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KRAFT FOODS

SUPPLIER

QUALITY EXPECTATIONS MANUAL:

RESOURCE SUPPLEMENT

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SECTION A: FOOD DEFENSE

Suppliers should contact their Kraft Foods buyer/procurement professional to obtain samples of our Food Defense support materials such as a Food Defense Plan Guideline, site assessment tools, and training materials.

Suppliers are also encouraged to use the numerous public and government websites (a sampling is provided below) to assist with their Food Defense program development.

C-TPAT

Please note that shipments from outside the U.S. must meet the C-TPAT Import Security Criteria, please click on the link for specific information:

(http://www.customs.ustreas.gov/xp/cgov/import/commercial_enforcement/ctpat/criteria_importers/ctpat_importer_criteria.xml)

C-TPAT members: http://www.cbp.gov/xp/cgov/trade/cargo_security/ctpat/ctpat_members/

C-TPAT Cargo Security http://www.cbp.gov/xp/cgov/trade/cargo_security/ctpat/

FOOD & DRUG ADMINISTRATION (FDA):

Federal Food, Drug, and Cosmetic Act, 21 USC 321, et. seq.

<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm>

FDA Guidelines, <http://www.fda.gov/ForIndustry/GuidanceDocuments/default.htm>

Reportable Food Registry Section 417 of the FDCA.

<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterIVFood/ucm088549.htm>

21 CFR 1-199, <http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200821>

42 CFR 73, http://www.selectagents.gov/resources/42_cfr_73_final_rule.pdf

FDA - "ALERT: Food Defense Awareness"

<http://www.accessdata.fda.gov/videos/CFSAN/ALERT/alrt01.cfm>

UNITED STATES DEPARTMENT of AGRICULTURE (USDA) & FOOD SERVICE INSPECTION SERVICES (FSIS)

USDA - Food Safety and Inspection Service (FSIS) "Developing a Food Defense Plan for Meat and Poultry Slaughter and Processing Plants", January 2007

http://www.fsis.usda.gov/PDF/Food_Defense_Plan.pdf

FDA/USDA - "An Introduction to Food Security Awareness"

<http://www.fda.gov/ora/training/orau/FoodSecurity/startpage.html>

DEPARTMENT OF HOMELAND SECURITY (DHS)

CBP – Customs-Trade Partnership Against Terrorism Security Criteria

http://www.cbp.gov/xp/cgov/trade/cargo_security/ctpat/security_criteria/



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SECTION B: CORRECTIVE AND PREVENTIVE ACTIONS (C&PA)

An effective C&PA program (see Section 2.8 of the *SQE Manual*) shall include the following steps:

- Identification of C&PA opportunities.
- Determination of immediate action(s) to be taken (including responsibility and timing).
- Root cause analysis and quantification of the problem (prioritization).
- Identification of long-term (permanent) solutions (including responsibilities and timing). When required, resources (e.g., personnel, capital, equipment) must also be identified.
- C&PA plan implementation.
- Further analysis of data to validate if the desired results were achieved (e.g., was the plan effective in resolving the root cause).
- Periodic review of C&PA by the management team.

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

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

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



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SECTION C: GOOD MANUFACTURING PRACTICES (GMPs)

Section 3.1 of the *SQE Manual* sets out requirements for a GMP program. Further specific requirements and guidelines include the following.

Personnel practices

The following actions are not allowed in GMP areas:

- Eating or drinking – permitted in authorized areas of the facility only.
- Chewing gum, candies, throat candies, throat lozenges and tobacco.
- Holding toothpicks, matchsticks or other objects in the mouth.
- Wearing false eyelashes, fingernails or fingernail polish.
- Carrying objects above the belt or waistline (e.g., pens, flashlights, thermometers, placing pens or cigarettes behind the ears)

Expectorating (spitting) in production areas.

- Rings (other than plain wedding bands), watches, earrings, necklaces, or other jewelry (including ornaments or piercing in exposed body areas such as the tongue and/or nose) must not be worn in GMP areas. Plain wedding bands are permitted to be worn by employees who do not handle or work in the proximity of exposed product.
- Additionally, the following rules must be observed:
- If smoking is permitted in facility, it is only permitted in designated areas, but never in GMP areas.
- Badges and clip-on identification cards, if used, must be worn below the waist. Visitor identification badges are permitted but must not be a source of contamination at the plant.
- Buttons, service pins or similar articles are not permitted on uniforms smocks, bump caps or hard hats.
- Lunches must be stored in designated areas. Lunches must be completely enclosed in cleanable / reusable containers or in single-use packaging (e.g., lunch paper bag or plastic bag/wrap).
- Personal lockers must be maintained free of trash and soiled clothing. Food and direct product contact tools must not be stored in employee lockers.

Clothing and personal equipment

- All clothing must be kept in good repair. Employee clothing should not be a source of contamination.
- GMP areas: Employees who work in GMP areas must wear only company-approved clothing. Clothing shall provide adequate coverage that ensures hair, perspiration or other foreign materials do not contaminate the product (e.g., no shorts, tank tops, sleeveless shirts). Non-production employees, contractors and visitors who enter GMP areas must wear a lab coat (or other approved covering) and wear appropriate footwear consistent with plant policy.
- Pockets above the waist must be removed or sewn shut. Only zippers, grippers or snaps may be used as the fasteners on shirts, coats, laboratory jackets, or smocks.
- Restricted uses: Work wear dedicated to specific product areas must be restricted to those areas. Such areas must be defined in local procedures (typically high care



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areas where clothing change is required on entry and exit). They are not permitted in other plant or non plant areas where they may be subject to allergen or micro contamination (e.g., cafeteria, external rest areas, any area not subject to GMP controls).

- Captive clothing policies: If a captive clothing and footwear policy exists, employees who work in microbiologically sensitive areas must not wear the company clothing and footwear outside of the plant. When not in use, such clothing should be stored in a sanitary manner (e.g., on hangers or hooks).
- Shoes: To help avoid product contamination (and for personal safety) shoes worn in GMP areas should be designed and constructed as follows: fully enclosed (no open toes, open weave, or sandals); made with leather or vinyl outer materials (no canvas or nylon mesh); low heeled; sole grooves depth must not be a source of contamination. Shoes in wet microbiologically sensitive areas must not allow passage of water from the base of the shoes (shoes should not trap or absorb water when walking through footbaths at room entrances).
- Safety helmets: Safety helmets must be maintained in a sanitary condition. Labels or stickers are prohibited. Helmets used in microbiologically sensitive areas must be cleaned and sanitized on a frequency determined by plant quality. Helmets must not be used for storing or carrying objects such as cigarettes, notepads, food, and pens.
- Ear protection devices: Ear protection devices must be secured to prevent product contamination. These include: ear plugs attached by string worn around neck, earplugs with rigid attachment worn around neck, and earmuffs attached by headband. If available, particularly in facilities where production lines are equipped with metal detectors, it is recommended that metal detectable earplugs are used.

Hands

- Personnel working in GMP areas must wash hands at the following times: before entering a GMP area; upon re-entering the GMP area; after each visit to the toilet facility, rest room, and/or lunch and break room facilities; prior to touching product or product contact surfaces; or any time when hands have become soiled or contaminated.
- Personnel working in a microbiologically sensitive area must sanitize their hands after proper washing and after touching non-product contact surfaces. If soil is observed on hands, hands must be washed prior to resanitizing.
- When working in GMP areas, the use of hands for unsanitary practices must be avoided. Specifically, hands should not be used to: scratch head or body, touch face or wipe forehead, place fingers on or in mouth, nose, or ears.
- Hand lotions must not be used if hands are in direct contact with product or product-contact surfaces. However, approved gloves may be worn over hands having non-perfumed lotion, if compatible with work conditions and regulatory rules.
- Personnel with minor cuts or injuries on hands must be able to protect the wound and keep it clean and free from infection. They will be allowed to work on production lines provided the cuts are bandaged and covered with an impermeable sanitary material. Adhesive bandages must be metal detectable in facilities where metal detectors are used.



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Hair

1. Hair must be maintained as follows in GMP areas:

- Hair must be kept clean.
- Hair curlers, hair combs, and bobby pins are not allowed.
- Barrettes (at least 5 cm or 2 inches long), clasps, scarves or bandannas may be worn neatly under the hair net.

2. Plant-supplied hair restraints must be worn in GMP areas.

- Hairnets/restraints must be of a close mesh type and be non elastic mesh (i.e., 1/8 x 1/8 in or 0.3 x 0.3 cm).
- Hairnets/restraints must completely contain the hair and cover the ears.
- If safety or bump helmets are used, they must be worn over appropriate hair restraints.

3. Facial hair must be maintained as follows in GMP areas:

- Employees must be clean-shaven or cover the exposed hair as completely as possible with a plant-supplied beard restraint.
- Sideburns must be trimmed and be no longer than the bottom of the ear or a beard net worn.

Proper storage

Product, ingredients and rework must be adequately protected and stored in a sanitary manner.

- Product or ingredient containers shall not be stored immediately adjacent to containers for waste or non-product items (e.g., cleaning compounds, laboratory solvents). Non-product items should be stored in separate, designated areas.
- Ingredients must be adequately protected and stored in a sanitary manner in their original, labeled container, or in another authorized sanitary container that is clearly marked for the use of the specific ingredient (e.g., sanitary pails or tote bins). Ingredient identification and lot number/traceability must be maintained. Containers must be properly closed/sealed/covered. When returning ingredient containers to storage, ensure ingredients are stored in the proper temperature environment.
- Bulk pre-weighed ingredients must be stored in appropriate containers and under appropriate conditions.
- Rework product shall be adequately covered/protected during intervals such as breaks, lunch periods, and downtime, with clean plastic or other suitable material. Traceability of rework shall be maintained.

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

- Material shall be covered to prevent contamination (e.g., closures, films).
- Packaging material must be removed from the area during wet cleaning.
- Packaging materials must not be stored directly on walking surfaces.
- Identification and traceability of packaging materials must be maintained.

All items shall be stored to avoid direct contact with the floor or walking surfaces (e.g., on pallets, slipsheets or racks).



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- Where slipsheeting operations are used, the slipsheeted product may be stored directly on the floor provided there are no sources of contamination.
- Pallets shall not be in contact with primary packaging or cause a risk of contamination through extraneous matter when stacked.
- Sitting or standing on product shipping cases is not acceptable.
- Product must be stacked to appropriate heights. Over-stacking must be avoided.

Cleaning and sanitation

Water must not be splashed from the floor or from unclean equipment onto cleaned equipment or processes during operation. Water from cleaning operations in one area must be prevented from flowing into areas where product is being produced.

Near sanitized equipment and in areas of exposed finished product, water hoses or compressed air hoses should not be used to clean the floor or equipment due to formation of aerosols. High pressure water greater than 100 psi/7 bar shall not be used during operation.

Gaskets must be handled and stored in a sanitary manner:

- Product-contact gaskets must be cleaned or replaced at a defined frequency.
- Used or damaged/worn gaskets must be discarded to prevent inadvertent later use.
- New gaskets must be washed before use.

To prevent product contamination, tools and equipment must be used only for the intended purpose, dedicated to these specific uses and handled and/or stored appropriately. For example, procedures must be in place to keep tools used in raw areas or with allergenic ingredients from being used for other purposes.

Receiving

When unloading bulk raw materials from trucks or railcars, the dome openings must be adequately screened to protect the materials within the tanker from potential extraneous matter contamination. The screening device must allow sufficient airflow into the tank to permit normal unloading and provide adequate protection from rainwater.

Bulk ingredients must be properly transferred through sanitary pipes and/or hoses, and filtered, screened or sifted as required.

Visitors Must Comply with GMPs

All visitors entering GMP areas, microbiologically sensitive, or restricted areas must comply with company and site-specific GMP rules – no exceptions!



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SECTION D: PATHOGENS INVOLVED WITH COMMUNICABLE DISEASE

Section 3.3 of the *SQE Manual* sets out requirements for control of communicable diseases. The following list shows the currently recognized pathogens/diseases from pathogens which can be transmitted by food that has been contaminated by an infected person.

OFTEN TRANSMITTED

- Hepatitis A virus*
- Norwalk (-like) viruses (Noroviruses)*
- Salmonella typhi*
- Shigella species*
- Staphylococcus aureus*
- Streptococcus pyogenes*

OCCASIONALLY TRANSMITTED

- Campylobacter jejuni*
- Entamoeba histolytica*
- Enterohemorrhagic Escherichia coli*
- Enterotoxigenic Echerichia coli*
- Giardia lamblia*
- Nontyphoidal Salmonella*
- Rotavirus*
- Taenia solium*
- Vibrio cholerae 01*
- Yersinia enterocolitica*
- Cryptosporidium parvum*



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SECTION E: PLANT STRUCTURE

Section 3.4 of the *SQE Manual* sets out requirements for a plant structure program. Further requirements and guidelines include the following.

Plant Design and Construction

- The internal and external structure shall be free of cracks, holes, openings, and pest entry or nesting areas.
- All exterior doors shall be self-closing and must form an adequate seal when closed. Loading docks shall be protected to prevent pest entry. Entrance of air shall be limited by vestibules or air curtains as appropriate.
- The roof must drain freely and must not leak.
- Windows present in production areas that can be opened must be adequately screened. All vents and fans shall also be adequately screened.
- Doors, windows, and other openings shall prevent access by unauthorized people.
- The plant structure must be designed to physically separate raw and processed zones, as necessary. Where raw and processed zones are utilized, traffic patterns between zones must be controlled. See also Section 3.10- Zoning in the *SQE Manual* and Section K: Zoning herein.
- Floors, walls, ceilings, overheads and drains shall be cleanable and constructed to resist deterioration from product or cleaning chemicals.
- Floors shall be sealed, in good repair, sloped adequately to avoid standing water, and pitched to a drain. The wall/floor juncture should be concave.
- Floor drains shall be trapped and vented to prevent sewer gas entry and must be accessible and cleanable. Existing floor drains which are not trapped and vented shall be sealed or replaced.
- During construction, adequate controls shall be in place to prevent contamination.
- Laboratories must be separated from the production areas. At a minimum, laboratories should be in a separate room with a door. Additional separation requirements apply to microbiology laboratories.

Personnel facilities

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



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SECTION F: UTILITIES

Section 3.5 of the *SQE Manual* sets out requirements for a utilities management program. Specific requirements and guidelines include the following.

Environmental Air

- Air quality shall be monitored, trended and reviewed by appropriate personnel, as necessary to ensure suitable microbiological quality. The Supplier program must include monitoring in production areas with exposed microbiologically sensitive materials that will not receive a subsequent kill step. Corrective action shall be taken for out of standard results.
- The integrity of air filters shall be checked as part of regular preventive maintenance.
- The Supplier shall maintain suitable air pressure differentials between adjacent areas in relationship to positive, negative or ambient airflow to prevent product contamination (please refer to Section 3.10- Zoning in the *SQE Manual*).
- All plant exterior air intake ports shall be visually examined for physical integrity at a frequency determined by risk assessment, but minimum annually. Examination shall be included in preventive maintenance plans.
- The air filtration requirements vary according to the classification of the different products and production areas (please refer to Section 3.10- Zoning in the *SQE Manual*):

Environmental and Compressed Air Action Standards

Environmental Air				Compressed Air
Product category	Organism	Air Exposure Plates	Air Sampler	< 0.04 cfu / ft ³ or < 0.001 cfu / or <1.4 cfu/m ³
Post heat treatment or pasteurization; products with Aw < 0.65 (processing, filling and packaging)	Yeast & Mold	< 100 cfu / 15 minutes	< 1 000 cfu / m ³	
Dairy powder	Yeast & Mold	< 10 cfu / 15 minutes	< 500 cfu / m ³	
Post heat treatment or pasteurization; products with Aw 0.65 - 0.95 (processing, filling and packaging)	Yeast & Mold	< 10 cfu / 15 minutes	< 500 cfu / m ³	
Post heat treatment or pasteurization: products with Aw > 0.95 (processing, filling and packaging), hot filled	Yeast & Mold	< 10 cfu / 15 minutes	< 500 cfu / m ³	



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Post heat treatment or pasteurization: products with Aw > 0.95 (processing, filling and packaging), cold filled	Yeast & Mold	< 5 cfu / 15 minutes	< 100 cfu / m ³
Meat products	APC	< 10 cfu / 15 minutes	< 500 cfu / m ³
Products allowing survival of microorganisms, but not supporting growth	Yeast & Mold	< 100 cfu / 15 minutes	< 1 000 cfu / m ³

Note: 1 m³ = 1000 liters (L)

Additional requirements for specific use:

- For all plant areas including cafeterias, raw areas, offices, and utility rooms; air sourced from outside the facility should be filtered with a minimum F5 (MERV 8-10 >25% efficient at 1 micron).
- Air for a processed area shall not be sourced from an unprocessed product area (raw).
- Air blown on the surface of microbiologically sensitive materials shall normally be sourced from within the processing area complying with the filtration requirements. Air sourced from outside shall be filtered to the level required for the given product.
- The air supplied to the filler in an aseptic filling system (for beverages) shall be filtered through a HEPA filter (H13).
- Where air is used to transport fine, particulate products and there is high incorporation of air into the product, it must be filtered by a F5 (MERV8-10) filter if it is used to transport non microbiologically sensitive ingredients or sensitive ingredients with a further kill step.
- Where air is used to transport sensitive ingredients with no further kill step, a filter size F7 (MERV 13-14) is required.

Compressed air

- Compressed air for general applications shall be dry, oil free and filtered to remove foreign particles.
- Compressors (installed after 2003) that provide air for direct or indirect product contact shall be of oil free design. Where air from existing oil lubricated compressors is used for direct or indirect product contact, the following requirements apply: only food grade oil shall be used, vapor and odor filters must be installed prior to use where possible, air pressure gauges must be installed and monitored, and oil and filter changes must be captured in the PM program.
- When used as an ingredient, or in contact with microbiologically sensitive materials, or their packaging, or in contact with product contact surfaces (e.g., during cleaning), compressed air shall be filtered at the point of use and dried to prevent condensation within the pipelines.
- Compressed air shall be filtered 0.3µ at the point of use if used with microbiologically sensitive products if compressed air is used: as an ingredient; in contact with



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microbiologically sensitive products or their packaging; and in contact with material or product contact surfaces (e.g., during cleaning) after the kill step. Alternatively, a risk assessment shall be conducted to determine product susceptibility and potential contamination sources, and suitable safeguards shall be implemented.

- When used as an ingredient or in contact with non-sensitive products or their packaging, or in contact with material or product contact surfaces prior to the kill step, compressed air shall be filtered 1.0µm at the point of use.
- Distribution piping shall be of approved material (ABS plastic, Zinc plated Steel, Stainless Steel, Aluminum).
- Preventive Maintenance of air filters to manufacturer specifications is of prime importance and shall be documented.

Water

- The potable water supply system (including ice that contacts the product) shall meet all applicable local and national regulatory requirements.
- The site shall have effective programs to control water microbiological quality and to verify that water meets specified requirements. Microbiological and other test data from water testing shall be trended and reviewed by appropriate personnel. Corrective action shall be initiated and documented for out of standard results (e.g., repeat sampling and testing, identify and eliminate source of contamination, clean piping, initiate chlorination).
- Microbiological tests shall be performed periodically (recommended weekly or monthly, based on product/process sensitivity). All water used as an ingredient or to clean in a product processed without a lethal step and all water applied to product or package post lethal step shall be analyzed weekly. All water used in a product processed with a lethal step or in acidified products, re-circulated cooling water for indirect product use, and fresh cut produce irrigation water shall be analyzed monthly. Each point of use has to be covered at least once per year. Microbiological tests also shall be performed after maintenance or repair.
- Water used as an ingredient, processing aid, reclaim water, hand wash water, for brine solutions, and as sanitation final rinse shall be tested for TVC and coliforms (including ice in contact with the product and re-circulated cooling water). Recommended limits: TVC < 500cfu/ml and coliforms < 1cfu/100 ml.
- Disinfection (e.g., chlorination, ozonation, UV light) of surface and well (ground) water is required for all direct product uses (e.g., ingredient, sanitation, rinse, drinking) and indirect product uses (e.g., re-circulated cooling water, hand wash). Residual chlorine and ozone must be periodically tested (e.g., daily) or less frequently if supported by historical data). Corrective actions shall be taken when levels do not meet the required limits.
- The extraneous matter risk in incoming water needs to be controlled using filters when needed (e.g. well water).
- Filtration systems (e.g., charcoal, reverse osmosis) shall be regularly inspected and maintained. Water systems must not have cross connections between treated and untreated supplies. Incoming water lines must be fitted with one way valves or a header tank.
- Requirements and instructions shall be available for the following water uses: ingredient, reclaim water, raw material wash water, CIP make up water, drinking water, ice, re-circulated cooling water, bulk water transported by tanker for further



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processing, cooling tower water, sanitation final rinse, laboratory water, produce irrigation and wash water.

- For surface or well water sources, a visual turbidity assessment shall be carried out daily. Incoming well water must pass through an extraneous matter filter (minimum 200 mesh/75 micron). Where alternate filtration methods are used (e.g., sand filtration, reverse osmosis) these must be shown to be equivalent. Testing shall also be carried out following any event which may adversely affect turbidity, such as abnormally heavy rain or flooding.

Steam

- Steam shall be of the appropriate quality and purity to meet process and usage needs.
- Process steam is steam used indirectly during processing (i.e., steam for jacketed equipment) or used for direct product contact surfaces with a subsequent rinse. Process steam shall be produced using water treatment and/or boiler additive chemicals that are approved under relevant local/national regulations. Levels of additives in process steam shall not exceed what is required for the intended functional purpose. Dairy products should utilize the 3A standards for the production of culinary steam.
- Culinary Steam or Clean Steam is suitable for direct product contact and can be directly injected into the product without a subsequent rinse or primary packaging. It is possible for culinary steam systems to contain small quantities of boiler chemicals or traces of pipe scale, which may cause contamination. To eliminate this risk, culinary steam shall be produced using only approved boiler chemicals that are: (1) passed through a separator, (2) filtered through a filter (typically a high efficiency stainless sintered steel filter – preferably one designed to remove particles greater than 10 microns), and then (3) delivered through stainless steel pipework to the point of use. Stainless pipework shall meet specification AISI 304 and 316. Clean steam is the same as Culinary steam, but raised in a steam generator or taken from outlets on a multi effect still with a de-ionized or distilled water source.
- Culinary, Clean and Process steam condensate quality shall be routinely evaluated for turbidity, off flavors and particulates at a frequency to demonstrate sufficient control (Culinary steam at least every 6 months, Process and Clean steam at least yearly).

Utilities chemicals

- Solvents, boiler chemicals, cleaning agents and other chemicals not in immediate use must be stored in locked areas with controlled access. An electronic or paper inventory of Utilities chemicals must be taken periodically. A physical inventory must be taken in the event of significant electronic or paper inventory discrepancies.



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SECTION G: EQUIPMENT DESIGN

Section 3.6 of the *SQE Manual* sets out requirements for an equipment design program. Further requirements and guidelines include the following.

Piping and Duct Work/Insulation

- The piping shall be identified at the time of installation. The piping identification program shall be in compliance within local regulatory requirements.
- Where pipes and ducts must be insulated to prevent product from being contaminated by condensate, the insulation must be cleanable, or coated to be cleanable, and maintained in good repair.
- Ductwork must be designed to enable internal cleaning.
- All horizontal process piping that needs to be cleaned and emptied shall be sloped to allow complete drainage of the system.

Food Contact Surfaces

- Food contact surfaces shall be made of approved or suitable food contact materials. The product contact surfaces must be smooth, continuously welded, and shall not have: braided (woven wire or fabric) covers on hoses, exposed threads, piano hinges, cotter pins (split pins), all-thread rods, socket-head screws, or painted surfaces.
- Use of nuts and bolts in product contact zones shall be avoided where possible..
- Welds must be polished, de-scaled and pickled to a standard of finish equal to that of the surrounding material.

Product Contamination Avoidance

- Equipment shall have adequate covers for exposed products and ingredients unless technological reasons prevent this.
- Equipment shall be designed such that it does not introduce extraneous matter. Nuts and bolts over exposed product zones shall be self locking.
- Only appropriate materials must be used to permanently modify equipment. Tape, duct tape, rubber bands, and wire are not appropriate.
- All lines, circuits and equipment cleaned by Cleaning In Place (CIP) shall be designed for proper drainage, contain no dead ends and have smooth impermeable surfaces. To assure no product stagnation occurs, any section extending from the intended product flow may not extend a distance greater than 1.5 times the diameter of the pipe. There shall be no cross connections that could result in product contamination. Where cross connections occur, a physical disconnect is required.
- Tubular steel equipment framework must be totally sealed and unpenetrated. Fasteners, such as bolts and studs, must be welded to the surface of the tubing and not attached via drilled and tapped holes.
- Pressure devices are required on heat exchangers to assure that the product side remains at a higher pressure than the heat exchange medium (or raw side of the regeneration section).



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Valves and Pumps

- Use of Butterfly valves (flap valves, throttle valves) is discouraged for product applications which could support the growth of microorganisms at any stage of the process. If Butterfly valves are in use, appropriate cleaning and maintenance schedules must be implemented. Periodic post cleaning swab verification must be carried out to assure that sanitary conditions are maintained.
- Ball valves shall not be installed in wet cleaned or micro sensitive processing areas, as they are not suitable for mechanical cleaning. Existing installations must be disassembled completely for manual cleaning.
- Closed Yoke Valves (cup valves, bell-shaped valves) shall be avoided for food contact equipment.
- Positive displacement pumps (hydropumps) should not have pressure relief face plates. If they do, a regular scheduled cleaning and maintenance program shall be implemented to assure any product which seeps behind the diaphragm is cleaned out.
- Portable pump mechanisms used for ingredients/semi-finished products in production areas must not contribute to product or ingredient contamination (e.g., raw milk vs. post-process product, leaking oil, allergenic compounds).

Equipment Fittings

- Strainer and magnets must be installed such that element removal will not result in contaminant falling into the processing line. Check valves or stop valves may be required to allow element removal during production.
- Magnets, strainers, and other fittings shall be designed and installed such that they do not create dead ends in the process.
- When instruments are installed, the following should be considered: orientation for line drainage, accessibility for calibration and servicing, shut-off valves or wells.

Vacuum and Dust Collection Systems

- Vacuum and dust collection systems must be designed to allow sufficient cleanability.
- Vacuum pumps must be designed to prevent oil from back flowing out of the pump into the product.



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SECTION H: EQUIPMENT MAINTENANCE

Section 3.7 of the *SQE Manual* sets out requirements for an equipment maintenance program. Further requirements and guidelines include the following.

- The equipment maintenance program shall detail the inspection required for evaluation of the condition of screens, filters, magnets, gaskets, and other equipment that must be periodically replaced, as well as any potential points of metal to metal wear.
- If the line does not have downstream detection equipment (e.g., metal detector, magnets, screen), a more frequent detailed evaluation of wear and condition of product contact equipment (e.g., scraper blades, conveyer belts, votator barrels, pasteurizer plates, grinder plates, valves, pumps, and gaskets) is necessary at defined intervals for detection of potential contamination.
- Routine preventive maintenance for compressed air and air used in product manufacture or packing shall be documented. This includes the inspection, cleaning or replacement of items such as air filters, O-rings, gaskets, pumps, and bearings.
- Only food-grade lubricants and heat transfer liquids shall be used on food processing equipment where direct or indirect contact between the fluid and food products is possible.
- All metal welds in product contact areas shall be sanitary (cleanable, free from pits, folds, cracks, crevices or inclusions).
- Tools shall be cleaned and sanitized, and an area shall be designated in which to wash and sanitize them.
- The Supplier shall establish and implement appropriate sanitation procedures and controls for tools that are moved from raw to cooked product areas.
- Equipment and tools used on the equipment must never be placed directly on the floor or walking surface (e.g., deck).
- Equipment repairs are intended to be permanent and must be performed using proper materials. Temporary fixes that may adversely impact the food safety or quality of a product must be dated, documented, and replaced in a timely manner by permanent repairs.



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SECTION I: SANITATION

Section 3.8 of the *SQE Manual* sets out requirements for a sanitation program. Further requirements and guidelines are set forth below.

The sanitation program shall include specific criteria and instructions for:

- Situations when prolonged equipment downtime can lead to microbiological growth.
- Protocols for extending production runs beyond established sanitation cycle times.
- Adequate product protection when sanitation activities occur adjacent to operating production areas shall be established.
- Cleaning In Place/Cleaning Out of Place (CIP/COP) or Assisted Cleaning Systems (ACS).
- Equipment that is wet cleaned which needs to be used in a dry condition.
- Post-cleaning or pre-start up inspections required to be performed to confirm that equipment is clean, properly assembled, free from chemical residues and sanitized prior to use.
- Verifying and documenting the effectiveness of the sanitation program. Examples of verification activities may include:
 - Cleaned equipment swabbing (using microbiology methods) and cleaned equipment teardown and inspection.
 - ATP measurement (adenosine triphosphate measurements are based on the detection of ATP by bioluminescence) can be the initial method of choice in monitoring the cleaning efficiency since it is a rapid measurement of the actual hygiene status of a sampled surface, allowing fast initiation of corrective actions in case of inadequate cleaning. ATP measurement, however, should not completely replace traditional techniques (e.g., swabbing), and should be integrated with traditional cultural techniques as part of a coherent surface cleanliness monitoring system. Although manufacturers of ATP measuring devices give general guidance on acceptable ranges for routine hygiene controls, internal standards have to be set for the given processing environments.
- Periodic cleaning of overhead structures, including scheduled frequencies and documentation.
- Floor drain sanitation, including a facility map with the exact location of each drain. High pressure hoses shall not be used as these promote aerosol formation and potentially enhance the spreading of organisms. Cleaning of drains must not be performed during production.
- Use of food grade cleaning, sanitizing, and disinfecting products.
- Appropriate sanitation-related measurement devices (e.g., thermometers, gauges, meters, solution strengths, circulation velocity) shall be calibrated.
- Disassembled product contact equipment shall be prohibited from direct floor contact.

Clean in Place (CIP)

This Section of the *Resource Supplement* establishes the requirement for records that describe the CIP, controls and programs. The records will demonstrate that conditions are met to assure adequate cleaning. The following are guidelines to follow when setting up a CIP circuit. It should be kept in mind that CIP effectiveness relies on four factors, the



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temperature of the water and/or the cleaning solution, the mechanical agitation (m/sec), chemical concentration and finally the circulation time.

The CIP control system (Control Book) shall contain:

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

CIP systems are recommended (where applicable) for direct product contact surfaces that are to be routinely wet cleaned. The minimum velocity requirement for pipes with diameters less than 3 inches /7.6 cm is 5 ft/second (1.5 m/s). For pipes with diameter 3 inches/7.6 cm, but less than 4 inches/10.2 cm), the minimum requirement is 6ft/second (1.8 m/s). For pipes with diameters 4 inches/10.2 cm or greater, the minimum requirement is 7 ft/second (2.1 m/s). Existing systems that do not meet these flow requirements are exempt if cleaning verification documentation demonstrates that the line is able to be cleaned with existing systems.

The CIP system shall have:

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

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

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

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



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Sanitation Verification (after wet cleaning)

Each manufacturing facility shall establish its own program and a baseline for the different indicators. Until a baseline is developed, the plants may utilize the guidelines defined in the table below. Plant history should also be taken into consideration when updating the program.

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

Clean Equipment Swab - Post Heat treatment- taken before sanitize:		<i>Post Heat treatment - taken before sanitize</i>		<i>Post Heat Treatment - pre-op taken after sanitize</i>	
		cfu/100 cm ²	cfu/40 in ²	cfu/100 cm ²	cfu/40 in ²
APC	Target	< 50	< 100	< 5	< 10
	Acceptable	< 500	< 1000	<50	< 100
Coliforms	Target	< 5	< 10	n/a	n/a
	Acceptable	<50	< 100	< 5	< 10
Lactobacillus	Target	< 5	< 10	n/a	n/a
	Acceptable	<50	< 100	< 5	< 10
Yeast & Mold	Target	< 5	< 10	n/a	n/a
	Acceptable	<50	< 100	< 5	< 10

Meat Products – Other

APC (Aerobic Plate Count)			Coliform		
Operational swabs	good	<1000 cfu/40 in ² or 500 cfu/100 cm ²	Brine	good	Negative / 100 ml
Brine	good	< 1000 cfu / ml			



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Specific Requirements for Natural Cheese Make In-process Action Levels and Actions

Process	Action Limits and Testing Frequency
Cheese Brine	APC (set dilution at 1:100 or 1:1,000) Mozzarella and Swiss Cheese - >20,000; Others - TBD by plant data. Coliform (set dilution at 1:10) >10 Yeast & Mold (set dilution at 1:10) >100 Testing frequency: beginning (after treatment or make-up), middle and end of run per week
Whey (Drain Tables or equivalent) and Cheese fines (point of use)	Coliform (set dilution at 1:10) >10 Testing frequency - Whey: Internal plants = Weekly. External suppliers = 3x per week. Testing frequency - cheese fines: Internal plants = 1 per day. External suppliers = 3x per day.
Natamycin Solution (stored 24 hrs)	APC > 1,000 (set dilution at 1:100) Coliform >10 (set dilution at 1:10) Testing frequency = daily (if held 24 hours)
Condensate of Whey (COW Water)	APC >500/ml Coliform Positive (Colilert) = ≥ 1 cfu/100 ml (MF) or > 1.1 cfu/100 ml (MPN, MMO-MUG) Testing frequency = monthly

Natural cheese in-process: coliform <10, Y&M, <10,000 - includes the process cheese in-process.



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SECTION J: PEST MANAGEMENT

Section 3.9 of the *SQE Manual* sets out requirements for a pest management program. Further requirements and guidelines include the following.

Exclusion shall be the first line of defense and primary method of controlling pests.

Efforts must be made to keep pests out of the building by using good exterior controls including:

- Eliminate all possible entrances into the facility. All doors, windows, and screens must fit tightly. Doors must be kept closed. Note that a mouse can enter through ¼ inch (1cm) openings.
- Pipe openings through facility walls must be sealed.
- Product pipes must be capped when not in use.
- High grass and weeds around the facility or in adjacent areas must be eliminated where possible. These provide excellent hiding areas for rodents.
- Item such as scrap, pallets, pipe, and drums, shall not accumulate on the grounds or parking lot.
- Metal refuse containers should have tight fitting covers and be stored on racks, if outside.
- All rat holes and burrows must be closed.
- All ingredients, equipment, and supplies received should be inspected upon receipt for rodent excreta or any signs of gnawing and chewing on the containers. Mice often enter the facility on supply loads.
- All openings on wall and roof penetrations must be screened to prevent insect or rodent ingress.

Secondarily, food and harborage must be controlled through proper sanitation, housekeeping, and storage practices.

Use of pesticides

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

The following practices shall be followed:

- Pesticide lot numbers shall be documented on usage records to assure traceability.
- All pesticide labels and Material Safety Data Sheets (MSDS) or equivalent material addressing safety precautions shall be available at the facility where the pesticide is used.
- All EPA registration numbers shall be maintained and available at the facility where the pesticide is used.
- Disposal of unused pesticides and of empty pesticide containers must comply with applicable regulatory requirements.
- Baits shall be used in situations where a specific pest is the target. Where used, bait stations shall be of solid construction, tamper resistant, and secure.



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- Rodenticides used must be in block form only. Rodenticidal granulates, pellets or powders shall not be used. Rodenticides shall be used on the exterior of the facility only.
- Multiple catch devices and mechanical traps are preferred for use inside of a building.
- Non-toxic indicator baits may be used for internal rodent monitoring

Light bulbs from the insect light traps must be replaced regularly (minimum of annually) to ensure maximum efficiency for these type of traps. The insect light traps shall be installed in the receiving or warehouse areas close to entrances, but shall be located so as not to attract insects into the building.



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SECTION K: ZONING

Section 3.10 of the *SQE Manual* sets out requirements for a zoning program. Further requirements and guidelines include the following.

As a consequence of the product risk assessment to microbial contamination, the different areas (zones) of the production facility can be classified according to the microbiology risk.

Production zones should be classified based on the risk of cross-contamination:

Non-manufacturing zone:

- There is no open product in this zone.
- Product could be stored but not manufactured; also includes offices, cafeteria, locker room, laboratory, etc.

High risk zone:

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

Controlled zone:

- Product that are not highly sensitive can be exposed to the environment and the operators.
- GMP practices are implemented and Kraft Foods air requirements are met.
- The controlled zone may also serve as transition from non-manufacturing or high risk zone to high control zone.
- Products of higher sensitivity may be present if they are completely enclosed.

High control zone:

- Product of high sensitivity can be exposed to the environment and/or the operators.
- Additional GMP practices, such as captive footwear/clothing, may be required and more stringent equipment/building sanitary design requirements are followed
- When product of sensitivity 4 are exposed, additional production practices, such as preventing cardboard, wooden pallets, etc may be implemented



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Examples of the production zones:

Product	High risk zone	Controlled zone	High control zone
Milk Processing/dairy plant	Raw milk receiving	Processing area after pasteurization	Cold filled area
Peanut and tree processing	Raw nut receiving and handling	Processing and filling after kill step	n/a
IQF Vegetables	Raw vegetable receiving area	Processing/Packaging after microbial reduction step (e.g.: final rinse, validated blanching, etc)	n/a
Spices	Spice receiving	Processing and filling after kill step	n/a
RTE Meat	Raw Meat receiving and handling	Processing after kill step	Packaging area

Considerations for risk assessment

The following questions can help determine where microbiological risk may be introduced, design the plant map indicating the different zone and deciding controls to put in place in transition areas to prevent cross contamination of sensitive products.

Physical measures/barriers:

- Is there physical separation between raw product receiving/storage and other manufacturing areas?
- Are waste areas physically separated from production areas?
- Are coolers/warehouses for storing raw ingredients and finished products or packaging supplies physically separated?

Traffic control:

- Are common elevators, hallways, staging areas etc. between different classes of areas prevented/adequately controlled?
- Are traffic patterns of people, trucks, materials, and equipment defined and controlled to prevent cross-contamination?
- Are separate vestibule facilities used as entrance/exit with coat/shoe changing measures and hand sanitation in place, where applicable?
- Are overhead drains adequately constructed/protected to prevent product/area contamination?



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Infrastructure:

- Are effluent-and wastewater drains coming from product areas with potentially higher contamination risk separated (i.e., no connection between drains in red and other areas or back-flow prevention installed)?
- Is the building designed to prevent water seepage between rooms/doors noted during sanitation?
- Are drains designed to prevent any back up issue?
- Are false ceiling designed to prevent any contamination (rigid, sealed, ventilated, etc)?

Utility Controls - Air and water:

- Are negative air pressures in place for raw areas when adjacent to process areas (e.g., raw milk intake/pasteurizer areas to cheese make)?
- Are positive air pressures in place compared to outside production areas for finished product areas where the products support growth (e.g., RTE filling/packaging rooms)?
- Is air appropriately filtered in all areas where necessary (e.g., RTE filling, cheese starter culture room, micro lab)?
- Are relative humidity levels and level of air turns/hr maintained in clean rooms (e.g., chill roll)?
- Is condensate adequately controlled in processing and storage areas to prevent product contamination?

GMP measures:

- Are employee uniforms and/or footwear worn only in the plant?
- Is dedicated clothing (lab coats, aprons, jackets) used in product areas?
- Are clothing restrictions and GMP rules enforced for visitors and outside contractors?
- Are hand wash & sanitizer stations installed, functioning & indicated by signs at entrances of manufacturing areas?
- Are hand sanitizing units available to all employees working with sensitive product contact?
- Are sticky mats/footbaths/foot washing stations/door foamers in place and maintained where applicable?
- Are maintenance tools and operator utensils/tools cleaned/sanitized after usage or dedicated to one area?
- Are common pipe connections for receiving or unloading of different liquid ingredients prevented or adequately controlled?

Sanitation controls:

- Are cleaning/sanitation procedures in place after equipment downtime and after maintenance activities (incl. activities of external companies) have been completed? Are sanitation controls/environmental sampling procedures in place before start-up after maintenance/repairs?
- Are "deep cleaning" equipment procedures in place after construction or after major repairs are completed? Are sanitation procedures and environmental swabbing procedures in place after new equipment installation and before start-up after maintenance/repairs?



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SECTION L: PATHOGEN ENVIRONMENTAL MONITORING (PEM)

Section 3.11 of the *SQE Manual* sets out requirements for a PEM program. Further information, requirements and guidelines include the following.

Background on pathogens and indicator organism

Salmonella are pervasive environmental microorganisms that are well adapted to dry and warm environments. They therefore show a high tenacity in production of products such as chocolate, dairy powders, and dry mixes. *Salmonella* are most frequently isolated from areas including floors, product scrapings, and drains. *Listeria* are ubiquitous environmental microorganisms that are well adapted to wet and cold environments. They therefore show a high tenacity in dairy and meat production. *Listeria* is most frequently isolated from drains, stagnant waters and floors. Indicator Organisms indicate unsanitary conditions and potential presence of pathogens. They include coliforms and *E. coli*. Enterobacteriaceae may be an alternative to coliforms and *E. coli*.

Sampling requirements

Environmental sampling for *Listeria* genus and *Salmonella* species is qualitative. The purpose of the testing is to determine presence or absence of these organisms. Environmental sampling for indicator organisms (excluding *Listeria* genus) is quantitative. The purpose of testing is enumeration of those organisms (e.g., coliforms and/or Enterobacteriaceae).

Site specific sampling locations shall reflect the most critical locations and are dependent upon such criteria as the material produced, equipment design, plant structure, traffic patterns, and previous findings. Sampling locations shall not include raw, unprocessed products and raw processing areas (e.g., raw meat, poultry, vegetables, fish, and unpasteurized milk and cream). Walls and floor drains located in relevant areas shall be included in any sampling plan.

Routine sampling must take place during production, at least 3-4 hours after start-up. The time frame for taking swabs (e.g., shift, midweek, end of week) should be changed on a periodic basis. Swab site locations should be audited and changed on a periodic basis. The results must enable a clear correlation to the particular sampling point.

Criteria for test results to be deemed acceptable

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

Corrective action plans

Corrective action plans shall address the source of the contamination issue and include mechanisms to verify the effectiveness of corrective actions. For example, corrective action may include improved cleaning or sanitation, redesign of the structure or equipment, improved GMPs, or redefined traffic patterns.



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

Areas for environmental sampling

Kraft Foods defines 5 different areas for sampling the environment, as described below:

1. *Direct product contact surfaces* mean all surfaces that are exposed to the product during normal equipment operation and all surfaces from which liquids may drain, drop, diffuse, or be drawn into the product or into the container. This includes, but is not limited to: pipeline interiors, conveyors, product storage vessels, fillers, product contact hands, worktables, grinders, slicers, and shredders.
2. *Indirect product contact surfaces* mean all surfaces that touch product contact surfaces during normal equipment operation. This includes, but is not limited to, surfaces such as product scrapers, utensils scrapings, and dust samples.
3. *Non product contact areas adjacent to product* mean all surfaces that, under normal operating procedures, do not contact the product or the product contact surfaces and includes exterior of equipment, chill units, framework, equipment housing (e.g., panel buttons, operator buttons), aprons, broom handles, gloves, and weight control data input.
4. *Non product contact areas within the processing room that are more remote from product contact surfaces* (e.g. hand trucks, wheeled items, forklifts, walls, drains, floors).
5. *Areas remote from product contact surfaces outside the processing room* (e.g. hallways, bathroom doors, cafeteria, coolers).

Further sampling guidelines

- Large surface areas should be sampled for qualitative analyses. A sponge is more effective and is recommended for sampling large surface areas. For smaller hard to access or irregular shaped areas, a cotton swab is more effective.
- At least 5 swab samples should be taken from each area each month.
- Samples within the same zone may be composited with up to five sample points in one composite. Swabs taken from floor contact areas (e.g., floor, drains, steps, wheels) may be composited only with other floor contact areas within the same zone.



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Test results acceptance criteria for Indicator Organisms:

- Sampling by Swabs or Sponges

Coliforms / Enterobacteriaceae		E. coli	
Cfu/100cm ²	rating	cfu/100cm ²	rating
<10	Target	absent	Target
10-20	Acceptable	<10	Acceptable
>20	Not acceptable	>10	Not acceptable

Note: Repeated results in the Acceptable range should be investigated and action taken to achieve target values.



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SECTION M: TRACEABILITY

Section 4.5 of the *SQE Manual* sets out requirements for a traceability program. Further requirements and guidelines include the following.

Upon receipt at the facility, the ingredient's lot number(s) shall be documented. Where internal plant identification systems are used, these must link back to the original lot code in receipt records. For ingredients that may not have a specific lot number, a method for unique identification and tracing shall be developed and implemented. Bulk use of ingredients shall be required to have a documented timeframe of known use. Each component shall be clearly identified and coded to enable traceability back to the lot or source and traceability forward to the material containing the component. Each material delivery ideally should contain only one batch/lot number. At a minimum each individual pallet shall be made up of only one batch/lot number

All production runs shall be identified with lot numbers that enable complete linkage from raw material receipt through final packaging. Traceability shall be maintained to enable linkage back to the date of manufacture and location for all finished packages.

Records shall support reconstruction of the product traceability history within 4 hours and with a goal of 100% traceability to the point where the product is no longer within the facility's control. It is recommended that representative samples from all lots produced for Kraft Foods be kept until the expiration of the material.

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



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SECTION N: ALLERGEN MANAGEMENT

Section 4.6 of the *SQE Manual* sets out requirements for an allergen management program. Further requirements and guidelines include the following.

Designing out allergens is preferred.

Where possible, allergens must be “designed out” of the product, making labeling unnecessary. This may be achieved by reformulation or by avoiding manufacturing cross-contact (via proper rework handling, product sequencing, change-over cleaning, or change-over flushing).

Process steps to consider for change-over cleaning or flushing:

When change-over cleaning or flushing are implemented with the purpose of eliminating the carry-over (and thus not declare the allergen), the following process steps should be considered as a CCP in the HACCP plan.

Rework handling: The following monitoring, corrective action and documentation requirements must be implemented if rework may be a source of undeclared allergens, in order to guarantee that rework containing an allergenic material is not added to a product that does not list that allergenic material on its ingredient label.

- Monitoring requirements: The origin and ingredients of each container of rework shall be documented in the rework inventory records (type, date, amount, lot number). Allergen containing rework shall only be reincorporated into the same and/or appropriately labeled product (per a rework matrix). Rework use must be documented on the process sheet.
- Corrective action requirements: If the origin and ingredients of rework cannot be determined, it must not be used. If allergen-containing rework is added to product that does not list the allergenic material on its ingredient label (per the rework matrix), place the affected product on Category I Hold. Corrective action must be documented.
- Documentation requirements: The following documents must be maintained: rework/product matrix record, process records, corrective action records, Hold and Release records. Process records and rework inventory shall be periodically verified by designated employee.

Equipment cleaning (for an allergen change-over): The following monitoring, corrective action and documentation requirements must be in place if cleaning is implemented with the purpose of eliminating the carry-over:

- Monitoring requirements: Compliance with the product sequencing/cleaning matrix and completion of cleaning shall be recorded in the Equipment Inspection Log. Prior each start-up, the Equipment Inspection Log must be reviewed to ensure the Equipment Cleaning Process was followed. The Equipment Cleaning Process must remove visible product/residue from all product contact surfaces and above exposed product zones.
Note: The efficacy of the Equipment Cleaning Process shall be validated to demonstrate that it removes visible residues from all product contact surfaces. This



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validation must be documented and must be based on trial runs on the specific line/process.

- Corrective action requirements: If review of the Equipment Inspection Log indicates non-compliance with the Equipment Cleaning Process, or if allergen-containing product residue is visible, clean the equipment surfaces to remove the residue prior to running the non-allergen (or different allergen) containing product, and document on the Equipment Inspection Log. If records review indicates that allergen-containing visible product residue may not have been removed, place the affected product on Category I Hold. Corrective action must be documented.
- Documentation requirements: The following documents must be maintained: Equipment Cleaning Process/Sanitation Records, Equipment Inspection Log/Sanitation Records, cleaning matrix, corrective action records, Hold and Release records. Records shall be periodically verified by designated employee.

Equipment flushing (for an allergen change-over): The following monitoring, corrective action and documentation requirements must be in place if flushing is implemented with the purpose of eliminating the carry-over:

- Monitoring requirements: Compliance with the product sequencing/cleaning matrix and completion of flushing must be recorded in the Equipment Inspection Log. The flushing material (e.g., water, ingredient, following product) shall be weighed or volumetrically measured. Length of flush time may be used as the measure of compliance if there has been no change to the process. The flushing material shall be discarded or reworked into product labeled as containing the specific allergen. Following compliance with the Equipment Flushing Process, a visual check of the equipment product surfaces must be made. Both the flushing and visual check must be recorded in the Product Flushing Log or equivalent. The Equipment Flushing Process must remove visible product/residue from all product contact surfaces and above exposed product zones.

Note: The efficacy of the Equipment Flushing Process shall be validated by appropriate analytical testing to demonstrate that it removes any detectable residue from all products contact surfaces. This validation must be documented and must be based on trial runs on the specific line/process.

- Corrective action requirements: If review of the Equipment Inspection Log indicates non-compliance with the Equipment Flushing Process or if allergen-containing product residue is visible, clean the equipment surfaces to remove the residue prior to running the non-allergen (or different allergen) containing product, and document on the Equipment Inspection Log. If records review indicates that allergen-containing visible product residue may not have been removed, place the affected product on Category I hold. If the flushing material is not properly disposed of and is added to product not listing the specified allergenic material, place all affected product on Category I hold. Corrective action must be documented.
- Documentation requirements: The following documents shall be maintained: Equipment Flushing Process/Sanitation Records, Equipment Inspection Log/Sanitation Records, flushing matrix, flushing material usage report (if reworked), corrective action records, Hold and Release records. Records shall be periodically verified by designated employee.



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SECTION O: DETECTION AND CONTROL OF EXTRANEOUS MATTER

Section 4.7 of the *SQE Manual* sets out requirements for a program on control of extraneous matter. Further requirements and guidelines include the following.

Guidelines for use of detection equipment

If the Supplier determines to control the risk of extraneous matter through use of detection equipment (e.g., installation of strainers, screens, filters, magnets, sieves, metal detectors, X-ray or other devices/programs deemed necessary on the line), the Supplier shall manage these devices in such a way to maximize the effectiveness. Focus shall be put on the following points:

- Location of the detection devices in the production line.
- Procedures to manage the devices.
- Start-up set up (e.g., check if magnet is in place; screen is properly seated in its housing; centrifuge is operating at required rpm's).
- Frequency of detection and rejection mechanism verification checks.
- Limits of acceptable and unacceptable results.
- Abnormal findings (shall be reported and documented).
- Corrective actions are taken where necessary.
- Devices are periodically calibrated.

The detection devices installed throughout the production line and their established detection limits must be adequate to address the risks identified in the risk assessment.

For sifters for free flowing powders (e.g., flour, sugar, starches), the use of nylon screens (e.g., Nitex or equivalent) is recommended. Screen sizes should be selected based on maximum ability to extract foreign material. If metal screens are used, the supplier should evaluate replacing existing metal screens with Nitex (or equivalent) screens. If metal screens are not replaced with nylon, 400 series stainless steel screens are required with a control program (e.g., a screen inspection program and rare earth magnets following the metal screens) to ensure that screens for all products are intact and operational both prior to production and at the end of each production run. Material must not be released until magnets are inspected and verified free of metal. Magnets shall be checked against established operating limits and cleaned on a scheduled basis and the results documented. Use of Centrifugal (Rotary) sifters is not recommended.

The detection limit for an end-point metal detector will depend on type of product, package, and the detection equipment. Detection equipment settings shall be determined and applied to achieve the most sensitive level possible to provide maximum protection from metal contamination. The detection sensitivity under production conditions must be better than 5.0mm for all metals. Guideline for metal detection unit: capable of detecting and rejecting pieces equal to or less than 1.5mm for ferrous, 2.0mm for non-ferrous (brass) and 2.5mm for stainless steel (316 grade). In cases where end point metal detection is not feasible or practical, a documented assessment must show that the risk of foreign material introduction into the product is low, or is controlled by some other method.

Functionality verification for electronic detection and rejection devices shall take place during production with the normal product flow. Minimum frequency for system verification shall occur at the following times: start up (e.g., the beginning of each shift or production



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start up if part way through a shift) and end of each shift; after a production change (e.g., product or primary packaging changeover); following any repairs; maintenance or adjustments; and on a regular basis as determined by the site (recommended maximum every 4 hours).

The functionality verification method shall ensure 100% detection and rejection of the test piece(s). At the start of production each day and at each package or product change, 2 passes of each test piece (ferrous, non-ferrous and stainless steel) must be detected and rejected. Consideration should be given to using a combination of leading edge and trailing edge passes where possible. The verification test pieces/packages shall be clearly identified and differentiated from product.

If a metal detector is not working at its design limit (e.g., if it fails to detect a test piece), the material produced since the last time the metal detector was verified to be operating at its design limit shall be placed on Category II hold (see Section 5.1 of the SQE Manual for Hold and Release requirements).

The Reject mechanism shall direct product rejects from the process flow automatically into an identified area, bin or container. An action level shall be defined based on historical trend analysis. If this action level is exceeded, then all diverted packages or product (rejects) shall be evaluated to determine the cause for rejection. Where no action level is defined, all rejects shall be evaluated to determine cause for rejection. Action limits and a description of available corrective actions if the action limits are exceeded must be available to the responsible operator. Action limits must include unusual findings and excessive rejects which would trigger an immediate corrective action. All the findings shall be documented. The responsibility and methodology for evaluating rejected packages shall be specified and documented.

Controls for light fixtures and other glass

Light fixtures must be designed, installed, and maintained to prevent product contamination in the event of breakage. Controls include at a minimum:

- Light fixtures with an enclosed safety design, with a gasket seal, are required in wash down areas.
- Any open bulbs shall be plastic coated.
- Fluorescent fixtures in manufacturing and warehousing areas shall have shatterproof or safety coated lamps.

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



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SECTION P: STORAGE AND TRANSPORTATION

Section 4.12 of the *SQE Manual* sets out requirements for a storage and transportation control program. Further requirements and guidelines include the following.

Storage control program requirements

- Sanitation and pest control of storage areas should be assessed (e.g., spacing equipment or material storage away from walls (guideline 30-50 cm/12-18 inches) for multiple pallet applications; sealed doors and windows; cleanable floors, walls, and overhead structures).
- Damaged bags or drums must be sealed to prevent product spillage and contamination. Ingredients contaminated through damage must not be used. Spills must be cleaned up to prevent potential for infestation or cross-contamination.
- Procedures that identify and track shelf life of raw materials and release status of finished goods should be implemented. An effective stock rotation system shall be in place.
- Appropriate temperature/humidity controls must be used, as required per specification. Storage temperatures and humidity (where applicable) shall be measured and documented using calibrated recording equipment.
- Storage must be off the floor. Pallets, racks and equipment shall be in good condition to prevent physical damage (e.g., free from nails, splinters). In some cases products may be stored on slip-sheets (without pallets) based on the type of product and packaging.
- Airflow from items such as heaters and refrigeration units must be directed away from products. Direct sunlight on product should be avoided where possible.
- Glass containers must be isolated from products during storage.
- Products with strong odors shall be segregated to avoid odor migration.
- Bulk storage of liquid ingredients susceptible to microbiological spoilage shall have adequate controls in place to prevent spoilage or contamination (e.g., insulated, temperature controlled and monitored).
- Where packaging materials are not in individual containers (e.g., film roll stock, cartons.), the pallets shall be covered and stretch wrapped, shrink wrapped, strapped, or net wrapped to maintain integrity and prevent potential for contamination.
- Pallets used for food products must be in good condition: clean, no broken boards, no evidence of mold or infestation, no off odors. Slipsheets shall be used to avoid raw material primary packaging contact with the pallet.

Specific transportation program requirements

- Procedures must be in place to ensure that products are pre chilled to required temperature prior to loading, and vehicles are pre chilled prior to loading for distribution (where applicable).
- Deliveries shall be on clean, dry, undamaged pallets (or slipsheets), free from off-odors and wrapped according to Kraft Foods specifications.
- Trucks and containers (including pipes and loading / unloading equipments) shall be verified to be in good condition, dry, clean and free of off-odors before loading. Wood racks are prohibited in trucks used for Kraft materials deliveries. If other materials



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would be transported in the same truck, supplier must make sure that it will not alter Kraft materials.

- Temperature controlled vehicles must carry suitable on-board temperature monitoring devices. The devices shall be verified at defined intervals.
- Bulk tankers should be of stainless steel construction, or other suitable food grade material. They shall bear the following mention: "For Food only", or any equivalent mention. Bulk tankers must be equipped with appropriate safety devices for safe unloading.
- For bulk tankers, cleaning certificates shall be available and checked before each loading. Verification frequencies for equipment sanitation shall be specified. The frequencies must take into account the microbiological sensitivity of the material transported and the allergenic and GMO status of the previous load. The cleaning certificate should be in local language (or at least in English) and must stipulate:
 - - Tanker plate number
 - - Nature of the previous load
 - - Date and hour of cleaning
 - - Numbers of the cleaned compartments
 - - Applied cleaning program (with water, with detergents, drying etc.)
 - - Seals numbers for tankers
- When possible, all openings (e.g., doors, inspection ports, hatches) on outbound shipments (including outbound trailers) shall be sealed with a numbered seal and the seal number(s) annotated on the shipping documentation.
- Inbound and outbound bulk containers shall be sealed. Acceptable seals include:
 - Drums with a locking ring secured with a numbered seal and number annotated on the shipping documentation.
 - Drums without a locking ring secured with tamper-evident tape readily identifiable with the Supplier's name and logo.
 - Large bags such as super-sacks or totes containing plastic liners having a bag closure that will readily reveal any tampering and will not permit removal and reinstallation without breaking the seal.
 - Corrugated cases effectively sealed with tamper-evident tape readily identifiable with the Supplier's name and logo.