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# KRAFT FOODS

## SUPPLIER

# QUALITY EXPECTATIONS MANUAL

	<b>Issued by:</b>	<b>Approved by:</b>	<b>Reviewed by:</b>
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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. We have several documents that you will need so you can do your part in ensuring the quality and safety of our products.

The *Kraft Foods Supplier Quality Expectations (SQE)* outlined here are intended to help current and prospective new suppliers 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 facilities producing materials for Kraft Foods must meet the expectations in this manual. This document does not apply to farm operations.

As a companion document to this manual, the *Kraft Foods Supplier Quality Expectations Manual: Resource Supplement* contains additional requirements. It also includes guidances and examples for suppliers to consider in strengthening food safety and quality programs across the supply chain.

Terms used in the *SQE Manual* and the *SQE Resource Supplement* are defined in Appendix 1: Definitions of this document. The English versions of these documents are considered the official contractual versions, but alternative languages may be available. For all suppliers, these documents supersede the previous version of the *SQE Manual* issued on February 12, 2008 and the *pSQE Manual* issued on June 23, 2005.

Our requirements for Hazard Analysis and Critical Control Points (HACCP)/Food Safety programs are set forth in *Kraft Foods Global, Inc. Supplier and External Manufacturer HACCP Manual*, which will be provided in conjunction with the *SQE Manual* and the *Kraft Foods Supplier Quality Expectations Manual: Resource Supplement*.

Requirements specific for packaging suppliers are found in Chapter 6, including a table highlighting which sections of the SQE are relevant to packaging suppliers.

Suppliers of certain specific ingredients may receive separate Process Guidelines as appropriate, e.g., Suppliers of beef or gelatin materials must comply with the *Global Kraft Foods Policy for Procurement of Meat Raw Materials Sourced from Beef* and the *Global Kraft Foods Policy for Procurement of Gelatin*. Other ingredients that have specific guidance documents for Suppliers include cocoa/chocolate, dairy, eggs, juice, tree nut and peanut products.



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The *Kraft Foods SQE Manual, Kraft Foods Global, Inc. Supplier and External Manufacturer HACCP Manual*, and Process Guidelines (where applicable) do not dictate how to set up specific product safety and quality systems. They contain 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
- Ensure The *Kraft Foods SQE Manual, Kraft Foods Global, Inc. Supplier HACCP Standard Manual* and Kraft Foods Specification are communicated to supplier and provide evidence of agreement to 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 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.. Kraft Foods employee 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.



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### 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 immediately of any, but not limited to, the following:

- Systematic product quality defect or process control deviation which could lead to a voluntary or involuntary recall or withdrawal of a Kraft Foods finished product.
- Discovery of potentially defective or adulterated ingredients or packaging materials associated with product in distribution.
- Non-routine regulatory agency 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.
- Inadvertent release from Hold of any material produced for Kraft Foods.
- Event that leads the Supplier to suspect that a non-conformance 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.
- Inability to deliver materials that meet Kraft Foods Specifications
- Changes to suppliers processes and/or facilities that could have an impact on materials supplied to Kraft Foods.
- In the event of a pathogen positive result, Kraft Foods Contracting Representative must be notified, even if the specific lot is not sent to Kraft Foods.

The Supplier must notify Kraft Foods by a phone call with a live person and by email. 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. However if the representative is not available in cases of emergency, contact Kraft Foods Headquarters Security at 001-847-646-2000 and ask to be put in contact with the Special Situations Management Team (SSMT).



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## 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 should ensure compliance with the *Kraft Foods Supplier Quality Expectations Manual*, *Kraft Foods Global, Inc. Supplier and External Manufacturer HACCP Manual*, Kraft Foods Specifications for the specific product, and applicable regulatory requirements of the production country and the destination to which the products will be delivered (both national and local requirements, as applicable).

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. Records must be legible, readily identifiable and retrievable. The Quality System will clearly set out the records that must be maintained to show effective implementation and controls needed for identification, storage, protection, retrieval, retention period and disposition of records. 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. For other countries, the minimum retention time shall be two years, or longer if required by applicable law.

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 complies with the same requirements the Supplier must meet.
- Manufacturing changes: The supplier must notify Kraft Foods of their 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, production facility 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 Supplier facility must be certified by the appropriate certifying body of the country in which Kraft Foods will receive the material.
- Genetically modified organism (GMO): No raw material shall be supplied that would require GMO labeling. Supplier shall ensure that raw material does not contain any trace of unauthorized GMOs in accordance with the regulation in the destination to which they may be delivered



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- No cloned animal products: No milk, meat, or other ingredients derived from cloned animals shall be used to make Kraft Foods materials.
- Ionization: No ionized ingredients shall be used to make Kraft Foods materials. Material itself shall not be ionized either.

## 2.2.Kraft Foods Audit/Inspection Requirements

All facilities producing materials for Kraft Foods must be approved by Kraft Foods. The following options will be considered;

- Third Party auditing supplier on behalf of Kraft Foods, or
- Kraft Foods employee, or
- Recognized industry standard.

The frequency and types of audits required by Kraft Foods are available from the Kraft Foods Contract Representative. Where appropriate, the Supplier shall schedule Food Safety and Quality Audits on a periodic basis.

Suppliers must permit Kraft Foods or its representatives to enter and audit any establishment manufacturing, storing or supplying materials for Kraft Foods. Material manufacturing locations usually will be required to complete an on-site Food Safety and Quality Audit by Kraft Foods auditors or submit an audit report from a Kraft Foods approved third party audit agent. To become and remain an approved Supplier, the audit findings must be acceptable to Kraft Foods.

Separate audits are required for every facility producing material for Kraft Foods. 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 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.

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



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### 2.3. Internal Audits

The Supplier shall establish and maintain written procedures for conducting internal audits to verify whether the Quality System is being adequately implemented and whether the Quality System should be revised. Internal audits shall be conducted at set intervals.

The internal audit procedure shall ensure that each relevant function/area is periodically audited. 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 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 agencies. 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 agency samples material produced for Kraft Foods. The Supplier shall contact the Kraft Foods Contracting Representative for instruction prior to shipment of the product to a Kraft Foods facility. Supplier will provide Kraft Foods with a duplicate sample of product from the lot examined by the regulatory agency. 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).



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## 2.5.Food Defense

Suppliers acting on behalf of Kraft Foods that manufacture, process, pack, or in any way handle ingredients or final product 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. At Kraft Foods we call these efforts Food Defense and we depend on our suppliers to do their part in helping us secure our combined portion of the world's food chain.

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.

(A) US-based suppliers and international suppliers shipping direct materials or finished product into the United States on behalf of Kraft Foods are expected to complete the below requirements and be prepared to provide Kraft Foods confirmation that they have completed these requirements.

1. Adopt and maintain a facility Food Defense program (outlined below (C)).
2. FDA facility registration list. Complete and maintain registration in the Kraft Foods FDA facility registration list.
3. One-Up-One-Down records maintenance. Maintain records to identify the immediate previous source of food or ingredient received and the immediate subsequent recipient of food or ingredient shipped.
4. Detained product. Ensure detained product is held as directed by Kraft Foods (See Chapter 8 – Measurement, Analysis and Improvement).
5. Meet C-TPAT Import Security Criteria if making shipments to the U.S. but originating elsewhere.

(B) Kraft Foods international suppliers which do not ship into the United States are expected to develop facility Food Defense programs that meet set standards (outlined below (C)) and be prepared to provide Kraft Foods confirmation they have met these requirements.

(C) A Food Defense Program shall include the following:

1. Program Administration
  - (a) A documented plan (contact your Kraft Foods Contract Representative to obtain examples) that explains the site's Food Defense procedures and strategies.
  - (b) Clearly-defined roles and responsibilities of those individuals responsible for maintaining the program.
  - (c) Procedures for reporting threats or acts of intentional contamination to Kraft



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Foods and others (as required by local law).

(d) Annual vulnerability self-assessments (see Appendix 10 for examples) and procedures for fixing gaps.

2. Access control. An access control system will deter people with the intent of harming our products from gaining access to do so. Suppliers must implement systems and procedures to identify people who are regularly on site (e.g., employees and contractors) as well as 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.

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 SQE Section 4.12 Storage and Transportation.

Additional information, related regulations and training are described in *Section A: Food Defense* in the *SQE Resource Supplement*

## 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 validated 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.



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- 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 upon request.

Samples from an Environmental Testing Program may be analyzed at the supplier's pathogen laboratory provided requirements for internal lab are met. If an on-site laboratory is used:

- 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 advise 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.

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.



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- Location of the equipment.
- Frequency of the calibration (*Note:* Equipment used to measure a CCP shall be calibrated at least every six months.)
- 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.

For further requirements and guidance on elements of an effective C&PA program, see *Section B: Corrective and Preventive Actions* in the *SQE Resource Supplement*.



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## 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

The GMPs must address personal hygiene, handling and storage of equipment and materials, proper cleaning and sanitation, and receiving. *Section C: Good Manufacturing Practices (GMPs)* of the *SQE Resource Supplement* sets out a summary of requirements and guidelines for GMP practices.

### 3.2. Personnel Training

The Supplier shall ensure that all employees receive appropriate training for their job functions. Specific training requirements are as follows:

- GMPs. All employees, including temporary and seasonal personnel, must receive GMP training 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, 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*, 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.



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### 3.3. Employee Illness and Communicable Disease

The Supplier shall establish written instructions for the control of employee illness and communicable disease that may result in pathogen transmission by food. These instructions shall be available and communicated to all applicable personnel.

The instructions shall, at a minimum, include:

- Information for recognition of symptoms of communicable disease such as: diarrhea, vomiting, open skin sores, boils, fever, dark urine, or jaundice, 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.
- Policies regarding employee return to work after illness.

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. For a list of relevant communicable diseases, refer to Section D: Pathogens Involved with Communicable Disease in the *SQE Resource Supplement*.

### 3.4. Plant Structure

The facility 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 products produced or handled. In facilities handling microbiologically sensitive ingredients, 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. For more requirements and guidelines, refer to Section E: Plant Structure in the *SQE Resource Supplement*.

### 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 and steam. For specific requirements and guidelines for the management of each of these utilities, refer to Section F: Utilities in the *SQE Resource Supplement*.

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.



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### 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 food-compatible materials with 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 Sanitary Design Review by a cross-functional team (e.g., quality, sanitation, production, maintenance) in the design phase of the project. This review shall address the ease of cleaning, functionality, material selection (e.g., made of compatible material and smooth surfaces) and workmanship of the equipment or process under review.

For more requirements and guidelines, refer to Section G: Equipment Design in the *SQE Resource Supplement*.

### 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:

- 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.

For more requirements and guidelines, refer to Section H: Equipment Maintenance in the *SQE Resource Supplement*.



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### 3.8. Sanitation

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

- Sanitation schedules, methods, and frequencies.
- Correct use of appropriate sanitation equipment and tools.
- Equipment disassembly and re-assembly.
- Verification of sanitation effectiveness.
- Non-pathogen environmental monitoring programs.
- Inspection procedures.
- Recordkeeping, record review, and corrective action plans.

Written sanitation instructions shall include (where applicable):

- Chemicals to be used and how they are to be used including chemical concentrations, contact time, temperatures, frequencies, and rinsing procedures.
- Circulation velocity.
- Clean in Place/Clean Out of Place (CIP/COP) steps.

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, 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.

For further specific criteria, instructions, and requirements, including details for CIP and Non-Pathogen Environmental Monitoring program, see Section I: Sanitation in the *SQE Resource Supplement*.



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### 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, and available corrective actions.
- Inspection procedures and frequencies.
- Required documentation of pest activity, and analysis of records for trends in activity.
- Training requirements.
- A map showing the location of pest control devices, such as indoor rodent traps, glue boards, insect light traps, outdoor bait stations, and pheromone traps.

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 that pesticide 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 also 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.

More requirements and guidance are described in the Section J: Pest Management in the *SQE Resource Supplement*.

### 3.10. Zoning

All Suppliers that manufacture or handle Kraft products shall have a Zoning program to reduce the potential for microbiological contamination of products by preventing environmental cross-contamination through the application of proper controls.

Zoning principles identify and differentiate processing areas within the facility where potential sources of pathogen and non-pathogen microbial contamination exist from air or traffic (e.g., people, equipment, and materials).

The Supplier should refer to the Kraft Foods Biologically Sensitive Ingredient Category List in Appendix B of the Kraft Foods Global, Inc. Supplier and External Manufacturer HACCP Manual to determine whether it manufactures or handles microbiologically sensitive materials. The evaluation should consider both potential pathogen and non-pathogen (e.g., spoilage) contamination.

If the Supplier manufactures or handles microbiologically sensitive materials, the Supplier, in cooperation with Kraft Foods (if applicable), shall establish a written zoning program comprised of three steps:

1. Identify potential sources of cross-contamination between processing areas and/or products (e.g., product handling areas, storage areas, processing areas, raw materials). Recognize that intermediate products may not have the same



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susceptibility as the finished product and during the manufacturing of a product the risk may increase from one step to the next. For example, the microbial contamination of a product before the kill step may not be as critical as its cross contamination after the kill step, and the controls applied to prevent contamination before the kill step may not be as stringent as the controls applied after the kill step. For a checklist to help identify potential sources of cross-contamination, see Section K: Zoning in the *SQE Resource Supplement*.

2. Identify and implement appropriate controls for each zone, based on zoning risk assessment. Examples of such controls include physical measures or barriers, traffic management, utility controls, GMP measures, and sanitation controls.
3. Periodically evaluate and verify effectiveness and compliance of zoning requirements. This includes, but is not limited to, environmental testing including pathogen testing, GMP audits, and routine pre-operational and operational inspections.

More details on possible sources of cross-contamination among the different plant areas and examples of area classifications are set out in Section K: Zoning in the *SQE Resource Supplement*.

### 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). This program shall:

- Enable the detection of pathogens, harborage areas, and organisms that indicate potential presence of pathogens in the processing environment.
- Verify the effectiveness of controls for preventing cross-contamination, including Sanitation, GMPs, preventive maintenance, and plant traffic controls.
- Provide for periodic training of personnel responsible for PEM activities.

The PEM requirement focuses on two specific pathogens, *Salmonella sp.* and *Listeria monocytogenes*, as well as indicator organisms which predict their presence in the processing environment. The written PEM program shall detail the following for each product or process that presents risk of contamination:

- Sampling location, frequency, and method of sampling for each applicable target or indicator organism. Site specific sampling locations shall reflect the most critical locations. Swab site locations and time frame for taking swabs (e.g., shift, midweek, end of week) should be audited and changed on a periodic basis.
- Criteria for test results to be deemed acceptable.
- Corrective action plans, including increased control procedures and verification requirements.

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). In the event of a pathogen-positive result the Kraft Foods Contracting Representative must be notified immediately, (see Section 1.2- Notifying Kraft Foods of Significant Events), even if the specific lot is not sent to Kraft Foods. The Supplier shall conduct an investigation to identify



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the potential source and document all corrective actions. They shall also verify the effectiveness of the corrective actions.

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).

For further requirements and guidelines, see Section L: Pathogen Environmental Monitoring in the *SQE Resource Supplement*. Suppliers should also refer to the *Kraft Foods - Biologically Sensitive Ingredient Category List* in Appendix B of the *Kraft Foods Global, Inc. Supplier and External Manufacturer HACCP Manual*. Material specific advice on PEM can be requested from Kraft Foods Corporate Quality.



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## CHAPTER 4 - PRODUCTION PROCESS CONTROLS

### 4.1. Specification Compliance and Contract Review

The Supplier shall ensure that Kraft Foods Specifications are implemented at the production location, or that the Supplier's own specifications include all chemical, physical and microbiological parameters present in the Kraft Foods Specifications. The supplier shall ensure appropriate plant personnel shall have access to the latest specifications for materials supplied to Kraft Foods.

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 designate required pathogen analyses as "critical," 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 or in similar products produced on the same line, prompt corrective action steps shall be taken and Kraft Foods shall be immediately notified, even if the specific lot is not sent to Kraft Foods.

Where Certificates of Analysis (COA) are part of the Specification requirements or have been separately requested by the Kraft Foods receiving plant, 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). The COA from the approved laboratory must be supplied to Kraft. Kraft Foods reserves the right to sample each delivery and to determine the appropriate disposition.

A COA shall contain:

- 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.
- Authorized signature of the Supplier and date of signature.
- Statement that the results are actual lot analysis results or composite results commonly used in commodity industries. The only exceptions would be for analysis that are indicated in the Kraft Food Specification.
- Test and analysis results for each lot, including Kraft Foods Specification target and range.
- Parameter being tested, test method, sample size and sampling method being used.
- Laboratory name and location performing the testing.



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The Supplier shall notify the Kraft Foods receiving location if a lot is split between two or more Kraft Foods locations.

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 the Material Monitoring Program in order to ensure compliance with our Specifications. The Material Monitoring Program is designed to check for potential contaminants across the supply chain by verifying that materials meet Kraft Foods Specifications and comply with all applicable regulatory (federal, state, and local) requirements and industry standards for the designated country of the Kraft Foods receiving location. Materials are selected for the program based on their Kraft Foods risk profile.

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. Test results will be released to Suppliers and Kraft Foods, simultaneously.

Program testing may include, but is not limited to: heavy metals, mycotoxins, nitrates, dioxin & PBB, PAH, veterinary drug residues, pesticides, adulteration, melamine, ergot alkaloid, regional considerations, heterocyclic amines, Rhoda mine B, Sudan red, sodium thiocyanate, leather protein hydrolysate, lactamases, and lead chrome green.

The specific lot of material submitted for testing may 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 and comply with all applicable regulatory requirements for the designated country of the Kraft Foods receiving location.

Kraft Foods will select the materials to be included in the program and the Suppliers selected to submit materials for testing will receive further communication from Kraft Foods detailing material(s) selected for testing, sample submittal date and shipping protocol and sample submittal form.

#### **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.

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.

For Kraft Foods requirements and guidance in developing and implementing a HACCP plan, the Supplier should consult the *Kraft Foods Global, Inc. Supplier and External Manufacturer HACCP Manual*.



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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 the quality of its own suppliers.

Quality expectations, requirements and/or specifications for purchased goods that are consistent with the programs in this *SQE Manual* shall be developed, documented, and provided to suppliers. Purchased goods specifications shall be consistent with Kraft Foods raw material Specifications.

Suppliers of purchased goods shall be monitored and tracked relative to their performance and compliance with quality requirements, expectations, and specifications on an ongoing basis. Program should include risk assessment and audit by company or 3<sup>rd</sup> party audits. Feedback shall be provided to the suppliers to facilitate continuous quality improvement.

**4.4. Incoming Materials: Inspection and Testing**

The Supplier shall ensure that incoming raw materials, ingredients, and packaging materials comply with applicable regulations and Supplier's specifications, including microbiological, physical, chemical criteria, residue requirements and GMO criteria. The Supplier shall establish and make available to Kraft Foods testing requirements, parameters and specified limits to ensure food safety and quality of all raw materials, ingredients, and packaging materials.

The Supplier shall ensure that incoming product is not used or processed until it has 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 commodities and raw material from animal origin must be evaluated to ensure compliance with chemical contaminant (e.g., pesticides residues, mycotoxins) and GMO regulations locally and where Kraft Foods receives or uses the materials. Such review may be conducted through analysis of the commodity 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 may include inspection of internal cleanliness, structural integrity, inspection of seal integrity, and measurement of internal temperature for refrigerated or frozen items.

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



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The Supplier's receiving procedures shall require verification of seals with accompanying shipping documentation and inspection of other tamper evident devices (e.g., tape) at moment of receipt (when applicable). Closed trucks shall be locked. When inbound truckloads and rail shipments are sealed, the Supplier must verify that the seal numbers match the transportation documentation (e.g., Bill of Lading) upon arrival in the facility.

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.

#### 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 finished 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. Mock recalls shall be conducted at least once a year to validate the effectiveness of the traceability program.

For further specific requirements and recommendations for the traceability program, see Section M: Traceability in the *SQE Resource Supplement*.

#### 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. Where possible, allergens must be "designed-out" of the product, so that allergen labeling is unnecessary.

An Allergen Assessment shall be carried out as part of HACCP Plan development to identify, review, and document allergens likely to be present. For information on this assessment, please refer to the *Kraft Foods Global, Inc. Supplier and External Manufacturer HACCP Manual*. The Allergen Assessment must consider all allergens on the *Kraft Foods Allergen Category List* (see Appendix C of the *Kraft Foods Global, Inc. Supplier and External Manufacturer HACCP Manual*) as well as any others identified in local regulations. 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.

The Allergen Assessment shall consider possible sources of allergens related to the formulation, process, and site-specific practices, including: raw materials/ingredients, rework addition and potential for cross-contact in manufacturing, storage or shipment practices.

Avoidable allergens introduced 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



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employee allergen awareness training. Allergen-containing materials shall be stored in a manner that will prevent cross-contact.

For processes that are adequately designed for wet cleaning or flushing, avoidable allergens introduced from manufacturing carry-over (production of a previous product with allergens in the same line) shall be managed through product change-over practices such as product sequencing, flushing, and cleaning. Please refer to *Section M: Allergen Management* in the *SQE Resource Supplement* for requirements and guidance regarding inspection and validation of cleaning/flushing following a run containing an allergen not present in the next product to be run on common equipment.

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 unlabelled allergens could be introduced to the product inadvertently and understanding the control methods applied.



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#### 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 extraneous matter, which may include:

- 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).
- Preventing introduction of extraneous matter into the product (for example, through GMPs, equipment design, preventive maintenance, covers on tanks or conveyor belts).
- 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). For more requirements and guidelines on effective use of detection equipment, see Section O: Detection and Control of Extraneous Matter in the *SQE Resource Supplement*.

When glass and hard plastic exist in the production area, a specific control program shall be in place for the management of these materials. Specific controls shall be applied to devices that can be a source of extraneous matter when damaged (e.g., sieves). For more requirements and guidelines on controls for light fixtures and other glass components in production areas, see Section O: Detection and Control of Extraneous Matter in the *SQE Resource Supplement*.

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.



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#### 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 manufacturer, packer or distributor, lot number, net quantity, "best if used before" date, 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.



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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.

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."

#### **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 packaging in food contact with the delivered materials must have food-grade certificates. This packaging shall not be from recycled packaging.

Packaging must not alter product organoleptic characteristics and shall not be source of foreign bodies. 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.

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.



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#### 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 is 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. Specific requirements and guidelines for the control of storage facilities are listed in Section P: Storage and Transportation in the *SQE Resource Supplement*.

If the Supplier uses third party warehouses to store raw materials, packaging materials, semi-finished or finished products, the Supplier shall conduct 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. For specific requirements and considerations for the transportation program, see Section P: Storage and Transportation in the *SQE Resource Supplement*.



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## 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 in third party 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, 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 potential food safety concern or a major regulatory or 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. Hold reasons may be coded for identification, but Hold signs shall not list the reason for the hold (unless required by a regulatory agency). Examples of category I holds are:
  - Undeclared Allergens identified in product
  - Failure to meet CCP requirements
  - Failure to meet specified legal requirements
  - Contamination due to employee illness
  - Unacceptable pathogen test result
  - Presence of an undeclared ingredient
- **Category II Hold** – Shall be used when a non-conformity poses a potential minor regulatory or product quality concern. 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. Examples of category II holds are
  - Materials that potentially contain unlabelled allergens
  - Product undergoing pathogen testing
  - A non conformance which causes the last two ingredients on the ingredient list to be in the wrong order
  - Foreign material issue with no food safety concern

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.



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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).

### 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.



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## CHAPTER 6 - PACKAGING REQUIREMENTS

### 6.1. Introduction

The *Kraft Foods Supplier Quality Expectations (SQE)* outlines the general requirements for all suppliers. Table 1 below details which other chapters of the *SQE* are relevant for packaging suppliers. This chapter and the *SQE* supersede the previous version of the *pSQE* issued June 23, 2005.

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 shall be accompanied by a declaration of compliance covering materials and conversion (e.g., inks, adhesives, coatings). The declaration shall demonstrate compliance of food grade quality based on (i) specific migration limits and regulatory requirements for direct or indirect food contact (per application), (ii) Codes of Practices, and (iii) Standards of the location where the products are produced and the destination to which products may be delivered. Where no dedicated national food packaging legislation for plastic material exists, Kraft Foods requires compliance with either the European or the U.S. federal (Food and Drug Administration (FDA) (21 CFR), U.S. Department of Agriculture (USDA), U.S. Environmental Protection Agency (EPA)) and state regulations. All corresponding raw data and documents must be maintained and available.

Requirements for supplier Hazard Analysis and Critical Control Points (HACCP) programs are set forth in the *Kraft Foods Global, Inc. Supplier and External Manufacturer HACCP Manual*.

**Table 1: Applicability of SQE to Packaging Suppliers**

Packaging suppliers must comply with sections of the SQE manual except the following

Packaging Type	SQE Sections Not applicable to packaging Suppliers
Food Contact Packaging and/or Contains Ingredient Line	Section 3.10 – Zoning Section 3.11 - Pathogen Environmental Monitoring Section 4.10 - Weight Control
Non-Food Contact and/or Does Not Contain Ingredient Line	Section 3.5 - Utilities Management Section 3.10 - Zoning Section 3.11 - Pathogen Environmental Monitoring Section 4.2 - HACCP Section 4.6 - Allergen Management Section 4.8 - Rework Control Section 4.9 - Label Control Section 4.10 - Weight Control



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## **6.2. Transfer of constituents from a food contact material to food**

Packaging materials that come in direct contact with the product, either by design or by foreseeable use, are defined by Kraft Foods as Primary Packaging. Suppliers must ensure that delivered packaging materials or components that contain an ingredient statement/list or food contact articles are manufactured in compliance with GMPs. Under their normal or foreseeable conditions of use, materials shall not transfer their constituents to foodstuffs in quantities that could endanger human health, cause an unacceptable change in the composition of the foodstuffs, or result in deterioration of the organoleptic (tainting) characteristics thereof. 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. Packaging Hygiene**

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. Kraft Foods accepts a hygiene management system according to the standards of BRC/IoP, EN 15593 or ISO 22000.

### **6.2.2. Constituents from plastic materials**

Plastic materials and articles intended to come in contact directly or indirectly with food must be sufficiently inert to prevent the migration of plastic constituents to food. Plastic materials and articles shall not transfer their constituents to foodstuff in quantities exceeding 10 mg/dm<sup>2</sup> (Overall Migration Limit; 1 dm = 10 cm) or the appropriate limit for which the materials will be used. This limit shall be 60mg/kg foodstuff for containers or comparable vessels having a volume between 500 ml and 10 litres and for articles for which the surfaces are impracticable to determine (e.g., caps, gaskets).

The material shall be tested under conditions related to the food type, time, and temperature that 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.

For safety reasons, the residual monomer content in PVC shall not exceed 1 mg vinyl chloride per kg polymer. In addition, vinyl chloride shall not be detectable in food.

### **6.2.3. Constituents from cellulose fiber 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, (ii) the



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Council of Europe Resolution on Paper and Board Materials and articles intended to come into contact with foodstuffs (AP 2002/1), or (iii) the German Recommendation XXXVI.

Films made of regenerated cellulose fibers must be of food 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.

#### **6.2.4. Metal in contact with packaging**

For primary packaging intended for use with daily 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.

Regarding polymeric coatings on metal cans and sheets see section 6.2.2.

#### **6.2.5. 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 packages to come in direct contact with food, unless Supercleaned processed. If compliance with food contact material regulations can be declared, we will make an exception for glass, metal, and 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 usage recycled material.

If post-consumer recycled material is part of a multi-component primary packaging system, but is not in the layer where it contacts the food, the use of the post-consumer recycled material will only be permitted subject to three requirements: (1) Kraft Foods must be pre-notified; (2) the Food Additive/Migration status must be ascertained with respect to the intended use; and (3) the material must be included in the Kraft Foods Packaging Specifications.

#### **6.2.6. Consumer acceptance**

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.

#### **6.2.7. Odor and Taste transfer**

Separate from solvent testing, the organoleptic characteristics of food contact paper and board materials (including promotional items) in direct or indirect contact with food shall be evaluated according to the following methods:

EN 1230 –1 Odor transfer test



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EN 1230 –2 Taint Transfer test (“Robinson test”)

For plastics and paper DIN 10 955 shall apply for both taste and odor transfer test

For direct and indirect confectionery packaging, the above mentioned taste tests are mandatory.

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 test a slight off-odor is perceived (median odor score < 2.5 with above mentioned methods);
- or any other methods agreed to by Kraft Foods are used that assure the sensory quality of the materials.

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

Questions should be addressed to your Kraft Foods Contracting Representative.

#### **6.2.8. 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<sup>2</sup> for Whole Bean / R&G Coffee applications
- 20 mg/m<sup>2</sup> for Soluble Coffee and Coffee Mix applications
- 20 mg/m<sup>2</sup> for Confectionery applications, thereof esters maximum 7mg/m<sup>2</sup> (e.g., ethyl acetate)
- 20 mg/m<sup>2</sup> 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.

#### **6.2.9. Printing inks**

Printing inks applied to the non-food contact side of a packaging shall not transfer any residues of toxicological concern. The inks must be of high purity to ensure that there is no migration of substances that have not been toxicologically evaluated and that there is no violation of any specific migration limit imposed for other materials.

Aromatic compounds (e.g., toluene, xylene) shall not be part of the formulation added to packaging materials during the production, printing or cleaning processes. However traces below 0.5 mg/m<sup>2</sup> shall be considered ‘aromatic’ free.

Kraft Foods requires compliance with the *[EuPIA guideline on printing inks applied to the non-food contact surface of food packaging materials and articles](http://www.eupia.org)* ([www.eupia.org](http://www.eupia.org)) and the *Swiss Ordinance on Materials and Articles in Contact with Food, Section 8b, Packaging Inks, Art. 26e – 26i1.*



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In the U.S., suppliers must have an FDA regulatory approval letter on file for approved use of specific inks used for indirect or direct product contact. (For ink layers with direct food contact see Section 2.2.10 - Printing in direct contact with food).

**6.2.10. Printing in direct contact with food**

When packaging materials are printed on the side that will be in direct contact with food and no functional barrier is in place, only food grade colorants can be used. Colorants must be approved for food use in the locations where the products are produced and may be delivered. In the U.S., inks used for direct product contact must be FDA approved food grade colorants.

This requirement applies to printings on the inner side of a package (e.g., for promotions). It 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).

**6.2.11. Packaging Material Ingredients and Processing Aids derived from Allergenic and Genetically Modified Sources**

Materials 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* (see [Appendix C](#) of the *Kraft Foods Global, Inc. Supplier and External Manufacturer HACCP Manual*).

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

**6.2.12. 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. Such materials must be accompanied by a declaration of compliance according to *EU Commission Regulation 450/2009*.

**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.

**6.3.1. Minimization of heavy metals, and other N-classified substances**

The supplier shall certify for all packaging materials that heavy metals are not introduced into Kraft Foods packages or packaging components. The supplier shall furnish a Heavy Metals Warranty to Kraft Foods prior to purchase of materials.



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The supplier shall certify that packaging materials supplied to Kraft Foods or used for any Kraft Foods labeled products do not contain more than a combined total of 100ppm by weight of the following heavy metals from any source: lead, mercury, cadmium and hexavalent chromium. The supplier must conduct periodic monitoring of materials (including adhesives, labels, inks, dyes and stabilizers) to assure compliance with this policy.

All materials delivered to Kraft Foods shall not contain substances classed as toxic (T) or highly toxic (T+) with risk statements R23, R24, R25, R26, R27, R28, R39 and R48 (according to Regulation EC 1272/2008 and its amendments). In addition the materials must be free of any carcinogenic, mutagenic or reprotoxic substances (CMR) categories 1, 2 and 3 (according to Regulation EC 1272/2008 and its amendments) unless the substance has been assessed within the framework of its usage for food contact and on condition of compliance with set limits as appropriate (QM and/or SML).

#### **6.3.2. Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)**

Kraft Foods requires compliance with REACH Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) for all packaging items that are preparations or articles containing substances to which the REACH obligations relate. Kraft Foods must be notified of contained substances of very high concern (SVHC) even below 0.1% and must receive an early warning if packaging composition is going to change due to discontinuation of substances or restrictions.

#### **6.4. Packaging Component Information Sheet (PCIS)**

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



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### 6.5. 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.

Note: Any reference made to an EC Directive or Regulation should be understood to include all subsequent amendments and/or other new Directives which revoke or repeal the existing one.

Packaging Material / Criteria	Specific U.S. Regulations 21 CFR Food & Drugs (includes method)	Specific Regulations E.U., national legislations, guidelines and methods
Food contact material in general	21 C.F.R. §§ <a href="#">174.5 to 174.6 - Indirect Food Additives: General</a>	<ul style="list-style-type: none"> <li>• EC-Regulation No 1935/2004</li> <li>• <u>Commission Regulation 2023/2006 – GMP on materials and articles intended to come into contact with food.</u></li> <li>• Migration testing: Food Simulants Directive 85/572/EEC, 2007/19/EC</li> <li>• Migration Testing Conditions Directives 82/711/EEC, 93/8/EEC, 82/711/EEC (Includes method guidelines)</li> </ul>
Organoleptical properties of packaging material	Kraft Foods requirement only; no specific regulation ASTM methods: <u>E460</u> Practice for Determining Effect of Packaging on Food and Beverage Products During Storage <u>E619</u> Practice for Evaluating Foreign Odors in Paper Packaging	<ul style="list-style-type: none"> <li>• EC-Regulation No 1935/2004</li> </ul> Methods: <ul style="list-style-type: none"> <li>• EN 1230 –1 Odor transfer test</li> <li>• EN 1230 –2 Taint Transfer test (“Robinson test”)</li> <li>• For all other materials DIN 10 955 <b>will</b> apply for both taste and odor transfer test.</li> <li>• ISO13302 Methods to assess modifications to the flavour of foodstuffs due to packaging</li> </ul>



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Packaging Material / Criteria	Specific U.S. Regulations 21 CFR Food & Drugs (includes method)	Specific Regulations E.U., national legislations, guidelines and methods
	E1870-04 Standard Test Method for Odor and Taste Transfer from Polymeric Packaging Film	
Plastics, Laminates	21 C.F.R. §§ <a href="#">177.1010 to 177.2910 - Indirect Food Additives: Polymers</a> 21 C.F.R. §§ <a href="#">178.1005 to 178.3950</a> – Indirect food additives: adjuvants, productions aids and sanitizers	<ul style="list-style-type: none"> <li>– Plastic Monomers Directive 2002/72/EC + amendments</li> <li>– Vinyl Chloride Monomer Limit Directive 78/142/EEC</li> <li>– Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food</li> <li>– Resolution AP (92) 2 on control of aids for plastic materials and articles intended to come into contact with foodstuffs</li> </ul> <p><u>Methods:</u></p> <ul style="list-style-type: none"> <li>– Determination of VCM in PVC, Directive 80/766/EEC,81/432/EEC</li> </ul>
Regenerated Cellulose	21 C.F.R. § <a href="#">177.1200 - Cellophane.</a>	<ul style="list-style-type: none"> <li>• Regenerated Cellulose Film Directive 2007/42/EC</li> </ul>
Ceramics		<ul style="list-style-type: none"> <li>• Ceramics Directives 84/500/EEC, 2005/31/EC</li> </ul>
Paper, Paperboards	21 C.F.R. §§ <a href="#">176.110 to 176.350 - Indirect Food Additives: Paper and Paperboard components</a>	<ul style="list-style-type: none"> <li>• Resolution AP (2002) 1 on paper and board materials and articles intended to come into contact with foodstuffs;</li> <li>• Recommendation XXXVI Paper and Boards of the German Federal Institute for Risk evaluation (BfR) - <a href="http://www.bfr.bund.de">www.bfr.bund.de</a></li> </ul>
Elastomers and rubbers	see plastics	<ul style="list-style-type: none"> <li>• Nitrosamine Directive 93/11/EC; Resolution AP (2004) 4 on rubber products intended to come in contact with food</li> </ul>
Silicones		<ul style="list-style-type: none"> <li>• Resolutions AP (99) 3 and AP (2004) 5 on silicones used for food contact application</li> </ul>



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Packaging Material / Criteria	Specific U.S. Regulations 21 CFR Food & Drugs (includes method)	Specific Regulations E.U., national legislations, guidelines and methods
Surface coatings (resins, lacquers, adhesives)	21 C.F.R. §§ <a href="#">175.105 to 175.390 - Indirect Food Additives: Adhesives and components of Coatings</a>	<ul style="list-style-type: none"> <li>• Epoxy Derivatives Directives 1895/2005/EC</li> <li>• Resolution AP (96) 5 on surface coatings intended to come into contact with foodstuffs</li> <li>• Resolution AP (2004) 1 on coatings intended to come into contact with foodstuffs</li> </ul>
Printing inks	FDA approval	<ul style="list-style-type: none"> <li>• Commission Regulation 2023/2006 – GMP on materials and articles intended to come into contact with food.</li> <li>• Swiss Ordinance on Materials and Articles in Contact with Food, Section 8b, Packaging Inks, Art. 26e – 26i1</li> <li>• EuPIA guideline on printing inks applied to the non-food contact surface of food packaging materials and articles</li> <li>• Resolution AP (2005) 2 on packaging inks applied to the non-food-contact side of food packaging</li> </ul>
Recycled plastics		<ul style="list-style-type: none"> <li>• Commission Regulation 282/2008 on recycled plastic materials and articles intended to come into contact with food</li> </ul>
Active and intelligent packaging		<ul style="list-style-type: none"> <li>• Commission Regulation 450/2009 on active and intelligent materials and articles intended to come into contact with food</li> </ul>
Packaging hygiene		<ul style="list-style-type: none"> <li>• BRC/IoP Global Packaging Standard</li> <li>• EN 15593 Management of hygiene in the production of packaging for foodstuffs</li> <li>• ISO 22000:2005 Food safety management systems</li> </ul>
Packaging as Waste	CONEG	<ul style="list-style-type: none"> <li>• Packaging &amp; Packaging Waste Directive 94/62/EC</li> <li>• Methods: EN 13427 – EN13432; CR 13688; CR 13695</li> </ul>



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## 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 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.



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**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 processing 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:** This encompasses any physical contact (i.e., solid, liquid, or gaseous exchange) between packaging and food under actual and foreseeable conditions.



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**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 Agency:** 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 Agencies, Trading Standards Agencies; USA agencies 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 Agency).

**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. Hazards can be biological, chemical or physical.

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

**Hold:** A status assigned to 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 are 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.



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**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.

**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. For more information, see *Kraft Foods Biologically Sensitive Ingredient Category List* in Appendix B of the *Kraft Foods Global, Inc. Supplier and External Manufacturer HACCP Manual*.

**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.

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**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.

**Primary Food Packaging (also "Primary Packaging"):** Packaging which has:

- a surface in direct contact with the food product, and/or
- material touching another packaging component not hermetically sealed (Air tight), and/or
- a surface in contact with the food product after opening

It does not include packaging that is not intended to directly contact the product.



<b>SUBJECT:</b> <b>Supplier Quality Expectations</b>	<b>ISSUE DATE/REVISION</b> May 10, 2010 <b>SUPERSEDES:</b> SQE, dated Feb 12, 2008 & pSQE dated June 23, 2005 <b>PAGE:</b> 45 of 45
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**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 agency 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 a specific lot of ingredient/component to the product that contains it; and to track a finished product to the primary external customer(s) or destination(s).