

Subject: **Supplier Quality Expectations**

Issue Date: April 12, 2013

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# **Supplier Quality Expectations**

## **Mondelēz Global LLC**

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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 Global LLC (abbreviation MG) 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 Global 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 Global LLC Supplier Quality Expectations* (this document) which supersedes the previous version of the *SQE Manual* and the *Resource Supplement* (published on May 10, 2010)
- *Mondelēz Global LLC Supplier and External Manufacturer HACCP Manual* - our requirements for Hazard Analysis and Critical Control Points (HACCP)/Food Safety programs
- Processing Expectations for Cocoa Beans, Dairy, Egg, Juice, Nuts and Seeds, Vinegar and Irradiated Raw Materials

These documents are available at the Mondelēz Global LLC Supplier Quality and Foods Safety web site at [www.mdlzsupplierquality.com](http://www.mdlzsupplierquality.com) or from your *Mondelēz Global 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 Global and industry standards. These expectations have been developed by Mondelēz Global after a review of product defects, quality audits of manufacturing sites and a study of product retrievals throughout the food industry. This review led us to identify which programs, if executed properly, help to prevent product retrievals, consumer complaints, rework and plant downtime, and produce high quality, safe products.

Each manufacturing location producing materials for Mondelēz Global 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 Global LLC SQE Manual*, *Mondelēz Global LLC Supplier and External Manufacturer HACCP Manual*, and Process Guidelines (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 Mondelēz Global Contracting Representative or by sending your questions to [SupplierQualityMondelēz@mdlz.com](mailto:SupplierQualityMondelēz@mdlz.com).

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

To differentiate between the finished product produced by the Supplier and Mondelēz Global finished product, the Mondelēz Global finished product will be called “**finished product**.” All other terms, such as “**material**,” “**ingredient**” and “**product**,” refer to the Supplier’s product.

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### 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:

- Only buy from MG approved manufacturing locations. The supplier manufacturing locations shall be disclosed to the MG Contracting Representative to assure that materials are only sourced from locations meeting MG requirements for quality and food safety.
- Notify the supplier that the specific material will be delivered to MG.
- Ensure that the *Mondelēz Global LLC SQE Manual*, *Mondelēz Global LLC Supplier and External Manufacturer HACCP Manual* and MG Specification are communicated to supplier and provide evidence to MG of agreement to the requirements by the supplier.
- The broker/distributor/trader has responsibility to ensure that supplier complies with those requirements
- The broker/distributor/trader shall be required to notify MG of any manufacturing location changes. New sites and new lines must be approved by MG prior to use.
- The broker/distributor/trader must demonstrate that traceability of materials to manufacturing location level is maintained.

## CHAPTER 2 - CONFIDENTIALITY

The contracts between MG 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 MG unless there is a contract in place protecting such disclosure. MG personnel shall not be asked or required to sign confidentiality agreements as a prerequisite to gaining access for audits prior to or at any time during a quality audit or other required technical visits/assessments.

## CHAPTER 3 – MG AUDIT REQUIREMENTS

### 3.1 General audit requirements

All facilities producing ingredients for MG must be approved by MG. The same applies to new suppliers of food contact package materials and package materials with ingredients line printed.

The frequency and type of approval audit required by MG is dependent on the type of material supplied and may include the following:

- Third Party auditing supplier on behalf of MG (3<sup>rd</sup> Party SQE), or
- MG employee SQE audit, or
- Recognized industry standard (GFSI certification).

The audit /inspection requirements are prioritized based upon the experience with the supplier and the type of material produced at that location. Table 1 shows the Mondelēz Global Audit Matrix. For the most updated version of this Matrix, please go to [www.mdlzsupplierquality.com](http://www.mdlzsupplierquality.com). Separate audits are required for each manufacturing site producing material for MG.

The MG audit/inspection shall extend to all areas, including all pertinent production and storage areas deemed necessary to evaluate whether the material produced for MG 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 MG SQE requirements will not audit or inspect financial data, sales data (other than that directly related to MG), 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.

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To become and remain an approved Supplier, the audit findings must be acceptable to MG. 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 MG. The Supplier must implement all corrective actions identified in the MG audit within the time frame agreed on in the audit corrective action plan.

MG 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 MG or third-party SQE report with other customers, a written authorization from MG is needed.

### 3.2 Global Food Safety Initiative (GFSI) Certification

Industry accepted certifications are now part of MG supplier Audit Matrix approval requirements (please see Table 1). MG's aim is to have all its raw material suppliers GFSI certified as defined in supplier Audit Matrix. Suppliers will receive further communication from MG about GFSI certification requirements. A current list of GFSI accepted certifications for ingredients can be obtained at [www.mygfsi.com](http://www.mygfsi.com). The certification scheme and scope shall be appropriate, e.g. must include all manufacturing areas relevant for ingredients supplied to MG.

The supplier shall share with MG 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 MG representative in the event that the certificate is surrendered or withdrawn by the certification body.

### 3.3 Supplier Food Safety Assessments (SFSA)

To support the move to more reliance of certification audits, MG operates a program of Supplier Food Safety Assessments for existing suppliers. These are on-site periodic Food Safety Assessments performed by MG personnel to evaluate key food safety programs including HACCP, validation of microbiological control points (please refer to HACCP Section 7.4.1), Utilities Management (Section 6.4), Sanitation Programs (Section 6.7), Hygienic Zoning (Section 6.9), Pathogen Environmental Monitoring (Section 6.10), and Supply Chain Quality Management (Section 7.2). Unacceptable audit findings can lead to disapproval and discontinuation of sourcing.

### 3.4 Audit requirements for packaging material suppliers

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

### 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 MG Chemical Audit which is an audit focused on selected SQE requirements according to the nature of the material.

A 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 or pharmaceutical grade, 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 in Appendix B of the Mondelēz Global LLC Supplier and External Manufacturer HACCP Manual*).
- There is no allergen risk.

The suppliers must provide a process description and MSDA/specification for the chemical in question.

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A pharmaceutical audit may be applicable if the material has active pharmacological properties used at low levels in pharma licensed products. An audit can be accepted from licensed Pharmaceutical auditors and GMP certificates issued by FDA or EU 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 Global LLC Supplier Quality Expectations Manual*, *Mondelēz Global LLC Supplier and External Manufacturer HACCP Manual*, MG 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. For ingredients delivered to MG that were produced or will be sold in the United States and Canada, records shall be retained for at least six years. For other countries, the minimum retention time shall be ten years.

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 MG Contracting Representative of any ingredient which is produced or processed in a plant not entirely owned or operated by the Supplier. Any outsourced process that affects material or ingredients produced for MG shall comply with the same requirements and be managed by the Supplier.
- Manufacturing changes: The supplier must notify MG 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 MG– such as changes in material formula, raw materials, production line, production facility or processes – and any change shall be approved by MG before being implemented. MG must be notified of such changes in writing. MG will assess whether a new approval is needed.
- Special certifications: If MG 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 MG 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 MG requirements. The MG requirements are available from your Contracting Representative. MG 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 Mondelēz Global materials.
- Ionization: Suppliers of irradiated raw materials and products must comply with the MG written expectation for these products (*Mondelēz Global LLC Quality Expectation for Suppliers of Irradiated Raw Materials*).



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## CHAPTER 5 – MANAGEMENT RESPONSIBILITY

### 5.1 Notifying MG of Significant Events

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

The Supplier shall notify MG 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 Mondelēz Global 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 MG. MG does not need to be notified of routine inspections, unless the inspection reveals that material produced for MG may not be in compliance with applicable law.
- Inadvertent release from Hold of any material produced for MG.
- Event that leads the Supplier to suspect that a non-conformance exists in product already shipped to MG.
- Product tampering or threat of tampering.
- Event or substance that could threaten product security. Notification by law enforcement or other authority of a potential product security event.
- Identification of an unlabeled allergen in material produced for MG.
- Changes to supplier's processes and/or facilities that could have an impact on materials supplied to Mondelēz Global.
- Inability to deliver materials that meet MG Specifications
- Event of a pathogen positive result in a product direct contact surface (from Environmental sample or Sanitation verification). Please refer to Sections 6.7.1 and 6.10.3.
- Event of a pathogen positive result in a Supplier product (even if the specific lot is not sent to MG).

The Supplier must notify MG by a phone call with a live person and by email. Voicemail, even coupled with an email, is not adequate. The MG Contracting Representative shall be the primary contact for any contact or notification required by this document. However, if the representative is not available in cases of emergency, contact MG Security at +1.973.503.2900.

### 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 MG (e.g. sampling for pathogen or GMO testing).

In the event a regulatory agency samples material produced for MG, 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 MG. The Supplier shall contact the MG Contracting Representative for instructions.

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## 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. 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. Additional requirements are described on chapters 13.1, 13.3, 13.4, 13.7 and 13.8 from ISO/TS22002-1. Further specific requirements include the following:

#### 6.1.1 Personnel practices

- Holding toothpicks, matchsticks or other objects in the mouth is 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).
- Shoes: To help avoid product contamination shoes worn in GMP areas shall be designed and constructed as follows: fully enclosed; low heeled; sole grooves depth must not be a source of contamination. Shoes in wet microbiologically sensitive areas shall not trap or absorb water when walking through footbaths at room entrances.
- 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.
- Hand lotions must not be used if hands are in direct contact with product or product-contact surfaces.
- 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.

#### 6.1.4 Hair

- Hair must be maintained as follows in GMP areas:
  - Hair curlers, hair combs, and bobby pins are not allowed.
  - Barrettes (at least 5 cm or 2 inches long), clasps, scarves or bandannas shall be worn neatly under the hair net.



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- 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.
  - 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.
- 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 risk assessment shall be conducted (as part of the HACCP) at each manufacturing location to determine the likelihood of an outbreak. If the risk 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.

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- A process by which the Supplier can evaluate the potential impact to product should an active employee be diagnosed with communicable disease.
- Procedures to ensure that employees afflicted with a communicable disease are removed from the manufacturing facility or are reassigned to a non-food contact area. In determining suitable work areas for affected employees, the Supplier shall consider the risk of cross infection to other employees.
- Policies regarding employee return to work after illness.

No person shall be admitted into a GMP area if he or she carries, or has been exposed to, any potential source of a microbial or viral contamination.

### 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

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

#### OCCASIONALLY TRANSMITTED

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

## 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 and steam.

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 risk assessment, but minimum annually. Examination shall be included in preventive maintenance plans.
- 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 zones shall not be sourced from an unprocessed product area (raw).
- Air filtration requirements vary according to the classification of the product, production process, and the microbiological risk. Table 2 shows the different types of filters. Table 3 provides guidance on air filtration requirements for different areas/ingredient/products. It should also be noted that air filtration requirements apply to storage tanks which cannot be located inside the facility.
- Air quality shall be monitored, trended and reviewed by appropriate personnel, as necessary to ensure suitable microbiological quality. The suppliers program must include monitoring in production areas with exposed microbiologically sensitive raw material as identified in Table 4.

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- The program shall describe the sampling locations, action limit, methods, corrective actions and responsible personnel. Table 5 provides guidance for Environmental and Compressed Air on acceptable limits.

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.

#### 6.4.2 Compressed air

- Compressed air for general applications shall 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 odor filters must be installed prior to use where possible, air pressure gauges must be installed and monitored, and oil and filter changes must be captured in the 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 0.3 $\mu$  at the point of use and dried to prevent condensation within the pipelines. Alternatively, a risk assessment shall be conducted to determine product susceptibility and potential contamination sources, and suitable safeguards shall be implemented.
- When used as an ingredient or in contact with non-sensitive products or their packaging, or in contact with material or product contact surfaces prior to the kill step, compressed air shall be filtered 1.0 $\mu$  (ISO 8573-1:2010 class 2.4.1) as close as physically feasible to the application.
- Distribution piping shall be of approved material (ABS plastic, Zinc plated Steel, Stainless Steel, or Aluminum).
- Preventive 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, action limit, methods, corrective actions and responsible personnel.
- Microbiological tests shall be performed periodically (weekly or monthly), based on product/process sensitivity. All water used as an ingredient or to clean in a product processed without a lethal step and all water applied to product or package post lethal step shall be analyzed weekly. The sampling plan shall cover all water circuits, and branches from main circuits. Microbiological tests also shall be performed after maintenance or repair. Incoming water from municipal source shall be analyzed quarterly. Certification from the municipal source is accepted.
- Water (including municipal water) used as an ingredient, processing aid (including ice), reclaim water, hand wash water, water for brine solutions, re-circulated cooling water, and water as sanitation final rinse shall be tested for TVC and coliforms. Recommended limits: 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).

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- 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 a risk assessment to determine if disinfection is required. The risk assessment shall include, but not limited to, historical data of microbiological compliance, history of water borne outbreaks, and local regulation.
- 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. Corrective actions shall be taken when levels do not meet the required limits.
- The extraneous matter risk in incoming water needs to be controlled using filters e.g. 200 mesh /75 micron 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.
- The extraneous matter risk of incoming municipal water shall be subject of a HACCP assessment based on historical data.
- For surface or well water sources, a visual turbidity assessment shall be carried out daily. Testing shall also be carried out following any event 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.

#### 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).

### 6.5 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 according to the requirements from ISO/TS22002-1 chapter 8.6 Preventive and Corrective Maintenance.

### 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

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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.
- 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 does 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, odor or mold.
- Facility design shall include correct and effective placement of all utilities required for sanitation.

Additional requirements for Personnel facilities shall be implemented according to ISO/TS22002-1 chapter 13.2.

#### 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, like tank and vessel linings, agitators, baffles, and other hollow product contact equipment structures must be totally sealed and un-penetrated.



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- 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. Like or 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.
- 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.
- 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.
- 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.
- Use of food grade cleaning, sanitizing, and disinfecting products.
- Calibration of sanitation-related measurement devices (e.g., thermometers, gauges and meters).

Proper tools and materials must be used to prevent extraneous matter, microbiological and/or chemical contamination of the product. Items that are known to be potential sources of contamination must be prohibited. Brushes and utensils for cleaning food contact surfaces shall be clearly identified (e.g., labeled and/or color coded) and stored separately from non-food contact tools. Floor drain cleaning brushes and equipment shall be clearly identified as such and maintained separately from other cleaning equipment. Equipment shall not be brought outside the building 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 bar shall not be used during operation.

Gaskets must be handled and stored in a sanitary manner:

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



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#### 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 rinsates 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 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.

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.

### 6.8 Pest Management

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

- Pest management plans, methods, schedules
- Inspection procedures and frequencies.
- Required documentation of pest activity log and analysis of records for trends in activity.
- Corrective actions for increased trends /activity.
- Training requirements.

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- A map showing the location of pest control devices, such as indoor rodent traps, glue boards, insect light traps, outdoor bait stations, and pheromone traps.
- Records of application of pesticides.

Exclusion shall be the first line of defense and primary method of controlling pests. Efforts must be made to keep pests out of the building by using good exterior controls. If pesticides are used, the Supplier shall ensure that they are used in accordance with local regulations.

The Supplier shall ensure that appropriate measures are taken to prevent pesticides from contaminating food products. Residual insecticides shall not be applied as a fog or an aerosol. Pesticide use and application shall be strictly controlled and in accordance with the label.

Chemicals used for pest control must be accurately labeled, inventoried and, when not in use, securely stored (by locked door/gate) with access granted to authorized and designated personnel only. Pest control activities shall be performed by certified pest control contractors or personnel with equivalent training.

Non-chemical methods, such as traps or glue-boards are preferred to control rodents inside manufacturing facilities and warehouses. Rodenticides should be avoided.

When using pesticides, the following practices shall be followed:

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

Insect Light Traps (ILT) shall be utilized as surveillance devices to monitor flying insect activity. They are not considered a control method. Light bulbs from the insect light traps must be kept clean and be replaced regularly (minimum annually) to ensure maximum efficiency. The insect light traps shall be installed in the receiving or warehouse areas close to entrances, but shall be located so as not to attract insects into the building. Trap contents must be evaluated monthly.

## 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.

Note: This requirement does NOT apply to the following Suppliers: Raw earthen materials (e.g. unprocessed materials mined from the earth); 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.

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#### 6.9.1 Hygienic Zoning assessment

The Supplier shall carry out a risk assessment to identify potential sources of cross-contamination between processing areas and/or products (e.g. product handling areas, storage areas, processing areas, raw materials) and document them 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 microbiological risk may be introduced, to design the plant map indicating the different zones, and for deciding which controls to put in place in transition 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 sensitive product contact?
- Are sticky mats/footbaths/foot washing stations/door foamers in place and maintained where applicable?
- Are maintenance tools and operator utensils/tools cleaned/sanitized after usage or dedicated to one area?
- Are common pipe connections for receiving or unloading of different liquid ingredients avoided?

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

##### Non-manufacturing zone:

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

##### Raw /limited process zone:

- Areas, such as raw meat/raw milk/raw nuts receiving and storage, that are known to be contaminated and which require controls to prevent contamination of higher hygiene zones.

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- These zones often require the use of dedicated employees and may be physically separated from controlled zone or high control zone.

#### Controlled zone:

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

#### High control zone:

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

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

### 6.9.2 Identification and implementation of controls to address risks and prevent cross contamination

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

### 6.9.3 Evaluation and verification of the Hygienic Zoning program.

The supplier shall periodically evaluate the effectiveness and compliance of zoning requirements. This may include, but is not limited to, environmental testing including pathogen testing, GMP audits, and routine pre-operational and operational inspections.

## 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 program depends on the product and process risk 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; Raw earthen materials (e.g. unprocessed materials mined from the earth); Sugar; Oils and Fats (except Dairy, and Cocoa); Food Additives; Raw Meat and Raw Meat Products; Food Chemicals. Material specific advice on PEM can be requested from your MG Contracting Representative or by sending an email to [SupplierQualityMondelēz@mdlz.com](mailto:SupplierQualityMondelēz@mdlz.com).

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The PEM requirement focuses on two specific pathogens, *Salmonella sp.* and *Listeria monocytogenes*, as well as indicator organisms which predict their presence in the processing environment. The 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.
- Swab 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 swabs (e.g. shift, midweek, end of week). Routine sampling must take place during production, at least 3-4 hours after start-up.
- 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 at least every 2 years or whenever a change occurs to the process or product (e.g. new equipment installation, modification or introduction of a new material). The PEM review shall be documented.

#### 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.

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, catwalks, scrap carts, HVAC vents, vacuum cleaners if used near product contact surfaces, air filters, 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, debris from vacuum collection points, floor debris, trash cans, 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.



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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.
- Walls and 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. Each zone shall be sampled every month.
- Once data on individual locations are available, compositing / pooling of samples may be considered. Samples within the same zone may be composited with up to five sample points in one composite. Swabs taken from floor contact areas (e.g., floor, steps, and wheels) may be composited only with other floor contact areas within the same zone. Drains samples shall not be composited.
- 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. 2<sup>nd</sup> or 3<sup>rd</sup> 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. Minimum mandatory test frequency is monthly (recommended weekly according to Table 8). 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.

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 result (e.g. *Salmonella* or *Listeria monocytogenes*) the MG Contracting Representative must be immediately notified, even if the specific lot is not sent to Mondelēz Global. 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.

Table 9 specifies the acceptable limits results for indicator organisms. Results above the guidance criteria or the plant limits shall be investigated and corrective actions implemented.

#### 6.10.4 Corrective action plans

In the event of a pathogen-positive result the Supplier shall conduct an investigation to identify the potential source and document all corrective actions. If multiple sites were composited (pooled), then re-sample after a positive to potentially 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. This must be completed within a 3-week time frame. 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. Likewise, Suppliers will ensure their suppliers adopt similar protocols and implement appropriate controls. At MG we call these efforts Food Defense.

The laws and government expectations regarding Food Defense vary from country to country. In order to achieve



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a common standard that is industry recognized worldwide and simple to manage and maintain, MG 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](http://www.mygfsi.com). Suppliers will receive further communication from MG about GFSI certification requirements.

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 Global that they have met all these requirements.

- Adopt and maintain a facility Food Defense program (outlined above).
- FDA facility registration list. Complete and maintain registration in the Mondelēz International FDA facility registration list.
- 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 (See Chapter 8 Measurement, Analysis and Improvement).
- Meet C-TPAT Import Security Criteria if making shipments to the U.S. which originate elsewhere.

Suppliers may contact their MG Contracting Representative to obtain further details or documentation of our Food Defense program, site assessment tools, and training materials. Suppliers are also encouraged to use the numerous public and government websites to assist with their Food Defense program development (examples on Table 10).

## CHAPTER 7 - PRODUCTION PROCESS CONTROLS

### 7.1 Specification Compliance and Contract Review

The Supplier shall ensure that MG Specifications are implemented at the production location and that appropriate plant personnel have access to the latest specifications for materials supplied to MG.

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

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

Supplier must fill in a complete GKIT (Global Ingredient Tool) form for each new ingredient. Complete GKITs forms must be sent to MG before first shipment to MG (including plant trial). Signed SARs must be sent to MG before commercialization.

Suppliers of ingredients and primary packaging materials that will be used in the manufacture or sale of products in the United States must submit a Continuing Pure Food Guarantee Letter to Mondelēz Global. A Pure Food Guarantee Letter is a common regulatory document that food industry suppliers use to assure customers that their products comply with the Federal Food, Drug, and Cosmetic Act and related requirements. Continuing Pure Food Guarantee Letter must be on file with MG prior to receiving the first shipment from the supplier.

#### 7.1.1 Certificate of Analysis (COA)

Where Certificates of Analysis (COA) are required, these must be provided to MG prior to acceptance of the material at MG locations. Certificate of Analysis shall be written in local language of the receiving MG plant. A COA shall contain as a minimum:

- Supplier name, address, phone number, and contact person.
- Address of the manufacturing plant where the material was produced.
- Material name, lot code, production date and MG identification number.
- Specification number (or purchase agreement) and issue date.
- Test and analysis results for each lot, including MG Specification target and range.
- Parameter being tested, test method, sample size, and date of test.

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- Signature of authorized agent of the supplier and date of signature.
- Statement that the results are actual lot analysis results or composite results commonly used in commodity industries.

#### 7.1.2 Certificate of Analysis for pathogens

In cases where the MG Specifications require pathogen analyses at the material that will be delivered to Mondelēz Global 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 MG (see Section 8.2 Testing Controls: Laboratory Requirements). The COA from the approved laboratory must be provided to MG and shall include the laboratory name, address and pathogen test results. MG 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 Mondelēz Global shall be immediately notified, even if the specific lot is not sent to MG.

#### 7.1.3 Testing for possible chemical contaminants

Mondelēz Global requires that some specific incoming raw materials be part of the Material Monitoring Program (MMP). This is a due diligence program designed to check for potential contaminants across the supply chain by verifying that materials meet MG Specifications and comply with all applicable regulatory requirements and industry standards for the designated country of the MG receiving location. This testing is in addition to tests that are required for MG Specification compliance.

MG will select the materials to be included in the program based on their MG risk profile. The Suppliers selected to submit materials for testing will receive further communication from MG 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 MG approved laboratory for analytical chemical testing. Test results will be released to Suppliers and MG, simultaneously.

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 MG locations or to contracted manufacturing facilities producing MG branded product until the results of the testing confirm that samples meet our Specifications and comply with all applicable regulation.

#### 7.1.4 Corporate Responsibility

Mondelēz Global contract provides the core commercial terms and also incorporates our corporate responsibility expectations such as legally enforceable provisions on child labor and worker safety among other expectations.

To assess the Supplier's Corporate Responsibility, MG partners with other companies in an initiative called PROGRESS. This industry initiative allows a supplier to provide common information to its customers so each customer can independently reach business decisions in accordance with its own corporate responsibility standards. For more information about the broader industry initiative on PROGRESS, visit [www.aim-progress.com](http://www.aim-progress.com).

Under this Program, Suppliers must submit the information and assessments requested to the SEDEX database ([www.sedexglobal.com](http://www.sedexglobal.com)). The Suppliers selected to register in PROGRESS will receive further communication from MG detailing the actions that must be taken.

### 7.2 Incoming Materials: Supply Chain Quality Management

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 MG Specifications, and provide them to their suppliers. Additional requirements are described on chapters 9.1 and 9.2 from ISO/TS22002-1.

The Supplier shall have a process to assure that materials classified as Tier 1 and Tier 2 (according to the MG Audit Matrix) which do not undergo a kill step at the Supplier's own manufacturing site, are adequately reviewed as part of the HACCP implementation. The performance objective of all processes/technologies used to eliminate

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target pathogenic organisms shall be defined and validated at the manufacturing facility of that specific raw material. Please refer to Section 7.4.1.

### 7.3 Incoming Materials: Inspection and Testing

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

The Supplier shall ensure that incoming materials are not used or processed until they have been inspected or otherwise verified as conforming to specified requirements. Where pathogen testing is conducted, a Hold and Release procedure shall be applied until testing is complete (see Section 8.4 Hold & Release).

Raw agricultural materials and ingredients from animal origin must be evaluated to ensure compliance with chemical contaminants (e.g. pesticides residues, mycotoxins) and applicable GMO regulations of the MG receiving country in compliance with MG Specifications.

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 (see Section 7.10 Warehousing and Transportation). Verification activities shall be documented and may include inspection of internal cleanliness, structural integrity, inspection of seal integrity (including that the seal numbers match the transportation documentation), and measurement of internal temperature for refrigerated or frozen items.

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.

### 7.4 Hazard Analysis and Critical Control Points (HACCP)

The Supplier shall have implemented a written HACCP plan for all materials produced for MG. The Supplier's products shall be designed, produced, and distributed using HACCP principles to minimize food safety risks systematically.

The Supplier shall establish a cross-functional HACCP team that is responsible for developing, reviewing, and modifying the plans and maintaining the system. The HACCP team shall ensure that each HACCP plan and its implementation is properly verified and validated on a regular, documented basis.

The Supplier shall consult the *Mondelēz Global LLC Supplier and External Manufacturer HACCP Manual*.

#### 7.4.1 Validation of the Microbiology CCP

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 reduction for the pathogen of concern, i.e. 2-log reduction for Salmonella.

Validation includes the scientific basis or technical information justifying the processing parameters (e.g., time and temperature to achieve the number of log reduction), and the data demonstrating that the process is capable of meeting those parameters.

The validation study must be available to MG. The validation is part of the overall audit process and it must be complete as minimum requirement for approval. Furthermore, Suppliers must re-validate their microbiological CCP at a minimum frequency of every two years or when a major change occurs. Material/process specific advice can be requested from MG Corporate Quality by sending an email to [SupplierQualityMondelēz@mdlz.com](mailto:SupplierQualityMondelēz@mdlz.com). Additional information can be found on Section 5.3 from the *Mondelēz Global LLC Supplier and External Manufacturer HACCP Manual*.

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## 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. An Allergen Assessment shall be carried out as part of HACCP Plan development to identify, review, and document allergens likely to be present.

The Allergen Assessment must consider all allergens on the *Mondelēz Global LLC Allergen Category List (Appendix C of the Mondelēz Global LLC Supplier and External Manufacturer HACCP Manual)* as well as any others identified in local regulations and regulations of the countries that the product is shipped to.

The Allergen Assessment shall consider possible sources of allergens related to the formulation, process, and site-specific practices, including: raw materials/ingredients, rework addition, and potential for cross-contact in manufacturing, storage or shipment practices. An assessment shall be conducted whenever the source of a raw/packaging material, formula or process has changed.

Where possible, allergens must be designed out of the product, making labeling unnecessary. This may be achieved by reformulation. Allergen-containing materials shall be stored in a manner that will prevent cross-contact.

Avoidable allergens introduced through cross-contact from other lines (no common equipment) or other production areas shall be strictly managed through raw material handling (e.g., use of color coded utensils and work tools), rework handling, GMP and employee allergen awareness training.

Rework product containing allergens as an ingredient shall be used only in products which contain the same allergen as an ingredient. Suppliers using rework containing allergens shall refer to the "Rework Model" in Appendix E of the *Mondelēz Global LLC Supplier and External Manufacturer HACCP Manual* for details.

For processes that are adequately designed for wet cleaning or flushing, avoidable allergens introduced from manufacturing carry-over (production of a previous product with allergens in the same line) shall be managed through product change-over practices such as product sequencing, flushing, and cleaning. When change-over cleaning or flushing is implemented with the purpose of eliminating the carry-over (and thus not declare the allergen), then models "Equipment Cleaning for Allergen Removal (Product Changeover)" or "Product Flushing for Allergen Removal (Product Changeover)" described in the *Mondelēz Global LLC Supplier and External Manufacturer HACCP Manual* shall be applied.

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

Controls shall be in place to make sure that MG is notified of all allergens present (as ingredients or traces). Where a new allergen is identified in a product where it was not previously present, and is therefore not labeled (e.g. discovery of an allergen cross-contact or change to the allergen profile of a raw material), MG must be notified immediately (see Section 5.1 Notifying MG of Significant Events).

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

## 7.6 Extraneous Matter

The Supplier shall have implemented a written program to prevent, detect, and control extraneous matter.

The Supplier shall perform a risk assessment to determine potential sources of extraneous matter, including: raw ingredients, packaging materials, equipment design, plant environment (e.g., ceilings, walls, floors), processing and packaging equipment, utensils, contamination from personnel or other operations such as cleaning and

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sanitation, contractor work, rework/work-in-progress protocol, maintenance or repair of equipment, and historical information of types of extraneous matter previously found or reported by consumers.

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

Based on the risk assessment, the Supplier shall develop an appropriate strategy for minimizing extraneous matter, which may include:

- Confirming control strategies at suppliers or sources of materials.
- Designing the risk of extraneous matter out of the process (such as eliminating metal-to-metal contact on equipment, replacing metal screens with Nitex or equivalent).
- Preventing introduction of extraneous matter into the product through the implementation of pre-requisite programs, for example, through GMPs, equipment design, preventive maintenance, covers on tanks or conveyor belt.
- Detecting and removing extraneous matter (e.g., installation of strainers, screens, filters, magnets, sieves, metal detectors, X-ray or other devices/programs deemed necessary on the line).

Specific controls shall be applied to devices that can be a source of extraneous matter when damaged (e.g., sieves, glass, hard plastic). The integrity of sieves and filters shall be checked in a frequency sufficient to demonstrate control. Requirements for glass and hard plastic are described on the chapter 10.4 from ISO/TS22002-1. Appropriate and timely corrective action shall be implemented in case any source of extraneous matter with potential of falling into the product stream is detected.

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). The program shall include calibration of the equipment, monitoring activities (e.g. internal regular verification, control of incoming flow and rejected quantities), maintenance, and sampling plan.

Where Metal Detection or X-ray detection devices are managed as a CCP, refer to the *Mondelēz Global LLC Supplier and External Manufacturer HACCP Manual* Appendix E “Extraneous Material Detection” for details.

#### 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. The detection sensitivity under production conditions must be better than 5.0mm for all metals, with recommended maximums of 1.5mm for ferrous, 2.0mm for non-ferrous (brass) and 2.5mm for stainless steel 316 grade.

Functionality verification for electronic detection and rejection devices shall take place during production with the normal product flow. Minimum frequency for system verification shall occur at the following times: start up (e.g. the beginning of each shift or production start up if part way through a shift) and end of each shift; after a production change (e.g. product or primary packaging changeover); following any repairs; maintenance or adjustments; and on a regular basis as determined by the site (recommended maximum every 4 hours).

If a metal detector is not working at its design limit (e.g. if it fails to detect a test piece), the material produced since the last successful test shall be placed on Category II Hold (see Section 8.4 Hold and Release).

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

#### 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 program shall include the application of statistical process controls, routine scale verification, periodic calibration, corrective action plans and guidelines for handling non-compliant product. Sampling criteria for all packaging lines shall be specified in the control plan. Data must be collected routinely and across the compliance lot.



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For statistical process controls used, documented results shall indicate that the material is in compliance with the specification. Corrective actions shall be taken if the process is trending out of control or is not centering on the target. Out of compliance lots must be held for further evaluation and disposition (see Section 8.4 Hold & Release).

#### 7.7.2. Packaging Material

All packaging in food contact with the delivered materials (e.g. big bags, multi-layer paper, etc.) 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 from the material itself.

Any proposed change in the size or type of packaging must be submitted to the appropriate MG 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 MG, and that labels meet applicable regulatory requirements and MG Specifications. In particular, the Supplier shall verify the accuracy of labels for allergen profile, ingredient information, nutritional information, net quantity and specific claims.

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

The Supplier must ensure through its procedures that labels and pre-printed packages are stored in a manner that minimizes mixed label batches and mixing together with other labels and packages. Special attention shall be given to packaging material changeover practices in line. Unused pre-printed labels at the end of a run must be accounted for or destroyed to ensure that the next run of materials is not inadvertently mislabeled. 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 implemented a written program for product traceability following GS1 requirements, assuring that package and pallet, lot codes, and date information are accurate and consistent across similar businesses and products. Traceability requirements apply to all products and all components used to produce products, including ingredients, in-process products, rework, primary packaging materials, and/or process intermediated.

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

Each material delivered to MG should contain only one batch/lot number. At a minimum each individual pallet shall be made up of only one batch/lot number. The Supplier shall notify the MG receiving location if a lot is split between two or more MG locations.

If requested, such as in the event of a product recall or other product-related issue, the Supplier must provide the relevant traceability information to MG within 4 hours. Mock recalls shall be conducted at least once a year to validate the effectiveness of the traceability program.



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### 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 MG.

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.

Additional warehousing control program requirements are:

- Product or ingredient containers shall not be stored immediately adjacent to containers for waste or non-product items (e.g. cleaning compounds, laboratory solvents). Non-product items shall be stored in separate, designated areas.
- Ingredients must be adequately protected and stored in a sanitary manner in their original, labeled container, or in another authorized sanitary container that is clearly marked for the use of the specific ingredient (e.g., sanitary pails or tote bins). Ingredient identification and lot number/traceability must be maintained. Containers must be properly closed/ sealed/ covered. When returning ingredient containers to storage, ensure ingredients are stored in the proper temperature environment.
- Bulk pre-weighed ingredients must be stored in appropriate containers and under appropriate conditions.
- Sanitation and pest control of storage areas shall be assessed e.g. spacing equipment or material storage away from walls (guideline 30-50 cm/12-18 inches) for multiple pallet applications; sealed doors and windows; cleanable floors, walls, and overhead structures.
- Procedures that identify and track shelf life of raw materials and release status of finished goods shall be implemented. An effective stock rotation system shall be in place.
- Appropriate temperature/humidity controls must be used, as required per specification. Storage temperatures and humidity (where applicable) shall be measured and documented using calibrated recording equipment.
- Airflow from items such as heaters and refrigeration units must be directed away from products. Direct sunlight on product should be avoided where possible.
- Glass containers must be isolated from products during storage.
- Products with strong odors shall be segregated to avoid odor migration.
- Bulk storage of liquid ingredients susceptible to microbiological spoilage shall have adequate controls in place to prevent spoilage or contamination (e.g. insulated, temperature controlled and monitored).
- Where packaging materials are not in individual containers (e.g., film roll stock, cartons.), the pallets shall be covered and stretch wrapped, shrink wrapped, strapped, or net wrapped to maintain integrity and prevent potential for contamination.
- Pallets used for food products must be in good condition (e.g. clean, with no broken boards, no evidence of mold or infestation and no off odors). Slip-sheets shall be used to avoid raw material primary packaging contact with the pallet. Over-stacking must be avoided.

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

- Procedures must be in place to ensure that products are pre chilled to required temperature prior to loading, and vehicles are pre chilled prior to loading for distribution (where applicable).
- Trucks and containers (including pipes and loading / unloading equipment) shall be verified to be in good condition, dry, clean and free of off-odors before loading. Wood racks are prohibited in trucks used for MG materials deliveries. If other materials would be transported in the same truck, supplier must make sure that it will not alter MG materials.
- Temperature controlled vehicles must carry suitable on-board temperature monitoring devices. The devices shall be verified at defined intervals.
- 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".

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- For bulk tankers, cleaning certificates shall be available and checked before each loading. Verification frequencies for equipment sanitation shall be specified. The frequencies must take into account the microbiological sensitivity of the material transported and the allergenic and GMO status of the previous load. The cleaning certificate shall be in local language (or in English) and must stipulate:
  - Tanker plate number
  - Nature of the previous load
  - Date and hour of cleaning
  - Numbers of the cleaned compartments
  - Applied cleaning program (with water, with detergents, drying etc.)
  - Seals numbers for tankers
- Inbound and outbound bulk containers shall be sealed. Acceptable seals include:
  - Drums with a locking ring secured with a numbered seal and number annotated on the shipping documentation.
  - Drums without a locking ring secured with tamper-evident tape readily identifiable with the Supplier's name and logo.
  - Large bags such as super-sacks or totes containing plastic liners having a bag closure that will readily reveal any tampering and will not permit removal and reinstallation without breaking the seal.
  - Corrugated cases effectively sealed with tamper-evident tape.

### 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 requirements. Calibration procedures for each piece of measuring and monitoring equipment, including equipment used to control, measure, or monitor critical control points (CCPs) and equipment used for laboratory testing, shall include the following information:

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

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

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

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

Calibration shall be performed under suitable environmental conditions, based on stability, purpose and degree of usage of such equipment. Calibration checks shall be documented including date, personnel initials and actual comparison results, and calibration results indicating the degree of inaccuracy and any adjustments made to bring the equipment back into calibration.

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, an assessment shall be carried out to determine any potential food safety risk with regard to product tested during the period when the equipment was possibly out of calibration.

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## 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 must be taken into account when planning future audits. Employees may conduct audits, but should only be assigned to audit areas in which they do not work. The audit procedures shall provide for follow-up audit activities to verify and record the implementation of corrective actions taken. The 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.

### 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 MG shall only be performed by laboratories that have been approved by MG Corporate Microbiology. A list of approved laboratories in each country is available from your MG Contract Representative and can be found on the web site [www.mdlzsupplierquality.com](http://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 signs must be posted to indicate that the area is restricted.
- The laboratory must participate in 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.

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### 8.3 Rework Control

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

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

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 MG to be incorrect.

Additional requirements are described on chapter 14 Rework from [ISO/TS22002-1](#).

### 8.4 Hold and Release

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

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 reconstruction of each hold event (e.g., quantities, code dates, lot numbers, product numbers, reasons for hold and/or release, investigative information, disposition, and traceability information).

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

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

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After release of a lot/code of product to MG, 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 MG is either inadvertently released from hold or is suspected of non-conformance but has already been shipped to MG, the MG Contracting Representative shall be immediately notified (see Section 5.1 Notifying MG of Significant Events).

## 8.5 Control and Disposition of Non-Conforming Products

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

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

Any labeled material, including semi-finished products with the brand name on it, that are dispositioned for destruction or animal feed must be disfigured, or destroyed or disposed of, in a manner that provides assurance that Mondelēz Global Trademarks cannot be reused in any manner.

## 8.6 Product Retrieval

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

Product retrieval procedures must include:

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

The retrieval system shall be tested on an annual basis and after any major system changes to confirm (1) the accuracy of all product and contact data and (2) the continuing effectiveness of procedures and traceability systems. The results of these tests and any corrective actions necessary shall be documented.

The MG Contracting Representative shall be notified immediately in the event of a product retrieval that impacts MG products (see Section 5.1 Notifying MG of Significant Events).

## 8.7 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 MG supplier shall inform MG and provide objective evidence that actions have been closed out (from audit or other source).

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

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) must also be identified.



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- C&PA plan implementation.
- Further analysis of data to validate if the desired results were achieved (e.g. was the plan effective in resolving the root cause).
- Periodic review of C&PA by the management team.

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

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

## CHAPTER 9 – PACKAGING REQUIREMENTS

### 9.1 Introduction

The *Mondelēz Global LLC 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.

At a minimum, all packaging materials supplied to MG 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. For materials where a declaration of compliance is not legislated (e.g. paper, metal containers), a safety assessment covering materials and conversion shall be provided. 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. It shall encompass all potentially migrating substances, both intentionally added ingredients and non-intentionally added substances present due to reactions, impurities and others.

This statement shall be renewed when any change in composition or production occurs that bring about changes in migration or when new scientific data becomes available.

Where no dedicated national food packaging legislation for plastic material exists, MG requires compliance with either the European or the U.S. federal (Food and Drug Administration (FDA) (21 CFR), U.S. Department of Agriculture (USDA), U.S. Environmental Protection Agency (EPA) and state regulations. All corresponding raw data and documents must be maintained and available.

#### 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 Section 3 Audit Requirements.

Packaging suppliers of materials with ingredient line information shall ensure that print runs items are not mixed on a pallet.



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#### 9.1.2 Printed Material Management: Destruction or Recycling of MG Labeled Packaging Material

The Supplier must ensure that any discarded or recycled materials (including any scrap or waste) containing any MG name, trademark or logo, or any other MG 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.

### 9.2 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 MG Food Contact Packaging. Under their normal or foreseeable conditions of use, materials shall not transfer their constituents to foodstuffs in quantities that could endanger human health, cause an unacceptable change in the composition of the foodstuffs (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).

All packaging materials and articles intended to come in contact directly or indirectly with food must be sufficiently inert to prevent the migration of plastic constituents to food. The Overall Migration limit for materials and articles is 10 mg/dm<sup>2</sup> (1 dm = 10 cm). For young children the limit shall be maximum 60mg per kg foodstuff.

#### 9.2.1 Constituents from plastic materials

Plastic material and articles shall not transfer specific constituents to foodstuff in quantities exceeding their toxicologically derived limits (expressed in mg/kg) based on the actual surface to volume ratio of the final item. For packaging having a content of less than 500ml or 500g, or more than 10 litres, the migration value shall be expressed in mg/kg foodstuff based on a surface to volume ration of 6dm<sup>2</sup> per kg food or in mg per article where surfaces are impracticable to determine e.g. caps, gaskets.

The material shall be tested under conditions related to the food type, time, and temperature that the packaged food is exposed during filling, processing, storage and preparation. The ingredients and composition of all plastic materials in a polymer must comply with all legal safety requirements.

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

#### 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, the following guidelines shall be followed: (i) *FDA's regulations in 21 CFR Part 176* or (ii) the *German Recommendation XXXVI*.

Films made of regenerated cellulose fibers must be of food grade quality. In the absence of applicable regulations, the following references shall be followed: *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

MG favors the use of recycled materials provided that strict requirements are established to ensure food safety. MG typically does not permit post-consumer recycled materials used for primary packages to come in direct

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contact with food, unless an authorized process has been used e.g. SuperClean. If compliance with food contact material regulations can be declared, MG will make an exception for glass, metal, and specific product applications when agreed to by your MG Contracting Representative and included in MG Packaging Specifications.

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

If post-consumer recycled material is part of a multi-component primary packaging system, but is not in the layer where it contacts the food, the use of the post-consumer recycled material will only be permitted subject to three requirements: (1) MG 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 MG Packaging Specifications.

#### 9.2.5 Odor and taste transfer testing

To fulfill legal requirements and to ensure consumer acceptance, food contact materials shall not change the organoleptic properties of the packed food. Food contact packaging materials supplied to MG must comply with Odor and taste transfer testing.

- Paper and board  
The organoleptic characteristics of food contact paper and board materials (including promotional items) in direct or indirect contact with food shall be evaluated per batch according to the following methods:
  - EN 123 –1 Odor assessment test
  - EN 1230–2 Taint transfer test (“Robinson test”)For direct and indirect confectionery packaging both of the above mentioned sensory tests are mandatory.
- Other materials  
An odor assessment according to EN 1230-1 shall be performed per batch for printed films for direct and indirect contact. For other materials the testing of the organoleptic characteristics can be based on risk assessment.
- Acceptance criteria  
These tests are based on a rating scale from 0 = no off-flavor or odor to 4 = strong off-flavor or odor. Primary packaging materials in direct or indirect food contact are acceptable if:
  - at the taint transfer test the off-taste is just perceptible, but difficult to define (median taste score 1.5 with above mentioned methods);
  - at the odor assessment test a slight off-odor is perceived (median odor score < 2.5 with above mentioned methods).

Note that sensory tests must be conducted systematically by suitable and trained panelists in a suitable environment. Other methods can be used if agreed to by MG and provided that the comparability is documented. Specific advice can be requested from MG Corporate Quality by sending an email to [SupplierQualityMondelēz@mdlz.com](mailto:SupplierQualityMondelēz@mdlz.com).

#### 9.2.6 Residual solvents

Food contact packaging materials supplied to MG must comply with Residual solvents, if applicable.

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

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

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

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

#### 9.2.7 Printing inks

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

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

Mondelēz Global 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](http://www.eupia.org)) and the “*Swiss Ordinance on Materials and Articles in Contact with Food*”, Section 8b, *Packaging Inks*, Art. 26e – 26i1.

In the U.S., suppliers must have an FDA regulatory approval letter on file for approved use of specific inks used for indirect or direct product contact. For ink layers with direct food contact see Section 9.2.8 Printing in direct contact with food.

#### 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 and no functional barrier is in place, only food grade colorants can be used. Colorants must be approved for food use in the locations where the products are produced and may be delivered. In the U.S., inks used for direct product contact must be FDA approved food grade colorants.

This requirement applies to printings on the inner side of a package (e.g. for promotions). It also applies to outside printed packages that could be taken into the mouth or placed in close or direct contact to an unpacked food (e.g., multi component packs that comprise of packaged and unpacked food).

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

Materials derived from allergenic sources shall not be used (exception oils derived from allergenic sources which have been refined, bleached and deodorized are allowed). Allergenic sources are defined in the *Mondelēz International Allergen Category List* (see *Appendix C* of the *Mondelēz Global LLC Supplier and External Manufacturer HACCP Manual*).

MG 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

MG 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 MG must comply with national environmental packaging and packaging waste regulations of the production location and destination location(s) where products will be produced, used, transported and disposed. Suppliers must consider source reduction and prevention, including an appropriate material delivery in terms of noise, urban congestion, transportation means, quantity and volume.

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#### 9.3.1 Minimization of heavy metals, and other N-classified substances

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

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

#### 9.3.2 Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

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

#### 9.3.3. Undesired substances

Mondelēz Global trusts and relies on safety assessments of internationally recognized food safety authorities such as FDA, EFSA and others. At the same time it also respects consumer preferences. Therefore MG must be notified about any materials that contain ingredients of public attention in the food contact layer.

The use of bisphenol A in food packaging shall be avoided or if not possible, notified.

### 9.4 Packaging Component Information Sheet (PCIS)

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

### 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.

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## APPENDIX TABLES

**Table 1 Audit Matrix**

Tier	Ingredient Categories ( <i>List is not all inclusive - refer to the Raw Material Tier Assignment list for details</i> )	Qualification Process ( <i>new</i> )	Accepted Audits & Certifications ( <i>ongoing</i> )	Target Frequency ( <i>years</i> )
1	RTE Meats, Cheeses, <u>RTE Raw</u> Fruits/Vegetables	MG Audit	MG Audit	1.5
2	RTE Nuts/Seeds/Coconut, Retorted & Aseptic Products (Low Acid Canned Foods), Cocoa/Chocolate/Confectionary, <u>Treated</u> Herbs/Spices/Seasoning; Tea & Tea Products; Egg & Egg Products; Dairy Products & Substitutes; Yeast; Enzymes	MG Audit	Certifications or 3 <sup>rd</sup> Party SQE + Supplier Food Safety Assessment (frequency determined by Food Safety Group)	2
2 4	Fruit & Fruit Products, Vegetable & Vegetable Products, Flavoring Ingredients ( <i>material assigned to tier 2 or 4</i> )			
4	Grain & Grain Products, Emulsifiers; Prepared Sauces/Spreads/Condiments, Coffee & Coffee Products, Bread & Bakery Products; Sugars & Sweeteners; Starter Media/Culture; Fats & Oils; Food Additives; Raw Meat & Raw Meat Products, Food Chemicals Hydrocolloids & Gums, Wafers; <u>Untreated</u> Herbs/Spices/Seasoning; Direct Contact Packaging Material Labeled and Unlabeled, Non-Contact Packaging Material Labeled; <sup>6</sup> Chemical-Distillation, Crystallization, Extraction	3 <sup>rd</sup> Party SQE or Certifications	3 <sup>rd</sup> Party SQE or Certifications	3
5	Raw Milk & Cream, Nationally Branded Confections; Green Coffee Beans; Compressed Gases; Raw Grains; Raw Nuts/Seeds/Coconut; Raw earthen materials (e.g., unprocessed materials mined from the earth); Alcoholic Substances (Spirits, Liquors); Liquid Whey and Liquid Milk (Bulk Only)	Audits may be required as result of a risk assessment by BU or Plant using the material		NA

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**Table 2 Filter type reference chart (air filters conversion table based on US and EU standards).**

US Filter Classification (MERV per ASHRAE Std 52.2-2007)	EU Filter Classification (per EN 779 and EN 1822- 2009 filter tests)	Composite average particle size removal efficiency (%) in size range (µm) per ASHARE 52.2-2007			Arrestance % of test dust captured by the filter by weigh per ASHRAE 52.2-2007 and EN 779-2002	Filter use and typical applications
		3-10	1-3	0.3-1		
1	G1	< 20			< 65	Primary filters for coarse dust
2	G2	< 20			65 - 70	
3		< 20			70 – 75	
4		< 20			≥ 75	
5	G3	20 - 35			≥ 80 - 90	
6	G4	35 - 50			≥ 90	
7		50 – 70				
8		> 70				
9	F5	> 85	< 50			Secondary filters to retain small particle dust to keep general food processing areas free from airborne contamination. Might be applied in some high risk areas based on risk assessment.
10		> 85	50 - 65			
11	F6	> 85	65 - 80			
12		> 90	> 80			
13	F7	> 90	> 90	< 75		Particles 3-10 µm: mold, spores, fines dust
14	F8	> 90	> 90	75 - 85		Particles 1-3 µm: larger bacteria (e.g. Legionella)
15	F9	> 90	> 90	85 - 95		Particles 0.3 - 1 µm: all bacteria
16		> 95	> 95	> 95		
	H10	Efficiency on particles 0.3 µm > 85				Small particulate air filters Semi-HEPA and HEPA type for high risk areas.  Particles < 0.3 µm: viruses, very fine dust
	H11	Efficiency on particles 0.3 µm > 95				
	H12	Efficiency on particles 0.3 µm > 99.5				
17	H13	Efficiency on particles 0.3 µm > 99.95				
18	H14	Efficiency on particles 0.3 µm > 99.995				High efficient air filters ULPA type for some lab work in cabinet and very special applications.
19	U15	Efficiency on particles 0.12 µm > 99.9995				
	U16	Efficiency on particles 0.12 µm > 99.99995				
	U17	Efficiency on particles 0.12 µm > 99.99995				

#### Notes

Standard 52.2-2007 does not address semi-HEPA (high efficiency particulate air), HEPA or ULPA (ultra low penetration air) type filters. These filters are classified only per standard EN 1822 – 2009, which determines the most penetrating particle size (MPPS) efficiency (%) and leakage rate of the filter based on test aerosols.

Always check the specific manufactures specifications of a filter before designing or installing a system, as this table provides approximations only.



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**Table 3 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	H13
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 and cooling of nuts products Liquid Egg products Prepared Sauces Spreads and Condiments Ready to Drink – Liquid Beverages, hot fill	13	F7
Dairy – Dry products bagging and filling rooms. Sensitive dry ingredients	11 or 12	F6
Equipment wash areas Analytical laboratory	9 or 10	F5
Non sensitive dry ingredients Vinegar production area	6	G4

**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	-

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**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 / ft <sup>3</sup> or < 0.001 cfu / litre
Dry sensitive raw materials (e.g., dairy powders, cocoa, nuts)	Yeast & Mould	< 100 cfu / 15 minutes	< 1,000 cfu / m <sup>3</sup>	
Post heat treatment or pasteurization; products with Aw 0.65 - 0.95 (processing, filling and packaging)	Yeast & Mould	< 10 cfu / 15 minutes	< 500 cfu / m <sup>3</sup>	
Post heat treatment or pasteurization: products with Aw > 0.95 (processing, filling and packaging), <b>hot filled</b>	Yeast & Mould	< 10 cfu / 15 minutes	< 500 cfu / m <sup>3</sup>	
Post heat treatment or pasteurization: products with Aw > 0.95 (processing, filling and packaging), <b>cold filled</b>	Yeast & Mould	< 5 cfu / 15 minutes	< 100 cfu / m <sup>3</sup>	
Ready-to-Eat Vegetable products	Yeast & Mould	< 100 cfu / 15 minutes	< 1,000 cfu / m <sup>3</sup>	

Note: 1 m<sup>3</sup> = 1,000 liters

**Table 6 Guidelines for Actions Standards for Clean Equipment Swabs**

Microorganism		Post Heat treatment - taken before sanitize		Post Heat Treatment - pre-op taken after sanitize	
		cfu/100 cm <sup>2</sup>	cfu/40 in <sup>2</sup>	cfu/100 cm <sup>2</sup>	cfu/40 in <sup>2</sup>
APC	Acceptable	< 500	< 1000	<50	< 100
Coliforms / Enterobacteriaceae	Acceptable	<50	<100	<5	<10
Lactobacillus	Acceptable	<50	< 100	< 5	< 10
Yeast & Mould	Acceptable	<50	< 100	< 5	< 10

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

Product	High risk zone	Controlled zone	High control zone
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

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**Table 8 PEM Reference Sampling Plans**

Testing Plan	PEM Zone	Test organisms	Minimum Test Frequency*
Plan A RTE refrigerated products in which <i>Listeria monocytogenes</i> may survive or grow; typically in wet and cold environments. Typically applied to Meat and Meat products	1, 2, 3	<i>Listeria</i> spp.	Once per week
	4	<i>Listeria</i> spp.	Once per month
Plan B Low moisture products in which <i>Salmonella</i> may survive and/or grow; Typically applies to cocoa, nuts, and biscuit products.	2, 3	<i>Salmonella</i> only	Once per week
	4	<i>Salmonella</i> only	Once per month
	2, 3	<i>Listeria</i> spp. to monitor conditions that could lead to the presence of <i>Listeria monocytogenes</i> , or other type of conditions susceptible to support the survival of <i>Listeria monocytogenes</i> (typically where water / moisture may be present).	Once per month
Plan C RTE refrigerated product in which <i>Listeria monocytogenes</i> may grow and <i>Salmonella</i> may survive or grow. Typically applies to Dairy products.	1	<i>Listeria</i> spp. and coliforms [optional <i>E.coli</i> ]	Once per week
	2, 3	<i>Listeria</i> spp. & <i>Salmonella</i> (or optional indicators to monitor conditions that could lead to <i>Salmonella</i> presence)	Once per week
	4	<i>Listeria</i> spp. & <i>Salmonella</i> (or optional indicators, to monitor conditions that could lead to <i>Salmonella</i> presence).	Once per month
Plan E RTE refrigerated and shelf-stable products that support pathogen survival; typically applies to Fruits and Vegetables products	1	Indicator organisms, coliforms [optional <i>E.coli</i> ]	Once per week
	2, 3	<i>Listeria</i> spp. & <i>Salmonella</i> (or optional indicators to monitor conditions that could lead to <i>Salmonella</i> presence)	Once per week
	4	<i>Listeria</i> spp. & <i>Salmonella</i> (or optional indicators to monitor conditions that could lead to <i>Salmonella</i> presence)	Once per month
Plan I To monitor hygienic conditions of products not covered under other Plans	2, 3	<i>Listeria</i> spp. and / or <i>Salmonella</i>	Once per month
	4	<i>Listeria</i> spp. and / or <i>Salmonella</i>	Once per quarter

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

**Table 9 PEM Guidance for Quantitative Indicator Organisms**

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

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

Customs-Trade Partnership Against Terrorism (C-TPAT)	<ul style="list-style-type: none"> <li><a href="http://www.customs.ustras.gov/xp/cgov/import/commercial_enforcement/ctp_at/criteria_importers/ctpat_importer_criteria.xml">http://www.customs.ustras.gov/xp/cgov/import/commercial_enforcement/ctp_at/criteria_importers/ctpat_importer_criteria.xml</a></li> <li>C-TPAT Cargo Security <a href="http://www.cbp.gov/xp/cgov/trade/cargo_security/ctpat/">http://www.cbp.gov/xp/cgov/trade/cargo_security/ctpat/</a></li> </ul>
Food and Drug Administration (FDA)	<ul style="list-style-type: none"> <li>Federal Food, Drug, and Cosmetic Act, 21 USC 321, et. seq. <a href="http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/default.htm">http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/default.htm</a></li> <li>FDA Guidelines, <a href="http://www.fda.gov/ForIndustry/GuidanceDocuments/default.htm">http://www.fda.gov/ForIndustry/GuidanceDocuments/default.htm</a></li> <li>Reportable Food Registry Section 417 of the FDCA. <a href="http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/FDCAChapterIVFood/ucm088549.htm">http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/FDCAChapterIVFood/ucm088549.htm</a></li> <li>21 CFR 1-199, <a href="http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200821">http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200821</a></li> <li>42 CFR 73, <a href="http://www.selectagents.gov/resources/42_cfr_73_final_rule.pdf">http://www.selectagents.gov/resources/42_cfr_73_final_rule.pdf</a></li> <li>FDA - "ALERT: Food Defense Awareness" <a href="http://www.accessdata.fda.gov/videos/CFSAN/ALERT/alrt01.cfm">http://www.accessdata.fda.gov/videos/CFSAN/ALERT/alrt01.cfm</a></li> </ul>
United States Department of Agriculture (USDA) and Food Service Inspection Services (FSIS)	<ul style="list-style-type: none"> <li>USDA - Food Safety and Inspection Service (FSIS) "Developing a Food Defense Plan for Meat and Poultry Slaughter and Processing Plants", January 2007 <a href="http://www.fsis.usda.gov/PDF/Food_Defense_Plan.pdf">http://www.fsis.usda.gov/PDF/Food_Defense_Plan.pdf</a></li> <li>FDA/USDA - "An Introduction to Food Security Awareness" <a href="http://www.fda.gov/ora/training/orau/FoodSecurity/startpage.html">http://www.fda.gov/ora/training/orau/FoodSecurity/startpage.html</a></li> </ul>
Department of Homeland Security (DHS)	<ul style="list-style-type: none"> <li>CBP – Customs-Trade Partnership Against Terrorism Security Criteria <a href="http://www.cbp.gov/xp/cgov/trade/cargo_security/ctpat/security_criteria/">http://www.cbp.gov/xp/cgov/trade/cargo_security/ctpat/security_criteria/</a></li> </ul>

**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. §§ <a href="#">174.5 to 174.6 - Indirect Food Additives: General</a>	<ul style="list-style-type: none"> <li>EC-Regulation No 1935/2004</li> <li><a href="#">Commission Regulation 2023/2006 – GMP on materials and articles intended to come into contact with food.</a></li> <li>Migration test conditions according to Plastics Implementing Measure (PIM) EU 10/2011 Plastic Materials and Articles Intended to Come into Contact with Foodstuffs</li> </ul>
Organoleptical properties of packaging material	<p>Mondelēz International requirement only; no specific regulation</p> <p>ASTM methods:</p> <p>E460 Practice for Determining Effect of Packaging on Food and Beverage Products During Storage</p> <p>E619 Practice for Evaluating Foreign Odors in Paper Packaging</p> <p>E1870-04 Standard Test Method for Odor and Taste Transfer from Polymeric Packaging Film</p>	<ul style="list-style-type: none"> <li>EC-Regulation No 1935/2004</li> </ul> <p>Methods for paper &amp; board:</p> <ul style="list-style-type: none"> <li>EN 1230 –1 Odor evaluation</li> <li>EN 1230 –2 Taint transfer test ("Robinson test")</li> <li>ISO13302 Methods to assess modifications to the flavour of foodstuffs due to packaging</li> </ul>

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Packaging Material / Criteria	Specific U.S. Regulations 21 CFR Food & Drugs (includes method)	Specific Regulations E.U., national legislations, guidelines and methods
Plastics, Laminates	21 C.F.R. §§ <a href="#">177.1010 to 177.2910 - Indirect Food Additives: Polymers</a> 21 C.F.R. §§ <a href="#">178.1005 to 178.3950</a> – Indirect food additives: adjuvants, productions aids and sanitizers	<ul style="list-style-type: none"> <li>Plastics Implementing Measure (PIM) EU 10/2011 Plastic Materials and Articles Intended to Come into Contact with Foodstuffs</li> <li>Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food</li> <li>Resolution AP (92) 2 on control of aids for plastic materials and articles intended to come into contact with foodstuffs</li> </ul>
Regenerated Cellulose	21 C.F.R. § <a href="#">177.1200 - Cellophane.</a>	<ul style="list-style-type: none"> <li>Regenerated Cellulose Film Directive 2007/42/EC</li> </ul>
Ceramics		<ul style="list-style-type: none"> <li>Ceramics Directives 84/500/EEC, 2005/31/EC</li> </ul>
Paper, Paperboards	21 C.F.R. §§ <a href="#">176.110 to 176.350 - Indirect Food Additives: Paper and Paperboard components</a>	<ul style="list-style-type: none"> <li>Resolution AP (2002) 1 on paper and board materials and articles intended to come into contact with foodstuffs;</li> <li>Recommendation XXXVI Paper and Boards of the German Federal Institute for Risk evaluation (BfR) - <a href="http://www.bfr.bund.de">www.bfr.bund.de</a></li> </ul>
Elastomers and rubbers	see plastics	<ul style="list-style-type: none"> <li>Nitrosamine Directive 93/11/EC;</li> <li>Resolution AP (2004) 4 on rubber products intended to come in contact with food</li> <li>Cold Seals BfR XXI on natural and synthetic rubbers</li> </ul>
Silicones		<ul style="list-style-type: none"> <li>Resolutions AP (99) 3 and AP (2004) 5 on silicones used for food contact application</li> <li>German BfR XV on silicones</li> </ul>
Surface coatings (resins, lacquers, adhesives)	21 C.F.R. §§ <a href="#">175.105 to 175.390 - Indirect Food Additives: Adhesives and components of Coatings</a>	<ul style="list-style-type: none"> <li>Epoxy Derivatives Directives 1895/2005/EC</li> <li>Resolution AP (2004) 1 on coatings intended to come into contact with foodstuffs</li> <li>Risk assessment based on Plastic Implementation measure No. 10/2011, BfR XXVII on lamination adhesives.</li> </ul>
Printing inks	FDA approval	<ul style="list-style-type: none"> <li>Commission Regulation 2023/2006 – GMP on materials and articles intended to come into contact with food.</li> <li>Swiss Ordinance on Materials and Articles in Contact with Food, Section 8b, Packaging Inks, Art. 26e – 26i1</li> <li>EuPIA guideline on printing inks applied to the non-food contact surface of food packaging materials and articles “low migration inks”</li> </ul>
Recycled plastics		<ul style="list-style-type: none"> <li>Commission Regulation 282/2008 on recycled plastic materials and articles intended to come into contact with food</li> </ul>
Active and intelligent packaging		<ul style="list-style-type: none"> <li>Commission Regulation 450/2009 on active and intelligent materials and articles intended to come into contact with food</li> </ul>
Packaging hygiene		<ul style="list-style-type: none"> <li>GFSI accepted packaging manufacturing standards: guidance document 6.1, table VII specific requirements on packaging</li> <li>PAS 223 Prerequisite programme and design requirements for food safety in the manufacture and provision of food packaging</li> <li>BRC/IoP Global Packaging Standard</li> <li>EN 15593 Management of hygiene in the production of packaging for foodstuffs</li> </ul>
Packaging as Waste	CONEG	<ul style="list-style-type: none"> <li>Packaging &amp; Packaging Waste Directive 94/62/EC</li> <li>Methods: EN 13427 – EN13432; CR 13688; CR 13695</li> </ul>

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## APPENDIX 1 - DEFINITIONS

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

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

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

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

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

**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 Allergen Category List:** Mondelēz Global list of recognized food allergens, available at the *Mondelēz Global LLC Supplier and External Manufacturer HACCP Manual*.



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**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.

**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 MG. MG 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.

**GS1:** The GS1 system of standards is the most widely-used supply-chain standards system in the world. Its label code naming elements have replaced the previous system EAN and UCC code systems. More information on the GS1 system of standards is available at <http://www.gs1.org/>.

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

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

**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 (MG) Contracting Representative:** The MG 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 MG 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 MG specification (SAR). For more information, see *Biologically Sensitive Ingredient Category List* in *Appendix B* of the *Mondelēz Global LLC Supplier and External Manufacturer HACCP Manual*.

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

**Our:** Belonging to Mondelēz Global LLC

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

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**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.

**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 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.

**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 RMA specification and sent to the supplier for formal agreement.

**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).

**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.

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## REVISION LOG – main changes

1	INTRODUCTION	Added reference to other quality documents ; Added email for enquires; Added additional explanation for brokers about MG approved manufacturing locations.
2.1	General Audit Requirements	Additional information on Audit Matrix, Supplier Tier classification, different types/acceptance of audits (GFSI, SFSA, Packaging and chemical audits).
3	Quality Systems controls	Modified the number of years required for records retention; Additional information regarding GMO requirements; Additional information regarding "Irradiation policy".
5.1	Notifying Mondelēz Global of significant events	Updated requirement on Notifying Mondelēz Global in case of pathogen positive environmental sample.
6.1	GMP	Reference to Standard ISO/TS22002-1
6.3	Employee Illness and Communicable Disease	Additional requirement on risk assessment related to possible pathogen outbreaks in water.
6.4	Utilities Management	Additional explanation on water requirements (e.g. examples of corrective actions, disinfection details, municipal water requirements), air requirements (air filter types, monitoring activities) and steam requirements (e.g. pipes, filters)
6.5	Equipment Maintenance	Reference to Standard ISO/TS22002-1
6.6	Sanitary Design: Plant Structure & Equipment Design	Additional information about Plant Structure (separation, condensation) and reference to ISO/TS22002-1. Equipment Design section was updated with emphasis on cleanability, materials (no use of caulk), accessibility, self-draining, join attachments and ventilation.
6.7	Sanitation Programs	Included requirement related to cleaning place (not outside of the building), additional details on wet cleaning verification, and explanation on the usage of ATP testing.
6.8	Pest Management	Additional explanation about use of rodenticides.
6.9	Hygienic Zoning Programs	Scope of the program now also include some non-sensitive material. Included additional general explanation about the program, and examples of control measures.
6.1	Pathogen Environmental Monitoring	Scope of the program was expanded to some non-sensitive ingredients. Included additional general explanation about the program and table with reference sampling PEM plans.
6.11	Food Defense	Acceptance of PAS 96 as Food Defense certificate.
7.1	Specification Compliance and Contract Review	Updated requirements related to the content of the CoA. New requirement for completion of the GKIT, SAR and Pure food Guarantee letters. New chapter on Corporate Responsibility (highlighting PROGRESS).
7.2	Incoming Materials: Supply Quality Management	Reference to Standard ISO/TS22002-1. 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	Additional explanation about validation of the process step used to eliminate pathogenic organisms. Reinforce that the validation study is part of the overall approval process.
7.6	Extraneous Matter	Additional explanation on other extraneous matter devices apart from metal detectors. Reference to Standard ISO/TS22002-1 for glass and hard plastic.
7.11	Calibration of Measurement and Monitoring Equipment	Modified frequency of calibration of CCP measure devices (from 6 months to 1 year). Additional explanation equipment that cannot be calibrated.
8.2	Testing Controls: Laboratory Requirements	The approved pathogen laboratories are available on the supplier web site. Additional explanation on laboratory air pressure difference and air filtration.
8.3	Rework	Reference to Standard ISO/TS22002-1.
8.4	Hold and Release	New definition and examples for Hold I and Hold II.
8.5	Control and Disposition of Non-Conforming Products	Additional explanation about destruction of product that contain MG brand name.
8.7	Corrective and Preventive Actions	Added specific instructions about closure of CP&A related to MG.
9.1	PACKAGING REQUIREMENTS Introduction	Added instructions about DoC; Added requirement on specific requirement related to mixed packaging material; Added requirement on destruction of labeled packaging material.
9.2	Transfer of constituents from a food contact material to food	Added/update migration limits; Additional explanation on Odor and Taste transfer test; Additional explanation on potential GM materials.