6.1 ACTIONS TO ADDRESS RISK AND OPPORTUNITIES

6.1.1 (2.4.2.1/ 2.4.2.2)

When planning for the quality management and Safe Quality Food systems, the organization has considered the issues referred in 4.1, the requirements in 4.2, (~~2.4.2~~ SQF Code, Good Manufacturing practices ~~Edition 8.1~~) and has determined the risks and opportunities that need to be addressed to:

- Give assurance that the QMS can achieve its intended results.
- Enhance desirable effects and prevent/ reduce undesired one's W 6.1.1 EMERGENCY AND CONTINGENCY PLAN
- Achieve improvement.
- Ensure the Good Manufacturing Practices described in modules 13 (as applicable) of the Food Safety Code for Manufacture of Food Packaging are applied D 6.1.1 NDA & GMP.

6.1.2 (2.1.5.1/ 2.1.5.2/ 2.1.5.3/ 2.1.5.4/ 2.6.3.1/ 2.6.3.2/ 2.6.3.3/ 2.6.3.4/ 2.6.3.5)

The organization has plan based on D 6.1.2 RISK RATING SCALE & MATRIX:

- Actions to address risk and opportunities.
- How to integrate, implement actions into QMS/ SQF as well as evaluate their effectiveness.

CRISIS MANAGEMENT PLANNING

A crisis management plan that is based on the understanding of known potential dangers (e.g., flood, drought, fire, tsunami, or other severe weather or regional events ~~such as warfare or civil unrest~~) 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 W 6.1.1 EMERGENCY AND CONTINGENCY PLAN.

The crisis management plan shall include as a minimum:

- A senior manager responsible for decision making, oversight and initiating actions arising from a crisis management incident;
- The nomination and training of a crisis management team;
- The controls implemented to ensure a response does not compromise product safety;
- The measures to isolate and identify product affected by a response to a crisis;
- The measures taken to verify the acceptability of food prior to release;
- The preparation and maintenance of a current crisis alert contact list, including supply chain customers;
- Sources of legal and expert advice;
- The responsibility for internal communications and communicating with authorities, external organizations and media.
- The crisis management plan shall be reviewed, tested, and verified at least annually. F 6.1.2 MOCK RECALL/ CRISIS RECORD.

The responsibility and methods used to withdraw or recall products shall be documented and implemented.

- Identify those responsible for initiating, managing and investigating a product withdrawal or recall;
- Describe the management procedures to be implemented including sources of legal, regulatory and expert advice and essential traceability information; and
- Outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident;
- SQFI, the certification body, and the appropriate regulatory authority shall be listed as an essential body and notified in instances of a food safety incident of a public nature, or product recall for any reason.

Investigation shall be undertaken to determine the root cause of a withdrawal, mock recall or recall and details of investigations and any action taken shall be documented.

The product withdrawal and recall system shall be reviewed, tested, and verified as effective at least annually. Testing shall include incoming materials (one back) and finished product (one up).

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.

Records of reviews of the crisis management plan, product withdrawals, recalls and mock recalls shall be maintained.

6.2 QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM

6.2.1

The organization has established quality objectives that are consistent with the quality policy, they are measurable, monitored and communicated, and focused on customer satisfaction. The quality objectives are reviewed and defined during Management Review Meeting.

6.2.2

The organization has determined D 6.2.2 QUALITY OBJECTIVES:

- What will be done. / Resources needed. /Responsible. / Completion. / How results will be evaluated.

6.3 (2.1.3.3) PLANNING OF CHANGES

When changes to the QMS, SQF systems are required, they will be in a planned manner considering:

- Purpose and their potential consequences.
- Integrity of both QMS and SQF systems.
- Availability of resources.
- Allocation or reallocation of responsibilities and authorities.
- impact on the site's ability to deliver safe food.

6.S (2.4.3.1/ 2.4.3.2/ 2.4.3.3/ 2.4.3.4/ 2.4.3.5/ 2.4.3.6/ 2.4.3.7/ 2.4.3.8/ 2.4.3.9/ 2.4.3.10/ 2.4.3.11/ 2.4.3.12/ 2.4.3.13/ 2.4.3.14/ 2.4.3.15/ 2.4.3.16/ 2.4.3.17)

FOOD SAFETY/ HACCP PLAN

- 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 outline the means by which the site controls and assures the manufacture of safe packaging product and included in the scope of the SQF certification and their associated manufacturing processes.
- The food safety plan 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 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.
- The scope of each food safety plan shall be developed and documented including the start and end-point of the manufacturing under consideration and all relevant inputs and outputs.
- Product descriptions shall be developed and documented for all packaging included in the scope of the food safety plans. This shall reference the finished product specifications (refer to 2.3.5.1) plus any additional information relevant to product safety, such as WVTR, gas permeability.
- The intended use of each product shall be determined and documented by the food safety team. This shall include requirements for further processing if applicable, and potential alternative use of the product.
- The team shall develop and document a flow diagram. The flow diagram shall include every step in the process, all raw material and service inputs (water, steam, gasses as appropriate), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team during all stages and hours of operation.
- The food safety team shall identify and document all packaging safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs.
- The food safety team shall conduct a hazard analysis for every identified hazard, to identify which hazards are significant, i.e. their elimination or reduction to an acceptable level is necessary to ensure food safety.

The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards.

- 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.
- Based on the results of the hazard analysis, the food safety team shall identify the steps in the manufacturing process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (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.
- For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product. The food safety team shall validate the critical limits to ensure the designated level of control of the identified safety hazard(s); and that all critical limits and control measures individually or in combination effectively provide the level of

control required.

- The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits. Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency.
- The food safety team shall develop and document deviation procedures that identify the disposition of affected packaging material 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.
- 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 occur which impact the safety of the product.
- Implemented food safety plans shall be verified as part of SQF System verification.
- Where applicable 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 applicable regulatory requirements.

6.S.1 (2.4.4.5/ 2.4.4.6/ 2.7.2.1/ 2.7.2.2/ 2.7.2.3/ 2.7.2.4) FOOD FRAUD

The methods, responsibility, and criteria for identifying the site's vulnerability to food fraud shall be documented, implemented and maintained. The food fraud vulnerability assessment shall include the site's susceptibility to product substitution, mislabeling, dilution, counterfeiting or stolen goods which may adversely impact food safety.

A food fraud mitigation plan shall be developed and implemented which specifies the methods by which the identified food fraud vulnerabilities shall be controlled.

The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually.

Records of reviews of the food fraud vulnerability assessment and mitigation plan shall be maintained.

REFERENCE OF DOCUMENTED INFORMATION

- W 6.1.1 EMERGENCY AND CONTINGENCY PLAN
- D 6.1.1 NDA & GMP
- D 6.1.2 RISK RATING SCALE & MATRIX
- F 6.1.2 MOCK RECALL/ CRISIS RECORD
- D 6.2.2 QUALITY OBJECTIVES