SQF Quality Audit Edition 8.1
Tone Products - Tone Products, Inc.

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
640982 | 130274

DECISION DATE
02/22/2021

AUDIT TYPE
RECERTIFICATION

RECERTIFICATION DATE
01/29/2022

AUDIT DATES
01/26/2021 - 01/27/2021

EXPIRATION DATE
04/13/2022

ISSUE DATE
02/22/2021

Facility & Scope

Tone Products (43029)
Tone Products, Inc.
2129 N. 15th Ave
Melrose Park, IL 60160
United States

Web Site: http://www.toneproducts.com

Food Sector Categories:
16. Ice, Drink and Beverage Processing
18. Preserved Foods Manufacture

Products:
16. Beverage concentrates, bloody mary mix, ready-to-drink cocktail mixers, ready-to-drink cocktail mixers with alcohol
18.Barbecue sauce, dressing, flavoured syrup, marinades, pancake syrup

Scope of Certification:
16. Receiving, mixing, processing, filling, packing, storage and dispatch 18. Receiving, mixing, cooking, filling, packing, storage and dispatch

Certification Body & Audit Team

SGS Systems & Services Certification Pty Ltd

10/585 Blackburn Road
Notting Hill, Victoria, 3168
Australia

CB#: CB-1-SGS
Accreditation Body: JAS-ANZ
Accreditation Number: Z2630103AS

Lead Auditor: Guray, Frank (9341)
Technical Reviewer: Mato, Roy (200391)

Hours Spent on Site: 12
Hours of ICT Activities: 12
Hours Spent Writing Report: 8

Section Responses

2.1.1 Quality Policy

Q 2.1.1 Review and accepted of the following evidence: Quality Mission Statement (also translated in Spanish)[06-Jun-2018]. Review and accepted of the following evidence: FS&Q Policy Statement - Signed by Plant Manager[11-Oct-2019], Food Safety Standards: Introduction and SQF - AP, SV, JP[15-Dec-2020, 30-Nov-2020, 17-Sep-2020].

2.1.1.1 The policy statement prepared and implemented by senior site management to communicate the commitment to food safety shall also include at a minimum: i. The site's commitment to establish quality objectives; ii. The site's commitment to comply with customers' quality requirements; iii. The methods used to measure the site's quality objectives, and iv. The site's commitment to continually improve its quality performance.

RESPONSE: COMPLIANT

2.1.1.2 The site's vision and mission statement shall also be displayed in a prominent position and communicated to all staff. The vision and mission statement may be included in, or separate from, the organization's food safety policy.

RESPONSE: COMPLIANT

2.1.2 Management Responsibility

Q 2.1.2 Food quality responsibilities are integrated with food safety responsibilities. The SQFQP and backup are the same individuals as the SQFP. Confirmed HACCP Certification, as well as application of quality risks / control measures via interview. In addition, confirmed SQFQP's ability to reduce process variation and drive root cause analysis of nonconformities. Competencies were confirmed through direct observation / interview All job descriptions include quality responsibilities. Reviewed website for use of certification marks, no conformance issues observed. Review of Visitor GMP Handout, no certification mark issues. Review and accepted of the following evidence: Quarterly Report 2020 Quality Assurance Department - Production Error and Defect Data | Customer Complaint Report and Trend Analysis | Corrective Action Plan | Summary of the Quarter's Goals, Objectives, and Corrective Action Plan | Statement of Next Quarter's Goals and Objectives - 6 complaints for Q3, 2 for Q4[01-Oct-2020, 04-Jan-2021, 30-Jun-2020], Visitors Guide - SQF Logo Usage[R0]. Review and accepted of the following evidence: Operations Organizational Chart - SQFP reports to President / CEO[14-Sep-2020], SQF Training - BP | Food Safety Standards: Introduction and SQF - MG[26-Dec-2009, 20-Nov-2020], JOB DESCRIPTIONS –Tone Products[11-Oct-2019], Quarterly Report 2020 Quality Assurance Department - Production Error and Defect Data | Customer Complaint Report and Trend Analysis | Corrective Action Plan | Summary of the Quarter's Goals, Objectives, and Corrective Action Plan | Statement of Next Quarter's Goals and Objectives - 6 complaints for Q3, 2 for Q4[01-Oct-2020, 04-Jan-2021, 30-Jun-2020].

2.1.2.1 The senior site management shall develop quality objectives and a process by which quality performance is measured.

RESPONSE: COMPLIANT

2.1.2.2 The reporting structure shall identify personnel performing key process steps and responsible for achieving quality objectives.

RESPONSE: COMPLIANT

2.1.2.3 The senior site management shall ensure adequate resources are available to achieve quality objectives and customer quality requirements, and to support the development, implementation, maintenance and ongoing improvement of the SQF Quality System.

RESPONSE: COMPLIANT

2.1.2.4 Senior site management shall designate an SQF quality practitioner for each site with responsibility and authority to: i. Oversee the development, implementation, review and maintenance of the SQF Quality System including quality fundamentals outlined in 2.4.2, and the quality plan outlined in 2.4.3; ii. Take appropriate action to ensure the integrity of the SQF Quality System; iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF Quality System; and iv. Ensure that site personnel have the required competencies to carry out those functions affecting product quality.

RESPONSE: COMPLIANT

2.1.2.5 In addition to the SQF Food Safety Code requirements, the SQF quality practitioner shall: i. Be competent to implement and maintain HACCP-based food quality plans; ii. Understand the SQF Quality Code and the requirements to implement and maintain a quality management system; and iii. Be competent in process control and/or other quality tools (e.g. process control charts, histograms, process capability etc.) to reduce process variation and achieve customer requirements.

RESPONSE: COMPLIANT

2.1.2.6 Senior site management shall ensure site personnel responsible for performing key process steps and meeting customer requirements, and corporate quality requirements where applicable, have the required competencies to carry out those functions.

RESPONSE: COMPLIANT

2.1.2.7 Senior site management shall develop and implement a quality communication program to ensure that all staff are informed of their quality responsibilities, are aware of their role in meeting the requirements of the SQF Quality Code and are informed of the organization's performance against quality objectives. The program shall include: i. the defined vision and mission statement of the site; ii. the site's quality objectives and the process by which quality performance is measured, and iii. The methods by which customer quality requirements, and corporate quality requirements where applicable, are met.

RESPONSE: COMPLIANT

2.1.2.8 Job descriptions for personnel performing key process steps and responsible for achieving quality requirements shall be documented and include provision to cover for the absence of key personnel.

RESPONSE: COMPLIANT

2.1.2.9 Senior site management shall establish a process to trend progress in quality performance against agreed measures and objectives. The performance data including comparisons with external sources (e.g. industry, customers) shall be reviewed at least annually (see also 2.1.3.2) to demonstrate effectiveness of the quality management System and continuous improvement. Results shall be part of communication program to staff (see also 2.1.2.7). Senior site management shall establish a process to trend progress in quality performance against agreed measures. Benchmarking shall be part of this process and the performance data shall be reported at least annually to demonstrate effectiveness of the quality management system and communicated to all staff.

RESPONSE: COMPLIANT

2.1.2.10 Sites that are certified to the SQF Quality Code may use the SQF quality shield. Use of the SQF quality shield shall follow the requirements outlined in Appendix 5: SQF Quality Shield Rules of Use

RESPONSE: COMPLIANT

2.1.3 Management Review

Q 2.1.3 The SQF Quality System is reviewed at least annually. Implementation and Maintenance reviews are done at least daily. Review and accepted of the following evidence: Quality Plan Management Review[02-Oct-2020], Quarterly Report 2020 Quality Assurance Department - Production Error and Defect Data | Customer Complaint Report and Trend Analysis | Corrective Action Plan | Summary of the Quarter's Goals, Objectives, and Corrective Action Plan | Statement of Next Quarter's Goals and Objectives - 6 complaints for Q3, 2 for Q4[01-Oct-2020, 04-Jan-2021, 30-Jun-2020], Daily HACCP Meeting Record[04-Jan-2021, 04-Dec-2020, 11-Nov-2020]. Review and accepted of the following evidence: SQF Program Review[01-Dec-2020], Daily HACCP Meeting Record[04-Jan-2021, 04-Dec-2020, 11-Nov-2020].

2.1.3.1 Senior site management shall be responsible for reviewing the SQF Quality System. Reviews shall include actions required to: i. Monitor compliance to specifications; ii. Measure and reduce process and product variation; iii. Meet customer requirements; iv. Take appropriate corrective action where applicable, and v. Ensure sufficient resources are allocated to maintain and improve the performance of the Quality System.

RESPONSE: COMPLIANT

2.1.3.2 The SQF practitioner(s) shall update senior site management on a minimum monthly basis on matters impacting the implementation and maintenance of the SQF System. The updates and management responses shall be documented. The SQF Quality System in its entirety shall be reviewed at least annually.

RESPONSE: COMPLIANT

2.1.3.3 The Quality System, including food quality plans, shall be reviewed when any changes are implemented that have an impact on the site's ability to meet customer requirements and corporate quality requirements where applicable.

RESPONSE: COMPLIANT

2.1.3.4 Senior site management shall ensure the integrity and continued operation of the Quality System in the event of organizational or personnel changes within the company or associated facilities.

RESPONSE: COMPLIANT

2.1.3.5 Senior site management shall document and implement a change management process that details how changes in specifications, materials, equipment or resources are evaluated for their impact on quality, communicated to customers and effectively implemented.

RESPONSE: COMPLIANT

2.1.3.6 Records of all Quality System reviews and reasons for amending documents, and changes to the SQF Quality System shall be maintained. Records shall include decisions for actions related to improvement of the Quality System and process effectiveness.

RESPONSE: COMPLIANT

2.1.4 Complaint Management

Q 2.1.4 All complaints, including those of a quality nature, are managed by the same system. Review and accepted of the following evidence: Quarterly Report 2020 Quality Assurance Department - Production Error and Defect Data | Customer Complaint Report and Trend Analysis | Corrective Action Plan | Summary of the Quarter's Goals, Objectives, and Corrective Action Plan | Statement of Next Quarter's Goals and Objectives - 6 complaints for Q3, 2 for Q4[01-Oct-2020, 04-Jan-2021, 30-Jun-2020], Nature of Complaint, Observations, Corrective action; Also Root Cause Corrective Action Report[21-Jul-2020], (No Food Safety Complaints since the last audit) - Complaint Investigation Spreadsheet - Spoilage ; The wrong label was used; The customer reported a cocked cap[16-Apr-2020, 10-Jul-2020, 27-Oct-2020].

2.1.4.1 The complaint management process shall include a requirement to identify and resolve the cause of all quality complaints resulting from activities at the site.

RESPONSE: COMPLIANT

2.1.4.2 Trends in quality complaints shall be included in the performance measures established for the Quality System.

RESPONSE: COMPLIANT

2.1.4.3 Corrective action shall be implemented based on the seriousness of the incident and as outlined in 2.5.3.

RESPONSE: COMPLIANT

2.1.4.4 Records of quality complaints, their investigation and resolution (if applicable) shall be maintained.

RESPONSE: COMPLIANT

2.1.5 Crisis Management Planning

Q 2.1.5 Crisis Management system is in place, and includes quality elements built within QA Manager Responsibilities Additional methods to deliver product while down include: Culinary Co Pack - 3rd Party Company. Customer contact process includes: "...b. Lead all necessary measures to ensure that crisis response does not compromise product safety or quality..." Review and accepted of the following evidence: Food Defense Crisis Management Plan[15-Mar-2020], Daily HACCP Meeting[15-Mar-2020], Crisis Management and Product Retrieval - Emergency Contacts – Regulatory Agencies[22-Sep-2015], Verification & Test – Initiated 3/4/2020 and remains in effect until a formal closeout is issued and communicated to all staff[23-Nov-2020], Verification & Test – Initiated 3/4/2020 and remains in effect until a formal closeout is issued and communicated to all staff[23-Nov-2020].

2.1.5.1 The crisis management plan prepared by senior site management shall include the methods by which the site shall, in the event of a crisis, maintain continuity of supply that meets the customers' product and service quality requirements.

RESPONSE: COMPLIANT

2.1.5.2 The site shall contact their customers in the event of a crisis that impacts their ability to supply quality product.

RESPONSE: COMPLIANT

2.2.1 Quality Management System

Q 2.2.1 All elements of the quality code has been incorporated, which includes the quality statement and organizational chart. The quality program is in place for all products within the scope of the facility.

2.2.1.1 A quality manual shall be documented and maintained in either electronic and/or hard copy form. It shall outline the methods the site uses to meet the requirements of the SQF Quality Code, be made available to staff, and include: i. A summary of the organization’s quality policies and the methods it will apply to meet the requirements of the ii. SQF Quality Code; iii. The policy statement and site organization chart; iv. A list of the products covered under the scope of certification; v. Finished product specifications agreed with customers’ or corporate quality requirements where applicable; and vi. A description of the applications of process control methods and other quality tools that are used to control and reduce process variation and meet customer specifications The quality system manual may be incorporated into, or independent from the SQF food safety system manual.

RESPONSE: COMPLIANT

2.2.2 Document Control

Q 2.2.2 The Quality document control system is the same as the one used in the FSMS.

2.2.2.1 The methods and responsibility for maintenance, storage, and distribution of quality documents shall be the same as those required for SQF Food Safety System documentation.

RESPONSE: COMPLIANT

2.2.3 Records

Q 2.2.3 The Quality Records Control system is the same as the one used in the FSMS. Monitoring and record control procedures are in place. Review of various records throughout the process. See specific element for further commentary. Records are maintained for at least 3 years.

2.2.3.1 The methods and responsibility for authorization, accessibility, retention and storage of quality records shall be the same as those required for SQF Food Safety System records.

RESPONSE: COMPLIANT

2.3.1 Product Development and Realization

Q 2.3.1 Elements required to be evaluated in new products include: Kosher, Non-GMO, Density Requirement, . Product Development and Realization process is in place. There have not been any new products that are not line extensions since the last audit. Review and accepted of the following evidence: Shelf Life Test Report[16-Apr-2020], FORMULA ROUTING SHEET - Digital Signatures[12-Jan-2021, 06-Aug-2020], New Product Hazard Analysis - CCP Requirements, New Ingredient analysis, PRP Review, Allergen Risks[15-Jul-2020, 15-Oct-2020, 12-Jan-2020].

2.3.1.1 The methods for designing, developing and converting product concepts to commercial realization shall include a comparison of process controls with specification limits (process capability analysis) to ensure that processes are able to consistently supply products that meet customer specifications

RESPONSE: COMPLIANT

2.3.1.2 Product formulation, manufacturing processes and the fulfillment of product quality requirements shall be validated by facility trials and product testing.

RESPONSE: COMPLIANT

2.3.1.3 Shelf life trials shall be conducted to establish and validate a product's packaging, handling, storage and customer use requirements through to the end of its commercial life and consumer use.

RESPONSE: COMPLIANT

2.3.1.4 A food quality plan shall be validated and verified for each new product and its associated process from conversion to commercial production and distribution, or where a change to ingredients, processes, or packaging occurs that may impact food quality.

RESPONSE: COMPLIANT

2.3.1.5 Records of all quality tests, product design, process development, and shelf life trials associated with product changes or new product development shall be maintained.

RESPONSE: COMPLIANT

2.3.2 Raw and Packaging Materials

Q 2.3.2 Confirmed appropriate use through letters of guarantee. No evidence of use that may cause a negative impact on quality. Labels are provided by Customers through approved suppliers. Walkthrough and inspection of raw materials and packaging in storage rooms revealed no issues. Specifications are provided by the supplier. Validation of packaging materials are addressed through letters of guarantees and / or certifications. Review and accepted of the following evidence: Specification / Product Data Sheet / Technical Data[20-Feb-2019, 21-Aug-2017, 12-Aug-2008], Letter of Guarantee[29-Jan-2019, 01-Mar-2018], First Case Check - Broken Glass, Fill Temp, Case Code, Allergens, Previous Production Labels, Product - Label, Best By photo, Case photo[11-Sep-2020, 02-Nov-2020, 09-Jul-2020], Food and Packaging Raw Material Register[R0].

2.3.2.1 Specifications for all raw and packaging materials, including, but not limited to ingredients, additives, agricultural inputs (where applicable), hazardous chemicals and processing aids that impact on finished product quality shall be documented and kept current.

RESPONSE: COMPLIANT

2.3.2.2 Raw and packaging materials quality parameters shall be verified upon receipt to ensure they meet specifications (see also 2.5.2 and/or 2.5.4).

RESPONSE: COMPLIANT

2.3.2.3 Product labels that are designed or specified by customers shall be approved by those customers. Records shall be maintained of customer approvals.

RESPONSE: COMPLIANT

2.3.2.4 The register of current raw and packaging material specifications shall include those raw and packaging materials impacting product quality and customer labels.

RESPONSE: COMPLIANT

2.3.3 Contract Service Providers

Q 2.3.3 Contract service providers have not been dropped for performance issues since the last audit. No contradictory evidence observed. Providers include SGS and Ajax. Training requirements include Escort and / or GMP Review and accepted of the following evidence: Contract Services Registry - includes SGS[12-Jan-2021].

2.3.3.1 Specifications for contract services that have an impact on in-process or finished product quality shall be documented, current, include a full description of the service to be provided and detail relevant training requirements of contract personnel.

RESPONSE: COMPLIANT

2.3.3.2 The register of contract service specifications shall include those services impacting product quality.

RESPONSE: COMPLIANT

2.3.4 Contract Manufacturers

Q 2.3.4 N/A. Contract Manufacturing is not managed by this site.

2.3.4.1 The methods and responsibility for ensuring all agreements relating to customer product requirements and their realization and delivery are specified and agreed shall be documented and implemented.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Contract Manufacturing is not managed by this site.

2.3.4.2 The site shall: i. Ensure that the processes in place at the contract manufacturer are capable of consistently meeting customer requirements, or corporate quality requirements where applicable; ii. iii. Verify compliance with the SQF Quality Code and that all customer requirements are being met at all times; iv. Audit the contract manufacturer annually at a minimum to confirm compliance to the SQF Quality Code and agreed arrangements, or accept the manufacturer's certification to the SQF Quality Code or equivalent; and v. Ensure changes to contractual agreements are approved by both parties, agreed with customers where necessary, and communicated to relevant personnel.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Contract Manufacturing is not managed by this site.

2.3.4.3 Records of all contract reviews and changes to contractual agreements and their approvals extend to quality records.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Contract Manufacturing is not managed by this site.

2.3.5 Finished Product Specifications

Q 2.3.5 Quality elements are built within the product specifications. Review and accepted of the following evidence: Formula Routing Sheet[27-Jul-2020, 19-Feb-2020, 30-Jul-2020], HACCP Finished Goods Register[R0].

2.3.5.1 Finished product specifications shall be documented, current, approved by the site and their customer, accessible to relevant staff and shall include product quality attributes, service delivery requirements, and labelling and packaging requirements.

RESPONSE: COMPLIANT

2.3.5.2 Customer product specifications and delivery requirements shall be communicated to appropriate departments and staff within the site.

RESPONSE: COMPLIANT

2.4.1 Customer Requirements

Q 2.4.1 Requirements and expectations is confirmed through customer feedback. Review of customer / consumer expectations is done during management review. N/A. Customer owned materials are not maintained at this site.

2.4.1.1 The requirements and expectations of customers and final consumers shall be continually reviewed to ensure the accuracy of specifications and the ability to supply to customer needs. A full review of customer/consumer expectations for product and delivery shall occur at least annually and shall illustrate how the site is conforming to those expectations and/or requirements that are part of legal contracts or corporate policy. The site shall have a procedure in place to notify essential customers where their ability to supply product that meets customer specifications is temporarily suspended or halted.

RESPONSE: COMPLIANT

2.4.1.2 Where customer products, materials or equipment are used within the facility, the site shall have measures in place to safeguard customer property and ensure its correct and proper use.

RESPONSE: NOT APPLICABLE

EVIDENCE: N/A. Customer owned materials are not maintained at this site.

2.4.2 Quality Fundamentals

Q 2.4.2 Calibration failures involving quality measurements and requiring revisiting product disposition have not occured since the last audit. No contradictory evidence observed. External and internal walkthroughs of the site revealed no quality impact issues. Calibration reports include checks on thermometers and scales. Direct observation of storage and transport of materials used revealed no issues regarding product integrity for loss, waste, or damage. Calibration failures involving food safety and / or regulatory measurements and requiring revisiting product disposition have not occured since the last audit. No contradictory evidence observed. Calibration procedures are in place. No damage or unauthorized adjustments detected. Systems are in place. Calibration include use of 3rd party certifications. Review and accepted of the following evidence: OP006[12-Oct-2020], Calibration Certificates[16-Dec-2020], pH Calibration Record[11-Sep-2020, 02-Nov-2020, 09-Jul-2020].

2.4.2.1 The buildings and equipment shall be constructed, designed and maintained to facilitate the manufacture, handling, storage and/or delivery of food that meets customer specifications or corporate quality requirements.

RESPONSE: COMPLIANT

2.4.2.2 The methods and responsibility for the calibration of measuring, test and inspection equipment used for quality testing of raw materials, work-in-progress, and finished product, food quality 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

2.4.2.3 Storage and transport of raw materials, work-in progress, and finished product shall be suitable to maintain the integrity of the product without loss, waste or damage.

RESPONSE: COMPLIANT

2.4.3 Food Quality Plan

Q 2.4.3 The Quality HACCP Program has been developed using the Codex method. The food quality program is organized in the same way as the food safety plan. The food quality intended use is organized in the same way as the food safety counterpart. Food quality threats include: Formulation, Packaging, Physical. CQPs include Density, Viscosity. Quality critical limits are defined through the agreed finished product specifications. Review and accepted of the following evidence: Tone Products Quality Team[25-Aug-2014], Product Description[15-Aug-2014], Flow Chart[13-Aug-2014], Process Hazard Analysis for Food Quality[20-Dec-2018], FQP SUMMARY AND CQP IDENTIFICATION[20-Dec-2018], Batch Ticket Report - Brix, pH, Density[09-Sep-2020, 31-Oct-2020, 09-Jul-2020], Quality Plan Management Review[02-Oct-2020].

2.4.3.1 A food quality plan shall be developed, effectively implemented, and maintained in accordance with the Codex Alimentarius Commission HACCP method. The food quality plan may be combined with, or independent from, the food safety plan, but must separately identify quality threats and their controls, and critical quality points.

RESPONSE: COMPLIANT

2.4.3.2 The food quality plan shall outline the means by which the site controls and assures the quality attributes of the products or product groups and their associated processes.

RESPONSE: COMPLIANT

2.4.3.3 The food quality plan shall be developed and maintained by a multidisciplinary team that includes the SQF practitioner and those site personnel with technical, production, and marketing knowledge of the relevant products and associated processes. Where the relevant expertise is not available on site, advice may be obtained from other sources to assist the food quality team. The composition of the food quality team may be different from the food safety team.

RESPONSE: COMPLIANT

2.4.3.4 The scope of the food quality plan shall be developed and documented including the start and endpoint of the process under consideration and all relevant inputs and outputs.

RESPONSE: COMPLIANT

2.4.3.5 Product descriptions shall be developed and documented for all products included in the scope of the food quality plan. This shall include information in the finished product specifications (refer to 2.3.5.1) plus any additional quality or service attributes established by agreement with the customers.

RESPONSE: COMPLIANT

2.4.3.6 The intended use of each product shall be determined and documented by the food quality team. This shall include as appropriate target consumer groups, ease of use by consumers, consumer instructions, tamper evidence, and other applicable information affecting product quality.

RESPONSE: COMPLIANT

2.4.3.7 The food quality team shall review the flow diagram developed and confirmed as part of the food safety plan, and ensure process steps, process delays, and inputs that impact product quality are included.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.9 The food quality team shall conduct a quality threat analysis for every identified quality threat, to identify which threats are significant, i.e. their elimination or reduction to an acceptable level is necessary to ensure or maintain product quality. The methodology for determining threat significance shall be documented and used consistently to assess all potential quality threats.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.11 Based on the results of the threat analysis (refer to 2.4.3.9), the food quality team shall identify the steps in the process where control must be applied to eliminate a significant threat or reduce it to an acceptable level. These steps shall be identified as Critical Quality Points or CQPs.

RESPONSE: COMPLIANT

2.4.3.12 For each identified CQP, the food quality team shall identify and document the quality limits that separate acceptable from unacceptable product. The food quality team shall validate the critical quality limits to ensure the designated level of control of the identified quality threat (s); and that all critical quality limits and control measures individually or in combination effectively provide the level of control required.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.4.3.15 The documented and approved food quality plan shall be fully implemented. The effective implementation shall be monitored by the food quality team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, specifications or inputs occur which may affect product quality.

RESPONSE: COMPLIANT

2.4.3.16 Implemented food quality plans shall be verified as part of SQF Quality System verification (refer to 2.5).

RESPONSE: COMPLIANT

2.4.4 Approved Supplier Program

Q 2.4.4 Materials are provided by an approved supplier. Review and accepted of the following evidence: Receiving Log - with COA[02-Jan-2020, 21-Oct-2020, 30-Oct-2020], MAT001[02-Oct-2019]. Review and accepted of the following evidence: ISO22000[17-Sep-2021], Supplier Approval contact list and register[R0].

2.4.4.1 Raw materials, ingredients, packaging materials, and services that impact on finished product quality shall be supplied by an approved supplier.

RESPONSE: COMPLIANT

2.4.4.2 Material suppliers shall be selected and approved based on their ability to supply materials that meet quality specifications. The evaluation program shall require suppliers to: i. Maintain controlled and current copies of specifications; ii. Have processes that are capable of consistently supplying materials that meet specification and other defined quality metrics (e.g. delivery. service, adherence to specifications, etc.); iii. Provide evidence that supplied product meets agreed specifications; and iv. Have a complaints and corrective action process in place.

RESPONSE: COMPLIANT

2.4.4.3 Material suppliers shall only be accepted into the facility based on either certificates of analysis for every lot received, or inspection at receipt to ensure materials comply with specification.

RESPONSE: COMPLIANT

2.4.4.4 The approved supplier program shall include an agreement with suppliers for the return or disposal of materials that fail to meet specifications or are damaged or contaminated.

RESPONSE: COMPLIANT

2.4.5 Non-conforming Product or Equipment

Q 2.4.5 Nonconforming product process is in place and addresses both food safety, as well as food quality defects found. Reasons for holds include running out of labels. Confirmed hold process effectiveness with the following hold tag found in operations: 'GoCanvas - Anchor Glass Hold - 26 pallets[19-Jan-2021].

2.4.5.1 Non-conforming product shall include products that fail to meet in-process or product requirements for quality.

RESPONSE: COMPLIANT

2.4.5.2 Non-conforming equipment shall include equipment that is not suitable for use and is not capable of producing products that meet in-process or product requirements for quality.

RESPONSE: COMPLIANT

2.4.5.3 The site shall document and implement a procedure to accept returned product that does not meet finished product specifications. The procedure shall include handling of returned goods to prevent redistribution or contamination of other products.

RESPONSE: COMPLIANT

2.4.6 Product Rework

Q 2.4.6 Rework procedures are in place and addresses both food safety, as well as food quality defects to be corrected. N/A. Only rework with regards to product repair. No blending into different lot codes occur at this site.

2.4.6.1 Procedures shall be documented and implemented to ensure product quality or formulation is not compromised by the rework process.

RESPONSE: COMPLIANT

2.4.7 Product Release

Q 2.4.7 Product release requires all planned analyses and results being received and being within specifications. No contradictory evidence observed. Non-defective product is considered to be released upon completion of packaging. No early release events detected during the onsite or records review.

2.4.7.1 The site shall document and implement a positive product release procedure to ensure that, at the time of delivery to its customer, the food supplied complies with all agreed customer requirements including, but not limited to, product specifications, sensory, packaging and package integrity, labelling, delivery and service requirements.

RESPONSE: COMPLIANT

2.4.7.2 Records of all product release shall be maintained.

RESPONSE: COMPLIANT

2.5.1 Validation and Effectiveness

Q 2.5.1 Quality criteria is based on Customer specifications. Validation and effectiveness confirmation procedures are in place. Validation activities is documented through the Internal Audit and Management Reviews.

2.5.1.1 Validation activities shall include those necessary to authenticate critical quality limits, process controls, and other quality tests established to meet customer requirements.

RESPONSE: COMPLIANT

2.5.1.2 Records of validation of quality criteria shall be maintained.

RESPONSE: COMPLIANT

2.5.2 Verification Activities

Q 2.5.2 Verification procedures are in place. Review and accepted of the following evidence: Master Verification Schedule[17-Sep-2020].

2.5.2.1 The verification schedule shall include activities designed to ensure the effectiveness of process controls and quality tests.

RESPONSE: COMPLIANT

2.5.2.2 The methods, responsibility and criteria for verifying the effectiveness of monitoring critical quality points and other process and quality controls shall be documented and implemented. The methods applied shall ensure that personnel with responsibility for verifying monitoring activities authorize each record.

RESPONSE: COMPLIANT

2.5.2.3 Verification activities shall include a comparison of process control limit with specification limits to ensure alignment and appropriate process control corrections.

RESPONSE: COMPLIANT

2.5.2.4 Records of the verification of quality activities shall be maintained.

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action

Q 2.5.3 Corrective actions are in place for CQPs.

2.5.3.1 Corrective and preventative action methods shall include the identification of the root cause and resolution of non-compliance of critical quality limits and deviations from quality requirements.

RESPONSE: COMPLIANT

2.5.4 Product Sampling, Inspection and Analysis

Q 2.5.4 Visual inspection of on-site laboratories. Direct observation of checks conducted for CQPs, as well as interview for calibration elements. Sensory evaluation is done at the QC lab stations. Company uses measurements of Sigma - measurement of performance quarter to quarter - 6 is highest. Review and accepted of the following evidence: OP011A - Back Sheets - Color / Smell Taste - Screen Checks[10-Sep-2020, 02-Nov-2020, 09-Jul-2020], OP011A - Back Sheets - Color / Smell Taste - Screen Checks[10-Sep-2020, 02-Nov-2020, 09-Jul-2020], Quarterly Report 2020 Quality Assurance Department - Production Error and Defect Data | Customer Complaint Report and Trend Analysis | Corrective Action Plan | Summary of the Quarter's Goals, Objectives, and Corrective Action Plan | Statement of Next Quarter's Goals and Objectives - 6 complaints for Q3, 2 for Q4[01-Oct-2020, 04-Jan-2021, 30-Jun-2020], Weight Sheet - Fill Temp, Printed Code Date, Correct Label, Cap/Seal OK[09-Jul-2020].

2.5.4.1 Processing parameters or in-process measurements shall be established, validated, and verified at a determined frequency to meet all customer requirements.

RESPONSE: COMPLIANT

2.5.4.2 On-site laboratories and inspection stations shall be equipped and resourced to enable testing of in-process and finished products to meet customer expectations and meet quality objectives.

RESPONSE: COMPLIANT

2.5.4.3 Process control methods shall be used to effectively control and optimize production processes to improve process efficiency and product quality and reduce waste. Control charts and/or other quality tools shall be in use for control of key processes.

RESPONSE: COMPLIANT

2.5.4.4 A sensory evaluation program shall be in place to ensure alignment with agreed customer requirements. Sensory evaluation results shall be communicated with relevant staff and with customers where appropriate

RESPONSE: COMPLIANT

2.5.4.5 Records of all quality inspections and analyses, and statistical analyses, shall be maintained.

RESPONSE: COMPLIANT

2.5.5 Internal Audits

Q 2.5.5 Internal audit procedures are in place. Quarterly System Audit, unless a customer audit, government audit, or SQF audit occurs within that quarter. Site inspections are done monthly. No conflict of interest detected. System Internal audits are done 1 / year. Review and accepted of the following evidence: Internal Audit - JR[31-Mar-2020], Building A GMP Inspection with Corrective Actions[29-Oct-2020, 30-Nov-2020, 30-Dec-2020], Module 2, 9 - SQF Checklist[Q4-2020].

2.5.5.1 Internal audit plans and methods shall include food quality plans, process controls, quality tests, and other activities implemented to meet finished product specifications and customer requirements.

RESPONSE: COMPLIANT

2.5.5.2 Staff conducting the quality internal audits shall be trained and assessed in internal audit procedures and have knowledge and experience in the quality process and process control methods as they relate to the scope of certification.

RESPONSE: COMPLIANT

2.6.1 Product Identification

Q 2.6.1 Visual inspection of labels revealed no issues. Review and accepted of the following evidence: First Case Check - Broken Glass, Fill Temp, Case Code, Allergens, Previous Production Labels, Product - Label, Best By photo, Case photo[11-Sep-2020, 02-Nov-2020, 09-Jul-2020], First Case Check - Broken Glass, Fill Temp, Case Code, Allergens, Previous Production Labels, Product - Label, Best By photo, Case photo[11-Sep-2020, 02-Nov-2020, 09-Jul-2020]. Identification procedures are in place and were confirmed via walkthrough. Review and accepted of the following evidence: Production Schedules[10-Sep-2020, 02-Nov-2020, 09-Jul-2020], First Case Check - Broken Glass, Fill Temp, Case Code, Allergens, Previous Production Labels, Product - Label, Best By photo, Case photo[11-Sep-2020, 02-Nov-2020, 09-Jul-2020].

2.6.1.1 Finished product shall be labeled to the agreed customer, company or corporate requirements.

RESPONSE: COMPLIANT

2.6.1.2 Product changeover procedures shall include quality attributes required to meet finished product specifications and customer requirements.

RESPONSE: COMPLIANT

2.6.2 Product Trace

Q 2.6.2 Packaging is traceable back to the supplier. Review and accepted of the following evidence: First Case Check - Broken Glass, Fill Temp, Case Code, Allergens, Previous Production Labels, Product - Label, Best By photo, Case photo[11-Sep-2020, 02-Nov-2020, 09-Jul-2020]. Traceability procedures are in place. The traceability exercise is referenced within 2.6.3 for the mock recall program. Traceability link is described as the following: Receiving Log --> BOL --> Line Sheet --> Julian Date and Product #. Review and accepted of the following evidence: First Case Check - Broken Glass, Fill Temp, Case Code, Allergens, Previous Production Labels, Product - Label, Best By photo, Case photo[11-Sep-2020, 02-Nov-2020, 09-Jul-2020], BOL[02-Jan-2020, 21-Oct-2020, 30-Oct-2020], BOL (Stamped Trailer Inspection)[14-Sep-2020, 12-Nov-2020, 16-Jul-2020].

2.6.2.1 Finished product shall be traceable forward to the final customer, such as the retailer, distributor, or manufacturer.

RESPONSE: COMPLIANT

2.6.2.2 All raw materials, ingredients, and packaging materials used in manufacturing a finished product, and processing aids associated with the product, shall be identified with the finished product lot number and traceable back to the supplier (one back).

RESPONSE: COMPLIANT

2.6.3 Product Withdrawal and Recall

Q 2.6.3 Quality elements are included within the recall procedures. Program includes: "...4. Sorted product intended for redistribution shall be retested by TPI Quality Assurance to ensure that product quality standards are met..." Recall / Withdrawal Root Cause Analysis is addressed within: "...A review committee identified and led by the R/W Coordinator will establish the cause of the problem and will review corrective actions to determine if they are appropriate..."

2.6.3.1 The site's recall and withdrawal procedures shall apply to product recalled or withdrawn due to failure to meet customer specifications or corporate quality requirements.

RESPONSE: COMPLIANT

2.7.1 Food Fraud Vulnerability Assessment

Q 2.7.1 Food fraud instances have not been detected since the last audit. No contradictory evidence observed. Food fraud procedures are in place. The food fraud vulnerability assessment and mitigation plan is scheduled to be reviewed and verified at least 1 / year. Review and accepted of the following evidence: FDP 002 Food Defense Plan[17-Dec-2020], Existing Inventory Fraud Mitigation Inspection[10-Mar-2020, 09-Dec-2020].

2.7.1.1 2.7.1.1 The food fraud vulnerability assessment shall include the site’s susceptibility to ingredient or product substitution, mislabeling, dilution and counterfeiting that could adversely impact food quality.

RESPONSE: COMPLIANT

2.7.1.2 A food fraud mitigation plan shall be developed and implemented which specifies the methods by which the identified food fraud vulnerabilities that could adversely impact food quality shall be controlled.

RESPONSE: COMPLIANT

2.8.1 General Requirements for Identity Preserved Foods

Q 2.8.1 Kosher controls include use of Clam Powder(non-kosher) only used in Building B, no Kosher products in Building B Review and accepted of the following evidence: OU Kosher Certificate[25-Jan-2021, 25-Jan-2021].

2.8.1.1 The methods and responsibility for the identification and processing of food and other products requiring the preservation of their identity preserved status (e.g. Kosher, HALAL, organic, GMO-free, regional provenance, free from, free trade etc.) shall be documented and implemented.

RESPONSE: COMPLIANT

2.8.1.2 Identification shall include a statement of the product's identity preserved status of all ingredients, including additives, preservatives, processing aids and flavorings.

RESPONSE: COMPLIANT

2.8.1.3 Raw material and ingredient specifications to identity preserved foods shall include requirements for their handling, transport, storage and delivery prior to use.

RESPONSE: COMPLIANT

2.8.1.4 Assurances concerning the raw material or ingredient's identity preserved status shall be by agreement with the supplier of the material.

RESPONSE: COMPLIANT

2.8.1.5 The process description shall allow for a product's identity preserved status to be maintained during manufacturing.

RESPONSE: COMPLIANT

2.8.1.6 The processing of identity preserved foods shall be conducted under controlled conditions such that: i. Ingredients are physically separated from ingredients identified as incompatible with the identity preserved food; ii. Processing is completed in separate rooms; or scheduled as the first production run; or carried out after the completion of a thorough sanitation of the area and equipment; and iii. Finished product is stored and transported in separate units or isolated by a physical barrier from non- specialty product.

RESPONSE: COMPLIANT

2.8.1.7 The identity preserved status shall be declared in accordance with regulatory requirements.

RESPONSE: COMPLIANT

2.8.1.8 Additional customer-specific requirements concerning identity preserved foods shall be included in the finished product specification described in 2.3.5, or label register, and implemented by the site.

RESPONSE: COMPLIANT

2.9.1 Training Requirements

Q 2.9.1 The Training system is shared between the food safety, regulatory, and food quality systems.

2.9.1.1 Appropriate training shall be provided for personnel carrying out the tasks critical to the effective implementation of the SQF Quality System and the maintenance and improvement of quality requirements.

RESPONSE: COMPLIANT

2.9.2 Training Program

Q 2.9.2 The position training matches up with the job description for various positions. CQP and additional quality training aspects was confirmed via records review, interview, and direct observation.

2.9.2.1 The employee training program shall include the necessary competencies for specific duties and the training methods to be applied for those staff carrying out tasks associated with: i. Process control and monitoring of critical quality points (CQPs); ii. Steps identified as critical to effective implementation of the food quality plan and the maintenance of food quality, and iii. Product inspection and testing.

RESPONSE: COMPLIANT

2.9.2.2 The employee training program shall include applicable process control and quality tools training for line operators, quality inspectors and supervisory staff responsible for operating and inspecting key manufacturing processes.

RESPONSE: COMPLIANT

2.9.2.3 The training program shall include training, calibration and proficiency testing of internal laboratory personnel.

RESPONSE: COMPLIANT

2.9.3 Quality Instructions

Q 2.9.3 Language requirements are documented within 2.9.5 of this report. Review and accepted of the following evidence: QA002 Chemical Testing Procedure for WIP and finished goods[01-Jul-2014].

2.9.3.1 Instructions shall be available explaining how all tasks critical to meeting customer specifications, and quality and process efficiency are to be performed.

RESPONSE: COMPLIANT

2.9.4 HACCP for Quality Training Requirements

Q 2.9.4 Confirmed application of HACCP principles to address quality risks was done through interviews and direct observation. Review and accepted of the following evidence: HACCP Training - BP[17-Feb-2010], FSPCA Training - BP[26-May-2016].

2.9.4.1 Training in the application of HACCP principles for the identification and control of quality threats shall be provided to staff involved in development and maintenance of the food quality plan.

RESPONSE: COMPLIANT

2.9.5 Language

Q 2.9.5 Language spoken at this site is English with translations and interpreters available for Spanish Review and accepted of the following evidence: Reference Card cutouts English and Spanish[R0].

2.9.5.1 Training materials and the delivery of training shall be provided in language understood by staff.

RESPONSE: COMPLIANT

2.9.6 Refresher Training

Q 2.9.6 Refresher training is done 1 / year.

2.9.6.1 The training program shall include provision for identifying and implementing the refresher training needs of site personnel.

RESPONSE: COMPLIANT

2.9.7 Training Skills Register

Q 2.9.7 Sampling was done from individuals interviewed within the register to ensure completion. Review of training records within Alchemy. Review and accepted of the following evidence: Food Safety Standards: Introduction and SQF - AP, SV, JP[15-Dec-2020, 30-Nov-2020, 17-Sep-2020], Basic Food Facility Defense - MC[19-Dec-2020].

2.9.7.1 A training skills register describing who has been trained in relevant skills shall be maintained. The register shall indicate the: i. Participant name; ii. Skills description; iii. Description of the training provided; iv. Date training completed; v. Trainer or training provider; and vi. Supervisor's verification the training was completed, and that the trainee is competent to complete the required tasks.

RESPONSE: COMPLIANT