SUPPLIER AND EXTERNAL MANUFACTURER *HACCP MANUAL*

Mondelēz International

SNACKING MADE RIGHT

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TABLE OF CONTENTS

INTRODUCTION

The *Mondelēz International Supplier Quality Expectations Manual* requires Suppliers to have a documented Hazard Analysis Critical Control Point (HACCP) plan in place for all products, ingredients, and packaging materials (product-contact, labels, and labeled packaging materials) manufactured for Mondelēz International. The HACCP system is a preventive approach to managing food safety. Philosophically, HACCP moves away from end point testing to a more proactive, preventative approach to control potential hazards. While HACCP cannot guarantee that food safety issues will not arise, it does provide a mechanism to reduce risk. When utilizing HACCP, hazards are identified, associated risks are assessed, methods for control are identified, critical control points (CCPs) are specified, and criteria for compliance are clearly defined. HACCP plans are now a core requirement of Food Safety Plans required to be implemented in US facilities and facilities sending product to the US.

The *Mondelēz International Supplier and External Manufacturer HACCP Manual* was developed to communicate Mondelēz International requirements for HACCP plan development and implementation. This document is meant to be used by an expert cross-functional team formed to develop a HACCP plan and is not a substitute for the team approach.

For Mondelēz International developed formulas, product developers shall provide a partial HACCP plan including the Hazard Analysis to the Supplier/External Manufacturer (EM). This information is to be used by the Supplier and by the EM for their HACCP Plan. For products developed by Suppliers/EM, the Supplier/EM shall develop HACCP plans consistent with this guide.

This HACCP Guide contains the following sections:

1. **Prerequisite Programs (PP).** HACCP is not a stand-alone program but is part of a larger control program. Prerequisite Programs are defined as the procedures used to control the conditions in the plant environment which contribute to the overall safety of the product. Mondelēz International recognizes 2 types of documented prerequisite programs: 1) *Universal Prerequisite Programs (PP)*, which are applicable to hazards identified across the manufacturing site, and 2) *Specific Prerequisite Programs (sPP)*, which are applicable to hazards identified in specific processes at some manufacturing facilities (see definition in Section 1). Both types of Prerequisite Programs are the foundation of food safety management and they must be developed, implemented, and documented before attempting to put a HACCP plan in place. *Specific Prerequisite Programs* which control hazards identified in specific processes are required to be identified in the HACCP plan as part of US FSMA regulation requirements.

2. **Hazard Analysis and Hazard Assessment.** This is an initial step in the development of a HACCP plan. The preliminary steps to HACCP development include: 1) assemble the HACCP team, 2) describe the food and its distribution, 3) identify the intended use and consumers 4) create a process flow diagram, 5) conduct an on-site verification of the flow diagram, and 6) conduct a hazard analysis. During the hazard analysis, the team should determine all potential biological, physical, and chemical (including radiological) hazards

that can exist in the raw materials and during the manufacturing stages of the product. Once the hazards are identified, they are assessed for severity and likelihood of occurrence using the *Hazard Evaluation Flow Chart*. The chart is designed to guide the team through the evaluation to determine if the hazard identified needs to be controlled by the HACCP system or by a Prerequisite Program. Once the hazards to be controlled within the HACCP system have been identified, the Critical Control Points (CCPs) to control the hazards must be determined. The team shall use the *Codex Decision Tree for CCP Determination* and the guidance provided in Section 2 for the determination of the point(s) in the process that should be managed as the CCP(s).

3. **Standard for Hazards Which May be Managed by CCP.** This section provides guidance to the team as to the type of hazards that can and should be addressed in a HACCP plan. It also provides some general rules as to which hazards shall be managed by CCPs.
   Appendix A: Mondelēz International Biologically Sensitive Ingredient Category List
   Appendix B: Mondelēz International Food Allergen Category List

4. **HACCP Plan Documentation Components,** the required documentation for the HACCP plan is described. A link to Mondelēz International HACCP Forms is provided in *Appendix C***.** The content of the forms is required; however, the use of the forms is optional.
   Appendix D: Model Critical Control Points and Prerequisite Programs

5. **HACCP System Verification/Validation/Reanalysis Procedures.** This section describes the verification process for determining that the HACCP plan is accurate.

6. **Packaging Suppliers.** Suppliers of packaging material (product-contact, labels, and labeled packaging materials) manufactured for Mondelēz International shall develop HACCP plans consistent with this standard. Additionally, more specific guidelines for Packaging Supplier are outlined on this chapter.
   Appendix E: Packaging Model Critical Control Points and Prerequisite Programs

For any questions on the content in this document, please contact your Mondelēz International contracting representative.

1. PREREQUISITE PROGRAMS

Prerequisite Programs are defined as the universal (PP) and specific (sPP) procedures used to control the conditions in the plant environment, which contribute to the overall safety of the product. Mondelēz International considers documented Prerequisite Programs as the foundation of food safety management. CCPs are not a stand-alone control but are part of a Food Safety plan consisting of PPs and CCPs. Prerequisite Programs must be developed, implemented, and documented before attempting to put a HACCP plan in place. Effective implementation of HACCP relies on adherence to Prerequisite Programs. If any portion of a Prerequisite Program is not adequately controlled, then additional CCPs may have to be managed until Prerequisite Programs are adequate.

Universal prerequisite programs (PP) are applicable to hazards identified across the manufacturing site. These PP are defined by the ISO Standard 22000:2005(E) as the basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption.

The following is a list of Universal Prerequisite Programs (PP) that typically applies to manufacturing facilities. The exact set of Prerequisite Programs needed will vary since their application is product and process specific, just like a HACCP plan. Therefore, the following list is meant to be informative and may include programs which are not needed in some situations and may not include programs which are needed in other situations.

Premises

a) Building Structure and Utility Systems
b) Outside Property
c) Water Quality Program (Treatment and Testing)
d) Building/Grounds Security

Receiving/Storage

a) Raw Material Management
b) Receiving/Storage/Distribution
c) Letters of Guarantee
d) Hold and Release
e) Truck/Carrier Inspection
f) Label review for accuracy (e.g. “Keep Refrigerated”, Cooking Instructions, Ingredient List-Allergen)

Personnel Training Program

a) Employee Hygiene/Employee Practices
b) HACCP/CCP specific training

Health and Safety Recalls

a) Hold and Release
b) Recall Procedures
c) Traceability/Code Dating

Equipment Performance and Maintenance

a) Preventative Maintenance
b) Equipment Calibration
c) Compressed Air Filtration
d) Equipment Design

General Quality Systems / Monitoring Programs / GMPs

a) Use of Approved Chemicals
b) Use of Approved Suppliers
c) Rework Practices
d) Residual Chemical Testing
e) Formulation
(e.g. excess restricted ingredient addition)
f) Post Cook Chilling
g) Post Cook Recontamination (Prevention of)
h) Mycotoxin Testing
i) Antibiotic/Residue Testing
j) Environmental Monitoring for Pathogens
k) Product Sequencing
l) Use of Approved Pathogen Testing Labs
m) Extraneous Detection/Removal Programs
n) Brine Programs (treatment & testing)

Sanitation

1) Pest Control
2) Equipment Cleaning
3) Packaging Line Clearance Procedures
4) Housekeeping
5) Period Cleaning

Specifications

a) Raw Material
b) Formulas
c) Manufacturing Procedures
d) Finished Product
e) Packaging
f) Labeling

Specific Prerequisite Programs (sPP) are applicable to hazards identified in specific processes at some manufacturing facilities. Such sPP are defined by the ISO Standard 22000:2005(E) as the programs essential in order to control the likelihood of introducing food safety hazards to and/or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment. These sPP could be managed as a CCP depending on the outcome of the Hazard Assessment. Under US FSMA regulations, sPPs are required to be identified if they control an identified hazard which is not controlled via a CCP.

a) The following is a list of sPP examples (not exhaustive): Addition of restricted additives or supplements that support a claim but cannot exceed prescribed levels and which is controlled by formulation management

b) High moisture material holding time/temperature prior to a heat step when interdictive cleaning avoid product build up or when it is controlled by formulation

c) Extraneous Matter Management: sieving (of ingredients, semi-finished and finished product), magnet, metal detectors, X-ray in case there is a serious of control steps established which are combined considered suitable to control the identified hazard

d) Glass breakage procedure in case there is a serious of steps established to control the glass hazard

Example of Specific Prerequisite Program templates can be found in Appendix D.

2. HAZARD ANALYSIS AND HAZARD ASSESSMENT

In HACCP, a "hazard" is defined as a biological, chemical (including radiological) or physical contaminant or condition which may cause the product to be unsafe for consumption. Product safety hazards of potential significance are identified by completing a hazard assessment. An initial step in the development of any HACCP plan is the Hazard Analysis**.** This assessment should be performed by a cross-functional team which may include experts in areas such as microbiology, toxicology, product/process development, quality, operations, as appropriate.

- For Mondelēz International developed formulas, company product developers shall provide the Hazard Analysis and a partial HACCP plan to the Supplier/EM. The Supplier/EM will complete and implement the plans.
- For products formulated by the Supplier/EM, the Supplier/EM shall utilize their experts to develop HACCP plans consistent with this standard. Mondelēz International Quality can provide technical assistance, if needed.

2.1 Preliminary steps:

The preliminary steps to HACCP development include: 1) assemble the HACCP team, 2) describe the food and its distribution, 3) identify the intended use and consumers, 4) construct a process flow diagram, and 5) perform an on-site verification of the flow diagram. Forms and documentation requirements for the Product Description (Form A) and the Flow Diagram (Form B) are available in *Appendix C*.

Note: The content of the form is required, the template itself is not a requirement and it is provided as an example.

2.2 Conduct a Hazard Analysis:

The next step in HACCP development is to conduct a Hazard Analysis. During the Hazard Analysis, the team should determine all potential biological, physical, and chemical hazards that can exist in the raw materials and during the manufacture of the product. The Hazard Analysis requires the evaluation of the raw materials (Form C), the process and adjacent environment (Form D), and an allergen assessment from the raw materials to finished product including cross-contact within the process (Form E-1 and E-2). Documentation requirements and forms are available in *Appendix C.* It is critical that the Hazard Analysis be scientifically based and well documented.

2.3 Complete a hazard assessment:

The next step is to complete a hazard assessment on the hazards that have been identified. The risk of each hazard must be assessed for its severity and for the likelihood of occurrence in order to determine the significance and the control mechanism.

2.4 Determine nature of identified hazard(s) and control mechanisms (CCP/PP):

A key concept in hazard assessment is the nature of the identified hazard. For example, is the adverse effect of the hazard a result of a single exposure (acute), or does it take multiple or chronic (*i.e.,* long-term or lifetime) exposures? Is it likely to lead to significant illness or injury in a relatively short time frame (minutes, hours or

days) or does it take much longer (months or years)? Is it likely that the hazard could be present in the specific product and pose a risk to public health? The answers to these questions will determine if the hazard will be managed by a CCP or by a Prerequisite Program. These are some of the considerations that should be kept in mind while performing the risk assessment which could be supported by using the *Hazard Evaluation Flow Chart* (see Section 2.6).

Pathogens, microbial toxins, some extraneous matter, and under certain circumstances, allergens are examples of potential hazards that tend to be viewed as having the following characteristics: acute illness/injury and occurrence of adverse effects within minutes/hours of ingestion. Therefore, they shall be managed with a CCP.

2.5 **Establish the Critical Control Points:**

After the Hazard Analysis and hazard assessment have been completed, the next step is to establish the Critical Control Points. A “critical control point” is a point at which control can and should be applied so that a product safety hazard is prevented, eliminated, or reduced to an acceptable level. A Critical Control Point (CCP) will be such, that the entire product will be exposed to the control mechanism and monitored. Finished product testing does not meet the CCP criteria; therefore, it is not a CCP. Finished product testing may be part of the CCP verification process. Use the *Codex Decision Tree* to establish the Critical Control Points for the process (see Section 2.7)

2.6 **Hazard Evaluation Flow Chart**

Before using the flow chart (Diagram 1), a Hazard Analysis shall be completed and potential hazards associated with the product/process shall be identified based on scientific evidence. For example, pathogens clearly are capable of causing harm based on scientific evidence. However, other concerns which are thought of as “hazards”, such as molds, yeasts, and certain food intolerances, are not known to cause harm based on scientific evidence and should be addressed in a Prerequisite Program. Diagram 2 is a decision tree for CCP determination.

Diagram 1 - Hazard Evaluation Flow Chart

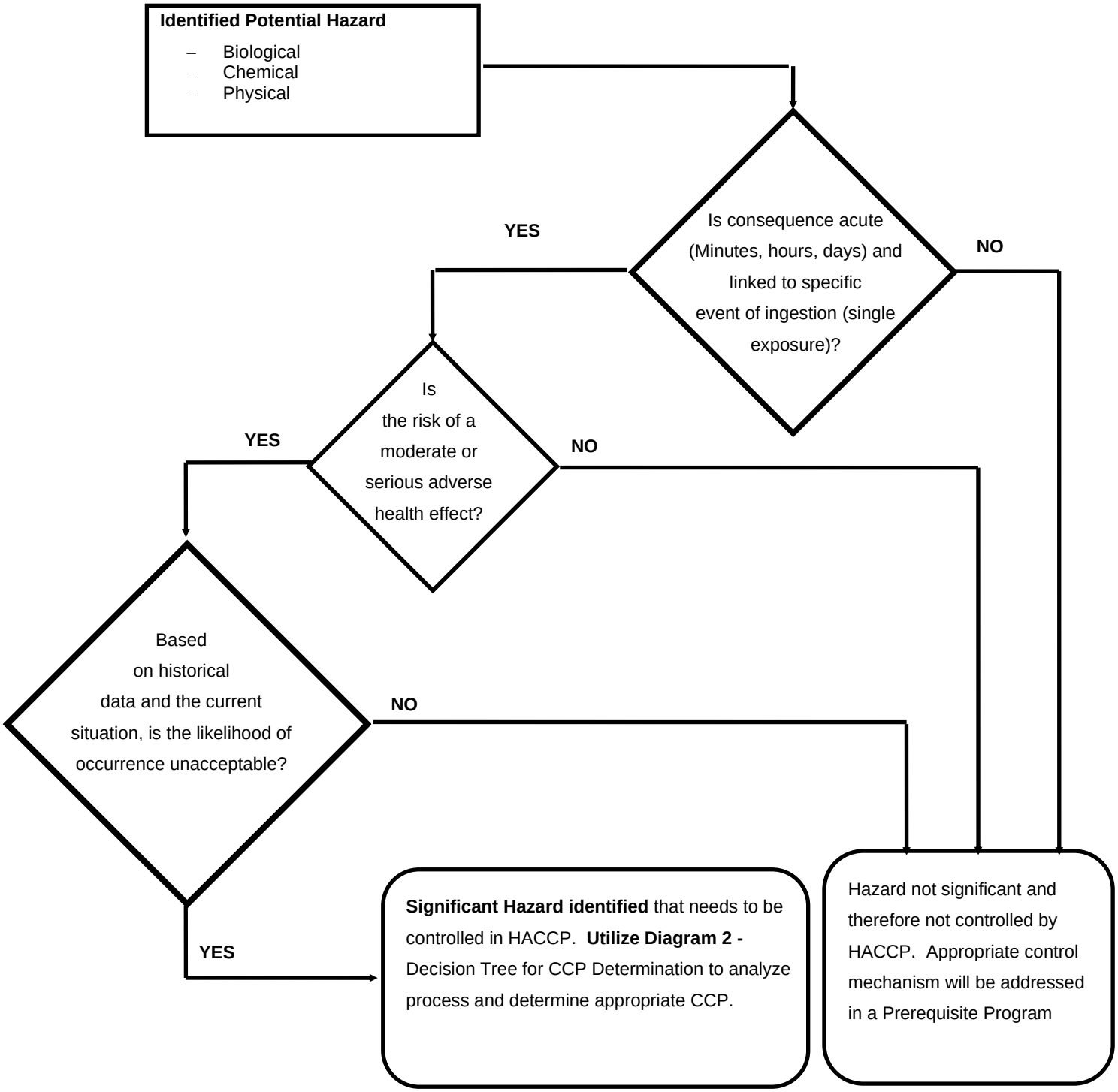
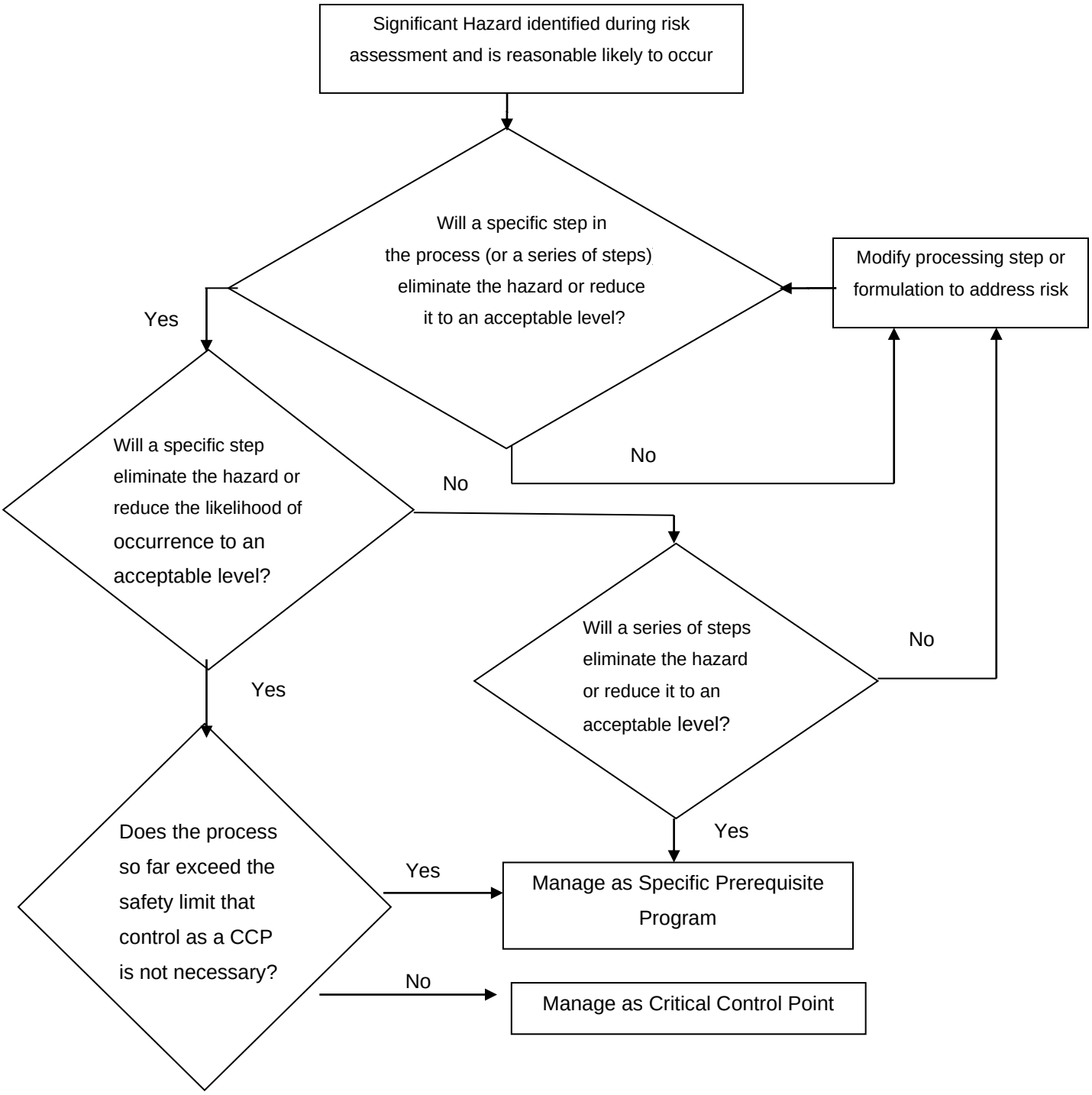


Diagram 2 – Decision Tree for CCP Determination



3. HAZARDS AND HAZARD MANAGEMENT CRITERIA

3.1 BIOLOGICAL - PATHOGENS AND MICROBIAL TOXINS

Pathogens and microbial toxins can represent a significant hazard in many foods. Many ingredients and finished products have the potential to contain pathogens or allow development of microbial toxins. Therefore, it is likely that inclusion of control mechanisms related to pathogens and microbial toxins will be an important component of many HACCP plans.

Pathogens are defined as microorganisms (bacteria, viruses, fungi) that cause, or can cause, disease. (Q&A, Liise-Anne Pirofski and Arturo Casadevall**;** *BMC Biology* 2012, 10:6) Such bacteria could also be called "bacterial hazards".

Microbial toxins are any poisonous substances produced by microorganisms (bacteria, fungi). Two general types are common: those formed within the cell (endotoxins) and those formed within the cell and excreted (exotoxins) (Mosby's Dental Dictionary, 2nd edition). Some microorganisms build toxins at certain growth stages in food. Although the food may be subject to a later treatment where the microorganisms are killed, the toxin can remain in the food and cause poisoning when eaten. Common examples are *Staphylococcus aureus* toxins, mycotoxins.

3.1.1 Biological Hazard and Hazard Assessment Matrix

For the biological hazards, the risk evaluation is performed by assessing the "probability of occurrence" of the presence of pathogens and/or their toxins in the specific ingredient or process being assessed and then assessing the severity posed by the presence of the pathogen(s) and/or toxin(s) of concern. Once these evaluations are complete, the significance of the identified hazard is determined. Finally, based on the significance score, the appropriate control mechanisms are identified to ensure the safety of finished products.

Most recent publication by the International Commission on Microbiological Specifications for Foods, ICMSF, Microorganisms in Foods, 7: microbiological testing in food safety management (2002).

Severity definitions:

Severity	Definition	Examples
	Indicator - An organism itself non-pathogenic, but often associated with pathogens. Includes groups or species of organisms whose presence in a food reveals exposure to conditions that might introduce hazardous organisms and/or allow their growth. As such, these are used as indirect indicators of a health hazard.	athogenic microorganisms;
	ate hazard - Pathogens (or their toxins) causing short-term disease not critically severe in its manifestations but can cause severe discomfort, is self-limiting and normally without sequelae	Staphylococcal enterotoxins and *Bacillus cereus* toxins.
	s/severe hazards - Pathogens (or their toxins) causing serious/severe disease, either in a healthy population or in a particularly susceptible group. Effects are of moderate or long duration, with severe hazards sometimes causing life-threatening disease.	*lla* spp., *Clostridium botulinum* (outgrowth and toxin formation), Enterohemorrhagic *Escherichia coli., Salmonella* spp., *Listeria monocytogenes*

Probability of occurrence definition:

Probability	Definition
	tory of pathogen presence or bacterial toxin(s) at harmful levels in this raw material, associated process or product
	d incidents of pathogen presence or source of bacterial toxin(s) at harmful levels. Potential concern as emerging pathogen for this raw material, process or product
	historical presence of pathogen or bacterial toxin(s) at harmful levels in this raw material, process or product. This includes ingredients in the sensitive categories

Severity Definitions

Severity Level 1: Class 1 - indicator. Historically, an organism itself non-pathogenic, but often associated with pathogens, used to portray a risk of the presence of pathogens for which feasible methods of detection were not generally available (sometimes called 'index organisms').This usage is currently expanded to denote groups or species of organisms whose presence in a food reveals exposure to conditions that might introduce hazardous organisms and/or allow their growth. Specific indicators are now used to reveal excessively contaminated raw materials; unsanitary manufacturing practice; contamination from fecal, nasopharyngeal, or suppurative sources; unsuitable time-temperature conditions of storage; or failure of a process.

Severity Level 2: Class 2 - moderate hazard. The hazard associated with ingestion of a food containing a pathogen or toxin which can cause a short-term disease not critically severe in its manifestations and normally without sequelae: for example staphylococcal food-poisoning.

Severity Level 3: Class 3 - severe hazard. The hazard associated with the presence of a pathogen or toxin in a food which when ingested is likely to cause severe disease, either in a healthy population or in a particularly susceptible group to which the food in question is often destined. Severity of hazard is largely determined by clinical severity of the disease induced. Pathogens of concern in this category include *Brucella* spp., *Clostridium botulinum* (outgrowth and toxin formation), and Enterohemorrhagic *Escherichia coli*. For the purposes of this matrix – both *Salmonella* and *Listeria monocytogenes* are considered class 3 organisms.

Probability of Occurrence (PO) (Likelihood) for Biological Hazards

Biologically Sensitive ingredient categories have been identified by Mondelez International as categories of ingredients which are likely to contain pathogens based on origin, historical and epidemiological data (see Appendix A). As an example: For ingredients in the sensitive categories, the probability of occurrence score should be 3.

3.1.2 ***Control and Monitoring Mechanisms for Biological Hazards (CCPs and sPP):***

Pathogen control is very product and process specific. A microbiologist must be involved during the biological portion of the hazard analysis and risk assessment step of HACCP plan development. In general, pathogen-free sensitive ingredients (reference *Appendix A*, *Mondelēz International Biologically Sensitive Ingredient Category List*), product formulation, and process steps that are specifically designed and intended to control pathogens in the finished product will be managed as CCPs. Some general standards for pathogen control are presented below.

- **Certificate of analysis (COA) Monitoring** or an EM or supplier generated test result indicating non-detectable pathogens will only be managed as a Specific Prerequisite Program (sPP) when the ingredient is used in a product with no lethal process step or when added after the lethal process step. A COA can also be managed as a part of a program including zoning and other controls, when its intended purpose is for the management of potential environmental cross-contamination within a facility (*e.g.,* sensitive ingredients for a process containing a kill step stored with those for a process that manages the COA as a sPP because there is no kill step).

- ***Thermal Processes:*** Products that are heat processed to control pathogens shall have a CCP for the heat process step. For batch processes, monitoring includes checking product temperature in the known coldest location or checking time and temperature of the process. For continuous processes, monitoring includes the time and temperature(s) of the process. Whenever possible, a process should be monitored continuously.

- ***Fermentation:*** Products that are fermented to control pathogens shall have a CCP for the measurement of acid development, e.g. pH of the product.

- ***Formulation:*** When product formulation is the primary control for pathogens, it shall be managed as a CCP(s). Examples include addition of acid, batch pH, addition of moisture, or water activity. Formulation can also serve as a secondary barrier for refrigerated foods. Secondary barriers may include pH, water activity, or the addition of nitrite. A secondary barrier is used to prevent spore germination and subsequent toxin production in the event that refrigeration, the primary barrier, fails.

- ***Drying:*** Products that are dried to control pathogens shall have a CCP for water activity (Aw) or moisture level. Low moisture foods, by their inherent nature, may not present a microbiological risk and therefore no CCP is necessary. If the formulation is close to a critical limit, the addition of ingredients may be a CCP and water activity measurement a verification of that activity.

  Holding Time/Temperature: Products that have an intermediate processing step that uses time/temperature relationship to prevent pathogen growth and toxin formation will have holding time/temperature as a CCP. For processes that include holding or storage times for high Aw material, growth potential of *Staphylococcus aureus* (as outlined in Model CCP: High Moisture Material Holding Time/Temperature Prior to Heat Step; Appendix D) and sporeformers has to be considered. For some cases where the model is applied, no additional control for sporeformers may be necessary, since the potential outgrowth of sporeformers may be covered with the application of that CCP. For other cases, the potential for sporeformer outgrowth for materials with an Aw of >0.91 and a pH-range of >4.6 and <9.0 shall need to be evaluated by the respective Mondelēz International regional microbiologists. The results of this evaluation shall be documented and covered in Form D (process evaluation) of the respective HACCP plans.

- ***Cool Down:*** For products that are susceptible to spore germination and are exposed to extended cooling, the cooling time/temperature may be a CCP.

3.2 CHEMICAL

Chemical hazards, including radiological hazards, to foods are commonly considered as unintended contaminants, but a list of chemicals may include literally any conceivable constituent within the environment. Pesticides, mycotoxins, radiological hazards, and heavy metals are common types of chemical hazards. The criteria for considering potential chemical hazards may include:

1) Source or origin of food or ingredient, including geographical location, since origin may affect occurrence and prevalence of contaminants, *e.g.,* mycotoxins
2) Method of manufacture or processing
3) Specification and Certificate of Analysis
4) Historical occurrence
5) Scientific judgment which may be influenced by prevailing events or circumstances

3.2.1 Chemical Hazard and Hazard Assessment Matrix

The accurate risk assessment of chemical hazards is a critical step in establishing effective control measures to minimize the risk of their occurrence. Chemical hazards can either be classified as ‘chronic’ or ‘acute’ hazards depending on the toxicity of the chemicals in question.

- Acute toxicity describes the adverse effects of a substance that result either from a single exposure or from multiple exposures in a short space of time (usually less than 24 hours). Chronic toxicity describes the adverse health effects from repeated exposures, often at lower levels, to a substance over a longer time period (months or years).
- The other factor to consider in the assessment of chemical hazards is the concentration of the contaminant which is referred to in toxicological terms as the “dose”. *i.e.,* low level dose of mycotoxins is less severe with chronic toxicity over long period of time vs. high level dose, which is more severe potentially resulting in acute toxicity.
- A chemical hazard assessment combines an assessment of ‘severity’ (chronic vs acute) against probability of occurrence (concentration itself and dose level). When assessing the risks associated with a global supply chain consideration needs also to be given to age to consumer (baby vs. adult), different global agricultural practices, the regulatory framework (*e.g.,* regulations on specific crop treatments or veterinary medicines) as well as differences in consumptions patterns.
- Chronic hazards could be managed by prerequisite programs (PP, sPP) and acute hazards by either CCPs or sPPs.
- Evaluations and controls of radiological hazards and hazards introduced intentionally should be reviewed and documented.

Severity -> Probability of Occurrence (PO)	No or Low Direct Health Hazard (Chronic, below established Mdlz Int. review limits) 1	Moderate (Chronic, above established Mdlz Int. review limits or dose) 2	Serious & Severe hazards (Acute) 3
No history of presence in this raw material or associated with this process step 1	1	2	3
Isolated incidents or potential concern as emerging chemical for this raw material or process 2	2	4	6
Known historical presence in this raw material or process 3	3	6	9

Significant Hazard: 1 - 3 = No: Controlled by (universal) pre-requisite programs (MMP, Supplier Qualifications, Specification, GMPs, Sanitation, Warehouse Good Practices, etc.)

Significant Hazard: 4 – 9 = Yes : Controlled via internal CCP, sPP, or series of sPP programs (Allergen labeling, Allergen Rework Handling, Allergen Cleaning, Materials and Tools Segregation, Allergen Flushing, Production Sequence, Formulation, Baking, etc)

Severity of chemical hazards

The Chemical Hazard Matrix can be used as guidance to assess the severity posed by the potential presence of a chemical contaminant. The key driver for the evaluation of severity is the assessment of the identified hazards being either chronic or acute.

Appendix B provides categories of food allergens that have been identified by Mondelēz International as categories of allergens which have either global or regional prevalence to trigger an immune-mediated reaction which could, in extreme circumstances, be life threatening (anaphylaxis). Those allergens are considered to cause serious and severe health concerns and typically result in an acute reaction. Therefore severity is rated as a 3.

Ingredients that are sources of Materials associated with food Sensitivity or Intolerance **(**MSI): Symptoms associated with these materials are not generally considered as acute health hazards as caused by “true” food allergens. They are therefore classified as moderate to low direct health hazard and are normally linked to chronic diseases and are typically rated with a severity of 1 or 2.

Chemical hazards other than allergens such as pesticides, heavy metals, veterinary residues, dioxins, etc., are normally below established company limits and therefore would have no or low direct health hazards and severity is typically rated as 1.

The Acrylamide (AA) hazard has not been defined being an acute health concern and there is not conclusive clinical data to suggest that a reaction is related to a specific event of ingestion. It is rather considered to be a long-term health risk over the life cycle of a consumer. The health significance of acrylamide in food has not been determined and there is no agreed level at which health effects are detected. Therefore severity is typically rated as 1 and considered a low direct health hazard.

Probability of Occurrence (PO) (Likelihood) for chemical hazards

Categories of food allergens (global and regional) are included in Appendix B. As an example: For ingredients which are an allergen source, the probability of occurrence is 3. For ingredients that are a source of MSI (material which cause sensitivity and intolerance), the probability of occurrence score varies between 2 and 3 depending on the nature of the raw material and the concentration of the MSI. For chemical hazards other than allergens and MSIs the PO is rated either 1 or 2.

3.2.2 ***Importance of Controlling Food Allergens:***

Foremost, it should be realized that those foods implicated in allergies are inherently safe and wholesome foods or food ingredients, but pose a health risk to certain sensitive individuals. The *Mondelēz International Food Allergen Category List* (*Appendix B)* consists of those foods, or food ingredients, that are known to produce severe, life-threatening reactions in sensitive individuals. A true allergic reaction involves the sensitive individual's immune system, and basically constitutes an immune response to a foreign protein. A small amount of food protein (*i.e.,* the allergen) enters the blood stream and elicits a reaction with certain immune system components (*i.e.,* IgE immunoglobulins) and initiates the allergic response. The exact amount or level of these allergens necessary to elicit a serious reaction can vary in sensitive individuals, but is believed to be extremely small (possibly in milligram quantities or less) in those subpopulations that are exquisitely sensitive.

Non-immunological reactions and non-IgE mediated immunological reactions to foods, also known as a Food Intolerance or Sensitivity, are generally less severe but have been associated, in some instances with severe reactions or chronic illness. An example of a severe reaction is sulfite-induced asthma and an example of a chronic illness is Coeliac Disease (an autoimmune enteropathy).

Prevalence of Food Hypersensitivities

The exact prevalence of reactions to each of the allergens is unknown, but the prevalence of all true food allergies has been estimated globally to be about 3-4% of the population. Children tend to have a greater prevalence of allergic reactions (about 4-8%), but some of these may disappear with age (e.g. milk allergies). The number of allergic individuals who are exquisitely sensitive to a particular allergen is unknown.

3.2.2 ***Criteria for Allergens List***

While it is generally believed that nearly every food or food ingredient could potentially cause an adverse reaction in at least one individual, there are just a small group of substances that are known to cause severe life-threatening reactions to a significant degree in the global food-allergic population.

. The criteria used to delineate these substances are as follows:

- Food Allergic Reaction is proven to be through an IgE–mediated mechanism,
- Confirmed by Double Blind Placebo Controlled Food Challenge Studies,
- Prevalence rate in the range of Food Allergens as defined by Codex Alimentarius (1996, Report of

the FAO technical consultation of food allergies),

- Documented cases severe and/or life threatening reactions in credible scientific and/or medical publications,
- High potency (low levels documented in credible scientific and/or medical publications) to provoke severe reactions,
- Other factors: High prevalence of severe and/or life threatening cross-reactivity documented in credible scientific and/or medical publications to provoke severe reactions to substances residing in the *Mondelēz International Food Allergen Category List*.

If any of these criteria are not met with any degree of certainty, then inclusion on the list can be based on the scientific judgment of at least two (2) independent, recognized scientists and based on an assessment of the relevant scientific data on the life-threatening potential of a food or ingredient.
The list of these substances is not expected to change significantly, but additions or deletions could be made as more evidence becomes available.

3.2.3 ***Use of the List: Appendix B***

Food allergy is a very complex subject, and the information included here should not be considered as comprehensive. The list in *Appendix B* shall be used to identify foods and food ingredients which may present a hazard to sensitive individuals. During the development of a HACCP plan, it is recommended that an individual with appropriate experience and expertise in food allergen management be included as a part of the cross-functional team

In addition to the Mondelēz International Global Food Allergen Category List, the supplier/EM has to consider the following:

- A number of countries or geo-political regions have enacted regulatory requirements for the label declaration of specified foods deemed to be food allergens. The local regulatory requirements of the country of manufacture and distribution of Mondelēz International products must be strictly followed. When ingredients that are not included in or exempted from the *Mondelēz International Food Allergen Category List* are utilized in products commercialized in countries and/or regions that have defined regulatory requirements for their labeling, these ingredients must be appropriately identified to meet the applicable labeling requirements.
- Mondelēz International maintains a list of food allergens associated with documented regional occurrence of allergic reactions or local regulatory allergen control expectations. These allergens are listed in *Appendix B* of this document.
- **Sulfiting ingredients** such as sodium metabisulfite have historically been associated with food allergens. However, these ingredients are not food allergens and generally have regulatory requirements to be included in an ingredient line when the product contains greater than 10 ppm of added sulfites. Additionally, efforts must be taken in the manufacturing setting to ensure that products containing greater than 10 ppm added sulfites do not cause other products produced in the same facility or on shared equipment to exceed the 10 ppm labeling requirement.

For further information regarding the *Appendix B* or its application, please contact your regional Mondelēz International representative.

*3.2.4 **CCPs and sPPs for Allergens***

The following activities generally require mechanisms for the control of allergens. They may be designated as CCPs or PPs depending on the findings of the Hazard Analysis:

- *Rework Handling*
- *Labeling Application*
- *Equipment Cleaning (Product Changeover)*
- *Product Flushing (Product Changeover)*
- *Packaging Line Changeover*

Select CCP models are included in Appendix D.

- **Rework Handling:** Allergen containing rework or holdover product used as an ingredient has only to be used in products which contain the same allergen as an ingredient that is declared on the package ingredient line (*i.e.,* like into like). It shall not be used in products where the allergen is declared on the package as a result of manufacturing cross contact.
- **Label Application:** Undeclared allergens/sulfites can result from applying the wrong label on the finished product due to similar label appearance. Therefore, documentation would be required to assure that the product packaging/labeling is correct for the formula being produced.
- **Product Changeover (Equipment Cleaning /Product Flushing):** Removal of allergen containing material after producing the allergen containing product prior to producing the non-allergen containing product through activities such as cleaning, flushing, and inspection. Printed packaging material must also be removed from the packaging line to prevent potential for mislabeled products/unlabeled allergens.
- **Packaging Line Changeover:** Removal of labeled packaging material from packaging equipment and the immediate production area and thorough inspection of equipment (prior to running a product containing an allergen) to prevent potential for a product containing an allergen to be packed in a package not labeled for that allergen**.**

Declaration Exemptions

- There are few worldwide exceptions to the Food Allergen Category List (Appendix B). Additional exceptions, including those involving cross contact, will be handled on a case-by-case basis, and will be determined by Mondelēz International.

*3.2.5 **Additional Controls for Allergen Management***

- **Product Sequencing:** When possible an allergen-containing product must never be followed by a product that does not contain an allergen. By scheduling the allergen-containing product at the end of the manufacturing run, the risk of cross-contamination can be significantly reduced.

- **Traffic Patterns:** The movement of raw material and ingredients can become a primary source of cross-contamination. Controls may include covering belts that transport materials to prevent allergen-containing ingredients from falling from one belt to another.
- **Ingredient Assessment:** The ingredient specification should include a statement that the ingredient being purchased is free of foreign material, including allergens that are not listed on the ingredient declaration. It is important to confirm that there are no unlabeled allergens in these ingredients. Close cooperation and communication with suppliers is essential.

3.3 PHYSICAL: EXTRANEOUS MATTER

Pieces of glass, metal, hard plastic, etc. are potential physical hazards. Extraneous matter does not usually present a significant risk of a severe adverse health effect, potentially causing only minor injuries with typical limited exposure. Extraneous matter is best controlled by Prerequisite Programs such as supplier selection and approval, preventative maintenance, etc. However, in some cases, the characteristics (size, shape and type) of the extraneous matter may potentially cause serious harm. On that basis, some extraneous management controls including detection/removal devices may be managed as specific Prerequisite Programs and/or CCPs.

*3.3.1 **Definition***

In general, extraneous matter is defined as any object/material that may become part of the product being produced that is not designed to be a part of such product. Relative to HACCP, extraneous matter pertains to objects that may potentially cause serious harm during consumption of the product. Typically these objects will be hard or sharp in nature.

Foreign Material Hazard Assessment Matrix

The Foreign Material Hazard Assessment Matrix is a tool for guidance through the physical risk assessment process. Hazard is assessed by the following calculation:

Hazard = Severity (S) x Probability of Occurrence (PO)

There are 3 levels of Severity identified to be used for the calculation:

Severity level 1: No physical discomfort or health issue
Examples include, but are not limited to:
Soft plastic, cardboard, insects, metal dust, hair, finger nails

Severity level 2: Could cause consumers discomfort and/or which can be considered to be present due to the nature of the raw material
Examples include, but are not limited to:
Hard parts from plants, metallic flow wrap pieces, stones

or pits from cherries or cucumbers, bones from meat or chicken, cap stems and stalks in dried fruit (i.e. raisins)

Severity level 3: Could cause consumers injury because of its hardness, sharpness, size, or shape.
Examples include, but are not limited to:
Glass without any exception, metal, stone, hard plastic, and wood of a sharp/irregular shape and/or of a hazardous size (choke hazard and/or > 5 mm)

There are 3 levels of Probability of Occurrence (PO) to be used for the calculation:

PO level 1: *Rare defect*
Contamination not exceeding specification values, has never happened in the factory history or happened once by accident, the frequency is not measurable, and/or:
Consensus of the HACCP team is for a null probability of occurrence

PO level 2 *Frequent defect annual to monthly*
Contamination exceeds specification level, it has happened recurrently but spaced, the frequency is measurable, and/or:
Consensus of the HACCP team is for a significant probability of occurrence, considering produced volume

PO level 3: *Recurrent defect monthly to weekly*
Contamination exceeds specification level, it has happened recurrently and more often (weekly), the frequency is measurable, and/or: Consensus of the HACCP team is for a high probability of occurrence, considering produced volume

Hazard / Severity	1	2	3
PO (plant) 1	1	2	3
2	2	4	6
3	3	6	9

Hazard is considered as significant 4-9= yes: Management by specific Prerequisite Program (and/or combination of sPPs) or by CCP

Hazard is considered as not significant:1-3= No Management by universal Prerequisite Programs

CCPs and PPs for Physical Hazards

CCPs models are located in Appendix D.

Some examples for extraneous matter control are presented below.

Glass Breakage Clean-up

The PP for glass packaging is the cleanup of glass post package prior to package capping, (if a detection / removal device for glass is not on the line). The inspection of the cleaning process must be documented.

3.3.2 ***Management as a CCP or Prerequisite Programs (PP or sPP)***

When the *Hazard Evaluation Flow Chart* identifies the need to control the potential physical hazard posed by extraneous matter in HACCP, the following criteria establishes the CCP(s) or PP/ sPP:

- The PP for glass packaging is the clean-up of glass (following a breakage incident), post filling (or after the glass cleaner/inverter), prior to package capping, if a detection/removal device for glass is not on the line. The inspection of the cleaning process must be documented. In addition, glass filling lines must have covered conveyors over exposed open jars after the jar cleaner/inverter (prior to filling and capping) to minimize potential for extraneous glass falling into an open jar.
- An extraneous detection/removal device that is present on a line/process is a CCP if its primary purpose is to prevent, eliminate, or reduce hazardous extraneous matter in the product and it is the last and/or most effective extraneous detection/removal device on that line/process.
- In some cases, more than one extraneous detection/removal device on a line/process may be managed as a CCP if the devices are effective for removing different types of extraneous matter
- Extraneous removal/detection devices may include:

- *Density Detectors*
- *De-stoners*
- *Magnets*
- *Metal Detectors*
- *Filters*
- *Screens*
- *Sieves*
- *Strainers*
- *Vision Systems*
- *X-Rays*

4. HACCP PLAN DOCUMENTATION COMPONENTS

documentation forms are provided in *Appendix C*. The content of the forms is required; however, the format of the forms is optional. HACCP Plan documentation should include a **Product Description, Process Flow Diagram, Hazard Analysis, CCP Documentation, Document Index, Plant Layout and Product Category HACCP Plan Cross Reference Index.** For document control reasons, all pages of the HACCP plan should be dated with the issue date, supersedes date, page number, and a plan identification name or number.

4.1 Product Description (Form A)

Describes the end products covered by this HACCP plan. The information contained in the product description is the starting point for the hazard analysis. Recommended information included in a Product Description: product/ product Category, process, food safety characteristics, intended market, customer/consumer use, labeling/label instructions, packaging, shelf life and storage & distribution .

4.2 Process Flow Diagram (Form B)

The flow diagram shows graphically all processing steps from raw material receiving to finished product storage which are directly under the control of the manufacturing facility. Recommended information included on a Process Flow Diagram:

- Raw material receiving & storage
- Addition of ingredients, pre-mix, intermediate product
- Use of air or other gases
- Animal Feed Waste Streams Filters, screens, metal and magnet detectors
- Process equipment (e.g. heat exchangers)
- Tanks and continuous systems (e.g. mix, balance, surge, buffer, cook, fill, cool)
- Filling and packaging equipment
- Recirculation, overflow (e.g. immediately returned to process)
- Rework, holdover, reclaim (e.g. material not immediately returned to process - stored material)
- Storage
- Numbered Critical Control Points (CCPs) and sPP shown at identified process steps
    - CCPs can only be numbered after CCP Documentation (Form G) is completed.
    - CCPs for different Hazard categories shall be separate.
- Block diagram format is the minimum requirement. Graphics are acceptable

A process flow diagram typically does not show information related to quality aspects such as pH, color, etc.

4.3 Information included in a Hazard Analysis

4.3.1 Ingredient/Packaging Assessment (Form C)

This is to assess ingredients, ingredient packaging materials, rework or finished product contact packaging materials in order to identify the probability of occurrence and the severity of potential biological, chemical (including radiological), and physical hazards, as well as hazards that are

intentionally introduced for purposes of economic gain. To determine the control mechanisms for the hazards identified as significant. To evaluate and control radiological hazards and hazards introduced intentionally for the purposes of economic gain.
List the raw material number and the ingredient name. The ingredient list shall include all raw materials, processing aids, rework, holdover, and packaging materials in direct contact with finished product, or non-product-contact materials that will become product-contact materials in normal course of use by the consumer (*i.e.,* re-sealable lids for multiple-use containers, drinking straws for RTD pouches, eating utensils built into lidding material) must be included in this list as well. Fully describe the name or type of material, for example, starch is corn starch. List carriers for flavors, for example: lactose; propylene glycol; ethyl alcohol; corn maltodextrin; salt; refined, bleached, and deodorized cottonseed oil.

List the storage condition, for example, A=ambient, R=refrigerated, F=frozen. Determine if the hazard is significant or not and enter “Yes” or “No” for each type of hazard (Biological, Chemical, and Physical) in the Significant Hazard column. In case a numeric matrix is used enter the score for PO x Severity in addition to “Yes” or “No”.
If no potential hazard exists, list “None” for the potential hazard and “None” for the Significance. For numeric assessments, list “none” for potential hazards if these do not exist and in the Hazard evaluation column for Severity and Probability of Occurrence state each time “1”, which results also in “1-None” for the Significance.
Describe the rationale behind the decision for each hazard, and determine the control mechanism(s). Determine if the control mechanism(s) shall be a Critical Control Point (CCP) or specific Prerequisite Program (sPP).
Note 1: DO NOT LEAVE ANY SECTIONS BLANK. List “None” or “NA” (not applicable) if appropriate and avoid the use of acronyms (*e.g.,* CMC is carboxymethyl cellulose).
Note 2: Hazard assessments should also consider regulatory requirements (*e.g.,* soya lecithin could be considered in Form C)

*4.3.2 **Processing Step Evaluation (Form D)***

This is to identify biological, chemical (including radiological), and/or physical hazards that may be introduced from the process and/or processing environment, and to determine the control mechanisms for the identified hazards. To evaluate and control radiological hazards and hazards introduced intentionally.

While referencing the process flow diagram, (Form B), list all processing steps from raw material receiving to finished product storage. For consistency, it is recommended to use the same step name and-numbers in Form D and the flow diagram. For example, list the step of the addition of ingredients, rework, direct steam, cooking, grinding, slicing, shredding, hydrating, mixing, etc. Assess for biological, chemical, and physical contamination potential for each step. Considerations should include:

- Steps that holds slurries where composition, time and temperature could result in staphylococcal enterotoxin formation

- Environmental facts such as areas/equipment where ingredients, products, or rework are exposed to potential extraneous matter contamination
- Double jackets where a potential leakage could contaminate the product stream

Determine if the hazard is significant or not and enter “Yes” or “No” for each type of hazard (Biological, Chemical, and Physical) in the Significant Hazard column. In case a numeric matrix is used enter the score for PO x Severity in addition to “Yes” or “No”.
If no potential hazard exists, list “None” for the potential hazard and “None” for the Significance. For numeric assessments, list “none” for potential hazards if these do not exist and in the Hazard evaluation column for Severity and Probability of Occurrence state each time “1”, which results also in “1-None” for the Significance.
Describe the rationale behind the decision for each hazard, and determine the control mechanisms. Determine whether the control mechanism(s) shall be a Critical Control Point (CCP) or Specific Prerequisite Program (sPP).

Note: DO NOT LEAVE ANY SECTIONS BLANK. List “None” or “NA” (not applicable) if appropriate.

4.3.3 ***Allergen Cross-contamination Product Assessment (Form E-1 & E-2)***

This is to identify whether the product(s) being assessed can introduce undeclared allergens / sulfites into other products currently run on the manufacturing line -OR - whether products currently run on the manufacturing line can introduce undeclared allergens / sulfites into the product(s) being assessed. Identify or describe the control mechanism to manage the allergen / sulfite. Determine whether the control mechanism(s) shall be a Critical Control Point (CCP) or Specific Prerequisite Program (sPP).
Note: Full Allergen Assessment consists of content Forms E-1 (raw material assessment) and E-2 (allergen line assessment).

4.3.4 ***Product/Process Hazard Evaluation Summary (Form F)***

It provides a summary of identified hazards, control mechanisms, identification of the CCP and sPP model(s), and an overview of hazard management.
Note: If control mechanisms have been determined for all identified hazards and documented in Forms C, D, and E, then the content of Form F is optional.

4.4 **CCP Documentation (Form G)**

This is to define food safety limits and monitoring and corrective action requirements. The procedures in the CCP / Preventive Control documentation need to be clear and complete. Detail is important to assure a properly functioning HACCP system. Information included in CCP / Preventive Control documentation:

- CCP or sPP number and description of the step in the process
- Hazard which is being controlled. This can be either generic or specific terms depending on the CCP or sPP
- Control Mechanism (CCP)
- Specific Prerequisite Program (sPP)
- Critical Limits for control of the hazard
- Monitoring (method, frequency, who, what, where, when)

- Corrective action plan(s) (method, who) - identify product & disposition; identify & eliminate cause; restore control of the process; prevent recurrence
- Record and its location (monitoring, corrective action, and verification records)
- Minimum CCP/sPP verification activity (includes records review)
- Scientific basis for critical limit

For Mondelēz International developed formulas, a company product developer will provide to the supplier a partial HACCP plan. A partial plan shall include Forms A - F and the required/ recommended CCP provided in Form G. Examples of CCP documentation are provided in *Appendix D* and *Appendix E.*

4.5 **HACCP Documentation Index (Form H)**

Identifies the products covered by the HACCP plan. It also provides documentation of final approval to assure that the HACCP Plan was developed using a cross-functional team approach and complies with the HACCP Standard.

Recommended information included on a Document Index:

- Plant name, location, address
- Product(s)/Process covered - Name of the product and/or process is required
- Plan author and team members

4.6 **Plant Layout (Form J)**

To assess both microbiological and allergen (where applicable) cross-contamination potential between processing areas and identify Prerequisite Programs to manage and prevent cross-contamination.

- Microbiological assessment:
  - Consult the “Zoning Principles for Prevention of Cross Contamination” with a Mondelēz International microbiologist for more information.
- Allergen assessment:
  - Each area or line shall be assessed and potential sources of allergen cross contact shall be documented. Indicate product areas/lines on Form J if the ingredient assessment for each line (Form E1) shows that potential allergen cross contact may occur.
  - An allergen cross- contact assessment per manufacturing line shall be done using Form E2 based on the results of the Allergen Controls Checklist.

Note: Food Drink Europe provides a good reference to an allergen control checklist: http://www.fooddrinkeurope.eu/uploads/publications_documents/Guidance_on_Food_Allergen_Management.pdf

4.7 **Product Category HACCP Plan Cross Reference Index (Form K)**

It should be clear in documentation that a formula is covered by a HACCP plan. The manufacturing plant could maintain an index of all HACCP Plans cross-reference to formula numbers.

5. HACCP SYSTEM VERIFICATION AND VALIDATION PROCEDURES

5.1 HACCP System Verification

Verification consists of periodic activities, in addition to monitoring that evaluate that the HACCP System is operating in compliance with the requirements identified during the validation and that they are according to the HACCP Plan documentation and procedures. The Codex Alimentarius definition of HACCP verification is the following: “The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP Plan”.

The question we want to answer is: ***Are we doing what we planned to do?***

Please note that only the verification of the Prerequisite Program related to food safety and therefore included in the HACCP Plans belongs to the HACCP System Verification activities.

5.1.1 *1st level: Individual CCP Verification activities (and PP included in the HACCP Plan)*

These are the CCP Verification activities as described in the individual CCP Models (*Appendix D*) under the “Minimum CCP Verification activities” section. These verification activities are generally performed by a trained line supervisor.

CCP verification consists of activities which evaluate that on a day to day basis the CCP requirements in the HACCP Plan are being executed as per Plan. CCP records must be kept and must comply with the CCP requirements (CCP limits) or documented corrective actions taken and verified to be effective. Frequency is generally daily. CCP Verification activities would include (but are not limited to):

- Daily review of monitoring records (process parameters) to see if the CCP requirements in the HACCP Plan are being met (according to CCP Model requirements) *e.g.,* time, temperature, pH, Aw.
- Daily review of the equipment functionalities checks *e.g.,* divert valve “cut in”, “cut out”; metal detector; pressure differential checks (according to CCP Model requirements).
- Checking that the calibration has been done at the required frequency for the equipment used to monitor CCPs and PPs process parameters. For critical measurement devices frequency of calibration is 6 month as a minimum.
- Review of corrective action activities, follow up and close out in cases where deviations occurred. When a deviation occurs corrective actions must be taken as soon as feasible. This may be verified both by the supervisor on the same day (1st level), and later on (3rd level verification).

Review of records also involves checking for approval, presence of signature and date.

5.1.2 *2nd level: HACCP System Verification activities*

These activities are performed annually by the plant’s HACCP team and the plant’s internal audits. The objective of this verification is to review records over weeks or months to identify trends and root cause issues and to confirm that the plant still follows the requirements identified during the validation. It also verifies that the plant HACCP plans are current, thus all produces products are covered and grandfathered products are removed.

An annual HACCP System Verification is required as minimum. HACCP System Verification activities are the responsibility of the HACCP Team. Internal plant Quality Audits, or any other internal activity which involves reviewing the HACCP system, can also form part of the HACCP System Verification activities.

Note: Information gathered from the verification of the HACCP System might be used to decide that changes need to be made to the HACCP Plan which will have to be validated and the HACCP Plans consequently re-approved.

5.1.3 ***3rd level: HACCP Systems External Audits***

This is performed by persons external to the plant. Corporate Quality Audits or any other third party audit activities and information generated from these audits can indicate the need for a HACCP System Validation.

5.2 **HACCP System Validation**

The HACCP System Validation involves the collection and evaluation of scientific, historical and technical information to assess whether the HACCP Plan efficiently identifies and controls all food safety hazards and emerging issues associated with the product or process. It is conducting a systematic collection and evaluation of data from the process (series of measurements, adjustments, checks) to establish scientific evidence that a process, piece of equipment or system can successfully and consistently operate to control identified hazards by eliminating or minimizing the risk below set critical limits.

HACCP System Validation Activities Include:

5.2.1 *Validation of the HACCP Plan:*

This validation ensures that the HACCP Plan is based on current good science and information and is appropriate to control food hazards associated with the product and process.

Validation of the HACCP Plan implies determining if the Critical Control Points and associated critical limits as well as the Prerequisite Programs and their control mechanisms are adequate and sufficient to actually prevent, eliminate or reduce to an acceptable level identified microbiological, chemical and/or physical food hazards.

The questions we want to answer are:

- Is the HACCP Plan well founded?
- Are all hazards introduced by the raw materials, packaging material, the processes and the process environment identified in the HACCP Plan?
- Are the controls sufficient to manage the given hazards?
- Is this the right thing to do?
- Did it work?
- Will it work?

Validation involves checking the effectiveness and aims to continuously improve the HACCP System.

5.2.2 ***HACCP Plan Validation/Reanalysis Frequency***

Validation/Reanalysis Frequency is every two years and in case of

- **Major** changes to product, ingredients, process/processing equipment, packaging or storage/distribution conditions.
- **New** hazards being recognized
- New scientific information concerning the product/process
- Unexplained system failure/when deviations occur
- Safety driven consumer complaints or product rejections. Whenever there is a systematic or reoccurring product safety issue or industry recall of a similar product, a Validation/ reanalysis would be performed using the Validation Checklist or equivalent.

For new HACCP Plans or brand-new product categories after 6 months the Validation Team shall decide whether a HACCP Plan Implementation Validation is required.

Notes:

- If a non-significant change is made, this can be incorporated directly into the current HACCP plan and would not trigger a validation.
- It should be noted that whenever there are changes to product, package or process, as appropriate, the HACCP Team should be convened to review the effect on the existing HACCP plan. The review during validation/reanalysis is intended only to verify that all changes made since the last validation/reanalysis are reflected in the Hazard Analysis, that the right management has been identified and, as needed, captured in the HACCP plan itself.

5.2.3 *HACCP Plan Validation/Reanalysis Responsibilities*

It is the responsibility of a dedicated function to lead the HACCP system Validation/Reanalysis process. The Designated Function shall provide the necessary resources to assure the adequacy of the validation/reanalysis and the “4 eye” principle. The plant’s HACCP team shall participate in the validation/reanalysis process.

Validation of the Process or Equipment: A process and equipment validation study of processing equipment that is used for CCP or specific PP control shall be carried out:

- before the equipment is first used in production,
- at the time of any changes to the equipment/product which could potentially impact the lethality/effectiveness of the process,
- if the level of the hazard is higher than originally encountered (*e.g.,* new scientific literature),
- If information indicates that the hazard is not being controlled to the level specified. (*e.g.,* if the product / process has been involved in a food safety issue)

During the periodic HACCP plan validations, the equipment installation shall be verified to ensure that it complies with appropriate equipment validation tests.

This does not preclude the conducting of additional validation or verification studies that are not required according to the conditions set forth above.

Process and equipment that typically have to be validated are (but not limited to):

- Allergen cleaning
- Nut roasting
- Cocoa bean heat treatment
- UHT
- HTST
- Baking Ovens
- Ultra High Pressure Processing
- Extraneous matter detection

Note: For some specific processes where Mondelēz International has developed *Process Guidelines* (*e.g.,* Nut, Cocoa, Dairy, Egg, Juice, Fruits & Vegetables, Meat Products), the frequency of the process/equipment validation/reanalysis shall be in accordance with the Guidelines.

Process/Equipment validation/reanalysis Responsibilities:

The equipment validation/reanalysis is typically done by Plant Engineering/experts or R&D and if required with the support of a food safety expert.

6. PACKAGING SUPPLIERS HAZARD ANALYSIS AND PREREQUISITE PROGRAMS

Suppliers of packaging material (product-contact, labels, and labeled packaging materials) manufactured for Mondelēz International shall develop HACCP plans consistent with this standard. For Packaging Suppliers, Mondelēz International has defined PCCPs. These are Packaging Critical Control Points, which do not fulfill the Codex requirements as limits cannot always be precisely defined and monitored. For example, a CCP fulfilling the Codex requirement would be pasteurization; in the pasteurizer the product can be controlled, such that every particle is fully pasteurized, *i.e.,* reaches 72°C (161ºF) for 15 seconds. The PCCPs given in the *Appendix E*, however, are not able to give evidence of every production second, but are meant to draw special attention to certain processing steps. Therefore they should be applied in the relevant areas to minimize the anticipated risk.

Note: For processes and products that are determined not to have any CCPs or PCCPs, a documented HACCP hazard analysis must be available for all products produced for Mondelēz International. Appropriate Prerequisite Programs must also be in place.

6.1 Hazard Analysis and Hazard Assessment

For the purpose of packaging materials, where possible the risks associated with the materials should be considered from the end point use by Mondelēz International manufacturing plants and consumers using the Mondelēz International packaged products. It should also consider potential hazards in relation to direct contact with food during the process flow (such as rework containers with direct contact to food).

6.1.1 *Potential microbiological risks*

The following list includes some potential microbiological risk areas that must be reviewed concerning packaging material defects that could lead to post-process microbiological contamination of containers used for thermally processed or aseptically filled low-acid canned foods (most of these hazards should be managed by one or more CCP's in addition to appropriate Prerequisite Programs):

- Environmental post-process contamination of primary packaging material, e.g. drips from roof leaks directly onto primary contact film or paperboard (most likely managed by a prerequisite program vs. a CCP
- Manufacturing defects leading to packaging leakages, e.g., seaming and sealing of cans, cups, pouches, etc.

Examples of CCP's for some of the above processes could be the inspection and reject devices used to detect and eliminate the defective materials from the production line. Inspection of cans by the can manufacturer could be the CCP for can manufacturing (see *Appendix E*).

6.1.2 Potential chemical risks

The following list includes some potential areas for chemical risks that where possible shall be reviewed based on the packaging material and the intended use by the consumer:

- Raw materials and processing aids used for primary packaging (product contact or potential product contact) including printing inks, varnishes, adhesives, etc. that release substances that can transfer from the packaging to the food (*e.g.,* migration or set-off)

Note: Also consider rework management and potential direct contact with food

- Changeover from conventional packaging conversion to food packaging (*e.g.,* high purity demand of printing inks, physical hazards resulting from broken parts, dust in containers)
- Inadequate processing or curing of the materials (adhesives, inks, coatings)

6.1.3 ***Potential mixing labels risk***

In addition, manufacturers of labels and labeled packaging materials must include a risk assessment and have controls in place for preventing or controlling the risk of mixing labels or labeled materials (allergen/non-allergen labeling). Persons with food allergies rely on correct labeling of products to prevent ingesting a potential life-threatening allergenic protein. This is a serious risk for products where some varieties contain allergens and others do not and product labels appear similar. Adequate controls must be in place at all points of the label and labeled packaging material processes to assure labels are not mixed.

Note: This is also applicable for substances that can cause sensitivity and intolerance reaction to some sensitive individuals (like sulfite, gluten)

The following list includes some identified potential manufacturing errors (allergen mislabeling) for manufacturers of labels and labeled packaging materials, which could lead to chemical hazards with the end-consumer (if a product containing allergens is mislabeled). These risks and the specific process steps associated with each material must be reviewed and controls must be in place to prevent inadvertent mixing of labels or labeled packaging materials by the supplier.

- Incorrect label printing for allergen (printing or print copy error—allergen missing or incorrect)
- Mixing of non-allergen with allergen labeled containers, labels, film, or lids. Allergen and non-allergen labels printed on same printing plate/sheet (potential for mixing during cutting, stacking, and sorting operations)
- Printed film spliced to different printed film (allergen/non-allergen) on the same roll
- Labels or labeled packaging materials left in equipment and mixed at changeover (previous run mixed with new run of different material) and in storage area
- Case and/or pallet mislabeled
- “reuse” of rejects

Multiple systems may be required to assure adequate control.

In some examples listed above the identified risks could be controlled by use of vision systems or UPC scanners to identify potential mixing of labels or labeled materials. However, many of these risks are the result of human error or equipment and process limitations and must be identified and controlled. Controls must include strict employee handling procedures and work processes that must be documented and performed by trained, accountable employees. At a minimum, line clearance procedures at line changeovers or SKU changes for label or labeled materials at line should be managed as a CCP or a Prerequisite Program for most types of operations (see *Appendix E*). Also, Cut and Stack Labels have higher risk of mixing due to equipment limitations and optimization of print layout (*e.g.,* labels may slide on top of another stack of unlike labels during the cutting process. See *Appendix E*).

BIOLOGICALLY SENSITIVE INGREDIENT CATEGORY LIST

The most effective method of managing potential biological hazards in ingredients belonging to a Biologically Sensitive Ingredient Category shall be determined by the Hazard Analysis Team.

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

* "flavouring substances" as defined by European Flavouring Directive 1334/2008/EEC
Worldwide Exclusion(s) (established by Mondelēz International Corporate Microbiologists) Ingredients/products, sourced from approved suppliers: - Fully deodorized: cocoa butter - Anhydrous oils, fats and lecithin - pasteurized & hot filled fruit purees /pastes/juice concentrate Note: Raw materials that are • aseptically processed and packaged • retorted (canned) • propylene oxide or ethylene oxide treated or irradiated in the package • pasteurized in the package shall be assessed by the respective Mondelēz International process authority for the adequacy of the process and based on the outcome could be exempted from biological sensitivity.

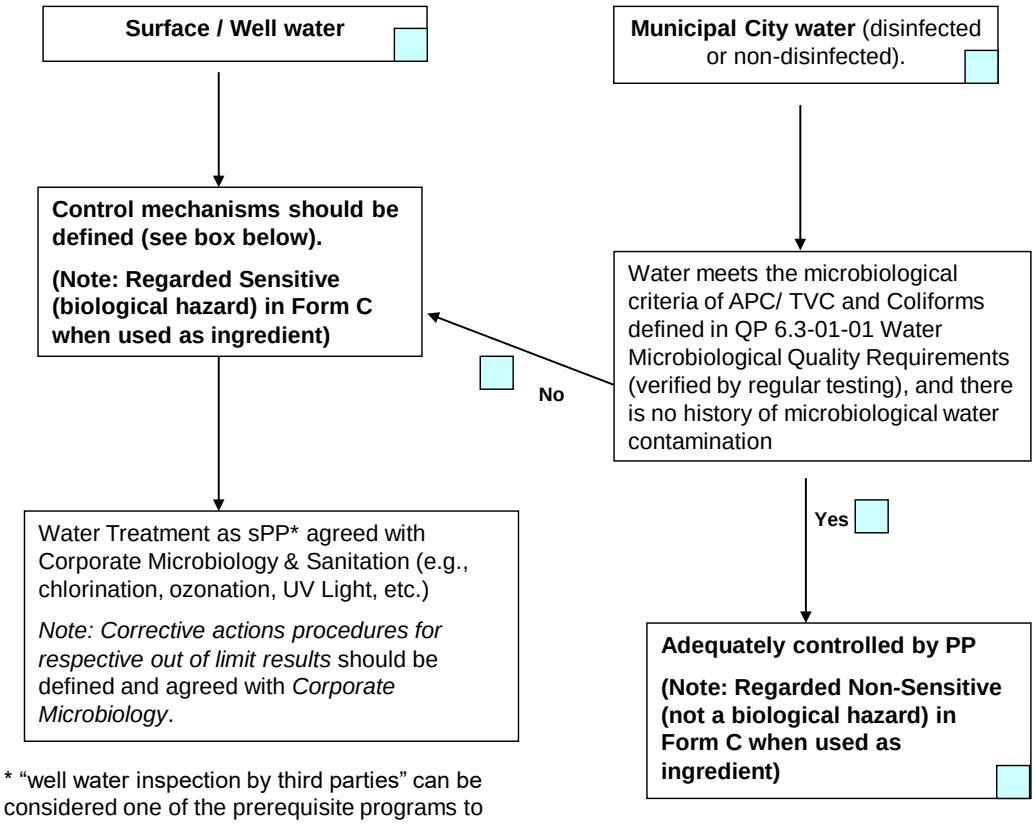
Note: Suppliers and External Manufacturers should reach out to designated Mondelēz International key contact(s) to obtain additional information on the scientific basis related to exclusions indicated for biological hazards.

WATER MICROBIOLOGICAL HAZARD ASSESSMENT

Water may be a source of pathogens. Due to the nature of the potential contamination, water is best managed through prerequisite programs which either ensure the source is clean ground water or treated water (*e.g.,* chlorinated). These prerequisites are verified through regular testing for APC (Aerobic Plate Count) and coliforms.
In addition, the risk of contamination with viruses and/or parasites has to be assessed using the respective risk assessments.
Surface water is commonly analysed for *Clostridium perfringens* (sporeformer). This parameter is used as an "indicator" for parasites, as the bacterial spores are considered similar resistant to disinfection measures. In general, sporeformers are not considered as pathogens of concern in water supplies. They are not able to grow due to the limited amount of nutrients available in water. No outbreaks related to water and sporeformers have been reported.
In case of unforeseen / unusual events, such as severe droughts, heavy rainfall or flood, turbidity checks and microbiological tests should be carried out immediately. When established values are exceeded water usage as ingredient should be stopped and expert advice asked for. Actions can include immediate high disinfection until water quality has resumed.
A decision tree with respect to assessing the risks related to water can be used and is included in EMQR Water Micro 6.3-01-01.
Note: Review history of sourced water test results and municipal water reports with respect to parasite findings / boiled water notices and include this in the risk assessment for parasite contamination.

WATER MICROBIOLOGICAL HAZARD ASSESSMENT

Tick all blue boxes ☑ (applicable) or ☒ (N/A)



* "well water inspection by third parties" can be considered one of the prerequisite programs to manage water safety

INCOMING WATER

Tick all blue boxes ☑ (applicable) or ☒ (N/A)

Parasite Hazard Assessment

Has there been a history of epidemiological data / warnings /outbreaks in the water supply?

No ☐

☐ **Epidemiological data / Public warning – (water boiling advice)**

Has a defined action plan being established in that case ?

No ☐

Yes ☐

Non Sensitive (not a biological hazard)
Action Plan defined and attached to Form C ☐

Outbreak (Incidences of infected persons) ☐

No further action required
Managed through established GMP as per risk assessment in the global HACCP standard (Section 19, HACCP standard) ☐

Sensitive (biological hazard)
Prerequisite programs should be defined as control mechanisms in Form C.
Prerequisite programs to be established with Corp Micro /Food Safety ☐

Virus Hazard Assessment

Has there been a history of outbreaks or epidemiological data in the water supply?
Are there cross connections known between treated and untreated (waste, sewage, irrigation) supplies?

No ☐

Yes ☐

No further action required
Managed through established GMP as per risk assessment (Section 19, HACCP standard) ☐

Sensitive (biological hazard)
Prerequisite programs should be defined as control mechanisms in Form C. Prerequisite programs to be established with Corp Micro /Food Safety ☐

FOOD ALLERGEN CATEGORY LIST

General Exemptions (only those listed).

1. Highly refined or refined, bleached, and deodorized oils from any of the food allergens and their derivatives (hydrogenated oils).

2. Enzymes produced by a fermentation process where Soya, wheat or milk protein containing material is used as source of protein for the enzyme-producing microorganism and include a process for protein removal.

3. Cultures grown in a media containing soya, wheat or milk protein as source of protein and include a process for protein removal.

4. Derivates manufactured from exempted ingredients e.g. citric acid produced using wheat.

In addition to the allergens from the list below, the following substances have to be managed as allergens (also called "Regional Allergens EMQR 7.3-01 Allergen CL R02"):

Celery and Mustard: only for Europe (including political EU, Nordic countries, Switzerland, Central Europe, and Eastern Europe), Middle East, and Africa

The Regional Food Allergen List is a list of food allergens that meet all of the criteria for inclusion on the Global Food Allergen Category List except for the global prevalence criteria.

The materials listed below may potentially produce severe, life-threatening, reactions in sensitive individuals.

Category of Food Allergen	Positive List of Ingredients or Foods includes (but not limited to):	Examples of foods that often contain this material	Exemptions to the Category of Food Allergen
Crustacean	*e.g.,* Shrimp, crab, lobster, crawfish Each species within this category, must be regarded as a separate allergen	Glucosamine Hydrochloride containing foods	
Egg	*e.g.,* Hen's and other avian species Ovalbumin, whole egg, egg yolk, egg white, lysozyme, hydrolyzed egg protein	Mayonnaise, meringue	
Fish	*e.g.,* Cod, Haddock, Flounder, Trout Each species within this category, must be regarded as a separate allergen		Gelatin from fish used as a carrier for vitamin or carotenoid preparations . Gelatin from fish used as a fining agent in wine, beer and cider.

Lupine/ Lupin	Lupine flour, lupini beans		
Milk	*e.g.,* Cow's, sheep's, goat's Butter, buttermilk, casein, cheese, cottage cheese, curds, whey, lactoglobulin, lactose*, malted milk, cream, sodium caseinate, sour cream, yoghurt, hydrolyzed milk protein **Only if it contains protein*	Margarines, milk chocolate, ice cream, custard, nougat pudding	Lactose and lactitol which contains no protein (specification must indicate process for protein removal) Alcoholic distillates derived (including ethyl alcohol) from whey
Mollusk / Mollusc	*e.g.,* Clams, oysters, mussels Each species within this category, must be regarded as a separate allergen	Calcium Supplements	
Peanut	Peanut butter, nut pieces, peanut flour, peanut protein, hydrolyzed peanut protein	Mixed nuts	
Seeds: Sesame seeds	Sesame paste, Tahini paste	Hummus, biscuits, dressings and sauces	
Soybean /Soya bean / Soy	Soya derived vegetable protein or textured vegetable protein, miso, tofu		Soy lecithin; tocopherol extracts (antioxidant used in flavours) purified by vacuum distillation or purified by other means as long as they are not a source of allergenic proteins. Acid hydrolyzed soy proteins greater than 62% Amino Nitrogen/Total Nitrogen (85% minimum degree of hydrolysis) Phytosterol or phytosterol esters derived from soy
Tree nuts: Almond Brazil Nut Cashew Hazelnut (Filbert) Macadamia Nut Pine Nuts Pistachio Pecan Walnut	Only those tree nuts identified. Each tree nut type within this category must be regarded as a separate allergen	Mixed nuts Some chocolates	Alcoholic distillates including ethyl alcohol of agricultural origin derived from treenuts
Wheat	Wheat derived bran, wheat extracts, dextrin, meal, farina, graham flour, malt, flour, germ, gluten, starch including enzymatically/acid treated or chemically modified starches, semolina, hydrolyzed wheat protein; Spelt, Khorasan wheat, Kamut	Breadcrumbs, crackers, bread, pasta	Wheat derived glucose, glucose syrup, dextrose, dextrose monohydrate, maltodextrin (all DEs), sugar alcohols, and caramelized glucose. Alcoholic distillates including ethyl alcohol of agricultural origin derived from wheat Vinegars (including spirit vinegar) derived from wheat

The list of these substances is not expected to change significantly, but additions or deletions could be made as more evidence becomes available. This Global Food Allergen Category List is comparable with allergen lists by the following organizations: (1) International Food Biotechnology Council; (2) Codex; and, (3) International Life Sciences Institute Europe.

When ingredients that are not included in or exempted from the Mondelēz International Global Allergen Category List are utilized in products commercialized in countries and/or regions that have defined regulatory requirements for their labeling, these ingredients must be appropriately identified to meet the applicable labeling requirements.

Note: Suppliers and External Manufacturers should reach out to designated Mondelēz International key contact(s) to obtain additional information on the scientific basis related to exemptions indicated for allergens.

List of Materials associated with food Sensitivity or Intolerance (MSI)

Category of Sensitivity / Intolerance	Positive list of ingredients includes, but is not limited to	Examples of foods that often contain this material	Exemptions to Labeling on Control
Sulfites / Sulphites	Sodium Bisulfite, Sodium Metabisulfite, Sulfur Dioxide, Potassium Bisulfite	Wine, Dried Fruits, bulk processed potatoes, dried vegetables.	Less than 10 ppm expressed as Sulfur dioxide in the final MDLZ food product 'as sold'. Where regulations do not specify, this can be extended to products 'as prepared'.
Gluten sources other than wheat	Oats, Barley, Rye, Triticale, Mir, Other cross bred hybrids		Alcoholic distillates including ethyl alcohol of agricultural origin derived from cereals containing gluten Vinegars (including spirit vinegar) derived from cereals containing gluten Barley derived glucose syrup

Materials on this list given which are directly added to the product (including addition via rework) must appear in the ingredient declaration using consumer friendly language. The list of these substances is not expected to change significantly, but additions or deletions could be made as more evidence becomes available

Chemical Contaminants

Chemical hazards are classified as agents that will cause adverse health effects such as external or internal chemical burning, significant gastrointestinal effects, or cause long term damage. Some chemical hazards can cause acute toxicity (adverse effects arising from a single exposure *e.g.,* food allergen or from multiple exposures in a short space of time or due to extreme high concentrations of the contaminant) However the vast majority of hazards relevant to Mondelēz International could result in chronic toxicity (adverse health effects from repeated exposures, often at lower levels, to a substance over a longer time period, *e.g.,* mycotoxins, antibiotics, heavy metals, pesticides and acrylamide).

Normally these categories of chemical hazard are controlled via prerequisite programs such as Supplier Quality Assurance (supplier approval process, specifications / Certificates of Analysis. Process related contaminants (such as acrylamide) should mainly be managed through internal control mechanisms from the design phase to production and are monitored to verify effectiveness.

Detailed in the table below are broad catagories of raw materials relevant to Mondelez International with associated chemical hazards classified as either high or low occurrence potential based on recently published scientific surveys and literature reviews of the occurrence of emerging and re-emerging chemical hazards

Categories	High Occurrence Potential	Low Occurrence Potential
Cereal/Biscuits	Mycotoxins, Heavy metals, pesticides, Acrylamide (if baked RM)	Melamine, Ergot alkaloids, Pyrrolizidine alkaloids
Coffee (beans and roasted)	Mycotoxin, Pesticides, Acrylamide (if roasted RM)	Heavy Metals, Furan
Nuts (incl. Peanuts)	Mycotoxin	Pesticides, Heavy metals
Dairy	Mycotoxin, Melamine (Adulteration), Vet Residue	Pesticides, Dioxins, Heavy Metals, Sodium thiocyanate, Histamine (cheese)
Cocoa (beans, butter, liquor etc.)	Mycotoxin, Pesticides, Heavy Metals	PAH, Pesticide, Dioxins
Fruit (includes juices)	Mycotoxin, Pesticides, Heavy Metals, Sulfites	Cyanoglucosides (apricot)
fat & oil		PAH, Heavy Metals, Mineral oil
Vegetable	Mycotoxin, Pesticides,	Heavy Metals, Sulphites, Formadehyde, Nitrate
Sweetener (honey)	Veterinary residues, HMF	Heavy Metals, Pesticides, Sulphites
Seeds	Mycotoxin, Pesticides	Heavy Metals, Morphine (poppy seed)
Egg	Veterinary residues,Melamine (Adulteration)	Heavy Metals, Pesticides, Dioxins
Meat	Veterinary residues	Dioxins, PCB's Melamine, Heavy Metals
Water (ground/well)	Nitrates	Pesticides, Heavy Metals,
Spices/Herbs (include colored spices)	Mycotoxin, Pesticides, Adulteration	Heavy Metals, Illegal dyes
Fish & Shellfish	Veterinary residues (malachite green farmed fish), Histamine	Heavy Metals, Melamine, dioxins
Tea	Pesticides	Heavy Metals, Mycotoxin,
sugar (cane, beet)	-	Heavy Metals , Pesticides, Sulphites
Flavor	PAH (if smoked)	Heavy Metals, Flavour specific chemicals
Hydrocolloid	-	Dioxin (Guar Gum), Heavy Metals
Vitamins	-	Heavy Metals, Adulteration
Starch	-	Heavy Metals
Chemical	-	Heavy Metals, Melamine (Adulteration)
Sweetener (artificial)	-	Heavy Metals
Color (artificial)	-	Heavy metals, Illegal Dyes (Adulteration)
Color (Natural)	Illegal Dyes (Adulteration)	Heavy Metals
Gelatin	-	Heavy Metals, Melamine
Alcohol	-	Heavy Metals, Ethyl carbamate
Soy Protein	-	Heavy Metals, Pesticides, Melamine (Adulteration)
Tapioca	-	Cyanoglucosides

PRODUCT/PRODUCT CATEGORY DESCRIPTION

Form A

PURPOSE: To describe the product characteristics and storage and distribution factors as related to food safety.

Product/Product Category* (e.g. Name, type, size)	
Process (e.g. Cold pack, hot fill, aseptic, freeze dried)	
Food Safety Characteristics process and finish product related (biological, chemical and physical)	
Consumer & Intended Market (e.g. General public, age, adult, child, retail, food service, countries, regions, national)	
Use by Consumer/Customer (e.g. Ready to consume, heat and consume, mix and consume)	
Labelling/Label Instructions List should include but is not limited to::Preparation instruction, Allergen and MSI information)	
Packaging material (e.g. Foil , plastic, glass, cup, can), Sealing (e.g. hermetically sealed, tamper evident), barrier requirements (e.g. gas permeable, modified atmosphere packaging)	
Shelf Life (e.g. Days)	
Storage & Distribution (e.g. Ambient, refrigerated, frozen, relative humidity, high altitude)	

ROCESS FLOW DIAGRAM

Form B

PURPOSE: To provide a graphical representation of **all** processing steps from raw material receiving to finished product storage which are directly under the control of the manufacturing facility.

The following check list may be used as a guide in the development of a flow diagram.

- ☐ Raw material receiving & storage
- ☐ Addition of ingredients, pre-mix, intermediate product
- ☐ Use of air or other gases
- ☐ Filters, screens, metal and magnet detectors
- ☐ Process equipment (e.g. heat exchangers)
- ☐ Tanks and continuous systems (e.g. mix, balance, surge, buffer, cook, fill, cool)
- ☐ Filling and packaging equipment
- ☐ Recirculation, overflow (e.g. immediately returned to process)
- ☐ Rework, holdover, reclaim (e.g. material not immediately returned to process - stored material)
- ☐ Storage
- ☐ **Required by FSMA (USA facilities only): Indication of animal feed output**
- ☐ Numbered Critical Control Points (CCPs) shown at identified process steps
  - CCPs can only be numbered after CCP Documentation (Form G) is completed.
  - CCPs for different Hazard categories shall be separate.
  - Block diagram format is minimum. Graphics are acceptable

INGREDIENT/PACKAGING ASSESSMENT

Form C

PURPOSE:

- To assess ingredients, ingredient packaging materials, rework or finished product contact packaging materials in order to identify the probability of occurrence and the severity of potential biological, chemical (including radiological), and physical hazards, as well as hazards that are intentionally introduced.
- To determine the control mechanisms for the hazards identified as significant.
- Evaluate and control radiological hazards and hazards introduced intentionally, as documented Appendix B

Note: Food Safety Control mechanisms of Significant Hazard (Column H, Hazard 4 - 9) for biological, physical, and chemical hazards shall be listed on Form C. Other controls, not significant hazards, such as sPPs, can be listed on Form F.

RELEVANT SECTION REFERENCES:

- Section 1 Prerequisite Programs
- Section 3 Hazards and Hazard Management Criteria
- Section 6 Packaging Suppliers Hazard Analysis and Prerequisite Programs
- Appendix A: Mondelez International Biologically Sensitive Ingredient Category List and Water Microbiological Hazard Assessment
- Appendix B: Mondelēz International Food Allergen and Chemical Contaminate Category List
- Appendix D: Model Critical Control Points and Prerequisite Programs

List the Raw Material (RM) number. The ingredient list shall include all raw materials, processing aids, rework, packaging materials in direct contact with finished product, or finished product non-contact packaging materials that will become contact packaging materials during consumer use (i.e. resalable lids for multiple-use containers, drinking straws for RTD pouches, eating utensils built into lidding material). Fully describe the name or type of material, for example, starch is corn starch. List carriers for flavours, for example: lactose; propylene glycol; ethyl alcohol; corn maltodextrin; salt; refined, bleached, and deodorized cottonseed oil.

List the storage condition, for example, A=ambient, R=refrigerated, F=frozen. Describe the hazards and assess the severity and likelihood of occurrence (significance) for each hazard. Complete the Biological, Chemical and Foreign Material Hazard Assessment Matrix (Reference relevant HACCP Standard) for determination of potential physical hazards. Describe the rationale behind the decision for each hazard, and determine the Preventive Control mechanism(s).List the names of CCP and specific Prerequisite Programs. Determine if the control mechanism(s) shall be a Critical Control Point (CCP) or specific Prerequisite Program (sPP). If no Hazards exist, indicate “None”.
DO NOT LEAVE ANY SECTIONS BLANK. List “None” or “NA” (not applicable) if appropriate and avoid the use of acronyms (*e.g.,* CMC is carboxy methyl cellulose).

INGREDIENT/PACKAGING ASSESSMENT

Form C

RM Number	INGREDIENT NAME	STORAGE CONDITION A=Ambient F=Frozen R=Refrigerate	POTENTIAL FOOD SAFETY HAZARDS (B) VP = Vegetative Pathogen (B) SP = Spore forming Pathogen (C) Chemical (P) Physical	HAZARD EVALUATION			SIGNIFICANT HAZARD: DO ANY POTENTIAL FOOD SAFETY HAZARDS REQUIRE A PREVENTIVE CONTROL?	RATIONALE or BASIS: JUSTIFY YOUR DECISION	CONTROL MECHANISMS: WHAT PREVENTIVE CONTROL MEASURES CAN BE APPLIED TO SIGNIFICANTLY MINIMIZE OR PREVENT THE FOOD SAFETY HAZARD? (including CCPs, process, allergen, sanitation, supply chain, or other preventive controls (sPP/CCP)) Refer to Section 1, Section 3 and Appendix D	CCP or sPP?
			(B) Hazard evaluation performed by HACCP team based on information provided in Section 3.1 and Appendix A. (C) Allergen hazard evaluation performed in Form E1/E2. Chemical hazard evaluation based on information provided in Section 3.2 and Appendix B. (P) Hazard evaluation done by Hazard Calculation Matrix Section 3.3.	Severity (S) of the hazard	Probability of occurrence (PO) of the hazard	Hazard Evaluation Outcome (S x PO)	From Hazard Outcome Column, enter: 1 - 3 = No 4 - 9 = Yes **Biological**: Refer to Section 3.1 and Appendix A for Significance **Chemical:** Refer to Section 3.2 and Appendix B for Significance **Physical:** Refer to Section 3.3:			
			(B)				(B)	(B)	(B)	
			(C)				(C)	(C)	(C)	
			(P)				(P)	(P)	(P)	
			(B)				(B)	(B)	(B)	
			(C)				(C)	(C)	(C)	
			(P)				(P)	(P)	(P)	
			(B)				(B)	(B)	(B)	
			(C)				(C)	(C)	(C)	
			(P)				(P)	(P)	(P)	
			(B)				(B)	(B)	(B)	
			(C)				(C)	(C)	(C)	
			(P)				(P)	(P)	(P)	

PROCESSING STEP EVALUATION

Form D

PURPOSE:

- To identify biological, physical and chemical hazards (including radiological hazards) that may be introduced from the process and/or processing environment, and to determine the control mechanisms for the identified hazards.
- Evaluate and control radiological hazards and hazards introduced intentionally, as documented Appendix B

RELEVANT SECTION REFERENCES:

- Section 1 Prerequisite Programs
- Section 3 Hazards and Hazard Management Criteria
- Section 6 Packaging Suppliers Hazard Analysis and Prerequisite Programs
- Appendix A: Mondelez International Biologically Sensitive Ingredient Category List and Water Microbiological Hazard Assessment
- Appendix B: Mondelēz International Food Allergen and Chemical Contaminate Category List
- Appendix D: Model Critical Control Points and Prerequisite Programs

While referencing the process flow diagram, (form B), list all processing steps from raw material receiving to finished product storage. For example, list the addition of ingredients, rework, cooking, grinding, slicing, shredding, hydrating, mixing, etc. Assess for biological, chemical, and physical contamination potential for each step. Examples include if a slurry containing proteins exceeds time/temperature requirements, this could result in Staphylococcal enterotoxin formation, or for example, if there are areas/equipment where ingredients, products, and rework are exposed to the environment or personnel handling, extraneous matter contamination could occur.

Describe the hazards and assess the severity and likelihood of occurrence (significance) for each hazard. Describe the rationale behind the decision for each hazard, and determine the control mechanism(s). List names of CCP and specific Prerequisite Programs. Determine whether the preventive control mechanism(s) shall be a Critical Control Point (CCP) or specific Prerequisite Program (sPP). **DO NOT LEAVE ANY SECTIONS BLANK. If no hazards exist, indicate "None"**

PROCESS STEP (Numbering Optional)	POTENTIAL FOOD SAFETY HAZARDS (B) VP = Vegetative Pathogen (B) SP = Spore forming Pathogen (C) Chemical (P) Physical	RISK EVALUATION			SIGNIFICANT HAZARD: DO ANY POTENTIAL FOOD SAFETY HAZARDS REQUIRE A PREVENTIVE CONTROL?	RATIONALE or BASIS: JUSTIFY YOUR DECISION	CONTROL MECHANISMS: WHAT PREVENTIVE CONTROL MEASURES CAN BE APPLIED TO SIGNIFICANTLY MINIMIZE OR PREVENT THE FOOD SAFETY HAZARD?	CCP or sPP?
	(B) Hazard evaluation performed by HACCP team based on information provided in Section 3.1 and Appendix A. (C) Allergen Hazard evaluation performed in Form E1/E2. Chemical Hazard evaluation based on information provided in Section 3.2 and Appendix B. (P) Hazard evaluation done by Hazard Calculation Matrix Section 3.3.	Severity (S) of the hazard	Probability of occurrence (PO) of the hazard	Hazard Evaluation Outcome (S x PO)	From Hazard Outcome Column, enter: 1 - 3 = No 4 - 9 = Yes **Biological**: Refer to Section 3.1 and Appendix A for Significance **Chemical:** Refer to Section 3.2 and Appendix B for Significance **Physical:** Refer to Section 3.3:		(including CCPs, process, allergen, sanitation, supply chain, or other preventive controls (sPP/CCP)) Refer to Section 1, Section 3 and Appendix D	
	(B)				(B)	(B)	(B)	
	(C)				(C)	(C)	(C)	
	(P)				(P)	(P)	(P)	
	(B)				(B)	(B)	(B)	
	(C)				(C)	(C)	(C)	
	(P)				(P)	(P)	(P)	
	(B)				(B)	(B)	(B)	
	(C)				(C)	(C)	(C)	
	(P)				(P)	(P)	(P)	
	(B)				(B)	(B)	(B)	
	(C)				(C)	(C	(C)	
	(P)				(P)	(P)	(P)	
	(B)				(B)	(B)	(B)	
	(C)				(C)	(C)	(C)	
	(P)				(P)	(P)	(P)	
	(P)				(P)	(P)	(P)	

Ingredient Allergen Assessment (Form E –1)

Note: Full Allergen Assessment consists of Forms E-1 and E-2

Purpose: To identify whether the product(s) being assessed can introduce undeclared allergens/sulphites into other products currently run on the manufacturing line – **OR** – whether products currently run on the manufacturing line can introduce undeclared allergens / sulphites into the product(s) being assessed. Identify or describe the control mechanism to manage the allergen / sulphite. Determine whether the control mechanism(s) shall be Critical Control Point (CCP) or specific Prerequisite Program (sPP). List CCP Model name and specific Prerequisite Program name.

MANUFACTURING LINE REFERENCE:

For each manufacturing line on plant there should be a separate E1 and E2 form (or add additional column and line label). Do not leave blank spaces and use non-applicable (N/A) as appropriate.

A	B	C
List all ingredients and rework used on the line: containing allergens and/or /sulfites (>10ppm in final formula) as per Food Allergen Category List (Appendix B) and /or containing carryover allergens and/or sulfites (>10ppm in final formula) per allergen profile of raw material spec. List any processing aids that may come in contact with product contact surfaces or product itself that contains allergens or sulfites >10ppm	**List identified allergens and/or sulfites (>10ppm in final formula) of ingredients or components of ingredients (listed as contain in raw material specification)**	**List identified carryover allergens and/or sulfites (>10ppm in final formula) in the ingredients that are not direct components of the raw materials (listed as "may contain" or "trace of " in raw material specification)**
Plant Allergen Profile Specification Report:		

Allergen Cross- Contact Production Assessment (Form E –2)

Note: Full Allergen Assessment consists of Forms E-1 and E-2

Purpose: To identify whether the product(s) being assessed can introduce undeclared allergens/sulphites into other products currently run on the manufacturing line – **OR** – whether products currently run on the manufacturing line can introduce undeclared allergens / sulphites into the product(s) being assessed. Identify or describe the control mechanism to manage the allergen / sulphite. Determine whether the control mechanism(s) shall be Critical Control Point (CCP) or specific Prerequisite Program (sPP). List CCP Model name and specific Prerequisite Program name. Control mechanisms (Column D) should be underlined, then indicate the name for the control (For example, Sanitation Control: Allergen Changeover (CCP) ; Process Control: Rework Handling (CCP)

Manufacturing Line reference:

For each manufacturing line on plant there should be separate E1 and E2 form (or add additional column and label line). No blank spaces use N/A.

A	B	C	D	E	F	G	H
List all finished products (current and new ones) produced on the manufacturing line	List all Allergens and/or sulphites (>10ppm in final formula) from the ingredients allergen profile (E1)	List all Allergens and/or sulphites (>10ppm in final formula) coming from cross contamination on the line (use Allergen profile of Line	List control mechanism that prevent cross contamination from the line (sPP/CCP /risk assessments).	Allergen and/or sulphites (>10ppm in final formula) profile of product as manufactured.	Allergen and/or sulphites (>10ppm in final formula) profile from label.	List difference of allergen and/or sulphites (>10ppm in final formula) profile between 'as manufactured' and 'label'.	If allergen and/or sulphites (>10ppm in final formula) profile is different explain.
Product Name	Contain:	Carry over:		Contain:	Ingredients line allergen profile (contains):	Contain:	
	May Contain:	Possible carry over of carry over:		May Contain:	May Contain:	May Contain:	

PRODUCT/PROCESS HAZARD ASSESSMENT AND PREVENTIVE CONTROL SUMMARY

Form F

PURPOSE:

Form F provides a summary of identified Preventive Controls from HACCP Forms C and D, and the CCP and sPP model(s) associated with them.

REFERENCE Section 1, Section 3, and Appendix D

Supporting documents are identified in last column, if applicable. List CCP Model name or specific Prerequisite Program name, from the Section 1 and Appendix D

All preventive controls from Forms C and D in the facility's Food Safety Plan must be listed in Form F.

Note: Form F may also be used to summarize other (non-preventive control) activities/controls, such as universal (u)PPs.

Note1: For FDA registered plants this form is mandatory

Note2: For non FDA registered plants: If control mechanisms have been determined for all identified hazards and documented in Forms C, D and E's, then Form F is optional.

Note 3: Control mechanisms (Third Column) should be underlined, then indicate the name for the control (For example, Process Control: Product Bake; Process Control: Rework Handling

HAZARD IDENTIFIED (Copy from Forms C and D)	HAZARD CONTROL MECHANISM(S)	If the hazard is managed as a CCP, list CCP Model name (Refer to Appendix D)	If the hazard is managed as a specific Prerequisite Program, list the specific Prerequisite Program name (Refer to Section 1).	Optional to list PP/uPP local procedures in this column, if desired
BIOLOGICAL				
CHEMICAL				

HAZARD IDENTIFIED (Copy from Forms C and D)	HAZARD CONTROL MECHANISM(S)	If the hazard is managed as a CCP, list CCP Model name (Refer to Appendix D)	If the hazard is managed as a specific Prerequisite Program, list the specific Prerequisite Program name (Refer to Section 1).	Optional to list PP/uPP local procedures in this column, if desired
PHYSICAL				

CRITICAL CONTROL POINT (CCP) and sPP DOCUMENTATION

Form G

PURPOSE: To define food safety limits and monitoring and corrective action requirements that are consistent with the CCP models.

Line Number and Product	
Preventive Control Identification	
Process Step	
Hazard	
Critical Limit(s) for CCP **Control Measures/Limits for sPP**	
Monitoring Activity & Frequency **1. Responsibility (Who)** **2. Activity (What)** **3. Location (Where)** **4. Frequency (When)** **5. Method (How)**	
Corrective Action Activity:	
Records & Location	
Minimum Preventive Control Verification Activities 1. Activity (What?) 2. Frequency (How often?) 3. Responsibility (Who?)	
List the model name. If CCP or sPP Model does not exist, cite scientific basis for Critical Limit or Control Measures	

HACCP PLAN APPROVAL

Form H

PURPOSE: Provides documentation of final approval to assure that the HACCP Plan was developed using a cross-functional team approach.

Form H is optional for FSMA compliant or FDA registered facilities

The following check list may be used as a guide in the development of an approval form.

☐ Reason for Approval Request

NEW PLANS *e.g.,* New Product, New Process, New Package

MODIFICATIONS TO EXISTING PLAN *e.g.,* Product line extension, new or changed ingredients, "fast adapt" situation, modified/relocated process, addition of Critical Control Point(s), elimination of Critical Control Point(s), revise plan to comply with company requirements, other.

CHANGE DESCRIPTION Describe all change(s), reason for change(s) and their location in the documentation.

☐ List and attach (or reference) the following documents

Document	Form	Date Issued	Page Number
Product/Product Category Description	A		
Process Flow Diagram	B		
Ingredient / Packaging Assessment	C		
Processing Step Evaluation	D		
Allergen Cross-Contact Production Assessment Allergen Line Assessment	E1 E2		
Product/Process Hazard Evaluation Summary	F		
Critical Control Point (CCP) Documentation	G		
HACCP Plan Approval	H		
Plant Layout	J		
Product Category HACCP Plan Cross-Reference Index	K		

☐ Optional to Identify Hazard Analysis Team Members by name.

Must include at a minimum:

- Plant HACCP Coordinator or Preventive Control Qualified Individual (PCQI)

_____ _____

(Plant HACCP Coordinator)/PCQI ***(Date)***

Should also include:

- R&D Project Leader
- Other Experts (*e.g.,* Microbiology, Toxicology, Quality Function)

_____ _____

(Date)

_____ _____

(Date)

_____ _____

(Date)

☐ Signature of person(s) **approving** Plan (required – Plant Manager and Quality Function; optional – R&D Project Leader)

_____ _____

(Plant Manager) ***(Date)***

_____ _____

(Quality Function) ***(Date)***

_____ _____

(Date)

_____ _____

(Date)

HACCP Plan Approval

Form M

Purpose: Provides documentation of final approval to assure that the Food Safety Plan is reanalysed in compliance with US FDA 21 CFR 117:170

Production Facility: _____

Address: _____

Reason for Approval

	Addition of Preventive Control (s)
	Removal of Preventive Controls (s)
	Food Safety Plan Reanalysis (Validation)
	Food Safety Plan Reanalysis (Verification)
	Revision of Plan to Comply with new standards
	Other, *please specify*

Details of Reason for Approval: Please list the changes to the HACCP Plan below

Please add details here

Documents Reviewed as part of Approval		Date Issued
	HACCP Plan Overview/Background	
	HACCP Plan(s) Please list all cited	
	Master Form F	
	Recall Plan	
	Implementation Records	
	Food Safety Plan Team Record Maintenance	

Food Safety Pan APPROVED BY:

_____ _____

(Plant Manager) ***(Date)***

_____ _____

(Food Safety Plan Coordinator/PCQI) ***(Date)***

PLANT LAYOUT

Form J - Plant Generated Hygienic Zoning/Allergen Path Map

PURPOSE: To identify and document manufacturing areas, as related to the microbiological cross contamination and allergen cross-contact, assessing the food safety risk for the company products.

Form J consists of 2 parts, the Hygienic zoning map, and the Allergen Path map. These can be presented on one layout or as separate layouts. Either method of documentation is appropriate.

PART 1. Hygienic Zoning Map:

Each area or room shall be assessed and classified into one of four environmental zones.

1. **Non-Manufacturing Zone** – No exposed product allowed in these areas. Includes non-production areas such as utility rooms, offices, cafeteria/break rooms/smoking areas, locker rooms, laboratories, etc. Includes ingredient storage in closed containers such as warehouses that do not fall under the raw/limited processed zone
2. **Raw-Zone/Limited Processed Zone –** Areas such as raw product receiving and storage, areas of product preparation that will be thermally or otherwise processed and that are known/ have the potential to be contaminated and that may require controls to prevent contamination of high control zones.
3. **Controlled Zone –** Product of low to medium microbiological susceptibility which can be exposed to the environment and the operators. GMP practices are implemented and company's air requirements are met. The controlled zone may also serve as transition from non-manufacturing or raw/limited processed zone to high control zone.
4. **High Control Zone –** Product which supports growth of the pathogen of concern and can be exposed to the environment and/or the operators.

The zoning map should be constructed with the support of a Microbiologist.

The plant shall conduct a self-assessment and document it. The different zones shall be marked on the plant layout according to the definitions above. A legend should appear on the layout to explain the zoning map.

PART 2. Allergen Map:

Plant should identify the allergens in the facility and their storage areas. An allergen map should be created identifying:

- The storage areas of the allergen
- Traffic flow from storage to allergen usage areas
- Allergen usage areas

The Allergen map should be constructed with the support of Food Safety personnel.

If more than one Hygienic zone is identified in one processing room, and/or more than one allergen cross-contact path is identified in one processing area, then the facility shall ensure that applicable Prerequisite Program(s) are documented and implemented.

Prerequisite Programs may include:

- Building structure and utility systems (*e.g.,* walls, barriers, airflow)
- Employee hygiene /practices (*e.g.,* traffic patterns)
- Prevention of post-cook recontamination
- Environmental monitoring for pathogens
- Allergen changeover

Note: Additional information on allergen management can be found in the following Food Drink Europe publication: http://www.fooddrinkeurope.eu/uploads/publications_documents/Guidance_on_Food_Allergen_Management.pdf

PRODUCT CATEGORY HACCP PLAN CROSS REFERENCE INDEX

Form K - Plant Generated

PURPOSE: To enable the plant to cross reference products to specific HACCP plans by number.

PRODUCT CATEGORY _____

Product Name	Formula Number	HACCP Plan Number	Date HACCP Plan Issued	Validation Date

Plant HACCP Coordinator

Name: _____

Phone: _____

Contact plant HACCP Coordinator for the latest update of this document, if over 24 months from the last plan validation date or per regulatory time requirement.

NOTE 1: Critical Control Point (CCP) Models for specific product categories (dairy, fruits and vegetables, nuts, cocoa, and egg) are included in individual processing expectations prepared by Mondelēz International Subject Matter Experts. These processing expectations are available upon request through your Mondelēz International contracting representative.

NOTE 2: The scientific justification on the processing parameters of the following models is available by request through your Mondelēz International contracting representative.

GENERAL THERMAL PROCESSING MODEL

General Statement:

This general thermal process model consolidates several sections of individual models for simplification and harmonization. It shall be used in conjunction with the following "Specific" Thermal processing models, which are contained in product category processing expectations:

- Fillings and Sauces Heat Treatment (low Aw)
- Fruit fillings and sauce heat treatment low pH
- Meat Cooking – Batch
- Milk Heat treatment
- Ultra Pasteurized extended shelf life heat treatment
- Pasteurization Batch
- Pasteurization HTST/HHST
- Process Cheese Cook
- Product Cook
- Product Cook – Non-fat based products
- UHT heat treatment

The following sections which are specific to individual products can be found in the specific models:

Critical Control Point ID — Critical Limit
Process Step — Scientific Basis
Hazard

Note: Local regulations shall apply if more stringent than the requirements set forth in this document

MONITORING AND RECORDING ACTIVITY/FREQUENCY:

The scale to record the critical parameters has to allow for an effective verification of product safety.

Batch Processes

Hold time required

***Temperature**:* Critical product temperature is recorded to a permanent record.
Manual recording is acceptable at the start and end of the holding period as long as:

- the system is alarmed at the critical limit
- the alarm is recorded
- a correction to the hold time is made in case the temperature drops below the critical limit.

The measurement location shall be at the coldest point. In case this is not possible and there is an offset between the coldest point and the measuring location this temperature difference must be accounted for in the critical limit and any associated alarms.

Time: Monitoring and recording that the correct hold time for a specific recipe has been used must be made to a permanent record or alternatively can be manually recorded to demonstrate that product safety has been achieved.

Instantaneous (≤0.5 sec)
Permanent record of critical product temperature at the coldest point is required. In case this is not possible and there is an offset between the coldest point and the measuring location this temperature difference must be accounted for in the critical limit and any associated alarms.

Continuous Processes
Hold time required
***Temperature*:** Critical product temperature must be recorded to a permanent record at a frequency sufficient to demonstrate control. The measurement shall be at the coldest point of the holding tube. The system shall be alarmed at the critical limit or a flow diversion device (FDD) is in place to prevent under processed product from contaminating adequately processed production. The alarm shall be recorded.
Note: In general, if the hold tube is not heated, the coldest point is at the discharge or end of the holding tube.
When product temperature is not available at the coldest point, consult with a process authority for further actions
Time: One or both of the following parameters must be documented:

- Flow rate: recorded at a frequency to demonstrate control to a permanent record.
- Pump setting: recorded manually at least once per shift or after a change in speed setting
  or
- The pump seal integrity (sealed by authority or plant) is recorded daily
  or
- It is technically not possible to exceed the time requirements (this must be documented as part of the plant HACCP plan).

Instantaneous (≤0.5 sec)

***Temperature*:** Critical product temperature must be recorded to a permanent record at a point, where the product temperature is uniform, at a frequency to demonstrate control.
Manually recording is acceptable as long as:

- The system is alarmed at the critical limit and the alarm is recorded

or

- Flow diversion system is in place to prevent under processed product from contaminating adequately processed production and position is recorded

***Time*:** Not required (instantaneous).

Flow-Diversion-Device (FDD)/ Divert Valve

- FDD/Divert valve shall be in place to prevent under processed product from contaminating adequately processed production. The position (forward/divert) of the device must be permanently recorded at a frequency to demonstrate control.
- When FDD/Divert valve position is not recorded, an assessment shall be conducted and documented to prove that other adequate control measures are in place.
- Alternative systems used to prevent contamination by under processed product must be approved by a process expert in consultation with a microbiologist.

Pressure differential

- To control potential leakage a pressure differential measurement is required when the treated product is used to (pre)-heat untreated (cold) product and the separation between treated and untreated product is only a thin plate (Plate heat exchanger). The system shall be designed, operated, and controlled so that the pressure of the treated product is always greater than the pressure of any untreated product in the system.
- The pressure shall be 1 psi (0.07 bar or 7 kPa) higher on the pasteurized side.
- When pressure differential is < 1 psi product must be treated as under processed.
- If automatic recording of the pressures is not available, the system design shall demonstrate that the required pressure differential is achieved during processing.
- In systems where pressure differential is not available justification needs to be approved by an appropriate process authority.
- Pressure differential monitoring is not required in cases where the preheating medium is not already treated product (*e.g.,* water, oil).and the heating medium does not present a food safety risk (this must be documented as part of the plant HACCP plan, *e.g.,* form D, separate risk assessment).

CORRECTIVE ACTION ACTIVITY:

- When critical limits are not met, under-processed product is automatically diverted and/or reheated to the minimum required temperature and time or discarded.
- If there is an alarm and the product is not automatically diverted, under processed product must be isolated and appropriate corrective action must be taken

- In systems where Flow Diversion Device (FDD)/Divert Valve is in place, production must be stopped and system sanitized/ sterilized in the following circumstances:
  - When the FDD is positioned after the cooling section
  - When the FDD is positioned after the evaporator section
  - When FDD function is covered by a combination of valve systems leading to dead areas during divert

  - If the product is found to be under processed based on document review or inadequate handling of under processed product, all affected product shall be placed on Category I hold to await disposition from Designated Quality Function.
  - All the affected equipment shall be cleaned and disinfected before returning to standard production.
  - Corrective actions and hold / release records for CCP deviations must be documented.

RESPONSIBILITY: (Monitoring and Corrective Action)

Designated, trained employees

RECORD / LOCATION*: (include but not limited to)

Temperature charts and / or cook sheets
Flow Records (pump speed, flow, etc.)
Divert valve position
Hold and Release
Corrective Action Records
Change control records
Documentation of critical product temperature probe position and uniformity of measurement
Correlation of flow rate/ holding time for the fastest particle assessed during the equipment validation and a new product must be documented and filed with the HACCP plan.
Verification Records
* designate the location of each record

MINIMUM CCP VERIFICATION ACTIVITIES:

- Designated responsible employee, other than the operator (usually the Supervisor) reviews and signs the processing and any deviation records. A daily review is recommended but shall be completed before the finished product is out of plant control.
- All temperature, pressure measuring devices used to monitor critical control parameters shall be calibrated or verified to be within the accuracy tolerance limits at a frequency sufficient to demonstrate control (min. every 6 month).
- Flow meters when used to control minimum residence time needs to be verified for accuracy (*e.g.,* tank weight changes, when the deviation higher than acceptable then the flow meter must be replaced or sent back to the manufacturer).

- For systems with timing pump: Flow rate (salt test or other acceptable technique) versus pump speed will be verified yearly
- FDD/divert valve verification: Daily cut in cut out is required. (every 24hrs),
- Daily cut in cut out is not required in the following case:

o where FDD/divert valve position is recorded

And

o Fail safe valve is used

And

o evidence of the valve operation during CIP and the PLC (automation) functions related to FDD function are recorded

In this case the FDD/divert valve verification shall be carried out at least every 6 months and shall include functioning of the valve and reaction time of the system.

- If the food safety of the system is reliant on the automation/ software management, system operation shall be locked and changes to the automation shall be documented and verified to maintain food safety critical parameters
- Batch Cookers: Verify the accuracy of the hold time using a stopwatch at least every six months unless a digital timer is used.
- If the site uses alarms these should be verified at a minimum of every 6 months.

Note: Salt -Test for holding time: refer to Pasteurized Milk Ordinance (PMO) Section: TEST 11. CONTINUOUS-FLOW HOLDING TUBES - HOLDING TIME
http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM291757.pdf

HIGH MOISTURE MATERIAL HOLDING TIME AND TEMPERATURE PRIOR TO HEAT STEP

This model applies to high moisture (a_w greater than 0.85) products with a pH range of greater than 4.5 and less than 9.6 that permit the growth of *Staphylococcus aureus* and therefore, potential toxin formation.

The following products are exempted:

- Products that have been found not to support sufficient growth of *S. aureus* to allow enterotoxin production (confirmed by challenge studies, other research or scientific basis).
- Product that has been subjected to a HACCP compliant heat treatment may be excluded (post heat treatment) when post process contamination is able to be prevented (e.g. Product held in a closed system directly after the heat treatment (UHT or pasteurization)).
- Bakery products that contain active yeast as an ingredient.
- Products that undergo an active microbial fermentation as part of the design (e.g. lactic acid bacterial fermentation of cheese).
- Products whose processes meet the definition of continuous*.

CRITICAL CONTROL POINT ID:

Holding time and temperature in order to prevent more than 10 multiplications of *Staphylococcus aureus*.

Note: Additional control for Spore formers is not necessary when this CCP is applied, since the potential outgrowth of Spore formers is covered within that application. However, Spore former control needs to be considered if the product/process has been exempted from this model for one of the above reasons or by challenge testing or other research.

PROCESS STEP:

High moisture materials, (*e.g.,* egg slurries, wafer dough and dairy slurries) Holding time/temperature prior to the heat step.

Processes that do not meet the criterion of continuous must meet the model for material holding times and temperatures.

*Continuous is defined as a process that does not accumulate product that could remain stagnant during production (*e.g.,* hang-up points, buildup, dead ends), does not have holding steps, and passes a risk assessment involving a microbiologist or designated food safety representative. The risk assessment can include break down of lines and equipment to evaluate for product which has accumulated over 24 hours on the inside of lines or tanks.

In the absence of any product build up, the process would be considered continuous. When a process defined as continuous has an interruption, the model is applicable and the time and temperature of holding must be monitored, recorded, and verified that the limits of use have not been exceeded.

Product that remains in the line (buildup) during normal operation can be exempt from the requirements of the model if the system is purged (*i.e.,* using a pig/gopher for lines or a hot water flush for tanks and lines) to remove product build up every 24 hours. Less frequent cleaning is an option if the time/temperature conditions comply with the model.

HAZARD:

Biological (*Staphylococcus aureus* enterotoxin)

CRITICAL LIMIT:

STORAGE TEMPERATURE	MAXIMUM STORAGE TIME (HOURS)**
< 8 °C (< 45 °F)	only for product quality
>8°C - 10°C (45 - 50 °F)	60
>10°C - 12ºC (50 - 54 °F)	42
>12°C - 14°C (54 - 57 °F)	30
>14°C - 16°C (57 - 61 °F)	23
>16°C - 18°C (61 - 64 °F)	18
>18°C - 20°C (64 - 68 °F)	15
>20°C - 22°C (68 - 72 °F)	12
>22°C - 24°C (72 - 75 °F)	10
>24°C - 26°C (75 - 79 °F)	8
>26°C - 29°C (79 - 84 °F)	7
>29°C - 31°C (84 - 88 °F)	6
>31°C - 34°C (88 - 93 °F)	5
>34°C - 50°C (93 - 122 °F)	4
>50 °C (> 122 °F)	Only for product quality

** Holding times in the above table may vary based on challenge study results.

To allow for more flexibility the maximum holding time at varying temperatures can be calculated by using the following calculation worksheet:

The critical limit is defined as the point when the number in the F column reaches 10 (equaling 10 multiplications).

A	B	C	D	E	F
Process	Temperature (°C or °F)*	Holding Time (h)*	Multiplication rate/h (see table below)	Multiplication (column C*column D)	Accumulated multiplication

** Always use the maximum time/maximum temperature for the separate steps!*

Example:

A	B	C	D	E	F
Process	Temperature (°C or °F)*	Holding Time (h)*	Multiplication rate/h	Multiplication (column C*column D)	Accumulated multiplication
Mixing	30°C	4	1.48	5.92	5.92
Holding	25°C	3.5	1.028	3.598	(5.92+3.598=) 9.518

Multiplication rates / h (used to complete column D) at different temperatures

Temperature (°F)	Temperature (°C)	Multiplication rate/h
46	8	0.106
48	9	0.134
50	10	0.165
52	11	0.2
54	12	0.238
55	13	0.279
57	14	0.323
59	15	0.371
61	16	0.422
63	17	0.476
64	18	0.534
66	19	0.595
68	20	0.659
70	21	0.726
72	22	0.797
73	23	0.871
75	24	0.948
77	25	1.028
79	26	1.112
81	27	1.199
82	28	1.29
84	29	1.383
86	30	1.48
88	31	1.58
90	32	1.684
91	33	1.79

93	34	1.9
95	35	2.012
97	36	2.13
99	37	2.25
100	38	2.373
102	39	2.5

MONITORING ACTIVITY/FREQUENCY:

Holding time and temperature of each batch is monitored and recorded. The temperature is monitored and recorded for each batch at the frequency sufficient to demonstrate control.

If the holding time is based on the maximum possible storage temperature, then the temperature does not need to be monitored.

If storage temperature is greater than 8ºC (45ºF) or less than 50ºC (122ºF), temperature for each batch must be monitored and recorded at a frequency sufficient to demonstrate control.

CORRECTIVE ACTION ACTIVITY:

If critical limit for time/temperature is exceeded, then the batch has to be discarded and the appropriate equipment such as troughs, mixers, holding tanks, and/or lines shall be cleaned and sanitized before preparing the next batch. Identify the equipment containing the products as “on hold” (Category I) until disposal. Notify designated responsible person.

If records review indicates that non-conforming high moisture material was used, place all affected product on hold and notify Designated Quality Function for disposition.

Hold / Release documentation is required.

Corrective actions must be documented.

MINIMUM CCP VERIFICATION ACTIVITIES:

Designated responsible employee (usually the Supervisor) reviews and signs processing records at least daily.

All measuring devices used to monitor critical control parameters shall be calibrated at a frequency sufficient to demonstrate control.

REWORK HANDLING

CRITICAL CONTROL POINT ID: Proper segregation, identification, and use of allergen containing rework.
Note: The term rework applies to unpackaged or packaged product, removed from the flow of normal production processes due to equipment downtime, formulation issue, etc., to be brought back to the production line

PROCESS STEP:
Allergen Control - Rework Handling

HAZARD:
Chemical (Food Allergen) - Reference the *Appendix B.* Improper introduction of an undeclared allergen through the use of uncontrolled rework.

CRITICAL LIMIT:
No rework containing an allergenic material is added to a product that does not have that allergenic material listed on its ingredient label.

MONITORING ACTIVITY/FREQUENCY:
All containers of rework need to be labeled with a description of the product (product name, production date and any other relevant information).
The origin and ingredients of each container of rework are documented in the rework inventory records. Allergen containing rework or holdover product will only be reincorporated into the same and/or appropriately labeled product and will be documented on the process sheet OR rework / holdover product containing a food allergenic material is cross-referenced to the product ingredient label to confirm the allergenic material is identified on that label each time rework is added to a product, and is documented on the process sheet.

CORRECTIVE ACTION ACTIVITY:
If the origin and ingredients of rework cannot be determined, do not use the rework.
If rework contains a food allergenic material not listed on the ingredient label of the product being made, do not use the rework in that product.
If allergenic containing rework is added to product that does not list the allergenic material on its ingredient label, place the affected product on Category I hold, and notify Designated Quality Function to determine product disposition.
Hold/Release documentation is required. Corrective action must be documented.

RESPONSIBILITY: (Monitoring and Corrective Action):
Designated, trained employee

RECORD/LOCATION:

Rework Inventory Records
Process Records
Hold and Release Records
Corrective Action Records
Verification Records

MINIMUM CCP VERIFICATION ACTIVITIES:

Designated responsible employee (usually the Supervisor) reviews and signs Rework Inventory Records and / or Process Records at least daily.

EQUIPMENT CLEANING FOR ALLERGEN REMOVAL (PRODUCT CHANGEOVER)

CRITICAL CONTROL POINT ID:

Remove allergen containing product residue from all product contact surfaces, and adjacent areas above exposed product zones, by cleaning and inspecting the equipment.

PROCESS STEP:

Allergen Control - Equipment Cleaning (Product Changeover)
The visual inspection of the processing/packaging equipment and above exposed product zones to ensure no visual residue after a product changeover, from product containing known food allergen(s) to product that does not contain the same allergenic material(s).

HAZARD:

Chemical (Food Allergen) - *Reference Appendix B:* Hazard resulting from improper cleaning of equipment resulting in allergen cross-contact.

CRITICAL LIMIT:

No visible product residue on the surface of the processing/packaging equipment and above exposed product zones.

MONITORING ACTIVITY/FREQUENCY:

After each allergen changeover, prior to start up, the equipment shall be inspected to ensure that there is no visible product residue on product contact surface and other areas above exposed product zones. This inspection shall be documented.
If the equipment is cleaned using a Clean in Place (CIP) or Assisted Cleaning System (ACS), review the documented equipment cleaning process, and the record of its completion.
Note: the efficacy of the equipment cleaning process should be documented, and should be based on trial runs on the specific line / process.

CORRECTIVE ACTION ACTIVITY:

If during the inspection, allergen containing product residue is visible or if the review indicates non-compliance with the Equipment Cleaning Process, re-clean the equipment surfaces to remove the residue prior to running the non-allergen (or different allergen) containing product.

If records review indicate that allergen containing visible product residue was not removed or the equipment clean was not completed prior to startup with non-allergen containing product or a product with a different allergen profile, place all of the affected product on Category 2 hold and notify Designated Quality Function to determine disposition.

Hold/Release documentation is required. Corrective action must be documented.

RESPONSIBILITY (Monitoring and Corrective Action):

Designated, trained employee

RECORD/LOCATION:

Equipment Cleaning Process / Sanitation Records
Equipment Inspection Log / Sanitation Records
Hold and Release Records
Corrective Action Records
Verification Records

MINIMUM CCP VERIFICATION ACTIVITIES:

Designated responsible employee (usually the Supervisor) reviews and signs post allergen clean Inspection log at least daily or whenever allergen cleans occur.

For products that are not cross contact labeled, and if allergen test kits are available, the processing facilities shall verify cleanliness with the analytical kit.

For CIP and ACS, perform teardown inspection at a frequency sufficient to demonstrate control.

PRODUCT FLUSHING FOR ALLERGEN REMOVAL (PRODUCT CHANGEOVER)

CRITICAL CONTROL POINT ID:

Remove allergen containing product residue from the equipment via flushing with product (not containing the allergen) or ingredients (*e.g.,* sugar or water).

PROCESS STEP:

Allergen Control - Product Flushing - (Product Changeover)
Product flush after a product changeover from a product containing a known food allergen to a product that does not contain that allergen.

HAZARD:

Chemical (Food Allergen) - *Reference Appendix B:* Improper flushing of equipment resulting in the cross-contact of an allergen.

CRITICAL LIMIT:

The efficacy of the equipment flushing process applies to all critical limits and should be documented. The critical limit should be based on trial runs on the specific line / process to ensure the removal of the allergen.

All equipment product contact surfaces are flushed with X lbs./kgs. or gallons/liters of water; are flushed for Y length of time, such as to be in compliance with the validated documented equipment flushing process;

or

All equipment product contact surfaces are flushed with X lbs./kgs. or gallons/liters of an ingredient, such as to be in compliance with the validated documented equipment flushing process;

or

All equipment product contact surfaces are flushed with X lbs./kgs/ or gallons/liters of the following product that does not contain the allergen(s) or with the same allergen profile as the next scheduled product , such as to be in compliance with the validated documented equipment flushing process.

For some production lines the flush is combined with a cleaning process (*e.g.,* bakery lines). If such a partial clean or quality clean is required prior to flushing, compliance to the validated cleaning procedure is part of this CCP. The quality clean and the flush are part of the validation that needs to take place before the implementation of this CCP.

MONITORING ACTIVITY/FREQUENCY:

The flushing material (water, ingredient, following product, etc.) is weighed at the beginning of the process or accumulated, weighed or volumetrically measured at the end of flushing, and recorded each time there is a changeover from product containing a known food allergenic material to product that does not contain that allergenic material.

When a partial clean the equipment is required before the product flush, an inspection shall be performed to ensure that the partial clean has been performed before the product flush.

CORRECTIVE ACTION ACTIVITY:

If specified flushing procedures were not followed (or if records indicate they may not have been followed), place all affected product on Category 2 hold and notify Designated Quality Function to determine disposition.

If the flushing material is not properly disposed of and is added to product not listing the specified allergenic material, place all affected product on Category I hold and notify Designated Quality Function to determine disposition.

Hold/Release documentation is required. Corrective action must be documented.

RESPONSIBILITY (Monitoring and Corrective Action):

Designated, trained employee

RECORD/LOCATION:

Equipment Flushing Process
Product Flushing Log
Production Schedule
Product Batching Sheets
Flushing Material Usage Report (if reworked or relabeled)
Hold and Release Record
Corrective Action Record
Verification Records

MINIMUM CCP VERIFICATION ACTIVITIES:

The designated responsible employee (usually the supervisor) reviews and signs product flushing documentation whenever allergen changeovers (involving flushing) occur.
For products that are not cross contact labeled, if allergen test kits are available, verify the effectiveness of the flush with the kits.

EXTRANEOUS MATERIAL DETECTION

CRITICAL CONTROL POINT ID:

Metal Detector or in line X-Ray unit

PROCESS STEP:

Extraneous Material Detection

HAZARD:

Physical (Extraneous Material) of the size and shape to pose a health hazard in finished product. *E.g.,* Metal, Glass, Stones, Wood, Hard and/or Sharp Plastic

CRITICAL LIMIT:

Lines and/or processes identified as reasonably likely to pose a potential extraneous material hazard to finished product shall be equipped with a functioning extraneous material detection device (metal detector or in-line X-Ray unit).

and

The Plant HACCP Team shall identify in the HACCP plan both the quantity of product (packages, pounds, pieces) as **X**, and the time frame or length of production time as **Y** to establish the critical limit parameters. Once determined, the process shall be managed as follows:

- The process is considered to be in control when there are less than or equal to **X** confirmed contaminated packages/pieces/pounds of product in **Y** production hours.
- The process is considered to be out of control, and a deviation to the critical limit has occurred, when more than **X** packages/pieces/pounds of product are confirmed contaminated in **Y** production hours.

Note: When determining process control status, the **X** 'confirmed contaminated' packages/pieces/pounds of product can also be considered 'number of diverted' packages/pieces/pounds of product in cases where on-line confirmation of contamination is not feasible

(Facilities may use as a guideline that **X** be no greater than 10 and **Y** be no greater than 2).

NOTE:

- Determination for critical limit values for X and Y should be made based on product history.
- Extraneous material detection for raw materials and in-process products supplied to a Mondelēz International facility shall be compliant to the requirements of this model
- Use a standard set of terms to describe the findings (metal fines, nut, bolt, glass fragment, stone, etc.)
- Hazardous extraneous matter is material which is sharp and hard.
- Photographs of acceptable/unacceptable amounts and types of material are recommended.

MONITORING ACTIVITY/FREQUENCY:

Continuous: All packages/product shall pass through the operating extraneous material detection device.

Rejected packs/pieces/pounds shall be evaluated to determine cause for rejection where feasible, based on the nature of the finished product. Based on the product evaluation, the number of packages/pieces/pounds of product rejected due to confirmed contamination event shall be recorded to identify when a critical limit deviation has occurred.

If the nature of the product precludes inspection, each rejection event will be assumed to be a confirmed contamination event. In this case, the number of packages/ pieces/ pound of product diverted shall be either automatically or manually recorded at defined frequencies sufficient to identify when a critical limit deviation has occurred.

CORRECTIVE ACTION ACTIVITY:

If a critical limit deviation occurs, stop the process, place all products (packaged, unpackaged, rework, or other) produced during the suspect timeframe on Category II hold. Notify designated responsible person to determine disposition.

The suspect timeframe is the y hour run time if the deviation is associated with **X**, either:

- confirmed contaminated packages/pieces/pounds of product

  or

- total rejected packages/pieces/pounds of product in cases where on-line confirmation of contamination is not feasible.

An investigation shall be conducted to identify the root cause of the deviation, including attempts to isolate and identify the actual contaminants. Part of the investigation may include efforts to evaluate the potential of false rejects that are associated with the operation of the extraneous matter detection device instead of actual contamination events. This may include re-running rejected material through the device two or more times to check for additional rejection, or sieving of powdered product to determine the presence of any foreign material. If false rejection is initially suspected, this part of the investigation can occur prior to stopping the line and placing product on hold. Based on the investigation results, those additional actions will occur as needed.

After investigation, product determined to be contaminated with extraneous material of the size, shape, and/or nature to pose a food safety risk shall be placed on Category I hold. Notify Designated Quality Function for product disposition.

If investigation reveals the nature of the contaminant does not meet the criteria to pose a food safety risk, but rather is considered a product quality concern (*e.g.,* metal dust, soft plastic packaging material, etc.), retain product on Category II hold. Based on internal risk assessment of the Quality team the product can be released. In case of uncertainty notify Designated Quality Function for product disposition.

If a detection device is not working at its design limit, stop the line and repair or replace the device. The suspect timeframe is back to the last acceptable equipment verification event if the detection device is found not to be working at its design limit during a verification check. Place the product produced since the last time the device was verified to be operating at its design limit on Category II hold. Re-run the held product through a properly operating device. (If a detection device cannot be repaired or replaced, the line can continue to run if the product produced is placed on Category II hold and run through a properly operating detection device later, or disposition of product can be determined using an alternate method as documented in the HACCP plan.)

Hold/Release documentation is required.

Corrective action must be documented.

RESPONSIBILITY (Monitoring and Corrective Action):

Designated trained quality, production, and/or maintenance employees.

RECORD/LOCATION:

Extraneous Material Detector Log
Hold and Release Records
Corrective Action Records
Verification Records
* designate the location of each record

MINIMUM CCP VERIFICATION ACTIVITIES:

I. The extraneous material detection device is verified to be:

1. Set at its design detection limit for the finished (*i.e.,* converted) product being run. HACCP Plans must list the size and type of target extraneous material that the detector will detect (mm). External manufacturers and suppliers shall contact their Mondelēz International representative to obtain information on the size criteria for test pieces required by the organization.
2. Operating at the design limit by passing the required test pieces through the detection device in the manner and at the frequencies appropriate to demonstrate control.
3. Operating with a functional reject mechanism.

NOTE: Ideally the reject mechanism should automatically divert the test pieces and attached product/package to an isolated identified bin or area to prevent reentry into the product flow. Where automated diversion of rejected test pieces and/or product is not feasible due to the nature of the product or equipment, at minimum the rejection mechanism shall stop the production line when the test pieces and attached product/package are passed through the aperture, with a trained operator responsible to remove the test pieces and attached product/package from the production line.

II. Verification activities shall be documented and included as part of the records review indicated below.

III. Designated responsible employee (usually the supervisor) reviews and signs extraneous material detector records and verification records at least daily.

CERTIFICATE OF ANALYSIS (COA) FOR SENSITIVE INGREDIENT ADDED POST-LETHAL PROCESS [SPECIFIC PREREQUISITE PROGRAM MODEL]

RATIONALE:

Each lot of sensitive ingredients will be pre-tested and found to contain no detectable target pathogens of concern prior to use. Pre testing can include supplier test results in the form of a certificate of analysis (COA) or a Mondelēz International Laboratory generated test result (please see note below). Results must be generated by a laboratory that has been approved by Mondelēz International and participates in an approved pathogen check sample program.

PROCESS STEP:

Sensitive Ingredient Post-Lethal Process Addition or

Sensitive Ingredient Addition to Process with No Lethal Process Step

HAZARD:

Biological (Vegetative Pathogens)

CONTROL MEASURE OR LIMITS:

Each lot of sensitive ingredient must have a supplier COA certifying ingredient negative for the target pathogen(s) or Mondelēz International generated test results that indicate materials are negative for the target pathogen(s) per a predetermined sample size tested, (*e.g., Salmonella* negative per 10 x 25 gram samples.)

Note: Target pathogen(s) and the sample size to be tested are defined in the ingredient specification. Any deviations must be approved by a Mondelēz International Corporate Microbiologist.

MONITORING ACTIVITY AND FREQUENCY:

Receipt and verification of result of COA, or Mondelēz International generated test results for each lot received.

Verification that product remains on hold until test result received

Verify that the COA came from a Mondelēz International approved lab and testing was performed at the required sampling size and method.

CORRECTIVE ACTION ACTIVITY:

If the COA or test results are not received for each lot, then that lot of sensitive ingredient will remain on hold until COA (stating material negative for pathogens) is received. Hold/release documentation is required.

If the COA result is positive for target pathogen(s), reject that lot of material upon receipt. If Mondelēz International generated test result is positive for target pathogen(s), place material on hold and notify the supplier and designated quality function.

Hold/Release documentation is required.

Corrective action must be documented.

RESPONSIBILITY: (Monitoring and Corrective Action)

Designated, trained employee

RECORDS AND LOCATION:

COA Records or Mondelēz International generated Test Records

Hold and Release Records

Corrective Action Records

Verification Records

* designate the location of each record

MINIMUM VERIFICATION ACTIVTIES:

Receipt and verification of result of COA, or Mondelēz International generated test results for each lot received.

Verification that product remains on hold until test results are received.

Note: Suppliers and External Manufacturers shall contact their Mondelēz International representative to obtain information on the list of Mondelēz International-approved laboratories.

PRODUCT BAKING (HEAT PROCESSING INTERNAL PRODUCT TEMPERATURE) [SPECIFIC PREREQUISITE PROGRAM MODEL]

RATIONALE:

Where the validated processing temperature/time profile to achieve finished product quality parameters (saleable products) is above critical limit of 180ºF (82.2ºC), the oven bake step may be handled as a Specific Prerequisite Program (sPP). Relevant data (baking validation) must be available to support this decision and/or must be approved by Mondelēz International Corporate Food Safetyprior to implementation.

Note: Any dense or atypical filling or centers (i.e. meat, cream) or dough Aw <0.65 will require additional and product specific validation studies to determine appropriate processing parameters.

PROCESS STEP:

Product Bake (Continuous or Batch) – typical flour based products with dough aw>0.65

POTENTIAL HAZARD:

Biological (*Salmonella* spp.)

CONTROL MEASURE:

In Oven: The Product internal temperature is heated to above 180ºF (82.2ºC)

MONITORING ACTIVITY & FREQUENCY:

Finished product moisture and / or color will be monitored at the exit of the oven at a frequency sufficient to demonstrate control (example: once per shift).

CORRECTIVE ACTION ACTIVITY:

Finished Product moisture must range between X – Y determined by specification. If moisture is above upper limit of this specification confirm oven settings as established during baking validation and by process specification, measure
- For biscuits product temperature at the exit of the oven at current settings,
- For wafers confirm oven plate temperatures.

If the product is determined to be under processed per monitoring of validated product/process specified profiles or if the product center temperatures are found to be less than 180°F (82.2ºC) at oven exit, or if product moisture does not meet specification the product shall be placed on Category II. The plant Quality Supervisor should be notified and a root cause analysis shall be immediately initiated. If a Food Safety concern after investigation is confirmed or if product is determined to be under processed, place product on Category I hold to await disposition from Corporate Quality Function

RESPONSIBILITY:

Designated, trained employee

***RECORDS & LOCATION:**

Baking Validation Records

Baking Monitoring Records

Hold and Release Records

Corrective Action Records

* designate the location of each record

Minimum sPP Verification Activities

1. Baking Record review (moisture and / or color)
2. Each batch
3. Designated employee

GLASS BREAKAGE – PACKAGING
[PREREQUISITE PROGRAM MODEL]

OBJECTIVE: Assure zero broken glass packages in exposed or open product / package zone, no visible broken glass pieces in exposed product/package zones or above package conveyor and no more than x broken packages in y time (minutes, hours) of package filling. The following monitoring, corrective actions and documentation requirements must be implemented if glass packaging is used:

MONITORING ACTIVITY:

- Designated responsible employee inspects the packaging line:
  - prior to starting operations
  - after each glass breakage occurrence
- Designated responsible employee inspects Electronic sensor devices to detect broken packages at filling equipment. If electronic sensors are not available then employees must continuously observe line for breakage. Each line break and time of the break shall be recorded.

CORRECTIVE ACTION:

- If broken glass is found in exposed product/package zones at or above package conveyor, do not start up process and perform cleaning procedures again.
- If broken glass is found in exposed product/package zones at or above package conveyor while production is running, stop the production and perform cleaning procedures. Notify designated responsible personnel.
- If critical limit for the number of broken packages in a given period of time is exceeded, stop the process and investigate the cause for the excess breakage on line. (Common causes are bad glass, over torqueing on closure, misalignment, etc.) Correct the cause of the breakage and start up process.
- Corrective action must be documented. Reference plant glass breakage procedures.

RECORD/LOCATION: Designate the location of each record

- Production/Filler Records
- Corrective Action Records
- Hold and Release Records

These documents must be reviewed as part of the record review procedures (at least monthly is recommended).

PRINTED PACKAGING MATERIAL AND LABELS
LINE CHANGEOVER/CLEARANCE PROCEDURES

CRITICAL CONTROL POINT ID: Changeover of packaging equipment and printed packaging materials (including but not limited to: cut and stack labels; peel and stick labels/rollstock; cartons; film rollstock; rigid containers; lids; foil lidstock; sleeves, etc.).

PROCESS STEP: Identify the appropriate step for the process line under consideration.

HAZARD: Mixing of printed packaging materials (mixed *Mondelēz International Resource Codes*) due to leaving previous printed packaging materials in or on equipment at product changeovers or mixing products or materials within a finished case or pallet leftover from the prior run. (Hazard is potential for later putting a food product that has an allergen in a package that is not labeled as containing the allergen.)

CRITICAL LIMIT: Strict controls and line clearance procedures are in place to prevent inadvertent mixing of labels. At product changeovers, all printed packaging materials are removed from the production equipment and physically removed from the immediate production area. All materials removed are properly stored and identified.

MONITORING ACTIVITY/ FREQUENCY: At product changeovers/before start-up of a different *Mondelēz International Resource Code*, the operator utilizes a documented checklist and visually checks all pieces of equipment and the immediate area to assure that no printed packaging materials from the previous run are left inside equipment, on equipment, or in the immediate production area. The first material off the line is verified as being the correct *Mondelēz International Resource Code* and documented on the production records.

CORRECTIVE ACTION ACTIVITY: If production was started and equipment was not clear of previous printed packaging materials, notify supervisor, place affected materials on Category II Hold, and investigate. If *Mondelēz International Resource Codes* are confirmed as being mixed, place affected materials on Category I Hold. Include rework and production rejects in the hold if applicable. Management and quality staff will determine the appropriate disposition for the materials involved. This could involve write-off and destruction or sorting and re-labeling to correct the error.

RESPONSIBILITY: Designated trained* employee(s). *All operators have received training in allergen awareness and understand the critical nature and potential food safety risk of inadvertent mixing of labels or pre-labeled packaging materials.

RECORD/LOCATION: (Designate a location for each record)
Logs/checklists of changeover and start-up activities
Employee training records
Production run material reconciliation records
Corrective actions taken for CCP violation situations

Verification Records

MINIMUM VERIFICATION ACTIVITIES:

Designated responsible employee (usually a supervisor) reviews, signs and dates the documents daily to confirm that correct procedures were followed and documentation is correct and complete.

PRINT COPY VERIFICATION

Critical Control Point ID: Verification that print copy from actual press plates or cylinders match the print copy of the proof submitted by the customer.

HAZARD: Hazard is the potential to have a mislabeled or unlabeled allergen on a food package after food is packaged by the food manufacturer (customer).

CRITICAL LIMIT: Print copy from actual printing press plates and/or cylinders must be exact match to print copy proof provided by customer (hazard specifically for film that has allergen ingredients listed, allergen ingredients and wording must be correctly printed).

MONITORING ACTIVITY: Print copy accuracy is verified with each new plate or cylinder made by the plate maker or set-up technician prior to use on printing press operation (for some operations this is only possible with the first press sample from the printing press).

CORRECTIVE ACTION:
If production was started with plates that were found to have incorrect allergen information, printing press must be stopped, all film produced with the incorrect print shall be segregated and placed on Category I Hold. Production may resume after replacing the incorrect plates or cylinders with new plates or cylinders that have been verified as having the correct print and following the appropriate Line Changeover / Clearance Procedures.
If film produced with the incorrect print has multiple rows of print and some rows are correct printing, film may be reworked per appropriate documented rework process. Good film (with correct printing) may be released to normal distribution. All printed material with incorrect allergen printing must be destroyed. Film may not be used for recycle unless written permission from Mondelēz International is obtained.

RESPONSIBILITY: Designated trained* employee(s). *All operators have received training in allergen awareness and understand the critical nature and potential food safety risk of inadvertent mixing of labeled packaging materials.

RECORD/LOCATION Records can include (designate a location for each record):
Logs/checklists of print verification (including original proof copy from customer)
Employee training records
Production run material reconciliation records
Corrective actions taken for CCP violation situations
Verification Records

MINIMUM VERIFICATION ACTIVITIES: Designated responsible employee (usually a supervisor) reviews, signs and dates the documents prior to release of plates or cylinders to pressroom to confirm that correct procedures were followed and documentation is correct and complete.

CUT AND STACK LABELS [MODEL PREREQUISITE PROGRAM]

OBJECTIVE: Assure labels with different Mondelēz International Resource Codes are not mixed in stacks, cases or pallets. Cases and pallets are correctly labeled. The following monitoring, corrective actions, and documentation requirements must be implemented if printed sheets containing more than one type of label are slit or die cut, segregated into stacks, bundled sorted, cased and palletized.

MONITORING ACTIVITY:

The operator visually monitors and documents (at least twice per hour or at a frequency adequate to demonstrate control) each process: strip cutters, die cutters, binding/shrink wrapping, casing and palletizing to make sure that no labels are inadvertently mixed in a stack, case, or pallet. Only like labels are cut simultaneously in the same cutter. The operator visually checks and manually sorts each bundle prior to casing and monitors that the label on the case matches the bundle. If collation marks are present on labels, marks are checked as the bundles are placed into cases to assure all marks are aligned and are correct for the label being produced. The operator visually monitors that each case is being placed onto the appropriate pallet and that the cases and pallets are correctly identified. At the start of a production run and at the start of each shift a label is compared to a standard reference label and checks are documented.

CORRECTIVE ACTION:

If it is determined that potential exists for labels to be mixed in a stack, case, or pallet (e.g., due to human error; monitoring activities not being followed; detection/sorting devices malfunctioning; or production run reconciliation records not matching up), notify supervisor immediately, stop production, and place all material produced since the last good check on Category II Hold. If mixed *Mondelēz International Resource Codes* are confirmed in stacks, cases, or on pallets, suspect material is placed on Category I Hold pending evaluation and/or sorting. Management and quality staff will determine the appropriate disposition for the materials involved. This could involve write-off and destruction or sorting and re-labeling to correct the error.

RECORD/LOCATION:

Log of monitoring activities
Corrective actions taken records
Hold and Release Records
These documents must be reviewed as part of the record review procedures (at least monthly is recommended).

VALIDATION:

The label segregation procedure must be reviewed anytime a new/modified process or equipment is introduced.

GLOSSARY

Biologically Sensitive Ingredients

The *Mondelēz International Biologically Sensitive Ingredient Categories List* (*Appendix A*) consists of ingredients that may likely contain zero-tolerance pathogens, or support the growth of pathogens. Sensitivity of an ingredient is based on origin, the manner in which it is processed, and/or based on epidemiological and historical data. Sensitive ingredients may include rework/salvage, which has been handled.

Biologically Sensitive Ingredients with Non-Detectable Pathogen Testing Results

Sensitive ingredients that are tested using a Mondelēz International- approved pathogen laboratory and found to have no detectable target pathogens in a predetermined sample size. The target pathogen(s) and sample size will be determined by a Mondelēz International corporate microbiologist. The Supplier/EM would provide results in the form of a Certificate of Analysis (COA).

Codex* or *Codex Alimentarius

An international organization of scientists chartered by the United Nations World Health Organization to address food safety issues worldwide. The membership is composed of delegates from industry, academia and government.

Critical Control Point (CCP)

It is a point at which control can and should be applied so that a product safety hazard is prevented, eliminated, or reduced to an acceptable level. A Critical Control Point (CCP) will be such, that the entire product will be exposed to the control mechanism and monitored.

Cross-Contact Labelling (CCL)

"Cross-contact" occurs when a residue or trace amount of an allergenic food becomes incorporated into another food not intended to contain it and, as a result, the potential presence of the allergen is indicated in the product label.

Designated Quality Function

Individual in the Quality organization assigned the responsibility of HACCP plan approval and validation:

HACCP

Hazard Analysis Critical Control Point.

HACCP Team

A cross-functional team of experts responsible for the development of a HACCP Plan.

Hazard

A biological, chemical or physical agent that may cause a food to be unsafe for consumption.

Hazard Analysis

An evaluation of the ingredients and the process to determine if hazards exist. The analysis is documented to include ingredient / packaging assessments, processing step evaluations, allergen cross-contact production assessments and a product / process hazards evaluation summary.

Hold, Category-1 Product Hold

The product / material will be placed in a segregated and secured area when possible. All affected product will be visually identified and physically obstructed. For example, hold stickers / tags on pallets and chains placed across the bay / rack, or hold tape wrapped around the cases, or product placed in caged / fenced area that is locked. These controls also apply to facilities that use automated or computerized storage / inventory systems. Inventory is confirmed daily.

Hold, Category-2 Product Hold

The product / material will be placed in a segregated area when possible. All affected product will be visually identified and / or physically obstructed, as long as the method adopted effectively prevents inadvertent movement. These controls also apply to facilities that use automated or computerized storage / inventory systems. Inventory is confirmed weekly.

Manufacturing Plant

Any facility where Mondelēz International products are manufactured (internal facilities and external manufacturers).

Microbial Toxins

Toxins are protein or lipopolysaccharide compounds which are produced by microorganisms and cause specific harmful effects on the host. Examples of food related toxins are those of *Staphylococcus aureus* and *Clostridium botulinum.*

Monitoring

Monitoring is conducting a planned sequence of observations or measurements, at specified times, to assess whether control measures are operating as intended. It is a means to determine the current status of a parameter and to assess if expected performance levels are actually being achieved or if corrective action should be initiated. The regular repetition is a central element of monitoring in order to be able to drive conclusions by data comparison. Monitoring answers the question “Have it worked every time we did it?”

Prerequisite Program (PP)

Prerequisite program: The universal procedures used to control the conditions in the plant environment which contribute to the overall safety of the product.

Primary Preventive Control Mechanism

It is defined as the main mechanism for controlling pathogenic microorganisms in foods. *E.g.,* CCP(s) or refrigeration temperature for refrigerated foods. Refrigeration, which is normally the primary control mechanism for sporeformers,

will be considered a secondary control mechanism if the product is designed for refrigeration but it is likely to be kept out of refrigeration by the consumer or trade (*e.g.,* due to similar products on the market designed for ambient).
Note: Regional differences shall be taken into account as to whether refrigeration is considered a primary or secondary control mechanism for a particular product category.

Process Authority

A Process Authority may be an in-plant employee, an outside consultant or other professional who has specialized training for the process under review.

Refrigeration

Temperature storage conditions from +1 to 4ºC (35 to 40ºF). Refrigeration, which is normally the primary barrier to prevent sporeformers proliferation, will be considered as a secondary barrier if the product is designed for refrigeration but it is likely to be kept out of refrigeration by the consumer or trade (*e.g.,* due to similar products on the market designed for ambient storage). Note: There may be regional differences whether refrigeration is considered primary or secondary barrier for a particular product category.

Retorting

Processing in a cooker used to cook hermetically sealed canned foods utilizing pressure and super-heated steam or super-heated water to achieve commercial sterility.

Rework

Unpackaged or packaged product, removed from the flow of normal production processes due to equipment downtime, formulation issue, etc., to be brought back to the production line. Other terms that may be used include: Overflow, holdover, carryover, trim, salvage, re-chop, recycle, rinsing, surge, flushing masses, flushing sugar, etc.

Hazard Analysis

A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard or hazards in food.

Secondary Preventive Control Mechanism

An additional hurdle in a food system, which is not a CCP but is relied upon in the event of a primary mechanism failure, *e.g.,* pH in a refrigerated product to help protect product in the event of temperature abuse.

Specific Prerequisite Program (sPP)

Specific Prerequisite Programs (sPP) are applicable to hazards identified in specific processes at some manufacturing facilities. Such sPP are defined as the programs essential in order to control the likelihood of introducing food safety hazards to and/or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment.

Sporeforming Pathogen: An organism capable of producing chemical/heat resistant spores which upon outgrowth may produce toxin of public health significance that can cause illness or death in humans. Examples include:

- *Bacillus cereus,*
- *Clostridium perfringens*
- *Clostridium botulinum* proteolytic and non-proteolytic.

Thermal Process

Heating process that delivers lethality to pathogenic and spoilage microorganisms in an ingredient or a food product. Heat processes may include the following examples: pasteurization, Ultra High Temperature (UHT), cooking, roasting, baking, blanching, and retorting.

Validation/Reanalysis

The validation process is a systematic collection and evaluation of data from the process (series of measurements, adjustments, and checks) to establish scientific evidence that a device, piece of equipment, or system can successfully and consistently operate as designed and planned to control identified hazards by eliminating or minimizing the risk below set critical limits. It answers the questions: “Are we doing the right thing?” and “will it work?” It is also the part of the verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards. The first occurrence of this collection and evaluation of data is considered a “validation” while all subsequent re-validations are now referred to as “reanalysis”.

Vegetative Pathogen*:* A non-sporeforming, foodborne microorganism recognized as a public health hazard that can cause illness or death in humans. Below are some examples of bacteria, parasites and viruses, which fall into this category:

Bacteria	**Protozoan Parasites**
Listeria monocytogenes	*Cryptosporidium parvum*
*Staphylococcus aureus**	*Cyclospora*
Yersinia enterocolitica	*Entamoeba histolytica*
Enterohemorrhagic *E. coli* (*E. coli* O157:H7*)*	*Giardia lamblia*
Enterotoxigenic *E. coli*	**Zoonotic Parasites**
Enteropathogenic *E. coli*	*Taenia solium*
Enteroinvasive *E. coli*	*Toxoplasma gondii*
Shigella species	*Trichinella spiralis*
Salmonella species	**Viruses**
Campylobacter jejuni	Hepatitis A virus
Vibrio species	Noroviruses
Aeromonas hydrophila	Rotaviruses
Cronobacter sakazakii	

**vegetative pathogen producing heat-stable toxin*

Verification

The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan. Verification is the periodic application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the requirements identified during the validation process. Verification in its most simple terms is the actual comparison of design output with design input (settings done during Validation). Verification answers the question “Are we doing what we planned to do?”

Zero-tolerance pathogen

Any pathogen for which a zero tolerance has been established by Mondelēz International or regulatory authorities for the sample size tested. For example, pathogens recognized as zero tolerance by U.S. authorities include: Toxigenic *E. coli, Salmonella* species, and *Listeria monocytogenes*.

Revision Log:		
Date Revised:	**Supersedes:**	**Summary of Revision:**
July 2019	11-May-2010	Addition of revision log; logo and references to Kraft Foods were changed to Mondelēz International.
July 2019	11-May-2010`	Introduction; Sections 1 and 2: A definition of Specific Prerequisite Programs with examples was added; hazard evaluation flow and decision tree for CCP determination were updated.
July 2019	11-May-2010	Section 3 on hazards and hazard management criteria was updated and risk assessment matrices for biological and chemical hazards were added.
July 2019	11-May-2010	Sections 4 on HACCP plan documentation components and Section 5 on HACCP system verification/validation procedures were updated.
July 2019	11-May-2010	Appendices A to C were edited: HACCP plan review checklist was removed; the biologically sensitive ingredients category list was updated and the water risk assessment was added; the allergen category list was updated and Materials associated with food Sensitivity or Intolerance (MSI) and chemical contaminants were added; HACCP plan documentation forms were updated and examples were removed. A template for specific prerequisite programs was added.
July 2019	11-May-2010	Appendix D: CCP models section was updated and relevant models were kept. The general thermal processing model was added. Two specific prerequisite program models were added: Certificate of analysis (COA) for sensitive ingredient added post-lethal process, and product bake.
July 2019	11-May-2010	Appendix F: A glossary was added.