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Supplier & Co-Manufacture Quality Expectations

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(1) Introduction:

At John B. Sanfilippo & Son, Inc. (JBSS), we inspire trust by making safe food. The safety and quality of our products are of the highest importance to us– as are the trust and confidence of our consumers and customers. We recognize that the safety of our products is the foundation on which the success of our business is built. Safe food is at the core of our heritage and is ingrained in our culture. One of the ways we achieve this is by ensuring the strength of our food safety and quality systems. We expect that our suppliers and co-manufacturers share this commitment and for that purpose we have developed the JBSS Supplier/Co-manufacturing Quality Expectations (SCQE) Manual.

The SCQE Manual is available at JBSS by contacting a JBSS Procurement Representative or by visiting the JBSS Quality homepage (https://jbssinc.com/about-us/quality/). The SCQE outlined here are intended to help current and prospective new suppliers of ingredients, packaging materials and co-manufacturers to ensure that their own food safety and quality systems meet JBSS and Industry standards. These expectations have been developed by JBSS after a review of product defects, quality audits of manufacturing sites and a study of product retrievals throughout the food industry. This review led to the identification of programs, if executed properly, which help to prevent food safety incidents, product retrievals, consumer complaints, rework, and plant downtime, and produce high quality, safe products. All suppliers and co-manufacturing sites are required to be approved by JBSS prior to use. Approved manufacturing locations producing materials for JBSS must meet the expectations in this manual except for packaging suppliers for whom some sections do not apply.

The *JBSS SCQE Manual* contains elements that we believe are essential for the effective management of Food Safety, Quality and Food Defense. These are JBSS requirements. They are not intended to alter or eliminate any requirements that may be set in any contract, specification, or government regulation. Any questions about these standards should be addressed by contacting the appropriate JBSS Representative. By accepting any purchase order from JBSS, the Supplier acknowledges its acceptance of these expectations and its intention to comply with these requirements.

Definitions:

Terms	Definitions	Applicable sections of Manual (minimal)
Suppliers	all vendors including RTE Materials Suppliers, Warehousemen, Intermediaries, Raw Materials Suppliers and Co-Manufacturers as defined below.	See RTE, Raw, Warehouse or Co-Man
RTE Materials	Edible ingredients that are subjected to a validated kill step or have undergone a documented risk assessment that establishes that such edible ingredients are ready to eat. This would also include packaging that comes into contact with RTE Materials	N/A
RTE Material Suppliers	Vendors that supply RTE material	All chapters
Warehouseman	Third parties that store JBSS finished goods	1, 2, 5
Raw Materials	Edible ingredients that are not RTE, and packaging that does not contact any RTE Material	N/A
Intermediaries	Importers, distributors, and traders through whom JBSS purchases Raw Materials that are processed by third parties with whom JBSS has no contractual relationship.	None – but sources should meet applicable category sections (RTE, Raw, etc.)
Raw Material suppliers	Suppliers of Raw materials including Intermediaries. This includes warehousemen that are not storing finished goods and contract manufacturers who are not making RTE items	1, 3, 5
Contract Manufacturers	Third parties with whom JBSS contracts to process JBSS owned Raw Materials in whole or in part to make RTE materials or finished goods. For clarification, Co-Manufacturers would include Suppliers who perform pasteurization and PPO service.	Risk assessed by JBSS to determine requirements

Intermediate steps for commodity handling (e.g., blanchers, warehouse storage, accumulators, buying points) are not considered contract manufacturers.

For Brokers, Distributors and Traders
In cases where materials are being procured through brokers, distributors, and traders the following requirements must be followed:

- Only buy from JBSS approved manufacturing Locations. Supplier manufacturing locations must be disclosed to the JBSS Procurement Representative to assure that materials are only sourced from locations meeting JBSS requirements for quality and food safety.
- When food safety is a concern, distributor/broker may need to notify the supplier that the specific material will be delivered to JBSS
- The broker/distributor/trader has responsibility to ensure that supplier complies with these requirements
- The broker/distributor/trader must be required to notify JBSS of any manufacturing location changes. New sites and new lines must be approved prior to use.
- The broker/distributor/trader must demonstrate that traceability of materials to manufacturing location level is maintained.

(1.1) Confidentiality

The contracts between JBSS and the supplier will govern confidentiality of information shared by either company. All supplier personnel should take care not to disclose supplier confidential information to JBSS, unless there is a contract in place providing such disclosure. Auditors shall not be asked or required to sign confidentiality agreements as a prerequisite to gain access for audits prior to or at any time during a quality audit.

Auditors checking compliance to JBSS SQE requirements will not audit or inspect financial data, sales data, or pricing data unless it relates to JBSS. Auditors will not inspect personnel data, other than data relating to qualifications or training of technical and professional personnel performing functions pertinent to the audit.

(1.2) Notification of Significant Events (MANDATORY CONTACT)

Communication in the supply chain is critical when events occur that could affect food safety, quality, or processing. The supplier must establish procedures to ensure JBSS is immediately notified of these occurrences. The supplier shall notify a JBSS Procurement Representative immediately of any, but not limited to, the following:

- Systematic product quality defect or process control deviation which could lead to a recall or withdrawal of a JBSS finished product.
- Discovery of potentially defective or adulterated ingredients or packaging materials associated with product in distribution.
- Inadvertent release from Hold of any material produced for JBSS.
- Non-routine Regulatory Authority investigations, testing, sampling, reporting, or other contact or action with the potential to affect material produced for JBSS. JBSS does not need to be notified of routine inspections, unless the inspection reveals that material produced for JBSS may not be in compliance with applicable law.
- Any event that leads the supplier to suspect that a non-conformance (specification, Regulatory, etc.) exists in product already shipped to JBSS.
- Product tampering or threat of tampering.
- Event or substance that could threaten product security.
- Notification by law enforcement or other authority of a potential product security event.
- Changes in allergen profile or nutritional information in material produced for JBSS.
- Changes to supplier's processes and/or facilities
- Inability to deliver materials that meet Material Specifications.
- If any of the supplier sites manufacturing products for JBSS loses any type of certification (e.g. GFSI, AIB, Kosher, HALAL, Organic, GE etc.).

The supplier must notify JBSS with a phone call with a live person **and** by email. A voicemail, even coupled with an email, is not adequate. JBSS Procurement Representative shall be the primary contact for any contact or notification required by this document.

(1.3) Receiving Requirements

Materials will only be received by JBSS from approved suppliers. In no event, shall materials from a supplier, other than that agreed upon, be delivered unless previously authorized by JBSS.

- Raw materials (excluding nuts) shall have at least 50% of total shelf life remaining upon receipt for raw ingredient. Exceptions will require Procurement and Quality approval prior to arrival.
- When required by JBSS, Certificate of Analysis (COA) must accompany each lot of material. COA and other documents must contain at a minimum:
  - Supplier Business Name
  - Manufactured location address

- Commercial and/or technical name for product
- Lot number
- Testing results
- Quantity shipped
- PO number
- Date of Manufacture

- Ideally, each material delivery to JBSS should contain only one batch/lot number, however, each shipment may contain a maximum of **THREE** different lots, unless previously approved by Procurement. Exceptions will be made for suppliers when orders exceed batch size. All lot codes and their respective quantities must be clearly stated in the documentation submitted together with the shipment. If mixed lot pallets are utilized, the supplier shall clearly identify the pallet as a MIXED LOT. Ingredient suppliers shall include the MIXED LOT identification on all four sides of the pallet.
- Materials should be delivered with clean slip sheets between the material and the pallet.

(1.4) **Contract Manufacturing**

Contract manufacturers are defined as facilities that are contracted by JBSS to produce, process, pack and/or store part of or all of one or more products included in the sites SQF scope of certification.

JBSS contract manufacturers are held to the same food safety and quality standard as our suppliers. As such, the term "supplier" used throughout this document is applicable to co-manufacturers. Contract Manufacturers will be risk assessed to determine applicable sections.

Proposition 65

Suppliers providing material containing a chemical or chemicals listed by the State of California pursuant to the Health and Safety Code Section 25249.5 et. sec. (commonly called "Proposition 65") shall notify JBSS in writing of the material name, listed chemical(s) involved, expected concentrations, and the warning statement the supplier provides with the material. If the material is not expected to contain such chemicals at a concentration requiring a warning, suppliers should provide a statement to that effect.

Non-conforming Materials

When a delivery, either in part or whole, is evaluated to be unacceptable, the supplier will be contacted and could result in one or more of the following options, dependent on the circumstances:

- Return of the product to the supplier (costs to be paid by the supplier).
- Supplier sending a representative to examine the batch, sorting, and uplifting non-conforming items.
- Supplier paying for the costs incurred by JBSS in the sorting of the batch (in which case costs would be agreed in advance between JBSS and the supplier).

In the case of a proven defective article causing a cost to JBSS, JBSS retains the right to obtain compensation.

(2) QUALITY SYSTEM CONTROLS

The supplier shall have implemented a written Quality Management System (QMS) to ensure that the material produced conforms to specified requirements. At a minimum, the Quality System shall ensure compliance with the JBSS SCQE, the agreed upon specification for the specific product, and all applicable Regulatory requirements of the production country and the destination to which the products will be delivered. The Quality System shall clearly set out the source of each food safety and quality requirement. The Quality System shall also set forth the specific personnel responsible for compliance with each requirement through use of an organizational chart. The supplier shall review the Quality System on a regularly scheduled basis to verify that it remains adequate to comply with all requirements.

The supplier shall maintain records sufficient to show effective implementation of the Quality System. The Quality System will clearly identify the records that must be maintained to show effective implementation, and controls needed for identification, storage, protection, retrieval, retention, and disposition of records.

- The records be kept as original records, true copies, or electronic records
- That records contain the actual values and observations obtained during monitoring
- That records be accurate, indelible, and legible
- That records be created at same time activity being documented occurs, i.e., real time and be detailed as needed to provide a history

- That the records include (1) the name and location of the plant or facility; (2) the date and time of the activity documented; (3) the signature or initials of the person performing the activity; and (4) where appropriate, the identity of the product and the production code

For ingredients delivered to JBSS that were produced or will be sold in the United States and Canada, records shall be retained for at least two years. In addition to the requirements set out above, the supplier's Quality System shall specifically include controls to ensure the following:

- Outsourcing: Any outsourced process that affects material or ingredients produced for JBSS shall meet the same requirements and be managed by the supplier.
- Special certifications: If JBSS specifications require specific certifications – such as Organic, Kosher, non-GE or Halal certification – then the Manufacturing Location must be certified by an appropriate certifying body of the country in which JBSS will receive the material.
- No cloned animal products: No milk, meat, or other ingredients derived from cloned animals shall be used to make JBSS materials.
- Irradiation: Suppliers of irradiated raw materials and products must comply with Regulations for these products both in the local country and the country of use. If material is irradiated in package, a certificate of process is required (no COA required). If material is irradiated and re-packaged, both a certificate of analysis and certificate of process are required. Supplier shall utilize JBSS approved irradiation process based on the specific material and the needed lethality.

(2.1) JBSS AUDIT/INSPECTION REQUIREMENTS

All Manufacturing Locations producing ingredients for JBSS must be approved by JBSS. The same applies to new suppliers of food contact package materials and package materials with ingredient statements printed. Approval requires documentation-relevant to the ingredient being procured as well as an audit.

The frequency and type of approval audit required by JBSS is dependent on the type of material supplied and includes the following:

- JBSS employee
- GFSI or other recognized food safety audit report (through a 3rd party), corrective actions **AND** certificate will be requested by JBSS as part of the approval

Suppliers must permit JBSS or its representatives to enter and audit any establishment manufacturing, storing or supplying materials for JBSS. The audit /inspection requirements are prioritized based upon the experience with the supplier and the type of material produced for JBSS at that location.

JBSS utilizes a tier process for ingredients purchased. Placement of the ingredients into the appropriate tier on the matrix is based on several risk factors that include, but are not limited to the following: microbial sensitivity of the ingredient, type of manufacturing process, experience with supplier, etc. More sensitive ingredients may require an audit by JBSS while a 3rd party audit (GFSI required) may be acceptable for less sensitive ingredients. Audit frequencies are dictated based on supplier/material risk. To become or remain an approved supplier, the appropriate material documentation must be kept current and audit findings must be acceptable to JBSS.

General audit requirements

Separate audits are required for each manufacturing location that produces material for JBSS. The supplier shall inform JBSS if they plan to change the manufacturing location of the materials supplied to JBSS to allow time to assess whether a new approval is needed. The supplier shall notify the JBSS representative of any ingredient which is produced or processed in a plant not entirely owned or operated by the supplier.

The JBSS audit/inspection shall extend to all areas, including all pertinent production and storage areas, deemed necessary to evaluate whether the material produced for JBSS meets requirements and specifications. The audit/inspection may include, but is not limited to, equipment, finished and unfinished materials, containers, labeling, records, processes, and controls. The supplier must implement all corrective actions identified in the JBSS audit within the time frame agreed on in the audit corrective action plan. In addition, for audits conducted by JBSS, corrective actions shall be reviewed by a JBSS employee at a maximum of 6 months post the distribution of the final audit report.

Global Food Safety Initiative (GFSI) Certification

As a company we continue to move towards more industry-accepted certifications, and to this end, it is expected that all domestic ingredient suppliers to JBSS attain Global Food Safety Initiative (GFSI) certification. Current certifications accepted for ingredients can be found at www.mygfsi.com.

(2.2) INTERNAL AUDITS

The supplier shall establish and maintain written procedures for conducting internal audits to verify whether the Quality System and food safety programs, including the relevant content of this SQE Manual, are adequately implemented. The internal audit program shall ensure that each function /area is audited at a defined frequency.

Results of previous audits must be considered when planning future audits. Employees may conduct audits but should only be assigned to audit areas in which they do not work. The audit procedures shall provide for follow-up audit activities to verify and record the implementation of corrective actions taken. The effectiveness of the corrective action shall be verified, and additional actions must be implemented where necessary. The audit must be completed and closed-out within an established timeframe. Supplier's management shall review audit results, corrective actions, and follow-up as part of regular meetings.

(2.3) REGULATORY AUDITS

The supplier shall have written procedures and designated, trained personnel to manage inspections by and contacts with Regulatory Authorities. Procedures shall address how the supplier will follow up and obtain closure of any issues arising from such inspections or contacts. The supplier shall maintain, at the facility, records of all Regulatory inspections and contacts, including any reports issued by inspectors, facility responses, and corrective actions taken, for a period according to local Regulatory requirements.

In the event, a Regulatory Authority samples material produced for JBSS, the supplier shall contact JBSS Procurement Representative for instruction. Refer to Section 1.2, Notification of Significant Events

(2.4) FOOD DEFENSE PLAN

Suppliers acting on behalf of JBSS that manufacture or in any way handle purchased materials will develop specific procedures to secure our product, to deter and prevent intentional contamination, and will have protocols in place to identify, respond to, and contain threats or acts of intentional contamination quickly and accurately. Likewise, suppliers will ensure their suppliers adopt similar protocols and implement appropriate controls.

The laws and government expectations regarding Food Defense vary from country to country. JBSS has defined a set of Food Defense standards to help us meet legal and consumer expectations. The standards may exceed the requirements of a specific country or area. However, all suppliers for JBSS are expected to develop Manufacturing Location Food Defense programs that meet set standards outlined below and be prepared to provide JBSS with confirmation that they have met these requirements.

Requirements for a Food Defense program applicable to all suppliers:

1. Program Administration
   (a) A documented plan that explains the site's Food Defense procedures and strategies.
   (b) Clearly defined roles and responsibilities for maintaining the program.
   (c) Procedures for reporting threats or acts of intentional contamination/adulteration to JBSS.
   (d) Annual vulnerability self-assessments and procedures for fixing gaps.
   (e) Compliance to FSMA Intentional Adulteration Rule

2. Access control - a system which will deter people with the intent of harming our products from gaining access to do so. The system shall include procedures to identify people who are regularly on site (e.g., employees and contractors) and to limit access to restricted areas to authorized people only. Specifically:

   (a) Processing and Manufacturing areas
   (b) Ingredient and raw material storage areas (to include packaging stocks)
   (c) Hazardous and chemical storage areas
   (d) Shipping and receiving areas

3. Shipping and Receiving: The supplier shall take deliberate steps, and implement procedures, to monitor and verify the integrity of incoming and outgoing shipments.

(2.5) FOOD FRAUD

The supplier shall have a food fraud program to address acts of potential intentional adulteration in food ingredients and products. Suppliers shall assess the risk for their operation and take appropriate steps to prevent issues that may impact product safety

or quality. A food fraud program should include a vulnerability assessment and food fraud mitigation strategies to prevent food fraud in the supply chain. Also, a food fraud program should address economically motivated adulteration (EMA) and product misbranding. Types of food fraud are defined below:

Dilution: mixing an ingredient of high value with an ingredient of lower value
Substitution: replacing an ingredient or part of the product of high value with another ingredient of lower value
Concealment: hiding low quality food ingredients or product
Unapproved enhancements: adding unknown and undeclared materials to food products to enhance their quality attributes
Mislabeling/misbranding: placing false claims on packaging or economic gain
Counterfeiting (IPR): copying the brand name, packing concept, recipe, processing method, etc. of food products for economic gain
Grey Market Production/Overrun/Theft/Diversion: products sold by a manufacturer or their authorized agent outside the terms of the agreement between the reseller/distributor and the manufacturer

Any acts of food fraud by a supplier or Co-manufacturer as listed above may result in disapproval as a JBSS supplier.

(2.6) CONTROLS FOR TESTING

The supplier shall ensure that personnel responsible for conducting testing and/or monitoring have access to all necessary information, such as laboratory methods manuals, raw material specifications, packaging specifications, finished product specifications, test requirements and parameters, and laboratory procedures, in order to be able to carry out properly their responsibilities with respect to materials produced for JBSS. Testing and monitoring programs shall be based on generally recognized methods or test methods that have been approved by JBSS for their intended use.

All supplier plant laboratories and laboratory personnel shall comply with Good Laboratory Practice requirements including, but not limited to, the following:

- The supplier shall implement a procedure to identify samples submitted to the laboratory to ensure traceability from the sample to the reporting of a result.
- Laboratory chemicals with high toxicity, bacterial positive control cultures and solvents not in immediate use must be secured and locked, with access restricted to authorized personnel. A secured laboratory (access controlled, locked when not occupied, and periodic inventory) is adequate for the storage of chemicals used on a routine basis.
- Laboratory materials shall be restricted to use in the laboratory, except as needed for sampling or other appropriate use activities. Unexplained additions and withdrawals must be immediately investigated and reported to appropriate law enforcement and public health authorities.
- Procedures must be in place for positive control, tracking and disposition of sensitive materials.

Laboratory requirements for pathogen testing

Pathogen testing required for materials delivered to JBSS shall only be performed by accredited laboratories using ISO standards. Samples from an Environmental Testing Program may be analyzed at the supplier's pathogen laboratory provided requirements for internal lab are met as follows:

1. The laboratory design and practices must prevent the potential for cross-contamination of pathogens by restricting access to authorized personnel.
2. At a minimum, signs must be posted to indicate that the area is restricted.
3. Relative air pressure of the pathogen laboratory shall be negative to the adjacent rooms.
4. The air in microbiology laboratories shall be filtered by a F8 (MERV 14-15) filter.
5. Any potentially infectious material shall be sterilized prior to disposal.
6. Annual participation in proficiency sample program (ISO 43 accredited) to demonstrate capability
7. The methods used shall be AOAC validated

(2.7) CONTROLS FOR TESTING: MEASURING AND MONITORING EQUIPMENT

The supplier shall have implemented a written process that is available to all appropriate personnel to inspect, test, and calibrate measuring and monitoring equipment. The process shall ensure the precision and accuracy of the equipment such that measurement capability is consistent with the measurement requirements. Calibration procedures for each piece of measuring and monitoring equipment, including equipment used to control, measure, or monitor critical control points/process preventive controls (CCPs/PCs) and equipment used for laboratory testing, shall include the following information:

- Whether the equipment is used to control, measure, or monitor CCPs/PCs.
- Minimum required accuracy or allowable tolerance for the device.
- Corrective actions to be taken when the results of a calibration are out of specified limits.

The supplier shall establish and maintain a master list of all measuring and monitoring equipment that can affect food safety and/or product quality to be controlled by the program including:

- Name of the equipment and a unique identifier.
- Location of the equipment.
- Calibration frequency (*Note*: Equipment used to measure a CCP/PC shall be calibrated once per year or more frequent in accordance with equipment history)
- The method of calibration
- What the equipment is used for
- Personnel responsible for the activity

Critical Measurement Equipment must be calibrated at or near the process parameter. Calibration shall be against known and valid standards which are traceable to international or national measurement standards. Where no such standards exist, the method of establishing and maintaining the standard for calibration shall be documented.
Calibration shall be performed under suitable environmental conditions, based on stability, purpose and degree of usage of such equipment. Calibration checks shall be documented including date, personnel initials and actual comparison results, and calibration results indicating the degree of inaccuracy and any adjustments made to bring the equipment back into calibration.

Product that may have been affected due to equipment being out of calibration shall be evaluated. If the equipment is used to monitor or measure a CCP/PC, an assessment shall be carried out to determine any potential food safety risk with regard to product tested during the period when the equipment was possibly out of calibration.

(2.8) CORRECTIVE ACTION / PREVENTIVE ACTION - CAPA

All programs mandated by this *SQE Manual* require that Corrective and/or Preventive Actions be taken in the event of non-conformances. The supplier shall have an effective CAPA program tracking such actions to ensure that non-conformances in any program are addressed in an appropriate and timely manner.

An effective CAPA program shall include the following steps:

- Issue is defined elements to include in description (what, where, who, when and extent)
- Documentation of root cause analysis tools/process (i.e., 5 Why tool, fishbone diagram)
- Implementation Plan and Action register identifying task to be completed, task owner, scheduled close out date and actual close out date
- Identification of long-term (permanent) solutions (including responsibilities and timing). When required, resources (e.g., personnel, finances, equipment) must also be identified.
- Verification of effectiveness with documented evidence and timing
- Periodic review of CAPA by the management team.

The CAPA program shall include procedures for analysis of effectiveness of corrective actions for, at a minimum, each of the following:

- Out of specification process or product
- Products found to deviate from critical limits/parameters of a CCP/PC.
- Customer/Consumer feedback, including complaints.
- Failure to meet external, Regulatory or customer requirements.
- Issues arising from internal audits, external audits, and Regulatory inspections/contacts.
- Product retrieval.
- Supplier performance measures.

The CAPA program shall address proper means of managing incoming customer contacts to enable an accurate, appropriate, and timely response.

(3) FACILITY ENVIRONMENTAL CONTROLS

(3.1) GOOD MANUFACTURING PRACTICES (GMP)

All persons entering the Supplier facility (plant personnel, visitors, and outside contractors) shall be trained and comply with GMP requirements. GMPs shall be based on 21CFR Part 110 and 117 (FSMA) and the Codex Alimentarius Commission's

recommendations for general principles of food hygiene and comply with Local or National Regulatory requirements. GMPs must be in writing and available to all personnel. Supplier shall review and update GMP requirements on a periodic basis.

A supplier shall maintain hygienic GMPs by requiring the following practices:

- Any person affected by disease considered to be communicable shall not work in an area whereby food contamination may occur. This would include, but not be limited to, persons affected with severe colds, boils, infected sores, etc.
- Individuals working the in the manufacturing area must wear clean outer garments in a manner that will protect against the contamination of food, food contact surfaces, or food packaging materials.
- Wear appropriate hair and beard nets. Beard nets shall be worn whenever there is facial hair present of if a moustache extends below the limps and/or extends beyond the width of the mouth.
- Rings (other than plain wedding bands), watches, earrings, necklaces, or other jewelry (including ornaments or piercing in exposed body areas such as the tongue and/or nose) must not be worn in GMP areas. Plain wedding bands are permitted to be worn by employees who do not handle or work in the proximity of exposed product.
- Hand washing is required before starting work and before returning to workstation after performing other functions (e. g. after eating, drinking, or smoking, handling contaminated material or sanitation materials, or after using the restroom).
- Lunches/food must be stored and consumed in designated areas only.

Storage of Materials

- All items shall be stored to avoid direct contact with the floor or walking surfaces (e.g., on pallets, slip sheets or racks). The storage area shall be designed to allow maintenance and cleaning, prevent contamination, and minimize deterioration.
- Product, ingredients, and rework must be adequately protected and stored in a sanitary manner
- Ingredients must be adequately protected and stored in a sanitary manner in their original, labeled container, or in another authorized sanitary container that is clearly marked for the use of the specific ingredient (e.g., sanitary pails or tote bins). Ingredient identification and lot number/traceability must be maintained. Containers must be properly closed/sealed/covered. When returning ingredient containers to storage, ensure ingredients are stored in the proper temperature environment
- Rework product shall be adequately covered/protected, and traceability of rework shall be maintained

Packaging Materials must be adequately protected and stored in a sanitary manner.

- Material shall be covered to prevent contamination (e.g., closures, films)
- Packaging material must be removed from the area during wet cleaning
- Direct product contact packaging must be properly covered and sealed during storage and staging

(3.2) PERSONEL TRAINING

The supplier shall ensure that all employees receive appropriate training for their job functions and shall maintain records of training. Specific training requirements are as follows:

- GMPs - All employees, new, temporary, and seasonal personnel, must receive GMP training, including a section on Employee Illness and Communicable Disease (see more below), as part of the orientation process.
- Production Personnel - Training for supplier personnel who work in production areas must include the following principles: Quality, Food Safety Plans/HACCP, Allergens, Foreign Object Prevention, Food Defense, and Food Fraud.
- Critical Control Point / Preventive Control (CCP/PC) Monitors - Employees monitoring CCPs/PCs must receive further specific training on monitoring, documentation, verification, and corrective actions if critical limits are not met.
- Additional Requirements based on job specific functions, such as Regulatory inspections, pest management, hold & release and pathogen environmental monitoring where requirements are set forth in other sections of this manual.

Training shall be provided to new employees before starting work in production. Refresher training on these topics shall be **provided at least annually**. The supplier shall maintain records of personnel education, training, skills, and experience. The supplier shall also periodically evaluate the effectiveness of its training programs.
The supplier shall provide visitors and contractors with site specific training programs, as necessary, prior to performing activities which may affect product safety or quality.

Employee Illness and Communicable Disease

The supplier shall establish instructions which include provisions for recognition and identification of symptoms of employee illness or communicable disease such as, but not limited to: diarrhea; vomiting; open skin sores; boils; fever; dark urine; jaundice or any other symptoms associated with geographical, region-specific diseases as defined by local medical experts.

Note: Local regulations, customs and practices concerning what information employees can be required to provide vary significantly from country to country, must be respected, and may vary the requirements of this policy. This policy shall be implemented in those cases where employees with a disease communicable via food have made information about their Illness available to the company either voluntarily or in response to permissible questions. In all cases the employee's right to confidentiality of the information provided shall be respected.

Supplier instructions shall be available and communicated to all applicable personnel. The instructions shall, at a minimum, include:

- No person shall be admitted into a GMP area if he or she carries, or has been exposed to, any potential source of a microbial or viral contamination.
- Information for recognition of symptoms of communicable disease as well as symptoms associated with region-specific diseases as defined by local medical experts.
- A process by which the supplier can evaluate the potential impact to product should an active employee be diagnosed with communicable disease.
- Procedures to ensure that employees afflicted with a communicable disease are removed from the Manufacturing facility or are reassigned to a non-food contact area. In determining suitable work areas for affected employees, the supplier shall consider the risk of cross infection to other employees.
- Policy should include a written medical certification of recovery to be obtained prior to the employees returning to work in a direct product contact function.

(3.3) PLANT STRUCTURE

The Manufacturing Location shall be of adequate design and construction to ensure production of safe and high quality materials. The facility, including utility fixtures, shall be designed to prevent potential contamination sources from affecting the purchased materials. The plant structure shall provide adequate physical separation to prevent any cross contamination (e.g. raw and processed, allergen and non-allergen). Facility grounds must be maintained to address food defense considerations. The Location and design of waste bins, toilets and hand washing, drying and sanitizing facilities shall be adequate to comply with GMPs. The supplier shall ensure that the facility is satisfactorily maintained.

Plant Design and Construction

- The internal and external structure shall be free of cracks, holes, openings, and pest entry or nesting areas.
- All exterior doors shall be self-closing and must form an adequate seal when closed. Loading docks shall be protected to prevent pest entry. Entrance of air shall be limited by vestibules or air curtains as appropriate.
- Windows present in production areas that can be opened must be adequately screened. Open windows are prohibited in manufacturing areas with exposed sensitive products. All vents and fans shall also be adequately screened.
- Doors, windows, and other openings shall prevent access by unauthorized people.
- The plant structure must be designed to physically separate raw and processed zones, as necessary. Where raw and processed zones are utilized, traffic patterns between zones must be controlled.
- Floors, walls, ceilings, overheads and drains shall be cleanable and constructed to resist deterioration from product or cleaning chemicals.
- Floors shall be sealed, in good repair, sloped adequately to avoid standing water, and pitched to a drain. The wall/floor juncture should be concave.
- Floor drains must be accessible and cleanable.
- Laboratories must be separated from the production areas. At a minimum, laboratories should be in a separate room with a door. Additional separation requirements apply to microbiology laboratories.

Personnel facilities

- The location and number of hand washing, drying and sanitizing facilities provided shall be adequate for the location and number of employees in the facility.
- Hot and cold water, soap/sanitizer, hand drying facilities and a waste bin must be available at hand washing and cleaning stations.
- Separate sinks and cleaning stations must be provided for hand washing, food contact equipment cleaning, and the disposal of wastewater.
- The location and number of toilet facilities shall be adequate, and each facility must include hand washing and drying facilities.
- Toilets and shower facilities shall not have direct entrances to food production areas.
- Toilets shall have a flushing mechanism and be of appropriate design to prevent contamination of employee's clothes and shoes

(3.4) UTILITIES MANAGEMENT

The Supplier shall have implemented programs to ensure safe provision of Utility Services in food production areas. Utility Services include environmental air, compressed air, water, steam, and centralized hydraulic systems.
The Supplier shall control access points for the above referenced Utility Services, as well as electricity, heating, and ventilation. Access may be controlled by any means deemed effective, such as locked facilities which only authorized employees can open.

Environmental Air

- Air quality shall be monitored, trended, and reviewed by appropriate personnel, as necessary to ensure suitable microbiological quality. The Supplier program must include monitoring in production areas with exposed microbiologically sensitive materials that will not receive a subsequent kill step. Corrective action shall be taken for out of standard results.
- The integrity of air filters shall be checked as part of regular preventive maintenance.
- The Supplier shall maintain suitable air pressure differentials between adjacent areas with different microbiological sensitivities in relationship to positive, negative, or ambient airflow to prevent product contamination. (please refer to Section 3.9 - Zoning in the SQE Manual).
- Exterior air intake ports shall be examined periodically for physical integrity.
- Air for a production area shall not be sourced from an unprocessed product area (raw).
- Air blown on the surface of microbiologically sensitive materials shall be sourced from within the production area.

Compressed Air

- Compressed air for general applications, to include ingredient, product contact, non-product contact, and packaging, shall be dry, oil free and filtered to remove foreign particles.
- Compressors that provide air for direct or indirect product contact shall be of oil free design. Where air from existing oil lubricated compressors is used for direct or indirect product contact, the following requirements apply: only food grade oil shall be used, vapor and odor filters must be installed prior to use where possible, and filter changes shall be managed by maintenance
- When used as an ingredient, or in contact with microbiologically sensitive materials, or their packaging, or in contact with product contact surfaces (e.g., during cleaning), compressed air shall be filtered at the point of use and dried to prevent condensation within the pipelines.

Water

- The potable water supply system (including ice that contacts the product) shall meet all applicable local, national, and international regulatory requirements.
- The site shall have effective programs to control water microbiological quality and to verify that water meets specified requirements. Microbiological tests shall be performed periodically and reviewed by appropriate personnel to demonstrate adequacy. Corrective action shall be initiated and documented for out of standard results.
- Water used as an ingredient, processing aid, reclaim water, hand wash water, for brine solutions, and as sanitation final rinse shall meet specified quality and microbiological requirements relevant to the product.
- Disinfection (e.g., chlorination, ozonation, UV light) of surface and well (ground) water is required for all direct product uses (e.g., ingredient, sanitation, rinse, drinking) and indirect product uses (e.g., re-circulated cooling water, hand wash). Residual chlorine and ozone must be periodically tested. Corrective actions shall be taken when levels do not meet the required limits.
- The extraneous matter risk in incoming water needs to be controlled using filters when needed (e.g., well water).
- Filtration systems (e.g., charcoal, reverse osmosis) shall be regularly inspected and maintained. Water systems must not have cross connections between treated and untreated supplies. Incoming water lines must be fitted with one-way valves or a header tank.
- For surface or well water sources, a visual turbidity assessment shall be carried out at a defined frequency. Testing shall also be carried out following any event which may adversely affect turbidity, such as abnormally heavy rain or flooding.

Steam

- Steam shall be of the appropriate quality and purity to meet process and usage needs.

- Culinary Steam or Clean Steam is suitable for direct product contact and can be directly injected into the product without a subsequent rinse or primary packaging if filtered and delivered through stainless steel pipework that meets AISI 304 and 316 specifications.
- Culinary, Clean and Process steam condensate quality shall be routinely evaluated for turbidity, off flavors and particulates at a frequency to demonstrate sufficient control
- Where process steam is used for product contact applications it must be delivered from a boiler system treated with approved food grade chemicals

Utilities Corrective Action Standards

- All utilities testing standards shall be set for applicable areas based on a risk assessment.
- Environmental/compressed air, steam, and water shall be monitored on a periodic basis.
- Applicable corrective action limits shall be defined and followed for all out of specification test results.
- Recordkeeping and record review shall be in place for corrective action plans

Utilities chemicals

Solvents, boiler chemicals, cleaning agents and other chemicals not in immediate use must be stored in locked areas with controlled access.

(3.5) Equipment Design & Validation

The supplier shall ensure that equipment design is adequate for production of materials that meet food safety and quality parameters. Equipment used in the manufacture of food ingredients or food contact packaging shall be:

- Cleanable
- Made of materials compatible with food and sanitation
- Smooth and accessible surfaces
- Capable of protecting product from contamination
- Self-draining
- Free from openings that could allow product or water to penetrate voids
- Designed to allow for proper ventilation

Each new capital installation or modification to existing equipment design shall undergo a documented Sanitary Design Review by a cross-functional team (e.g., quality, sanitation, production, maintenance) in the design phase and commissioning phase of the project. The review shall evaluate the design against applicable industry sanitary design standards.

Piping and Duct Work/Insulation

- Where pipes and ducts must be insulated to prevent product from being contaminated by condensate, the insulation must be cleanable, or coated to be cleanable, and maintained in good repair.

Food Contact Surfaces

- Food contact surfaces shall be made of approved or suitable food contact materials. The product contact surfaces must be smooth, and continuously welded.
- Use of nuts and bolts in product contact zones shall be avoided where possible.

(3.6) Equipment Maintenance

The supplier shall ensure that equipment and materials used for production are suitable for the purpose intended and in good repair. The supplier shall have implemented a written program for preventive and corrective maintenance that is up to date and includes:

- All devices used to monitor and/or control food safety hazards
- A list of food handling equipment.
- Procedures detailing the maintenance required for each piece of equipment, including requirements for release back into production and frequency of maintenance.
- Measures to ensure that, after maintenance activities (e.g., drilling, cutting, polishing and welding) have occurred, the equipment and facilities are clean, sanitized, and in good repair prior to release for production.
- Appropriate measures to protect products during repair or maintenance activities.
- Procedures for isolating maintenance work areas from active production lines.
- A description of required maintenance records.

The program shall be tailored to the specific products or facilities. Priority shall be given to maintenance of pieces of equipment that may affect food safety, quality, or employee safety. Preventive maintenance frequency shall be adjusted in accordance with equipment history and the outcome of the last intervention.

Equipment repairs are intended to be permanent and must be performed using proper materials. Temporary fixes that may adversely impact the food safety or quality of a product must be dated, documented, and replaced in a timely manner by permanent repairs.

(3.7) Sanitation

The supplier shall have implemented a written Sanitation program that ensures cleanliness of the food production environment, equipment (including tankers inbound and outbound) and tools. The program shall address:

- Sanitation schedules, procedures, methods, and frequencies.
- Correct use of appropriate sanitation equipment and tools
- Equipment disassembly and re-assembly
- Use of food grade cleaning, sanitizing, and disinfecting products
- Chemicals to be used and how they are to be used including chemical concentrations, contact time, temperatures, frequencies, and rinsing procedures
- Verification of sanitation effectiveness
- Hygiene (non-pathogen) monitoring programs
- Cleaning Effectiveness
- Recordkeeping, record review, and corrective action plans

The following considerations shall be considered when designing the Sanitation program:

- Type of cleaning process:
    - Dry cleaning: method used to clean equipment that does not involve the direct use of water. Examples: scraping, brushing, vacuums, and equipment wipe down with damp disposable wipes.
    - Wet cleaning: method used to clean equipment to a microbiological level that involves the direct use of water and chemicals. Examples: rinsing, foaming, bucket, and brush.
- Equipment idle time: Situations when prolonged equipment downtime can lead to microbiological growth. Plants should have a program that defines the maximum idle time that can occur prior to inspection, sanitizing, or full re-clean being required.
- Protocols with controls for extending production runs beyond established Sanitation cycle times.
- Adequate product protection when Sanitation activities occur adjacent to operating production areas.
- Clean–In Place/Cleaning Out of Place (CIP/COP).
- Equipment that is wet cleaned which needs to be used in a dry condition. General housekeeping, equipment cleaning and sanitation and facility cleaning and sanitation programs and procedures shall be in place, documented and appropriately conducted to assure the appropriate standards of food hygiene are maintained at all times and the risk of product contamination is minimized. The requirements of this policy also apply to all outside service providers of cleaning and/or sanitation services
- Post-cleaning or pre-start up inspections to confirm that equipment is clean, properly assembled, free from chemical residues and sanitized prior to use.
- Verification and documentation of the effectiveness of the Sanitation program.

(3.8) Pest Management

The supplier shall have implemented a written pest management program to monitor and control pest activity in the facility and the surrounding area effectively. The pest management program shall include:

- Pest management plans, methods, schedules
- Inspection procedures and frequencies for plant infrastructure, pests, and all pest devices that demonstrate control
- Required documentation of pest activity log and analysis of records for trends in activity
- Documented corrective actions for increased trends /activity
- Training requirements.
- A dated map showing the Location of pest control devices, such as indoor rodent traps, glue boards, insect light traps, outdoor bait stations, and pheromone traps
- Records of application of pesticides and inventory
- An effective bird control program (if needed) and bird control practices
- Regulatory laws shall be checked before attempting bird control
- Nesting in sight or places to roost may attract birds and shall be eliminated
- An effective Sanitation program that eliminates food sources must be maintained

Wherever feasible and practical, non-pesticide pest management practices or alternative methods and tools shall be employed for controlling pests (e.g., strategies of exclusion and trapping of pests). If pesticides are used, the supplier shall ensure that they are used in accordance with local regulations and those pesticide's residues do not exceed limits established by the law of both the location of the facility and the location where JBSS will receive the material. The supplier shall ensure that appropriate measures are taken to prevent pesticides from contaminating food products.

Pest control activities shall be performed by certified pest control contractors or personnel with equivalent training.

Use of pesticides

Residual insecticides shall not be applied as a fog or an aerosol. Pesticide use and application shall be strictly controlled and in accordance with the label. Chemicals used for pest control must be accurately labeled, inventoried and, when not in use, securely stored (by locked door/gate) with access granted to authorized and designated personnel only.
The following practices shall be followed:

- Pesticide lot numbers shall be documented on usage records to assure traceability.
- All pesticide labels and Safety Data Sheets (SDS) or equivalent material addressing safety precautions shall be available at the facility where the pesticide is used.
- All EPA registration numbers, where applicable, shall be maintained and available at the facility where the pesticide is used.
- Disposal of unused pesticides and of empty pesticide containers must comply with applicable Regulatory requirements.
- Baits shall be used in situations where a specific pest is the target. Where used, bait stations shall be of solid construction, tamper resistant, and securely anchored to the ground or building.
- Rodenticides used must be in block or gel type form only; granular, pellet or powdered form shall not be used. For routine monitoring, rodenticides shall only be used on the exterior of the facility.

Insect Light Traps (ILT) / Pheromone Traps

ILTs shall be utilized as surveillance devices to monitor flying insect activity. They are not considered a control method. Light bulbs from the insect light traps must be kept clean and be replaced regularly (minimum annually) to ensure maximum efficiency. The insect light traps shall be installed in the receiving or warehouse areas close to entrances but shall be located so as not to attract insects into the building. It is recommended that the trap contents be evaluated monthly, and pheromone traps be inspected bi-weekly.

(3.9) Hygienic Zoning

All suppliers that manufacture JBSS materials shall have a Hygienic Zoning program designed to reduce the potential for environmental microbial cross contamination of materials and products from the environment or other materials. Hygienic Zoning refers to the division of areas of the facility based on barriers, cleaning procedures, employee practices and control of movement of people, equipment, and materials necessary to protect products from potential microbiological hazards originating from the Manufacturing environment and its surroundings. Hygienic Zoning programs shall focus on ensuring that appropriate controls exist to protect product, raw materials, and packaging during their movement from one area to another in a facility, and to protect the production environment where exposed product and materials might become contaminated from higher risk areas of the Manufacturing Location.

The importance of Hygienic Zoning programs will vary based on the product type and design of the Manufacturing process and process flow. The evaluation should consider both potential pathogen and spoilage contamination.

A Hygienic Zoning program shall consist of three parts:

1. Hygienic Zoning assessment:

The supplier shall carry out a risk assessment to identify potential sources of cross-contamination between production areas and/or products (e.g., product handling areas, storage areas, production areas, raw materials) and document them on a map of the Manufacturing Location. This assessment shall be reviewed and updated in the event of changes to plant layout and the introduction of new lines or processes. Based on the Hygienic Zoning assessment, the different areas of the production facility shall be classified as follows:

Non-Production or Non-Manufacturing Area:

- Areas where there is no open product.
- Includes non-production areas such as utility rooms, offices, cafeteria, locker room, laboratories

Transition Area:

- Areas adjacent to basic GMP areas, raw areas, and/or primary pathogen control areas (PPCA) where it is required for employees to change into personal protective equipment (e.g., smocks, hairnets, shoe covers), required for employees to wash hands at handwash stations, and step through foot sanitizer.
- Includes production entry area/room or smock changing areas/rooms within the production area

Basic GMP area:

- Areas that must be kept clean to meet basic GMP requirements.
- Includes general receiving and storage areas as well as general processing areas

Raw Area:

- Areas, such as raw meat/raw milk/raw nuts receiving, storage and processing areas, that are known to potentially be contaminated and which require controls to prevent contamination of higher hygiene areas such as PPCA.
- These areas often require the use of dedicated employees and may be physically separated from basic GMP areas, PPCA, and high hygiene areas.

Primary Pathogen Control Area (PPCA):

- Areas that contain Ready-to-Eat (RTE) ingredients / products that can be exposed to the production environment and the operators (e.g., packaging areas for finished products, processing areas with exposed RTE ingredients/products).
- More stringent sanitation requirements may be required in these areas to minimize the potential for cross-contamination
- Controlled personnel access (e.g., color-coded uniforms, shoe covers, captive footwear) and dedicated equipment (e.g., carts, forklifts) may be required in these areas.
- Environmental monitoring for pathogens of concern (e.g., *Salmonella, Listeria* spp.) is a focus in these areas for verification of sanitation effectiveness
- GMP practices are implemented, and appropriate air requirements are met.
- When products are exposed, additional production practices, such as prohibiting the use of cardboard, wooden pallets, etc. should be implemented

Sensitive / High Hygiene Area:

- Product which supports growth of pathogens (*Salmonella* or *Listeria monocytogenes*) and can be exposed to the environment and/or the operators.
- Areas that include production areas/rooms that are used to make food products specifically for sensitive populations (e.g. infants, clinical settings like hospitals).
- Additional GMP practices, such as captive footwear/clothing, may be required and more stringent equipment/building sanitary design requirements are followed
- When products are exposed, additional production practices, such as prohibiting the use of cardboard, wooden pallets, etc. should be implemented

2. Identification and implementation of controls to address risks and prevent cross contamination

The supplier may need to introduce or adjust controls such as physical measures or barriers, traffic management, utility controls, GMP measures, and Sanitation controls.

3. Evaluation and verification of the Hygienic Zoning program

The supplier shall periodically evaluate the effectiveness and compliance of zoning requirements. This may include, but is not limited to, environmental testing including pathogen testing, GMP audits, and routine pre-operational and operational inspections. Physical measures/barriers, Traffic Control, Infrastructure, Utility Controls and GMP measures should all be considered during the risk assessment for the zoning program.

(3.10) Pathogen Environmental Monitoring

Where deemed necessary based on the microbiological risk assessment and regulatory requirements (e.g. FDA FSMA), a robust pathogen environmental monitoring program shall be implemented. The program should be based on the zoning principles. Definitions of each zone is described in the table below.

Zone 1	Product Contact Area	Product contact, area vertically above product contact surface up to the ceiling, and all surfaces from which liquids or particulates may drain, diffuse, or be drawn into the product or onto a product contact surface.
Zone 2	Non-Product Contact Area	Non-product contact surfaces that are in proximity or adjacent to food and food-contact surfaces. This may include exterior of equipment, framework, equipment housing, carts staged near production lines, operator control buttons and switches, weight scales, panels, tools, hoses, and drains that are in close proximately to Zone 1.
Zone 3	Non-Product Contact Area	Non-food-contact surfaces that are in the production or processing areas but are more remote. Includes floors, walls, ceilings, drains, and other equipment (e.g. carts, lifts, pallet jacks)

Zone 4	Non-Product Contact Area	Non-product contact surfaces outside the process/packaging areas. Includes employee welfare areas (e.g. break rooms, locker rooms, and offices) and non-manufacturing areas (e.g. finished product warehouse, maintenance shop, and trash compactor room).

Areas to swab: The pathogen environmental monitoring swabbing sites shall include Zone 2, 3, and 4 areas. Limited swabbing can be done in raw areas based on risk assessment.

Areas not to swab: Zone 1 product contact surfaces should not be swabbed for pathogens unless dictated by regulatory requirements and appropriate controls (e.g. entire production lot of product is on hold until testing results are received and appropriate full sanitation breaks between production runs) are in place.

When to swab: Samples are to be taken no sooner than 3 to 4 hours into the production run. Vary the times that swabs are taken during the production run (e.g. different shifts, different days). If an area is cleaned by sanitation, wait a minimum of 3 to 4 hours before swabbing that area.

Swabbing technique: Use a standardized and aseptic technique for swabbing. Use aseptic technique, swab an area within arm's reach to cover as much surface area as possible.

Frequency: At least once a month (preferably weekly) on a rotation.

Number of swabs: The number of swabs taken depend on the size of the facility and the complexity of the manufacturing line(s) with a minimum of 5 swabs per line. More swabs should be taken in Zone 2 and 3 than Zone 4.

What to test for: Swabs shall be tested for the pathogens of concern (Listeria genus and Salmonella). In some cases, other pathogens (e.g. E. coli, Cronobacter) may need to be tested based on the product and regulatory requirements.

Specification limits: Specification limits shall be established (e.g. expected results for pathogens are Negative).

Shipping swab samples: Swab samples should be appropriately labeled. Keep swabs refrigerated until shipping to the testing laboratory. Optimal time between swab sample collection and testing is 24 to 48 hours. Samples shall be sent to an accredited laboratory (e.g. ISO 17025, A2LA) using appropriate standard approved methods (e.g. FDA BAM, AOAC, ISO).

Corrective actions: Presumptive (suspect positive) and positive results shall be investigated immediately. Corrective actions shall be documented for any positive results. Some examples of corrective actions include vector swabbing, cleaning/sanitation, and re-swabbing. The action taken should be equal to the seriousness of the finding. If positive results are obtained, the swab must be repeated at least with 3 re-swabs of negative results to ensure the corrective action has been effective.

FINISHED PRODUCT PATHOGEN TESTING

Samples shall be collected throughout the production run for finished product pathogen testing. Standardized microbiological testing schemes shall be used (e.g. International Commission on Microbiological Specifications for Foods (ICMSF), FDA BAM Chapter 1). For Salmonella sampling and testing, FDA BAM shall be followed as outlined below.

Food Category I	Foods that would not normally be subjected to a process lethal to Salmonella between the time of sampling and consumption and are intended for consumption by the aged, the infirm, and infants.	60 sample units	4 x 375 g
Food Category II	Foods that would not normally be subjected to a process lethal to Salmonella between the time of sampling and consumption.	30 sample units	2 x 375 g
Food Category III	Foods that would normally be subjected to a process lethal to Salmonella between the time of sampling and consumption.	15 sample units	1 x 375 g

When a finished product has tested positive for pathogens, all products made on the line on which the product was run since the last wet cleaning under the plant's control shall be put on hold. Immediately following the sampling of the product, the line on which the product was made shall be shut down and wet cleaned and sanitized. If the results of the testing are unacceptable, the product should be properly placed on hold and appropriately dispositioned.

(4) PRODUCTION PROCESS CONTROLS

(4.1) Specification and Compliance Contract

The supplier shall ensure that the agreed upon specification(s) are implemented at the Manufacturing Location and that appropriate plant personnel have access to the latest specifications for materials supplied to JBSS.

Supplier will be notified of the specifications and/or updated specifications when available. Supplier shall ensure delivery of the specifications and updated specifications to Supplier's Manufacturing Locations, production facilities and appropriate plant personnel.

The supplier must deliver materials that meet these Specifications. If the supplier anticipates that it will not be able to meet an updated specification, a JBSS Representative shall be notified immediately (see *Section 1.2- Notifying JBSS of Significant Events*).

In cases where JBSS require pathogen analysis, each lot must be sampled, and the samples must be collected across the lot according to a statistical sampling plan (ICMSF, FDA BAM) that represents the lot. If target pathogen(s) are detected in the lot, prompt corrective action steps shall be taken and JBSS shall be immediately notified. Certificates of Analysis (COA) are required for all received materials and must be provided to JBSS prior to acceptance of the material at JBSS locations. If a pathogen test is required for the COA based on JBSS request or specification, the test must be performed by an ISO standard accredited laboratory (see *Section 2.5 – Testing Controls: Laboratory Requirements*). JBSS reserves the right to sample each delivery and to determine the appropriate disposition. The COA from the laboratory or a supplier generated COA (e.g., through SAP), must be provided to JBSS and shall include the following information as a minimum:

- Approved laboratory name, address of Location performing any pathogen testing.
- Supplier name, address, phone number, and contact person
- Address of the Manufacturing plant where the material was produced.
- Material name, lot code, production date and JBSS identification number (if available)
- Specification number (or purchase agreement) and issue date.
- Test and analysis results for each lot, preferably including JBSS specification target and range.
- Parameter being tested, test method, sample size and date of test.

Certificate of Analysis should be written in local language of the receiving JBSS plant.

(4.2) Food Safety Plans and Hazard Analysis and Critical Control Points (HACCP)

The supplier's products shall be designed, produced, and distributed using Food Safety principles to minimize food safety risks systematically. The supplier shall have implemented a written Food Safety Plan/HACCP plan for all materials produced for JBSS. Hazards should be identified, associated risks assessed, Critical Control Points/ Preventive Controls (CCPs/PCs) identified and defined, Prerequisite Programs specified, methods for control identified and criteria for compliance clearly defined, as described by the **Codex Guidelines seven principles of HACCP** (Codex Alimentarius CAC/RCP 1-1969, Rev. 4 (2003), the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) HACCP guidelines and FDA Food Modernization Act "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (21 CFR Part 117). The supplier shall establish a cross-functional Food Safety/HACCP team that is responsible for developing, reviewing, and modifying the plans and maintaining the system. The Food Safety/HACCP team shall ensure that each Food Safety/HACCP plan and its implementation is properly verified and validated on a regular, documented basis. Ingredient suppliers should have a written Food Safety Plan/HACCP approved or have plans to become approved within the first 3 months of becoming a JBSS approved supplier.

When producing goods for JBSS, the performance objective of all processes/technologies used to reduce target pathogenic organisms must be defined and validated. A validation is a collection and evaluation of scientific and technical information (or conducting studies) to determine if the treatment when properly applied, will effectively control the hazard. Validations studies are required for process technologies implemented as a Process Preventive Control for pathogen reduction in foods. Validation studies must be performed or overseen by a Preventive Controls Qualified Individual (PCQI) and have Process Authority expertise in validations. Data demonstrating effective processing (capable processing) must be made available to JBSS, upon request. Further, supplier program requirements must include on-going verification of effectiveness conducted at a minimum frequency of every two years or validation when a major change occurs (e.g. equipment change, process change, validation method change).

(4.3) Incoming Materials: Supplier Quality Management

The supplier shall buy materials only from suppliers who are approved through a program designed to manage their quality and food safety. The program should include a risk assessment and audit by the company, GFSI, or accredited 3rd party auditor.

The supplier shall develop and document quality expectations, requirements and/or specifications for purchased goods that are consistent with the programs in this *SCQE Manual* and provide them to their suppliers. Purchased goods specifications shall be consistent with JBSS raw material specifications (when applicable).

The supplier shall have a process to review higher risk materials which do not undergo a kill step at the supplier's own Manufacturing site. This review should meet Industry Standard assessments (i.e. ICMSF). An emergency plan for accepting goods from a non-approved supplier shall also be in place.

The supplier shall monitor suppliers of purchased goods and provide feedback with respect to their performance and compliance with quality requirements and specifications.

(4.4) Incoming Materials: Inspection and Testing

The supplier shall ensure that incoming ingredients and packaging materials comply with applicable regulations and the supplier's specifications, including microbiological, physical, chemical criteria, and residue requirements. The supplier shall establish and, upon request, make available to JBSS testing requirements, parameters, and specified limits to ensure food safety and quality of all ingredients and packaging materials.

The supplier shall ensure that incoming materials are not used or processed until they have been inspected or otherwise verified as conforming to specified requirements. Where pathogen testing is conducted, a Hold and Release procedure shall be applied until testing is complete.

Raw agricultural materials and ingredients from animal origin must be evaluated to ensure compliance with chemical contaminant (e.g., pesticides residues, mycotoxins) and applicable GE regulations of the JBSS receiving country and as per JBSS specifications. Such review may be conducted through analysis of the material or through controlled oversight of the grower, producer and other persons handling the product.

Prior to accepting incoming materials, the supplier must verify that delivery vehicles (such as trucks or railcars) have maintained the quality and safety of the materials during transit. Verification activities shall be documented and shall include inspection of internal cleanliness, structural integrity, inspection of seal integrity (including that the seal numbers match the transportation documentation e.g., Bill of Lading, and measurement of internal temperature for refrigerated or frozen items. Trucks should remain locked when not in use.

Tankers shall be dedicated to food only – with records available for the previous product shipped. If applicable, they should be adequately cleaned and sanitized.

Inbound loads suspected of any type of tampering shall be investigated by supplier. The shipment shall be rejected if the source of tampering cannot be determined. Access points to material receiving lines shall be identified, capped, and locked unless otherwise approved.

(4.5) Traceability

The supplier shall have implemented a written program for product traceability based upon the GS1 Recall standard, assuring that package and pallet, lot codes, and date information are accurate and consistent across similar businesses and products. Traceability requirements apply to all products and all components used to produce products, including ingredients, in-process products, rework, primary packaging materials, and/or process intermediated being shipped to JBSS.

If requested, such as in the event of a product recall or other product-related issue, the supplier must provide the relevant traceability information to JBSS within 4 hours with a goal of 100% traceability to the point where the product is no longer within the facility's control. Mock recalls shall be conducted at least once a year to validate the effectiveness of the traceability program.

For ingredients that may not have a specific lot number, a method for unique identification and tracking shall be developed and implemented. Bulk use of ingredients shall be required to have a documented timeframe of known use. At a minimum each individual pallet shall be made up of only one batch/lot number or labeled that pallet contains multiple lots. It is recommended that representative samples from all lots produced for JBSS be kept until the expiration of the material.

In the United States, the Bioterrorism Act, mandates that all members of the food chain shall be able to trace goods at least one step forward and one step backward, as well as know the shipper/transporter of the goods.

(4.6) Allergen Management

The supplier shall have an effective program to evaluate, identify, and control food allergens to ensure that specific allergens are not inadvertently incorporated as an undeclared component of any product. The information provided by the supplier should allow for an unambiguous determination of the need for allergen declaration in a JBSS product.

An Allergen Assessment shall be carried out as part of Food Safety Plan/HACCP Plan development to identify, review, and document allergens likely to be present. The Allergen Assessment shall consider possible sources of allergens related to the formulation, process, and site-specific practices, including raw materials/ingredients, processing aids, rework addition and potential for cross-contact in manufacturing, storage, or shipment practices. The Allergen Assessment must consider the eight major food allergens (milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soybeans) and sesame, mustard, sulfites, and gluten (when appropriate) as well as any others identified in local regulations and regulations of the countries to which the product is shipped to. An assessment shall be conducted whenever the source of a raw/packaging material, formula or process that impacts material produced for JBSS has changed.

Where possible, allergens must be "designed out" of the product, making labeling unnecessary. This may be achieved by reformulation or by avoiding manufacturing cross-contact (via proper rework handling, product sequencing, change-over cleaning, or change-over flushing). Avoiding the introduction of allergens through cross-contact from other lines (no common equipment) or other production areas shall be strictly managed through raw material handling (e.g., use of color-coded utensils and work tools), rework handling, GMP and employee allergen awareness training. Allergen-containing materials shall be stored in a manner that will prevent cross-contact. Rework product containing allergens as an ingredient shall be used only in products which contain the same allergen as an ingredient.

Allergen, cleaning, and sanitation processes of product contact surfaces between line changeovers shall be validated and verified at a frequency to demonstrate control.

Avoiding the introduction of allergens from manufacturing carry-over (production of a previous product with allergens in the same line, including the use of common equipment) shall be managed through product change-over practices such as product sequencing, flushing, and cleaning.

Allergens present through manufacturing cross-contact or carry-over product that cannot be avoided through product sequencing and cleaning due to technical limitations (e.g., nature of product, design of process) shall be properly identified and labeled. Strict control is necessary in cases where different varieties have similar labels. However, the cross-contact information shall not be used as a substitute for an effective food allergen control program. Where cross-contact labeling is implemented, all reasonable precautions must still be taken to minimize the risk of cross-contact. Producing products containing the same allergens on dedicated lines is preferred if cleaning or other limitations restrict the ability to ensure the line is free of allergens from the prior run.

Controls shall be in place to make sure that JBSS is notified of all allergens present (as ingredients or traces). Where a new allergen is identified in a product where it was not previously present, and is therefore not labeled (e.g., discovery of an allergen cross-contact or change to the allergen profile of a raw material), JBSS must be notified immediately (see *Section 1.2- Notifying JBSS of Significant Events*).

Allergen training must be provided so that all involved personnel are equipped with essential information and skills relative to their job responsibilities and the site allergen risk profile. This includes identifying ingredients and products that contain allergens, knowing the process steps where allergens could be introduced to the product inadvertently and understanding the control methods applied.

(4.7) Extraneous Matter

The supplier shall have implemented a written program to prevent, detect, and control extraneous matter in material produced for JBSS. The supplier shall perform a risk assessment to determine potential sources of extraneous matter, including: raw ingredients, packaging materials, equipment design, plant environment (e.g., ceilings, walls, floors), processing and packaging equipment, utensils, contamination from personnel or other operations such as cleaning and Sanitation, contractor work, rework/work-in-progress protocol, maintenance or repair of equipment, and historical information of types of extraneous matter previously found or reported by consumers.

Periodic reassessments shall be conducted, particularly following changes to the plant environment and instances of non-conformances (e.g., consumer complaints, CCP failures). Based on the risk assessment, the supplier shall develop an appropriate strategy for minimizing and documenting extraneous matter, which shall include (if applicable):

- Confirming control strategies at suppliers or sources of materials.
- Designing the risk of extraneous matter out of the process (such as eliminating metal-to-metal contact on equipment, replacing metal screens with Nitex or equivalent).
- Implementing a glass breakage program and glass/brittle plastic register to document details of location and condition. Program shall be audited at frequency to demonstrate control.
- Preventing introduction of extraneous matter into the product through the implementation of pre-requisite programs, for example, through GMPs, pre-operational inspections, internal audits, equipment design, preventive maintenance, covers on tanks or conveyor belt.
- Detecting and removing extraneous matter (e.g., installation of strainers, screens, filters, magnets, sieves, metal detectors, X-ray or other devices/programs deemed necessary on the line).

Specific controls shall be applied to devices that can be a source of extraneous matter when damaged (e.g., sieves). Appropriate and timely corrective action shall be implemented in case any source of extraneous matter with potential of falling into the product stream is detected.

Use of End-Point Metal Detection Devices

The detection limit for an end-point metal detector will depend on type of product, package, and the detection equipment. Detection equipment settings shall be determined and applied to achieve the most sensitive level possible to provide maximum protection from metal contamination. The detection sensitivity under production conditions must be better than 3.0 mm or less for all metals. Functionality verification for electronic detection and rejection devices shall take place with product flow with a minimum of 2 passes for each test piece. Minimum frequency for system verification shall be set at a frequency to demonstrate control. If a metal

detector is not working at its design limit (e.g., if it fails to detect a test piece), the material produced since the last successful test shall be placed on hold status.

Glass components in other equipment should be avoided where possible. Equipment which has glass components as a part of the design, such as computer screens and pH electrodes must be adequately protected to prevent contamination in the event of breakage. Glass and hard plastics in the processing area shall be identified and verification activities performed at a frequency sufficient to demonstrate control.

Lines of bulk materials shall place in-line/pipeline Metal or X-ray detectors in the product stream immediately or as close as practical prior to filling the bulk container. For in-line/pipeline detectors, the detection limits must be as sensitive as end of line detectors and must be documented.

Where in-line detection at the filling point is not possible, the detector may be placed further back in the product stream such as large end of line detectors for large bulk cartons or cases, or alternative control measures such as inline magnets or fine mesh filters, screens or sieves must be implemented.

End-point metal detectors that are Process Preventive Controls or Critical Control Points shall be calibrated/validated at least annually.

(4.8) Rework Control

The supplier shall have implemented a written program to control the use of rework materials in any product supplied to JBSS. If rework is to be reincorporated into product as an 'in-process' step (not simply repackaging or re-casing finished product), then the conditions for use of rework must be clearly set out in the product formula and/or specifications, and equivalent local documents (e.g. Manufacturing recipe, rework matrix).

The conditions of use of rework must include: the type and quantity of rework that can be added to the target product, conditions of storage, reprocessing steps in which it will be added, method of addition, identification of allergens, shelf life, special handling requirements and lot number identification for traceability. If rework is identified as potentially containing allergens, it must be segregated, controlled, and incorporated only into the same and/or appropriately labeled product.

Additionally, all rework shall be:

- Handled and stored in a manner that ensures the maintenance of product safety and quality.
- Clearly identified with product name, production date and any other relevant information.

(4.9) Material Packaging

All food-contact of the delivered materials must have food-contact material certificates which meet regulatory acceptance or approval criteria from an approved regulatory agency. This packaging shall not be from recycled packaging.

Packaging must not alter product organoleptic characteristics and shall not be a source of foreign material. Staples or metal objects of any kind shall not be used on packaging or on the pallet. All plastic bags or liners in direct contact with materials must be of a different color from the material itself.

Packaging materials must be appropriate for the specific food product being shipped and must not impart odor or taste to a specific food product being shipped. Additionally, for shipping to the U.S, packaging materials must meet Food and Drug Administration regulations for "indirect food additives."

Any proposed change in the size or type of packaging must be submitted to the appropriate JBSS Procurement Representative for approval prior to modification. Records shall be maintained for raw and material packaging specifications.

(4.10) Storage and Transportation

The supplier shall have implemented systems to manage warehousing and transportation to ensure that the safety, quality, and security of materials and products are maintained at all stages from receipt of materials through delivery of products to JBSS.

The supplier shall use designated storage areas or stock rooms to prevent damage to, deterioration of or tampering with material. In order to detect deterioration due to such things as pest infestation, unsanitary conditions and temperature/humidity control abuses, the condition of product in stock shall be assessed at appropriate intervals. Storage facilities shall be neat and orderly.

If the supplier uses third party warehouses to store raw materials, packaging materials, semi-finished or finished products, the Supplier shall conduct documented periodic assessments to ensure that the requirements of this *SQE Manual* are met.

The supplier's transportation program shall ensure that products are temperature controlled properly at all times during transportation, and maintained in good condition, clean, dry, and sealed.

(4.11) Business Continuity Plan

Suppliers shall have a documented plan in place to ensure that materials ordered for JBSS with an adequate agreed lead time shall be supplied in a timely manner. The plan shall also include contingency plans to provide finished goods, ingredients or packaging goods in the event of a crisis situation. The plan may be included in their preventive control program,

(5) INCIDENT MANAGEMENT

(5.1) Hold and Release

The supplier shall have a written Hold and Release control program that clearly establishes roles and responsibilities for effective implementation. The Hold and Release program shall apply to product on the supplier's premises or other facilities used by the supplier. Materials that are on Hold must be controlled by a defined and effective system which is intended to prevent inadvertent movement. Inventory reconciliation must occur to verify proper control.

The program shall include controls for non-conforming raw materials, materials pending testing (e.g., pathogen testing, sterility testing or Certificate of Analysis (COA) verification), packaging, labels, semi-finished product (work-in-progress), finished product, and rework. The supplier must maintain records sufficient to enable reconstruction of each hold event (e.g., quantities, code dates, lot numbers, product numbers, reasons for hold and/or release, investigative information, disposition, and traceability information).

Prior to release, documentation must demonstrate the following:

- Evidence that control measures have been effective beyond the monitoring system (i.e. analytical or microbiological testing results)
- The control measures (i.e. CCP) comply with the performance intended of that product (CCP charts, retest data, evidence of rework)
- The results of sampling, analysis and/or other verification activities demonstrate that the product complies with the identified acceptable levels for the food safety hazard(s) concerned

If any material produced for JBSS is either inadvertently released from hold or is suspected of non-conformance but has already been shipped to JBSS, a JBSS Procurement Representative shall be immediately notified (see *Section 1.2- Notifying JBSS of Significant Events*)

(5.2) Product Retrieval

The supplier shall have written retrieval procedures in place that promptly and effectively respond to product issues that represent an unacceptable risk to JBSS and/or the consumer.

Product retrieval procedures must include:

- Notification procedures, including contact lists and customer contacts.
- Protocol for retrieval and disposition of all affected product, with designated authority and assigned responsibilities to ensure that sufficient controls are followed to allow for complete retrieval of product.
- Identification of delivery points, dates and quantities for affected product delivered further into the supply chain or to customers.
- Protocol for isolation of affected stocks and/or materials remaining under control.

The retrieval system shall be tested on an annual basis at minimum, and after any major system changes to confirm (1) the accuracy of all product and contact data and (2) the continuing effectiveness of procedures and traceability systems. The results of these tests and any corrective actions necessary shall be documented. A JBSS Procurement Representative shall be notified immediately in the event of a product retrieval that impacts JBSS products (see *Section 1.2- Notifying JBSS of Significant Events*).

(5.3) Control and Disposition of Non-Conforming Materials

Disposition of materials on Hold that do not comply with specific approved JBSS specifications must be effectively controlled and documented. The supplier shall have written procedures for the identification, documentation, evaluation, segregation (where practical) and determination and execution of the final disposition of non-conforming products.

Rejected material shall be clearly identified. The reason for rejection of the material, code dates, quantities involved, and its disposition shall be noted on the batch/lot record. Records of actions and outcomes shall be maintained (for example, certificates or other evidence of product destruction or burial). Disposition shall be completed in a timely manner.

(6) SOCIAL RESPONSIBILITIES

It is JBSS intent to utilize a supply chain which has a shared standard of working conditions globally. To this end, JBSS requires all partners in our global supply chain to meet minimally the standards set forth below.

(6.1) Child Labor

JBSS in committed to the elimination of the "worst forms of child labor," as defined by ILO Convention 182, from its supply chain. We expect our suppliers to support and participate in industry efforts aimed at the elimination of such practices wherever they exist in the supply chain. The use of child labor on farms as permitted by applicable local and national laws and regulations is not a violation of this code.

(6.2) Forced/Prison Labor

Suppliers must not utilize or benefit in any way from forced or compulsory labor, not utilize factories or subcontractors that force unpaid labor. Official prison rehabilitation programs are not a breach of this code.

(6.3) Working Hours and Wages

Suppliers should provide wages at least equal to the applicable legal minimum wage and any associated statutory benefits. If there is no legal minimum wage, suppliers must ensure that wages are at least comparable to those at similar companies in the local area or to prevailing industry norms. Working hours should reflect applicable legal norms and overtime hours should be paid at the legally mandated premium or at least the same rate as regulator hours worked if there is no mandate premium.

(6.4) Freedom of Association

Suppliers should respect employees' rights to freedom of association including the right to collectively bargain, consistent with local national laws and regulations and ensure that all employee relationships are of a voluntary nature.

(6.5) Non-Discrimination

Hiring and employment decisions, including those relating to compensation, benefits, promotion, training and development, discipline, and termination, shall be made solely on the basis of the skill, ability and the performance of workers. Discrimination is not permitted on the basis of race, religion, gender, political opinion, national extraction, or social origin. (ILO Conventions 100 and 111)

(6.6) Health and Safety

The supplier must provide employees with a safe and healthy working environment for all employees that include appropriate controls, safety procedures, preventative maintenance, and protective equipment. Practices must comply with all relevant local and national laws, codes, and regulations.

(7) ENVIRONMENTAL POLICY

Environmental impact is a key part of the JBSS's business practices, and the company is committed to supporting sustainable operational and agricultural production practices. At a minimum, suppliers must fully comply with all applicable local and national environmental laws and regulations and should strive to conduct their operations in a way that conserves natural resources.

(7.1) Pollution and Prevention and Resource Reduction

Suppliers should reduce waste and usage of all types by implementing appropriate conservation measures in their operations. Improvement plans for waste reduction, recycling, energy conservation and greenhouse gas mitigation policies should be in place, along with demonstrable evidence of implementation.

(7.2) Environmental Permits and Reporting

Supplies must obtain, maintain, and keep current all required environmental permits (e.g., discharge monitoring) and registration and any operational and reporting requirements shall be followed.

(7.3) Wastewater and Solid Waste

Wastewater and solid waste are to be monitored, controlled and treated as required by applicable local and national laws and regulations prior to discharge or disposal and records of effluent monitoring shall be maintained.

(7.4) Air Emissions

Air emissions generated from operations are to be characterized, monitored, controlled, and treated as required by applicable local and national laws and regulations prior to discharge and records of air monitoring shall be maintained.