Supplier Quality Expectations

Mondelēz International

Version 2020

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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 Mondelēz International (abbreviation MDLZ) 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.

Mondelēz International is committed to delivering high-quality products. One of the ways we achieve this is by ensuring the strength of our food safety and quality systems. We expect that our suppliers share this commitment and for that purpose the following documents are available for you:

- *Mondelēz International Supplier Quality Expectations* (this document)
- Processing Expectations for Cocoa Beans, Dairy, Egg, Juice, Nuts and Seeds, Vinegar, Fruits & vegetables, and Irradiated Raw Materials
- CCP Models, CCP 26: High Moisture Material Holding Time / Temperature; CCP 52 Product Cook Fat Based Products; CCP 58 Product Cook – Non-fat Based Product; CCP 68 – Product Bake (see table 15)

These documents are available at the Mondelēz International Supplier Quality and Food Safety web site at www.mdlzsupplierquality.com or from your *Mondelēz International (MDLZ) Contracting Representative*. The English version of these documents is considered the official contractual version, but alternative languages may be available.

The Supplier Quality Expectations (SQE) outlined here are intended to help current and prospective new suppliers of ingredients and packaging materials ensure that their own food safety and quality systems meet Mondelēz International (MDLZ) and industry standards. These expectations have been developed by MDLZ and Subject Matter Experts following a review of product defects, quality audits of manufacturing sites and a study of product retrievals throughout the food industry. This review has 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.

To each *manufacturing location* producing materials for Mondelēz International must meet the expectations in this manual. Please note the following exceptions:

- Packaging suppliers to whom some sections do not apply (see Table of Contents);
- Material Suppliers to whom the Sections 6.9 (Hygienic Zone) and 6.10 (Pathogen Environment Monitoring) may not apply (see further explanation under these sections);
- This document does not apply to *farm operations*.

The *Mondelēz International SQE Manual,* Process Expectations and CCP Models (where applicable) contain the elements we believe are essential for the effective management of Food Safety, Quality and *Food Defense*. 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 MDLZ Contracting Procurement Representative.

Terms defined in *Appendix: Definitions* of this document are highlighted (*italic and underlined*). The Tables are at the end of the document.

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

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

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

1.1 For Brokers, Distributors and Traders

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

- Materials MUST come from MDLZ approved manufacturing sites and lines and MUST adhere to the agreed MDLZ specification
- The broker / distributor / trader is responsible for ensuring that the requirements of the Supplier Quality Expectations are met AND the manufacturer is clear on and has agreed to the material specification.
- The contracted supplier, if in this case a broker / distributor / trader must have signed the Specification Acknowledgement Report (SAR) for raw materials and food contact packaging
- In the event of the following, the supplier shall contact their procurement representative in the first instance prior to any change:
    - Supplying a new material from an existing approved site
    - Supplying an existing material from a different approved site and lines
    - Supplying a material from a new manufacturing site

  . In the event of change as specified above an Approval audit maybe required (either on site or remote)
- The supplier manufacturing locations shall be disclosed to the MDLZ Contracting Representative to assure that materials are only sourced from locations meeting MDLZ requirements for quality and food safety.
- Ensure that the *Mondelēz International SQE Manual* and MDLZ Specification are communicated to supplier and provide evidence to MDLZ of agreement to the requirements by the supplier.
- The broker/distributor/trader shall be required to notify MDLZ of any manufacturing location changes.
- The broker/distributor/trader must demonstrate that *traceability* of materials to manufacturing location level is maintained according to the requirements in section 7.9 of this document.
- MDLZ can revoke the approval of the manufacturing site AND the Broker / Distributor / Trader at any time on the basis of food safety or quality concerns.
- The broker / distributor / trader shall have a procedure for approving storage facilities and warehousing, ensuring that any warehousing used to store goods operates Good Warehousing Practice (GWP) being able as a minimum to operate traceability of goods-in and out, first-in first-out (FIFO), pest management and sanitation program.

CHAPTER 2 - CONFIDENTIALITY

The contracts between MDLZ and the Supplier will govern confidentiality of information shared by either company. All Supplier personnel shall take care not to disclose Supplier confidential information to MDLZ unless there is a contract in place protecting such disclosure. MDLZ personnel shall not be asked or required to sign confidentiality agreements as a prerequisite to gain access for audits prior to or at any time during a quality audit or other required technical visits/assessments.

CHAPTER 3 – MDLZ QUALITY PERFORMANCE VERIFICATION PROGRAMS

3.1 General Audit Requirements

All facilities supplying raw materials and packaging to MDLZ shall be approved.

The frequency and type of approval audit required by MDLZ is dependent on the type of material supplied based on risk assessment and may include the following:

- Third Party auditing supplier on behalf of MDLZ selected by MDLZ (3rd Party SQE), or selected by the supplier from the MDLZ approved list
- MDLZ employee SQE audit, or
- Recognized industry standard (GFSI certification). All materials supplied must be in scope of the certification

For the above audits the supplier will not request any auditor to sign an additional agreement in order to conduct the audit. This is covered by MDLZ and supplier contractual requirements.

Each manufacturing site producing material for MDLZ is required to undertake one of the aforementioned audits. Note that the manufacturing site may be required to complete a questionnaire either in lieu of or in advance of an audit, or that the site registers with and submit information to a third party that MDLZ has selected to manage audit information.

The audit /inspection requirements are prioritized based upon the experience with the supplier, performance and the type of material produced at that location. MDLZ operates a risk assessment process for this.

The MDLZ audit/inspection shall extend to all areas, including all pertinent production and storage areas deemed necessary to evaluate whether the material produced for MDLZ 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. Auditors checking compliance to the MDLZ SQE requirements will not audit or inspect financial data, sales data (other than that directly related to MDLZ), or pricing data. Auditors will not inspect personnel data, other than data relating to qualifications or training of technical and professional personnel performing functions pertinent to the audit.

To become and remain an approved Supplier, the audit findings must be acceptable to MDLZ. Any adverse finding in an audit will result in a requirement that the supplier implement corrective action and may, depending on the severity of the finding and/or the supplier's quality or audit history, result in a down rating or termination of the supply relationship with MDLZ. The Supplier must implement all corrective actions identified in the MDLZ audit, record in the MDLZ audit management system, within the time frame agreed on in the audit corrective action plan.

MDLZ will bear its own internal costs and the Supplier will bear all other audit costs (including those of the third-party auditors). If the Supplier wants to share MDLZ or third-party SQE report with other customers, a written authorization from MDLZ is needed.

In the event of changes to supplier's processes, critically CCPs / critical limits, lines, equipment and/or facilities and change in manufacturing location that could have an impact on materials supplied to Mondelēz International, the contracting representative must be contacted before the change is made to enable timely effective approval steps.

3.2 Global Food Safety Initiative (GFSI) Certification

Industry accepted certifications are now part of MDLZ supplier approval requirements . MDLZ's aim is to have all of its material suppliers GFSI certified. A current list of GFSI accepted certifications for materials in scope can be obtained at www.mygfsi.com. The certification scheme and scope shall be appropriate, e.g. must include all manufacturing areas relevant for ingredients supplied to MDLZ.

The supplier shall share with MDLZ the current complete GFSI audit report and a valid certificate in order to become or continue as an approved supplier. The supplier shall also provide an updated audit report and certificate at certification renewal. The supplier shall notify MDLZ representative in the event that the certificate is surrendered or withdrawn by the certification body.

If, during a MDLZ SQE audit discrepancies between in audit findings versus the GFSI audit results in areas relating to food safety, MDLZ may choose to invite the supplier to discuss these with the Certification Program Owner (CPO) in the goal of continuous improvement for the MDLZ and GFSI audit programs.
MDLZ shall have no liability for any loss or damage incurred by supplier as a result of or in connection with any information disclosed in accordance with the provisions above.
Note: Suppliers of less than 50K$ spend/year, Venezuela supplier or any other Approved specific case are exempt from GFSI requirements.

3.3 Technical Visits

MDLZ operates a risk-based approach for re-approval audits. Additional Technical visits can be made by MDLZ Supplier Quality, Audit, Food Safety teams or approved external partner for specific improvement plans and/or corrective action verification.

3.4 Audit Requirements for Packaging Material Suppliers

All packaging supplier should be approved and reassessed as per Audit Table Matrix (Table 1.). Tier 4 suppliers having food contact with ingredient declaration & Food contact without ingredient declaration should be GFSI certified while Non- food contact with ingredient declaration may have either GFSI or ISO certification.

Where supplier approval is based on GFSI / ISO certification the supplier shall share with Mondelēz International the valid certificate and the complete GFSI/ISO audit report to become (or remain) an approved supplier. Upon each certification renewal the supplier shall also provide the new renewed certificate and complete audit report.

Where Supplier do not have a GFSI/ISO certification, or any exception applied or approved, MDLZ CQ auditing team based on risk will define 3rd Party assessment /MDLZ technical visit /remote assessment to determine site Quality program adequacy for use material to MDLZ.

The current accepted GFSI certification audits for approval of *food contact* and /or contains ingredient line packaging materials are as follows: BRC/IoP Global Standard for Packaging and Packaging Materials, FSSC 22000; SQF Packaging Standard; IFS PAC secure standard; ISO 9001 for *non-food* contact.

3.5 Audit Requirements for Chemical Material Suppliers

Some food grade raw materials (classified as chemicals) may be subject to different types of audits such as MDLZ Chemical Audit which is an audit focused on selected SQE requirements according to the nature of the material. Request for information is conducted to determine if a supplier qualifies for a chemical audit. These audits may apply to substances that meet the following criteria:

- Single chemical substances that are commercially produced with chemical reactions, extractions, and/or distillations using specialized processes. It may also include blending of the specialized chemicals.
- The materials must be food grade, NOT pharmaceutical grade (unless requested as such in the specification), and shall comply with regulations in force for use in food and/or pharmaceutical products, preferably produced in a closed system, and tested for levels of purity using highly accurate lab equipment (i.e. gas liquid chromatography).
- The material is non-sensitive (according to the *Biologically Sensitive Ingredient Category List)*
- There is no allergen risk.

The suppliers shall provide a process description and specification for the chemical in question.

A pharmaceutical audit may be applicable if the material has active pharmacological properties used in pharma licensed products (it is an Active Pharmaceutical Ingredients, API) and are assessed on a case by case basis by Corporate Auditing. An audit can be accepted from licensed Pharmaceutical auditors and GMP certificates issued by FDA or EU or other accepted country regulators.

CHAPTER 4 – QUALITY SYSTEM CONTROLS

The Supplier shall have implemented a written Quality Management System to ensure that the material produced conforms to *our* specified requirements. At a minimum, the Quality System shall ensure compliance with the *Mondelēz International Supplier Quality Expectations Manual and* MDLZ Specifications for the specific product, and all applicable regulatory requirements of the production country and the destination to which the products will be delivered.

The Quality System shall clearly set out the source of each food safety and quality requirement. The Quality System shall also set forth the specific personnel responsible for compliance with each requirement through use of an organizational chart. The Supplier shall review the Quality System on a regularly-scheduled basis.

The Supplier shall maintain records sufficient to show effective implementation of the Quality System. Records must be legible. The Quality System will clearly identify the records that must be maintained to show effective implementation, and controls needed for identification, storage, protection, retrieval, retention and disposition of records. Records shall be retained as a minimum of shelf life plus 2 years unless otherwise specified by regulation.

In addition to the requirements set out above, the Supplier's Quality System shall specifically include controls to ensure the following:

- Outsourcing: The Supplier shall notify the MDLZ Contracting Representative of any material supplied to MDLZ which is produced or processed in a plant not entirely owned or operated by the Supplier (e.g. sub-contractor). Any outsourced process that affects material or ingredients produced for MDLZ shall comply with the same requirements and be managed by the Supplier. If a supplier is sub-contracting any part of the production process to a third party the supplier must inform procurement and engage supplier quality and auditing.
- Repacking: The Supplier shall notify the MDLZ Contracting Representative if material is being re-packed at a different location to the manufacturing site into either a different packaging format or being bulk stored for future packing or bulk loading.
- Manufacturing changes: The supplier must notify MDLZ 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 MDLZ– such as changes in material formula, raw materials, production line, production facility or processes – and any change shall be approved by MDLZ before being implemented. MDLZ must be notified of such changes in writing. MDLZ will assess whether a new approval is needed.
- Special certifications: If MDLZ Specifications require particular certifications – such as Organic, Kosher or Halal certification – then the Supplier facility must be certified by an appropriate certifying body of the country in which MDLZ will receive the material.
- Genetically modified organism (GMO): All suppliers shall have a GMO management procedure in place to ensure that no raw material is supplied that would require GMO labeling, unless authorized on the specification. The Supplier shall ensure that raw materials do not contain any trace of unauthorized GMOs in accordance with the regulations in the destinations to which they may be delivered. Additionally, the supplier shall ensure that they comply with any additional regional or local MDLZ requirements. The MDLZ requirements are available from your Contracting Representative. MDLZ local requirements may include (but not limited to):
    - Certificate of origin
    - Certificate of analysis (on the ingredient and/or the original raw material, e.g. analysis of the maize/soy from where the ingredient comes from)
    - Traceability history
- No cloned animal products: No milk, meat, or other ingredients derived from cloned animals shall be used to make MDLZ materials.
- Ionization: Suppliers of irradiated raw materials and products must comply with the MDLZ written expectation for these products (*Mondelēz International Quality Expectation for Suppliers of Irradiated Raw Materials*).

CHAPTER 5 – MANAGEMENT RESPONSIBILITY

5.1 Notifying MDLZ of Significant Events

Communication in the supply chain is critical when events occur that could affect food safety, food defense, quality, or processing. The Supplier must establish procedures to ensure MDLZ is immediately notified of these occurrences:

The Supplier shall notify MDLZ immediately of any, but not limited to:

- Systematic product quality defect or process control deviation which could lead to a voluntary or involuntary *recall* or withdrawal of a MDLZ 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 MDLZ. MDLZ does not need to be notified of routine inspections, unless the inspection reveals that material produced for MDLZ may not be in compliance with applicable law.
- Inadvertent *release* from Hold of any material produced for MDLZ.
- Event that leads the Supplier to suspect that a non-conformance exists in product already shipped to MDLZ.
- Product tampering, threat of tampering or acts of food fraud on material produced / shipped to MDLZ.
- Event or substance that could threaten product security. Notification by law enforcement or other authority of a potential product security event.
- Identification of pathogen positive in material produced for MDLZ.
- Event of a pathogen positive result in a Supplier product (even if the specific lot is not sent to MDLZ) produced at the same line and / or shared equipment for MDLZ products.
- Event of a positive PEM (pathogen environmental monitoring) sample in production and cleaning areas.
- Identification of an unlabeled allergen or GMO in material produced for MDLZ.
- In Case of Loss of relevant certification, or any other certification as per approved certification e.g. GFSI /ISO, Organic, Kosher or Halal

The Supplier must notify MDLZ by a phone call with a live person and by email. Voicemail, even coupled with an email, is not adequate. The MDLZ Contracting Representative shall be the primary contact for any contact or notification required by this document. The supplier shall also have an emergency contact available 24/7 to the MDLZ contracting representative. If the MDLZ representative is not available in cases of emergency, contact MDLZ Security at +1.973.503.2900 (note: this number should be used for all regions globally) and explain who you are, the nature of the call giving all the necessary contact information.

The supplier shall review such events fully, identify the root cause, put in place effective corrective and preventive action.

5.2 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.

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 MDLZ (e.g. sampling for pathogen or GMO testing).

In the event a regulatory agency samples material produced for MDLZ, the Supplier shall collect and store 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 MDLZ. The Supplier shall contact the MDLZ Contracting Representative for instructions.

5.3 Food Safety & Quality Culture

The supplier shall have a program in place to continuously improve the culture of the facility in food safety and quality.

This may include but is not limited to:

- Clear management commitment to food safety and quality through documented policy and objectives
- Objectives for management and shop floor workforce
- Key Performance Indicators (KPIs)
- Employee recognition program
- Training, education and forums
- Food safety and quality communications

CHAPTER 6 – RESOURCE MANAGEMENT

6.1 Good Manufacturing Practices (GMP)

All persons entering the Supplier facility (plant personnel, visitors and outside contractors) shall comply with GMP requirements. 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. GMP requirements must be in writing and available to all personnel. Procedures must address personal hygiene, handling and storage of equipment and materials, proper cleaning and sanitation, and receiving. Further specific requirements include the following unless risk assessment deems unnecessary e.g. completely enclosed production process (this shall be documented):

6.1.1 Personnel practices

- Holding toothpicks, matchsticks or other objects in the mouth are not allowed in GMP areas.
- Carrying objects above the belt or waistline (e.g., pens, flashlights, thermometers) is not allowed 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.
- Food must not be stored in employee lockers.

6.1.2 Clothing and personal equipment

- All clothing must be kept in good repair. Employee clothing shall not be a source of contamination.
- Restricted uses: Work wear dedicated to specific product areas must be restricted to those areas. Such areas must be defined in local procedures (typically high care areas where clothing change is required on entry and exit). They are not permitted in other areas where they may be subject to allergen or micro contamination (e.g., cafeteria, external rest areas, and any area not subject to GMP controls).
- Footwear shall be fully enclosed, made of non-absorbent materials, conform to local safety requirements, and be suitable and dedicated for use in production areas.
- Where temporary shoe covers are required for hygiene area controls, they shall be robust and not present an extraneous matter risk.
- Safety helmets must be maintained in a sanitary condition. Helmets used in microbiologically sensitive areas must be cleaned and sanitized.
- Ear protection devices must be secured to prevent product contamination, e.g. ear plugs attached by string or with a rigid attachment worn around neck, and earmuffs attached by headband.

6.1.3 Hands

- Personnel working in GMP areas must wash hands before entering a GMP area; upon re-entering the GMP area; after each visit to the toilet facility, 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 re-sanitizing. 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 or provided in a contrasting colour to allow visual detection.

6.1.4 Hair

- Hair must be maintained as follows in GMP areas:
  - Hair curlers, hair combs, and bobby pins are not allowed.
  - Barrettes, clasps, scarves or bandannas shall be worn neatly under the hair net.
- Hair restraints must be worn in GMP areas.
  - Hairnets/restraints must be of a close mesh type and be non-elastic mesh and must completely contain the hair and cover the ears.
  - Hijabs and turbans are acceptable alternatives if they fully cover the hair and do not have clasps or other detachable fastening devices (in which case a disposable hair covering shall be worn over the top).
  - If safety or bump helmets are used, they must be worn over appropriate hair restraints.
- Facial hair must be maintained as follows in GMP areas:
  - Employees must be clean-shaven or cover the exposed hair with a beard restraint.
  - Sideburns must be trimmed and be no longer than the bottom of the ear or a beard net worn.

6.2 Personnel Training

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

- GMPs. All employees, including temporary and seasonal personnel, must receive GMP training (including Employee Illness and Communicable Disease) as part of the orientation process. All employees shall also receive refresher training or verification of GMP knowledge at defined intervals. In addition, specific training programs to instruct personnel on the requirements of this document shall be provided as required and applicable.
- Production Personnel. Training for Supplier personnel who work in production areas must include the following principles: Quality, HACCP, Allergens, Foreign Object Prevention, and Food Defense.
- *Critical Control Point (CCP)* Monitors. Employees monitoring CCPs must receive further specific training on monitoring, documentation, verification and corrective actions if critical limits are not met. There should be a method to evaluate the operator's competence.
- 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 handle non-GMO materials).
- Additional Requirements. Training requirements for Regulatory Inspections, Pest Management, Hold & Release and Pathogen Environmental Monitoring are set forth in the respective sections of this manual.

Training shall be provided to new employees before starting work in production. Refresher training on these topics shall be provided. 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.

6.3 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.

6.3.1 Prevention

Waterborne and food borne outbreaks related to city/municipal poor infrastructures (or other specific conditions in a region) may require preventative measures to be put into place. In those cases, a hazard assessment shall be conducted (as part of the HACCP) at each manufacturing location to determine the likelihood of an outbreak. If the hazard is likely to occur, preventative measures shall be considered and may include increased employee training, additional water purification, vaccination, etc.

6.3.2 Instructions

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 and/or Health Authorities and Food Safety 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, as well as related to visitors / contractors not entering premises when suffering from illnesses (see table 6.3.3 for relevant illnesses to consider)
- 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.

6.3.3 Pathogens involved with Transmission 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	OCCASIONALLY TRANSMITTED
Noroviruses	*Campylobacter jejuni*
Hepatitis A Virus	*Cryptosporidium parvum*
Salmonella Typhi	*Entamoeba histolytica*
Shigella species	Enterohemorrhagic *Escherichia coli*
Staphylococcus aureus	Enterotoxigenic *Escherichia coli*
Streptococcus pyogenes	*Giardia lamblia*
	Nontyphoidal *Salmonella*
	Sapoviruses
	Taenia solium
	Vibrio cholerae 1
	Yersinia enterocolitica

6.4 Utilities Management

- The Supplier shall have implemented programs to ensure safe provision of Utility Services in food production areas. Utility Services include environmental air, compressed air, water, steam and special gasses (N2, CO2 and other gasses).
- The Supplier shall control access points for the above referenced Utility Services, as well as electricity, heating, and ventilation. Access shall be controlled by any means deemed effective, such as locked facilities which only authorized employees can open. Further specific requirements include the following:

6.4.1 Environmental Air

- All plant exterior air intake ports shall be visually examined for physical integrity at a frequency determined by hazard analysis but minimum annually. Examination shall be included in preventive maintenance plans.
- Intakes shall be positioned and shrouded in a manner that will not allow rain or other precipitation to be drawn into the system. In cold climates, intakes shall be elevated sufficiently to avoid snow encasement. The location of inlet air used in processed product and/or area shall be in complete separation and in long distanced from the raw zone outlet air in order to avoid contaminated air being sucked by the system.
- 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 6.9 Hygienic Zoning). Air for Controlled or High Control areas shall not be sourced from an unprocessed product area (raw).
- If more than one type of process is used in a common area, the most stringent filtration standard shall be applied (i.e., in a space where cheese and crackers are packaged together, the filtration shall be according to that required for cheese which has a stricter filtration requirement than crackers). Air flow shall be from higher to lower zone and extracted from the lower zone.
- Air contaminated with combustible dust, allergen dust, dust from raw zone, odors, flavors in processing rooms/areas is required additional filtration at suction point of return air duct.
- Air filtration requirements vary according to the classification of the product, production process, and the microbiological risk. Table 2 shows Air Filtration Requirements, Table 3 ISO8573-1:2010 Compressed Air Purity Classes, Table 4 Sensitive Raw Material Categories requiring Environmental Air monitoring, Table 5 Suggested Action Standards for Environmental Air and Compressed Air & Table 6 Guidelines for Actions Standards for Clean Equipment Swabs. It shall also be noted that air filtration requirements apply to storage tanks which cannot be located inside the facility.
- Exception: Raw milk, granulated sugar, raw flour are exempted from the microbiological filter requirements as above. However, they must be protected from extraneous matter contamination with a screen of 18 mesh (1 mm / 0.04 inches) to prevent the entry of extraneous materials or pests. The requirement for air filtration of external storage tanks used for other materials, not already stated, shall be based on risk, usage and controls at the production site. This shall be assessed and approved by Mondelez Quality & Food Safety.
- Air quality shall be monitored, trended and reviewed by appropriate personnel, as necessary to ensure suitable microbiological quality. The supplier's program must include monitoring in production areas with exposed *microbiologically sensitive raw material* as identified in Table 4.
- The program shall describe the sampling locations, frequency, action limit, methods, corrective actions and responsible personnel. Table 5 Suggested Action Standards for Environmental Air and Compressed Air .
- Additional requirements for specific use:
- 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 non-microbiologically sensitive ingredients or sensitive ingredients with a further kill step, it must be filtered to F5 (MERV-9-10).
- Where air is used to transport sensitive ingredients with no further kill step, a filter size F7 (MERV 13) is required.
- Vacuum cleaners shall be fitted with H13 filters.

6.4.2 Compressed Air

- Compressed air for general applications must be dry, oil free and filtered to remove foreign particles.
- Compressors that provide air for direct or indirect product contact should 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 odour 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 preventive maintenance 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 to meet at minimum purity class 1.4.1 according to ISO 8573-1:2010 (see Table 3) at the point of use and dried to prevent condensation within the pipelines. Alternatively, an 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 (ISO 8573-1:2010 class 2.4.1) as close as physically feasible to the application.
- For sensitive materials / applications filters of 'Class 3' or higher for water, 'Class 1' for solid particulates (dust) and ‘Class 1’ for oil shall be applied.
- For existing installations main air distribution piping and fittings shall be of stainless steel, plastic, rubber, brass, copper, anodized aluminum, or galvanized.
- For new installations, main air distribution piping and fittings shall be of stainless steel or anodized aluminum.
- Piping & fittings after the final filter shall be of corrosion-resistant materials, including only stainless steel, anodized aluminum and plastic.
- Maintenance of air filters to manufacturer specifications is of prime importance and shall be documented.

6.4.3 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. The plant water program shall describe the sampling locations, frequency, action limit, methods, corrective actions and responsible personnel.
- Incoming water from municipal source shall be analyzed for microbiological indices quarterly. Certification from the municipal source is accepted.
- Microbiological tests shall be performed based on product/process sensitivity, however in a product processed without or after a pathogen reduction step all water used as an ingredient or to clean shall be analyzed weekly. The sampling plan shall cover all water circuits, and branches from main circuits.
- Microbiological tests shall also be performed after maintenance or repair to the water system.
- Microbiological tests shall as a minimum include but are not limited to analyses for TVC and coliforms. Recommended limits for water of potable quality: TVC < 500cfu/ml and coliforms < 1cfu/100 ml. Corrective action shall be initiated and documented for out of standard results (e.g. repeat sampling and testing, identification and elimination of the source of contamination, cleaning of piping, chlorination of water).
- Disinfection (e.g., chlorination, ozonation, UV light) of surface, well (ground) water, and untreated municipal water for all direct product uses (e.g. ingredient, sanitation, rinse, drinking) and indirect product uses (e.g. re-circulated cooling water, hand wash) shall be subject to an assessment to determine if disinfection is required. The assessment shall include, but not limited to, historical data of microbiological compliance, history of water borne outbreaks, and local regulation.
- Where water disinfection is carried out at supplier’s facility, this shall be done after filtration to ensure effective disinfection.
- Where chlorine treatment is used, residual chlorine and ozone must be periodically tested (e.g. daily or less frequently if supported by historical data), including municipal water. Free chlorine shall be 0.1 ppm or mg/L minimum and if levels exceed 5 ppm, contact municipality to establish cause or correct dosing at own source; i.e. check internal water chlorination system [level, retention time, indicator probes etc.]. Corrective actions shall be taken when levels do not meet the required limits.
- Ozone treated water shall be tested after de-ozonation, at each shift of production.
- If ozonation is used as an equipment sanitizer, water shall be sampled at the end of the sanitization circuit.
- The hazard of extraneous matter in incoming municipal water shall be suject of a HACCP assessment based on historical data.
- The extraneous matter hazards in incoming water needs to be controlled using filters, 200 mesh /75 microns for well water. Where alternative filtration methods are used (sand filtration, reverse osmosis, etc.) these must be shown to be equivalent. Filtration systems (e.g. charcoal, reverse osmosis) shall be regularly inspected and maintained.
- For surface or well water sources, a visual turbidity assessment shall be carried out regularly based on history. Testing shall be increased in the event of issues which may adversely affect water quality, such as abnormally heavy rain or flooding.
- 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 to prevent backflow into the potable water supply system as per local regulations.
- Potable water systems shall contain devices for preventing backflow, or cross-connection of fluid from waste or sewage water systems.
- Production sites shall have documented circuit diagrams/maps of their direct and indirect water system(s).

6.4.4 Steam

- 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.
- 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. 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 steam shall be produced using only approved food grade boiler chemicals. The piping assembly for direct steam shall: (1) contain an entrainment separator capable of removing particles 30 microns in size and larger located just prior to the injection heater /steam dispersal assembly and after the supply lines transporting steam from the boiler; (2) be delivered through stainless steel pipework to the point of use. Stainless pipework shall meet specification AISI 304 and 316. For Dairy applications, the steam should be filtered after the separator.
- Culinary, Clean and Process steam condensate quality shall be routinely evaluated for turbidity, off flavors and particulates at a frequency sufficient to demonstrate control (minimum 6 months for culinary steam and annually for process and clean steam).

6.4.5 Special Gasses (N2, CO2 and other gasses)

- Carbon dioxide, nitrogen and other gas systems used in manufacturing and/or filling shall be constructed and maintained so as to prevent contamination.
- Gases intended for direct or incidental product contact (including those used for transporting, blowing or drying materials, products or equipment) shall be pure products, 99.999% by volume and shall be certified for food contact use, filtered to remove dust, oil and water, if applicable.

6.5 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. The maintenance plan shall consider criticality of equipment for food safety. Tools such as FMEA (failure mode effect analysis) can be used to do this.If preventive maintenance is not in place it shall be clear that the equipment has been considered and PM is not required and run to failure is adequate. Should changes to the plan be required to equipment that could affect food safety there should be appropriate approval of the change.
- For invasive work, there shall be a protocol to ensure safe entry / access to equipment such as a Permit To Work. On completion of the work the protocol shall control hygienic hand-back to production including removal of tools, swarf and debris, cleaning / sanitizing and inspection.

Maintenance Hygiene -

- Workshops for maintenance of food contact equipment shall be kept in hygienic condition with adequate controls to prevent cross-contamination.
- There shall be a sanitation, inspection and clearance protocol following maintenance work on production equipment and food handling areas.
- Protocol shall be in place to control workwear for technicians and contractors preventing cross-contamination.

6.6 Sanitary Design: Plant Structure and Equipment Design

6.6.1 Plant Structure

The facility shall be of adequate design and construction to ensure production of safe and high quality materials, and satisfactorily maintained. The facility, including utility fixtures, shall be designed to prevent potential contamination sources from affecting the products produced or handled. The location and design of waste bins, toilets and hand washing, drying and sanitizing facilities shall be adequate to comply with GMPs. Construction materials used for the structure (e.g. floors, walls, ceilings, overheads and drains) must be completely compatible with the product, environment, cleaning materials used, and the method of cleaning.

Further specific requirements include the following:

- The internal and external structure shall be free of cracks, holes, openings, and pest entry or nesting areas. The roof must not leak.
- 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.
- In GMP areas there should not be direct access to external areas.
- 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.
- 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.
- It shall be assured that water, product, or *CIP* solutions do not pool in the product zones and that liquid cannot drain, be drawn, or drip onto product zone areas. Condensation control is required in exposed product zones.
- In facilities handling microbiologically sensitive ingredients, the plant structure must be designed to physically separate raw and processed zones (see Section 6.9 Hygienic Zoning). Dust in the air shall be minimized and allergen cross-contamination shall be prevented.
- Floor drains shall be trapped and vented to prevent sewer gas entry and must be accessible and cleanable.
- Microbiology laboratories must be separated from the production areas. At a minimum, laboratories shall be in a separate room with a door.
- The plant shall provide adequate space and separation from adjacent structures and equipment to prevent (microbiological or allergen) cross-contamination and to facilitate cleaning (allows for appropriate cleaning techniques for the application/design, which may range from *dry cleaning* on secondary packaging equipment to wet cleaning of direct product contact surfaces).
- Adequate ventilation or appropriately filtered air must be provided to prevent the formation of condensation, odour or mold.
- Facility design shall include correct and effective placement of all utilities required for sanitation.

6.6.2 Equipment Design

The Supplier shall ensure that equipment design is adequate for the production of materials that meet food safety and quality parameters. Equipment (e.g. batching, processing, storage, filling, transfer, piping) shall be constructed and maintained to sustain cleanability to reduce bacterial survival, growth and reproduction; the risk of chemical (allergen) cross-contamination; and the risk of extraneous matter contamination.

- Equipment materials of construction must be inert, nonporous and nonabsorbent. Equipment must be accessible for maintenance, cleaning, and inspection.
- All parts of the equipment product zone shall be free of pits, cracks, corrosion, recesses, open seams, gaps, lap seams, protruding ledges, inside threads, bolts, rivets and dead ends.
- Equipment non-product contact zones must be designed to ensure sanitary conditions are maintained and must be accessible for periodic controls and includes control panels, guards, and gear covers.
- Hand cleaned or manually set up designs shall be readily accessible for cleaning, sanitizing and inspection. Assemblies should be designed ergonomically.
- Equipment and framework shall utilize appropriate shapes and angles so as not to form traps, recesses or pocket that would allow water, dust, soil or product accumulation. Design must be robust and be able to sustain the self-draining properties over the life cycle.
- Framework and joint design must prevent microorganisms, soils, liquids, and insects from entering areas that are not accessible and cannot be cleaned.
- Equipment framework and components, (e.g. tank and vessel linings, agitators, baffles, and other hollow product contact equipment structures) must be totally sealed and un-penetrated.
- Continuous welding shall be used to join surfaces. Bolts, studs, etc. must be welded to the surface of the tubing and not attached via drilled and tapped holes.
- Caulk (Silicon / Latex) shall not be used for sealing on processing equipment. Equivalent or original base materials shall be used for joining surfaces. Enclosures must maintain their seal.
- Adequate air turns/ventilation shall be used to prevent condensation from forming at culinary steam piping, during CIP, and during sanitation or other operational conditions
- Wet cleaned equipment shall be CIP /COP compatible and/or can be disassembled easily and efficiently with minimal use of simple hand tools.

6.7 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.
- Chemicals to be used and how they are to be used including chemical concentrations, contact time, temperatures, frequencies, and rinsing procedures.
- Equipment disassembly and re-assembly.
- Verification of sanitation effectiveness.
- Hygiene (non-pathogen) monitoring programs. Such as sanitation verification
- Inspection procedures (including visual inspections).
- Recordkeeping, record review, and corrective action plans.

The following considerations shall be taken into account when designing the sanitation program:

- Situations when prolonged equipment downtime can lead to microbiological growth – idle time: additional sampling on start-up maybe required
- Protocols for extending production runs beyond established sanitation cycle times.
- Adequate product protection when sanitation activities occur adjacent to operating production areas.
- Cleaning in Place/Cleaning Out of Place (CIP/COP).
- Equipment that is wet cleaned which needs to be used in a dry condition.
- Post-cleaning or pre-start up inspections to confirm that equipment is clean, properly assembled, free from chemical residues and sanitized prior to use.
- 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, and cleaning of drains must not be performed during production or present a risk to product. The activity should be performed by a dedicated operator to prevent cross-contamination to other cleaning activities and equipment.
- Use of cleaning and sanitizing products, which are suitable for the food industry.
- Calibration of sanitation-related measurement devices (e.g., thermometers, gauges and meters).

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

equipment. Equipment shall not be brought outside the GMP areas for cleaning, and additional precautions are required when equipment from Controlled areas and High Control areas are cleaned in raw areas or vice versa.

Near sanitized equipment and in areas of exposed product, high pressure water hoses or compressed air hoses shall not be used to clean the floor or equipment due to formation of aerosols. High pressure water greater than 100 psi /7 bars 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 and sanitized before use.

6.7.1 Sanitation Verification (after *wet cleaning*)

The Supplier shall document and implement a plant specific program to monitor hygiene conditions and the effectiveness of sanitation for wet cleaned equipment, using swabbing. Clean equipment swabs shall be taken after the microbiological control step (e.g. heat treatment, formulation).

The procedure shall be documented and shall define the following:

- Target organism (product and process dependent);
- Sampling location;
- Frequency of testing (recommended minimum monthly);
- Methods and test result acceptance criteria;
- Process for corrective actions (including testing to confirm the effectiveness of the actions taken).

Each manufacturing facility shall establish its own program and a baseline for the different microbial indicators taking into account the product, manufacturing process and plant history. Until a baseline is developed, plants may utilize the guidelines defined in the Table 6 for the product target organisms.

Swabbing shall be performed after cleaning, but before sanitizing procedures. If swabs must be taken after sanitizing, proper buffer solutions must be utilized to prevent inaccurate results. Individuals performing swabbing must receive proper training. If the equipment is not in use, clean equipment swabs shall be taken prior to the next use of the equipment. Bioluminescence (ATP) testing of swabs or rinses are not a replacement for microbiological swabs, however it is an additional tool that can be used during post-cleaning or pre-operational inspections or for trouble-shooting.

6.7.2 Clean in Place (CIP)

The following shall be followed when setting up a *Clean in Place (CIP)* circuit. CIP systems are recommended for direct product contact surfaces that are to be routinely wet cleaned. Records shall demonstrate that conditions are met to assure adequate cleaning. The CIP documentation 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 shall describe the cleaning steps, time and temperature, 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.
- A list of items in each circuit that require dismantling and manual cleaning.
- A description of automatic controls and interlocks.

Operating requirements shall include, as a minimum;

- Defined controls for shared CIP systems for raw and pasteurized/RTE operations and allergen change-overs.
- Sequenced cleaning (pasteurized/RTE system cleaned before the raw side). For new installations systems shall be separate for RTE and raw line cleaning.
- In case of any failed CIP cycles corrective actions shall be documented
- A validation and verification of the CIP cleaning shall be performed and documented
    - Validation: typically, a tear down of the lines (dismantling of the line and inspecting key points e.g. valves, connection points) after the cycle to check for cleanliness and debris/fouling removal. May include microbiological swabbing
    - Verification: can be visual inspection of rinse water (i.e. water is clear), parameters of cycle are satisfactory, microbiological swabs or visual inspection of key points

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 flow meter.
- 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.

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.

Exceptions to CIP Requirements:
Simple cleaning processes (e.g. vat and kettle flushes or line flushes) that may be single pass and designed and operated without return flow or PLC controls are exempt but the process must be documented and cleaning effectiveness must be verified and validated.

6.7.3 Cleaning Out of Place

Cleaning Out of Place (COP) systems & semi-automated parts washers must be monitored, verified and validated to demonstrate their cleaning effectiveness as is appropriate to the product & equipment.
If there is a HACCP-controlled kill step or allergen changeover and equipment parts used in raw and other manufacturing areas are cleaned in the same COP unit, the unit itself shall be cleaned and verified between the cleaning of equipment from raw and other manufacturing areas to prevent cross-contamination.
Zone 3 items must not be cleaned in the same COP tank that is used to clean equipment from zones 1 & 2

6.8 Pest Management

Facilities shall have effective pest management programs and pest control practices. The Pest Management program must be designed to address the reduction of pest activity as a continuous improvement.

The program shall include an escalation procedure with action limits whose rationale shall be determined and documented for each target pest based on historical pest activity trends, the environment, the type of trap, bait or monitor used and advice from the Pest Control Operator (PCO).

The facility shall implement and document appropriate and effective C&PA and RCA plans whenever pest activity breaches the action limits for any targeted pest species. This shall be applicable for sporadic and recurring pest activity.
The Supplier shall contract the pest control service to a professional pest control company or designate an appropriately trained, competent person to manage the pest control program on site. The supplier shall include the program in the internal audit plan and track the effectiveness of the program.

The Supplier shall maintain the facility, building & grounds to prevent pest entry into the facility

The pest management program shall include:

- All pests relevant to the facility, product, environment.
- Pest management plans, methods, schedules & approved pesticides
- Regular inspection reports
- An up to date map showing the location of all pest control devices, such as indoor rodent traps, glue boards, insect light traps, outdoor bait stations, and pheromone traps.
- Pesticide application log, bait and pheromone usage log
- Trend analysis for pest activity/ Pest activity log
- Action limits for each target pest – these should be reviewed annually with an objective to reduce limits.
- Corrective & preventative actions for increased trends /activity for all target pests
- Training requirements.
- KPIs to measure the pest control program

If pesticides are required, they must be restricted to trained personal, follow local regulatory legislation, and shall be controlled to avoid the risk of product safety hazards.

Pesticides should be used as a last resort of control & non-chemical methods should be the preferred option.

When using pesticides, the following practices shall be followed:

- Application of pesticides must follow the label instructions & local regulatory legislation.
- Pesticide lot numbers shall be documented on usage records to assure traceability.
- Records shall be stored for a defined period in line with local or company requirements
- All pesticide labels and Material Safety Data Sheets (MSDS) or equivalent material addressing safety precautions shall be available at the facility where the pesticide is used.
- All EPA registration numbers, where applicable, shall be maintained and available at the facility where the pesticide is used.
- Disposal of unused pesticides and of empty pesticide containers must comply with applicable regulatory requirements.
- Baits shall be used in situations where a specific pest is the target. Where used, bait must be placed in secured bait stations (e.g. securely anchored to the ground or building). Throw packs and loose rodenticide baits such as pellets and meals are not permitted, poisons shall not be used internally. Old bait shall be discarded periodically and replaced with fresh bait.

All monitors & control devices must be kept clean and well maintained and must not be positioned in a way that attracts pests into the facility. The use & placement of these devices must be in line with industry best practice and comply with local regulatory requirements

All monitors and control devices must be checked at a frequency based on risk & pest history of the facility & the frequency must be sufficient to identify early signs of pest activity before infestation is established.

The attractant must be changed at a frequency based on the manufacturers recommendation.

6.9 Hygienic Zoning

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

Hygienic Zoning controls shall also focus on the interfaces and movements between areas where the microbial profile changes such as between cooked and raw product.

Note: Provided there are no other microbiologically sensitive ingredients processed at the plant, this requirement does NOT apply to the following Suppliers of non-microbiologically sensitive materials (including all sub-ingredients), such as Sugar; Oils and Fats (except Dairy and Cocoa); Food Additives; Raw Meat and Raw Meat Products; and Food Chemicals.

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

The hygienic zoning program shall consist of three parts: assessment, implementation of controls, and evaluation and verification.

6.9.1 Hygienic Zoning assessment

The Supplier shall carry out a zoning assessment to identify and document potential sources of cross-contamination between processing areas and/or products (e.g. product handling areas, storage areas, processing areas, raw materials, exposed RTE product). The hygienic zoning areas must be documented on a map of the facility.

This assessment shall be reviewed and updated in the event of changes to plant layout and the introduction of new lines or processes.

The following questions can help in determining where a potential for microbiological cross contamination may exist, to design the plant map indicating the different zones, and for deciding which controls to put in place in transition areas (interfaces / movements between areas).

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?

Infrastructure:

- Are effluent and wastewater drains coming from product areas with potentially higher contamination risk separated (i.e. no connection between drains in raw and other areas or back-flow prevention installed)?
- Is the building designed to prevent water seepage between rooms/doors noted during sanitation?
- Are overhead drains adequately constructed/ protected to prevent product/area contamination?

Utility Controls:

- Are negative air pressures in place for raw areas when adjacent to process areas?
- Are high control zones under positive air pressures? Are relative humidity levels and levels of air turns/hour maintained?
- Is air appropriately filtered in all areas?
- 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 and sanitizer stations installed and used?
- Are hand-sanitizing units available to all employees working with product contact?
- Are sticky mats/footbaths/foot washing stations/ 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 avoided?

Based on the Hygienic Zoning assessment, the different areas (zones) of the production facility shall be classified as follows:

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

Raw /limited process Area
- Areas receiving, storing or handling raw agricultural products (e.g. raw milk, raw cocoa beans, flour, raw nuts) including areas of product preparation that will be thermally or otherwise processed and that are known to or have the potential to be contaminated by pathogens.
- These zones often require the use of dedicated employees and may be physically separated from controlled zone or high control zone.

Controlled Area zone:
- Products that are not highly sensitive (those which are low to medium micro-susceptibility, don't support pathogen growth) and which can be exposed to the environment and the operators.
- GMP practices are implemented and MDLZ air requirements are met.
- The controlled zone may also serve as transition from non-manufacturing or raw/ limited process zone to high control zone.
- Products of higher sensitivity may be present if they are completely enclosed.

High control Area
- Product which supports growth of pathogens (*Salmonella* or *Listeria monocytogenes*) and can be exposed to the environment and/or the operators.
- Additional GMP practices, such as captive footwear/clothing, may be required and more stringent equipment/building sanitary design requirements are followed.
- When products are exposed, additional production practices, such as prohibiting the use of cardboard, wooden pallets, etc. shall be implemented.
- Positive air pressure may be required as an additional control.

Table 7 provides examples of the zoning areas on different products/processes.

6.9.2 Identification and implementation of controls to prevent cross contamination

The Supplier may need to introduce or adjust controls such as physical measures or barriers, traffic management, utility controls, GMP measures and sanitation controls. Examples of control measures that should be considered (but are not limited to):
- The use of closed system (e.g. closed tanks and pipes);
- Structural separation of areas (e.g. separate building, walls), traffic control or and distance separation. If distance between a raw zone and exposed RTE product is used, it should be verified to be effective in the facility Pathogen Environment Monitoring Program.
- Restricted access to microbiology susceptible product areas (applies to employees not working in the area, visitor, etc.);
- Use of a vestibule as entrance and exit with personnel hygiene and changing measures;
- Use of designated and/or coded tools and equipment for microbiological susceptible product zoned areas or adequate cleaning programs for tools;
- Adequate filtration and pressure/flow of room air.
- Prevention of entry/exit from outside directly into the production area.

6.9.3 Evaluation and verification of the Hygienic Zoning program.

The supplier shall periodically evaluate the effectiveness and compliance of zoning requirements and also whenever a change occurs to the plant lay-out, process or product (e.g. new equipment installation, modification or introduction of a new material, moving production lines). The review may include, but is not limited to, environmental testing including pathogen testing, GMP audits, visual checks for product residues in environment/infrastructure and routine pre-operational and operational inspections. Specific evaluation may be required prior to execution of major project works in production areas and unusual events (back flow, flooding, water leaks etc). This may include restricting access, diverting traffic flow.

6.10 Pathogen Environmental Monitoring

Suppliers shall have implemented a program for pathogen environmental monitoring (PEM). The PEM program shall verify that the controls put in place during the Hygienic Zoning assessment are effective at preventing potential cross-contamination between different Hygienic Zones. The rigor of the plant PEM program depends on the product and process hazard evaluation, and the likelihood of pathogen(s) to survive or grow in the material during storage and distribution.

Note: This requirement does NOT apply to the following raw materials suppliers: Raw Milk and Cream; Green Coffee Beans, Roast, and Ground coffee facilities; Compressed Gases; Raw Grains; Raw Nuts/Seeds/Coconut; Sugar; Oils and Fats (except Dairy, and Cocoa); Food Additives (not containing microbiologically sensitive sub-ingredients and/or not processing microbiologically sensitive ingredients at the plant) : Raw Meat and Raw Meat Products; Food Chemicals; Commercially Sterile Food and Beverage Products – aseptic / UHT / retort. Material specific advice on PEM can be requested from your Supplier Quality contact. The PEM requirement focuses on two specific pathogens, *Salmonella* spp. and *Listeria monocytogenes*, as well as *indicator organisms* (e.g. *Listeria* spp.) to monitor conditions that could lead to presence of respective pathogens. The PEM program shall:

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

6.10.1 Monitoring requirements and instructions

Requirements and instructions for the plant PEM program shall be documented and include the following:
- Target organism(s) and sampling frequencies (please refer to Table 8).
- Testing methodology.
- Applicable products or processes.
- Sampling site locations which shall include the most critical location and are dependent upon such criteria as the material produced, equipment design, plant structure, traffic patterns, and previous findings.
- The time frame for taking samples (e.g. shift, midweek, end of week). Routine sampling must take place during production, at least 3-4 hours after start-up.
- The time period between sampling and start of analysis shall be kept to a minimum. It is important that repeat routine samples from the same sampling site or for the same purpose are held under consistent conditions (e.g. time, temperature) such that variations between samples are minimized.
- Samples shall be transported and stored under chilled conditions (>0°C and <10°C) to minimize microbial growth. Samples without transport medium shall be processed within 12 h. Samples with transport medium shall be processed within 48 h. Samples must not dry out.
- Test result acceptance criteria.
- Corrective action plans, including increased control procedures and verification requirements.
- Periodic training of personnel responsible for PEM activities.

The PEM program shall be reviewed periodically or whenever a change occurs to the hygienic zoning program. The PEM review shall be documented.

6.10.2 Sampling Locations

Site specific sampling locations shall be selected to identify potential harborage and niche sites, and the potential migration of pathogen(s) between zones. The sampling locations are identified as four different types of zones:

Zone 1: Sites that are direct or indirect product contact surfaces. Direct product contact surfaces are surfaces exposed to product during normal equipment operation. Indirect product contact surfaces are surfaces from which liquids or dust or other material may drain, drop, diffuse, or be drawn into the product or into the container, and surfaces that touch product contact surfaces or the container. Examples include but are not limited to: conveyor surfaces and product chutes, pipeline interior and storage fill hoppers, nozzles, formers, cut & wrap equipment, product scrapers/utensils, product contact gloved hands, etc. Product must be placed on hold should samples be taken in zone 1.

Zone 2: Sites that are environmental surfaces immediately adjacent to product-contact surfaces. All surfaces close to product contact surfaces that under normal operating procedures do not directly contact the product or the product contact surfaces of the container, including the exterior of processing equipment. Examples include but are not limited to: non-product contact gloves, equipment supports, frames, outside of tunnels, outside of enclosed filling cabinets or below filling equipment, control panels, weight scales, motor housings, scrap carts, etc.

Zone 3: Sites that are non-product contact; environmental surfaces within the processing room that are more remote from product contact surfaces. Examples include but are not limited to: hand trucks; forklifts; walls; drains; floors, equipment legs, ductwork, ceilings, fork truck and cart wheels, tools, brooms, squeegees, floor scrubbers, from vacuum collection points, trash cans/waste bins, traffic pathways into process area, ceiling drain pipes, wall/floor junctures, wash stations, ingredient storage areas, etc.

Zone 4: Sites that are remote from product contact surfaces outside the processing room but could impact processing areas through the movement of people, equipment or materials. Examples include but are not limited to: warehouses, hallways, break areas, locker rooms, mechanical rooms, offices, cafeteria, restrooms, coolers, floors, wheeled vehicles and materials, and trash/recycle collection areas.

Further sampling guidelines:

- Sampling locations typically do not include raw, unprocessed products and raw processing areas e.g. raw meat, poultry, vegetables, fish, and unpasteurized milk and cream. However, the sampling of transition zones/interfaces between raw/limited processed zones, controlled zones and high control zones may be useful to verify the effectiveness of zoning controls.
- Floor drains located in relevant areas shall be included in any sampling plan.
- Large surface areas shall be sampled for qualitative analyses. A sponge is more effective for sampling large surface areas. For smaller hard to access or irregular shaped areas, a cotton swab is more effective.
- The number of sampling locations for each zone shall be in accordance to the complexity of the site.
- Once data on individual locations are available, pooling of samples may be considered. Samples within the same zone may be pooled with up to five sample points in one sample after pre-enrichment. Samples taken from floor contact areas (e.g., floor, steps, and wheels) may be pooled only with other floor contact areas within the same zone. Note: “Pooling” refers to individual pre-enrichments pooled together for detection. Compositing of samples (i.e. combining of test samples prior pre-enrichment) is only allowed when data are available that the sensitivity / detection limit will not be impacted by that practice.
- Sample site locations should be changed on a periodic basis. The sites should be selected based on the potential to harbor pathogens.
- The plant team may develop a list of sites that could be sampled in rotation and be completely covered in a given timeframe, for example, monthly or quarterly. It is recommended that routine sampling should be varied to represent the entire production schedule, (e.g. 2nd or 3rd shift, and different week days).

6.10.3 Sampling plans and results

The Table 8 specifies the PEM zones, organisms, and minimum test frequency for each type of product. Materials not specified in table plan to be agreed with food safety. Please also note this frequency refers to the specific production area, not the frequency of sampling of each individual site specified in the plant PEM program. Collation and trending of PEM results is required.

Whenever product contact surfaces are tested for pathogens, affected product lots shall be placed on Hold pending the test results (see Section 8.4 Hold & Release).

In the event of a pathogen positive finding (e.g. *Salmonella* or *Listeria monocytogenes*) the MDLZ Contracting Representative must be immediately notified, even if the specific lot is not sent to MDLZ. When sampling Zone 1 for non-pathogens (*Listeria* spp.) it is not necessary to place product on hold unless directed by a government or regional regulatory agency.

Laboratories shall comply with requirements described on Section 8.2 Testing Controls.

6.10.4 Corrective action plans

In the event of a pathogen-positive result the Supplier shall conduct an investigation to identify the source, root cause and document all corrective actions. If multiple sites were composited (pooled), then re-sample after a positive to find the single positive site. Corrective action plans shall be initiated as soon as practically feasible. Corrective action may include improved cleaning or sanitation, redesign of the structure or equipment, improved GMPs, redefined traffic patterns, etc.

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.

The three samples shall be taken consecutively following the receipt of the previous sample result (i.e. when the first result is received the second sample shall be taken). This must be completed within a 3-week timeframe. Trend analysis of positive findings shall be made in order to detect areas of concern.

6.11 Food Defense

Suppliers shall develop specific procedures to secure their product, to deter and prevent intentional contamination, and shall have protocols in place to quickly and accurately identify, respond to and contain threats or acts of intentional contamination. The program shall cover the supply chain including warehousing and transportation Likewise, Suppliers will ensure their suppliers adopt similar protocols and implement appropriate controls. At MDLZ we call these efforts Food Defense.

The laws and government expectations regarding Food Defense vary from country to country. In order to achieve a common standard that is industry recognized worldwide and simple to manage and maintain, MDLZ accepts audit schemes that complies with the current version of *PAS 96*. A current list of GFSI accepted certifications for ingredients can be obtained at www.mygfsi.com.

US-based suppliers, and international suppliers shipping direct materials into the United States, are expected to meet the requirements below and be prepared to provide confirmation to Mondelēz International that they have met all these requirements.

- Adopt and maintain a facility Food Defense program (outlined above).
- 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.
- Detained product. Ensure detained product is held as directed by Mondelēz International
- Meet C-TPAT Import Security Criteria if making shipments to the U.S. which originate elsewhere.

Supplier may check MDLZ Supplier Portal to obtain additional guidance or information.

6.12 Food Fraud

The supplier shall have systems in place to minimise the risk of procuring raw materials which could present economically motivated adulteration or raw material substitution and to ensure that all product descriptions and claims are legal, accurate and verified.

The supplier shall have access to information for both developing and historical threats. This may come from a variety of sources such as:
Trade associations, Government sources or Publications

A vulnerability assessment shall be completed and documented on all food raw materials which assesses the potential risk of adulteration, fraud or substitution which is economically motivated. The assessment shall have a defined periodical review to reflect any market intelligence which may change or affect the risk.

Based on the output of the vulnerability assessment the supplier shall have a control plan to manage the identified risks. This can be in the form of, but not limited to:
Targeted and non-targeted testing
Traceability exercises
Audit

CHAPTER 7 - PRODUCTION PROCESS CONTROLS

7.1 Specification Compliance and Contract Review

The raw material supplier must fill in a MDLZ Ingredients Supplier Questionnaire form in full and to the expected time period of 10 days, unless otherwise agreed. For each new or existing raw material that MDLZ purchases for plant testing or production. MDLZ will then create or update the MDLZ Raw Material Specification should the data be acceptable.

Once the ingredient specification is approved by Mondelez, a Supplier Acknowledgement Request (SAR) along with the Ingredient Specification Report will be sent to the supplier. The supplier must acknowledge by signing the SAR that they can supply to the Mondelez Ingredient Specification. The supplier must reply to the SAR within a 10-day time period. Only after the SAR is signed, may the material be used at locations producing MDLZ finished goods.

For packaging the supplying site must have the latest specification available.

The Supplier shall ensure that MDLZ Specifications are implemented at the supplier's production location and that appropriate plant personnel have access to the latest specifications for materials supplied to MDLZ. Specific testing methods are described in the Specifications. If the Supplier uses a different method MDLZ must be informed, a validation / correlation study must have been performed in order to guarantee an equivalent output.

The Supplier must deliver materials that meet MDLZ Specifications. If the Supplier anticipates that it will not be able to meet the Specification, the MDLZ Contracting Representative shall be notified immediately (see Section 5.1).

Suppliers of ingredients and primary packaging materials that will be used in the manufacture or sale of products by MDLZ must conform to local rules and regulations.

7.1.1 Certificate of Analysis (COA)

Where *Certificates of Analysis* (COA) are required, these must be provided to MDLZ prior to acceptance of the material at MDLZ locations. Certificate of Analysis shall be written in local language of the receiving MDLZ plant or in English. A COA shall contains,

- Supplier Name and manufacturing location, contact details
- Material name, lot identity, production date and MDLZ identification number
- Supplier purchase order number
- MDLZ Specification number (or purchase agreement) and issue date
- Test results for each lot, including MDLZ specification and other parameters if required by local or national requirements
- Parameter being tested, test method, sampling plan and for microbiological samples the sample size.
- Total Count and Enterobacter results where spec requires (shall be reported as the actual test result number, cfu/g)
- Laboratory name and location performing the testing or other information to identify the laboratory

7.1.2 Certificate of Analysis for pathogens

In cases where the MDLZ Specifications require pathogen analyses the material that will be delivered to MDLZ plants, the samples must be collected across the lot according to a statistical sampling plan that represents the lot. The test must be performed by a laboratory approved by MDLZ (see Section 8.2 Testing Controls: Laboratory Requirements). The COA must be provided to MDLZ and shall include the requirements specified in section 7.1.1. MDLZ reserves the right to sample each delivery and to determine the appropriate disposition. 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 MDLZ shall be immediately notified according to section 5.1, even if the specific lot is not sent to MDLZ.

For materials / suppliers that require monthly sampling as part of the MDLZ CoA Verification program samples shall be taken against the agreed protocol and sent to the MDLZ approved laboratory. The material must not be released / shipped to MDLZ until acceptable results have been obtained.
MDLZ has a Sensitive Ingredient list, these materials require pathogen analysis. See Table 14. in the Appendix

7.1.3 Testing for possible chemical contaminants and adulteration

MDLZ requires that some specific incoming raw materials and packaging materials be part of the chemical contaminants testing program and/or food fraud scanning. This is a due diligence program designed to check for potential contaminants and/or adulteration across the supply chain by verifying that materials meet MDLZ Specifications and comply with all applicable regulatory requirements and industry standards for the designated country of the MDLZ receiving location. This testing is in addition to tests that are required for MDLZ Specification compliance.

MDLZ will select the materials to be included in the program based on their MDLZ risk profile. The Suppliers selected to submit materials for testing will receive further communication from MDLZ detailing material(s) selected for testing, sample submittal date and shipping protocol. Suppliers must then submit samples representative of the specified materials to a designated MDLZ approved laboratory for analytical chemical testing. Test results will be released to Suppliers and MDLZ, simultaneously.

Suppliers shall place the material unique lot on hold and NOT ship to MDLZ until clearance has been given confirming the material complies with the specification

Program testing may include, but is not limited to: *heavy metals*, mycotoxins, nitrates, dioxin and PCB, PAH, veterinary drug residues, *pesticides*, adulteration, melamine, etc. The specific lot of material submitted for testing shall not be shipped to MDLZ locations or to contracted manufacturing facilities producing MDLZ branded product until the results of the testing confirm that samples meet our Specifications and comply with all applicable regulation.

It is expected that raw material and direct contact packaging material suppliers will implement internal contaminant monitoring programs to monitor for chemical hazards appropriate to the materials manufactured and related to industry risk prevalence and regulatory requirements to ensure specifications agreed with MDLZ are maintained.

Suppliers contaminants testing programs can be used as a supplement or replacement for the above with agreement from the chemical contaminants program owner.

7.2 Incoming Materials: Management of Purchased Material

The Supplier shall develop and document Quality expectations, requirements and/or specifications for purchased goods that are consistent with the programs in this *SQE* and MDLZ Specifications and provide them to their suppliers.

Purchasing of materials which impact food safety and quality shall be controlled to ensure that the suppliers used have the capability to meet the specified requirements. The conformance of incoming materials to specified purchase requirements shall be verified. This includes that there is a process in place to assure that materials which do not undergo a kill step at the Supplier's own manufacturing site, are adequately reviewed as part of the HACCP implementation. Where a MDLZ supplier is reliant on their supplier's thermal processing kill step the MDLZ supplier shall have in place a program to ensure the step has been validated with defined log kill for target pathogen. This shall be compliant with the relevant MDLZ Processing Expectations

The validation shall cover all MDLZ microbiological sensitive ingredients and shall be documented within the HACCP program. It shall be available to MDLZ on request.

7.3 Receipt and Shipping controls, Inspection and Testing (Inbound and Outbound)

- The supplier shall have a program in place to manage incoming ingredients and packaging to ensure they comply with the specification and regulations. The program shall be documented including method of checking, inspection, verification and frequency of sampling / test. There shall be a system in place for recording traceability information such as batch or lot numbers.
- There shall be in place a hold & release procedure for materials that are tested for pathogens.
- Tankers shall be dedicated to food only. Inbound loads suspected of any type of tampering shall be investigated by the Supplier. The shipment shall be rejected if the source of tampering cannot be determined.
- During unloading of 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. Bulk ingredients must be properly transferred through sanitary pipes and/or hoses, and filtered, screened or sifted as required.
- Prior to accepting incoming materials, the Supplier must verify that delivery vehicles (such as trucks or railcars) have maintained the quality and safety of the materials during transit. Verification activities shall be documented and shall include:
  - i. Inbound and outbound vehicles shall be verified to be clean, dry, free from leaks, off-odours and unusual residual materials (powder or liquid) prior to loading/unloading.
  - ii. Materials and products shall be inspected for damage, infestation, and temperature abuse, potential security concerns such as perforated cases, exposure to moisture, unusual odours or unauthorized co-loads and damaged security / tamper evident seals.
  - iii. Outbound truckloads / containers, deliveries to MDLZ (Full and Less Than full Truckloads), shall be sealed at dispatch using a numbered, tamper resistant metal seal, number recorded on shipping documents. All trucks for multiple delivery drop points with no more than 24 hours delivery period from time of dispatch: it is sufficient for the vehicle to be under driver lock control, no seal requirement. Mondelēz International expects the transport company to maintain the integrity and security of the load throughout the transit and documentation shall be available to show the previous drop points.
  - iv. All openings (doors, inspection ports, hatches, etc.) on outbound shipments shall be sealed with a numbered, tamper evident, resistant seal and the seal number(s) annotated on the shipping documentation and loading control documents.
  - v. In the event that a security seal has been broken by an authorized person (e.g. border / customs, police officers) there shall be
    - a) Appropriate records to describe the reason for the seal removal.
    - b) A replacement numbered seal shall be applied, and details recorded on the load documents.
    - c) Where permissible, the credentials of delivery drivers should be verified in addition to the delivery documentation (for example, driver name shown on delivery documents, photo ID on license).
    - d) If there is evidence of unsatisfactory shipping practices or tampering, then the materials shall be either rejected and returned, or immediately placed on hold.
- Inbound and outbound bulk containers shall be sealed.
- Deliveries shall be palletized and wrapped according to Mondelēz International specifications.
- Big /Bulk bag delivered ingredients shall have temper evident seals on each bag

7.4 Hazard Analysis and Critical Control Points (HACCP)

The Supplier shall have implemented a written HACCP plan /Food Safety plan (for FDA registered sites) for all materials produced for MDLZ. The Supplier's products shall be designed, produced and stored using HACCP principles to systematically minimize product safety risks. 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/Food Safety plan and its implementation is properly verified and validated on a regular, documented basis. The supplier shall ensure and document that all relevant employees receive an appropriate training in HACCP.

7.4.1 Validation

Food Safety plan (FSP)/HACCP System Validation involves the initial collection and evaluation of scientific, historical and technical information to assess whether FSP/HACCP Plan effectively identifies and controls all food safety hazards and emerging issues associated with the product or process.

Validation of microbiological CCP's: As part of the HACCP implementation and validation, the performance objective of all processes/technologies used to eliminate target pathogenic organisms must be defined and validated. Note: Performance objective is the number of logarithmic (log_{10}) reduction for the pathogen of concern, i.e. 2-log reduction for Salmonella). It also includes the validation of data demonstrating that the process is capable of meeting those parameters.

Validation of allergen change over CCP: The effectiveness of an allergen cleaning occurring between an allergen containing and non-allergen containing / different allergen containing product must be demonstrated. This procedure requires the physical validation of the cleaning and pre-op inspection process and the analytical validation (based on a validated ELISA method for the nominated allergen) When no appropriate validated ELISA test kit for the analytical validation is available, allergen line validations must comply with the visibly clean standard.

Validation studies must be available to MDLZ. The validation is part of the overall audit process and it must be complete as minimum requirement for approval. Furthermore, suppliers must complete an in-depth verification of their microbiological CCP at a minimum frequency of every 2 years. There are also situations where a re-validation is required:

- When there is a system failure resulting in process deviations that cannot be identified;
- Whenever there is a change in the design of the processing equipment or conditions used - only that part of the system affected by the change needs to be re-validated – this includes where nib moisture content is lower than specified e.g. through pre-drying;
- Where MDLZ updates the target organism or log reduction target required, based on new information.

7.5 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. This program must include the following key principles

- An Allergen Assessment shall be carried out as part of HACCP Plan development to identify, review and document allergens present at site. This assessment must consider all allergens on the Mondelēz International Allergen Category List as well as any others identified in local regulations and regulations of the countries that the product is shipped to. If area or line assessments indicate that different lines and/or area profiles exist, the assessment shall be used to identify appropriate controls.

  The Allergen Assessment shall consider and appropriately manage:

  - Possible sources of allergens related to the raw materials and formulation
  - Process and site-specific practices, including: raw materials/ingredients handling and rework addition
  - Potential cross-contact possibilities from receiving, storage over manufacturing to shipment practices.
  - Potential implications of any change of raw/packaging material supplier or implications to formula or process changes.
  - Opportunity to design out allergens where ever possible
- A raw material supplier management program which is regularly reviewed
- Adequate systems to ensure the correct use of allergens in the formula, correct packaging materials and labelling.
- Adequate plant and equipment design to minimize allergen cross-contact (where practically possible, areas, lines and equipment's should be dedicated to a specific allergen profile in the facility. This may also include factory layout (physical segregation, zoning principles, minimize cross overs of product lines, shielding, covers).
- Tools to be color coded, appropriately labelled or a validated as part of the cleaning program in place
- Limit / restrict / control movement of people, materials, equipment, vehicles and maintenance tools between segregated areas. This may require change of work wear when moving from an allergen to a non-allergen area (dusty environment and an enhanced application of GMP) or an area of different allergen profile
- Carryover of allergens on shared lines must be mitigated, where this is not feasible then carry-over should be minimized, i.e. visible whole or partial pieces of allergen from the previous production are not regarded as cross-contact and are NOT acceptable. For processes where an allergen changeover is required a validated change over regime (Cleaning/Flushing/ Sequencing) shall be in place and documented.
- Where the supplier is producing a product that does NOT have any carry-over the change-over procedure shall be validated and managed as a CCP, unless the site has one unique allergen profile.
- Allergen validation shall be undertaken using industry best practice (i.e. post clean swabs & finished product sampling, analysis conducted by a lab accredited to ISO17025 and repeated on three separate occasions). Verification of the allergen cleaning shall be regularly verified (min. once per year). Carry over levels shall be established by conducting sampling of finished product following the site standard product changeover practices. This shall be verified through analysis on a specified periodical basis (guidance document is posted on the Supplier Portal).
- Change-over procedure MUST include: identified equipment and infrastructure; dismantling & cleaning instructions; visual inspection standards with photographs; identified Hard to Reach and hang-up locations; removal and clearance of packaging form the line and area; defined responsibility for approval of change-over standard; documented sign off as acceptable.
- Scheduling should be such that it minimizes cross-contamination risk.
- When confirmed that cross contact is warranted the cross-contact level shall be minimized). The cross-contact labelling is a last resort and shall not be used as a substitute for GMP or an effective food allergen control program.
- In cases where cross contact is identified, it must be confirmed as unavoidable through documented HACCP assessment based on the following criteria and where possible supported with analytical data:

  - Allergen can't reliably be cleaned off the line
  - Allergen presence is unintentional and sporadic
  - Theoretical calculated risk identified in risk assessment
- Rework product containing allergens as an ingredient shall be used only in products which contain the same allergen as an ingredient that is declared on the package ingredient line (i.e. like into like). It shall not be used in products where the allergen is declared on the package as a result of manufacturing cross contact.
- Suppliers delivering Raw materials for finished product labelled with "Allergen free from claims", a "free from" claim is an absolute claim (unless a regulatory limit has been set). Therefore, a rigorous assessment of the raw materials, the suppliers manufacturing process and environment is essential. Depending on the plant situation the allergen risk must be managed appropriately, following the "Allergen Control and Labeling – "Free From" Labeling Manual.

  The MDLZ Global Allergen list can be found in the Appendix Table 16.

7.6 Extraneous Matter

The Supplier shall have implemented program to prevent, detect and control extraneous matter. These requirements apply to any re-packing operation or bulk storage which is either company owned or outsourced. This requires that each supplier must have a documented program in place, based on hazard assessment, to minimize the potential of extraneous matter being introduced into the product.

Key elements of the hazard assessment are to

- Determine potential sources of extraneous matter
- Minimize the potential of extraneous matter being introduced into the product
- Minimize hazards prior to commercialization of new equipment, or modification to [or relocation of] existing equipment.
- Determine appropriate management strategy for minimizing extraneous matter

Appropriate strategy for minimizing extraneous matter may include (not limited to):

- Confirming control strategies at suppliers or sources of materials.
- Building and infrastructure maintenance program e.g. to prevent flaking paint, temporary repair from rope/string/tape
- Appropriate sanitary design of equipment/process
- Strengthen GMP's, covers on tanks or conveyor belt
- Establishing an effective preventive maintenance program
- Usage of an appropriate control device to effectively detect and remove extraneous matter (e.g., installation of strainers, screens, filters, magnets, sieves, metal detectors, X-ray or other devices/programs deemed necessary on the line
- Where practical for bulk materials a filter or sieve should be located in the vehicle discharging line (e.g. bulk tanker unloading hose) as close as reasonably practicable to the MDLZ unloading connection point.
- Inspection of packaging integrity e.g. to prevent string, loose stitching / fibres

Periodic reassessments shall be conducted, particularly following changes to the plant environment and instances of non-conformances (e.g., consumer complaints, CCP failures).

The supplier must have a documented program in place to manage any piece of equipment designed to detect and remove extraneous matter (e.g. X-ray, laser, metal detector, magnets, filters and sieves). The program shall include the integrity check of sieves, filters, strength of magnets in a *frequency sufficient to demonstrate control* the validation and calibration of the equipment (calibration should be annually minimum), for extraneous matter detection/ rejection devices (i.e. metal detectors, X-Rays, Optical Sorters) this should include Probability of Detection (PoD) and False Reject Rate (FRR) . It shall also include the monitoring activities (e.g. internal regular verification, control of incoming flow and rejected quantities) the maintenance and sampling plan. A record of what is being found on the protection / detection device shall be recorded during the specified monitoring (e.g. the number of abnormal findings which includes type, weight and/or size on extraneous matter.)

Glass and brittle materials including hard plastic components and equipment should be avoided in product areas where possible. If their use is necessary, a glass and hard plastic inspection program and breakage procedure shall be in place and documented.
MDLZ does have Processing Expectations for extraneous matter removal for specific material groups. These can be found on the Supplier Portal or supplied from MDLZ Supplier Quality.

A template to assist with PoD and FRR can be found on the Supplier Portal or supplied from MDLZ Food Safety.

7.6.1 Use of End-Point Metal Detection Devices

The detection limit for an end-point metal detector will depend on type of product, package, and the detection equipment. Detection equipment settings shall be determined and applied to achieve the most sensitive level possible to provide maximum protection from metal contamination.

Where end-point metal detection is not feasible or practical the metal detector shall be placed before, but as close as is practical to the point where the product enters the package. A documented risk assessment must be performed to show that the risk of metal introduction into the product after the detector is low or controlled by other measures. These measures shall be sufficient to control the metal risk identified (e.g. inline magnets, filters, screens, sieves, conveyor covers or various manual checks at a given frequency) and will be approved during HACCP.

Metal detection units must be capable and validated of detecting and rejecting spherical test piece standards equal to or smaller than 1.5 mm ferrous, 2.0 mm non-ferrous (e.g. brass), and 2.5 mm stainless steel (Recommended 316 grade, minimum same grade as used in production equipment). X-Ray units must to be capable of detecting and rejecting spherical test piece standards equal to or smaller than 2.5mm stainless steel (Recommended 316 grade, minimum same grade as used in production equipment).

Where the minimum test piece standards cannot be detected (e.g. due to the product matrix, metalized foil or size/bulk) alternative control measures such as magnets, filters, screens and/or line modifications to prevent extraneous matter introduction shall be considered and their effectiveness be verified. The detection sensitivity under production conditions must be better than 5.0mm for all metals (products of a matrix similar to that of block cheese may only fall outside of the 5.0mm requirement with an approved MDLZ Food Safety Risk Assessment. Alternative technology should be evaluated to deliver the same or better level of protection).

Where feasible, functional verification shall be carried out during production with the normal product flow. Where this is not practical, the reasons shall be documented. If the detector is a CCP, the frequency of checks during production shall be defined in the HACCP Plan
Functionality verification shall take place at minimum based on the criteria below:

- At the start and end of the manufacturing run and batch should a manufacturing run extend beyond a batch.
- After a shut down for sanitation
- At the restart of production after significant unplanned downtime (downtime exceeding agreed frequency of checks or exceeding 24 hours)
- At start up after product change where the physical form, size or composition of the pack changes
- After repair, maintenance or adjustment to the detection equipment

Functionality verification shall assure 100% detection and rejection of every pass of each of the test pieces used (1 pass of each test piece where a validation has been completed and a False Reject Rate (FRR) <0.1%). Suppliers must determine and document the frequency of the functionality verification (recommended max. every 4 hours) The reject mechanism shall divert 100% of the product rejects from the process flow into an identified bin or container to prevent re-entry into the process or product flow.

A limit for rejections shall be defined over a defined time frame. If this limit is exceeded the rejects shall be investigated to understand cause and source.

If a metal detection system is not working at its design limit (e.g. if it fails to detect a test piece), the material produced since the last successful test shall be placed on hold (see Section 8.4 Hold and Release and risk assessment conducted on it. This may include repassing of product. The risk assessment and action taken on the product must be documented

Fail-safe devices which form part of metal detection/rejection systems should be tested at the start of every shift. Testing should be carried out by passing a test pack down the line while temporarily interrupting the electrical supply to the reject device solenoid (e.g. by using a key switch held by an authorised person) and observing that the reject mechanism does not operate, and that the conveyor belt then stops.

7.6.2 Use of other End-Point Detection Devices

For other extraneous matter hazards, a documented hazard assessment must be performed to show that the potential of extraneous matter introduction into the product is low or measures are in place sufficient to control the hazard identified (e.g. X-ray, inline magnets, filters, screens, sieves, conveyor covers or various manual checks at a given frequency)

For control device to control other extraneous matter hazards than metal operating settings shall achieve the most sensitive detection level possible. In such cases, appropriate test pieces sizes must be defined and documented.

7.7 Net Content and Packaging Material (for ingredients delivered to MDLZ)

7.7.1 Net Content Control

The Supplier shall have implemented a written net content control program that complies with all applicable regulatory requirements. The plan, net contents claims and targets shall be reviewed on an annual basis or in the case of major changes to process, equipment, material or formulation likely to impact net contents results. The program shall include routine scale (off line weighing scale), check weighed and dynamic scale (in-line) verification, periodic calibration, corrective action plans and guidelines for handling non-compliant. Where weights are used for verification these should be calibrated, verification frequency should be defined e.g. every shift. Statistical process controls may be used. Sampling criteria for all packaging lines shall be specified in the control plan. Data must be collected and documented routinely and across the compliance lot of one shift of packing.

7.7.2. Packaging Material

All packaging in food contact with the delivered materials (e.g. big bags, multi-layer paper, etc.) shall be fit for purpose must have food-contact material certificates. Packaging must not alter product organoleptic characteristics and shall not be source of foreign material nor allergens. 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, preferably blue, from the material itself.

Any proposed change in the size or type of packaging must be submitted to the appropriate MDLZ Contracting Representative for approval prior to modification.

7.8 Label Control

The Supplier shall ensure that labels are correctly and consistently applied to materials supplied to MDLZ, and that labels meet applicable regulatory requirements and MDLZ Specifications. In particular, the Supplier shall verify the accuracy of labels for allergen profile, ingredient information (including GMO status), nutritional information, net quantity, specific claims, legal designation (product name), and appropriate registration information/number (if applicable).

Each label should clearly exhibit the material name, the name and address of the manufacturing site, packer and distributor (if applicable), as well as the lot number, net quantity, durability date (shelf life), storage conditions, preparation instructions (if applicable), allergens and the appropriate Kosher and Halal symbols if Kosher or Halal certifications are required. The durability date shall be consistent with the shelf life of the material as stipulated by the MDLZ Specification and regulations (where prescribed). All other voluntary claims such as “suitable for vegetarians”, “GMO free”, “gluten free” and organic claims etc. must be validated and verified before being applied to the label copy.

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. Strict control is necessary in cases where different material varieties have similar labels. The Supplier also shall have implemented procedures to ensure that labels match products.

7.9 Traceability

- The supplier shall have a documented and verified system for the identification and traceability of all materials sent to Mondelēz International. Where internal plant identification systems are used, these must link back to the original lot code in receipt records.
- This system shall allow the site to target trace within 4 hours the entire history of a specific lot from receipt through all stages of storage and shipping. This shall include identification of all materials handled and the customers to whom products were distributed (one step upstream – material received and handled; one step downstream – products distributed to including Mondelez sites and contracted sites). Time in excess of 4 hours may be allowed providing Mondelēz International have sufficient time to trace the full history of products within 24 hours.
- Traceability requirements apply to all finished products and material components including ingredients, in process products, bulk materials, re work, primary packaging materials, secondary packaging components when product ingredient line information printed on , pre packed subcomponents, premiums and part finished products and / or process intermediates being shipped to other locations for further processing
- Periodic recall exercises shall be carried out to verify system capability (minimum annually) and documented, including corrective actions identified.
- All supplied material and documents will bear information that allows effective product traceability. For ingredients that may not have a specific lot number, a method for unique identification and tracking shall be developed and implemented. Bulk use of ingredients shall be required to have a documented timeframe of known use.
- For microbiological sensitive materials steps must be taken to reasonably practicably deliver material to MDLZ containing only one batch/lot number and shall not be a split lot i.e. the batch / lot must not be delivered to more than one MDLZ location. At a minimum each individual pallet shall be made up of only one batch/lot number.
- Where split lot delivery is unavoidable you MUST inform the receiving site.

7.10 Warehousing and Transportation

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

The Supplier shall use designated storage areas or stock rooms to prevent damage to, deterioration of or tampering with material. Storage facilities shall be neat and orderly.

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

Terms in common use for Transport and Storage conditions are (unless specification requires otherwise):

Storage Type / Conditions

- **Ambient Storage**: Prevailing conditions with no control over temperature or humidity required or expected.
- **Dry Storage**: Prevailing conditions controlled to avoid absorption of humidity from air. Temperature range +10°C to +25 °C / 50°F to 77 °F, relative humidity < 65%.
- **Conditioned Storage T**emperature controlled within a defined range of +10°C to +20°C / 50°F to 68 °F. Humidity max 65%
- **Chilled / Refrigerated Storage:** Temperature controlled within a defined range of +1°C to +8°C (34°F to 45 °F). Humidity range not defined. Consistent with US FDA requirements.
- **Refrigerated:** Temperature controlled within a defined range of +1°C to +4°C / 34°F to 40 °F. Humidity range not defined. Procedures in place to assure that products are pre-chilled to required temperature prior to loading, and vehicles are pre-chilled prior to loading for distribution.
- **Frozen Storage:** Temperature controlled within a defined range, typically –18°C to –30°C / 0°F to -22 °F. Humidity range not defined. Procedures in place to assure that products are pre-frozen to required temperature prior to loading and vehicles are pre-frozen prior to loading for distribution.
- **Super Chill:** Temperature controlled within a defined range of -3°C to -0.5°C / 27°F to 31°F. Humidity range not defined. Procedures in place to assure that products are pre-chilled to required temperature prior to loading, and vehicles are pre-chilled prior to loading for distribution.
- **Protected:** Temperature controlled within a defined range of +1°C to +35°C / 34°F to 95°F. Humidity range not defined.
- **Tanker Transfer of Chocolate Masses & Fillings sold as product [e.g. to external manufacturer]:** Temperature controlled within a defined range typically within +40°C to +55°C /104°F to 131°F. Humidity range not defined.

Where local regulations or Material specifications specify conditions for Warehousing, Handling, Storage, Re-packing and Transportation of products these shall also be met. Effective operation of vehicle chiller units shall be verified by temperature measurement.

7.10.1 Warehousing / Storage Requirements

- Good Warehousing Practice must be followed.
- Fork lift trucks (FLT) shall be in good repair, clean, free from leaks. FLT utilized inside a facility shall preferably be electric powered. Liquid Petroleum Gas (LPG)(Propane) is acceptable. Gasoline or diesel-powered FLT only allowed to be used outside facility
- FLT batteries shall be stored in a designated area in such a way as to avoid risk of material or product contamination. New technology batteries, which have a lower risk level, may require less strict segregation.
- Access to storage areas, including products, packaging materials and exterior storage areas (e.g. tanks, silos) shall be restricted to authorized personnel only.
- An effective FIFO (first in first out) or FEFO (first expired, first out) system shall be in place for all materials or products stored for Mondelēz International.
- Products or materials which have a strong odour or display any other quality or food safety risk shall be segregated to avoid cross contamination
- Pallets, racks and equipment shall be maintained in good condition to prevent any physical damage to materials or products (e.g. free from nails, wood splinters etc.).
- Airflow from heaters / refrigeration units shall be directed away from materials and products.
- Food, returned products, waste and non–food items shall be handled and stored in a manner to avoid taint / contamination (e.g. moths in dry pet food), transfer of odours or any quality or food safety risk. Dividers or other precautions, e.g. traffic controls, separate air systems should be used for protection.

- Racking and storage areas (e.g. staging areas, bins) shall be adequately spaced from the walls (minimum 12 inches / 30 cm) to allow for inspection of areas for cleanliness, insect or rodent activity. Additionally, where rodent control devices are placed there shall be an 18 inch / 45 cm gap to allow for inspection. Where this is not possible, alternative means of access shall be demonstrated.
- Direct sunlight on product should be avoided.
- Where specified, monitoring of temperature and humidity shall be carried out using calibrated recording equipment. This recording equipment shall be located in representative locations. Additionally, a reporting system with corrective action plans for out of acceptable range results shall be defined.

- Packaging Storage Practices: Packaging materials in full or partial quantities shall be adequately protected and stored in a sanitary manner. Identification and traceability shall be maintained. All items should be stored to avoid direct contact with the floor (e.g. on pallets, slip sheets, or racks). Sitting or standing on product shipping cases is not acceptable. Over stacking of product shall be avoided.

- Glass and brittle materials including hard plastic components and equipment should be avoided in product areas where possible. If their use is necessary a glass and hard plastic inspection program and breakage procedure shall be in place and documented.

- Pallets shall be stored in areas that are free of moisture, dirt and litter and free of bird, insect or rodent contamination.
    - A pallet inspection program shall be in place to verify that pallets are suitable for use (e.g. clean, dry, free from mold, off-odors and infestation, no broken wood or loose nails).
    - In all cases pallets shall be maintained so they cannot pose any risk to the product
      Product and packaging shall have a pallet slip between the goods and the pallet

Grounds:

i. Collection or storage areas (eg. trash, recycling, idle equipment) shall be clearly identified and kept neat and tidy.
ii. Doors and gates (e.g. cargo doors) shall not be left open when not in use.
iii. Vegetation and grass close to the facility needs to be cut regularly and managed.

- 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.
- 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.

7.10.2 Transportation requirements – Bulk Tankers

- Bulk tankers shall be of stainless steel construction, or other suitable food grade material. They shall bear the following or equivalent statement: "For Food only".
- The supplier shall have a protocol / procedure in place for the approval of hauliers and bulk tanker providers.
- The supplier shall ensure that tanker providers are using cleaning facilities which are fit for purpose and have been approved by the tanker company.
- Tanker company shall conform to EFTCO requirements or other equivalent regional / national associations where they exist.
- Custom numbered seals or equivalent (e.g. electronic seals) must be used for all opening of the container after filling.
- Tankers (including pipes, air ducts and loading / unloading equipment) shall be verified to be in good condition, dry, clean and free of off-odors before loading.
- Truck compressor: compressed air must be dry, oil free and filtered through a M5 mesh size filter. A non-return valve must be installed between compressor and silo container.
- Seals must be applied for all screw connections for air line and air filter which are detachable by hand (permanent seals are acceptable for connections that are not opened regularly)
- Truck must have boxes for hoses, connections, gasket and sealing. Boxes must be locked or sealed.
- All conveyor hose ends must be capped for hygiene and foreign matter control reasons.

Unloading and Loading of products

- During loading and unloading chemical, physical and microbiological contamination mustn’t occur.
- Any pumps and hoses, tools, air system (used to dry the tankers and empty the tanks) used during unloading or loading of product must meet all applicable GMP guidelines. Hoses and connection boxes must be maintained in proper hygienic conditions (clean, free from foreign body and pests..)
- The EFTCO (or equivalent) cleaning certificate shall include all detachable parts.
- It is the responsibility of the supplier to confirm that the tanker has undergone a cleaning procedure and has been inspected before it is loaded. This should be documented in a procedure including how the inspection is done and on which parts of the tanker.
- The supplier shall have a loading matrix which defines when cleaning is required and load on load can be exercised. Microbiological sensitivity, allergen, GMO, taint and compatibility shall be considered.
- EFTCO certification or other regional / national equivalent shall be the basis for the cleaning certificate. In any other cases cleaning certificates shall indicate as a minimum:
    - ID of truck tank
    - Seals number for tankers
    - Last cargo / previous loaded product (Note: will vary if tank truck consists of separate chambers)
    - Name of the station /location where the cleaning was done
    - Name of the operator which did the cleaning and their signature
    - Applied cleaning technique
    - Date and hour of cleaning
    - Numbers of the cleaned compartments

- Visual inspections prior to loading to verify efficacy of cleaning and the validity of the cleaning certificate is required. The result of the inspection shall be documented.
- To prevent extraneous matter and water contamination of the product, any scraping of tankers and containers shall not be done and hatches shall remain closed.

Cleaning and Disinfection Details

- Associated parts which cannot be cleaned in place (e.g. fittings, pipe and hoses, connections, gaskets, lids, dustcovers, etc.) must be dismantled and cleaned off line (manually, in a COP tank or part washer) under hygienic conditions. After the wash/disinfection solution has drained, a final rinse with cold to warm water to remove all remains of the washing-/disinfecting-solution must be done. The last rinse shall be followed by a thorough draining. Chemicals shall be suitable for food industry. If steam is used for product contact surfaces, it must be food grade (culinary) For disinfection the steam must be filtered to prevent foreign matter and/or microbiological contamination according to the raw material risk.
- Air supply used for drying must be oil free and adequately filtered (minimum Filter size: F5)

Verification, Monitoring and Validation of cleaning

- The program must include physical inspection, microbiological tests (if applicable) and cleaning parameter checks that are performed and documented at a specified frequency.
  - Physical inspections must cover:
    - Absence of visual residues in tank and pipes, Absence of strong odors, Absence of humidity / condensate / water, Check of gaskets / connections / pipes / hoses for cleanliness and function
  - The need for microbiological test done by the cleaning company shall be individually defined based on the microbiological susceptibility of the transported material. Microbiological swabbing or ATP-testing for target organisms should be used for cleaning process validation at a defined frequency, minimum annual.

Trucks & Delivery Vehicles

- Trucks and containers shall be verified to be in good condition (e.g. no holes, rust), dry, clean and free of off-odors and pests before loading. Wooden racks are prohibited in trucks used for MDLZ materials deliveries.
- Product quality and integrity shall be preserved during transport.
- Solid top, hard-sided, lockable or reinforced soft-sided vehicles shall be used. In regions where such equipment is not practical or available, the supplier must ensure the integrity of the material is not compromised
- Vehicles should not contain mixed loads of incompatible materials where there is risk of cross-contamination. In all cases the food product shall be protected.
- Temperature controlled vehicles should have a method to record the conditions during transit.
- Procedures for dealing with vehicle or refrigeration systems breakdown shall be in place and include notification to the Mondelēz International receiving plant.
- 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.
  - 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.
  - Avoid storage of product directly in front of cooling equipment where this may impact product quality

All trailers used for the transport of Mondelēz International product will comply with

- The relevant legislation governing the transportation of such products as laid down but not necessarily limited to local legislations.
- All trucks shall be sealed once loaded, seal numbers shall be reflected on the paperwork.
- Product supplied to MDLZ must be protected for food defense purposes and therefore have appropriate seals and/or packaging to show evidence of tampering. If the pack type is unable to have a tamper evident device or the packaging itself does not provide tamper evidence, then the delivery truck itself must be sealed.
- For multi-drop deliveries procedure must be in place to ensure the integrity of the product throughout the delivery duration.
- Clean, Pest and Odor free
- Dry (no condensation on floor, walls or roof);
- In good overall condition;
- Robust floor, to enable safe loading and unloading operations
- Doors/curtains shall maintain an effective seal to the external environment
- Free from any material that may damage products
- Where internal lighting is present in trailers, it shall be protected. No unprotected glass bulbs no broken glass or broken hard plastic protective covers. Curtains should be in good condition (e.g. no holes) and completely closed in such a way to avoid ingress of water etc.

Intermittent unloading: Bulk railcars or trucks that are docked and/or connected to the facility for intermittent unloading for a period over 24 hours shall have adequate controls in place to prevent unauthorized access. Examples of these controls include:

- Sealed connection points
- Doors and hatches re-sealed or locked in between unloading
- Bulk railcars or trucks are contained within an enclosed space with a roof and secure doors (Note: Gates and fences are not considered sufficient to prevent access).

The controls shall be checked daily or upon resumption of unloading after a lapse of more than 24 hours to ensure there has been no unauthorized access.

Where specified, monitoring of temperature and humidity shall be carried out using calibrated recording equipment. This recording equipment shall be located in representative locations. Additionally, a reporting system with corrective action plans for out of acceptable range results shall be defined and documented

7.11 Calibration of Measuring and Monitoring Equipment

The Supplier shall have implemented a written process 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 equipment 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 material testing, shall include the following information:

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

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

- Name of the equipment and a unique identifier.
- Location of the equipment.
- Frequency of the calibration. *Note*: Equipment used to measure a CCP shall be calibrated at frequency sufficient to demonstrate control (at least once per year).
- The method of calibration. Use of the measurement device. Personnel responsible for the activity.

Calibration shall be against known and valid standards which are traceable to international or national measurement standards (whichever is stricter). Where no such standards exist, the method of establishing and maintaining the standard for calibration shall be documented.

Calibration shall be performed by qualified personnel and/or by the instrument supplier as a minimum during yearly service unless another frequency is specified by the manufacturer, or by shipment to a certified company for the device.

Special attention shall be given to critical machine set points which affect the functional and / or analytical properties of the material produced, e.g. critical to quality (CTQs)

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.

In cases where it is not feasible to calibrate the equipment (e.g. flow meter), an assessment of the equipment is required. If the equipment is out of the calibration range for that specific application, the equipment must be replaced by other equipment that meets the calibration requirements for the specific application.

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, a risk 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.

CHAPTER 8 - MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 Internal Audits

The Supplier shall establish and maintain written procedures for conducting internal audits to verify whether the Quality System and food safety programs are adequately implemented. The internal audit program shall ensure that each function /area is audited at a defined frequency.

Results of previous audits shall be taken into account when planning future audits. Trained competent employees must conduct the audits but should only be assigned to audit areas in which they do not work. They shall have strong knowledge on the audit scope and there shall be a process to monitor auditor competency. The audit procedures shall provide for follow-up audit activities to verify and record the implementation of corrective actions taken. 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.

Repeat findings in internal audits shall have thorough root cause analysis conducted due to corrective action not being effective.

Results of audits shall be published within the business to leadership and used to drive food safety culture.

8.2 Testing Controls: Laboratory Requirements

Through procedures in a written program, the Supplier shall ensure that personnel responsible for conducting testing or monitoring have access to all necessary information, such as laboratory methods manuals, raw material specifications, packaging specifications, finished product specifications, test requirements and parameters, and laboratory procedures.

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

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

8.2.1 Laboratory requirements for pathogen testing

Pathogen testing required for materials delivered to MDLZ shall only be performed by laboratories that have been approved by MDLZ Global Food Safety. A list of approved laboratories in each country is available from your MDLZ Contract Representative and can be found on the web site www.mdlzsupplierquality.com.

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

- The laboratory has demonstrated the ability to provide accurate and valid results using officially approved methodologies for environmental testing (e.g., AOAC/BAM, AFNOR, ISO).
- The laboratory design and practices must prevent the potential for cross-contamination of pathogens by restricting access to authorized personnel. At a minimum sign must be posted to indicate that the area is restricted, there should be a footwear and lab coat change moving into and out of the pathogen restricted area.
- In the event of any positive results (pathogen findings) laboratory errors shall be excluded (e.g. by characterizing the isolates to be distinct from the laboratory control strain(s) or other samples handled in parallel).
- The laboratory must participate in and successfully pass an annual proficiency test.
- Relative air pressure of the pathogen laboratory shall be kept negative to the adjacent rooms by appropriate air velocities through openings. A differential pressure control system shall be in place to ensure pressure differentials will not drop below 0.019 mm Hg (2.5 Pa).
- The air in microbiology laboratories shall be filtered by a F8 (MERV 14-15) filter. Laminar flow cabinet is also an acceptable solution if the air cannot be filtered.
- Any potentially infectious material shall be sterilized prior to disposal.

8.3 Rework Control

The Supplier shall have implemented a written program to control the use of rework materials.

This program 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
- 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

Material that has had confirmed pathogen results MUST not be reworked into material for MDLZ. 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 MDLZ to be incorrect.

8.4 Hold and Release & Control of Non-Conforming Product

- A written hold & release control program shall be in place to assure that materials and products which need to be specifically identified/isolated and held, pending determination of their final disposition, will not be inadvertently dispatched. The frequency of inventory check shall be defined.
- Personnel shall be designated with the authority and responsibility for management of Hold and Release Programs, including monitoring and tracking held product through to final disposition.

- The program shall include controls for non-conforming raw materials, materials pending testing (e.g., pathogen testing, sterility testing or Certificate of Analysis verification), packaging, labels, semi-finished product (work-in-progress), finished product, and rework. The Supplier must maintain records sufficient to enable reconciliation 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 site shall assure that product which does not conform to specified requirements is identified and controlled to prevent its unintended use or distribution
- The site should ensure that all holds are classified based on severity. Table 13 in Appendix can be used as a guide.
- A systematic evaluation/audit of the hold and release program will be conducted at least annually at each site to assure the system functions properly. This audit and the follow up and close out of relevant identified corrective actions need to be documented.
- Where product or material placed on holds needs to be moved to external storage or between facilities, procedures shall be in place to maintain the integrity of the hold status.
- Held product inventories shall be reconciled at the time when final disposition is implemented and at any inventory count action taking place.
- A training and awareness session shall be conducted at least annually for all personnel involved with hold and release activities.
- After release of a lot/code of product to MDLZ, the Supplier shall not initiate pathogen testing on either that lot/code of product or any ingredients used in that product. If any material produced for MDLZ is either inadvertently released from hold or is suspected of non-conformance but has already been shipped to MDLZ, the MDLZ Contracting Representative shall be immediately notified (see Section 5.1 Notifying MDLZ of Significant Events).
- If the product has tested positive for pathogens, the product MUST not be supplied to MDLZ. regardless of any further test results.
- Where product is sent for destruction, destruction certificates shall be retained or any other proof of destruction.
- If a supplier needs to retrieve product which has been despatched, there shall be a procedure in place to manage the retrieval and account for the product.

8.5 Corrective and Preventive Action (C&PA)

- All programs mandated by this *SQE Manual* require that Corrective and/or Preventive Actions be taken in the event of non-conformances. The Supplier shall have an effective C&PA program tracking such actions to ensure that non-conformances in any program are addressed in an appropriate and timely manner. After closure of C&PA relevant for MDLZ supplier shall inform MDLZ and provide objective evidence that actions have been closed out (from audit or another source). If it is identified through technical visit / supplier food safety assessment / SQE audit that previous non-conformances have not been actioned, this may affect the site's approved status. Therefore, suppliers shall review non-conformances and corrective action status prior to any such site assessment.

An effective C&PA program 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, equipment) shall 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.
- There shall be a process to verify C&PA effectiveness which is documented.

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

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

A formalized process shall be in place to identify root cause and implement appropriate C&PA for supplier quality notifications raised by MDLZ against your site (for Priority 1 and Priority 2 categories as a minimum, out of specification MMP results, incidents that have led to MDLZ early warnings or special situations – for definitions see table 12). These may include techniques such as:

- 5 whys
- Cause & Effect / Ishikawa / Fishbone

CHAPTER 9 – PACKAGING REQUIREMENTS

9.1 Introduction

The *Mondelēz International Supplier Quality Expectations (SQE)* outlines the general requirements for ingredient and packaging suppliers. The chapters which are NOT relevant for packaging suppliers are indicated on the Table of Contents(Page 2)

At a minimum, all packaging materials supplied to MDLZ 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 packaging materials* shall be accompanied by a *Declaration of Compliance* (DoC) covering materials and conversion (e.g. inks, adhesives, coatings) prior to the first material delivery and the DoC shall be validated by RDQ packaging. The declaration or assessment shall demonstrate compliance of food packaging grade quality based on (i) overall migration limit, 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 (as disclosed by Mondelēz to supplier). It shall encompass all potentially migrating substances, both intentionally added ingredients and non-intentionally added substances present e.g. due to reactions, impurities. This statement shall be renewed when any change in regulation, composition or production occurs that bring about changes in migration or when new scientific data becomes available or after 5 years which ever sooner.

Where no dedicated national food packaging legislation exists, MDLZ requires compliance with the European or the U.S. federal (Food and Drug Administration (21 CFR), U.S. Department of Agriculture (USDA), U.S. Environmental Protection Agency (EPA) and state regulations.

9.1.1 Packaging Manufacturing

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

Packaging suppliers of materials shall ensure that print runs items are not mixed on a pallet. The risk of mixing during the process of guillotining, punching, die cutting, packing and palletizing must be assessed and controlled. Procedure and compliance should be in place for a line change-over protocol or line clearance that ensures there is no product mix. This may include equipment clearance and inspection, start-up sign-off, bar-code readers and scanners.

9.1.2 Printed Material Management: Destruction or Recycling of MDLZ Labeled Packaging Material

The Supplier must ensure that any discarded or *recycled materials* (including any scrap or waste) containing a1ny MDLZ name, trademark or logo, or any other MDLZ identifying information, cannot be reused.

The supplier shall have a documented process for destruction and recycling of materials. When done by a third-party company, responsibilities and methods for assuring the destruction of the packaging material shall be specified in contracts including the verification of destruction.

9.1.3 Label Control & Print Copy Verification

In addition to requirements stipulated in section 7.8, items specific to packaging suppliers are listed in this section. The supplier shall have controls in place to assure that labels are correctly and consistently applied to packaging materials supplied to MDLZ.

- Label controls shall assure that labels applied to packaging materials supplied to MDLZ meet all regulatory requirements and specifications of MDLZ.
- Any MDLZ labeled finished packaging material that is to be discarded for trash must be disfigured or destroyed (crushed, shredded, etc.) so that the container labels, or caps could never be reused in any manner.
- Destruction of defective or obsolete MDLZ labels or MDLZ labeled packaging materials, cartons, and caps by disposal in a trash compactor is viewed as acceptable means of disposal/disfigurement. Materials must be physically de-faced/disfigured if disposal is in bulk trash bins.
- Scrap or waste packaging material (e.g., paper, corrugated, plastic) that is to be recycled by an external recycling site which contains intact materials with MDLZ labeling must be physically defaced or disfigured so that the material could never be reused in any manner.
- Suppliers producing actual labels or labeled packaging materials for MDLZ must have adequate controls in place to prevent inadvertent mixing of labels or labeled materials prior to delivery to MDLZ. This includes a detailed risk analysis of the production processes and procedures and must be addressed in the plant's HACCP plans.

9.1.4 Print copy verification of materials

Suppliers producing actual labels or printed packaging materials for MDLZ shall have an adequate program in place to ensure print copy verification is undertaken for each print run or batch of materials produced. Print copy verification shall ensure the accuracy of the run, including verification of actual print quality, legibility of print and be compared to specifications or master templates. Records of verification of print runs shall be maintained.

9.2 Transfer of constituents from 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 MDLZ Food Contact Packaging. Under their normal or foreseeable conditions of use, materials shall not transfer their constituents (intentionally added substances (IAS) and non-intentionally added substances (NIAS)) to foodstuffs in quantities that could endanger human health, cause an unacceptable change in the composition of the foodstuffs (color), or result in deterioration of the organoleptic (tainting, odor) 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. MDLZ via its specifications set additional requirements for chemicals of specific concern.

9.2.1 Constituents from plastic materials

Plastic material and articles shall be tested by suppliers under conditions for intended, food type, time and temperature during filling, processing, storage and preparation. If there are no applicable regulations in that case, follow EU10/2011 or 21 CFR guideline.

9.2.2 Constituents from paper and board materials

Paper and board for direct food contact shall be of suitable microbiological quality and shall not release any antimicrobial agents into food. In the absence of applicable regulations, materials shall be compliant with *FDA's regulations in 21 CFR Part 176* or the German BfR *Recommendation XXXVI* (BfR reports to the Federal Ministry of Food and Agriculture - BMEL)

Films made of regenerated cellulose fibers must be of food grade quality and should comply with European *regulation 2007/42/EC* or *U.S. 21 CFR Part 177.1200*.

9.2.3 Metal in contact with packaging

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

9.2.4 Recycled post-consumer material

MDLZ favours the use of *recycled materials* provided that strict requirements are established to ensure food safety. MDLZ typically does not permit post-consumer recycled materials used for primary packages to come in direct contact with food, unless an authorized process has been used. If compliance with food contact material regulations can be declared and accompanied by a DoC, MDLZ will make an exception for glass, metal, and specific product applications when agreed and included in MDLZ Packaging Specifications.

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) MDLZ 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 identified as being recycled in the MDLZ Packaging Specifications.
Recycled materials are allowed for packaging applications which have a functional barrier as primary packaging around the food.
Functional barriers are defined as one or more layers of food contact materials which ensure that compounds of concern do not migrate into the food above regulatory and safety limits during the shelf-life of the product

9.2.5 Odour and taste transfer testing:

Food contact materials shall not change the organoleptic properties of the packed food. Food contact packaging materials supplied to MDLZ must comply with Odour and taste transfer testing.

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

- EN 1230 –1 Odour assessment test
- EN 1230–2 Taint transfer test ("Robinson test")

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

Other materials

An odour assessment shall be performed per batch for printed films for direct and indirect contact. For other materials the testing of the organoleptic characteristics can be based on risk assessment (Guideline EN 10955 or ISO 13302 can be used)

 Acceptance criteria

These tests are based on a rating scale from 0 = no off-flavor or odour to 4 = strong off-flavor or odour. 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 odour assessment test a slight off-odour is perceived (median odour score < 2.5 with above mentioned methods).

That sensory tests must be conducted systematically by trained panellists in a suitable environment. Other methods can be used if agreed to by MDLZ and provided that the comparability is documented & reports should be made available for MDLZ when required.

9.2.6 Residual solvents

The total residual solvents in printed and converted materials shall be kept as low as possible. Aromatic compounds (e.g., toluene, xylene) shall not be part of the formulation added to packaging materials during the production, printing or cleaning processes. The amount of residual solvent shall not exceed 20 mg/m^2 material **or lower if local regulations are more stringent.,** thereof ketones and esters maximum 7 mg/m^2 material **or lower if local regulations are more stringent.** (e.g. ethyl acetate)

9.2.7 Printing inks for non-food contact side

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.

Mondelēz requires compliance with the “EuPIA guideline on printing inks applied to the non-food contact surface of food packaging materials and articles” (www.eupia.org) and Swiss Ordinance SR 817.023.21

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.

9.2.8 Printing in direct contact with food

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

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).

9.2.9 Packaging Material Ingredients and Processing Aids derived from Allergenic and Genetically Modified Sources

Materials derived from allergenic and genetically modified sources shall not be used (exception oils derived from allergenic sources which have been refined, bleached and deodorized are allowed).

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

9.2.10 Active and intelligent packaging

MDLZ 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*.

9.3 Environmental Impact of Packing

All materials supplied to MDLZ 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.

9.4. Other requirements

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

The supplier shall certify that packaging materials supplied to MG or used for any MG labeled products do not contain more than a combined total of 100 ppm 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. The materials must be free from substances that are carcinogenic, mutagenic or reprotoxic (CMR substances) and substances classified as toxic. All materials delivered to Mondelēz shall not contain substances with H statements H300, H301, H310, H311, H330, H331, H340, H350, H360, H370, H372.

Where applicable, MDLZ requires compliance with *REACH Regulation (EC) No 1907/2006* concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) for all packaging items that are preparations or articles containing substances to which the REACH obligations relate. The use of SVHC substances shall be avoided.

9.5 Reference List of Regulations and Methods

Table 11 provides a list of packaging regulations, Codes of Practices, and Standards. The list is a reference and is not all-inclusive.

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.

APPENDIX

Table 1. Packaging Material Audit Matrix

Material Supplied Classification	**Tier Rating**	**Supplier Qualification (New)**	**Supplier Qualification (Ongoing)**	**Audit Frequency**
Food Contact with*/without an ingredient declaration	4	GFSI	GFSI	3 Years
Non-Food Contact with an ingredient declaration*	4	GFSI or ISO 9001	GFSI or ISO 9001	3 Years
Non–Food Contact without a declaration	5	None Required	NA	None

Whenever there is an ingredient line declaration, specific controls are needed:

1 – print copy verification / 2- label mixing controls.

Note: Any exception to above table will be assess and approved by CQ auditor to have additional control.

Table 2 Air Filtration Requirements

Area/room examples	MERV filter grade (US)	Filter Grade (EU)
Natural cheese starter room, natural and process cheese chill roll room	17	H 11
Ready to Drink - Liquid Beverages, cold fill	15 or 16	F9
RTE Natural Cheese RTE Meat & Poultry slice and pack RTE Fish & Seafood products RTE Dessert products (excluding powders) RTE – Egg products Juice press/process room Microbiology laboratory	14	F8
Chocolate & Compound products Dairy products processing (post pasteurization) and filling rooms (excluding powders). Nuts, peanuts and seeds (after kill step) Liquid Egg products Prepared Sauces Spreads and Condiments Ready to Drink – Liquid Beverages, hot fill	9-10 9-10 13 13 9-10 9-10	M5 M5 F7 F7 M5 M5
Dairy – Dry products bagging and filling rooms. E.g powders Sensitive dry ingredients	11 or 12	F6
Herbs and seasonings	9 or 10	M5
Equipment wash areas Analytical laboratory	9 or 10	F5 M5
Non-sensitive dry ingredients Vinegar production area	6	G4

Table 3 ISO8573-1:2010 Compressed Air Purity Classes

Class	Solid Particulate				Water		Oil
	Maximum number of particles / m3			Mass Concentr, mg/m3	Vapor Pressure Dewpoint °C	Liquid g/m3	Total Oil (aerosol liquid and vapor) mg/m3
	0.1 - 0.5 µ	**0.5 - 1 µ**	**1 - 5 µ**				
0	As specified by the equipment user or supplier and more stringent than Class 1						
1	≤ 20 000	≤ 400	≤ 10	-	≤ -70	-	0.01
2	≤ 400 000	≤ 6 000	≤ 100	-	≤ -40	-	0.1
3	-	≤ 90 000	≤ 1 000	-	≤ -20	-	1
4	-	-	≤ 10 000	-	≤ +3	-	5
5	-	-	≤ 100 000	-	≤ +7	-	-
6	-	-	-	≤ 5	≤ +10	-	-
7	-	-	-	5 - 10	-	≤ 0.5	-
8	-	-	-	-	-	0.5 - 5	-
9	-	-	-	-	-	5 - 10	-
X	-	-	-	> 10	-	> 10	> 10

Table 4 Sensitive Raw Material Categories requiring Environmental Air monitoring

Cheese & Dairy products/substitutes	Cultures, Enzymes, Yeast and Starter Media	Peanut butter and tree nuts paste products
Ready to Drink – Liquid Beverages (excluding aseptic)	Ready-to-Eat Fish & Seafood products	Ready-to-Eat Meat & Poultry products
Ready-to-Eat Vegetable products	Ready-to-Eat Dessert products (excluding powder)	Prepared Sauces, Spreads, Condiments
Ready-to-Eat Eggs products	Ready-to-Eat Fruits products	-

Table 5 Suggested Action Standards for Environmental Air and Compressed Air:

Environmental air				Compressed air
Product category	Organism	Air Exposure Plates	Air Sampler	< 0.04 cfu / ft³ or < 0.001 cfu / litre
Dry sensitive raw materials (e.g., dairy powders, cocoa, nuts)	Yeast & Mould	< 100 cfu / 15 minutes	< 1,000 cfu / m³	
Post heat treatment or pasteurization; products with Aw 0.65 - 0.95 (processing, filling and packaging)	Yeast & Mould	< 10 cfu / 15 minutes	< 500 cfu / m³	
Post heat treatment or pasteurization: products with Aw > 0.95 (processing, filling and packaging), hot filled	Yeast & Mould	< 10 cfu / 15 minutes	< 500 cfu / m³	
Post heat treatment or pasteurization: products with Aw > 0.95 (processing, filling and packaging), cold filled	Yeast & Mould	< 5 cfu / 15 minutes	< 100 cfu / m³	
Ready-to-Eat Vegetable products	Yeast & Mould	< 100 cfu / 15 minutes	< 1,000 cfu / m³	

Note: 1 m3 = 1,000 liters

Table 6 Guidelines for Actions Standards for Clean Equipment Swabs

Sample	TVC/ APC		ATP		Coliforms / Enterobacteriaceae	
	Acceptable	Not acceptable	Acceptable	Not Acceptable	Acceptable	Not Acceptable
Clean equipment swabs	<1000 cfu/100cm^2	>1000 cfu/100cm^2	Site to specify	Site to specify	≤10 cfu/100cm^2	>10 cfu/100cm^2

Rinse water samples	≤500 cfu/ml (same limit as for direct product contact water)	>500 cfu/ml	Site to specify	Site to specify	<1 cfu/100ml (same limit as for direct product contact water)	>1 cfu/100ml

Table 7 Examples of the zoning areas on different products/processes.

Product	High risk Area	Controlled Area	High control Area
Milk Processing/dairy plant	Raw milk receiving	Processing area after pasteurization and dry filling areas	Cold filled area
Peanut and tree nut products; cocoa products	Raw nut/cocoa receiving and handling	Processing and filling after kill step	n/a
IQF or dried Vegetables/ Dried Fruits	Raw vegetable/fruit receiving area	Processing/Packaging after microbial reduction step (e.g.:final rinse, validated blanching, etc)	n/a
Spices	Spice receiving area	Processing and filling after kill step	n/a
Ready-to-eat Meat & Poultry; Ready-to-Eat Fish & seafood	Raw receiving and handling	Processing and filling after kill step	n/a
Cereal products	Raw flour receiving, milling and packaging	Processing/Packaging after baking	n/a

Table 8 PEM Reference Sampling Plans

"Minimum test frequency" refers to the specific production area, not the frequency of sampling of each individual site specified in the plant PEM program.

Product Category	Definitions	EXAMPLES	Refrigerated products / Frozen	Non Refrigerated	Plan Number	Zone	*Salmonella* spp.	*Listeria* spp.	Frequency
Meals Product Type A1 (Processed meat)	**Products in which *Listeria monocytogenes* may survive and/or grow; typically in wet and cold environments**	**Processed meat**	**Yes**	**NA**	**A1**	**Zone 1**	**NA**	**Yes**	**Weekly**
						Zone 2	**NA**	**Yes**	**Weekly**
						Zone 3	**NA**	**Yes**	**Weekly**
						Zone 4	**NA**	**Yes**	**Monthly**
Meals Product Type A2 (Cheese, other wet dairy products, Hummus, cookie dough)	**Product in which *Listeria monocytogenes* & *Salmonella* may survive and/ or grow.**	**Cheese[3], Hummus, cookie dough**	**Yes**	**Yes**	**A2**	**Zone 1**	**NA**	**Yes [1]**	**Weekly**
						Zone 2	**Yes**	**Yes**	**Weekly**
						Zone 3	**Yes**	**Yes**	**Weekly**
						Zone 4	**Yes**	**Yes**	**Monthly**
Biscuit , Chocolate, Nuts, Dried Dairy products, Dried fruit and vegetables, Dry mixes	**Products in which *Salmonella* may survive typically in a dry environment such as low moisture food manufacturing sites .**	**Biscuits & Chocolate**	**NA**	**Yes**	**B**	**Zone 1**	**NA**	**NA**	**Weekly**
						Zone 2	**Yes**	**NA**	**Weekly**
						Zone 3	**Yes**	**Yes [2]**	**Weekly**
						Zone 4	**Yes**	**Yes [2]**	**Monthly**
Gum and candy	**To monitor hygienic conditions of Controlled Hygienic Areas.**	**Candy**	**NA**	**Yes**	**I**	**Zone 1**	**NA**	**NA**	**Monthly**
						Zone 2	**Yes**	**Yes [2]**	**Monthly**
						Zone 3	**Yes**	**Yes [2]**	**Monthly**
						Zone 4	**Yes**	**Yes [2]**	**Quarterly**

[1] Zone 1 testing exemption for the products in which Listeria monocytogenes does not grow. Scientific evidence must be documented

[2] Listeria spp. testing is applicable for the products manufacturing plants in the United States of America (USA) and plants manufacturing finished ,semi-finished products for inclusion in products for export to the USA. Testing should be implemented only in wet areas of the plant (controlled zone/Area)"

[3] For cheese, enterobacteriaceae or coliforms can be used as an alternative to *Salmonella*.

Table 9 PEM Guidance for Quantitative Indicator Organisms

Zone	Coliform / Enterobacteriaceae		E. coli
	cfu/100cm²		cfu/100cm²
1	<10		<10
2	10-20		<10
3	<100		<10

Table 10 Public and government websites to assist with Food Defense program development

Customs-Trade Partnership Against Terrorism (C-TPAT)	• http://www.customs.ustreas.gov/xp/cgov/import/commercial_enforcement/ctpat/criteria_importers/ctpat _importer_criteria.xml • C-TPAT Cargo Security http://www.cbp.gov/xp/cgov/trade/cargo_security/ctpat/
Food and 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 Stated Department of Agriculture (USDA) and 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/

Table 11 List of Packaging regulations, Codes of Practices and Standards

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. §§ 174.5 to 174.6 - Indirect Food Additives: General	• EC-Regulation No 1935/2004 • Commission Regulation 2023/2006 – GMP on materials and articles intended to come into contact with food. • Migration test conditions according to Plastics Implementing Measure (PIM) EU 10/2011 Plastic Materials and Articles Intended to Come into Contact with Foodstuffs
Organoleptically properties of packaging material	Mondelēz International requirement only; no specific regulation ASTM methods: E460 Practice for Determining Effect of Packaging on Food and Beverage Products During Storage E619 Practice for Evaluating Foreign Odors in Paper Packaging E1870-04 Standard Test Method for Odor and Taste Transfer from Polymeric Packaging Film	• EC-Regulation No 1935/2004 Methods for paper & board: • EN 1230 –1 Odor evaluation • EN 1230 –2 Taint transfer test (“Robinson test”) • ISO13302 Methods to assess modifications to the flavour of foodstuffs due to packaging
Plastics, Laminates	21 C.F.R. §§ 177.1010 to 177.2910 - Indirect Food Additives: Polymers 21 C.F.R. §§ 178.1005 to 178.3950 – Indirect food additives: adjuvants, productions aids and sanitizers	• Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with foodstuffs •
Regenerated Cellulose	21 C.F.R. § 177.1200 - Cellophane.	• Regenerated Cellulose Film Directive 2007/42/EC
Ceramics		• Directive 84/500/EEC , 2005/31/EC
Paper, Paperboards	21 C.F.R. §§ 176.110 to 176.350 - Indirect Food Additives: Paper and Paperboard components	• Council of Europe Policy statement concerning paper and board materials and articles intended to come into contact with foodstuffs (incl. Resolution AP (2002) 1); • Recommendation XXXVI Paper and Boards of the German Federal Institute for Risk evaluation (BfR) - www.bfr.bund.de
Elastomers and rubbers	see plastics	• Nitrosamine Directive 93/11/EC; • Resolution AP (2004) 4 on rubber products intended to come in contact with food • Cold Seals BfR XXI on natural and synthetic rubbers
Silicones		• https://www.edqm.eu/sites/default/files/policy_statement_concerning_silicones_used_for_food_contact_applications_v1_june_2004.pdf • Council of Europe Policy statement concerning silicones used for food contact application (inl. Resolutions AP (99) 3 and AP (2004) 5) • German BRF XV on silicones
Surface coatings (raisins, lacquers, adhésives)	21 C.F.R. §§ 175.105 to 175.390 - Indirect Food Additives: Adhesives and components of Coatings	• Epoxy Derivatives Directives 1895/2005/EC • Council of Europe Policy statement concerning coatings intended to come into contact with foodstuffs (incl. Resolution AP (2004) 1) • BfR XXVII on lamination adhesives • Risk assessment based on Regulation (EU) No. 10/2011,.
Printing inks	FDA approval	• Regulation (EC) No 2023/2006 – GMP on materials and articles intended to come into contact with food. • Swiss Ordinance on Materials and Articles in Contact with Food, 817.023.21, Section 8b, Packaging Inks, Art. 26e – 26i1 • EuPIA guideline on printing inks applied to the non-food contact surface of food packaging materials and articles “low migration inks” • Council of Europe Policy statement concerning Packaging inks applied to the non-food contact surface of food packaging (incl. Resolution ResAP (2005) 2)
Recycled plastics		• Commission Regulation 282/2008 on recycled plastic materials and articles intended to come into contact with food
Active and intelligent packaging		• Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food
Glass		• Council of Europe Policy statement concerning lead leaching from glass tableware into food stuff
Packaging Safety		• GFSI recognized schemes: M- Production of Food Packaging ▪ BRC/IoP Global Standard for Packaging ▪ SQF ▪ FSSC 22000 ▪ IFS PACSECURE • ISO/TS 22002-4 Prerequisite programs on food safety – Part 4: Food packaging manufacturing • EN 15593 Management of hygiene in the production of packaging for foodstuffs - requirements
Packaging as Waste	CONEG	• Packaging & Packaging Waste Directive 94/62/EC • Methods: EN 13427 – EN13432; CR 13688; CR 13695

Table 12 – Quality Notifications (QNs)

Note: in the case of big impact on MDLZ finished product or MDLZ production lines, a daily update on progress of investigation from the supplier may be required in order to minimize the risk of business disruption

Priority level	Definition	Acknowledgement from supplier	Preliminary Investigation result (potential cause + size of the issue) + immediate correction	RCA + CAPA (plan agreed with MDLZ)
1	An issue that poses a potential product safety issue (Microbiological, chemical or physical contaminants, allergens), regulatory impact, or a high impact quality concern	1-2 business days	Max 4 days (business days) From initial communication – QN may follow	Target 10 business days, max 30 days unless otherwise agreed with MDLZ
2	Material non-conformity to specification or requirements with impact on process and product (functional/ organoleptic parameters, packaging integrity, etc) without food safety risk. No resolution to chronic/repeat issues.	3 business days	[redacted]	20 business days – RCA and CAPA
3	Non-conformity to specification or requirements with no impact on food-safety, process or product (quality of palletization, missing non-critical parameter in certificate, delivery conditions). Minor documentation errors.	3 business days	[redacted]	30 business days – RCA and CAPA

Table 13 – Category Holds Examples

TABLE 13	Category 1 Hold	Category 2 Hold	Category 3 Hold [Also called Controlled Hold]
Use for:	When a non-conformity poses a confirmed product safety issue, or major quality concern –for example: • Undeclared Allergens identified in product or material • Failure to meet CCP/sPP requirements as defined in individual CCP/sPP models • Contamination due to employee illness • Unacceptable pathogen test result • Presence of an undeclared ingredient	When a non-conformity, or any suspected non-conformity, poses a potential food safety issue or regulatory non-conformance, or a minor product or material quality defect– for example: • A non-conformance which causes the ingredients on the ingredient list to be in the wrong order. • Net Contents compliance lot average is below the stated label weight claim. • Non-conforming product pending corrective action completion, re-testing and, or final disposition decision. (for example, wrong product on pallet, open product, soft packs) • Deviation from a CCP/sPP requirement pending investigation or further actions • Finished product awaiting results of testing that is not required for a COA • In cases where pathogen testing on every lot of finished product is not specified: a) Rework pending pathogen testing results. b) Finished product made using materials or rework with pending pathogen test results. c) Finished product awaiting the results of verification pathogen testing (e.g. quarterly testing) • Finished product awaiting pathogen testing results where testing has been initiated by a government or regulatory agency, e.g. FDA Returned Material	When other reasons exist for needing to hold product or material, unrelated to food safety or regulatory issues. For example: o Finished product awaiting test results which are a required for a COA. (Excludes Pathogen testing – see Table 2) o Product produced as a result of a trial
Notify Mondelēz	Required	Required for regulatory non-conformances only	Not Required
Disposition	Designated person to manage disposition in collaboration with Mondelēz International. Quality Representative	Designated person will maintain communication with the appropriate facility manager and manage disposition activity.	Designated person will conduct the necessary communication to assure adequate control and manage disposition activity.
Identification & Segregation	Each of the following requirements shall be met: • Each shipping unit of product or material shall be visually identified with hold stickers, tags or tape. • Product or Material shall be placed in a segregated and secured area	All affected product or material shall be visually identified as being on hold within its storage location. (e.g. segregation of an entire bay using 'ON HOLD' tape/placard, or specified area within a high-rise facility designated only for product on hold). Where product or material need to be moved to external storage or between facilities, each shipping unit shall be visually identified as being on hold. Product or Material should be placed in a segregated area.	All affected product or material must be visually identified, or computer controlled, or both. The method adopted must provide effective control.
	For all Hold Categories: • „Inadvertent movement or use shall be prevented. • „Where computerized stock control systems are in use, product shall be electronically obstructed from movement/use and only designated, authorized employees shall have the ability to modify the status or location. Where it is feasible, physically obstruction of the goods shall also be used for additional control. In addition, there shall be a defined, documented and effective system in place and agreed with Mondelēz International to prevent inadvertent movement or use.		

	„Where no computerized stock control system is in place, or it is not possible to assign responsibilities only to specific authorized employees to modify the status or location of the product, product/materials shall be physically obstructed.		
Inventory Checks	Inventory checks for Category 1 & 2 holds shall account for physical quantities present and be reconciled against all hold records (including electronic warehouse records, hold forms, and electronic hold files)		A defined frequency, documented in local procedures, which is adequate to assure control.
	Verification daily on facility operating days.	Inventory verification minimum monthly, or at close-out of hold event if sooner.	

Table 14 – Sensitive Ingredients

Biologically Sensitive Ingredient Category	Category includes (but not limited to):	Exclusions for VP (only those listed):	Exclusions for SP
Milk/Dairy Products	Proteínas, e.g. caseinates; dulce de leche (liquid caramel)	Lactose; ultraclean filled Sweetened condensed milk	
Starter Media		Starter Cultures	Starter Cultures
Yeast/Yeast Extracts			
Enzymes/Rennets		Microbial origin	Microbial origin
Meat/ Fish/ Poultry/ Seafood			
Eggs/Egg Products			
Soy products	Soy flour, all types	Soy lecithin, Soy Sauce (liquid and dehydrated)	
Fruits/Fruit Products		Candied fruit, fruit in alcohol, jams/jellies	
Spices/Herbs	Flavours/enhancers made from spices/herbs	Extracts (e.g. alcohol/solvent based), e.g. oleoresins	Extracts (e.g. alcohol/solvent based), e.g. oleoresins
Tea	Instant teas	grain tea	
Coconut			
Vegetables/Vegetable Products	Mushrooms, Hydrolysed vegetable proteins (HVP), liquorice root	Brined vegetables (high acid / high salt), liquorice extracts	Liquorice extracts
Seeds/Seed Products	Sesame seed paste (tahini)		
Grains/Grain Products	Grinded grains, including all flour, powdered malt extract, pasta, gluten, native wheat starch	Other (modified) starch; heat extruded, e.g. corn flakes, rice crisps	
Cocoa Products	Pure pressed cocoa butter		
Natural Gums/Thickeners	Gelatine	Microbial origin (e.g. Xanthan gum), pectin, agar, micro reticulated cellulose	Microbial origin (e.g. Xanthan gum), pectin, agar, micro reticulated cellulose
Green Coffee beans			
Nuts/Nut Products	Nut pastes, marzipan		
Flavors See also “Note” at the end of the Chapter	With sensitive carrier (e.g. gum Arabic) or other components that are regarded as sensitive	Containing (w/w) (applicable to flavor and its sensitive ingredients) >10% ethanol, >30% propylenglycol, >80% Triacetin,, >2% benzyl alcohol, or essential oils as main carrier, or flavoring substances*	Containing (w/w) (applicable to flavor and its sensitive ingredients) >10% ethanol, >30% propylenglycol, >80% Triacetin,, >2% benzyl alcohol, or essential oils as main carrier, or flavoring substances*
Talc and calcium carbonate (lime)		Except if GFS approved the thermal process	Except if GFS approved the thermal process
* “flavoring substances” as defined by European Flavoring Directive 1334/2008/EEC			

Table 15 – CCP Models

CCP Model	Process Step and Product Description
CCP 26 High Moisture Material Holding Time / Temperature	This model applies to high water activity (a_w>0.85) products with a pH range of > 4.5 and < 9.6 and hold temperature > 8°C and < 50°C that permit the growth of *Staphylococcus aureus* and therefore, potential toxin formation.
CCP 52 Product Cook – Fat Based Products	Product Cook (Continuous or Batch) – fat containing products (e.g. Cream Cheese, Dips including dairy and non dairy, Sauces, RTE Puddings including high acid).
CCP 58 Product Cook – Non-fat Based Products	Thermal process step for high water activity (a_w>0.93) non fat containing products, e.g. BBQ, Catsup, Ketchup, Mustard, Tea Extracts, gelatin solutions
CCP 68 Product Bake	Product Bake (Continuous or Batch – e.g. cakes, breads, soft baked items, brownies, moon cakes or where quality specifications (moisture, color or water activity) cannot be used to verify the pathogen reduction step of baking

Table 16 – Food Allergens – MDLZ Global List

Category of Food Allergen	Positive List of Ingredients or Foods includes (but not limited to):	Examples of foods that often contain this material	Exemptions to the Category of Food Allergen
Crustaceans	e.g., Shrimp, crab, lobster, crawfish (crayfish) Each species within this category, must be regarded as a separate allergen	Glucosamine Hydrochloride containing foods	
Egg	e.g. Hen's and other avian species Ovalbumin, whole egg, egg yolk, egg white, lysozyme, hydrolyzed egg protein	Mayonnaise, meringue	
Fish	e.g., Cod, Haddock, Flounder, Trout Each species within this category, must be regarded as a separate allergen	Mixed seafood, fish sauce, Worcestershire sauce	Gelatin from fish used as a carrier for vitamin or carotenoid preparations. Gelatin from fish used as a fining agent in wine, beer and cider
Lupine/ Lupin	Lupine flour, lupine beans	Flour & baking mixes	
Milk	e.g., Cow's, sheep's, goat's Butter, buttermilk, casein, cheese, cottage cheese, curds, whey, lacto globulin, lactose*, malted milk, cream, sodium caseinate, sour cream, yoghurt, hydrolyzed milk protein *Only if it contains protein	Margarines, milk chocolate, ice cream, custard, nougat pudding	Lactose and lactitol which contains no protein (specification must indicate process for protein removal) Alcoholic distillates derived (including ethyl alcohol) from whey
Mollusk / Mollusc	e.g., Clams, oysters, mussels Each species within this category, must be regarded as a separate allergen	Mixed seafood, oyster sauce	
Peanut	Peanut butter, nut pieces, peanut flour, peanut protein, hydrolyzed peanut protein	Mixed nuts	
Seeds: Sesame seeds	Sesame paste, Tahini paste	Hummus, tahini, biscuits, dressings and sauces	
Soybean /Soya bean / Soy	Soya derived vegetable protein or textured vegetable protein, miso, tofu	Soya sauce	Soy lecithin; tocopherol extracts (antioxidant used in flavors) purified by vacuum distillation or purified by other means if they are not a source of allergenic proteins. Acid hydrolyzed soy proteins greater than 62% Amino Nitrogen/Total Nitrogen (85% minimum degree of hydrolysis) Phytosterol or phytosterol esters derived from soy
Tree nuts: Almond Prunus dulcis (Rosaceae) Brazil Nut Bertholletia excelsa (Lecythidaceae) Cashew Anacardium occidentale (Anacardiaceae) Hazelnut (Filbert) Corylus spp. (Betulaceae) Macadamia nut/Bush nut Macadamia spp. (Proteaceae) Pine nut/Pinon nut Pinus spp. (Pineaceae) Pistachio Pistacia vera L. (Anacardiaceae) Pecan Carya illinoensis (Juglandaceae) Walnut Juglans spp. (Juglandaceae)	Only those tree nuts identified. Each tree nut type within this category must be regarded as a separate allergen	Mixed nuts Some chocolates	Alcoholic distillates including ethyl alcohol of agricultural origin derived from treenuts

Category of Food Allergen	Positive List of Ingredients or Foods includes (but not limited to):	Examples of foods that often contain this material	Exemptions to the Category of Food Allergen
Wheat	Wheat derived bran, wheat extracts, dextrin, meal, farina, graham flour, malt, flour, germ, gluten, starch including enzymatically/acid treated or chemically modified starches, semolina, hydrolyzed wheat protein, Spelt, Khorasan wheat, Kamut	Breadcrumbs, crackers, bread, pasta	Wheat derived glucose, glucose syrup, dextrose, dextrose monohydrate, maltodextrin (all DEs), sugar alcohols, and caramelized glucose. Alcoholic distillates including ethyl alcohol of agricultural origin derived from wheat Vinegars (including spirit vinegar) derived from wheat

APPENDIX 1 - DEFINITIONS

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

Allergen Category List: MDLZ list of recognized food allergens, available from MDLZ Food Safety.

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

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 Mondelēz Global.

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.

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.

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.

Declaration of Compliance: A written statement describing the migration potential of the packaging material. Where content is not legally defined, it shall contain at minimum the following elements such as identification of the business operator and the material manufacturer, applied legislation, information about all potential migrants and their restrictions and conditions suitable to use the material safely. Disposition: Determining and authorizing what shall be done with product, ingredient or packaging which has been placed on hold. Examples would include:

- Accept – may be sold through normal channels
- May be further processed by Rework, repair or reclaim to meet specifications
    - May be accepted, with or without further processing, for alternative applications (Re-graded, for example to liquidation or distressed sales)

Reject or scrap. Destruction of products and packaging shall be carried out in a secure manner to prevent recovery or re-use.

Dry cleaning: Any equipment that is not wet cleaned for its regular cleaning but may be wet cleaned on an infrequent basis. Only a limited amount of water is used and drying after this wet cleaning is crucial. Usually with this "controlled" wet cleaning the surrounding production area (e.g. walls, ceilings) stay dry. This includes parts of equipment that are removed and taken to another room for wet washing. Typically dry cleaning is applied in plants producing confections/chocolate, dry mixes (flour, starches, coffee) or dry milk products etc.: sweeping, scrapping, brushing, wiping with proper tools (scraper, brush, broom cloths), vacuum cleaning.

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

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

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

Food Fraud: fraudulent activity in food products such as some forms of adulteration, counterfeiting, diversion and relabeling for purpose of economic gain.

Frequency to Demonstrate Control: The frequency to demonstrate control is a frequency which would not likely result in an excursion out of the prescribed limits between the two events.

GMO: Genetically modified organism.

GKIT: The Global (Kraft) Ingredient Tool, or GKIT form, is a form populated by raw material suppliers with composition, allergen, analytical, nutrition, storage conditions, and other data required by MDLZ. MDLZ reviews and validates the supplier data provided in the GKIT and uses that data to create an internal specification (RMAT spec) for the raw material.

Government Regulations: The laws and regulations of the location in which products are stored and the laws and regulations of the destination to which products may be shipped.

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

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

Hold: A status assigned to specified product indicating it shall all remain stopped from normal handling processes until further notice. Synonyms include: quarantined, blocked, segregated, contained, embargoed, etc.

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 spp.

ISO/TS22002-1 (PAS 220): Specifies requirements for establishing, implementing and maintaining prerequisite programs to assist in controlling food safety hazards.

Mondelēz Global (MDLZ) Contracting Representative: The MDLZ Contracting Representative shall be the primary contact for any contact or notification required by this document. The Mondelēz Global Contracting Representative will vary depending on the region and the product category.

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 shall not exceed the amount of material produced in one 24-hour period. For non-continuous processes, the batch, blend, shift, or other time segment may be used to identify a lot. For materials received in bulk, the lot is usually identified as the contents of the bulk vehicle.

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

Microbiologically Sensitive Materials (also "Sensitive Ingredient"): An ingredient deemed to be susceptible to contain pathogens or support the growth of pathogens. Sensitivity of an ingredient is based on origin, the manner in which it is processed, and/or on epidemiological and historical data. Sensitive ingredients are described as such in the micro section of the MDLZ specification (SAR).

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: Non-fulfilment of a need or expectation that is stated, generally implied, or obligatory

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

PAS 96: Publicly Available Specification 96 available at http://shop.bsigroup.com/en/Browse-by-Sector/Food--Drink/PAS-962010/. Provides guidance on approaches to the protection of food business, of all sizes and at all points in the food supply chain, from all forms of malicious attack including ideologically motivated attack and the procedures to mitigate and minimize the impact of such an attack.

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.

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

Purchased Materials: equipment, services or materials purchased for use in the Mondelez International operations.

Quality Program: A logical sequence of documented actions designed to assure specific product quality specifications are met.
Quality Records: Documents detailing the history of a lot of finished product, distribution steps, control charts, inspection results, amount stored, formal releases and disposition.

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

Quarantine: e.g. time for regular microbiological testing of finished product. During that time the goods shall be on hold and under Mondelēz International control (at Mondelēz International own or contacted facility).

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 Action: A seizure, embargo, hold of any product or a prosecution, injunction, citation, regulatory letter or notice of adverse findings from a regulatory authority or any federal, state, provincial or local court. Regulatory Agency: State or 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, USDA, FSIS, and in Canada CFIA.

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 (i.e. Kosher or Halal).

Regulatory Contact: A visit, inspection, audit, survey, inquiry or other contact by any regulatory authority that results in the identification of objectionable conditions which require a response. This does not include those visits made on a regular basis (i.e. daily, weekly, monthly), unless such a visit reveals a material or product destined for a Mondelez International facility is not in compliance with applicable laws or regulations.

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 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. Product in a form which is consumable without additional preparation to achieve food safety (e.g. RTE cheese, RTE raw vegetables).

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.

SAR: Supplier Agreement Report (SAR) is generated from the approved RMAT specification and sent to the supplier for formal agreement.

Special Situation: A Special Situation includes any product, facility issue or set of circumstances that has the likely potential, to expose:

- Consumers, employees or other individuals or entities or the environment to injury, loss, harm or damage, or
- The company, its employees, products, tangible or intangible assets to serious legal or regulatory liability, severe adverse publicity, sustainable negative public opinion or damage to the reputation of the company, or Mondelez International Business Operations to severe disruption.

Tankers: closed bulk haulage

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

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

Transport incident: Theft, partial theft, damages, clandestine intrusions or any other issues which occurred during the transportation of goods

Wet cleaning: Any equipment that is wet cleaned without restrictions in terms of the amount of water or a cleaning solution for its regular cleaning. Not only direct product contact surfaces must be considered, but also surfaces with indirect contact (e.g. splash areas). Typical wet cleaning: CIP (ACS), COP, foam/gel cleaning, high/low pressure cleaning.

REVISION LOG – Main changes

1	INTRODUCTION	MG changed to MDLZ throughout the document.
1.1	For Brokers, Distributors and Traders	Section reworded to break out more clearly the requirements. Responsible for ensuring warehousing being used is fit for purpose and follows GWP.
2.1	General Audit Requirements	Any discrepancy between MDLZ SQE audit and GFSI audit supplier could be invited to discuss with CPO
3.4	Audit Requirements for packaging material suppliers	Added additional guidelines to be in line with GFSI requirements.
5.1	Notifying Mondelēz Global of significant events	Food Fraud added as a requirement, some other wording amendments.
5.3	Food Safety & Quality Culture	New section detailing the need for a program to improve site food safety and quality culture.
6.1	GMP	Risk assessment can be completed to adjust GMP requirements depending on product risk.
6.3	Employee Illness and Communicable Disease	Pathogen and disease list updated.
6.5	Equipment Maintenance Controls	Specified maintenance plan should be based on equipment criticality to food safety. Maintenance hand-back procedure should be in place.
6.7	Sanitation Programs	Operating requirements listed for CIP in 6.7.2. Line idle time requirements have been added and requirements for COP.
6.8	Pest Management	The program must be effective
6.9	Hygienic Zoning	A zoning assessment shall be completed AND documented
6.12	Food Fraud	New section added on food fraud requirements.
7.1	Specification Compliance and Contract Review	Section 7.1 has been reworded. Timescale added for completion of SAR. Packaging added to the scope of MMP in 7.1.3.
7.2	Incoming Materials: Supply Quality Management	New requirements about validation of the process used to eliminate pathogenic organisms when this step is not performed on the supplier's facility.
7.4	HACCP	Food Safety Plan referenced in this section, validation section has been reworded with more specific detail.
7.5	Allergen Management	Carry-over levels should be established. Change-overs shall be clearly documented with procedures, visual standards, line acceptance, validation and verification of cleaning.
7.6	Extraneous Matter	More detail on false reject rates and probability of detection. Requirement to record abnormal findings on detection device. Rejection limits to be set and double pass of test piece not mandatory.
7.9	Traceability	Detail on split lots i.e. split lots not to be delivered to more than one MDLZ location unless unavoidable
7.10	Warehousing and Transportation	New sub section on bulk tanker management and cleaning requirements.
8.1	Internal Audit	Output of internal audits shall be brought to the attention on site leadership.
8.3	Rework	Rework control requirements have been split out.
8.4	Hold and Release & Control of Non-Conforming Product	Whole section has been restructured and combined with Control of Non-conforming product. The hold categories are for guide and not mandatory. The Product Retrieval section has been removed and incorporated into this section.
8.5	Corrective and Preventive Actions	Requirements laid out for supplier quality notifications, definitions are referenced Table 12. Root cause analysis added as a requirement
9,1	Introduction of Packaging requirements	This statement shall be renewed when any change in regulation, composition or production occurs that bring about changes in migration or when new scientific data becomes available or after 5 years which ever sooner.
9.1.1	Packaging Manufacturing	Added Line Clearance Expectation to Avoid Mix-up and Added expectation about bar-code readers and scanners
9.1.3	Label Control & Print Copy Verification	New section added for suppliers to control label processes
9.2.3	Metal in contact with packaging	New section Added
9.2.4	Recycled post-consumer material	Functional Barrier point edited for recycled material
9.2.5	Odour and taste transfer testing	Testing method & acceptance criteria updated
9.4.	Others requirement	All other packaging requirement updated here e.g. Heavy metal, REACH etc. either they were at different places in previous version .
	APPENDIX TABLES Table 1 Table 8 Table 11 Table 12	 Packaging Material Audit Matrix updated PEM Reference Sampling Plans updated List of Packaging regulations, Codes of Practices and Standards updated with current standard QN CAPA timelines expectation guideline updated