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# SUPPLIER AND EXTERNAL MANUFACTURER HACCP MANUAL

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## INTRODUCTION

*MDLZ 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 labelled packaging materials) manufactured for MDLZ. The HACCP system is a preventative 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.

The *MDLZ Supplier and External Manufacturer HACCP Manual* was developed to communicate MDLZ' 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 MDLZ' developed formulas, Kraft 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 universal procedures used to control the conditions in the plant environment which contribute to the overall safety of the product. MDLZ considers documented Prerequisite Programs as the foundation of food safety management. Prerequisite Programs must be developed, implemented, and documented before attempting to put a HACCP plan in place.
- 2. Hazard Analysis and Risk 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) construct 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 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 B:** MDLZ Biologically Sensitive Ingredient Category List

**Appendix C:** MDLZ Food Allergen Category List

- 4. HACCP Plan Documentation Components,** the required documentation for the HACCP plan is described. Forms for documentation and examples are provided in *Appendix D*. The content of the forms is required; however, the format of the forms is optional.

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**Appendix D:** HACCP Plan Documentation Forms and Examples

**Appendix E:** Model Critical Control Points and Prerequisite Programs


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

**Appendix A:** HACCP Review Checklist

6. **Packaging Suppliers.** Suppliers of packaging material (product-contact, labels, and labelled packaging materials) manufactured for MDLZ shall develop HACCP plans consistent with this standard. Additionally, more specific guidelines for Packaging Supplier are outlined on this chapter.

**Appendix F:** Packaging Model Critical Control Points and Prerequisite Programs

For any questions on the content contained within this document contact your MDLZ contracting representative.

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**1. PRE-REQUISITE PROGRAMS**

Prerequisite Programs are defined as the universal procedures used to control the conditions in the plant environment, which contribute to the overall safety of the product. MDLZ considers documented Prerequisite Programs as the foundation of food safety management. CCPs are not a stand-alone control but are part of a 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.

The following is a list of Prerequisite Programs that typically apply 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 informational. That is, it may include programs which are not needed in some situations and may not include programs which are needed in other situations. Occasionally, one of the Prerequisite Programs may be managed as a CCP (e.g., meat chilling for uncured ready-to-eat poultry). In some cases, a Prerequisite Program may be mandated by a regulatory agency.

**Premises**

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

**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

**Receiving/Storage**

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

**Equipment Performance and Maintenance**

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



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**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) Labelling

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## 2. HAZARD ANALYSIS AND RISK ASSESSMENT

In HACCP, a “hazard” is defined as a biological, chemical 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 risk 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 MDLZ developed formulas, Kraft product developers shall provide the Hazard Analysis and a partial HACCP plan to the Supplier/EM (a partial HACCP plan is described in Section 4.4). 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. MDLZ 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, 5) conduct 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 D* and Sections 4.1 and 4.2.

### 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 (Form D), and an assessment of allergen cross-contact within the process (Form E-1 and E-2).

Documentation requirements and forms are available in Section 4.3 and in *Appendix D*. It is critical that the Hazard Analysis be scientifically based and well documented.


### 2.3 Complete a risk assessment:

The next step is to complete a risk assessment on the hazards that have been identified. Summarize all the potential hazards on Form F and determine which hazards should be managed as CCPs and which hazards are to be managed by Prerequisite Programs. The risk of each hazard must be assessed for its severity, and for the likelihood of occurrence.

### 2.4 Determine nature of identified hazard(s):

A key concept in risk 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 as a CCP or in a Prerequisite Program. These are some of the considerations that should be kept in mind while 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.

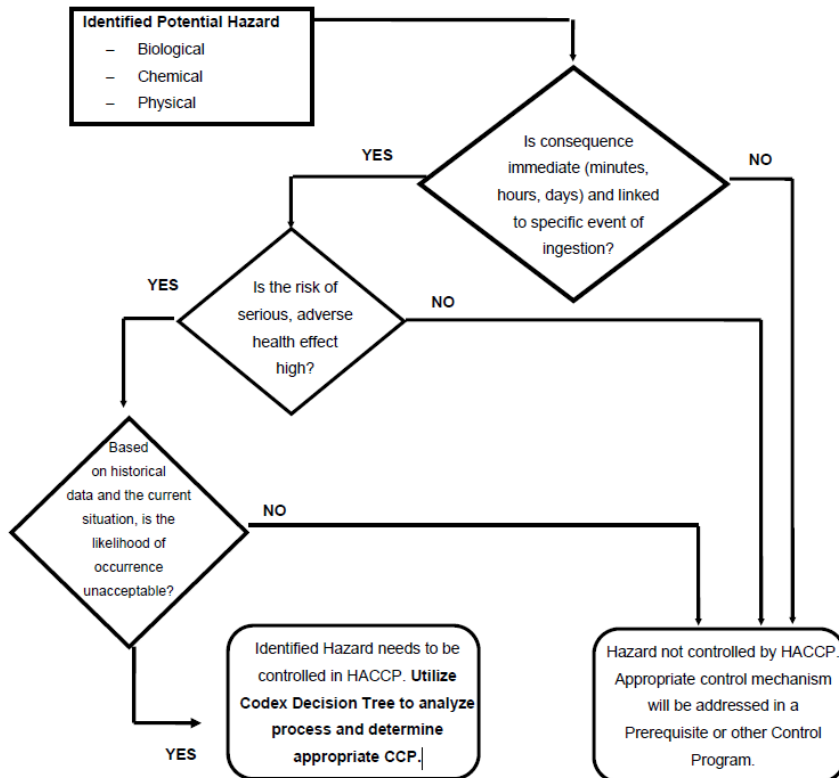
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### 2.5 Establish the Critical Control Points:


After the Hazard Analysis and risk assessment has 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 continuous, (all 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

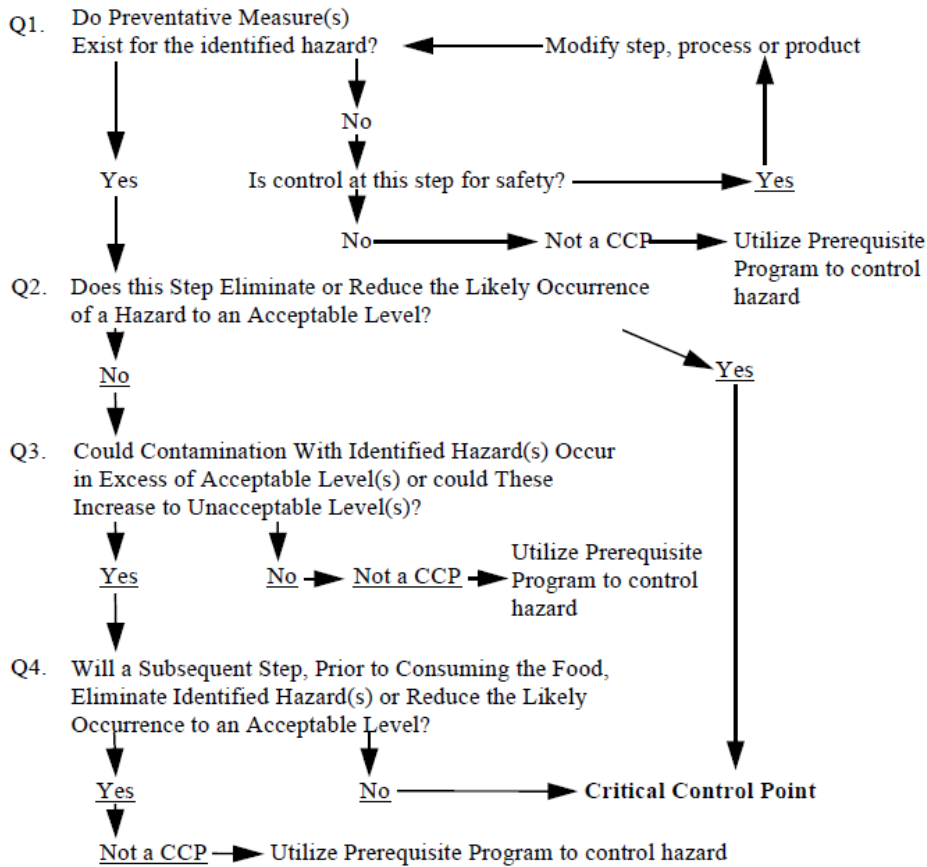
Before using this flow chart, a Hazard Analysis shall be completed, and potential hazards associated with the product/process shall be identified based on scientific evidence. For example, pathogens clearly are capable of causing harm based on scientific evidence. However, other concerns which are thought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






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**2.7 Codex Decision Tree for CCP Determination**



Edited From: Codex Alimentarius Commission. July 1993. *Revised Guidelines for the application for the Hazard Analysis Critical Control Point (HACCP) System.*  
 Note: If a CCP is determined to be post-manufacturing, then this shall be clearly communicated in the appropriate specification.

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### 3. STANDARD FOR HAZARDS THAT MAY BE MANAGED BY CCPs

#### 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.

##### 3.1.1 CCPs for Biological Hazards:

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 B, MDLZ 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.

- o **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 should include the time and temperature(s) of the process. Whenever possible, a process should be monitored continuously.

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

- o **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, 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.

- o **Drying:** Products that are dried to control pathogens may 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.

- o **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.

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

- o **Consumer Preparation:** Some products may rely on consumer preparation, rather than a CCP, as the pathogen kill step. Examples of these are Macaroni, highly perishable, short shelf-life, fresh, or raw products

##### 3.1.2 Definitions

- o **Vegetative Pathogen:** A non-spore forming, foodborne microorganism recognized as a public health hazard that can cause illness or death in humans. May include viruses, parasites and bacteria:


- Listeria monocytogenes*

- Staphylococcus aureus\**

- Yersinia enterocolitica*

- Enterohemorrhagic *E. coli* (*E. coli* O157:H7)

- Enterotoxigenic *E. coli*

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- Enteropathogenic *E. coli*
- Enteroinvasive *E. coli*
- Shigella* species
- Salmonella* species
- Campylobacter jejuni*
- Vibrio* species
- Cryptosporidium parvum*
- Cyclospora*
- Entamoeba histolytica*
- Giardia lamblia*
- Hepatitis A virus
- Noroviruses
- Rotaviruses
- Taenia solium*
- Toxoplasma gondii*
- Trichinella spiralis*
- Aeromonas hydrophilia*
- \*vegetative pathogen producing heat-stable toxin*

o **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 botulinum*, *Clostridium perfringens*.

o **Heat:** A thermal process that can deliver lethality to microorganisms. Heat processes may include the following examples: pasteurization, Ultra High Temperature (UHT), cooking, roasting, baking, blanching, and retorting.


o **Sensitive Ingredients (food safety):** The MDLZ Biologically Sensitive Ingredient Categories List (Appendix B) consists of ingredients that may likely contain zero-tolerance pathogens, or support growth of pathogens. Sensitivity of an ingredient is based on origin, the way it is processed, and/or based on epidemiological and historical data. Sensitive ingredients may include rework/salvage, which has been handled.

o **Zero-tolerance pathogen:** Any pathogen for which a zero tolerance has been established by MDLZ 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*.

o **Pathogen-free sensitive ingredients:** Sensitive ingredients that are tested using a MDLZ 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 MDLZ. The Supplier/EM would provide results in the form of a Certificate of Analysis (COA).

o **Certificate of Analysis (COA):** This is a document provided by the Supplier/EM that indicates results of specific tests/analyses performed on a defined lot of the supplier's/EM's product. The tests are performed either by the supplier/EM or an external testing firm and must be based on protocols/methods that have been approved and agreed by technical experts within the company (per MDLZ product specifications).

o **Primary Control Mechanism:** The main mechanism for controlling pathogenic microorganisms in foods, e.g. refrigeration temperature for refrigerated foods.

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

o **Refrigeration:** Temperature conditions not to exceed 8°C (45° F). Refrigeration normally the primary barrier for spore formers, will be considered as a secondary barrier if the product is designed for refrigeration but 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: There may be regional differences whether refrigeration is considered primary or secondary barrier for a particular product category.

### 3.2 Chemical

Mycotoxins, antibiotics, heavy metals, pesticides, food allergens and sulphites are potential chemical hazards. In most cases, due to the low likelihood of occurrence and/or the nature of the hazard, they are best controlled by Prerequisite Programs. However, in certain instances a CCP may be the appropriate control for a food allergen. Therefore, the following information regarding food allergens has been included.

#### 3.2.1 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 *MDLZ Food Allergen Category List (Appendix C)* consists of those foods, or food ingredients, that are known to produce severe, life-threatening reactions in sensitive individuals globally. 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. A non-immunological reaction to foods, also known as a Food Intolerance, are generally less severe but have been associated, in some instances with severe reactions. An example of a severe reaction is sulphite-induced asthma.

The exact prevalence of reactions to each of the allergens is unknown, but the prevalence of all true food allergies has been estimated 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. The criteria used to delineate these substances are as follows:

- o Food Allergic Reaction is proven to be through an IgE-mediated mechanism,
- o Confirmed by Double Blind Placebo Controlled Food Challenge Studies,
- o Prevalence rate in the range of Food Allergens as defined by Codex Alimentarius (1996, Report of the FAO technical consultation of food allergies),
- o Documented cases severe and/or life-threatening reactions in credible scientific and/or medical publications,
- o High potency (low levels documented in credible scientific and/or medical publications) to provoke severe reactions,
- o 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 *MDLZ Food Allergen Category List*.

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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 C

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

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

- o 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 MDLZ products must be strictly followed. When ingredients that are not included in or exempted from the *MDLZ Food Allergen Category List* are utilized in products commercialized in countries and/or regions that have defined regulatory requirements for their labelling, these ingredients must be appropriately identified to meet the applicable labelling requirements.

- o MDLZ 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 C* of this document.

- o **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 sulphites. Additionally, efforts must be taken in the manufacturing setting to ensure that

products containing greater than 10 ppm added sulphites do not cause other products produced in the same facility or on shared equipment to exceed the 10-ppm labelling requirement.

For further information regarding the *Appendix C* or its application, please contact your regional MDLZ representative.

### 3.2.4 CCPs and PPs 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:


- o **Rework Handling:** Allergen containing rework or holdover product will only be reincorporated into the same and/or appropriately labelled product.

- o **Labelling:** Undeclared allergens/sulphites 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/labelling is correct for the formula being produced.

- o **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 mislabelled products/unlabelled allergens.

- o **Packaging Line Changeover:** Removal of labelled packaging material from packaging equipment and the immediate production area and thorough inspection of equipment (prior to running a product containing an

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allergen) to prevent potential for a product containing an allergen to be packed in a package not labelled for that allergen.

### 3.2.5 Additional Controls for Allergen Management

- o **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.
- o **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.
- o **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 unlabelled allergens in these ingredients. Close cooperation and communication with suppliers is essential.

### 3.2.6 Scientific Basis

The *MDLZ Food Allergen Category List* was developed based on the scientific underpinning of over 4,000 peer-reviewed published articles. In addition, several authoritative bodies have developed allergen lists that are virtually identical to the *MDLZ Food Allergen Category List*, and thus independently confirming the MDLZ allergen list. These authoritative bodies, and the pertinent documents are:

- o International Food Biotechnology Council, “Allergenicity of Foods Produced by Genetic Modification”
- o Report of the FAO Technical Consultation of Food Allergies
- o International Life Sciences Institute - Europe, “Criteria for Selecting Relevant Allergenic Foods for Labelling”.

## 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. 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 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.

### 3.3.2 Management as a CCP or PP

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(s):

- o 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.

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o 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.

o 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

o Extraneous removal/detection devices may include:

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

#### 4. HACCP PLAN DOCUMENTATION COMPONENTS

HACCP Plan documentation forms and “filled in” examples are available in *Appendix D*. 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, food safety characteristics, process, how the product is used by the customer/consumer, packaging, intended consumer market, label instructions, special distribution and storage control, and shelf-life.

##### 4.2 Process Flow Diagram (Form B)

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.


Recommended information included on a Process Flow Diagram:

- o All processing equipment and steps that affect product characteristics. Include points of addition or generation of rework, air or gases used on product (or product contact), water introduced, etc.
- o CCPs are to be clearly labelled and numbered. CCPs for different hazard categories should not be combined into one CCP to avoid confusion.

##### 4.3 Information included in a Hazard Analysis

###### 4.3.1 Ingredient/Packaging Assessment (Form C)

List 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. List the storage condition, for example, ambient, refrigerated, or frozen.

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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). Determine if the control mechanism(s) shall be a Critical Control Point (CCP) or Prerequisite Program (PP).

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

This is to identify biological, chemical, 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.

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. Identify hazards introduced from the processing steps and the environment where ingredients, products, and rework are exposed. 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). Determine whether the control mechanism(s) shall be a Critical Control Point (CCP) or Prerequisite Program (PP).

**4.3.3 Allergen Cross-contamination Production Assessment (Forms E-1 & E-2)**

List all allergens in the product then review this list against all the products run on the specific processing line to determine if the noted allergen is found in all products produced on the line. If the allergen is not present in all products produced on the line, then there may be a risk of carryover of the allergen into a product where the allergen is not labelled. Further evaluation of the process must be conducted to determine the method of allergen control.

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

Finally, list all the hazards identified from the ingredients/packaging (Form C), the process (Form D), and the allergen cross-contamination production assessment (Forms E1 & E-2) on the summary (Form F). Also identify the control mechanisms, and the source of scientific or historical data, and then determine if the hazard is to be managed by a Prerequisite Program or a CCP. If control mechanism has been determined for all identified hazards and documented in Forms C, D, and E1 & E2, then Form F is optional.

**4.4 CCP Documentation (Form G)**


Describes the procedures necessary to control the identified hazard. The procedures in the CCP documentation need to be clear and complete. Detail is important to assure a properly functioning HACCP system. Information included in CCP documentation:

- o CCP number and description of the step in the process
- o Hazard which is being controlled. This can be either generic or specific terms depending on the CCP
- o Control Mechanism (CCP)
- o Critical Limits for control of the hazard
- o Monitoring (method, frequency, who)
- o Corrective action plan(s) (method, who) - identify product & disposition; identify & eliminate cause; restore control of the process; prevent recurrence
- o Record and its location (monitoring, corrective action, and verification records)
- o Minimum CCP verification activity (includes records review)

For MDLZ developed formulas, a MDLZ 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 E* and *Appendix F*.



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

Identifies the products covered by the HACCP plan. Recommended information included on a Document Index:

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

**4.6 Plant Layout (Form J)**


To assess cross-contamination potential between processing areas and identify Prerequisite Programs to manage and prevent cross-contamination. Review Plant Layout: each area or room shall be assessed and classified into one of three microbiological zones:

- o Areas which can be a potential source of contamination
- o Areas where product susceptible to pathogen survival is exposed
- o Areas where product susceptible to pathogen growth is exposed

If different microbiological zones are identified, and/or allergen cross-contamination potential are identified between processing areas, then the facility shall ensure that applicable Prerequisite Program(s) are documented and implemented. This assessment shall be documented e.g., mark the microbiological zones on Form J implement/modify local programs as required

**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.

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## 5. HACCP SYSTEM VERIFICATION AND VALIDATION PROCEDURES

### 5.1 HACCP Plan Verification Processes

Verification consists of activities, in addition to monitoring, that evaluate that the HACCP System is operating 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. Some PPs can be verified directly (e.g. cleaning and sanitation) by checking records and others indirectly (e.g. GMP) by checking training records or during GMP audits.

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

These are the CCP Verification activities as described in the individual CCP Models (*Appendix E*) under the “Minimum CCP Verification activities” section. These verification activities are generally performed by the 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:


- o 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.
  - o 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).
  - o Checking that the calibration has been done at the required frequency for the equipment’s used to monitor CCPs and PPs process parameters. For critical measurement devices frequency of calibration is 6 months as a minimum.
  - o 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 (3rd level verification).
- Please, note this list is not exhaustive. 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 (see *HACCP Review Checklist*). Objective of this verification is to review records over weeks or months to identify trends and root cause issues. The findings of these HACCP System Verification activities could indicate the need to initiate a HACCP Plan Validation.

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.

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### 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 Plan Validation

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.

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 prevent, eliminate or reduce to an acceptable level identified microbiological, chemical and/or physical food hazards. The questions we want to answer are:

- o Is the HACCP Plan well founded?
- o Are all hazards introduced by the raw materials or the processes identified in the HACCP Plan?
- o Are the controls sufficient to manage the given hazards?
- o Is this the right thing to do?
- o Did it work?
- o Will it work?

Validation involves checking the effectiveness and aims to continuously improve the HACCP System (see *Appendix A*).


Notes:

- o If a non-significant change is made, this can be incorporated directly into the current HACCP plan.
- o 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 is intended only to verify that all changes made since the last validation are reflected in the Hazard Analysis and, as needed, in the HACCP plan itself.

#### 5.2.1 When to Validate a HACCP Plan

Frequency every two years and:

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

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### 5.3 Process and Equipment Validation

A process and equipment validation study of processing equipment that is used for CCP control shall be carried out:

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

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

## 6. PACKAGING SUPPLIERS

Suppliers of packaging material (product-contact, labels, and labelled packaging materials) manufactured for MDLZ shall develop HACCP plans consistent with this standard. For Packaging Suppliers, Kraft has defined PCCPs.

These are Packaging Critical Control Points, which do not fulfil 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 (161°F) for 15 seconds. The PCCPs given in the *Appendix F*, 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 risk analysis must be available for all products produced for MDLZ. Appropriate Prerequisite Programs must also be in place.

### 6.1 Hazard Analysis and Risk Assessment


For the purpose of packaging materials, where possible the risks associated with the materials should be considered from the end point use by MDLZ manufacturing plants and consumers using the MDLZ packaged products.

#### 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):

- o Paperboard (primary packaging) manufacturing process—insufficient biocide during pulping and paperboard-make process (most likely managed by a Prerequisite Program vs. a CCP)
- o 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)
- o Glass manufacturing—defects that would allow leakage (e.g. cracks, chips, dips in finish)
- o Cap manufacturing—insufficient or incorrect sealing compound on caps
- o Can manufacturing—can seam defects on the manufacturer's end or inadequate sealing compound
- o Film used for lids—defects allowing leakage
- o Retort cups—defects allowing leakage
- o Retort pouch—defects allowing leakage

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 F*).

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**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:

- o 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)
- o Raw materials used for packaging material or printing where the material has a high probability of being ingested or put into the mouth (e.g. products targeted for small children)
- o Adhesives that have potential to contact food products (e.g. falling off carton into food when package is opened)
- o Changeover from conventional packaging conversion to food packaging (e.g. high purity demand of printing inks)

**6.1.3 Potential mixing labels risk**


In addition, manufacturers of labels and labelled packaging materials must include a risk assessment and have controls in place for preventing or controlling the risk of mixing labels or labelled materials (allergen/non-allergen labelling). Persons with food allergies rely on correct labelling of products to prevent ingesting a potential life-threatening allergen. 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 labelled packaging material processes to assure labels are not mixed.

The following list includes some identified potential manufacturing errors (allergen mislabelling) for manufacturers of labels and labelled packaging materials, which could lead to chemical hazards with the end-consumer (if a product containing allergens is mislabelled). 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 labelled packaging materials by the supplier.

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

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 labelled 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 labelled materials at line should be managed as a CCP or a Prerequisite Program for most types of operations (see *Appendix F*). 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 F*).

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**APPENDIX A: HACCP REVIEW CHECKLIST**

**Purpose:** A tool for the validation of HACCP Systems, based on recommendations of NCIMS/FDA & MDLZ HACCP team.

**How to use this checklist:**

- o If any “No” answers identified during the completion of the checklist, use the HACCP Plan Development Process to update the HACCP plan.
- o The validation team must evaluate if as a result of any “No” answers marked on this checklist there are any Food Safety implications by writing “Yes or No” in the Food Safety Implication column.
- o Then the team shall complete the modifications required either in the HACCP plan or in the actual facility or process and specify the completion date of these actions.
- o The completion of these actions should be tracked as part of the plants corrective actions program
- o List specific documents and records reviewed during the validation

Topic	Yes/No	If No Describe	FS Implication Yes/No	Corrective action Completion date
<b>1. Evaluate product &amp; process</b>				
Product description available and complete				
Is the risk for all Raw materials correctly assessed, including water as ingredient (Biological, physical and chemical)				
Is a flow diagram available and covers all process steps, including rework preparation? (Are new equipment /changes to equipment since last validation included)				
Does process step evaluation cover each process step mentioned in flow diagram and are all risk correctly identified (Biological, physical and chemical)				
Is an allergen assessment done and allergen zones indicated on plant lay out (if applicable)? - from ingredient - from cross contamination - from rework				
Where Allergen cleaning or flushing is applied has a validation been performed?				
Is the zoning correctly done and managed based on microbiological risk (raw, processed and high care zoning)?				
<b>2. Evaluate product category safety history/trends</b>				
Record review confirmed not evidence of trends of excessive CCP deviations (Process capability)				
In case pathogen testing of finished products is required are the results within specification?				
No trends detected in food safety related consumer complaints.				
Are all outstanding issues from last HACCP plan verification/validation closed out?				
<b>3. Evaluate adequacy of CCPs, Critical Limits, Monitoring, Corrective Actions, CCP Verification, and record keeping procedures. Review current CCP documentation. Review Prerequisite Programs.</b>				
Based on this manual are all identified hazards addressed in documents and correctly controlled?				
Based on Codex Decision Tree or other tools, are CCP's the right ones and adequate?				




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Have Processes or Equipment validation been performed to assure process complies critical limits?				
Is monitoring methods and frequency adequate to control the critical limits?				
Do corrective actions correct & control deviations?				
Do Prerequisite Programs identified in the Hazard Analysis controls the hazards identified?				
<b>4. Pathogen Environmental Monitoring (PEM)</b>				
Is a PEM plan available and implemented in line with MDLZ SQE 3.11 (for suppliers) or EMQR 6.3-05 (for EM)? (if yes, then the plan is considered agreed by MDLZ)				
Does review of PEM results shows no positive results?				
In case of positive findings: Were they in line with MDLZ requirements based on SQE 3.11 (for suppliers) or EMQR 6.3-05 (for EM) and did address and resolve the issue?				
<b>5. Non-pathogen environmental monitoring (non-PEM) / Water</b>				
Is water sampling plan and testing available? For Suppliers, according to Section G from the SQE Resource Document. For EM must be according to MDLZ EMQR 6.3-01-01 requirements.				
Does review of results shows no issues?				
In case of wet cleaning, are clean equipment swabs taken? For EM, is it in line with MDLZ Sanitation Manual?				
Is microbiological air monitoring performed? For EM, is it in line with MDLZ Sanitation Manual?				

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**APPENDIX B: MDLZ 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.


**General Exemptions (only those listed)**

Ingredients/products, sourced from approved suppliers:

- Fully deodorized: cocoa butter
- Anhydrous oils, fats and lecithin

<b>MDLZ Biologically Sensitive Ingredient Categories</b>		
<b>Category of Biologically Sensitive Ingredient</b>	<b>Category includes (but not Limited to):</b>	<b>Exclusions (only those listed):</b>
Milk/Dairy Products	Proteins, e.g. caseinates	Lactose
Starter Media		
Yeast/Yeast Extracts		
Enzymes/Rennet's		Microbial origin
Gelatine		
Meat/Fish/Poultry/Seafood		
Eggs/Egg Products		
Soy products	Soy flour	Soy lecithin
Fruits/Fruit Products		Candied fruit, fruit in alcohol, jams/jellies, dried fruits having an Aw of $\leq 0.81$ and a pH of $\leq 4.0$ , dried fruits having an Aw of $\leq 0.81$ with an initial sulphite content of 100 ppm minimum
Spices/Herbs	Flavours/enhancers made from spices/herbs	Extracts (e.g. alcohol/solvent based)
Tea		
Mushrooms		
Coconut		
Vegetables/Vegetable Products		
Seeds/Seed Products	Sesame seed paste (tahini)	
Grains/Grain Products		Starch and heat processed products, e.g. Corn flakes, rice crisps
Cocoa Products	Pure pressed cocoa butter	
Natural Gums/Thickeners		Xanthan gum, gelling agents (e.g. pectin, agar agar)
Green Coffee beans		
Nuts/Nut Products	Nut pastes, marzipan	
Flavours	With sensitive carrier (e.g. gum Arabic) or other components that are regarded as sensitive	Containing (w/w) (applicable to flavour and its sensitive ingredients) >10% ethanol, >30% propylenglycol, >50% Triacetin, or essential oils as main carrier, or flavouring substances (as defined by European Flavouring Directive 88/388/EEC)



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**NOTES:**


- 1) 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 MDLZ process authority for the adequacy of the process and based on the outcome could be exempted from biological sensitivity.

2) 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 TVC (Total Viable Count) and coliforms. This clean or treated water would be considered a non-sensitive ingredient. If the source water has results TVC: >500cfu/ml, coliforms positive/100ml or if surface water is used then this untreated or surface water must be considered sensitive and prior to use it must be treated, i.e. managed within Prerequisite Program (e.g. chlorination). If water is considered sensitive, then “well water inspection by third parties” can be considered one of the Prerequisite Programs to manage water safety.

In addition, the risk of contamination with viruses and/or parasites must be assessed.

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.

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**APPENDIX C: MDLZ 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.

**In addition to the allergens from the list below, the following substances must be managed as allergens:**

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

**Chestnut and Hickory:** only for Latin America (excluding products produced in Mexico for US)

<b>MDLZ FOOD ALLERGEN CATEGORY LIST</b>			
<b>Category of Food Allergen</b>	<b>Positive List of Ingredients or Foods includes (but not limited to):</b>	<b>Examples of foods that often contain this material</b>	<b>Exemptions to the Category of Food Allergen</b>
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, hydrolysed egg protein	Mayonnaise, meringue	
Fish	e.g., Cod, Haddock, Flounder, Trout Each species within this category, must be regarded as a separate allergen		Gelatine from fish.
Lupine/Lupin	Lupine flour, lupine 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, hydrolysed milk protein <i>*Only if it contains protein</i>	Margarines, milk chocolate, ice cream, custard, nougat pudding	Lactose and lactitol which contains no protein (specification must indicate process for protein removal)



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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, hydrolysed peanut protein	Mixed nuts	
Seeds: sesame seeds	Sesame paste, Tahini paste	Hummus, biscuits, dressings and sauces	
Soybean /Soya bean	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 hydrolysed soy proteins greater than 62% Amino Nitrogen/Total Nitrogen (85% minimum degree of hydrolysis)
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	
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, hydrolysed wheat protein	Breadcrumbs, crackers, bread, pasta	Wheat derived glucose, glucose syrup, dextrose, dextrose monohydrate, maltodextrin (all DEs), sugar alcohols, and caramelized glucose

**Scientific Basis for Exemptions to Allergen Category List**

**LACTOSE AND LACTITOL:** There are different processes to obtain lactose. If a process is used removing the protein, the process has been validated, and the specification indicates the process, then lactose is exempted from the MDLZ Food Allergen Category List.

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**TOCOPHEROL EXTRACTS:** Tocopherol extracts (antioxidant used in flavours) are usually purified by vacuum distillation, which eliminates the allergenic protein. If other means of purification are used, the process has been validated to eliminate the allergenic protein, and the specification indicates the process, then tocopherol extracts are exempted from allergen control.

**HIGHLY REFINED or REFINED, BLEACHED AND DEODORIZED OILS DERIVED FROM ALLERGENIC SOURCES (AND THEIR DERIVATIVES):** Edible oils described in studies as highly refined do not demonstrate a hazard to allergic individuals, as shown in studies using the “gold standard” for food allergy diagnosis, the double-blind placebo-controlled food challenge. To date, there is no in-vivo-evidence to support correlation of in-vivo reactivity with in-vitro IgE-binding to oil components in immunoblotting studies.

The majority of well-defined and performed studies support the position that refined oils are safe for the food-allergic population to consume (Hefle and Taylor: Food Technology, 53, No. 2, 62-70, 1999).

**SOY LECITHIN:** Search of the available scientific literature (FARRP, 1997) revealed no credible documented evidence that this material causes severe allergic reactions. Expert opinion rendered by S. Taylor/D. Skrypec 1997 (personal communication with S. Taylor; May 16, 1997, memo to T. Crincoli) and FARRP Expert Opinion 2006 (S. Taylor and S. Hefle, FARRP, 2006) supports this conclusion.

**WHEAT DERIVED GLUCOSE, GLUCOSE SYRUP, DEXTROSE, DEXTROSE MONOHYDRATE, MALTODEXTRINS (ALL DES), SUGAR ALCOHOLS, AND CARMALIZED GLUCOSE:** Evidence as specified below indicates that these materials contain no detectable protein using current analytical procedures.


Evidence: Data from the European Starch Manufacturers’ Association (AAC) of July 1998 and March 1999 and an SCF report of June 1999 provide evidence that no protein is present in starch hydrolysates derived from maize. If nitrogen is detectable, this corresponds only to fragments of polypeptides. Proteins are eliminated by several purification steps. The data have been judged to be equally applicable to wheat starch hydrolysates because for these the same purification procedures are used (T. Hatzold, after consultation with Mr. Plan from AAS, Brussels, November 1999). An analysis carried out by a MDLZ approved laboratory in July 1999 of three samples of wheat derived starch hydrolysates revealed "no protein". These values have been reviewed with the MDLZ analytical group and have been assessed as valid. Latest data from AAC (Oct 6, 2003) show that the protein level in wheat starch hydrolysates is below the detection limit.

References:

- AAC (Association des Amidonneries de Cereales del U.E.): Starch and Starch derivatives produced from Bt Maize, AAC Study on DNA Analyses, July 1998
- AAC (Association des Amidonneries de Cereales del U.E.): Letter to Prof. Tobback, Member of the SCF, re. Inclusion of Starch hydrolysates in the "negative list", Brussels, 16 March 1999


**GELATIN DERIVED FROM FISH:** Review of preliminary data from threshold study (Codfish-derived gelatine given to cod-allergic individuals in a double blind, placebo controlled oral challenge) supports this exemption. FARRP letter dated August 31, 2001. Interim results from two studies suggest a high likelihood that fish gelatine is not a problem for fish allergic individuals (S. Hefle opinion, Aug. 31, 2001). FARRP Expert Opinion: Allergenicity of Fish Gelatine (S. Taylor, S. Hefle, and J. Kabourek, November 06, 2003)

**CULTURES AND ENZYMES PRODUCED BY A FERMENTATION PROCESS USING AN ALLERGENIC PROTEIN SOURCE:** Search of the available scientific literature (FARRP literature search and S. Hefle opinion, December 2003) revealed that credible allergic reactions to enzymes produced by a fermentation process where allergenic protein containing

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material is used as source of protein did not exist. This exemption is further supported by the fact that immunological analysis has not detected allergenic proteins in a number of enzymes produced by this process.


**ACID HYDROLYZED SOY PROTEIN:** Acid hydrolysed soy proteins with a minimum value of 62% Amino Nitrogen/Total Nitrogen corresponding to a minimum 85% degree of hydrolysis have not been associated with a risk to soy allergic individuals. (Expert opinion S. Taylor, Ph.D., FARRP, September 2009).

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APPENDIX D: HACCP PLAN DOCUMENTATION FORMS AND EXAMPLES


**PRODUCT/PRODUCT CATEGORY DESCRIPTION**  
Form A

<b>Product/Product Category</b> (e.g. Name, type, size)	
<b>Process</b> (e.g. Cold pack, hot fill, aseptic, freeze dried)	
<b>Food Safety Characteristics</b> (e.g. pH, Aw, % salt, pasteurization, cooking, preservatives, refrigeration)	
<b>Intended Market</b> (e.g. General public, age, adult, child, retail, food service, countries, regions, national)	
<b>Consumer/Customer Use</b> (e.g. Ready to consume, heat and consume, mix and consume)	
<b>Labeling/Label Instructions</b> <b>List only those ingredients containing allergens, sulfites</b> (e.g. Preparation, storage needs, use by, best when used by)	
<b>Packaging</b> (e.g. Foil , plastic, glass, cup, can, hermetically sealed, gas permeable, tamper evident, modified atmosphere packaging)	
<b>Normal Run Time*</b> (Time between sanitation cycles) <b>Extended Run Time*</b> (Time and Date Approved) *Optional if no Food Safety Implication	
<b>Shelf Life</b> (e.g. Days and temperature conditions)	
<b>Storage &amp; Distribution</b> (e.g. Ambient, refrigerated, frozen, relative humidity, high altitude)	

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**PRODUCT/PRODUCT CATEGORY DESCRIPTION**  
**Example Form A**

<b>Product/Product Category</b>	Fat Free Brick Cream Cheese - 8 oz. Brick
<b>Process</b>	Pasteurized, cultured, hot packed dairy product
<b>Food Safety Characteristics</b>	Pasteurization, formulation, refrigeration, active fermentation
<b>Intended Market</b>	General Public
<b>Consumer/Customer Use</b>	Ready to Consume
<b>Labeling/Label Instructions</b>	Labeled allergens include: Milk protein Best when used by date Keep Refrigerated
<b>Packaging</b>	Brick - Hot packed in foil, plastic blue card, within display carton. After opening, use by date.
<b>Normal Run Time*</b> (Time between sanitation cycles)	24 hours
<b>Extended Run Time*</b> (Time and Date Approved)	40 hours - approved May 2009
<b>*Optional if no Food Safety Implication</b>	
<b>Shelf Life</b>	150 Days
<b>Storage &amp; Distribution</b>	35-45F refrigerated storage and distribution


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**PROCESS FLOW DIAGRAM  
Form B**

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
- 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.



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**INGREDIENT/PACKAGING ASSESSMENT**

**Form C**

**Purpose:** To identify biological, physical, and chemical hazards that may be introduced by ingredients, ingredient packaging materials, rework or finished product contact packaging materials, and to determine the control mechanisms for the identified hazards. Note: Listing of control mechanisms for biological, physical, and chemical hazards is optional on Form C if Form F (Product / Process Hazard Evaluation Summary) is completed.

**HACCP STANDARD references:**

- Sections 3 and 4.3 of this manual
- *Appendix B* for the list of ingredient categories containing biological hazards
- *Appendix C* for the list of allergens

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. resealable 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.

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 Prerequisite Program (PP).

Do not leave any sections blank. List "NA" (not applicable) if appropriate and avoid the use of acronyms (e.g. CMC is carboxy methyl cellulose).

RM Number	INGREDIENT NAME	STORAGE CONDITION A=Ambient F=Frozen R=Refrigerate	POTENTIAL HAZARDS ( B ) VP = Vegetative Pathogen ( B ) SP = Spore forming Pathogen ( C ) Chemical ( P ) Physical	SIGNIFICANT RISK Is a Hazard Reasonably Likely to Occur? (Yes or No)	RATIONALE or BASIS	CONTROL MECHANISMS	CCP or PP?
			(B)	(B)	(B)	(B)	
			(C)	(C)	(C)	(C)	



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**INGREDIENT/PACKAGING ASSESSMENT- Example Form C**

RM Number	INGREDIENT NAME	STORAGE CONDITION A=Ambient F=Frozen R=Refrigerate	POTENTIAL HAZARDS ( B ) VP = Vegetative Pathogen ( B ) SP = Spore forming Pathogen ( C ) Chemical ( P ) Physical	SIGNIFICANT RISK Is a Hazard Reasonably Likely to Occur? (Yes or No)	RATIONALE or BASIS	CONTROL MECHANISMS	CCP or PP?
522-0046-200	Milk	R	(B) VP	(B) Yes	(B) Pathogens may be present in raw material	(B) (VP) HTST Pasteurization	CCP# 1
			(B) SP			(B) (SP) Active Fermentation	PP
						(B) (SP) Formulation/Cooling	PP
			(C) Allergen milk protein	(C) No	(C) All the products on this line are labeled as containing milk allergen	(C) Labeling	PP
			(C) Antibiotics	(C) No	(C) Supplier certification programs and antibiotic testing of every milk load ensure that the risk for antibiotic contamination is low	(C) Supplier Certification (C) Testing Program	PP
			(P) Extraneous	(P) No	(P) Based on historical experience at the plant, hazardous materials are not likely to occur.	(P) Filter	PP
555-0841-000	Water	A	(B) VP	(B) Yes	(B) Pathogens may be present in un-treated surface water	(B) Process Cheese Pasteurization (B) Municipal Water Treatment-City	CCP# 2
			(B) Viruses	(B) Yes	(B) Viruses may be present in untreated surface water	(B) Plant Chlorination-Well	PP
			(C) None	(C) No	An expert toxicologist has reviewed this ingredient and relevant scientific literature and has concluded that	None	PP NA
			(P) None	(P) NA	there is no evidence that a chemical hazard exists. (P) Due to historical plant experience, extraneous is unlikely to be found in this material	None	NA
522-0018-004	Milk, nonfat dry	A	(B) VP	(B) Yes	(B) Pathogens may be present in raw material	(B) (VP) Process Cheese Pasteurization	CCP# 2
			(B) SP			(B) (SP) Formulation/Cooling	PP
			(C) Allergen milk protein	(C) Yes	(C) Milk is an allergen	(C) Labeling	PP
			(P) None	(P) NA	(P) Due to historical plant experience, extraneous is unlikely to be found in this material	None	NA
000-0000-000	Rework	R	(B) VP	(B) No	(B) Pathogens may be present in raw material	(B) (VP) Process Cheese Pasteurization	CCP# 2
			(B) SP			(B) (SP) Formulation/Cooling	PP
			(C) Allergen – Milk protein	(C) Yes	(C) Milk is an allergen	(C) Labeling	PP
			(C) Allergens from unlike rework	(C) Yes	(C) Allergen could carry over from use of unlike rework	(C) Rework Handling	CCP# 6
			(P) None	(P) No	(P) Based on historical experience at the plant, hazardous materials are not likely to occur.	None	NA
0400055 5700300	Foil – Direct Contact Packaging	A	(B) None	(B) No	(B) An expert microbiologist has reviewed this ingredient and relevant scientific literature and has concluded that there is no evidence that the material could pose a pathogen risk.	None	NA
			(C) None	(C) No	An expert toxicologist has reviewed this ingredient and relevant scientific literature and has concluded that there is no evidence that a chemical hazard exists.	None	NA
			(P) None	(P) No	(P) Based on historical experience at the plant, hazardous materials are not likely to occur.	None	NA

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**PROCESSING STEP EVALUATION**

**Form D**

**Purpose:** To identify biological, physical and chemical hazards that may be introduced from the process and/or processing environment, and to determine the control mechanisms for the identified hazards. Note: Listing of control mechanisms for biological, physical, and chemical hazards is optional on Form D if Form F (Product / Process Hazard Evaluation Summary) is completed.

**HACCP STANDARD references:**

- Sections 3 and 4.3 of this manual

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 if there are areas/equipment where ingredients, products, or rework are exposed.

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 CCP Model name and Prerequisite Program name.

Determine whether the control mechanism(s) shall be a Critical Control Point (CCP) or Prerequisite Program (PP).

Cite the scientific basis for the critical limit (e.g. regulatory guidelines, experimental studies, scientific publications).

Do not leave any sections blank.

If no hazards exist, describe with "None".

PROCESS STEP	POTENTIAL HAZARDS ( B ) VP = Vegetative Pathogen ( B ) SP = Sporeforming Pathogen ( C ) Chemical ( P ) Physical	SIGNIFICANT RISK Is a Hazard Reasonably Likely to Occur? (Yes or No)	RATIONALE or BASIS	CONTROL MECHANISMS	CCP or PP?
	(B)	(B)	(B)	(B)	
	(C)	(C)	(C)	(C)	
	(P)	(P)	(P)	(P)	



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**PROCESSING STEP EVALUATION- Example Form D**

PROCESS STEP	POTENTIAL HAZARDS ( B ) VP = Vegetative Pathogen ( B ) SP = Sporeforming Pathogen ( C ) Chemical ( P ) Physical	SIGNIFICANT RISK Is a Hazard Reasonably Likely to Occur? (Yes or No)	RATIONALE or BASIS	CONTROL MECHANISMS	CCP or PP?
Raw Milk Receiving	(B) None	(B) No	(B) No biological hazards are identified at this step in the process	None	NA
	(C) None	(C) No	(C) No chemical hazards are identified at this step in the process	None	NA
	(P) None	(P) No	(P) No physical hazards are identified at this step in the process	None	NA
Raw Milk Storage	(B) VP - growth	(B) No	(B) Growth of pathogens is prevented by proper refrigeration	(B) Refrigeration	PP
	(B) SP - growth				
	(C) None	(C) No	(C) No chemical hazards are identified at this step in the process	None	NA
Heat Milk in HTST Pasteurizer	(B) None	(B) No	(B) No biological hazards are identified at this step in the process	None	NA
	(C) None	(C) No	(C) No chemical hazards are identified at this step in the process	None	NA
	(P) None	(P) No	(P) No physical hazards are identified at this step in the process	None	NA
Cool cream and pump to cream silo	(B) VP-growth	(B) No	(B) Growth of pathogens is prevented by proper refrigeration	(B) Refrigeration	PP
	(C) None	(C) No	(C) No chemical hazards are identified at this step in the process	None	NA
	(P) None	(P) No	(P) No physical hazards are identified at this step in the process	None	NA
Add culture to media in culture tank	(B) VP- Handling, Viruses	(B) No	(B) Risk of biological hazard is unlikely because GMP's are strictly adhered to by employees	(B) GMPs	PP
	(C) None	(C) No	(C) No chemical hazards are identified at this step in the process	None	NA
	(P) Extraneous	(P) No	(P) From historical experience in the plant, the potential for hazardous materials is unlikely to occur	(P) Culture Handling	PP
Break cultured product at plant TA (acidity) and pH target	(B) VP - growth	(B) No	(B) Growth of pathogens is controlled by culture handling guidelines and manufacturing procedures that are designed to prevent growth.	(B) Culture Handling	PP
	(B) SP - growth	(B) No		(B) Manufacturing	PP
	(C) None	(C) No	(C) No chemical hazards are identified at this step in the process	Procedures	NA
	(P) None	(P) No	(P) No physical hazards are identified at this step in the process	None	NA
Pump rework to blender	(B) VP- Handling, Viruses	(B) No	(B) Risk of biological hazard is unlikely because GMP's are strictly adhered to by employees	(B) GMPs	PP
	(C) None	(C) No	(C) No chemical hazards are identified at this step in the process	None	NA
	(P) Extraneous	(P) No	(P) From historical experience in the plant, the potential for hazardous materials is unlikely to occur	(P) In-Line Filter	CCP# 3
Cooling-Scraped Surface Heat Exchanger	(B) None	(B) No	(B) No biological hazards are identified at this step in the process	None	NA
	(C) None	(C) No	(C) No chemical hazards are identified at this step in the process	None	NA
	(P) Metal from equipment	(P) Yes	(P) Extraneous metal could be generated during cooling step	(P) In-Line Filter	CCP# 3
Refrigerated storage	(B) SP-growth	(B) No	(B) Formulation and cooling patterns prevent the growth of pathogens	(B) Formulation/Cooling	PP
	(C) None	(C) No	(C) No chemical hazards are identified at this step in the process	None	NA
	(P) None	(P) No	(P) No physical hazards are identified at this step in the process	None	NA
Product Changeover	(B) None	(B) No	(B) Formulation and cooling patterns prevent the growth of pathogens	(B) Formulation/Cooling	PP
	(C) Allergen carryover	(C) Yes	(C) Carryover of unlabelled allergens from one product type to another	(C) Allergen Cleaning - Product Changeover	CCP# 4
	(C) Mixed label/printed packages	(C) Yes	(C) Mislabeling of allergens due to use of incorrect packaging	(C) Packaging Line Changeover	CCP# 5
	(P) None	(P) No	(P) No physical hazards are identified at this step in the process	None	NA

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## INGREDIENT ALLERGEN ASSESSMENT

### Form E –1

**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 Prerequisite Program (PP). List CCP Model name and Prerequisite Program name.

**Notes**

Full Allergen Assessment consists of Forms E-1 and E-2 PER MANUFACTURING LINE: (you should have as many E-1 and E-2 forms as manufacturing lines present in the plant)

**HACCP Standard Reference:**


- Sections 3.0 and 4.3 of this Manual
- *Appendix C:* for the list of allergens
- *Appendix D:* Form C for the list of ingredients

A	B	C
List all ingredients (as per Food Allergen Category List and Regional Allergens, if applicable. See <i>Appendix C.</i> ) <ul style="list-style-type: none"> <li>• containing allergens and/or sulfites (&gt;10ppm in final formula)</li> <li>• containing carryover allergens and/or sulfites (&gt;10ppm in final formula) per allergen profile.</li> </ul> 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	List identified carryover allergens and/or sulfites (>10ppm in final formula) in the ingredients that are not direct components of the raw materials

## INGREDIENT ALLERGEN ASSESSMENT

### Example Form E –1

A	B	C
List all ingredients (as per Food Allergen Category List and Regional Allergens, if applicable. See <i>Appendix C.</i> ) <ul style="list-style-type: none"> <li>• containing allergens and/or sulfites (&gt;10ppm in final formula)</li> <li>• containing carryover allergens and/or sulfites (&gt;10ppm in final formula) per allergen profile.</li> </ul> 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	List identified carryover allergens and/or sulfites (>10ppm in final formula) in the ingredients that are not direct components of the raw materials
Whole Raw Milk	Milk Protein	None
Lactic Culture	Milk Protein	None
Cream, Sweet Fluid	Milk Protein	None
Cream, Pasteurized	Milk Protein	None
Culture	Milk Protein	None
Nonfat Dry Milk	Milk Protein	None
Vegetable flavoring	Milk Protein	None
Salmon	Seafood Protein	
Rework	Milk Protein, Soy Protein, Seafood Protein	None

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**ALLERGEN CROSS-CONTACT PRODUCTION ASSESSMENT  
Form E –2**


**Notes**

- ☑ Full Allergen Assessment consists of Forms E-1 and E-2
- ☑ PER MANUFACTURING LINE: (you should have as many E-1 and E-2 forms as manufacturing lines present in the plant)

List all finished products produced on the manufacturing line including use of common equipment e.g. rework tanks, fillers etc.	Are all identified allergens listed in Form E-1 labeled on the package of the finished product (this should be done for each finished product listed in the first column of this form)?  <b>YES</b> (list allergens)	<b>NO</b> (list allergens)	If "No" identify control mechanism(s) ( _ - CCP ) ( _ - PP )

**ALLERGEN CROSS-CONTACT PRODUCTION ASSESSMENT  
Example Form E –2**

List all finished products produced on the manufacturing line including use of common equipment e.g. rework tanks, fillers etc.	Are all identified allergens listed in Form E-1 labeled on the package of the finished product (this should be done for each finished product listed in the first column of this form)?  <b>YES</b> (list allergens)	<b>NO</b> (list allergens)	If "No" identify control mechanism(s) ( _ - CCP ) ( _ - PP )
Plain Cream Cheese	Milk	Salmon, Soy	Product Sequencing-PP, Equipment Cleaning-CCP, Packaging Line Changeover-CCP, Rework handling-CCP, Label Application-PP
Vegetable Blend Cream Cheese	Milk, Soy	Salmon	Product Sequencing-PP, Equipment Cleaning-CCP, Packaging Line Changeover-CCP, Rework handling-CCP, Label Application-PP
Salmon Flavored Cream Cheese	Milk, Salmon	Soy	Product Sequencing-PP, Equipment Cleaning-CCP, Packaging Line Changeover-CCP, Rework handling-CCP, Label Application-PP

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**PRODUCT/PROCESS HAZARD EVALUATION SUMMARY**

**Form F**

**Purpose:** Provides a summary of identified hazards, control mechanisms, identification of the CCP model(s), and an overview of hazard management.

Also, Form F identifies Prerequisite Programs that must be documented and implemented. List CCP Model name and Prerequisite Program name. The scientific basis must be cited for the critical limit (e.g. regulatory guidelines, experimental studies, scientific publications). Note: If control mechanisms have been determined for all identified hazards and documented in Forms C, D, and E, then Form F is optional.

**HACCP STANDARD references:**

- Section 4.3 of this manual
- *Appendix D* for HACCP Plan Forms

HAZARD IDENTIFIED (Copy from Forms C, D, E)	CONTROL MECHANISM(S)	If the hazard is managed as a CCP, list CCP Model name.	If the hazard is managed as a Prerequisite Program, list the Prerequisite Program name.
BIOLOGICAL			
CHEMICAL			
PHYSICAL			



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**PRODUCT/PROCESS HAZARD EVALUATION SUMMARY- Example Form F**

HAZARD IDENTIFIED (Copy from Forms C, D, E)	CONTROL MECHANISM(S)	If the hazard is managed as a CCP, list CCP Model name.	If the hazard is managed as a Prerequisite Program, list the Prerequisite Program name.
<b>BIOLOGICAL</b>			
<b>Vegetative pathogen</b>			
Pathogens in Raw Milk	Pasteurization	"Pasteurization - HTST"	
Pathogens in Cream	Pasteurization	"Pasteurization - HTST"	
Salmonella in Locust Bean Gum	Supplier COA for Salmonella	"	Sensitive Ingredient Post - Lethal Process Addition"
S. aureus during culture addition	GMPs - chlorination		Manufacturing Procedure xx "Preparation Starter Culture"
Pathogen growth in milk and cream during storage	Refrigeration		Manufacturing Procedure xyz "Refrigeration"
Pathogen contamination during rework handling	GMPs  Cream Containers Cleaning  Refrigeration		Manufacturing Procedure xxx "Rework Addition" Sanitation Procedure xy  Manufacturing Procedure xyz "Refrigeration"
<b>BIOLOGICAL</b>			
<b>Sporeforming Pathogen</b>			
Pathogens in Raw Milk	Manufacturing Procedure		Manufacturing Procedure z "Active Fermentation"

HAZARD IDENTIFIED (Copy from Forms C, D, E)	CONTROL MECHANISM(S)	If the hazard is managed as a CCP, list CCP Model name.	If the hazard is managed as a Prerequisite Program, list the Prerequisite Program name.
Pathogens in Cream	Manufacturing Procedure		Manufacturing Procedure z "Active Fermentation"
<b>CHEMICAL</b>			
Milk protein allergen in raw milk, cream, starter culture, rework	Specification		Labeling
Wheat protein on direct contact packaging	Specification		Labeling
Antibiotics in raw milk & cream	Specification		Testing Program
Sulfite cross-contact from apples in apple / cinnamon cream cheese	Product Sequencing Equipment Cleaning  Rework Handling	"Equipment Cleaning (Product Changeover)" "Rework Handling"	(Daily Production Schedule) Product Sequencing
Salmon cross-contact from salmon cream cheese	Product Sequencing Equipment Cleaning  Rework Handling	"Equipment Cleaning (Product Changeover)" "Rework Handling"	(Daily Production Schedule) Product Sequencing
Soy cross-contact from vegetable blend cream cheese	Product Sequencing Equipment Cleaning  Rework Handling	"Equipment Cleaning (Product Changeover)" "Rework Handling"	(Daily Production Schedule) Product Sequencing
<b>PHYSICAL</b>			
Starter culture metal container	GMPs - training		Manufacturing Procedure y "Preparation of Starter Culture"
Metal from equipment	Sieve Inspection	"Filtration In-Line"	Manufacturing Procedure x "Equipment Inspection"



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**CRITICAL CONTROL POINT (CCP) DOCUMENTATION**


**Form G**

**Purpose:** To define food safety limits and monitoring and corrective action requirements that are consistent with the CCP models. Note: This form is in the same format as the Model CCPs (*Appendix E*).

**HACCP STANDARD references:**

- Sections 3 and 4.4 of this manual
- *Appendix D* for HACCP Plan Forms

<b>Critical Control Point ID</b>	
<b>Process Step</b>	
<b>Hazard</b>	
<b>Critical Limit(s)</b>	
<b>Monitoring Activity &amp; Frequency</b>	
<b>Corrective Action Activity</b>	
<b>Responsibility For Monitoring &amp; Corrective Action</b>	
<b>Records &amp; Location</b>	
<b>Minimum CCP Verification Activities</b> 1. Activity (What?) 2. Frequency (How often?) 3. Responsibility (Who?)	
<b>List the model name.</b> Cite scientific basis for Critical Limit	

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**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 and complies with the HACCP Standard.

**HACCP STANDARD references:**

- Sections 3 and 4.5 of this manual
- *Appendix D* for HACCP Plan Forms

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	E		
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		

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**PLANT LAYOUT  
FORM J**

**Purpose:** To assess cross-contamination potential between processing areas and identify Prerequisite Programs to manage and prevent cross-contamination.

**HACCP STANDARD references:**

- Sections 3 and 4.6 of this manual
- *Appendix B* for the list of ingredient categories containing biological hazards
- *Appendix C* for the list of allergens


**Each area or room shall be assessed and classified into one of three microbiological zones:**

- o zones which can be a potential source of contamination,
- o zones where product susceptible to pathogen survival is exposed,
- o zones where product susceptible to pathogen growth is exposed.

If more than one microbiological zone is identified and/or allergen cross-contamination potential are identified between processing areas, then the facility shall ensure that applicable Prerequisite Program(s) are documented and implemented.

This assessment shall be documented e.g. mark the different zones on Form J implement/modify local programs as required, e.g., Prerequisite Programs may include:

- Building Structure and Utility Systems (e.g. walls, barriers, airflow)
- Employee Hygiene / Practices (e.g. traffic patterns)
- Post Cook Recontamination (prevention of)
- Environmental Monitoring for Pathogens

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**PRODUCT CATEGORY HACCP PLAN CROSS REFERENCE INDEX  
Form K**

**Purpose:** To enable the Plant to cross reference products to specific HACCP plans by number.

**HACCP STANDARD references:**

- Section 4.7 of this manual
- *Appendix D* for HACCP Plan Forms

**PRODUCT CATEGORY**

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

Plant HACCP Coordinator


Name: \_\_\_\_\_

Phone: \_\_\_\_\_

**PRODUCT CATEGORY HACCP PLAN CROSS REFERENCE INDEX  
Example Form K**

**PRODUCT CATEGORY**

Product Name	Formula Number	HACCP Plan Number	Date HACCP Plan Issued	Validation Date
Plain Cream Cheese	300	003	10- Oct- 08	10- Apr- 09
Vegetable Blend Cream Cheese	301	006	10- Oct- 08	10- Apr- 09
Salmon Flavored Cream Cheese	412	007	10- Oct- 08	10- Apr- 09

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**APPENDIX E: MODEL CRITICAL CONTROL POINTS AND PREREQUISITE PROGRAMS**

***PASTEURIZATION – HTST / HHST***

**CRITICAL CONTROL POINT ID: Fluid Milk Products Pasteurization (hold time and temperature).**

**PROCESS STEP:** HTST Pasteurization (Fluid Milk Products, Cream, Whey, Ice Cream Mix, Starter Media, Whey/Salt Mixture), HHST Pasteurization (Fluid Milk Products)

**HAZARD:** Biological (Vegetative Pathogens)

**CRITICAL LIMIT:** Every particle of fluid milk or fluid milk products is heated by a pasteurizer which conforms to Sanitary Design Standards (e.g.: 3A, EHEDG) to one of the temperatures specified in the following table and held continuously at or above that temperature for at least the time specified. An equivalent time / temperature may be calculated using  $z=11.3^{\circ}\text{F}$  ( $6.3^{\circ}\text{C}$ ). The following are some examples:


<u>Minimum Temp</u>	<u>Minimum Time</u>
161°F (72°C)	15.0 seconds
167°F (75°C)	5.0 seconds
180°F (82°C)	0.4 seconds (= instantaneous)
185°F (85°C)	0.2 seconds
190°F (88°C)	0.05 seconds

Note: Local regulations shall apply if more stringent, e.g. the following PMO Standards. Lowest applicable temperature is 71.7oC/160oF.

The following are the more stringent requirements of the PMO Standards, which shall be applied if required by the authorities:

<u>PMO Minimum</u>	<u>Temp PMO Minimum Time</u>
161°F (72°C)	15.0 seconds
191°F (89°C)	1.0 second
194°F (90°C)	0.5 second
201°F (94°C)	0.1 second
204°F (96°C)	0.05 second
212°F (100°C)	0.01 second

**If the fat content of the milk product is 10% or more, or if it contains added sweeteners, the specified temperature shall be increased by 5°F (3°C).**

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**MONITORING ACTIVITY/FREQUENCY:**

**Temperature (processes with holding tube):** Temperature of the product at the end of the holding tube\* shall be continuously recorded to a permanent record, such as a temperature chart or a digital recording device. If the required holding time is instantaneous (0.5 sec or less), then the temperature sensor can be located after the last heating section of the heat exchanger. \*if the holding tube is heated, the temperature has to be recorded at the coldest spot of the tube.

**Temperature (processes without holding tube):** Temperature of the product at the coldest spot before the cooling section shall be continuously recorded to a permanent record, such as a temperature chart or a digital recording device.

**Time:** flow rate shall be recorded continuously to a permanent record, such as a chart or a digital recording device, or pump setting is recorded once per shift and after speed changes 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)

Note: The correlation flow rate/holding time for the fastest particle must be documented and filed with the HACCP Plan. A permanent record must be kept of the time during which the flow-diversion-device (FDD) or divert valve is in forward flow position must be kept.

**CORRECTIVE ACTION ACTIVITY:**

Under processed product shall be automatically diverted and reheated or discarded.

If the product is found to be under pasteurized based on document review, or if the pasteurizer malfunctions, all affected product shall be placed on Category I hold to await disposition from Designated Quality Function.

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

**RESPONSIBILITY (Monitoring and Corrective Action):** Trained Pasteurizer Operator

**RECORD/LOCATION:** designate the location of each record


- Pasteurizer Records
- Hold and Release Records
- Corrective Action Records
- Verification Records

**MINIMUM CCP VERIFICATION ACTIVITIES:**

Daily: Verify that the divert valve remains closed until the critical temperature is reached (cut in/cut out). Also compare recording thermometer reading to the indicating thermometer reading. Document the temperature indicated on the indicating thermometer. The difference in temperature shall not exceed 1°F (0.5°C).

Note: Cut-in/cut out not required for HHST systems provided that divert temperatures are set at z = 11.3°F (6.3°C) higher than the critical limits defined in this CCP model. For example, if the critical limit is 180°F (82°C) and the divert temperature is set at >191.3°F (89°C), and the system has been validated to divert at this higher temperature, then the daily cut in/cut out is not required. Temperature charts shall be reviewed to confirm divert in the event of a temperature drop, at a frequency to demonstrate control.

Indicating thermometer and recording thermometer accuracy will be verified at a frequency sufficient to demonstrate control (minimum every 6 months) by the water or oil bath method, or other acceptable technique. At the same time, compare the recording thermometer against the indicating thermometer. The difference in temperature shall not exceed 1°F (0.5°C).

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Designated responsible employee, other than the operator (usually Supervisor) reviews and signs pasteurizer records at least daily.

Recording time accuracy of chart recorder will be verified at a frequency sufficient to demonstrate control (minimum every 6 months).

Pressure differential: When a product-to-product regenerator is used to heat the cold unpasteurized product entering the pasteurizer by means of a heat exchange system, it shall be designed, operated, and controlled so that the pressure of the pasteurized product in the regenerator is always greater than the pressure of any unpasteurized product in the regenerator. Verify the differential pressure daily. The pressure shall be 1 psi higher on the pasteurized side. Verification of the measuring probes should be done at a frequency sufficient to demonstrate control (minimum every 6 months).

For systems with a timing pump: Flow rate (salt test or other acceptable technique) versus pump speed will be verified at a frequency sufficient to demonstrate control (minimum every 6 months).

For system with a flow meter: Flow meters do not require verification other than during installation or line modification.

Cut in/cut out by slow temperature increase: Verification of the divert valve should be done at a frequency sufficient to demonstrate control (minimum every 6 months).

**SCIENTIFIC BASIS:**


Regulation (EC) 852/2004

Regulation (EC) 853/2004

Regulation (EC) 2074/2005

Pasteurized Milk Ordinance (PMO), 2007 Revision.

Bradshaw J.G. et al (1985) Thermal resistance of *Listeria monocytogenes* in milk. J. Food Protection 54:12-14

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**PASTEURIZATION - BATCH**

**CRITICAL CONTROL POINT ID: Fluid Milk Products Pasteurization (temperature and holding time)**

**PROCESS STEP:** Batch Pasteurization (Fluid Milk Products, Cream, Whey, Ice Cream Mix, Starter Media)

**HAZARD:** Biological (Vegetative Pathogens)

**CRITICAL LIMIT:**

1) Batch pasteurizers shall be so operated that every particle of milk or milk product will be held at not less than 145°F (63°C) continuously for at least 30 minutes. Equivalent time / temperature parameters may be calculated using z=11.3°F (6.3°C). Lowest applicable temperature is 63oC/145oF.

**If the fat content of the milk product is > 10%, or if it contains added sweeteners, the temperature shall be increased to 150°F (66°C) for a 30-minute hold time.**

**For eggnog, and ice cream mix, the temperature shall be increased to 155°F (69°C) for a 30-minute hold time.**

2) The batch pasteurizer air space above the milk and milk products shall be at a temperature not less than 5°F (3°C) higher than the minimum required temperature of pasteurization during the holding period (EXCEPTION: starter media processed above 180°F (83°C) for at least 30 continuous minutes).

3) Inlet piping to the vat is disconnected during the holding and emptying periods (EXCEPTION: not necessary when vat pasteurizer inlet lines are equipped with leak-protector valves).

**MONITORING ACTIVITY/FREQUENCY:**

1) Product measured at the coldest point in the vat shall be continuously recorded throughout the holding period. Pasteurization start and stop time must be designated on the temperature recording chart.

2) Batch pasteurizer shall be equipped with an airspace thermometer. The temperature of the airspace shall be recorded on the recording temperature chart when product achieves pasteurization temperature each time the pasteurizer is in operation. (EXCEPTION: starter media processed above 180°F (83°C) for at least 30 continuous minutes).

3) Indicate on temperature chart that inlet piping has been disconnected from the vat prior to each pasteurization cycle.

**CORRECTIVE ACTION ACTIVITY:**

If product temperature drops below pasteurization temperature during the hold period or inlet piping was not disconnected, the pasteurization step must be restarted.

If time was not achieved, restart the pasteurization cycle.

If the product is found to be under pasteurized based on document review or the pasteurizer malfunctions, 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):** Trained Pasteurizer Operator

**RECORD/LOCATION:** designate the location of each record

- Pasteurizer Records
- Hold and Release Records
- Corrective Action Records
- Verification Records


**MINIMUM CCP VERIFICATION ACTIVITIES:** Designated responsible employee (usually the Supervisor) reviews and signs pasteurizer records at least daily.

**SCIENTIFIC BASIS:**

Pasteurized Milk Ordinance (PMO), 1993 Revision

Commented [GAA1]:



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**PRODUCT COOK**

**CRITICAL CONTROL POINT ID: Product Cook (time and temperature)**

**PROCESS STEP:** Product Cook (Continuous or Batch) – fat containing products (e.g. Cool Whip, Cream Cheese, Dips, Refrigerated RTE High Acid Puddings and Gelatines)

**HAZARD:** Biological (Vegetative Pathogens)

**CRITICAL LIMIT:**

Product is heated for not less than 25.8 continuous seconds at a temperature not less than 163°F (72.8°C). An equivalent time/temperature may be used provided that it is calculated using Z = 12.8°F (7.1°C). The following table has some calculated equivalent time/temperatures:

<u>Minimum Temp</u>	<u>Minimum Time</u>
150°F (65.6°C)	4.5 minutes
153°F (67.2°C)	2.6 minutes
155°F (68.3°C)	1.8 minutes
158°F (70.0°C)	1.1 minutes
159°F (70.5°C)	53.0 seconds
160°F (71.1°C)	44.3 seconds
163°F (72.8°C)	25.8 seconds
165°F (73.9°C)	18.0 seconds
168°F (75.6°C)	10.5 seconds
170°F (76.7°C)	7.3 seconds
173°F (78.3°C)	4.3 seconds
175°F (79.4°C)	3.0 seconds
178°F (81.1°C)	1.7 seconds
180°F (82.2°C)	1.2 seconds

The lowest applicable temperature is 60 °C/140 °F. An increase in time and temperature may be required when particles > 0.64cm (0.25in) in all 3 dimensions are added e.g. meat, vegetables. The necessary increase has to be assessed based on particle size and heat penetration.

**MONITORING ACTIVITY/FREQUENCY:**

**Continuous Cookers**


**Temperature (processes with holding tube):** Temperature of the product at the end of the holding tube\* shall be continuously recorded on a temperature chart. If the required holding time is instantaneous (0.5 sec or less), then the temperature sensor can be located after the heat exchanger.

\*if the holding tube is heated, the temperature has to be recorded at the coldest spot of the tube.

**Temperature (processes without holding tube):** Temperature of the product at the coldest spot shall be continuously recorded on a temperature chart.

**Time:** flow rate shall be recorded continuously, or pump setting is recorded once per shift and after speed changes 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)

Note: The correlation flow rate/holding time for the fastest particle must be documented and filed with the HACCP Plan

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**Batch Cookers**

**Temperature:** Product temperature, at the coldest point, is continuously recorded on a cook temperature chart. For instantaneous temperatures (no time), temperature readings can be manually recorded.

**Time:** Verify and document the timer setting at the beginning of each shift and the end of production.

**CORRECTIVE ACTION ACTIVITY:**

Batch: Under processed product shall be reheated to achieve a temperature of 85°C/185°F or equivalent. For digital, computerized cooker controls see note under verification.

Continuous: Under processed product shall be automatically diverted and reheated or discarded. The system diverts shall be reflected by the frequency pen marking on the temperature chart.

If the product is found to be undercooked based on document review, all the affected product shall be placed on Category I hold to await disposition form Designated Quality function. Hold/Release documentation is required.

Corrective action must be documented.

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

**RECORD/LOCATION:** designate the location of each record

- Cook Temperature Charts
- Cook Sheets
- Hold and Release Records
- Corrective Action Records
- Verification Records

**MINIMUM CCP VERIFICATION ACTIVITIES:**

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

**Continuous Cookers:**

Flow rate versus pump speed will be verified at a frequency sufficient to demonstrate control (minimum every 12 months). (Not necessary if flow rate is monitored and managed as CCP).

Perform Cut-in / Cut-out and compare recording thermometer reading to the indicating thermometer reading at least daily.

Note: Cut-in / cut-out not required for HHST systems provided that divert temperatures are set at 11.3oF (6.3oC) higher than the critical limits defined in this CCP Model, e.g. set at >191.3oF (89oC) for 0.4s, and have been validated to divert at this higher temperature.

Temperature charts shall be reviewed to confirm divert in the event of temperature drop, at a frequency sufficient to demonstrate control.


Verification of the divert (valve change) should be done at a frequency sufficient to demonstrate control (minimum every 6 months).

All measuring devices used to monitor critical control parameters shall be calibrated at a frequency sufficient to demonstrate control (minimum every 6 months).

**Batch Cookers:**


Verify cooker timer settings (for the actual cook time) and the accuracy of the hold time with a stop watch at least weekly.

Note: Record the time as + 1.0 second. Verify accuracy of temperature monitoring device at least weekly. For digital, computerized, automated cooker controls, verify that the hold timer setting is programmed to match the hold time of the specific product formula, at a frequency to demonstrate control.

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**SCIENTIFIC BASIS:**

National Food Laboratory Final Report on the Thermal Death Time Studies for a 4D *Listeria monocytogenes* process in Cool Whip (NFL #7 KGF18). 1994. Final results of this Study, requested by MDLZ, Inc. and conducted by the National Food Laboratory, are on file with MDLZ, Inc. Department of Microbiology and Food Safety (Glenview). February 10, 1994. Particle size confirmed by CCFRA (July '98) and NFPA (Sept. '00).

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**PRODUCT COOK – NON-FAT-BASED PRODUCTS**

**CRITICAL CONTROL POINT ID: Non-fat-based product Cook/Thermal Process (Temperature)**

**PROCESS STEP:** Thermal process step for non-fat based products e.g. Catsup, Ketchup, Mustard, Red Sauces, Tea Extracts

**HAZARDS:** Biological (Vegetative Pathogens)

**CRITICAL LIMIT:**

Batch cook:

An instantaneous temperature of 175°F (79.5 °C) or equivalent is achieved for each batch.

Time/temperature equivalents may be calculated using a z=11.3°F (6.3°C) and a time of 0.5 seconds. The lowest applicable temperature is 60oC/140oF. Note: if the critical limit temperature is <175°F (79.5°C), then the time is also part of the critical limit and must be monitored.

Continuous cook:

Product must reach a minimum instantaneous temperature of 175°C (79,5°C). Equivalent time /temperature parameters can be calculated using a z= 11.3 °F (6.3°C) and a time of 0.5 seconds.

**MONITORING ACTIVITY/FREQUENCY:**

**Continuous Cookers**

**Temperature (processes with holding tube):** Temperature of the product at the end of the holding tube\* shall be continuously recorded to a permanent record, such as a temperature chart or a digital recording device. If the required holding time is instantaneous (0.5 sec or less), then the temperature sensor can be located after the last heating section of the heat exchanger.

\*if the holding tube is heated, the temperature has to be recorded at the coldest spot of the tube.

**Temperature (processes without holding tube):** Temperature of the product at the coldest spot before the cooling section shall be continuously recorded to a permanent record, such as a temperature chart or a digital recording device.

**Time:** Flow rate shall be recorded continuously to a permanent record, such as a chart or a digital recording device, or pump setting is recorded once per shift and after speed changes 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)

Note: The correlation flow rate/holding time for the fastest particle must be documented and filed with the HACCP Plan.

A permanent record must be kept of the time during which the flow-diversion-device (FDD) or divert valve is in forward flow position.

**Batch Cookers**


**Temperature:** Product temperature, at the coldest point, is continuously recorded on a cook temperature chart. For instantaneous temperatures (no time), temperature readings can be manually recorded.

**Time:** Verify and document the timer setting at the beginning of each shift and the end of production.

**CORRECTIVE ACTION ACTIVITY:**

Batch: Under processed product shall be reheated to achieve a temperature of 175°F (79.5°C) or equivalent.

Continuous: Under processed product shall be automatically diverted and reheated or discarded.

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If the product is found to be undercooked based on document review, all the affected product shall be placed on Category I hold to await disposition form Designated Quality function. Hold/Release documentation is required. Corrective action must be documented.

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

**RECORD/LOCATION:** designate the location of each record

- Cook temperature charts
- Thermometer calibration log
- Hold and Release and Corrective Action Records
- Verification Records

**MINIMUM CCP VERIFICATION ACTIVITIES:**

Designated responsible employee, other than the operator (usually the Supervisor) reviews and signs cook records at least daily.

Flow rate versus pump speed will be verified at a frequency sufficient to demonstrate control (minimum every 12 months). (Not necessary if flow rate is monitored and managed as CCP).

Verification of the divert (valve change) should be done at a frequency sufficient to demonstrate control (minimum every 6 months).

All measuring devices used to monitor critical control parameters shall be calibrated at a frequency sufficient to demonstrate control (minimum every 6 months).


Batch Cookers: Verify cooker timer settings (for the actual cook time) and the accuracy of the hold time with a stop watch at least weekly. Note: Record the time as + 1.0 second.

Verify accuracy of temperature monitoring device at least weekly.

**SCIENTIFIC BASIS:**

Recommendations of the National Advisory Committee on Microbiological Criteria for Foods for Refrigerated Foods Containing Cooked, Uncured Meat or Poultry Products that are Packaged for Extended Refrigerated Shelf Life and that are Ready-To-Eat or Prepared with Little or No Additional Heat Treatment.

January 31, 1990. NACMCF Meat and Poultry Working Group. Document on file with MDLZ, Inc. Department of Microbiology and Food Safety (Glenview).

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**HIGH MOISTURE MATERIAL HOLDING TIME/TEMPERATURE  
PRIOR TO HEAT STEP**

This model applies to high moisture ( $A_w > 0.85$ ) products with a pH range of  $> 4.5$  and  $< 9.6$  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).
- 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 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\*.
- 

\*Continuous is defined as a process that does not accumulate product that could remain stagnant during production (e.g. hang-up points, build-up, dead ends), does not have holding steps, and passes a risk assessment. 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.

**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.

**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 criteria of continuous must meet the model for material holding times and temperatures.

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 (build-up) 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)

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**CRITICAL LIMIT:**

<u>STORAGE TEMPERATURE</u>	<u>MAXIMUM STORAGE TIME (HOURS)</u>
< 8 °C (< 45 °F)	only for product quality
>8°C - 10°C (45 - 50 °F)	60
>10°C - 12°C (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

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 (equalling 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



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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.



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**CORRECTIVE ACTION ACTIVITY:**

If critical limit for time/temperature is exceeded, then the batch has to be discarded and the holding tank and lines shall be cleaned and sanitized before preparing the next batch. Identify tank 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 action must be documented.

**RESPONSIBILITY: (Monitoring and Corrective Action):** Designated trained employee.

**RECORD/LOCATION** designate the location of each record


- Filled-in Calculation worksheet (if used)
- Holding Time records
- Temperature records
- Corrective Action Records
- Verification Records
- Individual challenge studies to be filed at the respective plants

**MINIMUM CCP VERIFICATION ACTIVITIES:**

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

**SCIENTIFIC BASIS:**

1. FDA 1993. Food Code Pub. No: PB94-113941AS, US Public Health Service, Springfield, Illinois.
2. Snyder, O.P. Use of time and temperature specifications for holding and storage of food in retail food operations; Dairy, Food and Environmental Sanitation vol. 16, No. 6 page 374-388.
3. ICMSF Chapter 17. Staphylococcus aureus in Microorganisms in Foods 5. Microbiological Specifications of Food Pathogens 1996 published by James and James.
4. Bergdoll, M.S. (1989). Staphylococcus aureus in Foodborne Bacterial Pathogens, edited by Michael Doyle. Published by Marcel Dekker, New York.
5. Ash, M. (1997). Staphylococcus aureus and Staphylococcal enterotoxins in Foodborne Microorganisms of Public Health Significance, 5th Ed. edited by Hocking, A.D.; Arnold, G.; Jenson, I.; Newton, K. and P. Sutherland. Published by Australian Institute of Food Science and Technology, Australia.
6. Tatini, S.R. (1973). Influence of food environments on growth of Staphylococcus aureus and production of various toxins. J. Milk Food Technology, 36:559-563.
7. Smith, J.L., Buchanan, R.L. and S.A. Palumbo (1983). Effect of food environment on staphylococcal enterotoxin synthesis: A review. J. Food Protection, 46:545-555.
8. Validation study performed by Kraft Microbiology laboratories in East Hanover, Glenview, and Munich referring to growth of Staphylococcus aureus in wafers, doughs, cheese blends, and dairy slurries. (On file with KNAC Microbiology, East Hanover and Glenview).
9. Validation swabbing studies on file with the HACCP plan at each plant.

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**PRODUCT BAKE**

**CRITICAL CONTROL POINT ID: Heat Processing Internal Product Temperature**

**PROCESS STEP:** Product Bake (Continuous or Batch) – typical flour-based products with or without fillings (i.e. cookie dough, cracker dough, Newton filler, bread dough) with final Aw <0.85 (*Staphylococcus aureus* toxin production). Any dense or atypical filling or centres (i.e. meat, cream) or dough RH <65.0 will require additional and product specific validation studies to determine appropriate processing parameters.

**HAZARD:** Biological (Vegetative Pathogens)

**CRITICAL LIMIT:**

All product is heated to an internal temperature of 180°F (82.2oC) to obtain a minimum 4 log reduction of vegetative pathogens (i.e. *Salmonella*), through bake (oven) zone temperatures as determined by POG's/SOP's (Process Operating Guideline/ Standard Operating Procedure) established for the specific product.

The following table has some demonstrated log kills for product dough that have been developed for product across the RH range of dough prepared for the bake step:

Product	RH	Log kill to or at 180°F(82.2oC)
XX Cookie	76.0	>4.0 logs
XY Cookie	71.0	>4.0 logs
ZY Base Cake	65.2	>4.0 logs

**PREREQUISITE CONTROL OPTION:**

If the validated processing temperature/time profile to achieve finished product quality parameters (saleable products) is significantly above critical limit (i.e. wafers and cones), the oven bake step may be handled as a Prerequisite program. Scientific data must be available to support this decision.


**MONITORING ACTIVITY/FREQUENCY:**

**Monitoring options:**

☑ **Finished Bake Temperature (Batch Process):** Finished cooked internal product temperature is manually or electronically measured in the known coldest location of the product using calibrated temperature measuring devices and is recorded per normal batch cycle. The temperature of the product shall be taken periodically during the cook process to determine the point at which product reaches the target temperature of 180°F (82.2oC).

☑ **Oven Air Temperature:** A relationship must be established between external oven air temperature profile or process set point and the internal product temperature profile. The validated Product/Process specific temperature profile must be monitored at an established frequency to assure that the internal temperature at the coldest point has reached critical temperature of 180°F (82.2oC).

**Finished Product Moisture (Moisture Loss Profile):** A relationship must be established between product moisture loss and the internal product temperature profile. The validated Product/Process specific moisture profile must be monitored at an established frequency to assure that the internal temperature at the coldest point has reached critical temperature of 180°F (82.2oC).

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**Monitoring Devices:** All measuring devices used to monitor critical control parameters shall be calibrated at a frequency sufficient to demonstrate control (minimum every 6 months). If the monitoring devices are found to be inaccurate, all affected product shall be placed on Category I hold to await disposition from the Designated Quality function.

**CORRECTIVE ACTION ACTIVITY:**

**Batch Process:** A product batch that has not reached the target processing temperature of 180°F (82.2oC) or equivalent shall be considered under processed, not removed from the oven, and cooking shall continue until such time as the target temperature is reached. Product that is removed from the oven that has not achieved critical limits (temperature/time relationship) shall be considered under processed product and shall be discarded.

**Continuous Ovens:** Under processed product shall be discarded. If the product is determined to be under processed per monitoring of validated product/process specified profiles or if the product centre temperatures are found to be less than 180°F (82.2oC) at oven exit (before cooling zones), the product shall be placed on Category I hold to await disposition from Designated Quality function. If the product is determined to be under processed due to final Aw >0.85 (*Staphylococcus aureus* toxin production) being measured for the product, all affected product shall be placed on Category I hold to await disposition from Designated Quality function. Hold/Release documentation is required. Corrective action must be documented.

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

**RECORD/LOCATION:** designate the location of each record

- Product/Process Specific Profile Records.
- Product Centre Temperatures Records
- Hold and Release Records
- Corrective Action Records
- Verification Records


**MINIMUM CCP VERIFICATION ACTIVITIES:** Designated responsible employee (usually the Supervisor) reviews and signs all process records at least daily.

**SCIENTIFIC BASIS:**

Thermal Death Time Studies for Salmonella in cookie dough (CCP Chips Ahoy! Validation 10/15/1999; CCP Newton Filler Validation 6/15/2000; CCP Pecanz Validation 11/27/2001; Product Bake Position Paper 7/14/2004)

Reduced RH Dough Challenge Study 5/19/2006

Final results of these studies conducted by Microbiology/Food Safety are on file with MDLZ, Inc. Department of Microbiology and Food Safety (East Hanover).

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**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 C*. 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 labelled 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 labelled 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.

**SCIENTIFIC BASIS:**

*Appendix C* from this Standard.

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**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 C-*. 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 nonallergen (or different allergen) containing product.


If records review indicates that allergen containing visible product residue was not removed or the equipment clean was not completed prior to start up 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

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**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 labelled, if Allergen test kits are available, verify cleanliness with the kit (for EM according to guidelines from MDLZ Corporate Sanitation).


For CIP and ACS, perform teardown inspection at a frequency sufficient to demonstrate control, and according to guidelines from Corporate Sanitation.

**SCIENTIFIC BASIS:**

*Appendix C* of this Standard.

Park, Douglas L., 2005, Performance Test Method Multiple Laboratory Validation Study of ELISA-Based Assays for the Detection of Peanuts in Food, *Journal of AOAC International*, Vol. 88, No 1, pp. 156-160 Jackson, Lauren S., Cleaning and Other Control Strategies To Prevent Allergen Cross-Contact in Food-Processing Operations, *Journal of Food Protection*, Vol. 71, No. 2, pp. 445-458

For products that are not cross contact labelled, report validating the flushing method: on file at the plant.

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**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 C.* 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/litres 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/litres 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/litres 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.

**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 1 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

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**RECORD/LOCATION:**

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


**MINIMUM CCP VERIFICATION ACTIVITIES:**

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 labelled, if allergen test kits are available, verify the effectiveness of the flush with the kits.

**SCIENTIFIC BASIS:**

*Appendix C* of this Standard.  
 Park, Douglas L., 2005, Performance Test Method Multiple Laboratory Validation Study of ELISA-Based Assays for the Detection of Peanuts in Food, *Journal of AOAC International*, Vol 88, No 1, p.p. 156 – 160  
 Jackson, Lauren S., Cleaning and Other Control Strategies To Prevent Allergen Cross-Contact in Food-Processing Operations, *Journal of Food Protection*, Vol. 71, No. 2, pp. 445-458  
 For product that are not cross contact labelled, report validating the flushing method on file at the plant.



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**EXTRANEOUS MATERIAL DETECTION**

**CRITICAL CONTROL POINT ID: Metal Detector or in line X-Ray unit**

**PROCESS STEP:** Extraneous Material Detection

**HAZARD:** Physical (Extraneous Material) e.g. Metal, Glass, Stones, Bone, Wood

**CRITICAL LIMIT:**

Operating Metal or X-Ray detector set at its design detection limit for the product being run. HACCP Plans must list the size and type of target extraneous material that the detector will detect (mm) and Greater than X diverted packages/pieces/pounds of product confirmed to contain extraneous material in Y hours (Actual quantity of packages and time frame length shall be determined. Facilities may use as a guide line 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.
- 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 matter material detection device. All diverted packages/product shall be evaluated to determine cause of rejection. The number of diverted packages/pieces/ amount of product rejected due to confirmed metal contamination shall be recorded every y hours of run time.

**CORRECTIVE ACTION ACTIVITY:**

If a detection device is not working at its design limit, stop the line and repair or replace the device. 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).


If more than x product and process specific diverted packages/ pieces/ amount of product during y hours of run time are found to contain extraneous material, stop the process, place all product (packaged, unpackaged, rework, or other) produced during the y hour run time on Category II hold. Notify designated responsible person to determine disposition.

After investigation, product determined to be contaminated shall be placed on Category I hold. Notify Designated Quality Function. Hold/Release documentation is required. Corrective action must be documented.

**RESPONSIBILITY (Monitoring and Corrective Action):** Designated, trained production or maintenance employee.

**RECORD/LOCATION** designate the location of each record:

Extraneous Material Detector Verification Log

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Hold and Release Records  
 Corrective Action Records  
 Verification Records

**MINIMUM CCP VERIFICATION ACTIVITIES:**

The extraneous material detection device and the divert mechanism shall be verified to be operating at their design limit, performed at the following frequencies (at start up after each product change every 4 hours during production, at the end of the shift if production will not continue into next shift, after repair, maintenance or adjustment to the detection equipment)

Test piece sizes used for assessing the detection and rejection functionality of detectors shall be documented.

Ferrous, non-ferrous (brass) and stainless steel spherical test pieces are used for metal detectors. Test pieces shall be clearly identified and differentiated from the product. Packaged products which are longer than 7 inches (17.8 cm) shall be set up using a combination of leading edge and trailing edge passes.

Functionality verification shall assure 100% detection and rejection of each of the test pieces used, with 2 passes of each piece. Where positioning of the test pieces is controllable, they should pass through the centre of the MD aperture (this is the least sensitive path).

For the 4 hourly and end of production verifications it is recommended that all 3 test pieces are used, but if production conditions impose limitations on metal detector test activity, or technical limitations of the detection equipment itself prevent the use of all 3 test pieces, it is acceptable to use 2 passes of the stainless steel and ferrous test pieces only for these checks. The reason for limiting these checks to ferrous and stainless steel only must be documented.

The Reject mechanism shall direct 100% of the product rejects from the process flow automatically into an identified area, bin or container which is designed to prevent re-entry into the process or product flow.

**NOTES:**

- ☒ X-Ray detectors used to detect metal are typically set up using only stainless-steel test pieces.
  - ☒ Detection and rejection criteria for x-ray detectors used to detect other materials, such as glass, shall be determined and documented. In such cases, appropriate test pieces must be defined.
- Designated responsible employee (usually the Supervisor) reviews and signs extraneous material detector records at least daily.

**SCIENTIFIC BASIS:**


Moberg, L.J. 1992. Establishing critical limits for critical control points in *HACCP Principle and Applications*. Pierson, M.D., and Corlett, Jr. D.A., eds., Van Nostrand Reinhold, NY. p.p. 50-61.

Lewis, D.F. 1993. A tutorial and comprehensive bibliography on the identification of foreign bodies found in food. *Food Structure*, 12, p.p. 365-378.

Hyman, F.N., Klontz, K.C., and Tollefson, L. 1993. Food and Drug Administration surveillance of the role of foreign objects in foodborne injuries. *Public Health Reports*, 108 (1). p.p. 54-59.

Hyman, F.N., Klontz, K.C., and Tollefson, L. 1993 Eating as a hazard to health: preventing, treating dental injuries caused by foreign objects in food. *JAM Dental Assoc*, 124, p.p. 65-69.

Lehman, A.J. 1958. Quarterly report to the editor on topics of current interest: glass and metal fragments in foods and beverages. *Assoc. Food Drug Off. Q Bull.*, 22 (1) p.p. 24-26.

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**FILTRATION IN-LINE**

**CRITICAL CONTROL POINT ID:** In-line filter/screen/sifter/sieve

**PROCESS STEP:** In-line Filtration

**HAZARD:** Physical - Extraneous Matter

**CRITICAL LIMIT:**

All product flows through an intact **x** size mesh size filter/screen/sifter of **y**  
and

The amount of and size of abnormal or hazardous type extraneous material collected by the filter per **z** time frame or amount of product (e.g., hours of operation, batches of product, pound of product) shall be defined. Specify size and shape of any one finding. Criteria for critical limit should be based upon health risk, history, and probability. Photographs of acceptable / unacceptable amount and of material are recommended

NOTE: Use a standard set of terms to describe the findings. Metal fines, nut, bolt, etc.

**MONITORING ACTIVITY/FREQUENCY:**

All product passes through the filter/screen/sifter. Amount, size and type of abnormal extraneous matter found are recorded every **x** hours of run time

**CORRECTIVE ACTION ACTIVITY:**

If filter/screen/sifter is not intact or in place during verification, put the product produced since the last acceptable check on Category II hold, stop the process, and replace filter/screen/sifter. Notify Designated Plant Employee to determine disposition of the product.

If any hazardous extraneous matter is found in product, elevate hold to a Category I hold. Notify Designated Quality Function to determine disposition of the product. Hold/Release documentation is required. Corrective action documentation is required.

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

**RECORD/LOCATION** designate the location of each record:


- Filter/Screen/Sifter Log
- Hold and Release Records
- Corrective Action Records
- Verification Records

**MINIMUM CCP VERIFICATION ACTIVITIES:**

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

Visual inspection of the filter/screen/sifter integrity every day of operation or at a frequency sufficient to demonstrate process control.

Upon installation of new filters/screens/sifters, verify correct mesh size/stock item number.

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**SCIENTIFIC BASIS:**


Moberg, L.J. 1992. Establishing critical limits for critical control points in *HACCP Principle and Applications*. Pierson, M.D., and Corlett, Jr. D.A., eds., Van Nostrand Reinhold, NY. p.p. 50-61.

Lewis, D.F. 1993. A tutorial and comprehensive bibliography on the identification of foreign bodies found in food. *Food Structure*, 12, p.p. 365-378.

Hyman, F.N., Klontz, K.C., and Tollefson, L. 1993. Food and Drug Administration surveillance of the role of foreign objects in foodborne injuries. *Public Health Reports*, 108 (1). p.p. 54-59.

Hyman, F.N., Klontz, K.C., and Tollefson, L. 1993. Eating as a hazard to health: preventing, treating dental injuries caused by foreign objects in food. *J AM Dental Assoc*, 124, p.p. 65-69.

Lehman, A.J. 1958. Quarterly report to the editor on topics of current interest: glass and metal fragments in foods and beverages. *Assoc. Food Drug Off. Q Bull.*, 22 (1) p.p. 24-26.

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**MAGNET**

**CRITICAL CONTROL POINT ID:** In-line magnet

**PROCESS STEP:** In-line Magnets

**HAZARD:** Physical Extraneous Ferrous Metal

**CRITICAL LIMIT:**

All product shall flow through or over a magnet made up of **x** plate size or **y** number of bars.

and

The amount of abnormal findings along with size and type of extraneous ferrous metal collected by the magnet per **z** time frame or amount of product. (e.g., hours of operation, batches of product, pound of product). Specify size and

shape of any one finding. Criteria for critical limit should be based upon health risk, history, and probability.

Photographs of acceptable/unacceptable amount and type of material are recommended. Unacceptable type material

includes but is not limited to Nails, Nuts, Bolts, Wire, Washers, and Screws.

NOTE: Use a standard set of terms to describe the findings. Metal fines, dust, turnings, nut, bolt, etc.

**MONITORING ACTIVITY/FREQUENCY:**

All products shall pass through or over a magnet.

Clean the magnet and record a description of extraneous matter found on the magnet after **z** time frame or amount of product, and at process shut down. It is recommended that **z** be no greater than once per shift.

**CORRECTIVE ACTION ACTIVITY:**


If the magnet is not in place or intact during verification, put the product produced since the last acceptable check on Category II hold. Replace magnet. Notify Designated Quality Function to determine disposition.

If the critical limit is exceeded for "abnormal" (amount, size, or type of extraneous matter), stop or do not start up the process, and place the product produced since the last "normal" check on Category II hold. Determine and correct the cause of the "abnormal" findings. If after investigation, product is determined to be contaminated, it shall be placed on category I hold. Notify Designated Quality Function to determine disposition

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

**RECORD/LOCATION:** designate the location of each record

- Magnet verification Log
- Hold/Release Records
- Corrective Action Records
- Verification Records
- Review Records
- Maintenance Log


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**MINIMUM CCP VERIFICATION ACTIVITIES:**

Designated responsible employee (usually the Supervisor) reviews and signs magnet log at least daily.  
 Visual inspection of the magnet integrity at a frequency sufficient to demonstrate process control.  
 Upon installation of new magnets, verify correct design and pull strength. Perform a "Pull Strength Test" at a frequency established.

**SCIENTIFIC BASIS:**

Moberg, L.J. 1992. Establishing critical limits for critical control points in *HACCP Principle and Applications*. Pierson, M.D., and Corlett, Jr. D.A., eds., Van Nostrand Reinhold, NY. p.p. 50-61.  
 Lewis, D.F. 1993. A tutorial and comprehensive bibliography on the identification of foreign bodies found in food. *Food Structure*, 12, p.p. 365-378.  
 Hyman, F.N., Klontz, K.C., and Tollefson, L. 1993. Food and Drug Administration surveillance of the role of foreign objects in foodborne injuries. *Public Health Reports*, 108 (1). p.p. 54-59.  
 Hyman, F.N., Klontz, K.C., and Tollefson, L. 1993 Eating as a hazard to health: preventing, treating dental injuries caused by foreign objects in food. *JAM Dental Assoc*, 124, p.p. 65-69.  
 Lehman, A.J. 1958. Quarterly report to the editor on topics of current interest: glass and metal fragments in foods and beverages. *Assoc. Food Drug Off. Q Bull.*, 22 (1) p.p. 24-26.

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**Model Prerequisite Program**  
**SENSITIVE INGREDIENT POST-LETHAL PROCESS ADDITION**

**OBJECTIVE:** 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).

**PROCESS STEP:** Sensitive Ingredient Post-Lethal Process Addition or Sensitive Ingredient Addition to Process with No Lethal Process Step

**HAZARD:** Biological (Vegetative Pathogens)

**MONITORING:** Each lot of sensitive ingredient must have a supplier COA certifying ingredient negative for the target pathogen(s) or MDLZ 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.

**CORRECTIVE ACTION ACTIVITY:**

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

If COA result is positive for target pathogen(s), reject that lot of material upon receipt. If the raw material is tested by the supplier and the result is positive for target pathogen(s), place material on Category I hold notify Designated Quality Function. Hold/Release documentation is required. Corrective action must be documented.

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

**RECORD/LOCATION** (designate the location of each record):


- COA Records or MDLZ generated Test Records
- Hold and Release Records
- Corrective Action Records
- Verification Records

**MINIMUM VERIFICATION ACTIVITIES:**

Receipt and verification of negative result of COA, or the supplier/EM generated test results for each lot received. Verification that product remains on hold until test result received.

**SCIENTIFIC BASIS:**

ICMSF. 1986. Microorganisms in foods 2 sampling for microbiological analysis: Principles and specific applications. 2nd Edition. ISBN 0-8020-5693-8.

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**APPENDIX F: PACKAGING MODELS PCCP AND PP**

***Model Prerequisite Program***  
**GLASS BREAKAGE - PACKAGING**

**OBJECTIVE:** Assure zero broken packages in exposed or open product / package zone, no visible broken glass 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 again after each glass breakage occurrence, and
- 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).



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**GLASS MANUFACTURING  
FOREIGN MATERIAL OR DEFECT DETECTION DEVICES**

**CRITICAL CONTROL POINT ID:** In-line foreign materials /defects detection device, based on light reflection

**PROCESS STEP:** Detection of glass packaging material

**HAZARD:** Physical - Extraneous Matter

**CRITICAL LIMIT:**

1. Operating detection device unit set for product being run.
- and**
2. Greater than **x** diverted glass packages confirmed to contain hazardous extraneous matter/ defects in **y** time (minutes, hours, pound of product) of operation.  
*(If there are Greater than x diverted packages of product in y time, then an investigation should be conducted to determine the cause of the diverts.)*

**NOTE:**

- Use a standard set of terms to describe the findings. Metal fines, nut, bolt, etc.
- Hazardous extraneous matter are those materials which are sharp and hard.
- Photographs of acceptable/unacceptable amount and type of material are recommended.

**MONITORING ACTIVITY:**

Continuous: All packages pass through an operating detection device.

**and**

All diverted packages are evaluated (if process allows) to determine cause for rejection (specify the evaluation procedures to be used.)


Number of diverted packages of product rejected due to confirmed extraneous matter or type of defect are recorded.

If equipment allows, automatic alert activated for abnormal number of rejects.

**CORRECTIVE ACTION ACTIVITY:**

If a detection device is not operational, stop the line or divert production to an accumulation table or to cullet (rework) until device is operational. Place the product produced since the last time the detection device was verified to be operating on Category II hold. The equipment must be repaired prior to resuming normal production. Re-run the held product through a properly operating detection device. Product re-run through the detection device may be released to normal production.

For continuous operations where glassware cannot be re-run through inspection devices, glass from the time period since the last satisfactory check must be placed on Category II hold. Glass must be 100% inspected (typically manually, with light box) starting at the time the equipment was noted as non-operational back through the previous X pallets (X = no less than 4 for Y number of containers) of product. If no defects are found in the X pallets of production (Y total containers), the remaining production on hold may be released. If any identified defects are found, the inspection must continue until a total of X pallets (Y containers) are inspected and are free of defects. Re-selected glass may be released to normal production If the number of diverted glass containers are found to contain extraneous matter or defects in excess of the critical limit, determine the defective mould number and set

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meld number reject device to reject all production from that specific mould. Identify cause of defect or extraneous from the specific mould and implement corrective action to repair the problem. If the problem with the specific mould cannot be repaired, all production from that mould must be rejected to rework (cullet) until the problem is resolved.

After investigation, product determined to be contaminated or defective shall be placed on Category I hold. Notify Designated Quality Function to determine disposition.

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

**RECORD/LOCATION:** designate the location of each record


- Detection device Log
- Hold/Release Records
- Corrective Action Records
- Verification Records
- Review Records

**MINIMUM CCP VERIFICATION ACTIVITIES:**

At start-up, a designated, trained employee verifies the detection device is operating at its design limits for the product being run by passing a test package of product, seeded with extraneous matter or known defect of concern for the product through the detector z (z = 3 minimum) times. The test containers must be diverted each time. If not diverted, then do not start production until operation of detection equipment can be confirmed.

The detection device and the divert mechanism are then verified to be operating at its design limit by a check similar to the above, performed at a minimum of every y hours of run time and at shut down.

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

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**AUTOMATED LABEL VERIFICATION – ALLERGEN CONTROL**

**CRITICAL CONTROL POINT ID: Automated label UPC scanning and/or vision detection of proper label application.**

**PROCESS STEP: Allergen Control – Label Application**

Proper label application on primary package and/or carton shall be considered as a food allergen CCP when products with different allergen profiles are made on the same line and where an automated detection system is present on the line. For example, if products containing different allergens are packaged in generic packaging with adhesive label(s) applied on the production line, then the label(s) must be continuously monitored to confirm that the correct labels are being applied. Manual visual review of proper label application should be considered a prerequisite program.

**HAZARD:** Chemical (food allergen) - Reference *Appendix C*. Unlabelled allergens, mislabelled product.

**CRITICAL LIMIT:**

Operating scanning or vision device set at its designed detection limit for the product with correct label being produced.

and

Greater than **X** unreadable/incorrect UPC or labels (depending on the speed of the line and the orientation of the package as it passes the scanning or vision device), within **Y** time period. For example, if 2 consecutive labels are unreadable or have the incorrect UPC; or 5 labels are unreadable or have the incorrect UPC in an hour.

NOTE: Determination of the critical limit values for X and Y should be made based on scanning and/or vision system’s operating procedures and product line history.

**MONITORING ACTIVITY/FREQUENCY:**

Continuous: All labelled packages or cartons passing through the operating scanning and/or vision system device.


All diverted packages/product and /or any packages/product causing stoppage to the line are evaluated to determine cause for rejection.

Number of diverted packages/cartons of product rejected or line stoppage due to mislabelled or no labels are recorded every **Z** hours of run time.

**CORRECTIVE ACTION ACTIVITY:**

When the scanner or vision device detects that an unreadable/incorrect UPC or label has been applied to package(s), the following activities must occur and be documented.

- a. Depending on the type of system, the plant should determine if a number of packages (example 10 packages) that have already passed the scanner should be checked to confirm correct labelling in the event that the device did not trigger immediately
- b. X packages (example 10 packages) prior to the scanner should be checked to confirm correct labelling. Also verify film roll stock, labels, or cartons in the cartoner to determine if there are other incorrect/non-readable UPC or labels loaded onto the line.
- c. Determine root cause – employee error, supplier error or other malfunction error and document as part of the corrective action process.

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d. If the scanner or vision device becomes inoperable, frequent label checks must be performed beginning immediately after the device is detected to be inoperable. Recommend manual check frequency is beginning of a new roll, after a splice on a roll or a new package of labels, and every 30 minutes of run time.

e. Manual label checks during inoperable device service must be documented.

f. If there is uncertainty as to when the device became inoperable, the Quality Manager (or designee) must be contacted and an appropriate amount of product should be placed on Category II hold. A statistical sampling plan to check for correct labelling of held product shall be developed and implemented.

g. After investigation, product with incorrect or missing labels shall be placed on Category I hold. Notify Designated Quality Function.

h. Hold/Release documentation is required.

i. Corrective action must be documented.


**RESPONSIBILITY (Monitoring and Corrective Action):** Designated, trained production or maintenance employee

**RECORD/LOCATION:** designate the location of each record

- Label Detection Log
- Hold and Release Records
- Corrective Action Records
- Verification Records

**MINIMUM CCP VERIFICATION ACTIVITIES:**

1. At the beginning of each shift and after each changeover, the scanner or vision device will be set up to recognize the correct label UPC or label and verified that incorrect label will be rejected or cause line stoppage. The operation type check for package and/or carton labels should be performed on a regular basis during operations.  
Label checks will be documented per plant scanner or vision device operational procedures.
2. At the end of the run or shift, an incorrect UPC or resource number will be scanned to confirm that the scanner or vision device will detect an incorrect label.
3. Designated responsible employee (usually the Supervisor) reviews and signs the Label detection records at least daily.

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**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/roll stock; cartons; film roll stock; rigid containers; lids; foil lid stock; sleeves, etc.).

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

**HAZARD:** Mixing of printed packaging materials (mixed *Kraft 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 labelled 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 *Kraft 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 *Kraft 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 *Kraft 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-labelling 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-labelled 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:**

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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 mislabelled or unlabelled 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 MDLZ 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 labelled 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.

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**Model Prerequisite Program**

**CUT AND STACK LABELS**

**OBJECTIVE:** Assure labels with different Kraft Resource Codes are not mixed in stacks, cases or pallets. Cases and pallets are correctly labelled. 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 *Kraft 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-labelling 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.

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***Model Prerequisite Program***  
***FOOD CAN SEAM INTEGRITY***

**OBJECTIVE:** Assure cans are hermetically sealed to prevent entry of microorganisms. The following monitoring, corrective actions, and documentation requirements must be implemented if cans are manufactured to make sure cans are hermetically sealed to prevent entry of microorganisms.

**MONITORING ACTIVITY:**

Can seam evaluations performed per regulatory rules for low acid canned foods. In U.S., can seams must comply with 21 CFR Part 113 Thermally Processed Low –Acid Foods Packaged in Hermetically Sealed Containers 9 CFR Part 318 – USDA Canning Regulations. Minimum one can from each head examined visually every 30 minutes and documented. Minimum one can from each head evaluated by teardown evaluation once every 4 hours of production and documented. Cooled, post process can vacuum checked by vacuum gauge minimum once per hour.

**CORRECTIVE ACTION:**

If can seam measurements are outside critical limits or visible defective seams are observed, all product must be placed on Category I hold from the time of the last acceptable check. If can seam defects are observed on the manufacturer’s end of the can or side seam, all product produced with the potentially defective lot of cans must be placed on Category I hold pending investigation and evaluation.

**RECORD/ LOCATION:**

The following shall be maintained and checked daily for completeness:

- Can seam teardown log sheets
- Can seam Visual Inspection log sheets

Note: In US all process and equipment records must be reviewed per regulatory requirements before release of product to distribution.