SQF Food Safety Audit Edition 9

Roha USA LLC

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
9575 | 310062

AUDIT RATING
97
Excellent

DECISION DATE
12/01/23

AUDIT TYPE
RE-CERTIFICATION

RECERTIFICATION DATE
10/04/24

AUDIT DATES
10/30/23 - 10/31/23

EXPIRATION DATE
12/18/24

ISSUE DATE
12/01/23

Facility & Scope

Roha USA LLC
5015 Manchester Ave
Saint Louis Missouri 631100
United States

Food Sector Categories:
19. Food Ingredient Manufacture

Products:
Liquid and Dry Dye Blends (Synthetic and Natural).

Scope of Certification:
Liquid and Dry Dye Blends (Synthetic and Natural).

Certification Body & Audit Team

CICS Americas Inc.
8350 Ashlane Way Suite 104,
The Woodlands, TX 77382

CB#: CB-1-CICS
Accreditation Body: ANSI
Accreditation Number: 1087

Lead Auditor: Luis Palacios (124403)
Technical Reviewer: Cesar Hernandez (120868)

Hours Spent on Site: 16
Hours of ICT Activites: 0
Hours Spent Writing Report: 8

Non-Conforming

2.5.1 Validation and Effectiveness (Mandatory)

Magnetic Pull Test CCP Verification, there is a report for this run every month: record is for the months: 1/11/23, 2/16/23, 3/21/23, etc. Up to 10/18/23. For instance: Magnet 466559, Bar 1: 11.5, Bar 2: 11.0, Bar 3: 11.5, Bar 4: 11, Bar 5: 10. / NCm: The methods, responsibility, and criteria for the validations of the GMPs, Critical food safety limits, and changes of processes or procedures were not found documented.

2.5.1.1 The methods, responsibility, and criteria for ensuring the effectiveness of all applicable elements of the SQF Program shall be documented and implemented. The methods applied shall validate that:
i. Good Manufacturing Practices are confirmed to ensure they achieve the required results;
ii. Critical food safety limits are reviewed annually and re-validated or justified by regulatory standards when changes occur; and
iii. Changes to the processes or procedures are assessed to ensure the controls are still effective.
Records of all validation activities shall be maintained.

RESPONSE: MINOR

EVIDENCE: NCm: The methods, responsibility, and criteria for the validations of the GMPs, Critical food safety limits, and changes of processes or procedures were not found documented.

ROOT CAUSE: Quality Manager resigned in Mid 2023. This left a void in the trained staff to conduct the reviews

CORRECTIVE ACTION: Getting the rest of the quality team trained in PCQI and HACCP to be able to conduct the reviews.

VERIFICATION OF CLOSEOUT: Training the team in PCQI and HACCP will provide the proper knowledge to validate the PCC limits and the rest of control measures.

COMPLETION DATE: 12/31/2023 **CLOSEOUT DATE**: 11/22/2023

2.5.4 Internal Audits and Inspections

There is a documented procedure for Internal Audit. Self-inspections are the responsibility of the QA Manager who is the lead internal auditor and complete the audit checklist. This procedure establishes that auditors must be independent of the area being audited. The procedure establishes as well that at a minimum of once per month an internal GMP audit is conducted. The audit includes observation of infrastructure. The findings are discussed with department heads. There is a routine monthly inspection based on the GMPs and the auditor could review all the monthly inspection reports. There is also the whole reviewing of the SQF system. NCm: there is only one member of the staff conducting the internal audit: the Operations Manager / Practitioner. Audit Independence is being compromise due to the fact that Op. Manager audits itw own processes.

2.5.4.2 Staff conducting internal audits shall be trained and competent in internal audit procedures. Where practical, staff conducting internal audits shall be independent of the function being audited.

RESPONSE: MINOR

EVIDENCE: NCm: there is only one member of the staff conducting the internal audit: the Operations Manager / Practitioner. Audit Independence is being compromise due to the fact that Op. Manager audits itw own processes.

ROOT CAUSE: Quality Manager resigned in Mid 2023. This left a void in the trained staff to conduct the reviews

CORRECTIVE ACTION: Getting the rest of the quality team trained in PCQI and HACCP to be able to conduct the reviews.

VERIFICATION OF CLOSEOUT: Training the team in PCQI and HACCP will provide the proper knowledge and competence to conduct internal audits and avoid the conflict of interest.

COMPLETION DATE: 12/31/2023 **CLOSEOUT DATE**: 11/22/2023

11.7.3	**Control of Foreign Matter Contamination** Standard Operating Procedures: FOREIGN MATERIAL CONTROL. Section 3.5.1. This foreign material control procedure is designed to protect consumers from illness and injury due to foreign material contamination. The Quality Manager is responsible for managing the foreign material contamination program and ensuring that all procedures are being carried out regularly; as well as monitoring for physical hazard by conducting the monthly glass inspections and monthly self-audit. All employees are responsible for complying with GMPs, adhering to the glass and brittle plastic policy, and monitoring their work area for sings of foreign material hazards. The production supervisor is responsible for ensuring that structures and equipment are maintained in a way that minimize the risk of foreign material contamination. Record of the inspection of glass and brittle plastic: 9/15/2023. NCm: during the tour it was observed that there are blades used in routine process but there is no specific inventory or particular control about the number of blades present in the whole plant.
11.7.3.8	Knives and cutting instruments used in processing and packaging operations shall be controlled, kept clean, and well maintained. Snap-off blades shall not be used in manufacturing or storage areas. **RESPONSE:** MINOR **EVIDENCE:** NCm: during the tour it was observed that there are blades used in routine process but there is no specific inventory or particular control about the number of blades present in the whole plant. **ROOT CAUSE:** The company did not have a written sharps control policy. Plant practices were in place, but not recorded **CORRECTIVE ACTION:** Created 5.5.1.16 (Sharps Control Policy) on 11/20/2023. This covers how the plant will issue and manage sharps on the plant and warehouse floor **VERIFICATION OF CLOSEOUT:** The site provided the SOP for sharps control and also the sharps log. **COMPLETION DATE:** 11/20/2023 **CLOSEOUT DATE**: 11/22/2023

Section Responses

Audit Statement	Audit
SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** BRIAN KALKBRENNER
SQF Practitioner Email	Email of the designated SQF Practitioner

	RESPONSE: BRIAN.KALKBRENNER@ROHAGROUP.COM
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** BRIAN KALKBRENNER: OPERATIONS MANAGER / PRACTITIONER, MERANDA BREECE: QUALITY TECHNICIAN / OBSERVER, LUIS PALACIOS: SQF AUDITOR
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** THIS PLANT IS DESIGNED TO BLEND FOOD COLORS IN LIQUID, DISPERSION, EMULSION AND DRY FORMS. USA PLANT IS PART OF THE ROHA CORPORATION, WITH HEADQUARTER OFFICE LOCATED AT ROHA DISTRICT OF MAHARASHTRA, INDIA, WHICH MEETS THE HIGHEST INTERNATIONAL STANDARDS AND NORMS. IN SUPPORT ARE ROHA'S OTHER MANUFACTURING CENTERS IN THE US, UK, SPAIN, SOUTH AFRICA, VIETNAM, INDONESIA, THAILAND, CHINA, EGYPT & MEXICO. PROCESSES INCLUDE: LIQUID COLOR PROCESS, COLOR DISPERSION, EMULSION AND VISCOUS LIQUID PROCESS, DRY BLEND COLOR PROCESS. ONE SHIFT OF PRODUCTION FROM MONDAY TO FRIDAY, FROM 6.00 AM TO 2.30 PM, WITH 10 OPERATIONS WORKERS, AND A GROUP OF SCIENTISTS IN RESEARCH AND DEVELOPMENT, SALES AND ADMINISTRATION STAFF. PLANT AND DISTRIBUTION CENTER IS LOCATED AT THE MANCHESTER AVENUE IN THE CITY OF SAINT LOUIS, MO. IT IS AN INDUSTRIAL ZONE. LAYOUT INCLUDES THE ADMINISTRATION OFFICES, RESEARCH AND DEVELOPMENT LABORATORIES -STATE OF THE ART-, PRODUCTION ROOMS, RAW AND PACKAGING MATERIALS WAREHOUSE, ON-HOLD PRODUCT WAREHOUSE, AND FINISHED PRODUCTS WAREHOUSE.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** BRIAN KALKBRENNER: OPERATIONS MANAGER / PRACTITIONER, MERANDA BREECE: QUALITY TECHNICIAN / OBSERVER, LUIS PALACIOS: SQF AUDITOR
Auditor Recommendation	Auditor Recommendation **RESPONSE:** PROCEED WITH RECERTIFICATION AFTER SOLVING THE NCS FOUND DURING THE AUDIT.
2.1.1	**Management Responsibility** Food Safety Policy: Commitment to Quality and Food Safety Statement. This is signed up by the CEO, date: 10/26/2023, and the Operations Manager, date: 10/26/2023. Some of the contents of this policy are: Our goal is to provide our customers with a range of high quality products through commitment to innovation, service and value, in a mutually profitable relationship while settng the standard for excellence in our industry. We will achieve this within a business culture of dignity and respect for our team members, facilities and long term partnership with our suppliers. We shall uphold a food safety and quality culture in our facility. SQF backup practitioner is Mr Matt Crabtree, FSPCA PCQI training certificate. For the main practitioner Mr Brian Kalkbrenner, FSPCA PCQI issued on 05/19/2017. Staff is prety much the same since last year. One visit from the FDA with no violations observed only recommendations. There is an organizational chart which shows the Operations staff, the Operations managers is the primary SQF Practitioner, and one of the Quality Technicians is the SQF Substitute Practitioner.

2.1.1.1 Senior site management shall prepare and implement a policy statement that outlines at a minimum the commitment of all site management to:
i. Supply safe food;
ii.Establish and maintain a food safety culture within the site;
iii. Establish and continually improve the site's food safety management system; and
iv. Comply with customer and regulatory requirements to supply safe food.
The policy statement shall be:
v. Signed by the senior site manager and displayed in prominent positions; and
vi. Effectively communicated to all site personnel in the language(s) understood by all site personnel.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.2 Senior site management shall lead and support a food safety culture within the site that ensures at a minimum:
i. The establishment, documentation, and communication to all relevant staff of food safety objectives and performance measures;
ii. Adequate resources are available to meet food safety objectives;
iii. Food safety practices and all applicable requirements of the SQF System are adopted and maintained;
iv. Employees are informed and held accountable for their food safety and regulatory responsibilities;
v. Employees are positively encouraged and required to notify management about actual or potential food safety issues; and
vi. Employees are empowered to act to resolve food safety issues within their scope of work.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.3 The reporting structure shall identify and describe site personnel with specific responsibilities for tasks within the food safety management system and identify a backup for the absence of key personnel.
Job descriptions for the key personnel shall be documented.
Site management shall ensure departments and operations are appropriately staffed and organizationally aligned to meet food safety objectives.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.4 Senior site management shall designate a primary and substitute SQF practitioner for each site with responsibility and authority to:
i. Oversee the development, implementation, review, and maintenance of the SQF System;
ii. Take appropriate action to ensure the integrity of the SQF System; and
iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.5 The primary and substitute SQF practitioner shall:
i. Be employed by the site;
ii. Hold a position of responsibility related to the management of the site's SQF System;
iii. Have completed a HACCP training course;
iv. Be competent to implement and maintain HACCP based food safety plans; and
v. Have an understanding of the SQF Food Safety Code: Food Manufacturing and the requirements to implement and maintain an SQF System relevant to the site's scope of certification

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.6 Senior site management shall ensure the training needs of the site are resourced, implemented, and meet the requirements outlined in system elements 2.9 and that site personnel meet the required competencies to carry out those functions affecting the legality and safety of food products.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.7 Senior site management shall ensure the integrity and continued operation of the food safety system in the event of organizational or personnel changes within the company or associated facilities.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.8 Senior site management shall designate defined blackout periods that prevent unannounced re-certification audits from occurring out of season or when the site is not operating for legitimate business reasons. The list of blackout dates and their justification shall be submitted to the certification body a minimum of one (1) month before the sixty (60) day re-certification window for the agreed-upon unannounced audit.

RESPONSE: COMPLIANT

EVIDENCE: No black out periods are defined in this site.

2.1.2 **Management Review**

There is a report of the SQF system review, they realized that they need to improve the record filling. Some issued in regard to the supplier approval. The vendors are not being flexible to the site, they are struggling to get the documents from the vendors. It is important to remark that for this site, the SQF Practitioner is the Operations Manager, the upper authority in the plant. They used to have another practitioner, the quality manager, who left the company at the beginning of the year. There are management meetings with the staff every month: CEO, Operations Manager, all the leaders: high level meetings. They review metrics, quality issues, etc. Sample of the monthly management meetings minute: Thursday 8/10/2023 RUSA Conference Room. Topics covered included: 2023 plant and office renovations.

2.1.2.1 The SQF System shall be reviewed by senior site management at least annually and include:
i. Changes to food safety management system documentation (policies, procedures, specifications, food safety plan);
ii. Food safety culture performance;
iii. Food safety objectives and performance measures;
iv. Corrective and preventative actions and trends in findings from internal and external audits, customer complaints, and verification and validation activities;
v. Hazard and risk management system; and
vi. Follow-up action items from previous management reviews.
Records of all management reviews and updates shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE: It is remarkable that in this site the senior site management is also the SQF Practitioner, and during the audit it was evident that he is totally involved in the SQF system and is aware of the status of the system. There are monthly meetings in which they talk about the food safety and quality topics, the Senior Operations Manager with the rest of the manageres and leadres, and also the internal audit is performed by the senior site manager so all the requirements of the review of the system are reviewed.

2.1.2.2 The SQF practitioner(s) shall update senior site management on at least a monthly basis on matters impacting the implementation and maintenance of the SQF System.
The updates and management responses shall be documented.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.3 Complaint Management

The operations manager commented that during the year they have changed a couple times the procedure to handle complaints: anything that customer comments like a missing information in a label they consider this a complaint. At this moment 149 complaints in the year 2023. No food safety problems in the year, only 12 quality issues in regard to color of the products. The Operations Manager commented about the quality problems, in regard to pH of the product and they are not working well to the customer and they are adjunting the parameters.

2.1.3.1 The methods and responsibility for handling, investigating, and resolving food safety complaints from commercial customers, consumers, and authorities, arising from products manufactured or handled on-site or co-manufactured, shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.3.2 Adverse trends of customer complaint data shall be investigated and analyzed and the root cause established by personnel knowledgeable about the incidents.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.3.3 Corrective and preventative action shall be implemented based on the seriousness of the incident and the root cause analysis as outlined in 2.5.3. Records of customer complaints, their investigation, and resolution shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.2.1 Food Safety Management

There are several documented programs and operational procedures that conform the Food Safety Management System, there is a HACCP Plan with the following contents: plant information, HACCP Team, Review frequency, product description. Site plan, raw material hazard analysis, liquid color process (water soluble dyes dissolved in water), color dispersion, emulsions & viscous liquids (lakes, dyes, natural pigments suspended in liquids in which it is not soluble & water soluble dye liquids w/less than 20% solid wt.), dry blend color process (dry blend of 2 or more ingredients). / A list of the raw materials and products covered under the scope of certification is available.

2.2.1.1 The methods and procedures the site uses to meet the requirements of the SQF Food Safety Code: Food Manufacturing shall be maintained in electronic and/or hard copy documentation. They will be made available to relevant staff and include:
i. A summary of the organization's food safety policies and the methods it will apply to meet the requirements of this standard;
ii. The food safety policy statement and organization chart;
iii. The processes and products included in the scope of certification;
iv. Food safety regulations that apply to the manufacturing site and the country(ies) of sale (if known);
v. Raw material, ingredient, packaging, and finished product specifications;
vi. Food safety procedures, prerequisite programs, food safety plans;
vii. Process controls that impact product safety; and
viii. Other documentation necessary to support the development, implementation, maintenance, and control of the SQF System.

RESPONSE: COMPLIANT

EVIDENCE:

2.2.1.2 Food safety plans, Good Manufacturing Practices, and all relevant aspects of the SQF System shall be reviewed, updated, and communicated as needed when any changes implemented have an impact on the site's ability to deliver safe food.
All changes to food safety plans, Good Manufacturing Practices, and other aspects of the SQF System shall be validated or justified prior to their implementation. The reasons for the change shall be documented.

RESPONSE: COMPLIANT

EVIDENCE:

2.2.2 Document Control

Document reference: DOCUMENT CONTROL, Methods and responsibility for maintaining document control are documented and implemented. / There is an index of Forms, a controlled copy, which includes forms such as: ADM/F001 Request for New Employee Form, No of copies per set 1,H: Drive./ Within the document control procedure several situations are considered: a) new standard operating procedure, b) revised Standard Operating Procedure, c) New Forms, d) Revised forms, e) Filling Form, etc.

2.2.2.1 The methods and responsibility for maintaining document control and ensuring staff have access to current requirements and instructions shall be documented and implemented.
Current SQF System documents and amendments to documents shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.2.3	**Records** Document Reference: RECORDS POLICY. Several guidelines are considered within the policy: i.e.: any correction made to a document or record must be signed or initialed and dated, the correction must permit the reading of the original information. Storage of critical records are supposed to be secured, with limited access only for authorized persons. The storage location must ensure adequate protection from loss, destruction or falsification and from damage due to fire, water, etc.
2.2.3.1	The methods, frequency, and responsibility for verifying, maintaining, and retaining records shall be documented and implemented. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.2.3.2	All records shall be legible and confirmed by those undertaking monitoring activities that demonstrate inspections, analyses, and other essential activities that have been completed. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.2.3.3	Records shall be readily accessible, retrievable, and securely stored to prevent unauthorized access, loss, damage, and deterioration. Retention periods shall be in accordance with customer, legal, and regulatory requirements, at minimum the product shelf-life or established by the site if no shelf-life exists. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.1	**Specification, Formulation, and Realization** The Operations Manager showed an example of a product formulation. The case is a customer requiring a product, and the company creates a new product. There is a form used for the creation of the new product: NEW PRODUCT RELEASE FORM, ID. 4.6.2.2. Developed for Customer: Nxxxx, Product Code: USL01296011, Product Description IDACOL Merlot Red Liquid. Projected annual volume 1750 lbs. After that it goes to the applications team: quality characteristics. The products are liquids, dispersion, dry blends. Any of these items will be covered by the HACCP plans. There are 4 HACCP plans and for 3 made up in the plant and 1 for the products bought in the factory.
2.3.1.1	The methods and responsibility for designing and developing new product formulations and converting product concepts to commercial realization shall be documented and implemented. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.1.2	New product formulations, manufacturing processes, and the fulfillment of product requirements shall be established, validated, and verified by site trials and product testing as required to ensure product safety. Product formulations shall be developed by authorized persons to ensure that they meet the intended use. Where necessary, shelf life trials shall be conducted to validate and verify a new product's: i. Pre-consumer handling and storage requirements, including the establishment of "use by," "best before dates," or equivalent terminology; ii. Microbiological criteria, where applicable; and iii. Consumer preparation, where applicable, and storage and handling requirements.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1.3 A food safety plan shall be validated and verified by the site food safety team for each new product and its associated process through conversion to commercial production and distribution or where a change to ingredients, process, or packaging occurs that may impact food safety.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1.4 Product formulations and manufacturing processes for products included in the scope of certification shall be reviewed when there are changes in materials, ingredients, or equipment.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1.5 The process flows for all new and existing manufacturing processes shall be designed to ensure that product is manufactured according to approved product formulations and to prevent cross-contamination.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.1.6 Records of product design, formulations, label compliance, process flows, shelf life trials, and approvals for all new and existing products shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2 **Specifications (Raw Material, Packaging, Finished Product and Services)**

New products are always related to one of the 3 existing HACCP plan categories. Hazards are identified and considered during development of new products, which are mostly variations of products within current product categories. Responsibility of verification and validation in develpment is done first by the Color Scientist, and secondly by the Quality & Regulatory Manger and Quality Control team. This is described in the SOP for new product development approval process. Methods and procedures are available and the O. Manager commented they are currently reviewing and updating this procedure: Issue no. 05, Section 7.1.1. Raw Material / Supplier Approval Process. Purpose: to describe the process to approve Raw Materials and Suppliers for use in production. There is a list of raw materials and suppliers, there is an Excel file called 4.4.1. Document Control for Approved Suppliers List. Sample Taken: Sun Chemicals, Ingredient Quality and Safety Related Information: this includes: ingredient composition (including all additivies or compound components), basic characteristics, function in cosmetics, etc. In regard to the packaging materials: B-WAY Corporation / date: 1-January-2014, From: Forrest burney, Product Development Engineer. Subject: Bisphenol A. Bisphenol A is used in the synthesis of polyesters, polysulfones, and polyether ketone, as an antioxidant in some plasticizers, and as a polymerization inhinitor. This is a 5 gallons container. Sample of a liquid product, which is best seller in the USA market: Material Specification, Material No USDL01330, Status: approved, Material Desc. IDACOL PURPLE LIQUID 7.27%, Revision date: 08/01/2023. Description of services for contract service providers: Contract Provider Service Approval SOP Doc ID: 3.9.1.1. Last review date: 10/5/2022. there are 34 contract service providers. Example: pest control, uniform, waste and recycling, fire alarm, etc.

2.3.2.1 The methods and responsibility for developing, managing, and approving raw material, finished product, and packaging specifications shall be documented.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.2 Specifications for all raw materials and packaging, including, but not limited to, ingredients, additives, hazardous chemicals, processing aids, and packaging that impact finished product safety shall be documented and kept current.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.3 All raw materials, packaging, and ingredients, including those received from other sites under the same corporate ownership, shall comply with specifications and with the relevant legislation in the country of manufacture and country(ies) of destination if known.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.4 Raw materials, packaging, and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.5 Site management shall require approved raw materials suppliers to notify the site of changes in product composition that could have an impact on product formulation (e.g., protein content, moisture, amino acid profiles, contaminant levels, allergens, and/or other parameters that may vary by crop or by season).

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.6 Verification of packaging shall include a certification of all packaging that comes into direct contact with food meets either regulatory acceptance or approval criteria. Documentation shall either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance, or a certificate from the applicable regulatory agency.
In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.7 Finished product labels shall be accurate, comply with the relevant legislation, and be approved by qualified company personnel.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.8 Description of services for contract service providers that have an impact on product safety shall be documented, current, include a full description of the services to be provided, and detail relevant training requirements of all contract personnel.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.9 Finished product specifications shall be documented, current, approved by the site and its customer, accessible to relevant staff, and shall include, where applicable:
i. Microbiological, chemical, and physical limits;
ii. Composition to meet label claims;
iii. Labeling and packaging requirements; and
iv. Storage conditions.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.10 Specifications for raw materials and packaging, chemicals, processing aids, contract services, and finished products shall be reviewed as changes occur that impact product safety. Records of reviews shall be maintained. A list of all the above specifications shall be maintained and kept current.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.3 Contract Manufacturers

This site does not use contract manufacturers.

2.3.4 Approved Supplier Program

There is a statement within the supplier handling procedure in regard to the Use of non-approved supplier: in the event that a raw material is needed to be purchased/approved prior to being on the approved supplier list, Quality will make the determination if that product can be used based on functionality, risk and available information from the supplier at the time. This will be documented per Section 12.1 CAPA programa as a change control. Supplier audits shall be based on risk: they send out a questionnaire: Supplier Questionnaire, sample taken: Beta Carotene. Date of the document: 09-09-2023. 8 to 10 pages of information. This is for every single item, so it a supplier provides 10 ingredientes, they need to fill it 10 times. There is a new form for the last couple months. This is a corporate decision. Validations for packaging materials come first from the vendors approval program, and second, by receiving the liters of guarantee. For the product that was chosen as sample, plastic tote: heavy metals for instance: based upon current information on file from suppliers, heavy metals (including lead, cadmium, hexavalent chromium, and mercury) are not intentionally added to any of the components of the company products /company name BWAY Corporation.

2.3.4.1 The responsibility and procedure for selecting, evaluating, approving, and monitoring an approved supplier shall be documented and implemented.
A current record of approved suppliers, receiving inspections, and supplier audits shall be maintained.

Code Amendment #2
Approved supplier registers shall include supplier contact details. All approved and emergency suppliers shall be registered.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.4.2 The approved supplier program shall be based on the past performance of a supplier and the risk level of the raw materials, ingredients, processing aids, packaging, and services supplied, and shall contain at a minimum:
i. Agreed specifications (refer to 2.3.2);
ii. Reference to the level of risk applied to raw materials, ingredients, packaging, and services from the approved supplier;
iii. A summary of the food safety controls implemented by the approved supplier;
iv. Methods for granting approved supplier status;
v. Methods and frequency of monitoring approved suppliers;
vi. Details of the certificates of conformance, if required; and
vii. Methods and frequency of reviewing approved supplier performance and status.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.4.3 Verification of raw materials shall include certificates of conformance, certificates of analysis, or sampling, and testing. The verification frequency shall be identified by the site.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.4.4 The receipt of raw materials, ingredients, processing aids, and packaging from nonapproved suppliers shall be acceptable only in an emergency situation and provided a receiving inspection or analysis is conducted and recorded before use.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.4.5 Raw materials, ingredients, and packaging received from other sites under the same corporate ownership shall be subject to the same specification requirements (refer to 2.3.2), approved supplier requirements, and receiving inspections as all other material providers.

RESPONSE: COMPLIANT

EVIDENCE: Thailand, and India. The process is the same.

2.3.4.6 Supplier audits shall be based on risk (as determined in 2.3.4.2) and shall be conducted by individuals knowledgeable of applicable regulatory and food safety requirements and trained in auditing techniques.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.1 **Food Legislation**
There is an SOP called Food Legislation Policy. Within the procedure it is written that Roha USA LLC belongs to or has employees in the following organizations to ensure the company is up-to-date with all local, federal, and international (when applicable) regulations: IFT - Institute of Food Technologist, IACM - International Association of Color Manufacturers: provides notifications for international and national legislation and hearing that are pertinent to color as a food additive. In the event the Crisis Management Plant is enacted this company has established that if plan is enacted contact must be made to foodsafetycrisis@sqfi, customer and supplier numbers are on file in the office.

2.4.1.1	The site shall ensure that at the time of delivery to customers finished products shall comply with food safety legislation applicable in the country of manufacture and sale. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen, and additive labeling, labeling of identity preserved foods, any other criteria listed under food legislation, and to relevant established industry codes of practice. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.1.2	The methods and responsibility for ensuring the site is kept informed of changes to relevant legislation, scientific and technical developments, emerging food safety issues, and relevant industry codes of practice shall be documented and implemented. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.1.3	SQFI and the certification body shall be notified in writing within twenty-four (24) hours as a result of a regulatory warning or event. Notification to SQFI shall be by email to foodsafetycrisis@sqfi.com. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.2	**Good Production Practices** A set of good manufacturing policies is the content of the GMP of the company. These policies include: visitor, clothing and jewelry, personnel policy, glass and brittle plastic, foreign materials control, environmental & fair trade policy, safety policy. As a sample one of these policies was reviewed deeply: Safety Policy: Newly hired employees receives a copy of Roha USA LLC's Safety and Health Management system during their new employee orientation. All employees receive safety related educational material on an on-going basis. The material is related to "on the job safety" and "off the job safety"
2.4.2.1	The site shall ensure the applicable Good Manufacturing Practices described in Module 11 of this Food Safety Code are applied or exempted according to a written risk analysis outlining the justification for exemption or evidence of the effectiveness of alternative control measures that ensure food safety is not compromised. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.2.2	The Good Manufacturing Practices applicable to the scope of certification outlining how food safety is controlled and assured shall be documented and implemented. **RESPONSE:** COMPLIANT **EVIDENCE:**

2.4.3 Food Safety Plan

There is a full documented HACCP Plan for ROHA USA LLC. The contents of this document are the following: Plant Information, HACCP Team, Review Frequency, Product Description, Site Plan, Raw Material Hazard Analysis, Packaging Material Hazard Analysis, Liquid Color Process (Liquid Color Process Flow Chart, liquid color process - hazard analysis, liquid color process - critical control point summary), etc. There are 3 different HACCP plans for each of the product families. Product Description: SQF certification food safety scope: all products manufactured / handled by the company (Natural & Synthetic Dry Blend and Liquid Colors). Liquid color: water soluble dyes dissolved in water, 1, 5, 30, 55c and 330 gallon HDPE container with tamper proof opening or any other customer specified packaging, with shelf life of 0-18 months at specified temperatures. Auditor took as a sample the best seller category which is the FDA GRAS Shelf Stable Liquid Color Process, Last change: 10/3/2022: update the food safety team. Food Safety Team: Operations Manager, Quality Manager, Warehouse Supervisor, Production Supervisor, and Quality Technician. Facility overview: facility location: St. Louis, MO. Product Name: liquid. Product description: water soluble dyes dissolved in water. Product usage: for edible and cosmetic product applications where further processing is carried out. Labeling instructions: store in cool dry place protected from light. The CCP in the system is the CHECK FILTER. In the dry family of products: Sifter of screen; and in the other one is the magnet. In the hazard analysis: 11. Filtering: P - metal, plastic, gloves: there is a potential for metal parts to break off into the product. There is a potential for gloves to break off into the product. There is a potential for plastic from packaging to break off into the product. CRITICAL CONTROL POINT MASTER SHEET - Liquid Color Process. Process Step: check filter CCP1. CCP Limits: 100 mesh filter screen must be intact in the house after filtering. No noticeable damage to filter screen. Records of the monitoring of the CCP were reviewed: Manufacturing log sheet: HACCP Record: this includes: filter properlly placed (no movement), filter intact (no damage). Date: 9-13, 9.40 am - 9-50 am. There is a record of the foreign materials they have found, for instance: plastic and paper, 3 times during the year 2022 and 2023.

2.4.3.1 A food safety plan shall be prepared in accordance with the twelve steps identified in the Codex Alimentarius Commission HACCP guidelines. The food safety plan shall be effectively implemented and maintained and shall outline how the site controls and assures food safety of the products or product groups included in the scope of the SQF certification and their associated processes. More than one HACCP food safety plan may be required to cover all products included in the scope of certification.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.2 The food safety plan or plans shall be developed and maintained by a multidisciplinary team that includes the SQF practitioner and those site personnel with technical, production, and engineering knowledge of the relevant raw materials, packaging, processing aids, products, and associated processes. Where the relevant expertise is not available on-site, advice may be obtained from other sources to assist the food safety team.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.3 The scope of each food safety plan shall be developed and documented including the start and endpoints of the processes under consideration and all relevant inputs and outputs.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.4 Product descriptions shall be developed and documented for all products included in the scope of the food safety plans. The descriptions shall reference the finished product specifications (refer to 2.3.2.9) plus any additional information relevant to product safety, such as pH, water activity, composition, and/or storage conditions.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.5 The intended use of each product shall be determined and documented by the food safety team. This shall include target consumer groups, the potential for consumption by vulnerable groups of the population, requirements for further processing if applicable, and potential alternative uses of the product.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.6 The food safety team shall develop and document a flow diagram covering the scope of each food safety plan The flow diagram shall include every step in the process, all raw materials, packaging, service inputs (e.g., water, steam, gasses as applicable), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team to cover all stages and hours of operation.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.7 The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.8 The food safety team shall conduct a hazard analysis for every identified hazard to determine which hazards are significant, i.e., their elimination or reduction to an acceptable level is necessary to control food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.9 The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.10 Based on the results of the hazard analysis (refer to 2.4.3.8), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e., a critical control point or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure.

RESPONSE: COMPLIANT

EVIDENCE: Liquid color process: CCP 1: Filtering; Color Dispersion and Emulsion Process: CCP1: Screen (batches 45 lb. or less) , for bigger amounts it goes to the magnet and the strainer. Dry Color Blend: CCP 1: Sifting.

2.4.3.11 For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product (critical limits). The food safety team shall validate all of the critical limits to ensure the level of control of the identified food safety hazard(s) and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1).

RESPONSE: COMPLIANT

EVIDENCE: For each identified CCP there is a document which establishes the CCP & Processing step, significant hazard, critical limit, monitoring, corrective action, frequency, person responsible, verification, and record keeping: For liquid color process: Filtering. Critical limit: 10 micro filter bag must be intact after filtering.

2.4.3.12 The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.11). Monitoring procedures shall identify the personnel assigned to conduct monitoring, the sampling and test methods, and the test frequency.

RESPONSE: COMPLIANT

EVIDENCE: Filtering: HACCP Record Filter properly placed: yes, Filter intact (no damage): yes. They use a new filter for each batch. For the Color Dispersion, Emulsion and Viscous Liquid Process: CCP 1 Magnet, CCP 2 Strainer, CCP 3 Screen: Magnet in place and intact, Magnet saturated, Strainer used and intact. for the product Red Lake Dispersion, Start Date: 08/26/2019, same date finished. Dry Blend Process: CCP 1 Sifting: Screen in place and intact, foreign material found on screen.

2.4.3.13 The food safety team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the safety failure.

RESPONSE: COMPLIANT

EVIDENCE: As a testimony from the SQF Practitioner, there have no deviation of any of the CCPs during last 2 years.

2.4.3.14 The documented and approved food safety plan(s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, inputs, or other changes affecting product safety occur.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.15 Procedures shall be in place to verify that critical control points are effectively monitored and appropriate corrective actions are applied. Implemented food safety plans shall be verified as part of SQF System verification (refer to 2.5).

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.16 Critical control point monitoring, corrective action, and verification records shall be maintained and appropriately used.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.17 Where food safety regulations in the country of production and destination (if known) prescribe a food safety control methodology other than the Codex Alimentarius Commission HACCP guidelines, the food safety team shall implement food safety plans that meet both Codex and food regulatory requirements.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4 Product Sampling, Inspection, and Analysis

For representative samples they make microbial sampling if the customer ask for, DEIBEL Laboratories, Name: Ultra Chemical Inc. Report of results: analysis date: 2023/10/19 Receiving temperature: 19.3, Sample conditions: okay. Description: USD01204 US23 100953 Ultracolor Red 33 Dye Solution 0.5%, test: APC, yeast and molds: < 10 cfu/g. This laboratory is accredited by the A2LA Food Testing Program Requirements under ISO 17025, Certificate number>: 2833.03, valid to: January 31, 2024. The staff conducting chemical resting are bachellors minimum like Biochemists and Biologist, and all of them having chemist background. This is a particular case in which the laboratory technicians have the proficiency for running the testing: Date: 9730/2022, Annual Quality Control Testing Competency. The plant is planning to run this internal proficiency testing on October/November, due to a unforseen situation that they had a fire in the facility and this situation affected all the scheduled events.

2.4.4.1 The methods, responsibility, and criteria for sampling, inspecting, and/or analyzing raw materials, work-in-progress, and finished product shall be documented and implemented.

The methods applied shall ensure that inspections and analyses are completed at regular intervals as required and to agreed specifications and legal requirements.

Sampling and testing shall be representative of the process batch and ensure that process controls are maintained to meet specification and formulation.

RESPONSE: COMPLIANT

EVIDENCE: There is a documented flow chart, called FDA Sampling and certification, effective date: 02/2023. Main steps: 1. Receipt of Material and preparation of sample. 2 Preparation of application and submission of samples. 3. Review of website for certification status. 4. FDA Certification. 5. Review of batches pending certification.

2.4.4.2 Product analyses shall be conducted to nationally recognized methods or company requirements, or alternative methods that are validated as equivalent to the nationally recognized methods.

Where internal laboratories are used to conduct input, environmental, or product analyses, sampling and testing methods shall be in accordance with the applicable requirements of ISO/IEC 17025, including annual proficiency testing for staff conducting analyses.

External laboratories shall be accredited to ISO/IEC 17025, or an equivalent international standard, and included on the site's contract service specifications list (refer to 2.3.2.11).

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4.3 On-site laboratories conducting chemical and microbiological analyses that may pose a risk to product safety shall be located separate from any food processing or handling activity and designed to limit access only to authorized personnel.
Signage shall be displayed identifying the laboratory area as a restricted area,
accessible only by authorized personnel.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4.4 Provisions shall be made to isolate and contain all hazardous laboratory waste held on the premises and manage it separately from food waste. Laboratory waste outlets shall at a minimum be downstream of drains that service food processing and handling areas.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4.5 Retention samples, if required by customers or regulations, shall be stored according to the typical storage conditions for the product and maintained for the stated shelflife of the product.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4.6 Records of all inspections and analyses shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.5 **Non-conforming Materials and Product**
HOLD REPORT: FSQA Hold #: H23-0009, ITEM Description: N/A, Hold date: 4/20/2023, Material number: use 01060013, Manufacture date: 4/20/2023, Batch Number: US23040346, Quantity: 6225.162 pounds. Reason for hold: amber yellow: product quality. Actions taken: Dropped out 6224.162 lb stopped production of this batch. There are no food safety issues in regard to non-conforming products, all the cases are quality related. Procedure: Quality and Regulatory Affairs, HOLD SOP Doc ID: 5.3.1.1.

2.4.5.1 The responsibility and methods outlining how to handle non-conforming product, raw material, ingredient, work-in-progress, or packaging, which is detected during receipt, storage, processing, handling, or delivery, shall be documented and implemented. The methods applied shall ensure:
i. Non-conforming product is quarantined, identified, handled, and/or disposed of in a manner that minimizes the risk of inadvertent use, improper use, or risk to the integrity of finished product; and
ii. All relevant personnel are aware of the organization’s quarantine and release requirements applicable to product placed under quarantine status.

RESPONSE: COMPLIANT

EVIDENCE: There is a documented procedure called "non conformance product". The purpose of this procedure is to handle non-conforming product. Procedures: placing material on hold: once in-process or finished product has been identified as non-conforming, the product code, batch number, and batch size is recorded in the HOLD log. A completed Quarantine sticker is applied to the pallet(s) or container(s) of non-conforming product by operations. The non-conforming product is placed in the designated area of the warehouse. Quality moves the product to blocked stock in SAP.

2.4.5.2 Quarantine records and records of the handling, corrective action, or disposal of nonconforming materials or product shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.6 Product Rework

SOP: Manufacturing Rework Procedure. Responsibility: Quality Control Technician. Manager - Quality and Regulatory Affairs. General Guidelines: 1. all rework must be authorized by Quality. 2. Product with allergens can only be reworked in product with like allergens. 3. All product will be 100% lot traceable using our standard method of lot code recording. 4. The finished products using rework will follow the standard QC approval process. Procedures: 1. Manufacturing Log Sheet Creation. 2. Quality Check of Batch to be Reworked. Place on hold in SAP. The instruction is to use ZWM_R325 to move the batch and/or block it depending on what the disposition is. This is in the electronic system. Materials with the disposition to rework need to be moved to RJMC Unrestricted. Rework batches shall be documented on the new batch's batch sheet. Materials that have the disposition need to be moved to RJMC Blocked. A Destruction Form (Doc ID 5.3.2.1.) will need to be filled out for materials with the disposition to destroy. Example taken: Manufacturing log: Amber Yellow, 720 pounds. Shelf life: 365 days.

2.4.6.1 The responsibility and methods outlining how ingredients, packaging, or products are reworked shall be documented and implemented. The methods applied shall ensure:
i. Reworking operations are overseen by qualified personnel;
ii. Reworked product is clearly identified and traceable;
iii. Reworked product is processed in accordance with the site’s food safety plan;
iv. Each batch of reworked product is inspected or analyzed as required before release;
v. Inspections and analyses conform to the requirements outlined in element 2.4.4.1;
vi. Release of reworked product conforms to element 2.4.7; and
vii. Reworked product does not affect the safety or integrity of the finished product.
Records of all reworking operations shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.7 Product Release

Quality and Regulatory Affairs, POSITIVE HOLD AND RELEASE SOP, Doc ID: 5.3.1.2. Last reviewed date: 10/05/2022. Requirements: Quality control test are to be performed before being release from SAP. IF the batch does not pass, they need an adjustment. During the audit, the auditor asked the staff to log in to the SAP system and to review this directly in the system. Sample was reviewed in the inspection log section: Barch: us2310*, lot created on: 10/30/2023. The information is large for the whole month of October 2023. COA print was reviewed to confirm the the product was released conforming the specifications. Certificate of Analysis: date 10/19/2023.

2.4.7.1 The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released by authorized personnel, and only after all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met.
Records of all product releases shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.7.2 Product release shall include a procedure to confirm that product labels comply with the food legislation that applies in the country of manufacture and the country(ies) of use or sale if known (refer to 2.4.1.1).
If product is packaged and distributed in bulk or unlabeled, product information shall be made available to inform customers and/or consumers of the requirements for its safe use.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.7.3 In the event that the site uses positive release based on product pathogen or chemical testing, a procedure shall be in place to ensure that product is not released until acceptable results have been received.
In the event that off-site or contract warehouses are used, these requirements shall be effectively communicated and verified as being followed.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.8 Environmental Monitoring

This facility is very low risk in regard to environmental monitoring. Quality and Regulatory Affairs, FDA Low Risk Environmental Program, Doc ID: 5.4.1.1. Last Review date: 03/28/2023. Requirements: On an annual basis, management shall observe the collection of samples. The purpose of this activity is to verify that the monitor is utilizing the proper technique in determining the sites to be sampled, as well as the prescribed aseptic method for sample collection and handling. Sample report taken: DEIBEL Laboratories, Date: 10/11/2023. Report of Results: Listeria Genus, Salmonella, results: negative. All the results were negative during the whole year.

2.4.8.1 A risk-based environmental monitoring program shall be in place for all food manufacturing processes and immediate surrounding areas, which impact manufacturing processes.
The responsibility and methods for the environmental monitoring program shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE: Responsibility: Operators/Helpers: to maintain the cleanliness of the facility in accordance with the master sanitation schedule. Perform additional cleaning as needed per corrective actions assigned // QA/QC: randomly sample selected sites seeking out pathogens and indicator organisms in the environment per the steps listed within. Enter data in the environment data log. Submit samples for testing. Conduct investigative sampling. Quarantine areas, equipment, and / or product as instructed by QA Manager per Non Conforming Product. // QA/QC Manager: ensure samplers are properly trained, review EMP result, ensure corrective actions, review EMP for trends.

2.4.8.2 An environmental sampling and testing schedule shall be prepared. It shall at a minimum:
i. Detail the applicable pathogens or indicator organisms to test for in that industry;
ii. List the number of samples to be taken and the frequency of sampling;
iii. Outline the locations in which samples are to be taken and the rotation of locations as needed; and
iv. Describe the methods to handle elevated or undesirable results.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.8.3 Environmental testing results shall be monitored, tracked, and trended, and preventative actions (refer to 2.5.3.1) shall be implemented where unsatisfactory results or trends are observed.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.1	**Validation and Effectiveness (Mandatory)** Magnetic Pull Test CCP Verification, there is a report for this run every month: record is for the months: 1/11/23, 2/16/23, 3/21/23, etc. Up to 10/18/23. For instance: Magnet 466559, Bar 1: 11.5, Bar 2: 11.0, Bar 3: 11.5, Bar 4: 11, Bar 5: 10. / NCm: The methods, responsibility, and criteria for the validations of the GMPs, Critical food safety limits, and changes of processes or procedures were not found documented.
2.5.1.1	The methods, responsibility, and criteria for ensuring the effectiveness of all applicable elements of the SQF Program shall be documented and implemented. The methods applied shall validate that: i. Good Manufacturing Practices are confirmed to ensure they achieve the required results; ii. Critical food safety limits are reviewed annually and re-validated or justified by regulatory standards when changes occur; and iii. Changes to the processes or procedures are assessed to ensure the controls are still effective. Records of all validation activities shall be maintained. **RESPONSE:** MINOR **EVIDENCE:** NCm: The methods, responsibility, and criteria for the validations of the GMPs, Critical food safety limits, and changes of processes or procedures were not found documented. **ROOT CAUSE:** Quality Manager resigned in Mid 2023. This left a void in the trained staff to conduct the reviews **CORRECTIVE ACTION:** Getting the rest of the quality team trained in PCQI and HACCP to be able to conduct the reviews. **VERIFICATION OF CLOSEOUT:** Training the team in PCQI and HACCP will provide the proper knowledge to validate the PCC limits and the rest of control measures. **COMPLETION DATE:** 12/31/2023 **CLOSEOUT DATE**: 11/22/2023
2.5.2	**Verification Activities (Mandatory)** Verification schedule: Food Safety plan: review CCP monitoring, verification, and corrective action documentation on manufacturing log sheets, interview/observe CCP employees. For every single Pre-requisite program there is a verification activity: for instance Personnel Practices, Clothing: review laundry service records; etc. The auditor reviewed the GMP inspection records. Another program that was reviewed for verification purposes was teh Training Register. Topics reviewed: document control, chemical training, ATP Swabs, Food Defense, HACCP/HARPC, Gmp, allergens, foodborn ilness, SQF.
2.5.2.1	The methods, responsibility, and criteria for verifying monitoring of Good Manufacturing Practices, critical control points, and other food safety controls, and the legality of certified products shall be documented and implemented. The methods applied shall ensure that personnel with responsibility for verifying monitoring activities authorize each verified record. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.5.2.2	A verification schedule outlining the verification activities, their frequency of completion, and the person responsible for each activity shall be prepared and implemented. Records of verification of activities shall be maintained. **RESPONSE:** COMPLIANT

EVIDENCE:

2.5.3 Corrective and Preventative Action

There is a documented procedure called "CAPA PROGRAM". The purpose/scope of this procedure is to outline the process used to document, define, investigate, resolve, manage, and control issues such as customer complaints, product/process non-conformances, audit findings, deviations and change controls at Roha USA LLC. Overview: in the event hat an issue occurs, a CAPA is initiated using LAB-F010. Issues can present themselves within many departments from Manufacturing to Customer Service. Issues are categorized in order to enable the tracking of occurrence in an effort to verify the effectiveness of the CAPA program. All CAPA'S initiated are assigned a unique identification number using LAB-R047. Example taken: OCAPA # 23-134, Date Opened: 8/25/2023. Company name: Weaver Popcorn Manufacturing, Complaint description: The driver that picked up this load arrived to us without a door attached to the trailer. We are unable to receive the freight known that it was exposed during the transit. Product name: Beta carotene: 22% HS and Spice Color OSL Revision 1. Response from the site: the load was returned and and I inspected it. The load was intact and no damange. We booked a truck on our account to get this to the customer and it just the plant. We just need to confirm with Weaver that they are lying the freight for this and issue a debit memo or change the invoice to PPA vs CPU. The auditor reviewed some examples of corrective actions taken by the site, CAPA- 23-134. Date 8/28/2023.

2.5.3.1 The responsibility and methods outlining how corrective and preventative actions are determined, implemented, and verified, including the identification of the root cause and resolution of non-compliance of critical food safety limits and deviations from food safety requirements, shall be documented and implemented.
Deviations from food safety requirements may include customer complaints, nonconformances raised at internal or external audits and inspections, non-conforming product and equipment, withdrawals and recalls, as appropriate.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.3.2 Records of all investigation, root cause analysis, and resolution of non-conformities, their corrections, and the implementation of preventative actions shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.4 Internal Audits and Inspections

There is a documented procedure for Internal Audit. Self-inspections are the responsibility of the QA Manager who is the lead internal auditor and complete the audit checklist. This procedure establishes that auditors must be independent of the area being audited. The procedure establishes as well that at a minimum of once per month an internal GMP audit is conducted. The audit includes observation of infrastructure. The findings are discussed with department heads. There is a routine monthly inspection based on the GMPs and the auditor could review all the monthly inspection reports. There is also the whole reviewing of the SQF system. NCm: there is only one member of the staff conducting the internal audit: the Operations Manager / Practitioner. Audit Independence is being compromise due to the fact that Op. Manager audits itw own processes.

2.5.4.1 The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System shall be documented and implemented. Internal audits shall be conducted in full and at least annually. The methods applied shall ensure:
i. All applicable requirements of the SQF Food Safety Code: Food Manufacturing are audited per the SQF audit checklist or a similar tool;
ii. Objective evidence is recorded to verify compliance and/or non-compliance;
iii. Corrective and preventative actions of deficiencies identified during the internal audits are undertaken; and
iv. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective and preventative actions.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.4.2 Staff conducting internal audits shall be trained and competent in internal audit procedures. Where practical, staff conducting internal audits shall be independent of the function being audited.

RESPONSE: MINOR

EVIDENCE: NCm: there is only one member of the staff conducting the internal audit: the Operations Manager / Practitioner. Audit Independence is being compromise due to the fact that Op. Manager audits itw own processes.

ROOT CAUSE: Quality Manager resigned in Mid 2023. This left a void in the trained staff to conduct the reviews

CORRECTIVE ACTION: Getting the rest of the quality team trained in PCQI and HACCP to be able to conduct the reviews.

VERIFICATION OF CLOSEOUT: Training the team in PCQI and HACCP will provide the proper knowledge and competence to conduct internal audits and avoid the conflict of interest.

COMPLETION DATE: 12/31/2023 **CLOSEOUT DATE**: 11/22/2023

2.5.4.3 Regular inspections of the site and equipment shall be planned and carried out to verify Good Manufacturing Practices and facility and equipment maintenance are compliant to the SQF Food Safety Code: Food Manufacturing. The site shall:
i. Take corrections or corrective and preventative action; and
ii. Maintain records of inspections and any corrective actions taken.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.4.4 Records of internal audits and inspections and any corrective and preventative actions taken as a result of internal audits shall be recorded as per 2.5.3.
Changes implemented from internal audits that have an impact on the site's ability to deliver safe food shall require a review of applicable aspects of the SQF System (refer to 2.3.1.3).

RESPONSE: COMPLIANT

EVIDENCE:

2.6.1	**Product Identification and Traceability** Documented procedure called PRODUCT IDENTIFICATION AND TRACEABILITY. The identification and traceability of product is performed by using the system SAP. For instance, track batches manufacturing using a particular lot of raw material: all batches will have a unique lot code using the following format: YY-MM/XXXX where YY is the year, MM is the month, and XXXX is the sequential number. Trace via SAP. Manufacturing Log Sheet, Process order: 900415488, Material: USDL08232, Ultracolor Modifiedl Trilogy Dye Solution, Batch: US23090823, Order Quantity: 2,225 lbs, Start date: 09/08/2023, End date: 09/08/2023.
2.6.1.1	The methods and responsibility for identifying raw materials, ingredients, packaging, work-in-progress, process inputs, and finished products during all stages of production and storage shall be documented and implemented to ensure: i. Raw materials, ingredients, packaging, work-in-progress, process inputs, and finished products are clearly identified during all stages of receipt, production, storage, and dispatch; and ii. Finished product is labeled to the customer specification and/or regulatory requirements. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.6.1.2	Product start-up, product changeover, and packaging changeover (including label changes) procedures shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label and that the changeover is inspected and approved by an authorized person. Procedures shall be implemented to ensure that label use is reconciled and any inconsistencies investigated and resolved. Product changeover and label reconciliation records shall be maintained. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.6.2	**Product Trace** The responsibilities and methods are outlined in a documented procedure. For the company, the most important tool is the SAP system. Traceability procedures is linked to Product Recall procedure. Company is able to trace products with the help of the SAP system. Evidence is provided by multiple reports, and a sample of them was taken, in particular to record the evidence of mock recall exercise, in the following element. Please see all the information of element product recall.
2.6.2.1	The responsibility and methods used to trace product shall be documented and implemented to ensure: i. Finished product is traceable at least one step forward to the customer and at least one step back from the process to the manufacturing supplier; ii. The receipt dates of raw materials, ingredients, food contact packaging and materials, and other inputs are recorded (refer to 2.8.1.8 for traceback of allergen containing food products.); iii. Traceability is maintained where product is reworked (refer to 2.4.6); and iv. The effectiveness of the product trace system is reviewed at least annually, as part of the product recall and withdrawal review (refer to 2.6.3.2). Records of raw and packaging material receipt and use and finished product dispatch and destination shall be maintained. **RESPONSE:** COMPLIANT **EVIDENCE:**

2.6.3	**Product Withdrawal and Recall (Mandatory)** Product Recall SOP Doc ID: 7.1.1. Last review date: 9/27/2022. 8.5 Notification of product recall: If the decision is taken to initiate a withdrawal we will notify: Senior Management of ROHA, Supply chain personnel, Regulatory authorities. If the decision is taken to initiate a recall we will notify: All people mentioned under inititation of a withdrawal, and consumers, and SQF certifying body (CICS) within 24 hours of food safety event that requires public notification. Mock Recall / Trace Exercise. Date of Mock Recall: 10/30/23, Plant to perform Mock Recall: St. Louis. Reason for Mock Recall: Monthly Mock FD&C Recall. Product name for mock recall: Sugar, Material number: RS00087, Lot Code: N22143, Time Initiated: 6.59 am, Time Mock Recall Completed: 7.13 am, Elapsed Time (HH:MM): 14 min. Recall Coordinator: Persons notified (name and position) at plant location for initiation and communication of mock recall: B.K. Product #: RS00087, Lot # N22143, Amount GRN: 2500, Amount remaining in inventory: 59.12 lb. Total amount accounted for EA: 2495.132, % Effectiveness: 99.805%. Time: 14 min.
2.6.3.1	The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall: i. Identify those responsible for initiating, managing, and investigating a product withdrawal or recall; ii. Describe the management procedures to be implemented, including sources of legal, regulatory, and expert advice, and essential traceability information; iii. Outline a communication plan to inform site personnel, customers, consumers, authorities, and other essential bodies in a timely manner appropriate about the nature of the incident; and iv. Ensure that SQFI, the certification body, and the appropriate regulatory authority are listed as essential organizations and notified in instances of a food safety incident of a public nature or product recall for any reason. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.6.3.2	The product withdrawal and recall system shall be reviewed, tested, and verified as effective at least annually. Testing shall include incoming materials (minimum traceability one step back) and finished product (minimum traceability one step forward). Testing shall be carried out on products from different shifts and for materials (including bulk materials) that are used across a range of products and/or products that are shipped to a wide range of customers. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.6.3.3	Records shall be maintained of withdrawal and recall tests, root cause investigations into actual withdrawals and recalls, and corrective and preventative actions applied. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.6.3.4	SQFI and the certification body shall be notified in writing within twenty-four (24) hours upon identification of a food safety event that requires public notification. SQFI shall be notified at foodsafetycrisis@sqfi.com. **RESPONSE:** COMPLIANT **EVIDENCE:**

2.6.4 Crisis Management Planning

Business Continuity Plan SOP Doc ID: 1.1.1.1.. Last reviewed: 09/30/2022. Report of the actual situation that this company suffered in September 2023. Timeline off events for the fire: 13:21 M. lights a cigarette, 13:22 M. puts the finished cigarette in the dumpster, 13.22: smoke appears from the dumpster, 13:34 J. notices the fire and runs inside. The flames are over the top of the dumpster, 13:35 A. and J. use the 1st set of fire extinguishers in an attempt to put the fire out. Flames are inside the building at the dock door. 13.37 Production employees evacuate the polant: J. and A. notify production and plant to evacuatio. M. runs to the front office to notify the office of a fire. In regard to the product involved in the fire situation: Here are the batches that were lost during the fire due to ash contamination: Red dispersion, Cocoa Dye and Carmine.

2.6.4.1 A crisis management plan based on the understanding of known potential dangers (e.g., flood, drought, fire, tsunami, or other severe weather events, warfare or civil unrest, computer outage, pandemic, loss of electricity or refrigeration, ammonia leak, labor strike) that can impact the site's ability to deliver safe food shall be documented by senior management, outlining the methods and responsibility the site shall implement to cope with such a business crisis. The crisis management plan shall include at a minimum:
i. A senior manager responsible for decision making, oversight, and initiating actions arising from a crisis management incident;
ii. The nomination and training of a crisis management team;
iii. The controls implemented to ensure any responses do not compromise product safety;
iv. The measures to isolate and identify product affected by a response to a crisis;
v. The measures taken to verify the acceptability of food prior to release;
vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers;
vii. Sources of legal and expert advice; and
viii. The responsibility for internal communications and communicating with authorities, external organizations, and media.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.4.2 The crisis management plan shall be reviewed, tested, and verified at least annually with gaps and appropriate corrective actions documented. Records of reviews of the crisis management plan shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.7.1 Food Defense Plan

Quality and Regulatory Affairs, Food Defense Plan SOP Doc ID: 8.1.1. Last review date: 9/30/2022. Roha has established a Food Defense Plan which addresses all potential risks and actions taken to mitigate them in all aspects of the facility's operations, including all equipment, measures, policies, and procedures in the facility relevant to facility security and bioterrorism in order to protect the food supply from acts of crimitality or terrorism that could render it a public health hazard and to ensure the safety the property and employees. The food defense is the plant manager. Food Defense Test, What: Outside contractor ledt strange bag near dock door. Where: Warehouse. When: 8/3/2023. Summary of activities: The quality group and operations manager purposefully had a contractor walk in and had him set a bag of white powder near a dock door around 9.10 am. This test was to confirm if an employee would notice the strange bag and inform the management team. The employee noticed the bag aroud 9.35 am after break and went to inform their manager. Corrective Actions: Training on food defense was complete on 8/3/2023. Additional refresher training shall occur each year. Conclusion: it was apparente from observation that team members can quickly identify food defense risks. The Roha USA facility needs to ensure that all employees feel empowered to speak up when they believe that site security and food defense is compromised. This was a test of Food Defense System and it was deemed succesful. Team members were observed identifying the gaps in food defense and followed food defense protocols.

2.7.1.1 A food defense threat assessment shall be conducted to identify potential threats that can be caused by a deliberate act of sabotage or terrorist-like incident.

RESPONSE: COMPLIANT

EVIDENCE:

2.7.1.2 A food defense plan shall be documented, implemented, and maintained based on the threat assessment (refer to 2.7.1.1). The food defense plan shall meet legislative requirements as applicable and shall include at a minimum:
i. The methods, responsibility, and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident;
ii. The name of the senior site management person responsible for food defense;
iii. The methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing, and storage areas through designated access points;
iv. The methods implemented to protect sensitive processing points from intentional adulteration;
v. The measures taken to ensure the secure receipt and storage of raw materials, ingredients, packaging, equipment, and hazardous chemicals to protect them from deliberate acts of sabotage or terrorist-like incidents;
vi. The measures implemented to ensure raw materials, ingredients, packaging (including labels), work-in-progress, process inputs, and finished products are held under secure storage and transportation conditions; and
vii. The methods implemented to record and control access to the premises by site personnel, contractors, and visitors.

RESPONSE: COMPLIANT

EVIDENCE:

2.7.1.3 Instruction shall be provided to all relevant staff on the effective implementation of the food defense plan (refer to 2.9.2.1).

RESPONSE: COMPLIANT

EVIDENCE:

2.7.1.4 The food defense threat assessment and prevention plan shall be reviewed and tested at least annually or when the threat level, as defined in the threat assessment, changes. Records of reviews and tests of the food defense plan shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.7.2 Food Fraud

Food Fraud Vulnerability Assessment. For the ingredient category: Color, Dry Blends, Fats and Oils, Food Chemicals, Liquids, Oleoresins, Packaging, Soy Proteins, Spices, Starches, Ice and Water. They mentioned that for fats and oils: coconut, sunflower and soybean, regiones: India, Europe, and Brail: desgination: low risk. Results: based on the assessment the ingredient categories listed as high risk for food fraud would be fats/oils and spices. More specifically, olive oil, and curmin have been identified as ingredients that have a high risk for food fraud based on history, location of sourcing and use in Roha manufacturing facilities. The methods and responsibility they are included also within the New Products development and Supplier approval. Food Fraud Mitigation Plan. Purpose: to effectively mitigate the possibility of intentional food fraud in raw material and finished product. Scope: to adaptation of the strategies in the Food Defense Mitigation Strategies Database (provided by the FDA) in order to combat food fraud. For Raw Materials: there is a documented raw material receiving standard operating procedure, all raw materials received are from approved vendors, detailed product specifications are on file for all raw materials, all raw materials require a COA when being received, risk level are assigned to all raw materials, anti-tampering packaging is required for all shipments received, a high level of transparency and communication is maintained within supply chain network, a letter of guarantee which includes food fraud assurance is required from all suppliers. For finished products: company has documented procedures for manufacturing products,

2.7.2.1 The methods, responsibility, and criteria for identifying the site's vulnerability to food fraud, including susceptibility to raw material or ingredient substitution, finished product mislabeling, dilution, or counterfeiting, shall be documented, implemented, and maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.7.2.2 A food fraud mitigation plan shall be developed and implemented that specifies the methods by which the identified food fraud vulnerabilities shall be controlled, including identified food safety vulnerabilities of ingredients and materials.

RESPONSE: COMPLIANT

EVIDENCE:

2.7.2.3 Instruction shall be provided to all relevant staff on the effective implementation of the food fraud mitigation plan (refer to 2.9.2.1).

RESPONSE: COMPLIANT

EVIDENCE:

2.7.2.4 The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually with gaps and corrective actions documented. Records of reviews shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.8.1	**Allergen Management** Quality and Regulatory Affairs Allergen Program, Doc ID: 9.1.1. Last Review Date: 10/5/2022. To control allergen-containing products so they do not contaminate non-allergen containing products. To oultine cleaning procedures when allergen ingredients are used and if non-kosher ingredients/process are used. Responsibility: manufacturing personnel, receiving personnel, quality personnel. Materials/equipment: allergen label, color coded utensils, process tanks, dry blenders, tank valves, sifters, magnets and strainers. Raw materials: Storage of all allergen containing raw materials will be in such a manner to prevent chance of cross contamination: a. Allergen containing raw materials will be stored in a designated area; b. Raw materials containing allergens must not be stored above items that do not contain the same allergen. Allergen Cleaning validation: 1. Allergen cleaning validation will be conducted on an annual basis, at a minimum. 2. Allergen swabs shall be taken to validate sanitation effectiveness and removal of allergens. 3. Process shall be documented. 4. If allergen swab is positive, then area shall be recleaned and reswabbed for corrective action.
2.8.1.1	The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those raw materials, ingredients, and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens that may originate from locker rooms, vending machines, lunchrooms, and visitors; iii. A list of allergens that is applicable in the country of manufacture and the country(ies) of destination, if known; iv. A list of allergens that is accessible to relevant staff; v. The control of hazards associated with allergens and incorporated into the food safety plan, and vi. Management plans for control of the identified allergens. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.2	Instructions shall be provided to all relevant staff involved in the receipt or handling of raw materials, work-in-progress, rework, or finished product on how to identify, handle, store, and segregate raw materials and products containing allergens. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.3	Provisions shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.4	Where allergenic material may be intentionally or unintentionally present cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact. Separate handling and production equipment shall be provided, where satisfactory line hygiene and clean-up or segregation are not possible. **RESPONSE:** COMPLIANT **EVIDENCE:**

2.8.1.5	Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be documented and effectively implemented. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.6	Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.7	The product identification system (refer to 2.6.1.1) shall make provision for clear identification and labeling, in accordance with the regulatory requirements of those products produced on production lines and equipment on which foods containing allergens are manufactured. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.8	The product trace system (refer to 2.6.2) shall take into consideration the conditions under which allergen-containing foods are manufactured and ensure full traceback of all ingredients and processing aids used. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.9	The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in progress and finished product are true to label with regard to allergens. Measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished product as appropriate, and product change over procedures. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.10	Re-working of product (refer to 2.4.6) containing food allergens shall be conducted under conditions that ensure product safety and integrity are maintained. Re-worked product containing allergens shall be clearly identified and traceable. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.11	Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introduced or unintended allergens through supplier, contract manufacturer, site personnel, and visitor activities. **RESPONSE:** COMPLIANT **EVIDENCE:** Soy, lecitin, coconut oil.

2.9.1	**Training Requirements** All employees involved in the manufacture, packaging, testing, handling of product, and/or the supervision of these activities are assigned a curriculum based on their job description. The curricula is maintained by the quality unit and reviewed annually by the department manager/supervisor for compliance and accuracy. Training is performed depending on the importance or criticality of the task to be performed. All training methods used are specified in the curricula and are recorded on the training register as training is performed. The training requirements are the SQF code topics that are mandatory. The current year's topics are: Food Defense, HACCP/HARPC, GMP, Document Control, Chemical Training, ATP Swabs, MSS Sheets, and others. For instance, each month there are some topics to cover: August 2023: Allergens, Foodborne Illness; September: SQF, October: First Aid, CPR, Safety Drills, Pest Controls, Pulse Survey.
2.9.1.1	The responsibility for establishing and implementing the training needs of the organization's personnel to ensure they have the required competencies to carry out those functions affecting products, legality, and safety shall be defined and documented (refer to 2.1.1.6). **RESPONSE:** COMPLIANT **EVIDENCE:**
2.9.1.2	Appropriate training shall be provided for personnel carrying out the tasks essential to the effective implementation of the SQF System and the maintenance of food safety and regulatory requirements. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.9.2	**Training Program** Training Program, The purpose of this program is to outline the training events to be utilized at Roha USA LLC. Detailing the competences required for personnel involved in various GMP and food safety/food quality functions, training methods to be used, the process for identifying and implementing refresher training and the documentation practices required for these activities. Recors od the training provided were reviewed by the auditor: Employee traininbg log, topic: Allergen, Micro / Food borne Illness; Trainer Meranda Brece; there is a list of the attendants: Printed Name / Signature / Title / Date. For this particular one: 8-17-23. The auditor reviewed the quizzes taken by personnel after a training: GMP / HACCP / HARPC, and food defense quiz. Date: 8-3-23. It was something remarkable by revieweing the tests, that the person who cause the fire event was also having bad scores in their tests, and have been provided a l ot of feedback.
2.9.2.1	A training program shall be documented and implemented that at a minimum outlines the necessary competencies for specific duties and the training methods to be applied to personnel carrying out tasks associated with: i. Implementing HACCP for staff involved in developing and maintaining food safety plans; ii. Monitoring and corrective action procedures for all staff engaged in monitoring critical control points (CCPs); iii. Personal hygiene for all staff involved in the handling of food products and food contact surfaces; iv. Good Manufacturing Practices and work instructions for all staff engaged in food handling, food processing, and equipment; v. Sampling and test methods for all staff involved in sampling and testing of raw materials, packaging, work-in-progress, and finished products; vi. Environmental monitoring for relevant staff; vii. Allergen management, food defense, and food fraud for all relevant staff; and viii. Tasks identified as critical to meeting the effective implementation and maintenance of the SQF code. The training program shall include provisions for identifying and implementing the refresher training needs of the organization.

RESPONSE: COMPLIANT

EVIDENCE:

2.9.2.2 Training materials, the delivery of training, and procedures on all tasks critical to meeting regulatory compliance and the maintenance of food safety shall be provided in language(s) understood by staff.

RESPONSE: COMPLIANT

EVIDENCE:

2.9.2.3 Training records shall be maintained and include:
i. Participant name;
ii. Skills description;
iii. Description of the training provided;
iv. Date training completed;
v. Trainer or training provider; and
vi. Verification that the trainee is competent to complete the required tasks.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.1 **Premises Location and Approval**
Site is located in urban zone, surrounded by industrial facilities. No source of environmental contamination is identified. FDA Registration expiration date 2024-12-31, Registration # xxxxxxxx426. City permit: City of Saint Louis, to date: 05/31/24, License # LC10009269. Business type: Manufacturing.

11.1.1.1 The site shall assess local activities and the site environment to identify any risks that may have an adverse impact on product safety and implement controls for any identified risks. The assessment shall be reviewed in response to any changes in the local environment or activities.
The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2 **Building Materials**
Product contact surfaces are constructed of materials that do not contribute a food safety risk, they are mainly stainless steel made. In general, floors are in good maintenance, drains located to be easily cleaned, and waste trap system located away from food handling zones. Walls, partitions, ceilings and doors are of durable construction. It was observed an improvement in cleaning an maintenance of walls, floors and ceilings, in comparison with last year's audit. The construction in solid, an industrial warehouse, therefore product is processed and handled with no risk of contamination due to unacceptable structure. Stairs, catwalks and platforms are designed and constructed adequately due to the nature of the process and the product.

11.1.2.1 Floors shall be constructed of smooth, dense, impact-resistant material that can be effectively graded, drained, impervious to liquid, and easily cleaned. Floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or wastewater under normal working conditions.
Where floor drainage is not available, plumbed options to handle overflow or wastewater shall be in place.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.2 Drains shall be constructed and located so they can be easily cleaned and not present a hazard.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.3 Waste trap system shall be located away from any food handling areas or entrances to the premises.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.4 Walls, partitions, ceilings, and doors shall be of durable construction. Internal surfaces shall have an even and regular surface and be impervious with a light-colored finish and shall be kept clean (refer to 11.2.5).
Wall-to-wall and wall-to-floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.5 Ducting, conduit, and pipes that convey ingredients, products, or services, such as steam or water, shall be designed and constructed to prevent the contamination of food, ingredients, and food contact surfaces and allow ease of cleaning.
A risk analysis shall be conducted to ensure food contamination risks are mitigated.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.6 Pipes carrying sanitary waste or wastewater that are located directly over product lines or storage areas shall be designed and constructed to prevent the contamination of food, materials, ingredients, and food contact surfaces and shall allow ease of cleaning.
A risk analysis shall be conducted to ensure food contamination risks are mitigated.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.7 Doors, hatches, and windows and their frames in food processing, handling, or storage areas shall be of a material and construction that meets the same functional requirements as for internal walls and partitions. Doors and hatches shall be of solid construction, and windows shall be made of shatterproof glass or similar material.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.8 Product shall be processed and handled in areas that are fitted with a ceiling or other acceptable structure that is constructed and maintained to prevent the contamination of products. Drop ceilings, where present, shall be constructed to enable monitoring for pest activity, facilitate cleaning, and provide access to utilities.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.9 Stairs, catwalks, and platforms in food processing and handling areas shall be designed and constructed so they do not present a product-contamination risk and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 11.2.5).

RESPONSE: COMPLIANT

EVIDENCE:

11.1.3 Lightings and Light Fittings

Lights are protected to avoid any potential contamination to product. Plant is well illuminated.

11.1.3.1 Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively and shall comply with local light-intensity regulations or industry standards.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.3.2 Light fixtures in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers, and recessed into or fitted flush with the ceiling.

Where fixtures cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials, and addressed in the cleaning and sanitation program.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.3.3 Light fixtures in the warehouse or other areas where product is covered or otherwise protected shall be designed to prevent breakage and product contamination.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.4 Inspection/ Quality Control Area

There is a quality control laboratory installed in the plant, with state of the art equipment, and fully educated and trained staff. It has easy access to handwashing facilities, and is kept clean. Liquid waste is handled by an outsourcing company, specification of the service was reviewed during the audit.

11.1.4.1 If online inspection is required, a suitable area close to the processing line shall be provided for the inspection of product (refer to 2.4.4). The inspection/quality control area shall be provided with facilities that are suitable for examination and testing of the type of product being handled/processed. The inspection area shall:
i. Have easy access to handwashing facilities;
ii. Have appropriate waste handling and removal; and
iii. Be kept clean to prevent product contamination.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.5	**Dust, Insect, and Pest Proofing** The presence of powder is normal, because most of the products are powders. On the other hand, plant is kept neat and clean. No source of dust from the exterior was identified. The plant is very closed, risk of pest to enter is very low. Electric insect control devices are only UV lights, they are located in such places that do not pose a risk of product contamination.
11.1.5.1	All external windows, ventilation openings, doors, and other openings shall be effectively sealed when closed, and proofed against dust, vermin, and other pests. External personnel access doors shall be effectively insect-proofed and fitted with a self-closing device and proper seals to protect against entry of dust, vermin, and other pests. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.5.2	External doors, including overhead dock doors in food handling areas used for product, pedestrian, or truck access, shall be designed and maintained to prevent pest ingress by at least one or a combination of the following methods: i. A self-closing device; ii. An effective air curtain; iii. A pest-proof screen; iv. A pest-proof annex; and v. Adequate sealing around trucks in docking areas. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.5.3	Electric insect control devices, pheromone, or other traps and baits shall be located and operated so they do not present a contamination risk to the product, packaging, containers, or processing equipment. Poison rodenticide bait shall not be used inside ingredients or product storage areas or processing areas where ingredients, packaging, and products are handled, processed, or exposed. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.6	**Ventilation** Ventilation system is working properly. During the audit tour it was observed the equipment working and no problem with ventilation, considering the nature of the products, as it was stated before, most of the products are powders.
11.1.6.1	Adequate ventilation shall be provided in enclosed processing and food handling areas. Where appropriate, positive air-pressure systems shall be installed to prevent airborne contamination. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.6.2	All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 11.2.5 to prevent unsanitary conditions. **RESPONSE:** COMPLIANT

EVIDENCE:

11.1.6.3 Extractor fans and canopies shall be provided in areas where open cooking operations are carried out or a large amount of steam is generated. Capture velocities shall be sufficient to prevent condensation build-up and to evacuate all heat, fumes, and other aerosols to the exterior via an exhaust hood positioned over the cooker(s).

RESPONSE: COMPLIANT

EVIDENCE:

11.1.6.4 Fans and exhaust vents shall be insect-proofed and located so they do not pose a contamination risk and shall be kept clean.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7 Equipment and Utensils

No food safety risk was observed related to equipment, utensils or protective clothing. Specification for equipment and utensils are implemented, for instance: color coding. Most of the materials for equipment and utensils are stainless steel. Personnel wear protective clothing. During the audit tour it was observed that equipment, utensils and in general the plant was in a very nice state of cleaning.

11.1.7.1 Specifications for equipment and utensils and procedures for purchasing equipment shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.2 Equipment and utensils shall be designed, constructed, installed, operated, and maintained to meet any applicable regulatory requirements and to not pose a contamination threat to products.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.3 Equipment storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers. Where possible, food contact equipment shall be segregated from non-food contact equipment.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.4 Product contact surfaces and those surfaces not in direct contact with food in food handling areas, raw material storage, packaging storage, and cold storage areas shall be constructed of materials that will not contribute to a food safety risk.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.5	Benches, tables, conveyors, mixers, mincers, graders, and other mechanical processing equipment shall be hygienically designed and located for appropriate cleaning. Equipment surfaces shall be smooth, impervious, and free from cracks or crevices. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.7.6	Product containers, tubs, and bins used for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious, and readily cleaned as per 11.2.5.1. Bins used for inedible material shall be clearly identified. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.7.7	All equipment and utensils shall be cleaned after use (refer to 11.2.5.1) or at a set and validated frequency to control contamination and be stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.7.8	Vehicles used in food contact, handling, or processing zones or cold storage rooms shall be designed and operated so as not to present a food safety hazard. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.7.9	Non-conforming equipment shall be identified, tagged, and/or segregated for repair or disposal in a manner that minimizes the risk of inadvertent use, improper use, or risk to the integrity of finished product. Records of the handling, corrective action, and/or disposal of non-conforming equipment shall be maintained. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.8	**Grounds and Roadways** The back area of the facility is the Saint Louis University Campus. The neighbors are a gym and a storage facility. No potential contaminants were observed from the environment surrounding the facility.
11.1.8.1	A suitable external environment shall be established, and the effectiveness of the measures shall be monitored and periodically reviewed. The premises, its surrounding areas, storage facilities, machinery, and equipment shall be kept free of waste or accumulated debris, and vegetation shall be controlled so as not to attract pests and vermin or present a food safety hazard to the sanitary operation of the site. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.8.2	Paths, roadways, and loading and unloading areas shall be maintained so as not to present a hazard to the food safety operations of the premises. They shall be adequately drained to prevent the pooling of water. Drains shall be separate from the site drainage system and regularly cleared of debris.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.8.3 Paths from amenities leading to site entrances shall be effectively sealed.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.1 **Repairs and Maintenance**

SOP Section 8.3, Preventative Maintenance Program, Review Date: 06/15/2023. This procedure is to ensure the equipment will operate in a safe manner and reduce downtime through proper maintenance of equipment. This program uses teh MaintainanceX Program (maintainx.com). This is an on-line system, the auditor observed the workorders for the month of october 2023. The company has been using this program about May-June 2023. Sample of a specific maintenance activity: B-1 (APS Plow Blender). Tool verification: all tools /parts reconciled and removed from the area? Maintenance is being performed by the technician Mr. J.T. who is the person in charge of maintenance in the plant, under the command of the Operations Manager. There is an approved list for chemical products used in the site, the Practitioner pulled up the chemical products that are food grade, for instance: Quat Sanitizer, Multipurpose Degreaser, Purity FG Heat Transfer Fluir (lubricant - food grade), etc.

11.2.1.1 The methods and responsibility for the maintenance and repair of plant, equipment, and buildings shall be documented, planned, and implemented in a manner that minimizes the risk of product, packaging, or equipment contamination.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.1.2 Routine maintenance of plant and equipment in any food processing, handling, or storage areas shall be performed according to a maintenance control schedule and recorded.
The maintenance schedule shall be prepared to include buildings, equipment, and other areas of the premises critical to the maintenance of product safety.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.1.3 Failures of plant and equipment in any food processing, handling, or storage areas shall be documented and reviewed, and their repair(s) incorporated into the maintenance control schedule.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.1.4 Site supervisors shall be notified when maintenance or repairs are to be undertaken in any processing, handling, or storage areas.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.1.5	The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance activities pose a potential threat to product safety (e.g., pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside operating times. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.1.6	Temporary repairs, where required, shall not pose a food safety risk and shall be included in routine inspections (refer to 2.5.4.3) and the cleaning program. There shall be a plan in place to address the completion of temporary repairs to ensure they do not become permanent solutions. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.1.7	Food contact equipment and equipment located over food contact equipment shall be lubricated with food-grade lubricant, and its use shall be controlled to minimize the contamination of the product. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.1.8	Paint used in a food handling or processing area shall be suitable for use, in good condition, and not be used on any product contact surfaces. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.2	**Maintenance Staff and Contractors** For the maintenance contractors there is a requirement for GMPs and training, for instance: Dock door and leveler repair: Starr Glass: must adhere to visitor GMPs. For the lab and hazardous waste removal: Must adhere to visitor GMPs, must be licensed and must provide proof of destruction. 80% of maintenance is performed by conttractors. the list is long, and includes: pest control, uniform, waste and recycling, RO unitr and DI water service, forklift repair, etc. Auditor reviewed the service reports from the Uniform Hazardous waste contractor, dated on 07/17/23, including: UN1993 Waste flammable liquidos: methanol, petroleum ether; waste self-heating solid organic: charcoal, sodium dithionitel, etc.
11.2.2.1	Maintenance staff and contractors shall comply with the site's personnel and process hygiene requirements (refer to 11.3). **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.2.2	All maintenance and other engineering contractors required to work on-site shall be trained in the site's food safety and hygiene procedures or shall be escorted at all times until their work is completed. **RESPONSE:** COMPLIANT **EVIDENCE:**

11.2.2.3 Maintenance staff and contractors shall remove all tools and debris from any maintenance activity once it has been completed, and inform the area supervisor and maintenance supervisor, so appropriate hygiene and sanitation can be conducted and a pre-operational inspection completed prior to the restarting of site operations.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.3 **Calibration**
Sample of calibration certificate: COLOR CALIBRATION GROUP, statement of calibration, this is ANAB accredited. Certificate # TB080223-02, Issue date: 8/4/2023. The instrument has been inspected and found to be in operable working condition. Instrument:Konica Minolta CM3700A, Calibration date: 08/02/23. There is a list of the equipment that need to be calibrated, including: balance, indicator, moisture analyser, luminometer, weight set, UV/VIS spectrophotometer. Certificate for the moisture analyser was reviewed as well: St. Louis Scale Corporation, date of calibration: 9.28.23.

11.2.3.1 The methods and responsibility for calibration and re-calibration of measuring, testing, and inspection equipment used for monitoring activities outlined in prerequisite programs, food safety plans, and other process controls, or to demonstrate compliance with customer specifications, shall be documented and implemented. Software used for such activities shall be validated as appropriate.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.3.2 Equipment shall be calibrated against national or international reference standards and methods or to an accuracy appropriate to its use. In cases where standards are not available, the site shall provide evidence to support the calibration reference method applied.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.3.3 Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers' recommended schedule.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.3.4 Procedures shall be documented and implemented to address the resolution of potentially affected products when measuring, testing, or inspection equipment is found to be out of calibration.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.3.5 Calibrated measuring, testing, and inspection equipment shall be protected from damage and unauthorized adjustment or use.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.3.6 A directory of measuring, testing, and inspection equipment that require calibration and records of the calibration tests shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.4 Pest Prevention

Pest Control Policy. Purpose: outline the program used by Roha USA to monitor and minimize the risk of rodent and insects infestation and contamination to the product. Persons responsible: contractor service provider, plant manager, quality manager. Pest´s controlled: ants, roaches, mice and rats, spiders. Outline: the pest control management program is outlined by the contract service provider. The contract service provider is responsible for plan management and maintenance. McCloud Pest Solucitons is the company used probably by 12 years. Company license: City of Saint Louis, W. B. McCloud & Co. Inc, business license: business license type: dwelling and building. To date: 05/11/24. The frequency of the visits is once weekly. Sample of a visit report was reviewed by the auditor: time in: 10/27/2023 7.30 am, time out: 10/27/2023 01.59 pm. Service description: TQA PM Program for food supply chain of custody: 1.0, interior and exterior rodedn: 1.0, ILT Program: 1.0, and IPM Trend analysis. Thend analysis report for the year 2023: there were 3 house mouse caught, interior roden trap: 1) boiler room, 2) warehouse, 3) warehouse. Device name: 40, 50, 54. Date: 11-16-22, 04-25-23, 05-03-23. Tech comment: inspected exterior rodent stations, treated perimeter to prevent occasional invaders; inspected interior traps, 1 capture in IRT 54, Reviewed finding with B.W.

11.2.4.1 A documented pest prevention program shall be effectively implemented. It shall:
i. Describe the methods and responsibility for the development, implementation, and maintenance of the pest prevention program;
ii. Record pest sightings and trend the frequency of pest activity to target pesticide applications;
iii. Outline the methods used to prevent pest problems;
iv. Outline the pest elimination methods and the appropriate documentation for each inspection;
v. Outline the frequency with which pest status is to be checked;
vi. Include the identification, location, number, and type of applied pest control/monitoring devices on a site map;
vii. List the chemicals used. The chemicals are required to be approved by the relevant authority and their Safety Data Sheets (SDS) made available;
viii. Outline the methods used to make staff aware of the bait control program and the measures to take when they come into contact with a bait station;
ix. Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits; and
x. Measure the effectiveness of the program to verify the elimination of applicable pests and to identify trends.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.4.2 Pest contractors and/or internal pest controllers shall:
i. Be licensed and approved by the local relevant authority;
ii. Use only trained and qualified operators, who comply with regulatory requirements;
iii. Use only approved chemicals;
iv. Provide a pest prevention plan (refer to 2.3.2.8), which includes a site map, indicating the location of bait stations traps and other applicable pest control/monitoring devices;
v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments;
vi. Provide regular inspections for pest activity with appropriate action taken if pests are present, and
vii. Provide a written report of their findings and the inspections and treatments applied.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.4.3 Pest activity risks shall be analyzed and recorded. Inspections for pest activity shall be conducted on a regular basis by trained site personnel and the appropriate action taken if pests are present. Identified pest activity shall not present a risk of contamination to food products, raw materials, or packaging.
Records of all pest control inspections and applications shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.4.4 Food products, raw materials, or packaging that are found to be contaminated by pest activity shall be effectively disposed of, and the source of pest infestation shall be investigated and resolved. Records shall be kept of the disposal, investigation, and resolution.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.4.6 No animals shall be permitted on-site in food handling and storage areas.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5 Cleaning and Sanitation

The company has established the cleaning and sanitation activities for the weekly, monthly, quarterly and annually frequency. So far they are performing this task by themselves, they used to have a janitor but this person is no longer with the company so the operators are responsible for the cleaning activities. For the monthly activity: MAN(F004 Monthly sanitation checklist: area: Manufacturing, Item: liquid area floors - complete cleaning - frecuency: monthly. Records were reviewed by the auditor: ROHA MAN/F005 Quarterly/Annual Sanitationn checklist: year 2023. Area: Manufacturing, Item: Liquid Area Walls, Ceiling, & Overheads. Frequency: Quarterly. Evidence of the cleaning performed on the quarters: 1st: 3/22; 2nd: 6/30, 3rd: 9/25. Pre-operational inspections: Pre-Process Checks: the questions included are: 1) any foreign material found in the tank/mixer? 2) Mixer shaft / tank free of loose parts? 3) Dust collector hose in good condition, 4) date of last saniation.

11.2.5.1 The methods and responsibility for the effective cleaning of the food handling and processing equipment and environment and storage areas shall be documented and implemented. Consideration shall be given to:
i. What is to be cleaned;
ii. How it is to be cleaned;
iii. When it is to be cleaned;
iv. Who is responsible for the cleaning;
v. Validation of the cleaning procedures for food contact surfaces (including CIP);
vi. Methods used to confirm the correct concentrations of detergents and sanitizers; and
vii. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.2 Detergents and sanitizers shall be suitable for use in a food manufacturing environment, labeled according to regulatory requirements, and purchased in accordance with applicable legislation. The organization shall ensure:
i. The site maintains a list of chemicals approved for use;
ii. An inventory of all purchased and used chemicals is maintained;
iii. Detergents and sanitizers are stored as outlined in element 11.6.4;
iv. Safety Data Sheets (SDS) are provided for all detergents and sanitizers purchased; and
v. Only trained staff handle sanitizers and detergents.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.3 Detergents and sanitizers that have been mixed for use shall be correctly mixed according to the manufacturers' instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations shall be verified and records maintained.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.5 Cleaning equipment, tools, racks, and other items used in support of the cleaning and sanitizing program shall be clearly identified, stored, and maintained in a manner that prevents contamination of processing areas, product handling equipment, and storage areas as well as the tools themselves.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.6 Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards, and other utensils used by staff. The areas for these cleaning operations shall be controlled so they do not interfere with manufacturing operations,
equipment, or product. Racks and containers for storing cleaned utensils shall be provided as required.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.7 Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure food processing areas, product contact surfaces, equipment, staff amenities, sanitary facilities, and other essential areas are clean before the start
of production. Pre-operational inspections shall be conducted by qualified personnel.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.8 Staff amenities, sanitary facilities, and other essential areas shall be inspected by qualified personnel at a defined frequency to ensure the areas are clean.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.9 The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared.
A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.1 Personnel Welfare

Good Manufacturing Practices were observed during the audit tour: personnel wearing uniforms, no personnel with exposed cuts, no smoking, chewing, eating, etc. In the plant. There is a documented policy related to personnel behavior within the plant.

11.3.1.1 Personnel who are known to be carriers of infectious diseases that present a health risk to others through the packing or storage processes shall not engage in the processing or packing of food or enter storage areas where food is exposed.

Code Amendment #1
A medical screening procedure shall be in place for all employees, visitors and contractors who handle exposed product or food contact surfaces.

RESPONSE: COMPLIANT

EVIDENCE: There is a documented policy related to personnel handling product and hygiene. Employees are prohibited from working in food handling areas when suffering from infectious and communicable diseases or have exposed cuts, sores or lesions. The policy requires that minor cuts or abrasions be covered with a waterproof, metal detectable and colored bandage.

11.3.1.2 The site shall have measures in place to prevent contact of materials, ingredients, food packaging, food, or food contact surfaces from any bodily fluids, open wounds, coughing, sneezing, spitting, or any other means.
In the event of an injury that causes the spillage of bodily fluid, a properly trained staff member shall ensure that all affected areas, including handling and processing areas, have been adequately cleaned, and that all materials and products have been quarantined and/or disposed of.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.1.3 Personnel with exposed cuts, sores, or lesions shall not engage in handling or processing exposed products or handling primary (food contact) packaging or touching food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored, metal-detectable bandage or an alternative suitable waterproof and colored dressing.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.2 Handwashing

Handwash basins are provided adjacent to all personnel access. During last's years FDA inspection, one violation was raised related to hand wash located at the platform of liquid products, with no hot water, but this was already solved by the plant. Hand wash basins are stainless steel made, provided with liquid soap, paper towel.

11.3.2.1 All personnel shall have clean hands, and hands shall be washed by all staff, contractors, and visitors:
i. On entering food handling or processing areas;
ii. After each visit to a toilet;
iii. After using a handkerchief;
iv. After smoking, eating, or drinking; and
v. After handling wash down hoses, cleaning materials, dropped product, or contaminated material.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.2.2 Handwashing stations shall be provided adjacent to all personnel access points and in accessible locations throughout food handling and processing areas as required.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.2.3 Handwashing stations shall be constructed of stainless steel or similar non-corrosive material and at a minimum supplied with:
i. A potable water supply at an appropriate temperature;
ii. Liquid soap contained within a fixed dispenser;
iii. Paper towels in a hands-free cleanable dispenser; and
iv. A means of containing used paper towels.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.2.5 Signage in appropriate languages instructing people to wash their hands before entering the food processing areas shall be provided in a prominent position in break rooms, at break room exits, toilet rooms, and in outside eating areas, as applicable.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.2.6 When gloves are used, personnel shall maintain the handwashing practices outlined above.

RESPONSE: COMPLIANT

EVIDENCE: Gloves are used normally in production, because of the nature of the product: dyes.

11.3.3 **Clothing and Personal Effects**
There is an outsourcing company for laundering clothing, this company comes every Friday, they pick up dirty clothes and drop off the laundered clothing's. Clothing is adequate to the nature of the process and the product. Some disposable aprons are available, as it was observed during the tour. Jewelry and other loose objects are not worn or taken into the food handling areas.

11.3.3.1 The site shall undertake a risk analysis to ensure that the clothing and hair policy protects materials, food, and food contact surfaces from unintentional microbiological or physical contamination.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.3.2 Clothing worn by staff engaged in handling food shall be maintained, stored, laundered, and worn so it does not present a contamination risk to products.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.3.3 Clothing, including shoes, shall be clean at the start of each shift and maintained in a serviceable condition.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.3.4 Excessively soiled uniforms shall be changed or replaced when they present a product contamination risk.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.3.5 Disposable gloves and aprons shall be changed after each break, upon re-entry into the processing area, and when damaged.
Non-disposable aprons and gloves shall be cleaned and sanitized as required and when not in use stored on racks provided in the processing area or in designated sealed containers in personnel lockers. They should not be placed or stored on packaging, ingredients, product, or equipment.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.3.6 Protective clothing shall be manufactured from material that will not pose a food safety threat and is easily cleaned.
All protective clothing shall be cleaned after use, or at a frequency to control contamination, and stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.3.7 Racks shall be provided for the temporary storage of protective clothing when staff leave the processing area and shall be provided nearby or adjacent to the personnel access doorways and handwashing facilities.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.3.8 Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or into any area where food is exposed. Wearing plain bands with no stones, prescribed medical alert bracelets, or jewelry accepted for religious or cultural reasons can be permitted, provided these items are properly covered and do not pose a food safety risk.
All exceptions shall meet regulatory and customer requirements and shall be subject to a risk assessment and evidence of ongoing risk management.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.4	**Visitors** All visitors are required to wear suitable clothing, for instance heartens. Visitors are required to sing in the list for access control.
11.3.4.1	All visitors shall be trained in the site's food safety and hygiene procedures before entering any food processing and handling areas or shall be escorted at all times in food processing, handling, and storage areas. **RESPONSE:** COMPLIANT **EVIDENCE:** All visitors are required to wear suitable clothing, for instance heartens. Visitors are required to sing in the list for access control. This is an acknowledge of the GMP principles and policies applied within the plant.
11.3.4.2	All visitors, including management staff, shall be required to remove jewelry and other loose objects in accordance with the facilities Good Manufacturing Practices and 11.3.3.8. All visitors shall wear suitable clothing and footwear when entering any food processing and handling area. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.4.3	Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food is handled and processed. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.4.4	Visitors shall enter and exit food handling areas through the proper staff entrance points and comply with all handwashing and personnel practice requirements. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.5	**Staff Amenities (change rooms, toilet, break rooms)** Staff amenities are supplied with appropriate lighting and ventilation. Toilets are designed and constructed so that they are accessible to staff and separate from any processing and food handling operations. Facilities are provided to enable staff and visitors to change into an out of protective clothing as requested. They have lockers, and all the necessary equipment. There is a separate lunch room provided away from food contact areas. It is equipped with refrigeration, microwaves, vending machine, television, etc. Signage instructing people to wash their hands is available.
11.3.5.1	Staff amenities shall have documented cleaning procedures, be supplied with appropriate lighting and ventilation, and shall be made available for use by all persons engaged in the handling and processing of product. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.5.2	Change rooms shall be provided to enable staff and visitors to change into and out of protective clothing as required. Change rooms shall be kept clean.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.5.4 Provision shall be made for staff to store their street clothing and personal items separate from clean uniforms, food contact zones, food, and packaging storage areas.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.5.6 Toilet rooms shall be:
i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations;
ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room;
iii. Sufficient in number for the maximum number of staff;
iv. Constructed so that they can be easily cleaned and maintained;
v. Located inside or nearby areas for storing protective clothing, outer garments, and other items while using the facilities; and
vi. Kept clean and tidy.
Tools/equipment used for cleaning toilet rooms shall not be used to clean processing areas.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.5.7 Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system in accordance with regulations.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.5.8 Handwashing basins shall be provided immediately outside or inside the toilet room and designed as outlined in 11.3.2.3.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.5.9 Separate break rooms shall be provided away from food contact/handling zones.
Break rooms shall be:
i. Ventilated and well lit;
ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting;
iii. Equipped with a sink serviced with hot and cold potable water for washing utensils;
iv. Equipped with refrigeration and heating facilities, enabling staff to store or heat food and to prepare non-alcoholic beverages if required; and
v. Kept clean and free from waste materials and pests.

RESPONSE: COMPLIANT

EVIDENCE:

11.4.1	**Staff Engaged in Food Handling and Processing Operations** It was observed during the audit tour that all personnel engaged in any food handling preparation, storing, sampling taking, etc. Ensure that products are handled in such a way to prevent product contamination. There is a department for product development, that has a full area for sensory evaluations and product testing, but this area is not part of the scope of the SQF system. It was observed that hoses are stored in racks.
11.4.1.1	All personnel engaged in any food handling, preparation, or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices: i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be open for extended periods when access is required for waste removal or receiving of product/ingredient/packaging; iii. Packaging, product, and ingredients shall be kept in appropriate containers as required and off the floor; iv. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; and v. All wash down and compressed air hoses shall be stored on hose racks after use and not left on the floor. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.4.1.2	Personnel working in or visiting food handling or processing operations shall ensure that: i. Staff shall not eat or taste any product being processed in the food handling/contact zones, except as noted in element 11.4.1.4; ii. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails, or fingernail polish is not permitted when handling exposed food; iii. Hair restraints and beard covers, where applicable, shall be used in areas where product is exposed. iv. Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. v. Drinking water is permissible only under conditions that prevent contamination or other food safety risks from occurring. Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging, tools, or equipment storage. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.4.1.3	The flow of personnel in food processing and handling areas shall be managed such that the potential for contamination is minimized. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.4.1.4	In circumstances where it is necessary to undertake sensory evaluations in a food handling/contact zone, the site shall implement controls and procedures to ensure: i. Food safety is not compromised; ii. Sensory evaluations are conducted by authorized personnel only; iii. A high standard of personal hygiene is practiced by personnel conducting sensory evaluations; iv. Sensory evaluations are conducted in areas equipped for the purpose; and v. Equipment used for sensory evaluations is sanitized, maintained, and stored separately from processing equipment. **RESPONSE:** COMPLIANT

EVIDENCE:

11.5.1	**Water Supply** Water is stored on site, this store facilities are adequately designed, constructed and maintained to prevent contamination.
11.5.1.1	Adequate supplies of potable water drawn from a known clean source shall be provided for water used as an ingredient during processing operations and for cleaning the premises and equipment. The source of potable water shall be identified as well as on-site storage (if applicable) and reticulation within the facility. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.5.1.2	Contingency plans shall be in place for instances when the potable water supply is deemed to be contaminated or otherwise inappropriate for use. **RESPONSE:** COMPLIANT **EVIDENCE:** The company can bring tankers of water in the case the City supply had a problem.
11.5.1.3	Supplies of hot and cold water shall be provided, as required, to enable the effective cleaning of the premises and equipment. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.5.1.4	The delivery of water within the premises shall ensure potable water is not contaminated. Testing of the backflow system, where possible, shall be conducted at least annually and records shall be maintained. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.5.1.5	The use of non-potable water shall be controlled such that: i. There is no cross-contamination between potable and non-potable water lines; ii. Non-potable water piping and outlets are clearly identified; and iii. Hoses, taps, and other similar sources of possible contamination are designed to prevent backflow or back-siphonage. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.5.1.6	Where water is stored on-site, storage facilities shall be adequately designed, constructed, and routinely cleaned to prevent contamination. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.5.2	**Water Treatment** There is a water treatment implemented, mostly because of the nature of the product and process, that requires the water to be in certain specification as raw material. Water is continuously tested.

11.5.2.1	Water treatment methods, equipment, and materials, if required, shall be designed, installed, and operated to ensure water receives effective treatment. Water treatment equipment shall be monitored regularly to ensure it remains serviceable. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.5.2.2	Water used as an ingredient in processing or for cleaning and sanitizing equipment shall be tested and, if required, treated to maintain potability (refer to 11.5.2.1). **RESPONSE:** COMPLIANT **EVIDENCE:**
11.5.2.3	Treated water shall be regularly monitored to ensure it meets the specified indicators. Water treatment chemicals usage shall be monitored to ensure chemical residues are within acceptable limits. Records of testing results shall be kept. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.5.3	**Water Quality** Deibel Laboratories, www.DeibelLabs.com, Reported: 7/27/2023. Report results: Deibel Lab #: SM-230725-022-011 Analysis Date: 2023/07/25, Receiving Temperature: 23.8oC, Sample condition: Okay. Description: RW31 Water Sample. Test: coliform MPN 10 Tube: < 1.1 MPN/100 mL, E. coli MPN 10 tube: < 1.1 MPN/100 mL, and APC: < 1 CFU/ml. From the city of Saint Louis water report, last available 2022: Inorganic Compounds: Arsenic (ug/L): 0.0122; Lead (mg/L): 90Th Percentile: 2.12, Organic: Atrazine (ug/L): ND, etc. all the analytes within the MCL/MCLG.
11.5.3.1	Water shall comply with local, national, or internationally recognized potable water microbiological and quality standards, as required when used for: i. Washing, thawing, and treating food; ii. Handwashing; iii. Conveying food; iv. An ingredient or food processing aid; v. Cleaning food contact surfaces and equipment; vi. The manufacture of ice; or vii. The manufacture of steam that will come into contact with food or be used to heat water that will come into contact with food. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.5.3.2	Microbiological analysis of the water and ice supply shall be conducted to verify the cleanliness of the supply, the monitoring activities, and the effectiveness of the treatment measures implemented. Samples for analysis shall be taken at sources supplying water for the process or cleaning or from within the site. The frequency of analysis shall be risk-based and at a minimum annually. **RESPONSE:** COMPLIANT **EVIDENCE:**

11.5.3.3 Water and ice shall be analyzed using reference standards and methods.

RESPONSE: COMPLIANT

EVIDENCE:

11.5.4 **Ice Supply**

There is no ice used in this facility.

11.5.5 **Air and Other Gasses**

No gases are used in manufacturing (nitrogen, carbon dioxide, etc.)

11.6.1 **Receipt, Storage and Handling of Goods**

Responsibility and methods for ensuring effective stock rotation principles are applied. Procedures are in place to ensure that all ingredients, materials, work in progress, rework, and finished products are utilized within their designated shelf-life. Auditor reviewed the flow-chart for the receiving of raw materials, section 7.2. The only updated information since last edition back in 2013 is the addition of the Trailer Inspection Form. It includes a visual inspection: is the carrier clean inside and is the floor safe?, is there any hazard material on the trailer? Sample of receiving record: Date of Receipt: 10-10-23, free from strong odours, vehicle suitable maintained, transport vehicle in clean dand hygienic conditions, signed by the carrier driver. Outbound record was also reviewed: date: 10-18-23. Carrier: ABF. if LTL with no seal, is it locked upon arrival: yes. Is there any signs of vermin? no, is there any strong, unusual of floul odours? No. Is there any non-food grade hazardous /chemicals: no.

11.6.1.1 The site shall document and implement an effective storage plan that allows for the safe, hygienic receipt and storage of raw materials (i.e., frozen, chilled, and ambient), ingredients, packaging, equipment, and chemicals.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.1.2 Controls shall be in place to ensure all ingredients, raw materials, processing aids, and packaging are received and stored properly to prevent cross-contamination risks. Unprocessed raw materials shall be received and stored separately from processed raw materials to avoid cross-contamination risk.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.1.3 The responsibility and methods for ensuring effective stock rotation principles shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.1.4 Procedures shall be in place to ensure that all ingredients, materials, work- in-progress, rework, and finished product are utilized within their designated shelf-life.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.2	**Cold Storage, Freezing and Chilling of Foods** No cold storage, freezing or chilling of foods in this site.
11.6.3	**Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods** Warehouse for the storage of product ingredients, packaging and other dry goods is adequate, away from wet production areas, racks are provided for the storage of packaging, the whole warehouse is constructed to prevent packaging from becoming a harborage for pest or vermin. Vehicles, such as fork lifts are in good maintenance.
11.6.3.1	Rooms used for the storage of product ingredients, packaging, and other dry goods shall be located away from wet areas and constructed to protect the product from contamination and deterioration and prevent packaging from becoming a harborage for pests or vermin. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.3.2	Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning and inspection of the floors and behind the racks. Storage areas shall be cleaned at a pre-determined frequency. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.4	**Storage of Hazardous Chemicals and Toxic Substances** Because of the nature of the products, chemical products are ingredients, all company is full of chemical products. But there are control measures implemented, in such a way to prevent cross contamination.
11.6.4.1	Hazardous chemicals and toxic substances with the potential for food contamination shall be: i. Clearly labeled, identifying and matching the contents of their containers; ii. Included in a current register of all hazardous chemicals and toxic substances that are stored on-site; and iii. Supplemented with current Safety Data Sheets (SDS) made available to all staff. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.4.2	Storage of hazardous chemicals and toxic substances shall be: i. Located in an area with appropriate signage indicating that the area is for hazardous storage; ii. Controlled, lockable, and accessible only by personnel trained in the storage and use of chemicals; iii. Adequately ventilated; iv. Stored where intended and not comingled (e.g., food versus non-food grade); v. Designed such that pesticides, rodenticides, fumigants, and insecticides are stored separately from sanitizers and detergents; and vi. Stored in a manner that prevents a hazard to finished product or product contact surfaces. Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances. **RESPONSE:** COMPLIANT **EVIDENCE:**

11.6.4.3 Hazardous chemicals and toxic substances shall be correctly labeled and:
i. Used only according to manufacturers' instructions;
ii. Controlled to prevent contamination or a hazard to raw and packaging material, work-InProgress, finished product, or product contact surfaces;
iii. Returned to the appropriate storage areas after use; and
iv. Be compliant with national and local legislation.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.4.4 Daily supplies of chemicals used for continuous sanitizing of water, as a processing aid, or for emergency cleaning of food processing equipment and surfaces in food contact zones may be stored within or in close proximity to a processing area, provided that access to the chemical storage facility is restricted to only authorized personnel.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.4.5 Personnel who handle hazardous chemicals and toxic substances, including pesticides and cleaning chemicals,:
i. Shall be fully trained in the purpose of the hazardous chemicals and toxic substances, their storage, handling, and use;
ii. Be provided first aid equipment and personnel protective equipment (PPE); and
iii. Ensure compliance with the proper identification, storage, usage, disposal, and clean-up requirements.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.4.6 The site shall dispose of empty, obsolete, and unused chemicals, pesticides, toxic substances, and containers in accordance with requirements and ensure that primary containers are:
i. Not reused;
ii. Segregated and securely stored prior to collection; and
iii. Disposed through an approved vendor.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.4.7 In the event of a hazardous spill, the site shall:
i. Have spillage clean-up instructions to ensure that the spill is properly contained; and
ii. Be equipped with PPE, spillage kits, and cleaning equipment.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.5	**Loading, Transport, and Unloading Practices** Standard Operating Procedures: LOADING AND TRANSPORT OF FINISHED PRODUCT. The purpose of this procedure is to ensure product is protected during loading, transport and unloading and to ensure that the shipping conditions do not pose a potential for product contamination. The major responsibility is for shipping/receiving operator. As ROHA does not ship its own products, the responsibility for developing, implementing, and carrying out transport, breakdown, and unloading procedures is delegated to the customers and carrier companies who do the shipping. As these carriers are reputable and reliable companies with know food safety standards and procedures, no oversight by Roha is deemed necessary at this time. Product is loaded onto trucks by the shipping/receiving operator. These employees are responsible for documenting product types, quantities, and date codes along with customer information at the time of loading. Shipping employees inspect the following at the time of shipping form. Type and quantity of product shipped, no visible signs of damage or deviance in product, interior of outgoing truck is clean and the floor are safe, no sign of pest.
11.6.5.1	The practices applied during loading, transport, and unloading of food shall be documented, implemented, and designed to maintain appropriate storage conditions and product integrity. Foods shall be loaded, transported, and unloaded under conditions suitable to prevent cross-contamination. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.5.2	Vehicles (e.g., trucks/vans/containers) used for transporting food within the site and from the site shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose, and free from odors or other conditions that may impact negatively on the product. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.5.3	Vehicles (e.g., trucks/vans/containers) shall be secured from tampering using seals or other agreed-upon and acceptable devices or systems. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.5.4	Loading and unloading docks shall be designed to protect the product during loading and unloading. Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product and package integrity during loading and transport. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.5.7	On arrival, prior to opening the doors, the food transport vehicle's refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently, and product temperatures shall be recorded at the start of unloading and regular intervals during unloading. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.5.8	Unloading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product and package integrity.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.1 High-Risk Processes

There is no high risk processes in this site.

11.7.2 Thawing of Food

No thawing of food in this site.

11.7.3 Control of Foreign Matter Contamination

Standard Operating Procedures: FOREIGN MATERIAL CONTROL. Section 3.5.1. This foreign material control procedure is designed to protect consumers from illness and injury due to foreign material contamination. The Quality Manager is responsible for managing the foreign material contamination program and ensuring that all procedures are being carried out regularly; as well as monitoring for physical hazard by conducting the monthly glass inspections and monthly self-audit. All employees are responsible for complying with GMPs, adhering to the glass and brittle plastic policy, and monitoring their work area for sings of foreign material hazards. The production supervisor is responsible for ensuring that structures and equipment are maintained in a way that minimize the risk of foreign material contamination. Record of the inspection of glass and brittle plastic: 9/15/2023. NCm: during the tour it was observed that there are blades used in routine process but there is no specific inventory or particular control about the number of blades present in the whole plant.

11.7.3.1 The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented, and communicated to all staff.
Inspections shall be performed (refer to 2.5.4.3) to ensure plant and equipment remain in good condition and equipment has not become detached or deteriorated and is free from potential contaminants.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.2 Containers, equipment, and other utensils made of glass, porcelain, ceramics, laboratory glassware, or other similar materials shall not be permitted in food processing /contact zones (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers are used, or MIG thermometers are required under regulation).
Where glass objects or similar material are required in food handling/contact zones, they shall be listed in a glass inventory, including details of their location and condition.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.3 Regular inspections of food handling/contact zones shall be conducted (refer to 2.5.4.3) to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass inventory.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.4 Glass instrument dial covers on processing equipment and MIG thermometers shall be inspected at the start of each shift to confirm they have not been damaged.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.5 In circumstances where glass or similar material breakage occurs, the affected area shall be isolated, cleaned, thoroughly inspected (including cleaning equipment and footwear), and cleared by a suitably responsible person prior to the start of operations.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.6 Wooden pallets and other wooden utensils used in food processing and handling areas shall be dedicated for that purpose, clean, and maintained in good order. Their condition shall be subject to regular inspection.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.7 Loose metal objects on equipment, equipment covers, and overhead structures shall be removed or tightly fixed so as not to present a hazard.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.8 Knives and cutting instruments used in processing and packaging operations shall be controlled, kept clean, and well maintained. Snap-off blades shall not be used in manufacturing or storage areas.

RESPONSE: MINOR

EVIDENCE: NCm: during the tour it was observed that there are blades used in routine process but there is no specific inventory or particular control about the number of blades present in the whole plant.

ROOT CAUSE: The company did not have a written sharps control policy. Plant practices were in place, but not recorded

CORRECTIVE ACTION: Created 5.5.1.16 (Sharps Control Policy) on 11/20/2023. This covers how the plant will issue and manage sharps on the plant and warehouse floor

VERIFICATION OF CLOSEOUT: The site provided the SOP for sharps control and also the sharps log.

COMPLETION DATE: 11/20/2023 **CLOSEOUT DATE**: 11/22/2023

11.7.3.9 Gaskets, rubber impellers, and other equipment made of materials that can wear or deteriorate over time shall be inspected on a regular frequency (refer to 2.5.4.3).

RESPONSE: COMPLIANT

EVIDENCE:

11.7.4 Detection of Foreign Objects

Filters, magnets and strainers are used in order to prevent contamination with foreign objects, and these are the CCPs of the HACCP plans. No complaints from clients regarding foreign objects, and through interview with supervisors it was evident that there are methods implemented to maintain the measures of detection of foreign objects.

11.7.4.1 The responsibility, methods, and frequency for monitoring, maintaining, calibrating, and using screens, sieves, filters, or other technologies to remove or detect foreign matter shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.4.2 Where detection and/or removal systems are used, the site shall establish limits for detection, based on a risk assessment of the product and its packaging, and identify the location(s) of the detector(s) in the process.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.4.3 Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated, and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.

RESPONSE: COMPLIANT

EVIDENCE: Even though there are no metal detection systems, there are magnets and sifters installed, and they work as CCP in the HACCP plan.

11.7.4.4 Records shall be maintained of the inspection of foreign object detection devices, of any products rejected or removed by them, and of corrective and preventative actions resulting from the inspections.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.4.5 In all cases of foreign matter contamination, the affected batch or item shall be isolated, inspected, reworked, or disposed of. Records shall be maintained of the disposition.

RESPONSE: COMPLIANT

EVIDENCE: In a case of a foreign matter contamination may affect a batch or item, provisions are made to isolate, inspect, rework or disposed of.

11.8.1 **Waste Disposal**

Standard Operating Procedures: WASTE MANAGEMENT POLICY, Section 4.1.: the purpose of this program is to ensure that adequate facilities, equipment and containers are maintained for the storage of waste and inedible materials prior to removal from the establishment. Waste is removed and facilities and container are cleaned and sanitized at an appropriate frequency to minimize contamination. / The production Supervisor oversees the waste disposal activities of the production and cleaning staff and is the primary contact for the contract waste removal companies. The QA Manager oversees the laboratory hazardous material disposal, tests the wastewater, and verifies the waste procedures of the production and warehouse staff. Production and warehouse personnel are responsible for removing waste regularly in their areas. The contract cleaning company removes waste from the office and laboratories. Liquid wastes go down the drains and enter the wastewater tank. The wastewater is tested by QA and must have a pH of 5.5 - 11.5; if not in this range it will be adjusted and retested. QA gives approval to production to flush out the wastewater tank. This is documented on form LAB-FO26 and must be signed by QA and the production operator. Sample of Wastewater pH Check. Date: 11/28/2022. Equipment T-3. Qty of wastewater: 1,000 gal.

11.8.1.1 The responsibility and methods used to collect and handle dry, wet, and liquid waste and how to store it prior to removal from the premises shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

11.8.1.2 Waste shall be removed on a regular basis and not allowed to build up in food handling or processing areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until external waste collection is undertaken.

RESPONSE: COMPLIANT

EVIDENCE:

11.8.1.3 Waste and overflow water from tubs, tanks, and other equipment shall be discharged directly to the floor drainage system or by an alternative method that meets local regulatory requirements.

RESPONSE: COMPLIANT

EVIDENCE:

11.8.1.4 Trolleys, vehicle waste disposal equipment, collection bins, and storage areas shall be maintained in a serviceable condition, cleaned, and sanitized regularly to prevent the attraction of pests and other vermin.

RESPONSE: COMPLIANT

EVIDENCE:

11.8.1.5 Adequate provision shall be made for the disposal of all solid processing waste, including trimmings, inedible material, and used packaging.

RESPONSE: COMPLIANT

EVIDENCE:

11.8.1.6 Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials waste considered high-risk for handling or other reasons. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance.

RESPONSE: COMPLIANT

EVIDENCE:

11.8.1.8 Waste held on-site prior to disposal shall be stored in a separate storage facility that is suitably insect proofed and located where it does not present any hazards.

RESPONSE: COMPLIANT

EVIDENCE:

11.8.1.9 Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall either be removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal where it does not present any hazards.

RESPONSE: COMPLIANT

	EVIDENCE:
11.8.1.10	Reviews of the effectiveness of waste management shall form part of regular site inspections (refer to 2.5.4.3), and the results of these inspections shall be included in the relevant inspection reports. **RESPONSE:** COMPLIANT **EVIDENCE:**