Kraft Foods Supplier Quality Expectations Manual

This document is intended to be used internally and externally.

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CHAPTER 1 - INTRODUCTION

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.

At Kraft Foods, we inspire trust by making safe food. 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.

Kraft Foods is committed to delivering high-quality products. One of the ways we achieve this is by ensuring the strength of our food safety and quality systems. We expect that our suppliers share this commitment and for that purpose we have developed the Kraft Foods Supplier Quality Expectations (SQE) Manual.

The SQE Manual is available at the Kraft Foods Supplier Quality and Foods Safety web site at www.kraftsupplier.*com*, or from your Kraft Foods contracting representative.

The *Kraft Foods Supplier Quality Expectations* (SQE) outlined here are intended to help current and prospective new suppliers of ingredients and packaging materials ensure that their own food safety and quality systems meet Kraft Foods and Industry standards. These expectations have been developed by Kraft Foods after a review of product defects, quality audits of Manufacturing sites and a study of product retrievals throughout the food industry. This review led us to identify which programs, if executed properly, help to prevent product retrievals, consumer complaints, rework and plant downtime, and produce high quality, safe products. All Manufacturing Locations producing materials for Kraft Foods must meet the expectations in this manual with the exception of packaging suppliers for whom some sections do not apply (see table of contents). This document does not apply to farm operations.

Terms used in the *SQE Manual* are defined in *Appendix 1: Definitions* of this document.

The *Kraft Foods SQE Manual* contains the elements we believe are essential for the effective management of Food Safety, Quality and Food Defense. These are Kraft Foods requirements. They are not intended to alter or eliminate any requirements that may be set in any contract, specifications, or government regulation. Any questions about these standards should be addressed by contacting the appropriate Kraft Foods Contracting Representative.

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 Kraft Foods approved Manufacturing* Locations (*see definitions). The supplier Manufacturing Locations shall be disclosed to the Kraft Foods Contracting Representative to assure that materials are only sourced from Locations meeting Kraft Foods requirements for quality and food safety.
- Notify the supplier that the specific material will be delivered to Kraft Foods.
- Ensure the *Kraft Foods SQE Manual is* communicated to supplier and provide evidence to Kraft Foods of agreement to the requirements by the supplier.
- The broker/distributor/trader has responsibility to ensure that supplier complies with those requirements
- The broker/distributor/trader shall be required to notify Kraft Foods 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 Kraft Foods 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 Kraft Foods unless there is a contract in place protecting such disclosure. Auditors shall not be asked or required to sign confidentiality agreements as a prerequisite to gaining access for audits prior to or at any time during a quality audit.

Auditors checking compliance to the Kraft Foods SQE requirements will not audit or inspect financial data, sales data (other than that directly related to Kraft Foods), or pricing data. 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. Notifying Kraft Foods of Significant events

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 Kraft Foods is immediately notified of these occurrences.

The supplier shall notify Kraft Foods Contracting 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 Kraft Foods 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 Kraft Foods.
- Non-routine Regulatory Authority investigations, testing, sampling, reporting, or other contact or action with the potential to affect material produced for Kraft Foods. Kraft Foods does not need to be notified of routine inspections, unless the inspection reveals that material produced for Kraft Foods 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 Kraft Foods.
- 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.
- Identification of an unlabeled allergen in material produced for Kraft Foods.
- Changes to supplier's processes and/or facilities that could have an impact on materials supplied to Kraft Foods (see *also Manufacturing changes in section 2.1*)
- Inability to deliver materials that meet Kraft Foods Specifications
- If any of the supplier sites Manufacturing products for Kraft Foods loses GFSI certification.

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

CHAPTER 2 – QUALITY SYSTEM CONTROLS

2.1. Quality Management System and Documentation

The supplier shall have implemented a written Quality Management System (the "Quality System") to ensure that the material produced conforms to our specified requirements. At a minimum, the Quality System shall ensure compliance with the Kraft Foods supplier Quality Expectations Manual, Kraft Foods Specifications 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 need 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 Kraft Foods that were produced or will be sold in the United States and Canada, records shall be retained for at least five 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 Kraft Foods shall meet the same requirements and be managed by the supplier.
- Manufacturing changes: The supplier must notify Kraft Foods of its intention to make any change that may affect the safety, quality, security, shelf-life, ingredient statement, allergen profile, nutritional labeling or functionality of material produced for Kraft Foods – such as changes in material formula, raw materials, production line, Manufacturing Location or processes – and any change shall be approved by Kraft Foods before being implemented. Kraft Foods must be notified of such changes in writing.
- Special certifications: If Kraft Foods Specifications require particular certifications – such as Organic, Kosher or Halal certification – then the Manufacturing Location must be certified by an appropriate certifying body of the country in which Kraft Foods will receive the material.
- Genetically modified organism (GMO): The Supplier shall ensure that raw materials do not contain any trace of unauthorized GMOs in accordance with the regulations in the destinations to which they may be delivered. No raw material shall be supplied that would require GMO labeling to describe a material difference (e.g., introduction of an allergen) created by the use of biotechnology. If GMO labeling is required for other purposes, such as a general disclosure of the use of biotechnology, the supplier shall (1) notify Kraft of any ingredients that are subject to such requirements and (2) follow any related instructions we may provide.
- No cloned animal products: No milk, meat, or other ingredients derived from cloned animals shall be used to make Kraft Foods 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 Kraft approved irradiation process based on the specific material and the needed lethality.

2.2. Kraft Foods Audit/Inspection Requirements

All Manufacturing Locations producing ingredients for Kraft Foods must be approved by Kraft Foods. The same applies to new suppliers of food contact package materials and package materials with ingredient statements printed.

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

- Third Party auditing supplier on behalf of Kraft Foods (3rd Party SQE), or
- Kraft Foods employee, or
- Recognized industry standard (GFSI certification), including a copy of the audit report or Executive Summary and certificate submitted to Kraft Foods as part of the approval.

Suppliers must permit Kraft Foods or its representatives to enter and audit any establishment Manufacturing, storing or supplying materials for Kraft Foods. The audit /inspection requirements are prioritized based upon the experience with the supplier and the type of material produced for Kraft Foods at that Location. Kraft Foods utilizes an audit tiering process for all 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. The more sensitive ingredients may require an audit by Kraft Foods while a 3rd party audit may be acceptable for less sensitive ingredients. Audit frequencies are dictated based on material risk. To become and remain an approved supplier, the audit findings must be acceptable to Kraft Foods.

Audit requirements for food contact packaging material suppliers

The accepted certification audits for approval of food contact packaging materials are as follows: BRC/IoP Global Packaging Standard, ISO 22000:2005 Food safety management systems, SQE Packaging Requirements, SQF Packaging Standard and EN 15593 Management of hygiene in the production of packaging for foodstuffs.

General audit requirements

Separate audits are required for every Manufacturing Location and production line producing material for Kraft Foods. The supplier shall inform Kraft Foods if they plan to change the production line or Manufacturing Location of the materials supplied to Kraft Foods in order to allow Kraft Foods to assess whether a new approval is needed. The timing to approve a supplier Manufacturing Location may take 3-4 months to complete. The supplier shall notify the Kraft Foods Contracting representative of any ingredient which is produced or processed in a plant not entirely owned or operated by the supplier.

The Kraft Foods audit/inspection shall extend to all areas, including all pertinent production and storage areas, deemed necessary to evaluate whether the material produced for Kraft Foods meets our 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 Kraft Foods audit within the time frame agreed on in the audit corrective action plan. In addition, all corrective actions shall be verified by a Kraft Foods employee at a maximum of 6 months post the distribution of the final audit report. Verification of corrective actions for all critical and major findings shall require an on-site visit.

Kraft Foods will bear its own internal costs and the supplier will bear all other audit costs (including those of the third-party auditors).

Global Food Safety Initiative (GFSI) Certification

As a company we continue to move towards more industry-accepted certifications, and to this end, it is a requirement that all ingredient suppliers to Kraft Foods attain Global Food Safety Initiative (GFSI) certification by Dec. 31, 2014 (except product categories exempt per corporate risk assessment).Current certifications accepted for ingredients can be obtained at www.mygfsi.com.

Food Safety Assessments

To support this move to increased reliance on GFSI certification, Kraft Foods additionally operates a supplier Food Safety Assessments program for existing suppliers. These are on-site periodic food safety assessments performed by Kraft Foods personnel to evaluate key food safety programs which may include, but are not limited to HACCP validations and verifications of Critical Control Points, Hygienic zoning, Allergen controls, Pathogen Environmental Monitoring, etc. These are regularly scheduled assessments based on the Kraft tiering matrix or the discretion of corporate food safety and microbiology.

2.3. 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 taken into account 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.

2.4. Regulatory Inspections and Contacts

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 inspection or contact. 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 Kraft Foods, the supplier shall contact the Kraft Foods Contracting Representative for instruction. The supplier will provide Kraft Foods with a duplicate sample of product from the lot examined by the Regulatory Authority. No further testing shall be initiated by the supplier without prior authorization from Kraft Foods.

Consideration must be given to the potential impact of an adverse result. In some cases it will be necessary to place product and/or material on hold pending results of Inspector sampling, for example:

- Where a non-conformance or defect has become apparent during the inspection.
- Where the stated reason for the sample being taken concerns an issue which may impact Kraft Foods (e.g. sampling for pathogen or GMO testing).

2.4.1. Pure Food Guaranty (Suppliers shipping to the United States only)

Suppliers of food products (including finished food products, food ingredients, and primary packaging materials) that will be used in the manufacture or sale of products in the United States must submit a Continuing Pure Food Guaranty to Kraft Foods. The Continuing Pure Food Guaranty must be on file with Kraft Foods prior to receiving the first shipment from the supplier.
A Pure Food Guaranty is a common Regulatory document that food industry suppliers use to assure customers that their products comply with the Federal Food, Drug, and Cosmetic Act and related requirements.

The form to be submitted to Kraft Foods is available via SQE website under Quality Support Material:
http://brands.kraftfoods.com/kraftsupplier/pdf_documents/PFG_Instructions.pdf

2.5. Food Defense

Suppliers acting on behalf of Kraft Foods that manufacture, process, pack, 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 quickly and accurately identify, respond to and contain threats or acts of intentional contamination. 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. Kraft Foods 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 Kraft Foods are expected to develop Manufacturing Location Food Defense programs that meet set standards outlined below and be prepared to provide Kraft Foods 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 to Kraft Foods
    (d) Annual vulnerability self-assessments and procedures for fixing gaps.
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. Background Screening. Suppliers will conduct background screening checks on employee candidates as required under the contract with Kraft Foods (except where prohibited under Local Regulatory authority).
4. Shipping and Receiving. The supplier shall take deliberate steps, and implement procedures, to monitor and verify the integrity of incoming and outgoing shipments. This includes the requirements described in Section 4.12 Storage and Transportation.

Suppliers located in the United States or shipping product to US

In addition to a Food Defense program as outlined above, US-based suppliers and international suppliers shipping purchased materials into the United States on behalf of Kraft Foods are expected to complete the following and be prepared to provide Kraft Foods confirmation that they have completed these requirements.

1. Complete and maintain registration in the FDA facility registration list.
2. Maintain "one up, one down" records to identify the immediate previous source of food or ingredient received and the immediate subsequent recipient of food or ingredient shipped.
3. Ensure detained product is held as directed by Kraft Foods (see section 5.1 Hold & Release).
4. Meet C-TPAT Import Security Criteria if making shipments to the U.S. but originating elsewhere.

2.6. Testing Controls: Laboratory Requirements

Through procedures in a written program, the supplier shall ensure that personnel responsible for conducting testing or monitoring (in connection with the programs required in this *SQE Manual*) 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 Kraft Foods.

Testing and monitoring programs shall be based on generally recognized methods or test methods that have been approved by Kraft Foods 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 final 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 Kraft Foods shall only be performed by laboratories that have been approved by Kraft Foods Corporate Microbiology. A list of approved laboratories in each country is available from your Kraft Foods Contract Representative and can be found on the Kraft Foods Supplier Quality and Food Safety web site under Quality Support Material.

http://www.kraftsupplier.com/

Samples from an Environmental Testing Program may be analyzed at the supplier's pathogen laboratory provided requirements for internal lab are met as follows:

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

For more information about pathogen testing requirements, see herein (*Section 3.11- Pathogen Environmental Testing)*.

2.7. Testing Controls: Measuring & 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 (CCPs) and equipment used for laboratory testing, shall include the following information:

- Whether the equipment is used to control, measure, or monitor CCPs.
- 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.

Frequency of the calibration (*Note*: Equipment used to measure a CCP 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, 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 and Preventive Action (C&PA)

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

An effective C&PA program shall include the following steps:

- Issue is defined elements to include in description (date, what, where, who, etc.)
- Documentation of root cause analysis (i.e. 5 Why tool)
- Action register with what, who, when and close out date
- Verification of effectiveness with documented evidence and timing
- Identification of long-term (permanent) solutions (including responsibilities and timing). When required, resources (e.g., personnel, finances, equipment) must also be identified.
- C&PA plan implementation.
- Periodic review of C&PA by the management team.

The C&PA 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 of a CCP.
- 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 C&PA program shall address proper means of managing incoming customer contacts to enable an accurate, appropriate, and timely response.

CHAPTER 3 – FACILITY ENVIRONMENT CONTROLS

3.1. Good Manufacturing Practices (GMP)

All persons entering the Supplier facility (plant personnel, visitors and outside contractors) shall comply with GMP requirements. GMPs must be in writing and available to all personnel. These GMPs reflect the minimum expectations but do not supersede any Local or National Regulatory requirements. Supplier shall review and update GMP requirements on a periodic basis.

The GMPs must address personal hygiene, handling and storage of equipment and materials, proper cleaning and sanitation, and receiving.

Personnel practices

The following actions are not allowed in GMP areas:

- Eating or drinking – permitted in authorized areas of the facility only.
- Chewing gum, candies, throat candies, throat lozenges and tobacco.
- Holding toothpicks, matchsticks or other objects in the mouth.
- Wearing false eyelashes, fingernails or fingernail polish.
- Expectorating (spitting) in production areas
- 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.
- If smoking is permitted in facility, it is only permitted in designated areas, but never in GMP areas.
- Lunches must be stored and consumed in designated areas only

Clothing and personal equipment

- All clothing must be kept in good repair. Employee clothing should not be a source of contamination.
- GMP areas: Employees who work in GMP areas must wear only company-approved clothing. Clothing shall provide adequate coverage that ensures hair, perspiration or other foreign materials do not contaminate the product (e.g., no shorts, tank tops, sleeveless shirts). Clothing used for food protection or hygiene purposes shall not be used for any other purpose. Non-production employees, contractors and visitors who enter GMP areas must wear a lab coat (or other approved covering) and wear appropriate footwear consistent with plant policy.
- Pockets above the waist must be removed or sewn shut. Only zippers, grippers or snaps may be used as the fasteners on shirts, coats, laboratory jackets, or smocks.
- Restricted uses: Work wear dedicated to specific product areas must be restricted to those areas. Such areas must be defined in local procedures (typically high care areas where clothing change is required on entry and exit)
- Shoes: To help avoid product contamination (and for personal safety) shoes worn in GMP areas should be designed and constructed as follows: fully enclosed (no open toes, open weave, or sandals); made with leather or vinyl outer materials (non-absorbent materials) and maintained in hygienic condition
- Personal protective equipment, where required, shall be designed to prevent product contamination and maintained in hygienic condition.

Hands

- Personnel working in GMP areas must wash hands at the following times: before entering a GMP area; upon re-entering the GMP area; after each visit to the toilet facility, rest room, and/or lunch and break room facilities; prior to touching product or product contact surfaces; or any time when hands have become soiled or contaminated.
- Personnel working in a microbiologically sensitive area must sanitize their hands after proper washing and after touching non-product contact surfaces. If soil is observed on hands, hands must be washed prior to resanitizing.
- Personnel with minor cuts or injuries on hands must be able to protect the wound and keep it clean and free from infection. They will be allowed to work on production lines provided the cuts are bandaged and covered with an impermeable sanitary material. Adhesive bandages must be metal detectable in facilities where metal detectors are used.

Hair

- Plant-supplied hair restraints must be worn in GMP areas.
- Hairnets/restraints must completely contain the hair and cover the ears.
- If safety or bump helmets are used, they must be worn over appropriate hair restraints.
- Employees must be clean-shaven or cover the exposed facial hair (i.e. mustaches, beards, etc.) as completely as possible with a plant-supplied beard restraint.

Proper storage

All items shall be stored to avoid direct contact with the floor or walking surfaces (e.g., on pallets, slipsheets 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. Personnel 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, including temporary and seasonal personnel, must receive GMP training (including a section on Employee Illness and Communicable Disease) as part of the orientation process. All employees shall also receive refresher training or verification of GMP knowledge at defined intervals. In addition, specific training programs to instruct personnel on the requirements of this document shall be provided as required and applicable.
- Production Personnel. Training for supplier personnel who work in production areas must include the following principles: Quality, HACCP, Allergens, Foreign Object Prevention, and Food Defense.
- Critical Control Point (CCP) Monitors. Employees monitoring CCPs must receive further specific training on monitoring, documentation, verification and corrective actions if critical limits are not met.
- GMOs. When appropriate, employees involved in handling GMO materials must be trained as to procedures for handling these products (e.g., preventing co-mingling, how to also handle non-GMO materials).
- Additional Requirements. Training requirements for Regulatory inspections, pest management, hold & release and pathogen environmental monitoring are set forth in other sections of this manual (see *Section 2.4-Regulatory Inspections and Contacts*, *Section 3.9-Pest Management*, *Section 5.1-Hold & Release*, and *Section 3.11-Pathogen Environmental Monitoring*).

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.

3.3. 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.

3.4. 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 (i.e. cheese, starter culture, etc.). 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. See also Section 3.10-Hygienic Zoning
- 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 waste water.
- 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

3.5. 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 3.10- 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 and other test data from water testing shall be reviewed by appropriate personnel. Corrective action shall be initiated and documented for out of standard results.
- Microbiological tests shall be performed periodically. Each point of shall be covered at least once per year and after maintenance or repair.
- 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 off of 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.

3.6 Equipment Design & Validation

The supplier shall ensure that equipment design is adequate for the 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.

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3.7. 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.

Further requirements include the following:

- The equipment maintenance program shall detail the inspection required for evaluation of the condition of screens, filters, magnets, gaskets, and other equipment that must be periodically replaced, as well as any potential points of metal to metal wear.
- If the line does not have downstream detection equipment (e.g., metal detector, magnets, screen), a more frequent detailed evaluation of wear and condition of product contact equipment (e.g., scraper blades, conveyer belts, votator barrels, pasteurizer plates, grinder plates, valves, pumps, and gaskets) is necessary for detection of potential contamination. (Left as is, it does not have to be with the lack of metal detection, it refers to the maintenance of equipment that contacts the product after the metal detection/magnets, etc.))
- Routine preventive maintenance for compressed air and air used in product manufacture or packing shall be documented. This includes the inspection, cleaning or replacement of items such as air filters, O-rings, gaskets, pumps, and bearings.
- Only food-grade lubricants and heat transfer liquids shall be used on food production equipment where direct or indirect contact between the fluid and food products is possible.
- The Supplier shall establish and implement appropriate sanitation procedures and controls for maintenance tools that are moved from raw to cooked product areas.
- Maintenance tools shall be maintained in a cleaned and sanitized manner.

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.

3.8. 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
- Inspection procedures
- Recordkeeping, record review, and corrective action plans

The following considerations shall be taken into account 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.

- Cleaning In Place/Cleaning Out of Place (CIP/COP).
- Equipment that is wet cleaned which needs to be used in a dry condition.
- 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.
    - Cleaned equipment swabbing (using microbiology methods) and cleaned equipment teardown and inspection.
    - ATP measurement (adenosine triphosphate measurements are based on the detection of ATP by bioluminescence) can be the initial method of choice in monitoring the cleaning efficiency since it is a rapid measurement of the actual hygiene status of a sampled surface, allowing fast initiation of corrective actions in case of inadequate cleaning. ATP measurement, however, should not completely replace traditional techniques (e.g., swabbing), and should be integrated with traditional cultural techniques as part of a coherent surface cleanliness monitoring system. Although manufacturers of ATP measuring devices give general guidance on acceptable ranges for routine hygiene controls, internal standards have to be set for the given production environments.
- A Periodic Cleaning program (PIC – periodic infrastructure cleaning) and PEC (periodic equipment cleaning) including scheduled frequencies and documentation.
- Floor drain cleaning and sanitizing procedure and schedule that include a facility map with the exact Location of each drain. High pressure hoses shall not be used and cleaning of drains must not be performed during production.
- Use of food grade cleaning, sanitizing, and disinfecting products.
- Calibration of Sanitation-related measurement devices e.g. thermometers, gauges and meters.

Proper tools and materials must be used to prevent extraneous matter, microbiological and/or chemical contamination of the product. Items that are known to be potential sources of contamination must be prohibited. Brushes and utensils for cleaning food contact surfaces shall be clearly identified (e.g., labeled and/or color coded) and stored separately from non-food contact tools. Floor drain cleaning brushes and equipment shall be clearly identified as such and maintained separately from other cleaning equipment.

The Sanitation program shall specify microbiological limits per business or food category requirements (e.g., Total Aerobic Count, Yeast, Mold, Coliforms, and other Indicator Organisms). Whenever results exceed or trend toward the specified limits, corrective actions must be taken and documented. If out-of-specification results are obtained, swabs must be repeated to ensure the corrective action was effective. If swabs are rotated, swabs should be repeated until three consecutive acceptable results are achieved.

Clean in Place (CIP)

Parameters for CIP systems shall be defined and monitored to include chemical concentration, contact time, temperature, and flow. CIP systems shall be separated from active product lines (e.g. pasteurized vs. unpasteurized)
The CIP control system (Control Book) shall contain:

- An index that lists all CIP units in the plant/department and product circuits and tanks that each unit cleans.
- The CIP program used to clean each circuit. It should describe the cleaning steps, time and temperature used, the type of cleaner and sanitizer, and the solution strengths.
- Simple schematics of CIP circuits to trouble-shoot and guide personnel in making jumper connections with product tanks, pipes, fittings and equipment.
- Orifice/reducer size and position are shown.
- A list of items in each circuit that require dismantling and manual cleaning.
- A description of automatic controls and interlocks.

The CIP system shall have:

- An automatic recording device for time and temperature located on the return pipe.
- An automatic recording of the supply pump discharge pressure or flowmeter.
- A method to detect return pressure (flow) that is capable of shutting down the system during the initial rinse cycle or contains an alarm that signals a manual shut down.
- A strainer located after the supply pump.

- An automatic recording device for chemical concentration (conductivity) on the return pipe.

The following parameters must be recorded, preferably electronically if not in a chart recorder:

- Time
- Temperature
- Chemical Concentration
- Flow or proof of flow
- Identify the circuit being run (can hand write on chart)
- Operator identification

If during a circuit the minimal conditions for temperature and/or concentration are not met the time shall be paused until acceptable conditions are re-established. Raw ingredients, starter (culture) rooms or pasteurizers shall have dedicated CIP systems that must not be mixed or crossed. Spray-balls designed to be removed should not be left in tanks during operations.

Sanitation Verification (after wet cleaning)

Each manufacturing facility shall establish its own program and a baseline for the different indicators. Plant history should also be taken into consideration when updating the program.

Swabbing should be performed after cleaning, but before sanitizing procedures. If the equipment is not in use, no clean equipment swab needs to be taken. Clean equipment swabs will be taken before the equipment is put back into use. At minimum, clean equipment swabs, shall be taken after the microbiological control step (e.g., heat treatment, formulation). If swabs must be taken after sanitizing, proper buffer solutions must be utilized to prevent inaccurate results. Individual performing swabbing must receive proper training.

3.9. 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 pesticides residues do not exceed limits established by the law of both the Location of the facility and the Location where Kraft Foods 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.

Exclusion shall be the first line of defense and primary method of controlling pests. Efforts must be made to keep pests out of the building by using good exterior controls including:

- Eliminate all possible entrances into the facility. All doors, windows, and screens must fit tightly. Doors must be kept closed.
- High grass and weeds around the facility or in adjacent areas must be eliminated where possible.
- Item such as scrap, pallets, pipe, and drums, shall not accumulate on the grounds or parking lot.
- All openings on wall and roof penetrations must be screened to prevent pest ingress.
- Pipe openings through facility walls must be sealed.
- Product pipes must be capped when not in use.

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 Material Safety Data Sheets (MSDS) 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.

3.10. Hygienic Zoning

All suppliers that manufacture or handle Kraft Foods products 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.

The 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. Some considerations for the initial risk assessment are as follows:Based on the Hygienic Zoning assessment, the different areas (zones) of the production facility shall be classified as follows:

Non-Manufacturing zone:

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

Raw /limited process zone:

- Areas, such as raw meat/raw milk/raw nuts receiving and storage, that are known to be contaminated and which require controls to prevent contamination of higher hygiene zones.
- These zones often require the use of dedicated employees and may be physically separated from controlled zone or high control zone.

Controlled zone:

- Products that are not highly sensitive and which can be exposed to the environment and the operators.
- GMP practices are implemented and appropriate air requirements are met.
- The controlled zone may also serve as transition from non-Manufacturing or raw/ limited process zone to high control zone.
- Products of higher sensitivity may be present if they are completely enclosed.

High control zone:

- Product which supports growth of pathogens (*Salmonella* or *Listeria monocytogenes*) and can be exposed to the environment and/or the operators.
- 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.

3.11. Pathogen Environmental Monitoring

Suppliers that manufacture or handle microbiologically sensitive materials for Kraft Foods shall have implemented a program for pathogen environmental monitoring (PEM). The PEM program shall verify that the controls put in place during the *Hygienic Zoning* assessment are effective at preventing potential cross-contamination between different Hygienic Zones. The rigor of the plant program depends on the product and process risk evaluation, and the likelihood of pathogen(s) to survive or grow in the finished products during storage and distribution. ?

The PEM program should focus on *Salmonella sp*. and *Listeria sp.*, as well as other organisms which can lead to the detection of potential changes in sanitary conditions in the production environment. The PEM program shall:

- Enable facilities to detect conditions that may lead to the potential presence of pathogens in controlled zones, high controlled zones and in certain non-Manufacturing zones
- Enable facilities to conduct investigative sampling when a potential pathogen harborage area is identified, escalate sampling/environmental analysis and potential finished product sampling and testing to assess the effectiveness of their corrective actions and assure sanitary conditions are maintained.
- Be designed to verify the effectiveness of control programs for preventing cross-contamination, including Sanitation, GMPs, preventive maintenance, and plant traffic controls.

Monitoring requirements and instructions

Requirements and instructions for the plant PEM program shall be documented and include the following:

- Target organism(s) and sampling frequencies
- Testing methodology.
- Applicable products or processes
- Swab site Locations, which include the most critical Locations, and are dependent upon such criteria as the material produced, equipment design, plant structure, traffic patterns, and previous findings. Sampling Locations shall not include raw, unprocessed products and raw production areas e.g., raw meat, poultry, vegetables, fish, and unpasteurized milk and cream. Walls and floor drains located in relevant areas shall be included in any sampling plan.
- The time frame for taking swabs (e.g., shift, midweek, end of week). Routine sampling must take place during production, at least 3-4 hours after start-up.
- The number of sampling locations for each zone shall be in accordance to the complexity of the site. Each zone shall be sampled for bacterial pathogens at least monthly, or more often if necessary to demonstrate control, placing more emphasis on zones with higher risk.
- Test result acceptance criteria appropriately defined.
- Corrective action plans, including increased control procedures and verification requirements.
- Training

Whenever product contact surfaces are tested for pathogens, affected product lots shall be placed on Hold pending the test results (see *Section 5.1-Hold & Release*). The supplier shall conduct an investigation to identify the potential source and document all corrective actions. They shall also verify the effectiveness of the corrective actions.

The sampling site Locations and the timing of sampling should be audited and changed on a periodic basis.
The PEM program shall be reviewed at least every 2 years or whenever a change occurs to the process or product (e.g., new equipment installation, modification or introduction of a new material). The PEM review shall be documented.

Criteria for test results to be deemed acceptable

Laboratories shall have demonstrated the ability to provide accurate and valid results using officially approved or standardized methodologies (e.g., AOAC/BAM, AFNOR, and ISO). A negative (blank) control taken at the Manufacturing site and/or testing laboratory is required to assure the validity of test results for both *Salmonella* and *Listeria.*

Corrective action plans

Corrective action plans shall address the source of the contamination issue and include mechanisms to verify the effectiveness of corrective actions.

The implicated and specific test site Locations shall be re-evaluated to verify the effectiveness of corrective actions. A minimum of three consecutive negatives or in-standard results must be achieved prior to returning to the routine testing and sampling schedule. This must be completed within a 3-week time frame. Sampling shall not be done immediately after the Sanitation/disinfection measures. Trend analysis of positive findings shall be made in order to detect areas of concern.

Areas for environmental sampling

Zone 1: Direct product contact surfaces mean all surfaces that are exposed to the product during normal equipment operation and all surfaces from which liquids may drain, drop, diffuse, or be drawn into the product or into the container.

Zone 2: Sites that are *indirect product contact surfaces* are surfaces adjacent to direct product contact. Indirect contact surfaces are these sites that could come into contact with direct product contact sites by draining or dripping onto them.

Zone 3: Non product contact areas within the processing room that are more remote from product contact surfaces

Zone 4: Sites that are remote from product contact surfaces outside the processing room but could impact processing areas through the movement of people, equipment or materials

CHAPTER 4: PRODUCTION PROCESS CONTROLS

4.1. Specification Compliance and Contract Review

The supplier shall ensure that Kraft Foods Specifications are implemented at the Manufacturing Location and that appropriate plant personnel have access to the latest specifications for materials supplied to Kraft Foods.

Supplier will be notified of the Specifications and updated Specifications through the Specification Agreement Report Program. 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 the Specification, Kraft Foods Contracting Representative shall be notified immediately (see *Section 1.2- Notifying Kraft Foods of Significant Events*).

Specific testing methods are described in the Specifications. When the supplier uses a different method, a validation study must have been performed in order to guarantee an equivalent output.

In cases where Kraft Foods Specifications require pathogen analyses each lot must be sampled, and the samples must be collected across the lot according to a statistical sampling plan that represents the lot. If target pathogen(s) are detected in the lot, prompt corrective action steps shall be taken and Kraft Foods shall be immediately notified Where Certificates of Analysis (COA) are required, these must be provided to Kraft Foods prior to acceptance of the material at Kraft Foods Locations. If a pathogen test is required for the COA based on Kraft Foods Specifications, the test must be performed by a laboratory approved by Kraft Foods (see *Section 2.6 – Testing Controls: Laboratory Requirements*).. Kraft Foods reserves the right to sample each delivery and to determine the appropriate disposition. The COA from the approved laboratory or a supplier generated COA (e.g., through SAP), must be provided to Kraft Foods 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 Kraft Foods identification number.
- Specification number (or purchase agreement) and issue date.
- Test and analysis results for each lot, preferably including Kraft Foods 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 Kraft Foods plant.

Material Monitoring Program

Kraft Foods requires that some specific incoming raw materials be part of a Material Monitoring Program. This Program was designed to check for potential contaminants across the supply chain and attest that materials consistently meet Kraft Foods expectations regarding specification, chemical food safety, and compliance with all applicable Regulatory requirements for the designated country of the Kraft Foods receiving Location. Materials are selected for the Program at the discretion of Kraft Foods.

Under the Program, suppliers must submit samples representative of Kraft Foods specified materials to a designated Kraft Foods approved laboratory for analytical chemical testing. This testing is in addition to tests that are required for Kraft

Foods Specification compliance and may include test parameters additional to those required by Specification. Test results will be released to suppliers and Kraft Foods, simultaneously.

The specific lot of material submitted for testing shall not be shipped to Kraft Foods Locations or to contracted Manufacturing facilities producing Kraft Foods branded product until the results of the testing confirm that samples meet our Specifications, do not present unacceptable chemical hazards, and comply with all applicable Regulatory requirements for the designated country of the Kraft Foods receiving Location.

4.2. Hazard Analysis and Critical Control Points (HACCP)

The supplier's products shall be designed, produced, and distributed using HACCP principles to minimize food safety risks systematically. The supplier shall have implemented a written HACCP plan for all materials produced for Kraft Foods. Hazards should be identified, associated risks assessed, Critical Control Points (CCPs) 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) or the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) HACCP guidelines. The supplier shall establish a cross-functional HACCP team that is responsible for developing, reviewing, and modifying the plans and maintaining the system. The HACCP team shall ensure that each HACCP plan and its implementation is properly verified and validated on a regular, documented basis.

When producing goods for Kraft Foods, the performance objective of all processes/technologies used to reduce target pathogenic organisms must be defined and validated. Data demonstrating effective processing (capable processing) must be made available to Kraft Foods, 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.

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 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 *SQE Manual* and provide them to their suppliers. Purchased goods specifications shall be consistent with Kraft Foods raw material specifications.
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 Kraft Foods 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 (see *Section 5.1- Hold & Release*).

Raw agricultural materials and ingredients from animal origin must be evaluated to ensure compliance with chemical contaminant (e.g., pesticides residues, mycotoxins) and applicable GMO regulations of the Kraft Foods receiving country as per Kraft Foods 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 following GS1 requirements, 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 Kraft Foods.

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 Kraft Foods 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 tracing shall be developed and implemented. Bulk use of ingredients shall be required to have a documented timeframe of known use. Ideally, each material delivery to Kraft should contain only one batch/lot number. 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 Kraft Foods be kept until the expiration of the material.

In the United States, the Bioterrorism Act, mentioned above, mandates that all members of the food chain shall be able to trace goods one step forward and one step backward, as well as know the shipper/transporter of the goods. (See *Section 2.5- Food Defense* for more information.)

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 Kraft Foods product.

An Allergen Assessment shall be carried out as part of 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 all allergens on the Kraft Foods Allergen Category List 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 Kraft Foods 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 Kraft Foods 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), Kraft Foods must be notified immediately (see *Section 1.2- Notifying Kraft Foods 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 Kraft Foods.

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 to 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 5.0mm 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 Category II hold. (See *Section 5.1 Hold and Release*)

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.

4.8. Rework Control

The supplier shall have implemented a written program to control the use of rework materials in any product supplied to Kraft Foods. 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.

Where rework activities involve removing product from filled or wrapped packages, the supplier shall have procedures in place to ensure proper removal and segregation of all packaging materials to avoid extraneous matter contamination of the product (e.g. use of appropriate sieves, filters, metal detectors).

The amounts and identification of rework used shall be documented to ensure complete traceability. Rework inventory and usage controls shall include stock rotation practices to ensure that the oldest rework is used first. The supplier shall ensure through its written program that expired rework is properly disposed of.

The supplier shall ensure that its use of rework complies with all applicable regulations, including labeling requirements, for the use of specific materials in the target product. For example, use of rework shall not cause the nutritional data or allergen information provided to Kraft Foods to be incorrect.

4.9. Label Control

The supplier shall ensure that labels are correctly and consistently applied to materials supplied to Kraft Foods, and that labels meet applicable Regulatory requirements and Kraft Foods Specifications. In particular, the supplier shall verify the accuracy of labels for allergen profile, ingredient information, nutritional information, net quantity and specific claims.

Each label must clearly exhibit the material name, the name and address of the Manufacturing site, packer and distributor (if applicable), as well as the lot number, net quantity, "best if used before" date (if applicable), storage conditions, preparation instructions (if applicable), allergens and the appropriate Kosher symbol if Kosher certification is required. The "best if used before" date shall be consistent with the shelf life of the material as stipulated by the Kraft Foods Specification.

The supplier must ensure through its procedures that labels and pre-printed packages are stored in a manner that minimizes mixed label batches and mixing together with other labels and packages. Special attention shall be given to packaging material changeover practices in line. Unused pre-printed labels at the end of a run must be accounted for or destroyed to ensure that the next run of materials is not inadvertently mislabeled. The supplier also shall have implemented procedures to ensure that labels match products.

4.10. Weight Control

The supplier shall have implemented a written weight control program that complies with all applicable Regulatory requirements. The weight control program shall include the application of statistical process controls, routine scale verification, periodic calibration, corrective action plans and guidelines for handling non-compliant product.

Sampling criteria for all packaging lines shall be specified in the net weight control plan. Data must be collected routinely and across the compliance lot.

For statistical process controls used, documented results shall indicate that the material is in compliance with the specification. Corrective actions shall be taken if the process is trending out of control or is not centering on the target.

Out of compliance lots must be held for further evaluation and disposition (see *Section 5.1- Hold & Release*).

4.11. 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 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 Kraft Foods Contracting Representative for approval prior to modification.

Records shall be maintained for raw and material packaging specifications.

4.12. 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 Kraft Foods.

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 properly temperature controlled at all times during transportation, and maintained in good condition, clean, dry and sealed.

Storage control program requirements

- Sanitation and pest control of storage areas should be assessed (e.g., spacing equipment or material storage away from walls for multiple pallet applications; sealed doors and windows; cleanable floors, walls, and overhead structures).
- Damaged bags or drums must be sealed to prevent product spillage and contamination. Ingredients contaminated through damage must not be used. Spills must be cleaned up to prevent potential for infestation or cross-contamination.
- Procedures that identify and track shelf life of raw materials and release status of finished goods should be implemented. An effective stock rotation system shall be in place.
- Appropriate temperature/humidity controls must be used, as required per raw materials specification. Storage temperatures and humidity (where applicable) shall be measured and documented using calibrated recording equipment.
- Storage must be off the floor. Pallets, racks and equipment shall be in good condition to prevent physical damage (e.g., free from nails, splinters). In some cases products may be stored on slip-sheets (without pallets) based on the type of product and packaging.
- Raw materials received in glass containers must be isolated from products during storage.
- Products with strong odors shall be segregated to avoid odor migration.
- Bulk storage of liquid ingredients susceptible to microbiological spoilage shall have adequate controls in place to prevent spoilage or contamination (e.g., insulated, temperature controlled and monitored).
- Pallets used for food products must be in good condition: clean, no broken boards, no evidence of mold or infestation, no off odors. Slipsheets shall be used to avoid raw material primary packaging contact with the pallet.

Specific transportation program requirements

- Procedures must be in place to ensure that products are pre chilled to required temperature prior to loading, and vehicles are pre chilled prior to loading for distribution (where applicable).
- Deliveries shall be on clean, dry, undamaged pallets/barrels/slipsheets), free from off-odors and wrapped according to Kraft Foods specifications.
- Trucks and containers (including pipes and loading / unloading equipment) shall be verified to be in good condition, dry, clean and free of off-odors before loading. Wood racks are prohibited in trucks used for Kraft materials deliveries. If other materials would be transported in the same truck, supplier must make sure that it will not alter Kraft materials.
- Temperature controlled vehicles must carry suitable on-board temperature monitoring devices. The devices shall be verified at defined intervals.
- Bulk tankers should be of stainless steel construction, or other suitable food grade material. They shall bear the following mention: "For Food only", or any equivalent mention. Bulk tankers must be equipped with appropriate safety devices for safe unloading.
- For bulk tankers, cleaning certificates shall be available and checked before each loading. Verification frequencies for equipment sanitation shall be specified. The frequencies must take into account the microbiological sensitivity of the material transported and the allergenic and GMO status of the previous load. The cleaning certificate should be in local language (or at least in English) and must stipulate:
  - Tanker plate number
  - Nature of the previous load
  - Date and hour of cleaning
  - Numbers of the cleaned compartments

- Applied cleaning program (with water, with detergents, drying etc.)
- Seals numbers for tankers

- When possible, all openings (e.g., doors, inspection ports, hatches) on outbound shipments (including outbound trailers) shall be sealed with a numbered seal and the seal number(s) annotated on the shipping documentation.
- Inbound and outbound bulk containers shall be sealed.

CHAPTER 5: INCIDENT MANAGEMENT

5.1. Hold & 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).

The Hold procedure shall address at least two levels of Holds:

- **Category I Hold** – Shall be used when a non-conformity poses a confirmed product safety issue, or major quality concern. Hold procedures shall ensure that product must be placed in a segregated and secured area or is physically obstructed. Each shipping unit must be labeled as being on hold. Inventory must be confirmed daily with a documented physical check of the stock on hold. Hold reasons may be coded for identification, but Hold signs shall not list the reason for the hold (unless required by a Regulatory Authority). Examples of category I holds are:
  - Undeclared Allergens identified in product
  - Failure to meet CCP requirements
  - Contamination due to employee illness
  - Unacceptable pathogen test result
  - Presence of an undeclared ingredient
- **Category II Hold** – Shall be used when a suspected non conformity, poses a potential food safety issue or Regulatory non-conformance, or a minor product or material quality defect. . A computerized Hold may be sufficient if the system effectively blocks selection and shipment of product. Alternatively, product must be visually labeled as on hold or physically obstructed. Inventory must be confirmed monthly. Examples of category II holds are
  - A non-conformance which causes the ingredients on the ingredient list to be in the wrong order.
  - Net Contents compliance lot average is below the stated label weight claim.
  - Non-conforming product pending corrective action completion, re-testing and, or final disposition decision.
  - Deviation from a CCP/sPP requirement pending investigation or further actions.

After release of a lot/code of product to Kraft Foods, the supplier shall not initiate pathogen testing on either that lot/code of product or any ingredients used in that product.

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

Prior to release, evidence shall be documented to demonstrate one of 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

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 Kraft Foods 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 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.

The Kraft Foods Contracting Representative shall be notified immediately in the event of a product retrieval that impacts Kraft Foods products (see *Section 1.2- Notifying Kraft Foods of Significant Events*).

5.3. Control and Disposition of Non-conforming Products

Disposition of materials on Hold that do not comply with specific approved Kraft Foods 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.

CHAPTER 6 – PACKAGING REQUIREMENTS

6.1. Introduction

The *Kraft Foods Supplier Quality Expectations (SQE)* outlines the general requirements for all suppliers. The chapters which are NOT relevant for packaging suppliers are indicated in the Table of Contents.

Food contact materials and food packaging materials in this document refer to all components of the package, including those materials that are intended for direct contact with the food, as well as those materials used on a non-food contact surface (e.g., printing inks) or used in applications where contact with food would only be incidental (e.g., adhesives). The term primary packaging refers to packaging for the food, while non-primary packaging would be wraps or containers used for holding pre-packaged food.

At a minimum, all packaging materials supplied to Kraft Foods must comply with all applicable laws, regulations, and Codes of Practices and Standards of the production country and the destination to which the materials will be delivered (both national and local requirements, as applicable).

All food contact materials (refer to glossary for details) shall be accompanied by a PMIS, with a supplier material data sheets or specifications and letter(s) of regulatory compliance, covering materials and conversion (e.g. inks, adhesives,

coatings). The regulatory compliance letter shall demonstrate compliance of the food packaging based on (i) applicable regulatory requirements for direct or indirect food contact, and (ii) standards of the location where the products are produced and the destination to which products may be delivered as specified by Kraft Foods.. All corresponding raw data and documents necessary to establish regulatory compliance must be maintained and available. Packaging suppliers must comply with all sections of the SQE manual except those identified in the index as not applicable.

6.1.1. Packaging Material Information Sheet (PMIS)

For all packaging materials produced or shipped to the U.S. or Canada, a Packaging Material Information Sheet (PMIS) must be obtained from Kraft Foods Packaging R&D, completed and returned to Kraft Foods. This must occur prior to Kraft Foods Packaging Specification development and purchase of material by Kraft Foods. A PMIS form also may need to be completed for other regions upon request.

6.1.2 Packaging Manufacturing

Food Contact Packaging shall not be a source of biological (e.g. microbial), chemical or physical (e.g. foreign bodies) hazards. Suppliers must demonstrate their ability to control food safety hazards in order to ensure that food is safe at the time of human consumption. Approval requirements for food contact suppliers are detailed in section *2.2. Kraft Foods Audit/Inspection Requirements*

6.1.3 Printed Material Management: Destruction or Recycling of Kraft Foods Labeled Packaging Material

The supplier must ensure that any discarded or recycled materials (including any scrap or waste) containing any Kraft Foods' name, trademark or logo, or any other Kraft Foods identifying information, cannot be reused. Packaging material must be defaced or destroyed (crushed, shredded, etc.) so that the no part of the material (containers, labels, caps, etc.) could be used in any manner. Trash compacting is viewed as acceptable means of disposal / disfigurement.

6.2 Transfer of constituents from food contact material to food

Suppliers must ensure that delivered packaging materials or food contact articles are of a purity suitable for their intended use and are manufactured in compliance with GMP requirements. Under their normal or foreseeable conditions of use, materials shall not transfer their constituents to food at levels that would cause the food to become adulterated or that would render the food unsafe for consumption. This requirement applies to all materials and articles intended to come in contact with food, either by physical contact, by head space exchange, or by insufficient barrier, under actual, intended, or foreseeable conditions. The requirement encompasses safety and consumer acceptance during both storage and after opening (i.e., during the preparation and consumption phase).

6.2.1 Constituents from plastic materials

The packaging material shall meet all appropriate end-tests when analyzed under conditions related to the intended application, and to the food type, time, and temperature to which the packaged food is exposed during filling, processing, storage and preparation. The ingredients and composition of all plastic materials in a polymer must comply with all legal safety requirements.

6.2.2 Constituents from paper and board materials

Paper and board for direct food contact shall be of suitable microbiological quality and shall not release any antimicrobial agents into food. In the absence of applicable regulations, the following guidelines should be followed: (i) FDA's regulations in 21 CFR Part 176 or (ii) the *German Recommendation XXXVI*.

Films made of regenerated cellulose fibers must be of food packaging grade quality. In the absence of applicable regulations, the following references should be followed: *European regulation 2007/42/EC* or *U.S. 21 CFR Part 177.1200*.

6.2.3 Metal in contact with packaging

For primary packaging intended for use with dairy products, there shall be no direct contact between the packaging and copper or any alloy containing copper. Suppliers shall take steps to ensure that primary packaging does not come into contact with these compounds either directly or indirectly through regular machine wear.

6.2.4 Recycled post-consumer material

Kraft Foods favors the use of recycled materials provided that strict requirements are established to ensure food safety. Kraft Foods typically does not permit post-consumer recycled materials used for primary packaging to come in direct contact with food, unless the recycled material is obtained from a process that is the subject of an FDA "No Objection" Letter, . If compliance with food contact material regulations can be declared, we will make an exception for glass and metal, as well as for specific product applications when agreed to by your Kraft Foods Contracting Representative and included in Kraft Foods Packaging Specifications.

Food contact packaging material suppliers (except for those exclusively supplying glass and/or metal) shall have a system in place to notify Kraft Foods of any products or materials supplied to Kraft Foods that contain post-consumer recycled material.

If post-consumer recycled material is part of a multi-component primary packaging system, but is not used in the layer where it contacts the food, the post-consumer recycled material may be permitted, provided the following three requirements are met: (1) Kraft Foods has been pre-notified of the use; (2) the supplier has determined that a functional barrier exists between the recycled material and food under the intended conditions of use effectively preventing migration of the recycled material to food; and (3) the material has been identified as being recycled in the Kraft Foods Packaging Specifications.

6.2.5 Organoleptic integrity of food contact package materials

To fulfill legal requirements and to ensure consumer acceptance, food contact materials shall not change the organoleptic properties of the packed food. Food contact materials, as defined in *section 6.1, supplied to Kraft Foods must comply* with *sections 6.2.7 Odor and taste transfer* and *6.2.8 Residual solvents, **if applicable***.

6.2.6 Odor and taste transfer testing

Paper and board

The organoleptic characteristics of food contact paper and board materials (including promotional items) in direct or indirect contact with food shall be evaluated per batch according to the following methods:

EN 1230 –1 Odor assessment test

EN 1230 –2 Taint transfer test ("Robinson test")

For direct and indirect confectionery packaging both of the above mentioned sensory tests are mandatory.

Other materials

An odor assessment according to EN 1230-1 shall be performed per batch for printed films for direct and indirect contact. For other materials the testing of the organoleptic characteristics can be based on risk assessment.

Acceptability rating

Primary packaging materials in direct or indirect food contact are acceptable if:

- at the taint transfer test the off-taste is just perceptible, but difficult to define (median taste score 1.5 with above mentioned methods);
- at the odor assessment test a slight off-odor is perceived (median odor score < 2.5 with above mentioned methods);

These tests are based on a rating scale from 0 = no off-flavor or odor to 4 = strong off-flavor or odor. Other methods can be used if agreed to by Kraft Foods and provided that the comparability is documented.

Note that sensory tests must be conducted systematically by suitable and trained panelists in a suitable environment.

Questions should be addressed to your Kraft Foods Contracting Representative.

6.2.7 Residual solvents

The total residual solvents in printed and converted materials shall be kept as low as possible. The solvent shall not exceed:

- 5 mg/m^2 for Whole Bean / R&G Coffee applications
- 20 mg/m^2 for Soluble Coffee and Coffee Mix applications
- 20 mg/m^2 for Confectionery applications, thereof esters maximum 7mg/m² (e.g., ethyl acetate)
- 20 mg/m^2 for all other applications

These values can be determined according to EN 13628-2 *Determination of residual solvents by static headspace gas chromatography - Industrial method*, equilibrating the samples at 110°C for 20 minutes prior to the analysis.

The *ASTM F 1884-04 Standard Test Method for Determining Residual Solvents in Packaging Materials* can be used accordingly.

6.2.8 Printing inks

Good manufacturing practices shall be implemented for printed food contact articles to prevent transfer of the printing inks to food at unsafe levels, which may result from migration of the inks from the food contact surface or through set-off of the inks on the nonfood-contact surface due to stacking of unfilled printed articles during storage or shipment.

Solvents used in printing inks should be adequately removed from the final printed article such that any residues will not transfer to packaged food at levels that would pose a health or safety concern. .

In the U.S., suppliers shall demonstrate that the inks have a suitable FDA status for the intended use in contact with food (For ink layers with direct food contact see Section 6.2.9 - Printing in direct contact with food).

6.2.9 Printing in direct contact with food

Printing inks that are in direct contact with food, i.e., used on the food-contact surface (such as for promotions) or on the side of the package closest to the food and for which no functional barrier has been established, shall have a suitable FDA status for the intended use.

This requirement also applies to outside printed packages that could be taken into the mouth or placed in close or direct contact to an unpacked food (e.g., multi component packs that comprise of packaged and unpacked food, such as LUNCHABLES packs).

6.2.10 Packaging Material Ingredients and Processing Aids derived from Allergenic and Genetically Modified Sources, or identified as a Nanomaterial derived from allergenic sources shall not be used. (Note that oils derived from allergenic sources which have been refined, bleached and deodorized are allowed). Allergenic sources are defined in the *Kraft Foods Allergen Category List*.

Kraft Foods must be notified about the use of rubber-based natural latex used in adhesives or other indirect potential contact applications and about the use of any materials derived from Genetically Modified sources (GMOs).

Kraft Foods must also be notified about the use of any material identified as a nanomaterial.

6.2.11 Active and intelligent packaging

Kraft Foods must be notified of the delivery of any active or intelligent packaging articles intended to come into contact with food.

6.3. Environmental impact of packaging

All materials supplied to Kraft Foods must comply with national environmental packaging and packaging waste regulations of the production Location and destination Location(s) where products will be produced, used, transported and disposed.

Suppliers must consider source reduction and prevention, including an appropriate material delivery in terms of noise, urban congestion, transportation means, quantity and volume.

6.4. Reference list of regulations and methods

The following list of packaging regulations and Codes of Practices and Standards is provided as a reference and is not all-inclusive. Each supplier must be aware of and meet all Regulatory requirements of both the country where material is produced and the country to which the material will be shipped.

Packaging Material / Criteria	**Specific U.S. Regulations 21 CFR Food & Drugs (includes method)**	**Specific Regulations, national legislations, guidelines and methods**
Food contact material in general	21 C.F.R. §§ 174.5 to 174.6 - Indirect Food Additives: General	
Organoleptic properties of packaging material	Kraft Foods requirement only; no specific regulation ASTM methods: E460 Practice for Determining Effect of Packaging on Food and Beverage Products During Storage E619 Practice for Evaluating Foreign Odors in Paper Packaging E1870-04 Standard Test Method for Odor and Taste Transfer from Polymeric Packaging Film	Methods for paper & board: • ISO13302 Methods to assess modifications to the flavor of foodstuffs due to packaging
Plastics, Laminates	21 C.F.R. §§ 177.1010 to 177.2910 - Indirect Food Additives: Polymers 21 C.F.R. §§ 178.1005 to 178.3950 – Indirect food additives: adjuvants, productions aids and sanitizers	
Regenerated Cellulose	21 C.F.R. § 177.1200 - Cellophane.	
Paper, Paperboards	21 C.F.R. §§ 176.110 to 176.350 - Indirect Food Additives: Paper and Paperboard components	
Elastomers and rubbers	see plastics	

Packaging Material / Criteria	**Specific U.S. Regulations 21 CFR Food & Drugs (includes method)**	**Specific Regulations, national legislations, guidelines and methods**
Surface coatings (resins, lacquers, adhésives)	21 C.F.R. §§ 175.105 to 175.390 - Indirect Food Additives: Adhesives and components of Coatings	
Printing inks	FDA approval	
Packaging hygiene		• GFSI accepted packaging Manufacturing standards: guidance document 6.1, table VII specific requirements on packaging • PAS 223 Prerequisite program and design requirements for food safety in the manufacture and provision of food packaging • BRC/IoP Global Packaging Standard
Packaging as Waste	CONEG	

APPENDIX 1 - DEFINITIONS

General Notes:

1. The terms used to designate requirements and recommendations stated in this document include:

   - **Shall, Will (also Must)** – Used to express an obligation or imperative, binding, with no exclusions (i.e., what is mandatory).
   - **Should** – Used to express a strong recommendation among other possible options.
   - **May** – Used to indicate an action which is permissible, but not mandatory.

2. To differentiate between the finished product produced by the Supplier and Kraft Foods finished product, the Kraft Foods finished product will be called "**finished product**." All other terms, such as "**material**," "**ingredient**" and "**product**," refer to the Supplier's product.

Alphabetical list of defined terms:

Accuracy: The degree of closeness to the target value of a certified reference or other standard.

Allergen Profile: The totality of the allergens which are present in a product by design, or are likely to be present due to cross-contact. The complete allergen profile must be properly identified on the label.

Calibration: The adjustment of measuring and monitoring equipment to assure that: 1) for equipment that measures across a range of values, the measurements are accurate across the entire range to the degree of accuracy stated; 2) for equipment that is used to measure a single point, that the measurement reaches the degree of accuracy stated.

Carry-Over: Traces of product from the previous product run, which cannot be adequately cleaned from the product line due to technical limitations

Category I Hold: Shall be used for situations when a non-conformity poses a potential food safety, major Regulatory, or major quality concern.

Category II Hold: Shall be used for situations when a non-conformity poses a potential product quality or minor Regulatory concern.

Certificate of Analysis (COA): A document provided by the Supplier which indicates results of specific tests/analysis performed on a defined lot of the Supplier's product. The tests are done either by the Supplier or an external testing firm, and must be based on protocols/methods that have been approved and agreed by technical experts within Kraft Foods.

Clean in Place (CIP): A Clean in Place (CIP) system is a system that cleans solely by circulation and/or flowing chemical detergent solutions and water rinses onto and over the surfaces to be cleaned by mechanical means.

Controlled Hold: A hold status that is used for the reasons other than those that are included in the definition of Category I and Category II Holds.

Critical Control Point (CCP): A point at which control can be applied to prevent, eliminate or reduce a food safety hazard to an acceptable level.

Critical Measurement Equipment: Any measurement equipment for which correct functioning under the prescribed conditions of the test is critical for the accuracy and precision of the end result; or any piece of equipment used for testing any CCP or food safety requirements.

Cross-Contact: The introduction of pathogens from a raw product to a cooked product, or the introduction of allergens into a product which are not part of the intended formulation, through environmental conditions. For example, cross-contact may arise from: 1) traces of product from a previous production run that cannot be adequately cleaned from the production line due to technical limitations; 2) physical contact at any point in the Manufacturing process with products or ingredients that are produced on separate lines, or in the same or adjacent production areas.

Disposition: The determination of what will be done with the object of the determination. For example, the disposition of non-conforming product that has been placed on Hold is the determination as to whether to release, destroy, or take other action with the product.

Extraneous Matter: Any object or matter that may become part of the product being produced, which is not designed to be part of such product. Extraneous matter may be a foreign object, foreign material or an aberration in the product or product ingredient. Examples may include: metal; stones; wood; plastic; paper and matter inherent to raw materials (e.g., bone, nut shells).

Farm Operations: Growing and harvesting of crops, the raising of animals (including seafood), or both.
Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting.

Food Allergy/Sensitivity: The immune-mediated state of hypersensitivity resulting from exposure to a food borne allergen (usually a protein or glycoprotein) which may cause serious adverse health reactions or death.

Food Allergen Category List: Kraft Foods list of recognized food allergens, available from the Kraft Foods Contracting Representative.

Food Contact Packaging (also **"Primary Packaging"**)**:** This encompasses any physical contact (i.e., solid, liquid, or gaseous exchange) between packaging and food under actual and foreseeable conditions. It includes packaging which has:

- a surface in direct contact with the food product, and/or
- a surface in air contact with the product e.g. material touching another packaging component that is not hermetically sealed (air tight) or that has low barrier properties, and/or
- a surface in contact with the food product after opening

Food Defense: Steps to safeguard the food supply against intentional acts (or the threat of an act), such as a mass contamination or product tampering.

Food Regulatory Authority: Any national or local government body appointed or authorized to oversee activities of the food Manufacturing and supply industry. Examples include European country specific Food Standards Authorities, Trading Standards Authorities; USA Authorities such as FDA (Food and Drug Administration), USDA (U.S. Department of Agriculture), BATF (Bureau of Alcohol, Tobacco, Firearms, and Explosives); and Canada's CFIA (Canadian Food Inspection Authority).

GMO: Genetically modified organism.

Government Regulations: The laws and regulations of the Location in which products are produced and the laws and regulations of the destination to which products may be delivered.

GS1: The GS1 system of standards is the most widely-used supply-chain standards system in the world. Its label code naming elements have replaced the previous system EAN and UCC code systems. The code structures have not substantially changed, but the two organizations have merged so the now unified GS1 code names are used in this document. More information on the GS1 system of standards is available at http://www.gs1.org/.

Hazard: The potential to cause harm to human health. Hazards can be biological, chemical or physical.

Heavy Metal: Silver, arsenic, barium, selenium, lead, mercury, cadmium and hexavalent chromium.

Hold: A status assigned to a specified product indicating it must remain stopped from normal handling processes until further notice. Synonyms include terms such as: quarantined, blocked, segregated, contained, and embargoed.

Illegal Residue: Substances (i.e., chemicals, drugs, food additives) remaining on or in a product, when shipped, that exceed tolerances established by Regulatory authorities. This also includes substances for which no tolerance has been set or which is not Generally Recognized as Safe (GRAS).

Immediate Notification: As soon as possible, and in no event later than 24 hours, after the Supplier learns of the event.

Indicator Organisms: Microorganisms that may not themselves be considered pathogenic, but whose presence may indicate unsanitary conditions and/or potential presence of specific pathogens. For the purposes of this *SQE Manual*, indicator organisms for *Salmonella* in wet environments would include total enteric bacteria or coliforms. Indicator organisms for *L. monocytogenes* would be *Listeria* genus.

Ingredient/Raw Material Label: A label to be used on products intended for further processing.

Kraft Foods Contracting Representative: The Kraft Foods Contracting Representative shall be the primary contact for any contact or notification required by this document. The Kraft Foods Contracting Representative will vary depending on the region.

Lot (Lot Number): A unique identity given to a defined quantity of a material usually based on time and Location of manufacture. For continuous processes, a lot may not exceed the amount of material produced in one 24 hour period. For non-continuous processes, the batch, blend, shift, or other time segment may be used to identify a lot. For materials received in bulk, the lot is usually identified as the contents of the bulk vehicle.

Manufacturing Location: the supplier facility where the ingredient or packaging material is produced and /or packaged into the final product that is sent to Kraft Foods Locations. This includes blending operations, chopping and any direct handling of the ingredient with the potential to introduce physical, microbiological or chemical risks including allergens.

Microbiologically Sensitive Materials (also **"Sensitive Ingredient"**)**:** An ingredient deemed to be susceptible to contain pathogens or support the growth of pathogens. Sensitivity of an ingredient is based on origin, the manner in which it is processed, and/or on epidemiological and historical data.

Mock Recall: A simulated recall process. This exercise helps to ensure that traceability procedures are adequate and identify opportunities for improvement in the event of a real recall situation.

Non-Conforming: A product or ingredient that fails to meet specifications or Regulatory requirements.

Our: Belonging to Kraft Foods Global, Inc.

Packaging Component: All elements of packaging including adhesives, labels, inks, dyes and stabilizers.

Packaging Critical Control Point (PCCP): A critical Packaging Control Point, which does not fulfill the Codex requirements (see CCP), but should be applied in the relevant area to minimize the anticipated risk.

Pathogen: A food borne microorganism recognized as a public health hazard that can cause illness or death in humans.

Pesticides: Compounds classified as such by the Regulatory authorities of the Location where materials or products are produced and the destination to which they may be delivered. These include, but are not limited to, fungicides, insecticides, rodenticides and herbicides.

Production Area: Any area where products, ingredients or packages are handled and may be subject to contamination, either directly or indirectly.

Production Record: Documents detailing the history of a lot of finished product, including amounts and lot numbers of all component materials and rework, processing steps, control charts, test results, amount produced, formal releases and disposition.

Product Retrieval: Any voluntary or involuntary retrieval of product that has been released for distribution.

Purchased Materials: Ingredients or materials purchased for use in the production or packaging of products or ingredients for Kraft Foods.

Quality Program: A logical sequence of actions designed to assure specific product quality specifications are met.

Quality System: Organizational structure, policies, programs and procedures needed to manage product quality.

Recall: Removal of a product from commerce because it is believed to be in violation of applicable law or regulations (e.g., misbranded or adulterated).

Recycled Material: A pre- or post-consumer use material that has been treated, salvaged, refurbished or otherwise reworked for re-use.

Release: The action to discharge a product from Hold status for use after the cause of the Hold has been investigated, and disposition determined.

Regulatory Authority: Any duly authorized agent or employee of any government Authority empowered to enforce laws relative to food products. Any religious organization, which defines requirements for special product certification (e.g., Kosher).

Rework: Any product or product component that fails to make it completely through the Manufacturing process in its first pass, but is suitable to be returned to the process stream. Rework can result from liquid or solid semi-finished product as well as from all finished products. Rework may include non-conforming product (finished or semi-finished), intermediate material or product used to flush ingredient and product delivery lines.

Risk: An estimate of the likely occurrence of a hazard or illness.

RTE: Ready To Eat

Sanitation: All actions dealing with cleaning or maintaining hygienic conditions of the facility. This ranges from cleaning/sanitizing specific equipment to periodic cleaning activities throughout the facility, including plant and grounds cleaning activities.

Tolerance: Allowable deviation from the target value of a certified reference or other standard.

Traceability: The ability to track materials on a lot number basis up and down the distribution chain; for example to trace a specific lot of ingredient/component from the supplier who delivered it, to the product that contains it and to track a finished product to the primary external customer(s) or destination(s).