; para el lavado de las uñas utiliza cepillo. Cuando utiliza uniforma con mangas cortas se lava hasta la altura de los codos. c) Se enjuaga con agua limpia, cuidando que no queden restos de jabón o detergente. Posteriormente puede utilizarse solución desinfectante. d) Se seca con toallas desechables o dispositivos de secado con aire caliente.	2
36.	En las áreas en donde el personal entra en contacto directo con materias primas, envase primario, producto en proceso y terminado sin envasar, equipos y utensilios, tiene el cabello corto o recogido con protección que cubra totalmente cabello, barba y bigote, usa ropa protectora y cubrebocas en buen estado, trae las uñas limpias, recortadas y sin esmalte, no usa joyas y/o adornos en manos, cara, boca, lengua, orejas, cuello y cabeza, no porta objetos (plumas, lapiceros, termómetros, sujetadores, etc.) en bolsillos superiores de la vestimenta	2
XIII.	TRANSPORTE	
37.	Los productos son transportados en vehículos que se encuentran limpios, en buen estado de mantenimiento y en condiciones que evitan la contaminación física, química, biológica y por plagas y en su caso, en refrigeración o congelación	2
XIV.	RETIRO DE PRODUCTO	
38.	Los productos retirados del mercado se mantienen bajo supervisión y resguardo en un área especifica e identificada de la empresa hasta que se determinen las acciones pertinentes	2
XV.	INFORMACION SOBRE EL PRODUCTO	
39.	Los productos preenvasados cuentan con clave para la identificación del lote	2
XVI.	DOCUMENTOS Y REGISTROS	
1.	CAPACITACIÓN	
40.	El personal que opera en las áreas de producción o elaboración se capacita en buenas prácticas de higiene y manufactura por lo menos una vez al año.	0
2.	CONTROL DE PLAGAS	
41.	Cuenta con un sistema, programa o plan o certificado para el control y erradicación de plagas, el cual incluye los vehículos propios de acarreo y reparto y quien lo realiza cuenta con Licencia Sanitaria.	2

Acta de Verificación Sanitaria No. 21-PL-0600-01062-XV

COMISIÓN ESTATAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS

ACTA DE VERIFICACIÓN SANITARIA DE PRÁCTICAS DE HIGIENE PARA FÁBRICAS DE ALIMENTOS, BEBIDAS O SUPLEMENTOS ALIMENTICIOS

En Cuauhtémoc, Col. siendo las 10:00 horas del día 09 del mes de Agosto de 2021, en cumplimiento a la orden de visita de verificación número 21-PL-0600-01062-XV de fecha 06 de agosto de 2021, emitida por Dr. Antonio Fermín Ochoa Meillon, en su carácter de Comisionado Estatal para la protección contra Riesgos Sanitarios, el(los) Verificador(es) QFB Amoldo Hinojosa Puga adscrito(s) a Comisión Estatal para la Protección contra Riesgos Sanitarios, quien (es) se identifica(n) con credencial(es) numero(s) 210600VS041P con fotografía, vigente(s) al 31 de Diciembre de 2021 expedida(s) el 05/01/2021, por el C. Licda. Leticia Guadalupe Delgado Carrillo, en su carácter de Secretaria de Salud y Bienestar Social, que me(nos) acredita(n) como verificador(es) sanitario(s) con fundamento en los Artículos: 4 fracción II inciso d, 11 fracciones IX, XI y XIV, y 15 fracción IV del Reglamento de la Comisión Federal para la Protección contra Riesgos Sanitarios y 396, 399, 400 y 401 fracción I de la Ley General de Salud; Acuerdo de Coordinación que para el ejercicio de facultades en materia de control y fomento sanitarios, celebran la Secretaría de Salud, con la participación de la Comisión Federal para la Protección contra Riesgos Sanitarios, y el Estado de Colima y los artículos 1, 2, 3, 4, 7 fracciones I, V y XV, 25 fracción IV inciso d, 42, 43 fracciones VII, VIII y IX, 47 fracciones I, III, V, VI, XI y XIX del Reglamento Interior del Organismo Público descentralizado "Servicios de Salud del Estado de Colima", publicado en el Periódico Oficial del Estado de Colima el 28 de enero de 2017. Constituido(s) en el establecimiento denominado Fleur de Sel S.A. de C.V. con giro o actividades de Elaboración de sal yodada fluorurada, con RFC FSE180612H80, ubicado en la calle de López Mateos, número 40 Colonia El Toreo Delegación o Municipio Cuauhtémoc Código Postal 28500 correo electrónico XXXXXXX, teléfono, 3281143, fax XXXXXX circunstancias que constaté(amos) visualmente y solicitando la presencia del propietario o representante legal, responsable, encargado u ocupante que atiende la visita, dijo llamarse Zoila Patricia Solís Montero y se identifica con INE012107163470, con domicilio en Cisnes # 24, Fracc. San Rafael, C.P. 28504, Cuauhtémoc, Col. y manifiesta ser el Propietaria del establecimiento, quien recibe original de la orden de visita en términos del artículo 399 de La Ley General de Salud, se le exhorta para que corrobore que la(s) fotografía(s) que aparece(n) en dicha(s) credencial(es) concuerda(n) con los rasgos fisonómicos del(los) que actúa(n). Acto seguido se le hace saber el derecho que tiene para nombrar a dos testigos de asistencia, y en caso de no hacerlo, éstos serán designados por el(los) propio(s) verificador(es), quedando nombrados como testigos por parte del C Zoila Patricia Solís Montero, quienes deberán estar presentes durante el desarrollo de la visita, el C Araceli Osorio Galindo, quien se identifica con IFE0122051188190, con domicilio en Colonia el Toreo, C.P. 28500, Cuauhtémoc, Col. y el C ****** quien se identifica con ****** con domicilio en ******

Acto seguido y habiéndose identificado plenamente los participantes en esta diligencia, en presencia de los testigos se le hace saber el objeto y alcance de la visita que se indica en la orden de verificación descrita anteriormente, y visto el contenido se procede a practicar la diligencia de verificación sanitaria en el establecimiento en los términos siguientes:

Objeto y alcance de la orden de visita sanitaria (Transcribir)

Objeto: Efectuar visita de verificación general y constatar requisitos de etiquetado sanitario. Alcance: Realizar visita de verificación general del establecimiento para constatar las condiciones físico sanitarias de las instalaciones y los controles de sus procesos así mismo, constatar que cuente con la identificación del lote, denominación y domicilio del fabricante de acuerdo con el aviso de funcionamiento, en caso de no ser así, anexar muestra de etiqueta y efectuar su aseguramiento, lo anterior con fundamento en los artículos 393,395,397,402,403,404 fracción X, y 414 de la Ley General de Salud y 260 del Reglamento de Control Sanitario de Productos y Servicios. Asentar en el acta la cantidad total de productos y etiquetas asegurado. Aplicar cuestionario anexo al acta de verificación sanitaria aplicada a establecimientos que procesan y/o envasan sal para consumo humano. Realizar la entrega de la carta de derechos de los visitados en verificaciones sanitarias. Para el desarrollo de las actividades, el personal de verificación designado podrá realizar toma fotográfica del establecimiento, de los productos y de las acciones que se realicen en cumplimiento de la presente orden. En caso de encontrar irregularidades que pongan en riesgo la salud de la población, proceder a ejecutar las medidas de seguridad previa anuencia de la autoridad sanitaria competente, de conformidad con los artículos 402,403,404 fracciones VII y X, 411, 412 y 414 de la ley general de salud.

Instrucciones:
Se deberán anotar los valores dentro del cuadro en blanco que conforman la columna denominada "Valor", de acuerdo a la calificación que amerite cada inciso según corresponda.

CALIFICACIÓN:	(2) Cumple Totalmente	(1) Cumple Parcialmente	(0) No cumple	(---) No aplica

Forma parte integral de esta acta el cuestionario, cuando este aplique, y la documentación que el verificador anexe.

INFORMACIÓN ADMINISTRATIVA:

Cuenta con aviso de funcionamiento: si (X) no ( )
Días laborales: L M M J V S Horario de labores: de 10:00 a 18:30 hrs Turnos: UNO
Número total de empleados: 8 Número de empleados en área de producción: 5
Volumen de producción diaria en piezas, kilogramos, litros, etc. (especificar unidades): 4 toneladas por semana
Se llena cuestionario de prácticas de higiene: si(X) no( ).
Se anexa documentación: si ( ) no (X) Número de hojas anexadas: XXXX
Se toma muestra de producto para dictamen de etiqueta: si (X) no ( ) Número de muestras: UNA

		Valor
I.	INSTALACIONES Y ÁREAS	
1.	Las instalaciones del establecimiento, incluidos techos, puertas, paredes, pisos, baños, cisternas, tinacos u otros depósitos de agua, y mobiliario se encuentran en buenas condiciones de mantenimiento y limpios.	1
2.	Las puertas y ventanas de las áreas de producción o elaboración están provistas de protección para evitar la entrada de lluvia y fauna nociva.	1
II.	EQUIPO Y UTENSILIOS	
3.	El equipo, utensilios y materiales que se emplean en la producción o elaboración, son inocuos y son resistentes a la corrosión y están instalados en forma tal que el espacio entre estos, la pared, el techo y el piso permite su limpieza y desinfección.	1
4.	Los equipos de refrigeración y/o congelación están provistos de termómetros o dispositivos para el registro de temperatura funcionando correctamente y en un lugar accesible para su monitoreo y no presentan acumulación de agua.	---
III.	SERVICIOS	
5.	Cuenta con abastecimiento de agua potable, instalaciones apropiadas para su almacenamiento y distribución.	1
6.	El agua no potable que se utiliza para servicios y otros propósitos, se transporta por tuberías completamente separadas e identificadas de las tuberías que conducen agua potable.	---
7.	El drenaje cuenta con trampa contra olores, coladeras y/o canaletas con rejillas, libres de basura, sin estancamiento y en buen estado, y en su caso trampas para grasa.	2
8.	Los sanitarios cuentan con separación física completa y no tienen comunicación ni ventilación directa hacia el área de producción o elaboración y están provistos con agua potable, retretes, lavabos, papel higiénico, jabón o detergente, toallas desechables o secador de aire de accionamiento automático y recipiente para basura con bolsa y tapa oscilante o accionada por pedal y cuentan con rótulos o ilustraciones que promuevan la higiene personal y el lavado de manos después de utilizar los sanitarios.	2

Araceli Osorio G

SERVICIOS DE SALUD
DEL ESTADO DE COLIMA

COMISIÓN ESTATAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS
SUBCOMISIÓN DE EVIDENCIA Y ANÁLISIS DE RIESGO
GERENCIA DE EVIDENCIA DE RIESGOS
AV. AYUNTAMIENTO ESQ. ARNOLDO VOGEL, COL. BURÓCRATAS MUNICIPALES, C.P. 28040

No. de Orden : 21-PL-0600-01062-XV

Colima, Col. viernes, 06 de agosto de 2021

Al Propietario, Responsable, Representante Legal, Encargado u Ocupante de:
FLEUR DE SEL S.A. DE C.V.
Ubicado en: **AV. LOPEZ MATEOS N° 40; COL. EL TOREO CUAUHTEMOC ; CUAUHTEMOC; COLIMA; .;**
Entre las calles :

Considerando que la salud debe ser protegida ya que junto con la vida es el bien más valioso que posee el ser humano; que uno de los medios de que puede valerse la autoridad sanitaria para llevar a cabo la comprobación de que se está observando y cumplimentando los requisitos, exigencias y especificaciones contenidas en la normativa sanitaria, es la visita de verificación y toda vez que la regulación de los establecimientos dedicados al proceso de alimentos, bebidas o suplementos alimenticios es competencia de esta Unidad Administrativa, con fundamento en los artículos 4° párrafo cuarto, 14 y 16 de la Constitución Política de los Estados Unidos Mexicanos; 1°, 3° fracción XXIV, 4° fracciones III y IV, 13 apartado B) fracciones I, VI y VII, 17 bis y 18, 132, 194, 393, 394, 395, 396 fracción I, 397, 398, 399, 400, 401, 401 bis, 402, 403, 404, 411, 412, 414, 431, 436 y 437 de la Ley General de Salud; 1°, 2° apartado C, fracción X, 36, 37 y 38 del Reglamento Interior de la Secretaría de Salud; 1°, 253, 254, 255, 256 y 260 del Reglamento de Control Sanitario de Productos y Servicios; Cláusulas Sexta y Octava del Acuerdo de Coordinación para la Descentralización Integral de los Servicios de Salud publicado en el Diario Oficial de la Federación en julio 04 de 2001; Acuerdo de coordinación que para el Ejercicio de Facultades en materia de Control y Fomento Sanitarios, celebran la Secretaría de Salud, con la participación de la Comisión Federal para la Protección contra Riesgos Sanitarios, y el Estado de Colima; 1°, 2° fracción V de la Constitución Política del Estado Libre y Soberano de Colima; 32 fracciones VIII, XI y XVII de la Ley Orgánica de la Administración Pública del Estado de Colima; 1°, 2°, 4°, 5°, 6°, 7°, 8°, 9°, 21 fracción II, 63, 64, 161, 163, 164, 165, 166, 167, 168, 169, 170, 174, 176 fracciones VII y IX, 179, 180 y 183 de la Ley de Salud del Estado de Colima; 3 , 4, 6, 9 numeral 1 fracciones I, III, V y XV, 26 numeral 1 fracción XIII, 27 numeral 1 fracción III inciso a, 103 numeral 1 fracciones I, II, III, IV, V, VII, VIII, XIV, XVI, XVIII, XIX, XX y XXXIX del Reglamento Interior del Organismo Público Descentralizado Servicios de Salud del Estado de Colima, publicado en el Periódico Oficial del Estado de Colima el 20 de marzo de 2021 y demás ordenamientos sanitarios aplicables.

Se expide la presente ORDEN DE VISITA DE VERIFICACIÓN SANITARIA DE TIPO ORDINARIA para ser practicada en ese establecimiento por el(los) verificador(es):

IQA. ALEJANDRO MORENO GUTIÉRREZ

QFB. ARNOLDO HINOJOSA PUGA

habilitados que actuarán en conjunto o indistintamente. La visita tendra el siguiente

OBJETO Y ALCANCE :
OBJETO: EFECTUAR VISITA DE VERIFICACIÓN GENERAL Y CONSTATAR REQUISITOS DE ETIQUETADO SANITARIO.
ALCANCE:REALIZAR VISITA DE VERIFICACIÓN GENERAL DEL ESTABLECIMIENTO PARA CONSTATAR LAS CONDICIONES FÍSICO-SANITARIAS DE LAS INSTALACIONES Y LOS CONTROLES DE SUS PROCESOS, ASÍ MISMO, CONSTATAR QUE CUENTE CON LA IDENTIFICACIÓN DEL LOTE, DENOMINACIÓN Y DOMICILIO DEL FABRICANTE DE ACUERDO CON EL AVISO DE FUNCIONAMIENTO, EN CASO DE NO SER ASÍ, ANEXAR MUESTRA DE ETIQUETA Y EFECTUAR SU ASEGURAMIENTO, LO ANTERIOR CON FUNDAMENTO EN LOS ARTÍCULOS 393, 395, 397, 402, 403, 404 FRACCIÓN X Y 414 DE LA LEY GENERAL DE SALUD Y 260 DEL REGLAMENTO DE CONTROL SANITARIO DE PRODUCTOS Y SERVICIOS. ASENTAR EN EL ACTA LA CANTIDAD TOTAL DE PRODUCTOS Y ETIQUETAS ASEGURADO. APLICAR CUESTIONARIO ANEXO AL ACTA DE VERIFICACIÓN SANITARIA APLICADA A ESTABLECIMIENTOS QUE PRODUCEN Y/O ENVASAN SAL PARA CONSUMO HUMANO. REALIZAR LA ENTREGA DE LA CARTA DE DERECHOS DE LOS VISITADOS EN VERIFICACIONES SANITARIAS. PARA EL DESARROLLO DE LAS ACTIVIDADES, EL PERSONAL DE VERIFICACIÓN DESIGNADO PODRÁ REALIZAR LA TOMA FOTOGRÁFICA DEL ESTABLECIMIENTO, DE LOS PRODUCTOS Y DE LAS ACCIONES QUE SE REALICEN EN CUMPLIMIENTO A LA PRESENTE ORDEN. EN CASO DE ENCONTRAR IRREGULARIDADES QUE PONGAN EN RIESGO LA SALUD DE LA POBLACIÓN, PROCEDER A EJECUTAR LAS MEDIDAS DE SEGURIDAD PREVIA ANUENCIA DE LA AUTORIDAD SANITARIA COMPETENTE, DE CONFORMIDAD CON LOS ARTÍCULOS 402, 403, 404 FRACCIONES VII Y X, 411, 412 Y 414 DE LA LEY GENERAL DE SALUD.

De conformidad con el artículo 400 de la Ley General de Salud, deberá darle(s) todo género de facilidades e informes al (los) verificador(es) designado(s) relacionado(s) con la verificación y su objeto y permitir el acceso a las instalaciones de la empresa. Solo podrá negarse el acceso cuando el verificador no se identifique con la carta credencial, esta orden, o la carta credencial no ostente la firma autógrafa de la Autoridad responsable o por presentarse personal no mencionado en este documento.
Si el (los) verificador(es) sanitario(s) advierte(n) violaciones a las disposiciones legales que pongan en peligro inminente la salud de las personas, queda(n) facultado(s) previa autorización de la Autoridad Sanitaria competente para ejecutar las medidas de seguridad previstas en los artículos 411, 414 y 431 de la Ley General de Salud.

Para cualquier orientación respecto de la autenticidad de la orden de visita de verificación, de los datos contenidos en la misma, de la identidad de el(los) verificador(es) encargado(s) de realizarla y/o presentación de quejas o inconformidades llamar al 01 800 REGULAS (01 800 734 85 27) o al 31 625 70.

ATENTAMENTE

COMISIONADO ESTATAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS

DR. ANTONIO FERMÍN OCHOA MEILLON

SERVICIOS DE SALUD
DEL ESTADO DE COLIMA
COMISIÓN ESTATAL PARA
LA PROTECCIÓN CONTRA
RIESGOS SANITARIOS

RJH/BRCG/ALGN

ESTE DOCUMENTO ES DE CARÁCTER INDIVIDUAL E INTRANSFERIBLE, NO SERA VALIDO SI PRESENTA BORRADURAS O ENMENDADURAS.

I. Las instalaciones de ...
mantenimiento y limpieza ...

07/14/2021 15:54:25

Created Date

2021-07-14 15:49:08.0

Registration Expiration Date

2022-12-31

Last Updated

2021-07-14

Registration Status

VALID

Registration Status Reason

Pending UFI Confirmation

Created by

fer99857

Section 1: Type of Registration

Facility Location : **Foreign Registration**

UPDATE OF REGISTRATION INFORMATION: *Registration Number:* ***16441296972*** Pin No **aG672xb2** **Modify Pin**

Are you the new owner of a previously registered facility?

Yes No

Previous Owner's Title:

Previous Owner's Name :

COFEPRIS

SALUD

COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS

CENTRO INTEGRAL DE SERVICIOS

Comprobante de Trámite

USO EXCLUSIVO COFEPRIS	FORMATO DE COFEPRIS-05
210601518X0372	Tipo de Trámite: **018**
10/08/2021 09:59 hrs.	Homoclave del Trámite: **COFEPRIS-05-018-X**
	Subtipo: **AVISO DE FUNCIONAMIENTO DEL ESTABLECIMIENTO DE PRODUCTOS Y SERVICIOS**
	Modalidad: **NO APLICA**

R.F.C. O C.U.R.P.:	**FSE 180612H80**
NOMBRE O RAZÓN SOCIAL:	**FLEUR DE SEL S A DE C V**
DOMICILIO:	
REPRESENTANTE LEGAL O RESPONSABLE SANITARIO :	
NÚMERO DE INGRESO DE REFERENCIA :	
ANEXOS:	**HOJAS ORIG.: 7 HOJAS COPIA: 35 OTROS: FORMATO, COPIA SIMPLE DE RFC, IFE REPRESENTANTE LEGAL Y PERSONA AUTORIZADA, Y ESCRITURA 1127 Y 43953**
LLAVE DE PAGO:	
REGISTRO SANITARIO:	
MODO DE INGRESO Y ENTREGA:	**CENTRO INTEGRAL DE SERVICIOS VENTANILLA**

IMPORTANTE: Con la finalidad de atender su petición con apego a la prerrogativa contenida en el artículo 8° de la Constitución Política de los Estados Unidos Mexicanos, su trámite se someterá a una primera revisión de conformidad con el *"Acuerdo por el que se dan a conocer los trámites y servicios, así como los formatos que aplica la Secretaría de Salud, a través de la Comisión Federal para la Protección contra Riesgos Sanitarios, inscritos en el Registro Federal de Trámites y Servicios de la Comisión Nacional de Mejora Regulatoria"* para constatar que su petición y el expediente que la acompaña, contengan cada uno de los documentos con los que pretende acreditar los requisitos que debe cumplir en su petición; en caso de no presentar alguno de estos documentos, no se le dará el trámite correspondiente y se le regresará para que subsane la documentación faltante.

Lo anterior, respetando en todo momento su derecho de poder presentar nuevamente su trámite con toda la documental completa requerida, en cumplimiento de los requisitos formales para el ingreso de su trámite establecidos en el mencionado Acuerdo.

Para obtener información sobre la disponibilidad de sus trámites usted podrá consultarnos en nuestra página **"www.gob.mx/cofepris"** en **Ligas de Interés** haga click en **Centro Integral de Servicios** y seleccione **"Consulta de Resoluciones Disponibles"** o bien comunicarse al **Centro de Atención Telefónica** al número: **800 033 5050**.

Si la resolución de su trámite se encuentra disponible podrá recogerla contra entrega de este comprobante de trámite original en el Centro Integral de Servicios, donde permanecerán disponibles durante 30 días naturales y solo será entregada al representante legal, responsable sanitario o personas autorizadas notificadas ante ésta Comisión Federal previa presentación de identificación oficial.

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CERTIFICATE

IQNet and **SIGE**

hereby certify that the organization

COMISIÓN ESTATAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS - COESPRIS

Av. Ayuntamiento S/N, esq. Arnoldo Vogel Carrillo, Col. Burócratas Municipales, C.P.28040, Colima, Colima, México

for the following field of activities

Proceedings and Services. Authorization. Administrative Decision. Sanitary Verification. Sanitary Dictate

has implemented and maintains a

Management System

which fulfils the requirements of the following standard

ISO 9001:2008

Issued on: 2014-05-09 Validity date: 2017-05-08

Registration Number : ***MX-2014CRE-319***

IQNet

Michael Drechsel
President of IQNet

Pedro CANO CALDERÓN
Operations Manager of SIGE

SIGE

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Firm/Supplier Evaluation Resources

The FDA firm and supplier database available on this site includes data associated with inspections classification, inspections citations, compliance actions, recalls, and imports.

Search by Firm Name or FEI Number Help

3014274322

No data found

Three FDA FSMA rules (Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals); Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food); and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-animal-food)) require that importers and facilities perform certain risk-based activities to verify that their suppliers are meeting applicable U.S. food safety standards. Under these rules, you must evaluate, among other things, the applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including whether the supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation.

Below is a list of publicly available resources that can be used to meet the requirement set out in these regulations as well as information on their use:

Collapse All | Expand All

- **Warning Letters**
- **Import Alerts**
- **Recalls**
- **Import Refusals**
- **Inspection Classifications**
- **Other Compliance Resources**

Contact

Questions and comments pertaining to the FDA Data Dashboard and source data may be directed by email to: **FDADataDashboard@fda.hhs.gov** (mailto:FDADataDashboard@fda.hhs.gov)

Dashboard Home (../index.htm)

Compliance Dashboards (../cd/index.htm)

Inspections (../cd/inspections.htm)

Compliance Actions (../cd/complianceactions.htm)

Recalls (../cd/recalls.htm)

Imports Summary (../cd/impsummary.htm)

Import Refusals

FSMA Data Search (index.htm)

Firm/Supplier Evaluation Resources (fser.htm)

Approved VQIP Importers (vqip.htm)

TPP Participants (tpp.htm)

Resources

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

Glossary (../glossary.htm)

API (../api/index.htm)

Notifications (../notifications.htm

Contact Us (../contact.htm)

(../cd/imprefusals.htm)

Imports
Entry
(../cd/impentry.htm)

Language Assistance Available: Español
(https://www.fda.gov/about-fda/about-website/language-assistance-services#spanish) | 繁體中文
(https://www.fda.gov/about-fda/about-website/language-assistance-services#chinese) | Tiếng Việt
(https://www.fda.gov/about-fda/about-website/language-assistance-services#vietnamese) | 한국어
(https://www.fda.gov/about-fda/about-website/language-assistance-services#korean) | Tagalog
(https://www.fda.gov/about-fda/about-website/language-assistance-services#tagalog) | Русский
(https://www.fda.gov/about-fda/about-website/language-assistance-services#russian) | العربية
(https://www.fda.gov/about-fda/about-website/language-assistance-services#arabic) | Kreyòl Ayisyen
(https://www.fda.gov/about-fda/about-website/language-assistance-services#creole) | Français
(https://www.fda.gov/about-fda/about-website/language-assistance-services#french) | Polski
(https://www.fda.gov/about-fda/about-website/language-assistance-services#polish) | Português
(https://www.fda.gov/about-fda/about-website/language-assistance-services#portuguese) | Italiano
(https://www.fda.gov/about-fda/about-website/language-assistance-services#italian) | Deutsch
(https://www.fda.gov/about-fda/about-website/language-assistance-services#german) | 日本語
(https://www.fda.gov/about-fda/about-website/language-assistance-services#japanese) | فارسی
(https://www.fda.gov/about-fda/about-website/language-assistance-services#farsi) | English
(https://www.fda.gov/about-fda/about-website/language-assistance-services#english)

Search Results

FEI Number	Firm Name	Physical Address	Mailing Address
3014274322	SOLYSAL DE COLIMA S.P.R DE R.L.	Adolfo Lopez Mateos 40el Toreo, Cuauhtemoc, Colima Me, MX	Adolfo Lopez Mateos 40el Toreo, Cuauhtemoc, Colima Me, MX