QUALITY POLICY TRAINING

HAZARD
ANALYSIS
CRITICAL
CONTROL
POINT

Good Manufacturing Practice

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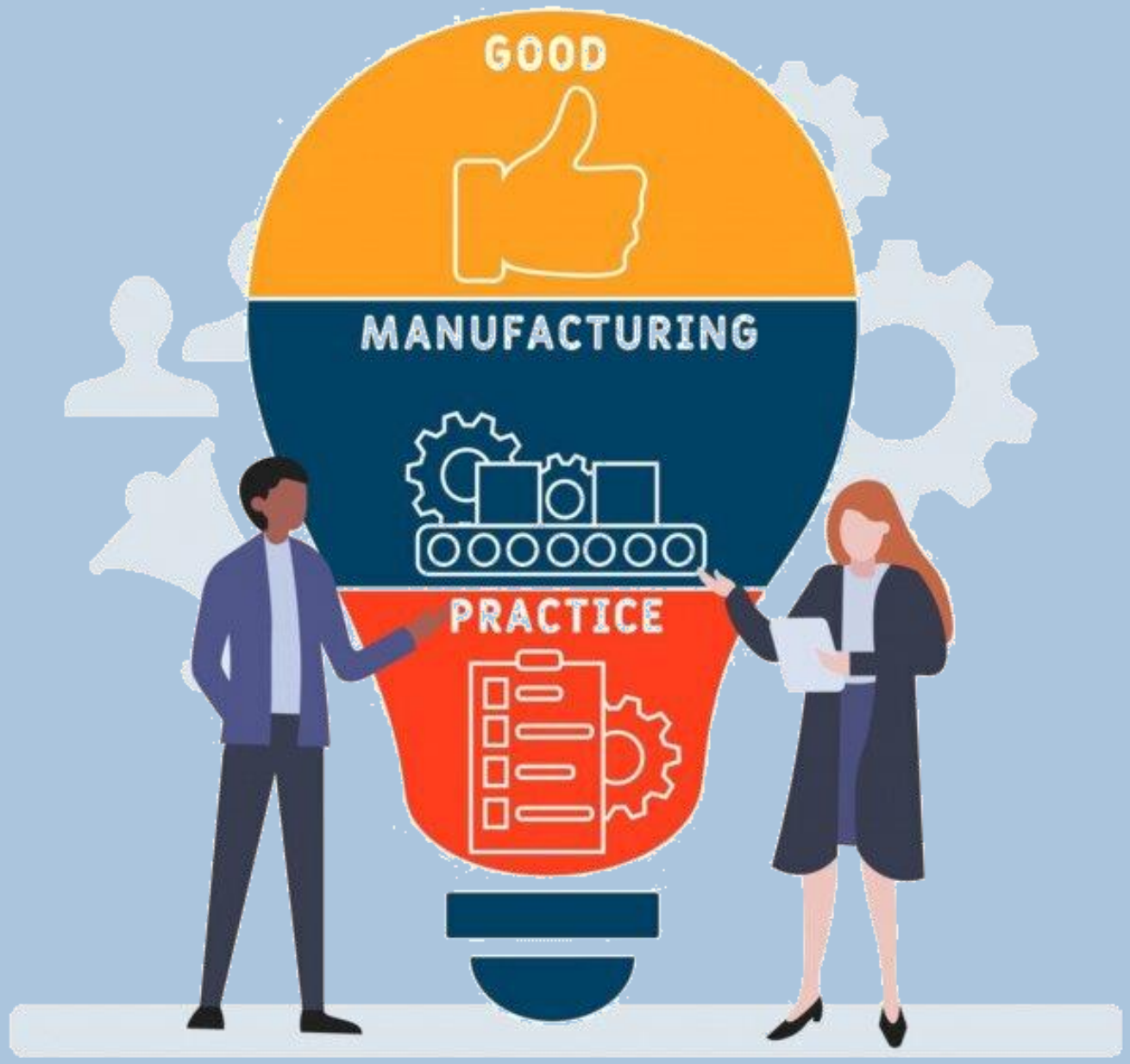

GOOD MANUFACTURING PRACTICES

QP

SOP

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PURPOSE

TO PROVIDE AWARENESS OF GMP STANDARDS AND OUR COMMITMENTS TO GMP

OBJECTIVE

TO MAKE SURE THAT OUR PRODUCTS ARE PRODUCED, STORED AND HANDLED IN SANITARY CONDITION

SCOPE

APPLIES TO ENTIRE SUPPLY CHAIN INVOLVED IN FOLLOWING

- PRODUCING, HANDLING AND DISTRIBUTION
- DESIGN, CONSTRUCT & MAINTAIN FOOD FACILITY, PROCESSES AND EQUIPMENT'S

PP ENTRY CHECKLIST

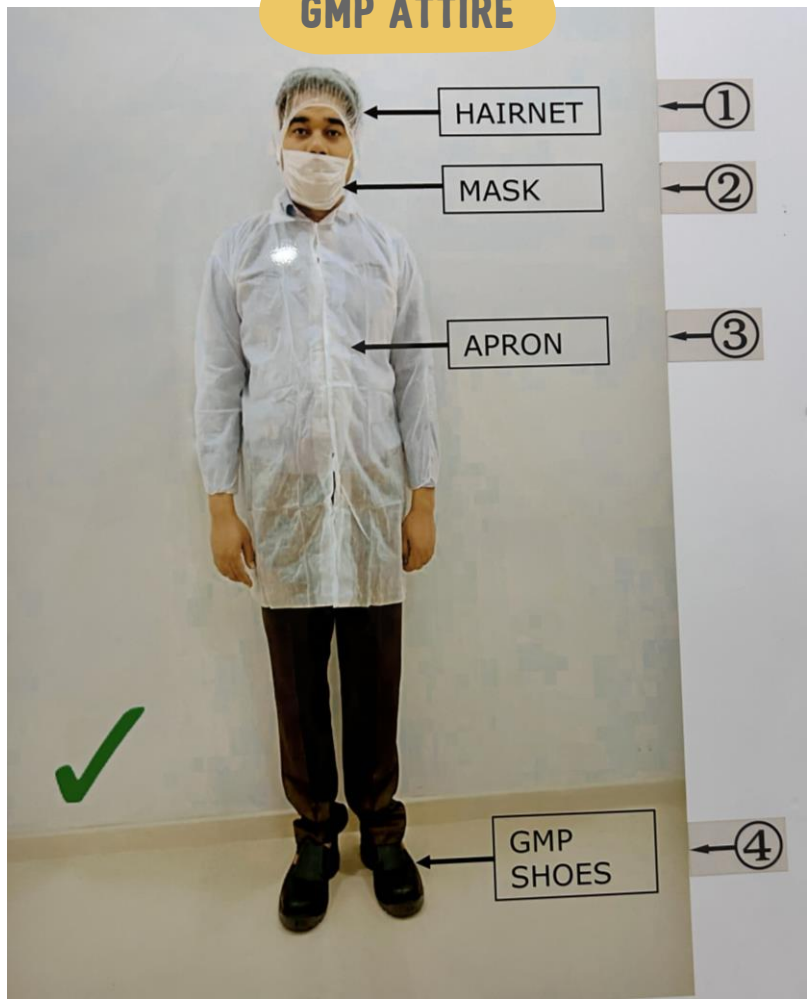
- MEDICAL SCREENING AND VACCINATION MANDATORY FOR NEW JOINERS

- ALL EMPLOYEE MUST MAINTAIN BASIC PERSONAL HYGIENE
- COMPLETE GMP ATTIRE IS MANDATORY BEFORE ENTERING PP

- EMPLOYEE WHO HAS REPORTED ILLNESS AND WAS ON SICK LEAVE (> 2 DAYS) SHALL PROVIDE FITNESS CERTIFICATE TO GET ACCESS TO PILOT PLANT.

- TRAINING IS MANDATORY FOR ALL PERSONAL BEFORE ENTERING PP

GMP ATTIRE



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PERSONAL HYGIENE

GOOD HYGIENE PRACTICES

1 PERSON ENTERING FOOD MANUFACTURING AREA SHALL MAINTAIN HIGH DEGREE OF PERSONAL HYGIENE.

PERSON SHOULD AVOID USE OF HAND FOR FOLLOWING

- SCRATCH HEAD OR BODY .
- TOUCH FACE OF WIPE FOREHEAD
-
- PLACING FINGER ON MOUTH NOSE, OR EARS

2 PERSON SHOULD FOLLOW HAND SANITIZING PRACTICE AS AND WHEN REQUIRED TO ENSURE PRODUCTS ARE SAFE.

3 SPITTING, LITTERING AND OTHER UNSANITARY ACTS SHALL BE PROHIBITED.

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APRON COLOR CODE FOR RESPECTIVE AREAS IN PILOT PLANT

NOTE :
WHILE SWITCHING BETWEEN AREAS IT IS MANDATORY TO CHANGE GMP ATTIRE

PLAIN WHITE APRON

CHOCOLATE AND COCOA BEVERAGES

GREEN PATCH APRON

REFRESHMENT BEVERAGES

RED PATCH APRON

RAW PILOTPLANT

DISPOSABLE APRON

VISITOR AND PACKAGING TEAM MEMBERS

JEWELLERY & ACCESORIES



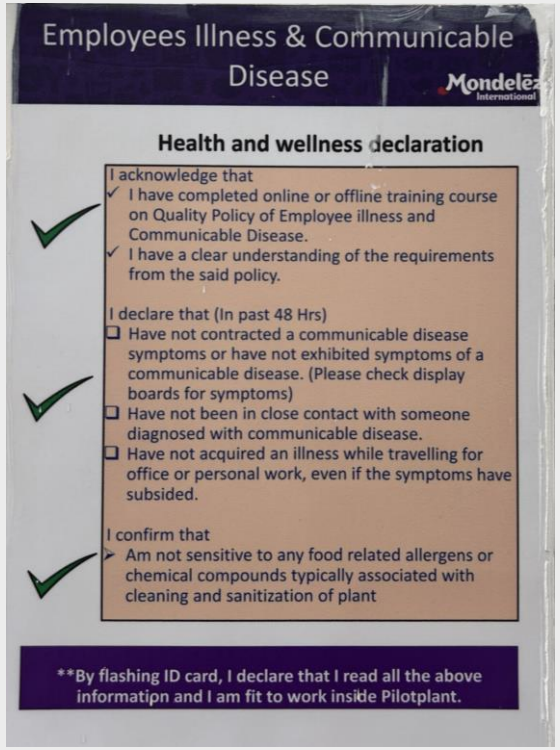



PLAIN WEDDING RINGS ARE ALLOWED TO BE WORN BY THE EMPLOYEE BUT SHOULD NOT IN DIRECT PRODUCT PROXIMITY.
GLOVES SHOULD BE WORN INSTEAD TO AVOID PRODUCT RISK


BADGES & ID CARDS


SELF DECLARATION:

THIS DECLARES THAT YOU READ THE INFORMATION CORRECTLY AND ARE FIT TO WORK IN PILOT PLANT



- USE OF BADGES AND CLIP-ON IDENTIFICATION (ID) CARDS ARE PERMITTED ACCORDING TO SITE SECURITY POLICY AND MUST BE WORN BELOW WAIST OR UNDER PROTECTIVE CLOTHING.
- VISITOR IDENTIFICATION BADGES ARE PERMITTED BUT MUST NOT BE A SOURCE OF CONTAMINATION AT THE PLANT.

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PROHIBITED ACTS

BELOW MENTIONED ACTS ARE NOT ALLOWED IN GMP AREAS TO PREVENT PRODUCT CONTAMINATION.

- CHEWING GUM, CANDIES, THROAT CANDIES, THROAT LOZENGES AND TOBACCO.
- HOLDING TOOTHPICKS, MATCHSTICKS, OR OTHER OBJECTS IN THE MOUTH.
- PLACING PENS OR CIGARETTES BEHIND THE EARS.
- WEARING FALSE EYELASHES OR FINGERNAILS.
- EXPECTORATING (SPITTING) IN PRODUCTION AREAS.
- CARRYING PILLS OR MEDICATION IN CLOTHING POCKETS. (EXCEPTIONS REQUIRE MEDICAL AUTHORIZATION AND THE APPROVAL OF THE FACILITY QUALITY MANAGER OR DESIGNATED MANAGER AT THE FACILITY.)
- SMOKING IN GMP AREAS.
- REMOVING PPE IN PILOT PLANT

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LOCKERS

1. PERSONAL LOCKERS MUST BE MAINTAINED FREE OF TRASH AND SOILED CLOTHING.

2. FOODS AND DIRECT PRODUCT CONTACT TOOLS MUST NOT BE STORED IN EMPLOYEE LOCKERS.

3. LOCKERS MUST BE KEPT CLEAN

4. SEPARATE SHELVES TO BE MAINTAINED FOR GMP SHOES

NON GMP LOCKERS

GMP LOCKERS

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PRODUCT TAMPERING

1. EMPLOYEE WHO OBSERVE ANY INTENTIONAL ACT WHICH MIGHT COMPROMISE THE SAFETY OF ANY INGREDIENT, PRODUCT OR PACKAGE ARE REQUIRED TO IMMEDIATELY REPORT THIS ACTIVITY TO AREA OWNER AND RESPECTIVE LINE MANAGER

2. ANY INTENTIONAL ACT OBSERVED SHOULD BE REPORTED IMMEDIATELY TO QUALITY TECHNICIAN OR MANAGER

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HYGIENIC ZONING AND ENVIRONMENTAL MONITORING

QP

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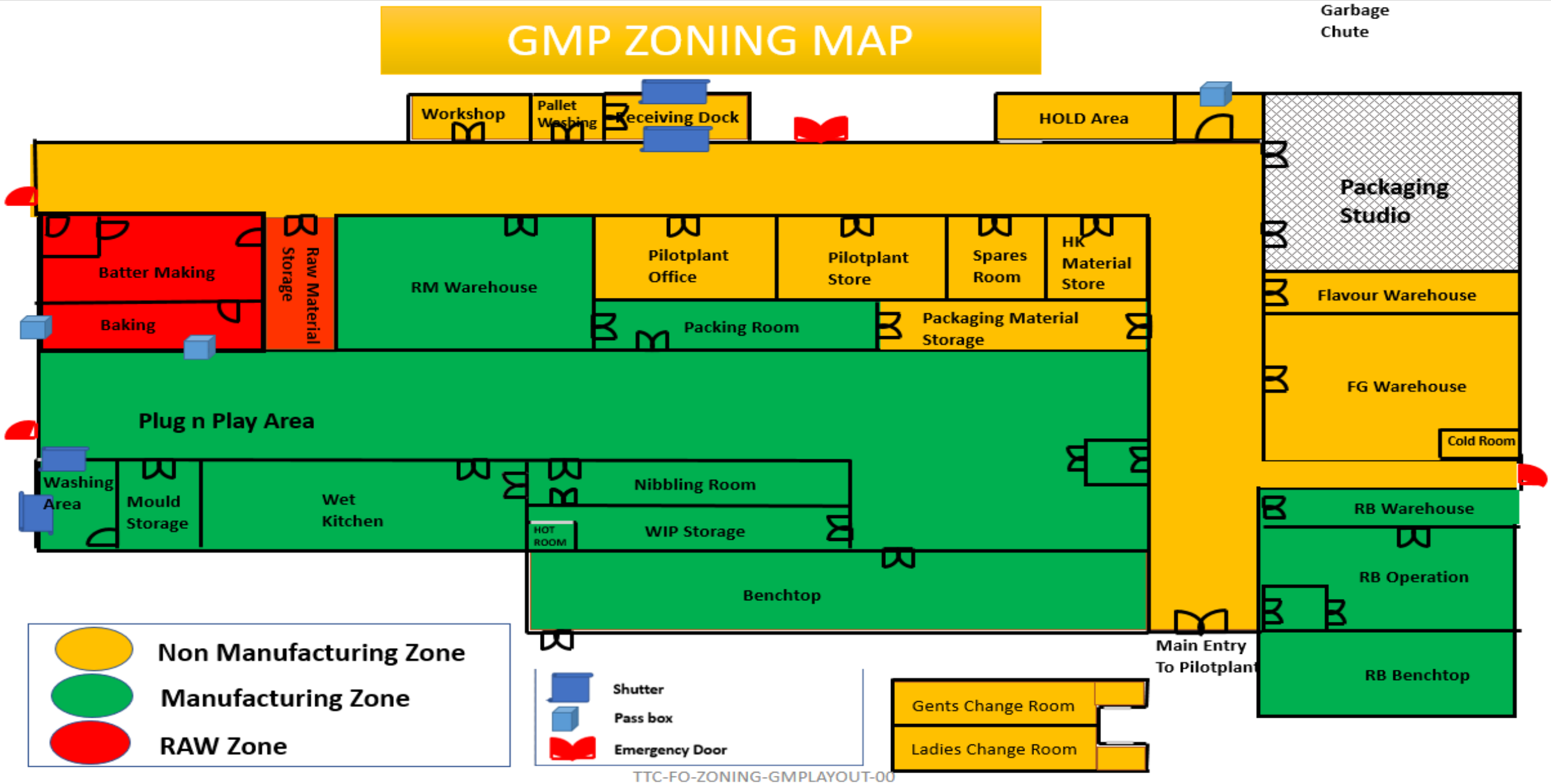
PURPOSE

PREVENT MICROBIAL CROSS CONTAMINATION AND TO ASSURE PRODUCT QUALITY AND SAFETY.

NOTE

EMPLOYEES MUST FOLLOW ESTABLISHED TRAFFIC PATTERNS AND CONTROLS TO PREVENT MICROBIAL CROSS CONTAMINATION WITHIN MANUFACTURING SITE.

GMP ZONING MAP FOR TTC PILOT PLANT



MANUFACTURING ZONE

AREAS IN MANUFACTURING ZONE

- CHOCOLATE AREA
- RB AREA
- RAW AREA

- HANDWASH FACILITY IS MANDATORY BEFORE ENTERING MANUFACTURING ZONE
- DEDICATED TROLLEYS FOR MATERIAL MOVEMENT
- DEDICATED UTENSILS TO BE USED TO PREVENT CROSS CONTANMINATION BETWEEN MANUFACTURING AREAS

NOTE

- COMPLETE CHANGEOVER IS MANDATORY BEFORE SHIFTING IN BETWEEN MANUFACTURING AREAS TO AVOID CROSS CONTAMINATION

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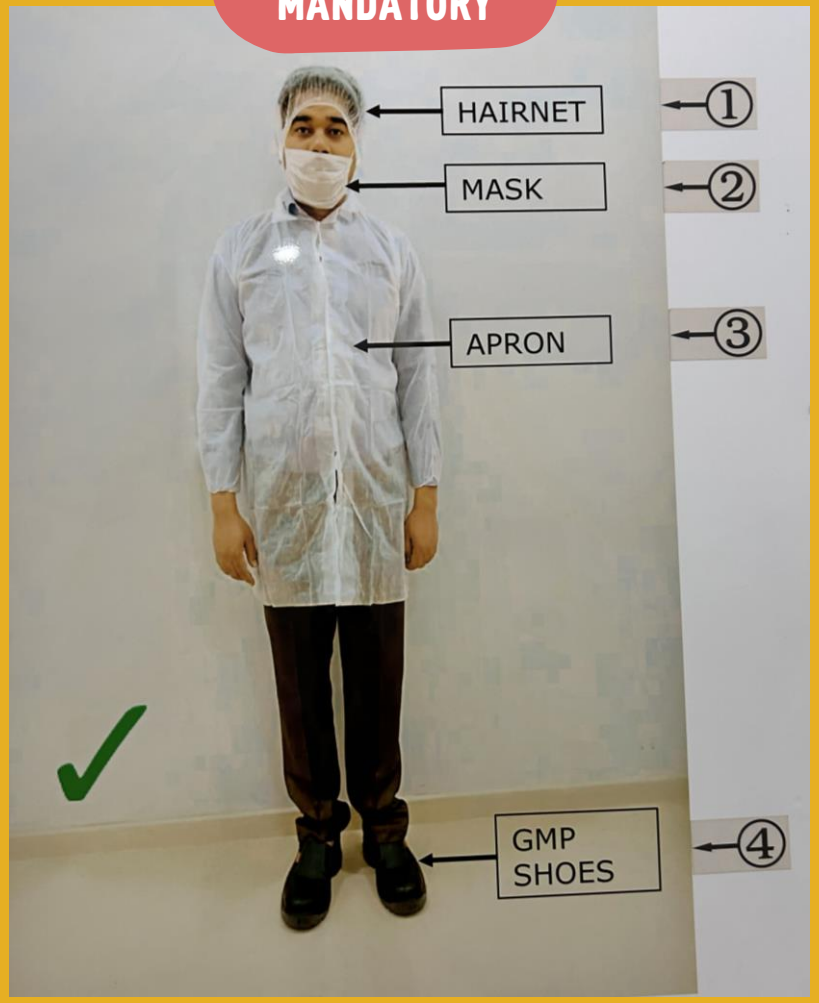
NON - MANUFACTURING ZONE

DEDICATED TROLLEY ONLY TO BE USED

GMP ATTIRE IS MANDATORY



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CHANGE OVER PROCESS

CHANGE HAIR NET

WEAR RED BAND APRON

WEAR RAW AREA DEDICATE SHOES

HANDWASH FACILITY IS MANDATORY BEFORE ENTERING RAW ZONE

RAW ZONE

DEDICATED TROLLEYS TO BE USED

RED MARKED/DEDICATED UTENSILS ONLY TO BE USED IN RAW AREA

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ZONING CLASSIFICATION

NON-MANUFACTURING ZONE

AREAS WHERE THERE ARE NO EXPOSED RAW MATERIALS, INTERMEDIATE OR FINISHED PRODUCTS OR FOOD CONTACT PACKAGING MATERIALS.

MANUFACTURING ZONE

AREAS RECEIVING, STORING, HANDLING OR PROCESSING RAW AGRICULTURAL PRODUCTS OR INGREDIENTS / RAW MATERIAL CONTAINING RAW AGRICULTURAL PRODUCTS

CONTROLLED ZONE

AREAS CONTAINING MATERIALS OR PRODUCTS OF LOW TO MEDIUM MICROBIOLOGICAL SENSITIVITY THAT ARE NOT FULLY ENCLOSED AND THEREFORE ARE EXPOSED TO THE ENVIRONMENT DURING ROUTINE OPERATION OR MAINTENANCE.

WAYS OF WORKING

1 RECEIVE MATERIAL

- MATERIAL RECEIVED AT DOCK
- APPROPRIATE DOCUMENTATION-COA FOR SENSITIVE INGREDIENTS, ION NUMBER
- YELLOW LABEL GENERATION WITHIN 7 DAYS

2 WAREHOUSE

- GREEN LABEL GENERATION WITHIN 15 DAYS
- ALLERGEN & NON-ALLERGEN MATERIALS STORED SEPARATELY IN EM WAREHOUSE

3 MATERIAL REQUEST

- FILLING & APPROVAL OF FORM L
- GENERATION OF TRIAL ID
- MATERIAL REQUEST 1 DAY PRIOR BY PRODUCT DEVELOPER (PD) VIA AUGMENTIR
- MATERIAL DISPENSING BY AREA OWNER

4 OPERATIONS

- PRE-BOOKING OF EQUIPMENTS VIA APP
- REMOVE LOTO ON EQUIPMENT
- WIP LABEL (FOR WORK IN PROGRESS MATERIALS)
- SPP & CCP DOCUMENTATION
- RECORDING TRIAL DOCUMENTATION

5 PACKAGING

- HERMETIC SEALING OF POUCHES
- NO THERMOCOLE BOXES IN PRODUCTION AREA
- NO BROWN CARTONS IN PRODUCTION AREA
- DONE IN DESIGNATED AREAS

6 FG WAREHOUSE

- YELLOW LABEL GENERATION BEFORE MICRO CLEARANCE
- ALLERGEN DECLARATION AS PER FORM L
- GREEN LABEL GENERATION AFTER MICRO CLEARANCE

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INCOMING MATERIAL RECEIVING & STORAGE

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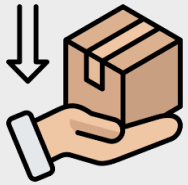
MATERIAL RECEIVING AND WAREHOUSING FLOW

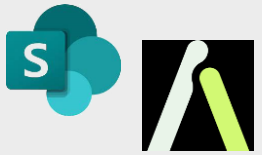


MATERIAL RECEIVING AT DOCK AREA

VISUAL INSPECTION BY LOGISTIC TEAM MEMBER

DOCUMENT VERIFICATION BY LOGISTIC TEAM MEMBER

CLEANING AND SANITIZATION DRY MOPPING + IPA



MATERIAL ENTRY ON SHAREPOINT AND AUGMENTIR

YELLOW LABEL GENERATION (TURN AROUND TIME 7 DAYS)

MATERIAL MOVEMENT TO EM WAREHOUSE / DESIGNATED AREA

GREEN LABEL GENERATION ON VALID COA/ RELEASE DOCUMENTS

MATERIAL RELEASED

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THANE TECHNICAL CENTRE

FSSQ GUIDE

Sr. No.	Scenarios	Examples	Requirements			
			Sensitive Ingredient	Non-Sensitive Ingredient	Raw Ingredient	Declarations
1	**Material through intra factory**		Batch Code*	Batch Code*	Batch Code	*Batch code (communication via mail or any other means to confirm that material is cleared from quality and food safety aspect for intra-factory transfer)
2	**Existing Ingredient in ION**		COA from approved Lab	Batch Code	Batch Code	
3	**New Ingredient**					
3.1	Similar Ingredient with known Micro Rating (Approved Supplier site and location) Within MDLZ control Refer to QP 08.5-05:- Requirements for R&D Pilot Plant and Bench Top Trials, Manufacturing Plant Trials and Consumer for additional ingredient information requirements	Similar flavours from the approved supplier location and site (composition is similar to existing Ion ingredient)	• Batch Code/Manufacturing Date • TDS (with Allergen & CC), COA from approved Lab	• Batch Code/ Manufacturing Date • TDS (with Allergen & CC)	• Batch Code/ Manufacturing Date	• Confirmation through email from Product Developer that allergens and all food safety parameters (level of sulphite, % of ingredients) are same, then COA is sufficient.
3.2	Similar Ingredient with known Micro Rating (New Supplier site and location) Refer to QP 08.5-05:- Requirements for R&D Pilot Plant and Bench Top Trials, Manufacturing	Roasted Hazelnut from new supplier	• TDS (with Allergen & Cross Contact allergen), COA from approved Lab • *Validated Kill step where applicable	• TDS (with Allergen & Cross Contact allergen), COA (good to have)	Batch Code	***Internal consumption (in MDLZ control):** Confirmation through email about Allergens and presence of any validated kill step through mail, then COA is sufficient. (PD to get the FSSQ approved before HUT)
	Plant Trials and Consumer for additional ingredient information requirements					**Out of MDLZ control**: FSSQ mandatory
3.3	New Ingredient with no known Micro Rating (from approved and not approved supplier)	Moringa powder, Jackfruit seed Powder	FSSQ self-signed with information from supplier	FSSQ self-signed with information from supplier	Batch Code	• FSSQ mandatory e.g. Moringa powder, Jackfruit seed Powder
4	**Retailers(supermarkets)**		Allergen & Cross contact allergen - Batch Code	Allergen & Cross contact allergen - Batch Code	Batch Code	• No micro testing will be done. Such ingredients to be used only within MDLZ control.

HAZARD ANALYSIS CRITICAL CONTROL POINT

QP

PLAN

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PURPOSE

ENSURE THAT THANE RDQ PRODUCTS ARE DESIGNED, PRODUCED, DISTRIBUTED AND STORED USING THE HACCP PRINCIPLES AND THE MONDELĒZ INTERNATIONAL HACCP STANDARD TO MINIMIZE PRODUCT/FOOD SAFETY RISKS.

SCOPE

APPLIES TO ALL THANE RDQ PRODUCTS (INGREDIENTS, PRIMARY PACKAGING, SEMI FINISHED AND FINISHED PRODUCTS), WHETHER MANUFACTURED INTERNALLY OR EXTERNALLY.

TYPES OF HAZARDS

BIOLOGICAL HAZARDS

SOURCES

- WATER
- HUMANS
- UNHYGIENIC PLANT ENVIRONMENT
- INSECTS, RODENTS & PESTS

PHYSICAL HAZARDS

SOURCES

- GLASS
- METAL
- PLASTIC
- DUST & ROCK
- HAIR
- SCREW & NUTS

CHEMICAL HAZARDS

SOURCES

- ALLERGENS
- SANITIZERS & CLEANERS
- CHEMICALS

SPECIFIC PREREQUISITE PROGRAMS (SPP)

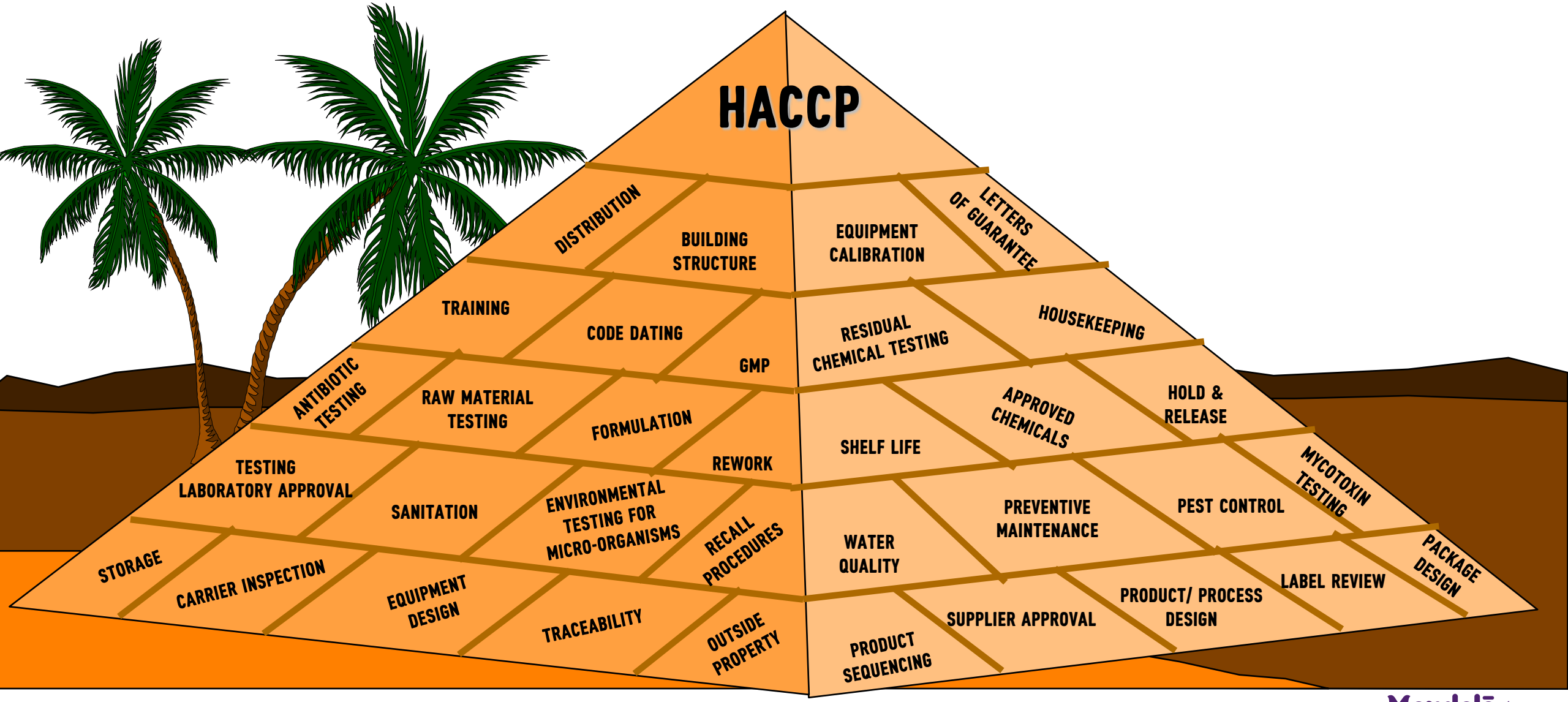
SPECIFIC PREREQUISITE PROGRAMS ARE PROCEDURES USED TO CONTROL THE CONDITIONS IN THE PLANT ENVIRONMENT WHICH CONTRIBUTE TO THE OVERALL PRODUCTION OF SAFE FOOD.

EXAMPLES INCLUDE:

- SANITATION
- GMPS
- TRAINING

➢ SPECIFIC PREREQUISITE PROGRAMS MUST BE IN PLACE BEFORE HACCP CAN BE IMPLEMENTED

TYPES OF SPECIFIC PREREQUISITE PROGRAMS



PYRAMID OF FOOD SAFETY

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CCP

METAL DETECTOR

- SANITIZE TEST PIECES BEFORE PRE PRODUCT PASS
- PRE PRODUCT PASS FUNCTIONALITY VERIFICATION USING TEST PIECES (FERROUS 1.5MM, NON-FERROUS 1.5MM, SS 2MM) BY PD – DONE TWICE
- POST PRODUCT PASS FUNCTIONALITY VERIFICATION USING TEST PIECES (FERROUS 1.5MM, NON-FERROUS 1.5MM, SS 2MM) BY PD – DONE TWICE
- RECORD ALL THE DETAILS PROPERLY ON AUGMENTER

- CRITICAL LIMIT: NOT MORE THAN 1 CONFIRMED METAL CONTAMINATED BAR IN EACH LOT
- IN CASE ANY ISSUES WITH DETECTION AND REJECTION, IMMEDIATELY INFORM HACCP COORDINATOR.

CCP

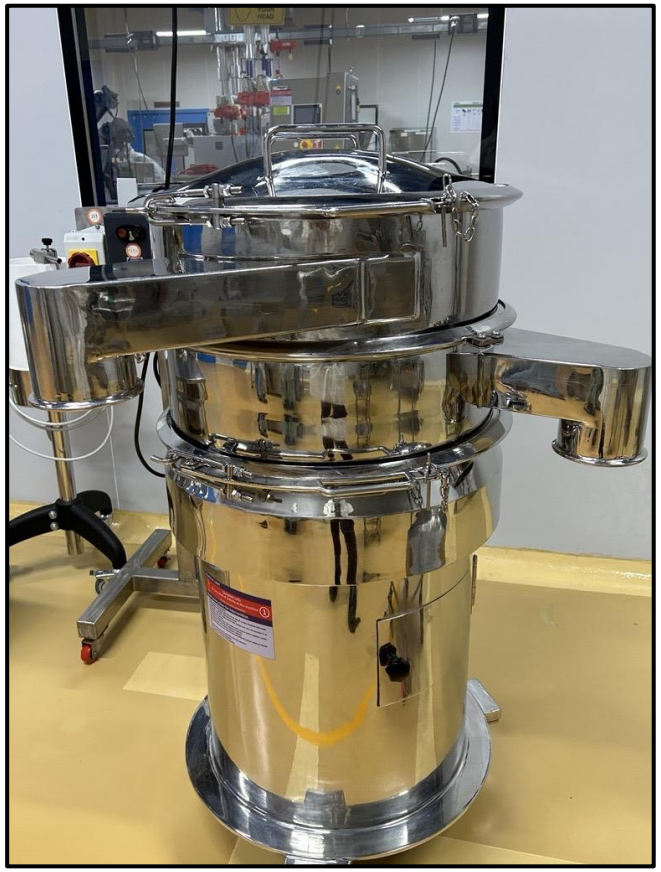
X-RAY

- SANITIZE OF TEST PIECES BEFORE PRE-PRODUCT PASS
- PRE PRODUCT PASS FUNCTIONALITY VERIFICATION USING TEST PIECE (SS 2MM) BY PD – DONE TWICE
- POST PRODUCT PASS FUNCTIONALITY VERIFICATION USING TEST PIECE (SS 2MM) BY PD – DONE TWICE
- RECORD ALL THE DETAILS PROPERLY ON AUGMENTIR

- CRITICAL LIMIT: NOT MORE THAN 1 CONFIRMED CONTAMINATED BAR IN EACH LOT
- IN CASE ANY ISSUES WITH DETECTION AND REJECTION, IMMEDIATELY INFORM HACCP COORDINATOR.

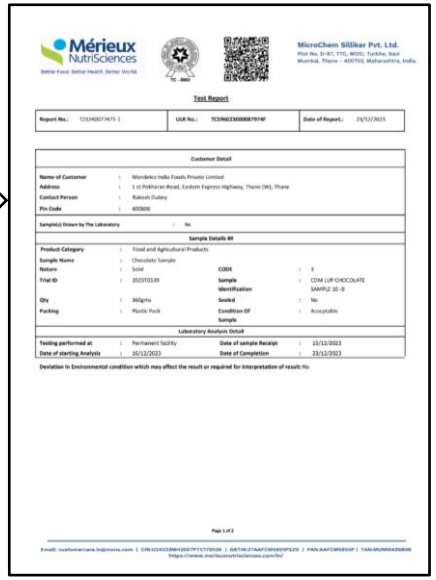
CCP
SIEVING

- STRAINERS/ SIEVING ARE ALSO A CCP



SPP

SPP	HAZARD	LIMITS FOR SPP
COA FOR SENSITIVE MATERIALS (MILK POWDER, SOY LECITHIN, COCOA BEANS, NUTS)	SALMONELLA	• MICRO COA • SHOULD TEST ABSENT OR NEGATIVE FOR SALMONELLA
ALLERGEN LABELLING	ALLERGEN CONTAMINATION / CROSS CONTAMINATION	• PROPER LABELLING OF ALLERGENS ON PRODUCTS AND INGREDIENTS • ALL GLOBAL ALLERGENS DECLARED ON EACH FINISHED PRODUCT PREPARED IN TTC AS "MAY CONTAIN"



Mérieux NutriSciences

MicroChem Silliker Pvt. Ltd.

Test Report

Applicable Allergen: Wheat, Milk Peanut, Sesame, soya, Treenuts (Almond, Cashew, Hazelnut, Brazil nut, Macadamia, Pecan, Pine, Pistachio, Walnut, Chestnut, Hickory)

SPP

SPP	HAZARD	LIMITS FOR SPP
SLURRY, BATTER, CRUMB AND E-MILK MAKING	BIOLOGICAL (VEGETATIVE PATHOGENS): STAPHYLLOCOCCUS AUREUS	• AT POINT WHERE WATER IS ADDED IN THE PRODUCTION OF THE DOUGH, BATTER OR SLURRY, THE HOLDING TIME PRIOR TO HEAT STEP SHOULD NOT EXCEED 4 HOURS (FOR SAFETY REASONS). • IF THE TIME EXCEEDS 4 HOURS, ALL MATERIAL SHALL BE PUT ON CATEGORY II HOLD AND DISCARD IMMEDIATELY WITHIN QUARANTINE AREA.
BAKING	BIOLOGICAL (VEGETATIVE PATHOGENS): SALMONELLA	• BAKING OF BATTER AT OR ABOVE 150°C. • ANY ISSUES WITH MOISTURE CONTENT DATA NEED TO INFORM TO QUALITY TEAM FOR FURTHER INVESTIGATION • IF THE SLURRY USAGE TIME EXCEEDS 4 HOURS, IF THE TEMPERATURE DOES NOT REACH/ BATTER IS NOT BAKED PROPERLY (VISUAL CHECK BY PD), ALL MATERIAL SHALL PUT ON CATEGORY II HOLD • WAFER/BISCUIT SHOULD NOT BE STORED IN RAW ZONE POST BAKING.

HACCP PLAN ACTIVITIES AND TRAININGS

ACTIVITY	WHEN?
HACCP PLAN REVIEW	EVERY 2 YEARS- CAN BE EXTENDED TO 3 YEARS WITH FS APPROVAL.
HACCP PLAN VALIDATION	DONE WITHIN 6 MONTHS OF THE FINAL FSP/HACCP PLAN APPROVAL
HACCP PLAN VERIFICATION	ANNUALLY
HACCP PLAN REANALYSIS	EVERY 2 YEARS- CAN BE EXTENDED TO 3 YEARS WITH FS APPROVAL.
HACCP TRAINING TO ALL EMPLOYEES & CONTRACTORS	PRIOR TO WORKING IN PILOT PLANT & MANUFACTURING FACILITIES
REFRESHER TRAINING	ANNUALLY

ALL HACCP TRAINING SHALL BE DOCUMENTED AND RECORDS RETAINED FOR REVIEW AS PER THE QUALITY POLICY FOR TRAINING.

FOOD ALLERGEN CONTROL AND MANAGEMENT

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PURPOSE

ENSURE ALLERGENS THAT ARE PRESENT ARE LABELED CLEARLY AND ARE CONSISTENT WITH REGULATORY AND MONDELĒZ INTERNATIONAL REQUIREMENTS AND ALLERGENS / MATERIALS OF SENSITIVITY AND INTOLERANCE (MSI) ARE NOT PRESENT UNLESS DECLARED.

SCOPE

APPLIES TO ALL INGREDIENTS, PRIMARY PACKAGING, SEMI FINISHED AND FINISHED PRODUCTS WHETHER MANUFACTURED INTERNALLY OR EXTERNALLY.

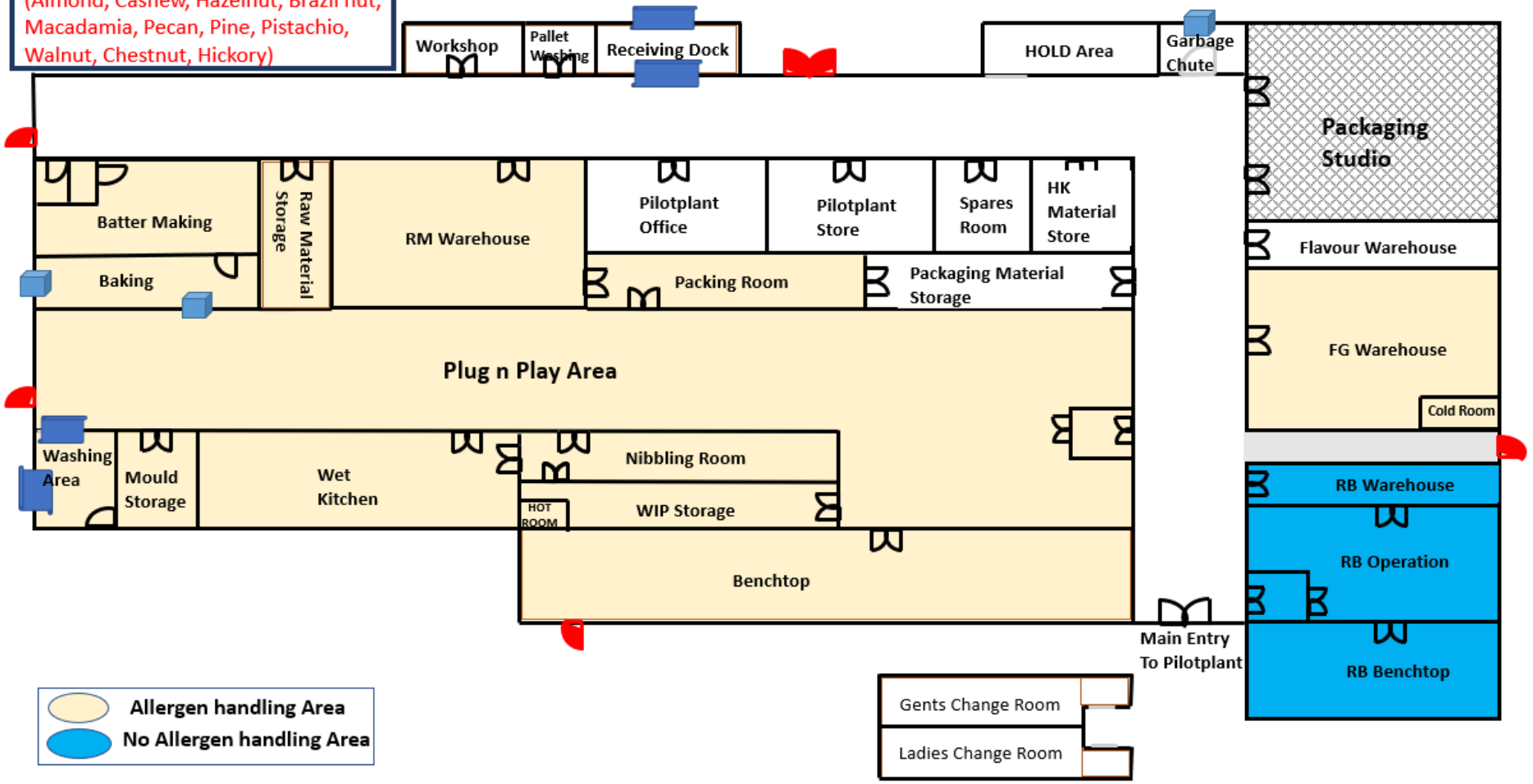
DIFFERENT TYPES OF ALLERGENS

AS PER REGULATORY, ONLY INDIAN VEG INGREDIENTS AND ALLERGENS ARE ALLOWED IN TTC

APPLICABLE ALLERGENS

Applicable Allergen: Wheat, Milk Peanut, Sesame, soya, Treenuts (Almond, Cashew, Hazelnut, Brazil nut, Macadamia, Pecan, Pine, Pistachio, Walnut, Chestnut, Hickory)

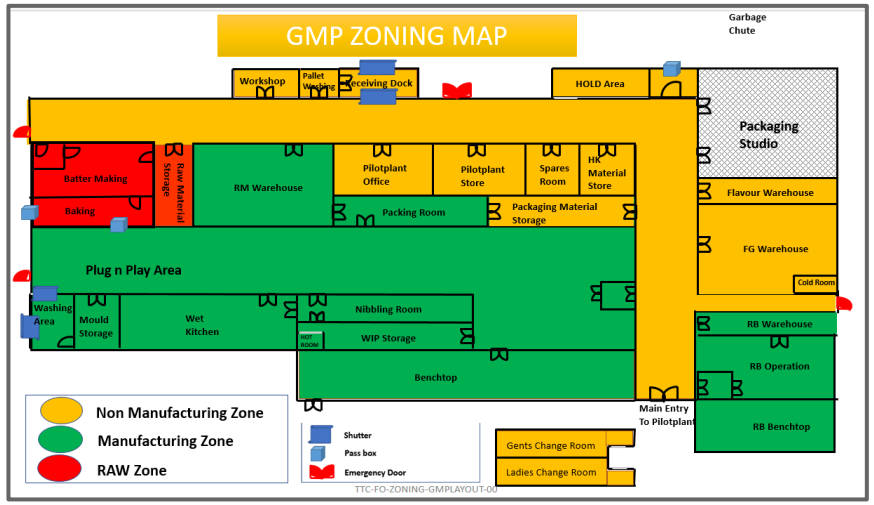
ALLERGEN ZONING MAP

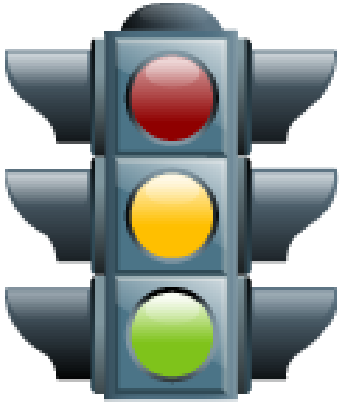


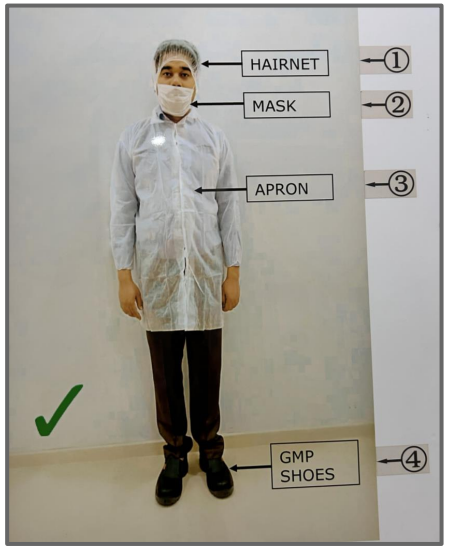
ALLERGENS SHALL BE IDENTIFIED AND DOCUMENTED IN THE SITE'S HACCP PLAN AND SPECIFICATION SYSTEM.

CONTROL ALLERGEN CONTAMINATION

- FOLLOW ZONING
- USE DESIGNATED TROLLEYS, UTENSILS AND PPE
- FOLLOW CHANGEOVER
- GMP ATTIRE
- SEPARATE STORING OF ALLERGENS AND NON-ALLERGENS
- USE DESIGNATED TRAFFIC ROUTES TO PREVENT CROSS-CONTAMINATION



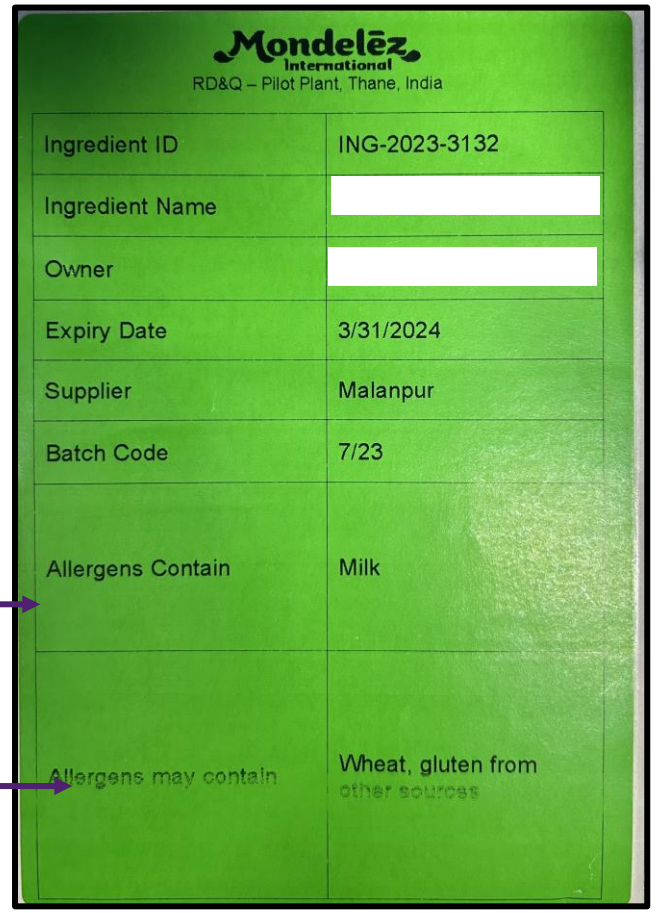


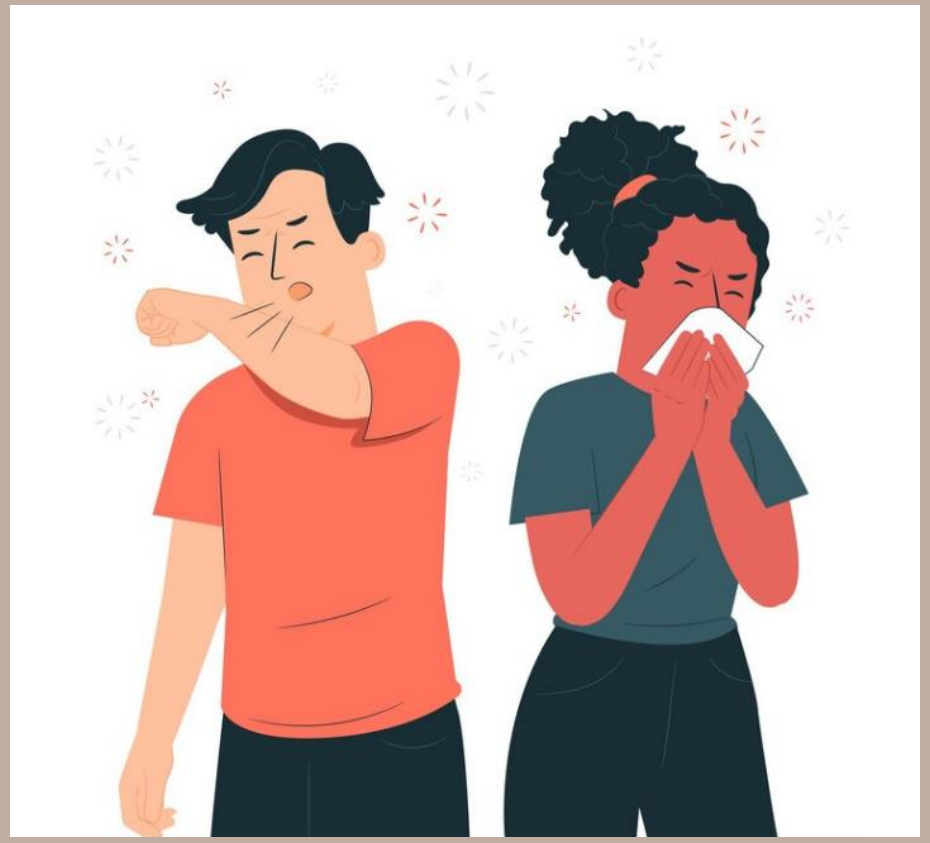


ALLERGEN MANAGEMENT

1. RM & PARTIALLY USED RM SHOULD BE FULLY SEALED, CLEARLY LABELED AND APPROPRIATELY STORED
2. PROPER LABELLING TO ENSURE TRACEABILITY OF THE ALLERGENS THAT ARE PRESENT.
3. IF UNDECLARED ALLERGENS ARE IDENTIFIED IN PRODUCT OR MATERIAL IT IS CONSIDERED IN CATEGORY 1 OF HOLD AND RELEASE
4. PD MUST LOG IN FG DETAILS IN FORM L INCLUDING ALLERGEN PROFILE ALONG WITH OTHER PRODUCT DETAILS.
5. RM SHALL BE LABELED, HANDLED AND STORED TO MINIMIZE ALLERGEN RISKS

MENTIONING OF ALLERGENS "CONTAINS" & "MAY CONTAINS"





EMPLOYEE ILLNESS AND COMMUNICABLE DISEASE & CONTROL

QP

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PURPOSE

MANAGEMENT OF EMPLOYEE ILLNESS INVOLVING A DISEASE COMMUNICABLE VIA FOOD TO HELP PREVENT PRODUCT EXPOSURE TO COMMUNICABLE DISEASE.

SCOPE

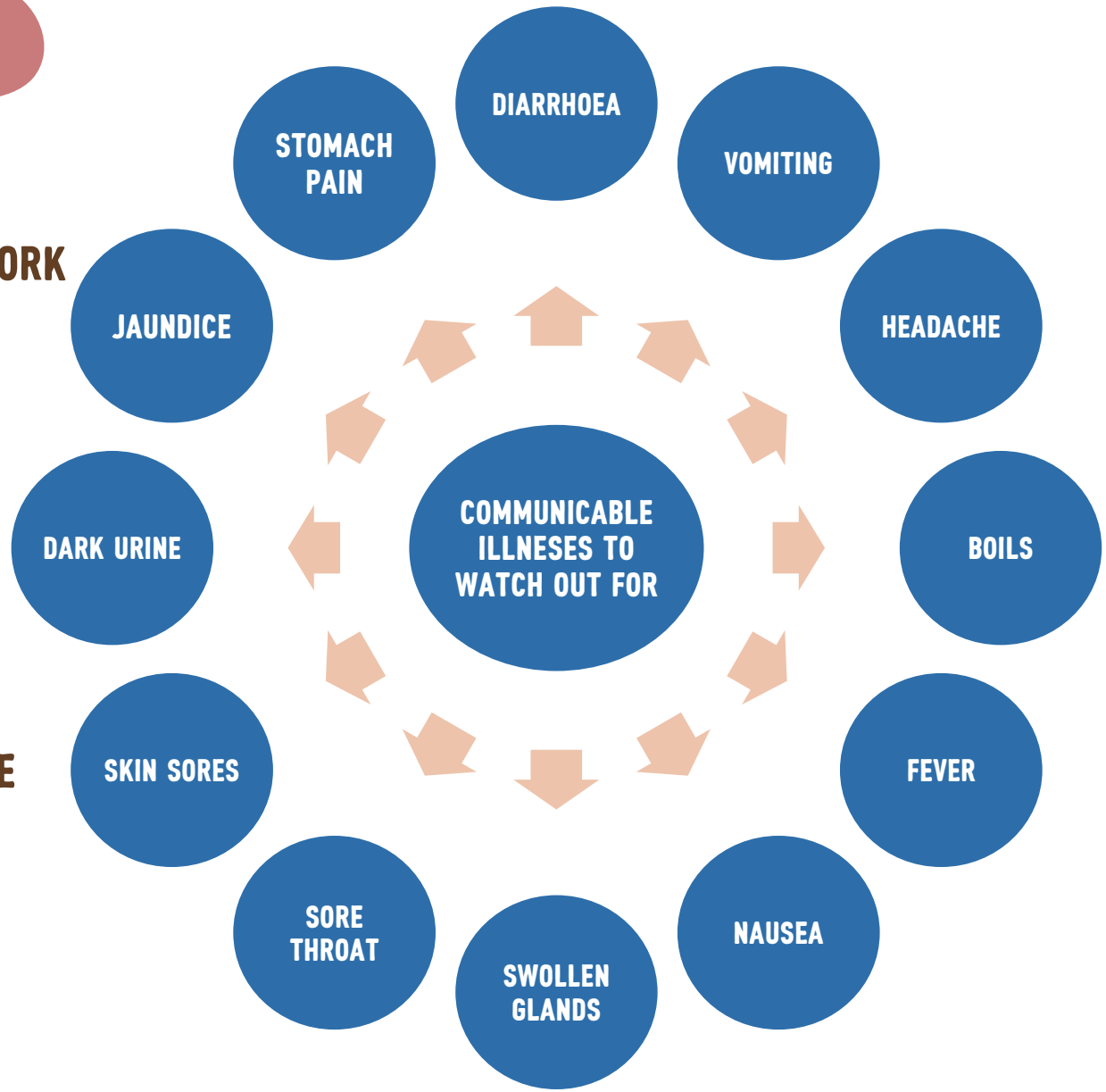
COMPANY PERMANENT EMPLOYEES, CONTRACTUAL EMPLOYEES, AND VISITORS OF THANE SITE

ILLNESS ASSESMENT AND CONFIRMATION

1. EMPLOYEE WITH SIGNS OR SYMPTOMS OF A COMMUNICABLE DISEASE WILL NOT BE ALLOWED TO WORK WITHIN THE MANUFACTURING AREA.

2. HE/SHE SHOULD BE EXAMINED AND HAVE OBTAINED CERTIFICATION FROM A PERSONAL PHYSICIAN OR FMO STATING THAT HE/SHE IS FREE OF A COMMUNICABLE DISEASE TO RETURN TO WORK.

3. EMPLOYEE WITH A POTENTIAL COMMUNICABLE DISEASE SHOULD NOTIFY THE LINE MANAGER IMMEDIATELY



COMMUNICABLE DISEASE SIGNAGES IN AND OUTSIDE TTC-PP

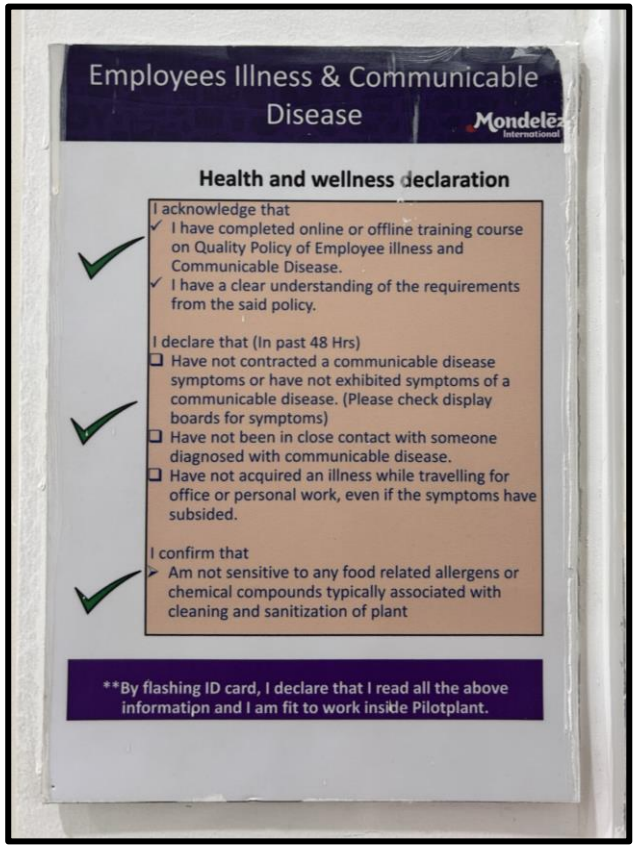
	1.4	Pathogens that can be transmitted by food from an infected person include: (1)	Facility, R&D	x

OFTEN TRANSMITTED (1)	**OCCASIONALLY TRANSMITTED (2)**
Norovirus	*Campylobacter jejuni*
Hepatitis A virus	*Cryptosporidium* species
Salmonella Typhi and Paratyphi	*Entamoeba histolytica*
Shigella species	Shiga toxin-producing *Escherichia coli*
Staphylococcus aureus	Enterotoxigenic *Escherichia coli*
	Giardia lamblia and *intestinalis*
	Non-typhoidal *Salmonella*
	Rotavirus
	Sapovirus
	Taenia solium
	Yersinia enterocolitica
	Vibrio cholerae

(2) These pathogens usually cause disease when food is intrinsically contaminated or cross-contaminated during processing or preparation.

	Facility, R&D	x

INSTRUCTIONS / GUIDELINES FOR DISEASE CONTROL



- MEDICAL SCREENING AND VACCINATION MANDATORY FOR NEW JOINERS
- ANY DISEASE MUST BE REPORTED TO THEIR SUPERVISOR PRIOR TO REPORTING TO THEIR WORK AREA
- ENTRY TO MANUFACTURING AREA IS PROHIBITED TO PERSONNEL INFECTED OR A CARRIER WITH MICROBIAL OR VIRAL CONTAMINATION
- A COMPANY-APPROVED PHYSICIAN WILL MAKE THE FINAL DECISION.

EMPLOYEE REASSIGNMENTS & RE-JOINING

TO BE ADHERED BY EMPLOYEE AVAILING SICK LEAVE FOR 2 OR MORE DAYS

1. INFORM LINE MANAGER/HR
2. ENTRY PROHIBITED IN PILOT PLANT
3. CONTACT THE DISPENSARY
4. SUBMIT MEDICAL REPORT TO SITE FMO
5. GET FITNESS CERTIFICATE FROM FMO
6. SUBMIT FITNESS CERTIFICATE TO HR & LINE MANAGER

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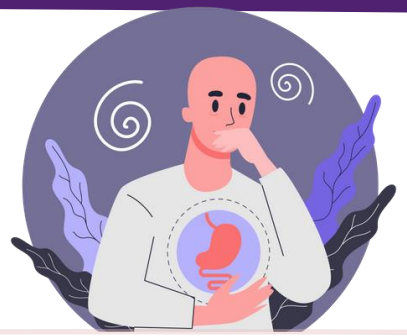
WOUND CONTROL

ANY CUT, OPEN SORE OR WOUND IS TO BE ATTENDED IMMEDIATELY BY A TRAINED FIRST AIDER

PROTECT THE WOUND AND KEEP IT CLEAN AND FREE FROM INFECTION

ANY MINOR CUTS ON HANDS, FINGERS, ARMS OR EXPOSED SKIN ARE TO BE COVERED WITH A BAND-AID & GLOVES ARE TO BE WORN

VOMITTING AND BODY FLUID INCIDENT



1. ISOLATE THE INDIVIDUAL & PEOPLE AROUND THE INDIVIDUAL
2. INFORM QUALITY TEAM & HK TEAM
3. STOP THE ACTIVITY OR PRODUCTION IN AFFECTED AREA
4. ISOLATE THE AFFECTED AREA AND BARRICADE
5. PP-TECHNICIAN NOTIFIES QUALITY MANAGER ABOUT INCIDENT. ASSESSMENT DONE
6. IDENTIFICATION& SEGREGATION OF POTENTIALLY CONTAMINATED PRODUCTS & INGREDIENTS
7. APPOINTING DEDICATED HK PERSONNEL WEARING BLACK UNIFORM TO CLEAN & DISINFECT AFFECTED AREA
8. DEDICATED HK PERSON TO BE ASKED TO LEAVE ONCE ACTIVITY IS COMPLETED
9. SWAB OF CLEANED & DISINFECTED EQUIPMENT. DISPOSITION OF THE CONTAMINATED PRODUCTS
10. MEDICAL CERTIFICATE REQUIRED BEFORE THE REASSIGNMENT OF THE EMPLOYEES
11. INCIDENT REPORT IS PREPARED

HOLD & RELEASE

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PURPOSE

TO ENSURE THAT THE SITE IS HAVING EFFECTIVE HOLD & RELEASE CONTROLS TO ASSURE THAT PRODUCTS AND MATERIALS WHICH NEED TO BE ISOLATED AND HELD PENDING THEIR FINAL DISPOSITION MUST NOT INADVERTENTLY USED IN PRODUCTION OR INTRODUCED INTO THE MARKETPLACE.

SCOPE

APPLICABLE TO ALL MATERIALS RECEIVED, PRODUCED, AND STORED AT THANE RDQ PLANT WHICH INCLUDES BUT NOT LIMITED TO BELOW CATEGORIES:

- THE RAW EDIBLE /PACKING MATERIALS, BULK MATERIALS RECEIVED
- ALL FINISHED PRODUCTS
- SEMI-FINISHED PRODUCTS
- INTERMEDIATE MATERIALS

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WHAT IS HOLD & RELEASE?

HOLD AND RELEASE MEANS ENSURING THAT THE PRODUCT AND MATERIAL THAT MAY OR DO NOT, FULLY MEET SPECIFICATION ARE PREVENTED FROM UNINTENDED USE UNTIL THEIR FINAL DISPOSITION IS KNOWN.

HOLD AND RELEASE PROGRAM REQUIREMENTS

- IDENTIFICATION, SEGREGATION AND STORAGE REQUIREMENTS FOR THE HELD MATERIALS AND PRODUCTS.
- COMMUNICATION WITH INVOLVED FUNCTIONS REGARDING THE MATERIALS ON HOLD.
- INVENTORY REQUIREMENTS TO ASSURE THE PRODUCT IS UNDER CONTROL.
- FINAL DISPOSITION.
- DOCUMENTATION.
- DESIGNATED PERSONNEL WITH AUTHORITY AND RESPONSIBILITY TO FOLLOW UP AND CLOSE OUT ON EACH CASE.

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WHAT ARE HOLD CATEGORIES?

CATEGORY	DESCRIPTION
CATEGORY I	WHEN A NON-CONFORMITY POSES A CONFIRMED PRODUCT SAFETY ISSUE, OR MAJOR QUALITY CONCERN.
CATEGORY II	WHEN A NON-CONFORMITY, OR ANY SUSPECTED NONCONFORMITY, POSES A POTENTIAL FOOD SAFETY ISSUE OR REGULATORY NON-CONFORMANCE, OR A MINOR PRODUCT OR MATERIAL QUALITY DEFECT
CATEGORY III	WHEN OTHER REASONS EXIST FOR NEEDING TO HOLD PRODUCT OR MATERIAL, UNRELATED TO FOOD SAFETY OR REGULATORY ISSUES.

EXAMPLES

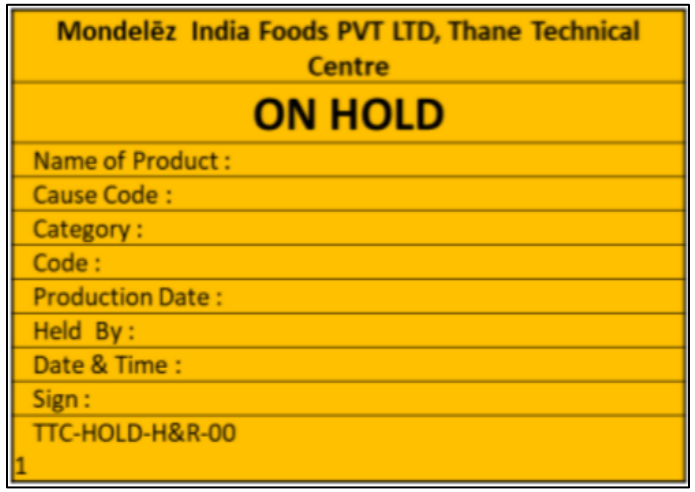
- UNDECLARED ALLERGENS IDENTIFIED IN PRODUCT OR MATERIAL
- UNACCEPTABLE PATHOGEN TEST RESULT

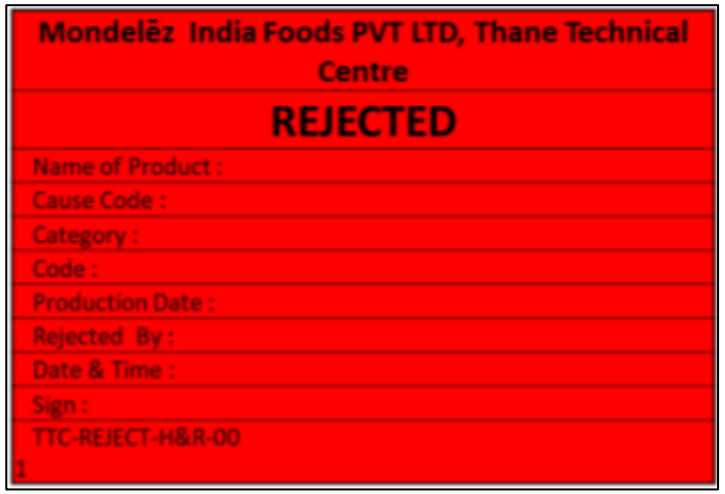
- DEVIATION FROM A CCP/SPP REQUIREMENT PENDING INVESTIGATION OR FURTHER ACTIONS AS DEFINED IN INDIVIDUAL CCP/SPP MODELS.

- FINISHED PRODUCT AWAITING TEST RESULTS WHICH ARE A REQUIRED FOR A COA. (EXCLUDES PATHOGEN TESTING)

TABLE 1			
	Category 1 Hold - Confirmed FS, Verification Testing, Major QA	**Category 2 Hold** - Potential FS, Quality or Regulatory Issue	**Category 3 Hold** - Routine Hold
Use for: **NOTE:** For Pathogen Tests, see **Table 2** that defines Hold categories to use and additional requirements specific to pathogen testing	When a non conformity: - poses a confirmed product safety issue, or - a major quality concern	When a non conformity, or any suspected non conformity: - poses a potential food safety issue, OR - regulatory non-conformance, OR - a minor product or material quality defect for a parameter that is mentioned in the specification.	When other reasons exist for needing to hold product or material, unrelated to food safety or regulatory issues.
	For example, but not limited to: • Undeclared Allergens identified in product or material • Failure to meet CCP/sPP requirements as defined in individual CCP/sPP models • Contamination due to employee illness • Unacceptable pathogen test result • Presence of an undeclared ingredient.	For example, but not limited to: • A non conformance that causes the ingredients on the ingredient list to be in the wrong order. • Net Contents compliance lot average is below the stated label weight claim. • Non conforming product pending corrective action completion, re-testing and, or final disposition decision. • Deviation from a CCP/sPP requirement pending investigation or further actions as defined in individual CCP/sPP models. • Product awaiting results of testing that is not required for a COA (Excludes Pathogen testing –see **Table 2**). • Finished product awaiting allergen testing results required to ensure compliance to allergen-free or materials causing sensitivity or intolerance (MSI) free label claims.	For example, but not limited to: • Finished product awaiting test results that are a required for a COA. (Excludes Pathogen testing – **see Table 2**) • Product produced as a result of a trial
Notify BU Quality	Required	Required for regulatory non-conformances only	Not Required
Disposition	Designated person (usually from plant quality) to manage disposition in collaboration with BU Quality and CS&L.	Designated person will maintain communication with the appropriate facility manager and manage disposition activity.	Designated person will conduct the necessary communication to assure adequate control, and manage disposition activity.
Identification & Segregation	Each of the following requirements shall be met: • Each shipping unit of product or material shall be visually identified with hold stickers, tags or tape. Automated warehouses do not have to conform with the physical identification requirement as long as equivalent measures are in place. • Product or Material shall be placed in a segregated and secured area.	All affected product or material shall be visually identified as being on hold within its storage location (e.g. segregation of an entire bay using 'ON HOLD' tape/placard, or specified area within a high risk facility designated only for product on hold). Automated warehouses do not have to conform with the physical identification requirement as long as equivalent measures are in place. Where product or material need to be moved to external storage or between facilities, each shipping unit shall be visually identified as being on hold. Product or Material shall be placed in a segregated area.	All affected product or material shall be visually identified, or computer controlled, or both. The method adopted shall provide effective control.
Inventory Checks	Inventory checks for Category 1 & 2 holds shall account for physical quantities present and be reconciled against all hold records (including electronic warehouse records, hold forms, and electronic hold files).		A defined frequency, documented in local procedures that is adequate to assure control.
	Verification daily on facility operating days.	Inventory verification minimum monthly, or at ***close-out*** of hold event if sooner.	

HOLD AND RELEASE LABELS





LABEL CONTROL AND PROPER STORAGE

QP

SOP

PURPOSE

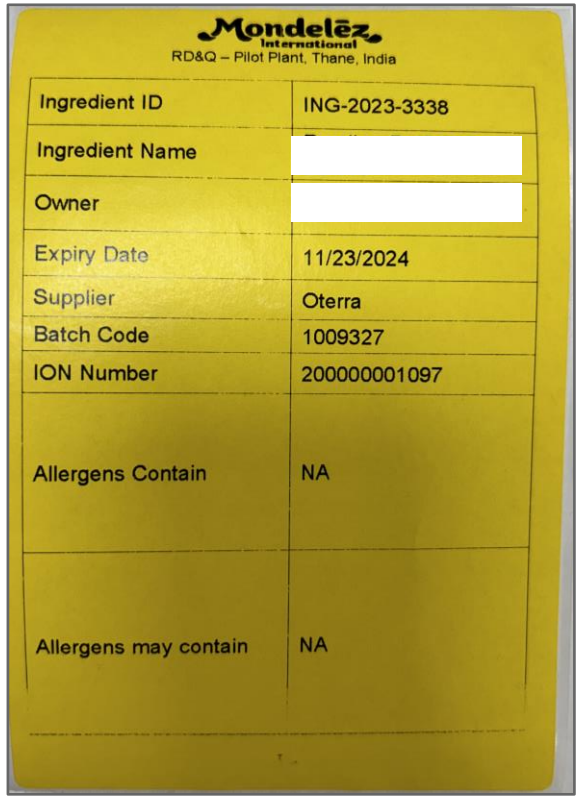
FOR THE CONTROL ON LABEL APPLICATION PROCEDURE. TO ASSURE THAT LABEL INFORMATION MEETS ALL REGULATORY AND CORPORATE REQUIREMENTS AND LABELS ARE CORRECTLY APPLIED AT PILOT PLANT.

SCOPE

APPLICABLE TO ALL LABELS USED FOR INCOMING EDIBLE & PACKING MATERIAL, WIP, FINISHED PRODUCTS USED & ONLINE PROCESS WHERE INFORMATION IS REQUIRED.

STORAGE PRACTICES

LIST OF LABELS



1

INCOMING INGREDIENTS
BEFORE APPROVAL

2

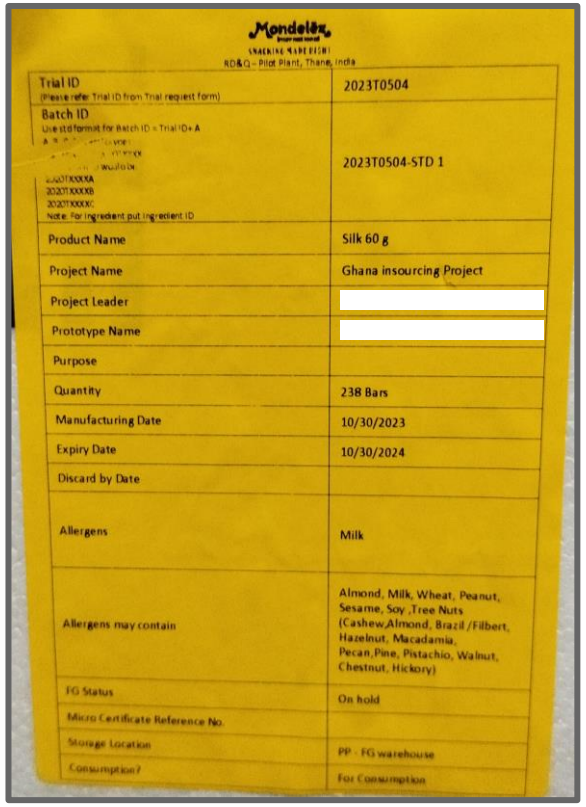
AFTER APPROVAL
(EM)

3

WIP MATERIALS

STORAGE PRACTICES

LIST OF LABELS



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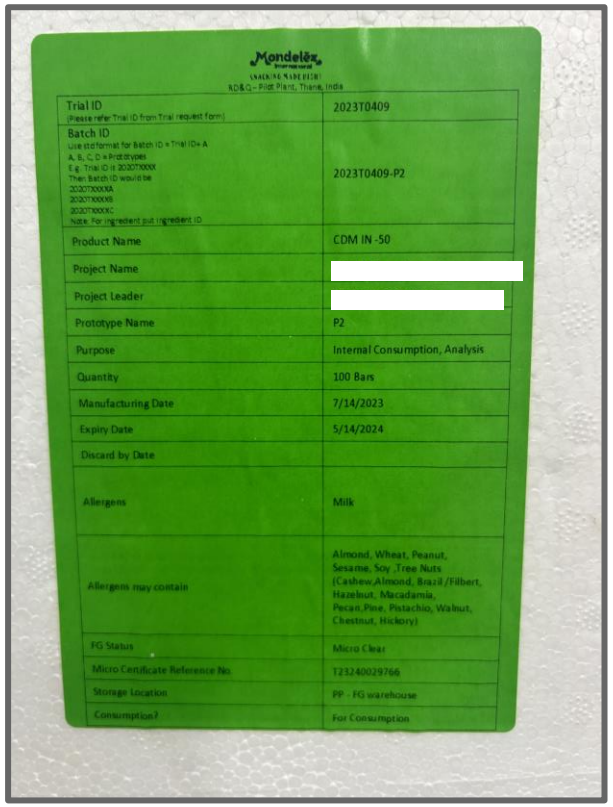
RD&Q – Pilot Plant, Thane, India

Trial ID (Please refer Trial ID from Trial request form)	2023T0504
Batch ID Use std format for Batch ID = Trial ID+ A A, B, C, D = Prototypes E.g. Trial ID is 2020TXXXX Then Batch ID would be 2020TXXXXA 2020TXXXXB 2020TXXXXC Note: For ingredient put ingredient ID	2023T0504-STD 1
Product Name	Silk 60 g
Project Name	Ghana insourcing Project
Project Leader	
Prototype Name	
Purpose	
Quantity	238 Bars
Manufacturing Date	10/30/2023
Expiry Date	10/30/2024
Discard by Date	
Allergens	Milk
Allergens may contain	Almond, Milk, Wheat, Peanut, Sesame, Soy ,Tree Nuts (Cashew,Almond, Brazil /Filbert, Hazelnut, Macadamia, Pecan,Pine, Pistachio, Walnut, Chestnut, Hickory)
FG Status	On hold
Micro Certificate Reference No.	
Storage Location	PP - FG warehouse
Consumption?	For Consumption

4

BEFORE MICRO CLEARANCE (FG)



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RD&Q – Pilot Plant, Thane, India

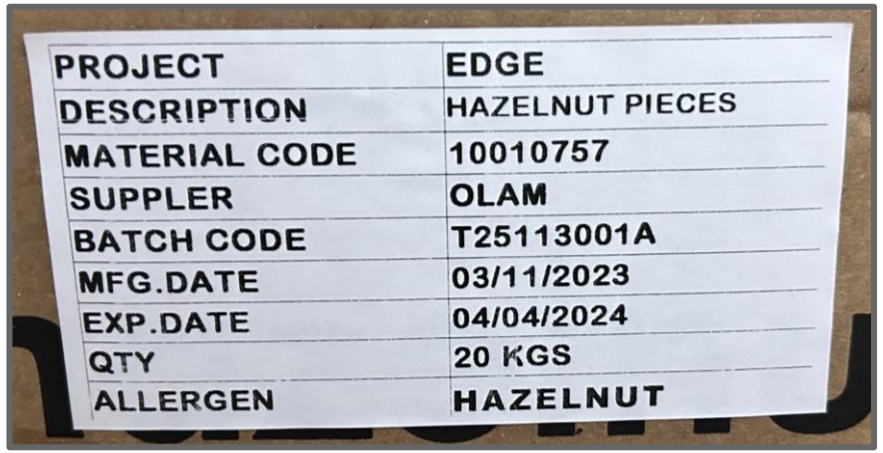
Trial ID (Please refer Trial ID from Trial request form)	2023T0409
Batch ID Use std format for Batch ID = Trial ID+ A A, B, C, D = Prototypes E.g. Trial ID is 2020TXXXX Then Batch ID would be 2020TXXXXA 2020TXXXXB 2020TXXXXC Note: For ingredient put ingredient ID	2023T0409-P2
Product Name	CDM IN -50
Project Name	
Project Leader	
Prototype Name	P2
Purpose	Internal Consumption, Analysis
Quantity	100 Bars
Manufacturing Date	7/14/2023
Expiry Date	5/14/2024
Discard by Date	
Allergens	Milk
Allergens may contain	Almond, Wheat, Peanut, Sesame, Soy ,Tree Nuts (Cashew,Almond, Brazil /Filbert, Hazelnut, Macadamia, Pecan,Pine, Pistachio, Walnut, Chestnut, Hickory)
FG Status	Micro Clear
Micro Certificate Reference No.	T23240029766
Storage Location	PP - FG warehouse
Consumption?	For Consumption

5

AFTER MICRO CLEARANCE (FG)

STORAGE PRACTICES

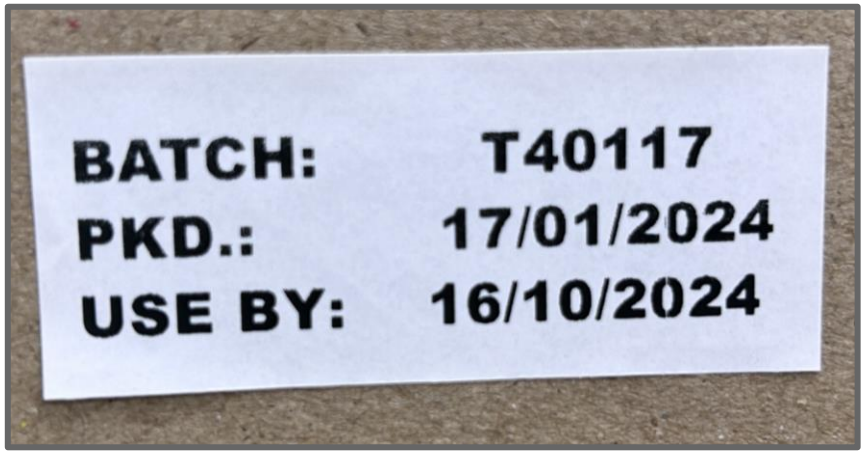
LIST OF LABELS - T&L



PROJECT	EDGE
DESCRIPTION	HAZELNUT PIECES
MATERIAL CODE	10010757
SUPPLER	OLAM
BATCH CODE	T25113001A
MFG.DATE	03/11/2023
EXP.DATE	04/04/2024
QTY	20 KGS
ALLERGEN	HAZELNUT

6

WIP LABEL



7

FG LABEL

PROPER STORAGE PRACTICES

- PRODUCT OR INGREDIENT CONTAINERS MUST NOT BE STORED NEAR TO CONTAINERS FOR WASTE
- INGREDIENTS MUST BE STORED IN ORIGINAL LABELED CONTAINERS IN SANITARY MANNER
- INGREDIENT IDENTIFICATION & LOT NO. TRACEABILITY MUST BE MAINTAINED
- CONTAINERS & POUCHES MUST BE PROPERLY CLOSED/ SEALED/ COVERED
- ENSURE INGREDIENTS ARE STORED IN THE PROPER TEMPERATURE ENVIRONMENT
- PACKAGING MATERIAL MUST BE REMOVED FROM THE AREA DURING WET CLEANING
- REWORK MUST BE ADEQUATELY COVERED/PROTECTED DURING BREAKS, LUNCH PERIODS, DOWNTIME, ETC & MAINTAIN TRACEABILITY
- ALLERGENS AND NON ALLERGENS ARE STORED SEPARATELY
- PACKAGING MATERIAL MUST BE STORED IN DESIGNATED AREA

PROPER STORAGE PRACTICES

REWORK HANDLING & STORAGE

- PROPERLY HANDLED AND STORED.
- TRACEABILITY OF REWORK SHALL BE MAINTAINED.

RECEIVING, STORAGE, HANDLING &SHIPPING

- MATERIALS STACKING REQUIREMENTS OBSERVED.
- MATERIAL SPACED FROM THE WALLS (MINIMUM 12 INCHES / 30 CM).
- MATERIALS AND PALLET HANDLING – PREVENT CONTAMINATION, DAMAGE

STORAGE & HANDLING OF FINISHED PRODUCT

- ALL ITEMS SHOULD BE STORED TO AVOID DIRECT CONTACT WITH THE FLOOR OR WALKING SURFACES (E.G-PALLET)
- SITTING OR STANDING ON PRODUCT SHIPPING CASES IS NOT ACCEPTABLE.
- OVER-STACKING OF PRODUCT MUST BE AVOIDED

EXTRANEOUS MATTER MANAGEMENT

QP

SOP

PURPOSE

TO ESTABLISH AN EFFECTIVE PROGRAM TO PREVENT, CONTROL AND DETECT EXTRANEOUS MATTER.

SCOPE

APPLICABLE TO ALL THE PRODUCTS MANUFACTURED AT THANE TECHNICAL CENTRE.

WHAT IS EXTRANEOUS MATTER ?

EXTRANEOUS MATTER IS MATTER THAT IS NOT DESIGNED TO BE AND SHOULD NOT BE PART OF THE PRODUCT

EXAMPLES INCLUDE: PLASTIC, GLASS, SCREWS, METAL, HAIR

EXTRANEOUS MATTER IS A QUALITY AND FOOD SAFETY ISSUE.

EXTRANEOUS MATTER RESULT IN CONSUMER COMPLAINTS, POSSIBLE CONSUMER INJURY, AND IN EXTREME CASES THE NEED FOR PRODUCT RETRIEVAL FROM THE MARKETPLACE.

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EXTRANEOUS MATTER PROGRAM REQUIREMENTS

- CONTROL OF EM IN RAW MATERIALS IS MANAGED TO DEFINED, ACCEPTABLE LIMITS THROUGH SPECIFICATIONS (E.G. NUT SHELLS)
- THERE MUST BE LOCAL PROCEDURES AND INSTRUCTIONS TO DEFINE MONITORING REQUIREMENTS, FOLLOW UP AND CORRECTIVE ACTION IF EM IS FOUND, ROOT CAUSE IDENTIFICATION, AND WHAT TO DO IF THE CONTROL MECHANISM FAILS (E.G. NON-FUNCTIONAL METAL DETECTOR)
- EVALUATE NEW EQUIPMENT, PROCESSES OR PRODUCTS PRIOR TO INSTALLATION OR START UP – TAKE ACTION TO ELIMINATE, PREVENT OR DETECT EM (E.G. EM ASSESSMENT PROTOCOL)
- AVOID INTRODUCING EQUIPMENT WHICH IS A POTENTIAL SOURCE OF EM, SUCH AS WOODEN PALLETS OR GLASS MEASURING DEVICES
- REGULARLY REVIEW EM FINDINGS TO ASSURE THAT THE SYSTEM REMAINS EFFECTIVE
- PROVIDE TRAINING ON EM PREVENTION TO ALL NEW EMPLOYEES IN RELEVANT POSITIONS. IN AREAS WHERE EM CONCERNS EXIST, PROVIDE REGULAR REFRESHERS

EXTRANEOUS MATTER MANAGEMENT

TO MINIMISE THE POTENTIAL OF EXTRANEOUS MATTER BEING INTRODUCED INTO THE PRODUCT

1. ASSESSMENT TO DETERMINE POTENTIAL SOURCES OF EM
2. PERIODIC REASSESSMENT, PARTICULARLY FOLLOWING CHANGES TO THE PLANT ENVIRONMENT
3. DETERMINATION OF CONTROL METHODS
4. DESIGN OUT THE RISK (E.G. NO METAL TO METAL CONTACT POINTS)
5. PREVENTIVE MEASURES (E.G. COVERS ON TANKS)
6. DETECTION MEASURES (INCLUDING X-RAY AND METAL DETECTORS, AND REMOVAL BY SIEVES, MAGNETS)
7. CONTROL OF SUPPLIERS
8. PREREQUISITE PROGRAMS OR CCP CONTROLS MUST ADDRESS POTENTIALLY HAZARDOUS EM (GLASS, SHARP METAL, HARD PLASTICS)

EXTRANEOUS MATTER MANAGEMENT CONTROLS

1. FOLLOW ALL GMP RULES-UNIFORM, HAIRNET, FINGERNAIL AND JEWELLERY, ETC. POLICIES.
2. HOUSE KEEPING &SANITATION RULES KEEP YOUR AREAS CLEAN AND TIDY & FOLLOW ALL SANITATION PROCEDURES.
3. PREVENTATIVE MAINTENANCE PROGRAM – COMPLETE AS SCHEDULED, REPORT AND CORRECT ISSUES.
4. ALL PRE-OPERATIONAL INSPECTIONS TO IDENTIFY ISSUES SUCH AS FRAYING BELTS, LOOSE EQUIPMENT FASTENERS, FLAKING PAINT, ETC. DOCUMENT AND CORRECT THE ISSUE PRIOR LINE START UP.
5. INGREDIENTS AND PACKAGING – IF YOU IDENTIFY A RISK, E.G. INSECTS, GLASS, STONES, ETC. DO NOT USE IT.
6. REPORT ANY CONCERNS- BBQ

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SANITATION PROGRAM

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POINTS TO REMEMBER

1. WATER MUST NOT BE SPLASHED FROM UNCLEAN EQUIPMENT ONTO CLEANED EQUIPMENT OR PROCESSES DURING OPERATION
2. PRODUCT-CONTACT GASKETS NEED TO BE CLEANED OR REPLACED AT A DEFINED FREQUENCY
3. CLEAN PARTS MUST NOT BE STORED IN UNCLEAN CONTAINERS OR WITH DIRTY PARTS
4. MAINTAIN GOOD HOUSEKEEPING PRACTICES IN PRODUCTION AREAS
5. WATER HOSES OR COMPRESSED AIR HOSES SHOULD NOT BE USED TO CLEAN THE FLOOR OR EQUIPMENT DUE TO THE FORMATION OF AEROSOLS.

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DRY SANITATION

- PRE SANITATION PREPARATION
- SECURE & DISMANTLE
- PRE-CLEAN
- CLEANING & INSPECT
- DRYING & SANITATION
- ASSEMBLE
- FINAL INSPECTION & DOCUMENT

PROCESS:

- SCRUB OR SCRAP THE SURFACE
- DRY MOP OR WET MOP WITH 2% TOPAX 66 SOLUTION
- WET MOP WITH HOT WATER
- DRYING
- SANITIZE WITH IPA 70% OR STERBAC 1%

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WET SANITATION

- PRE SANITATION PREPARATION
- SECURE & DISMANTLE
- SOAP & SCRUB
- RINSE & INSPECT
- DRYING AND SANITATION
- ASSEMBLE
- FINAL INSPECTION & DOCUMENT

PROCESS:

- SCRUB OR SCRAP THE SURFACE
- WET CLEAN WITH HOT WATER JET
- FOAMING WITH 2% TOPAX 66 OR APPLY MANUALLY ON CONTACT SURFACE
- WET CLEAN WITH HOT WATER JET
- DRYING
- SANITIZE WITH IPA 70% OR STERBAC 1%

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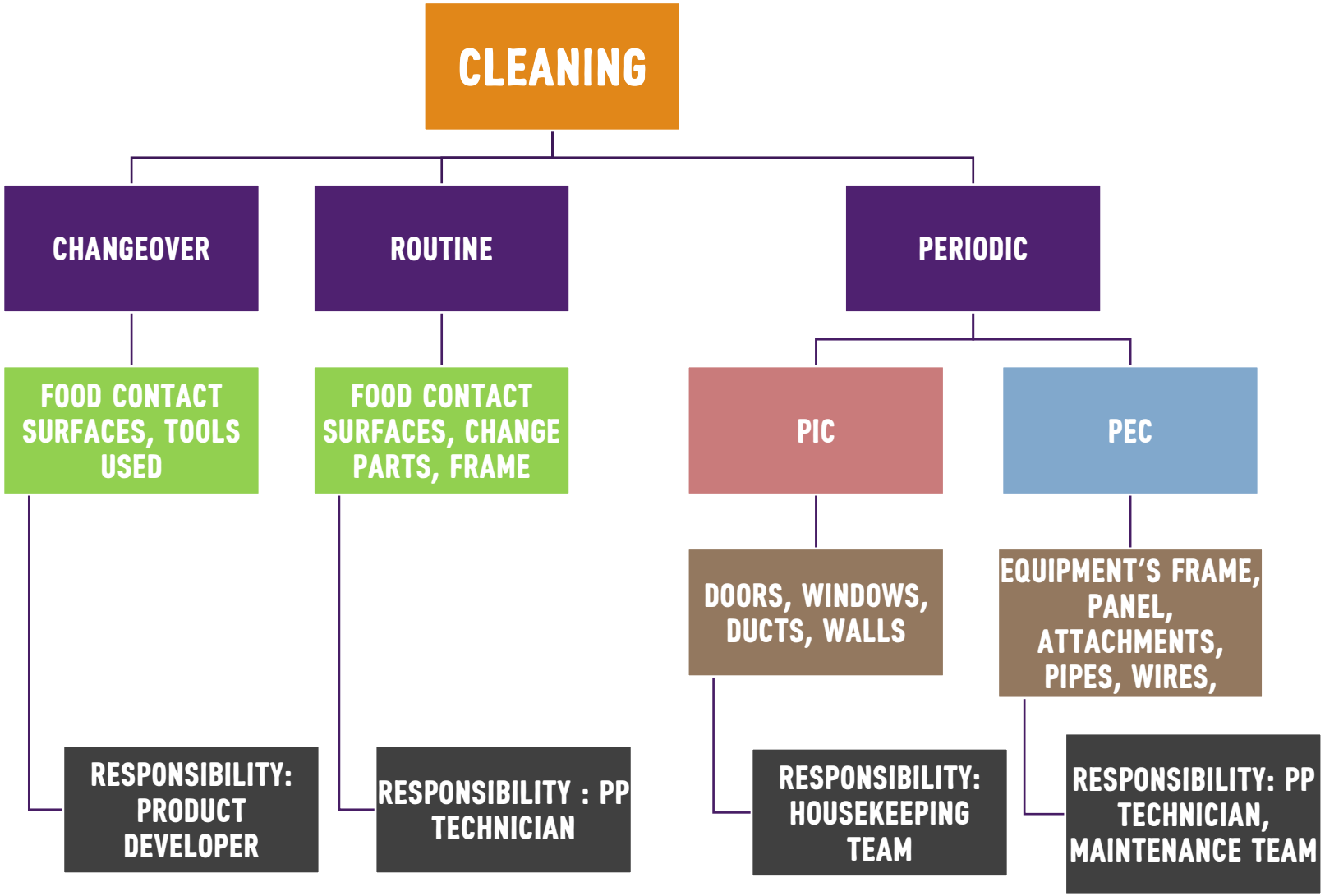
CLEANING CATEGORIES AND RESPONSIBILITIES



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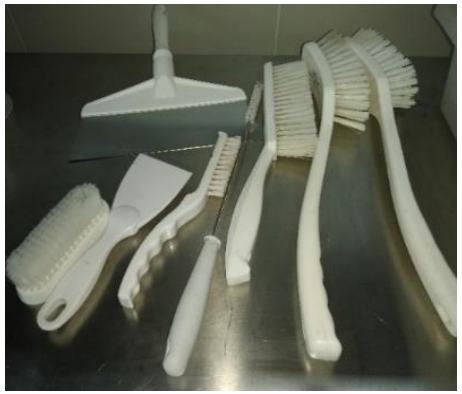
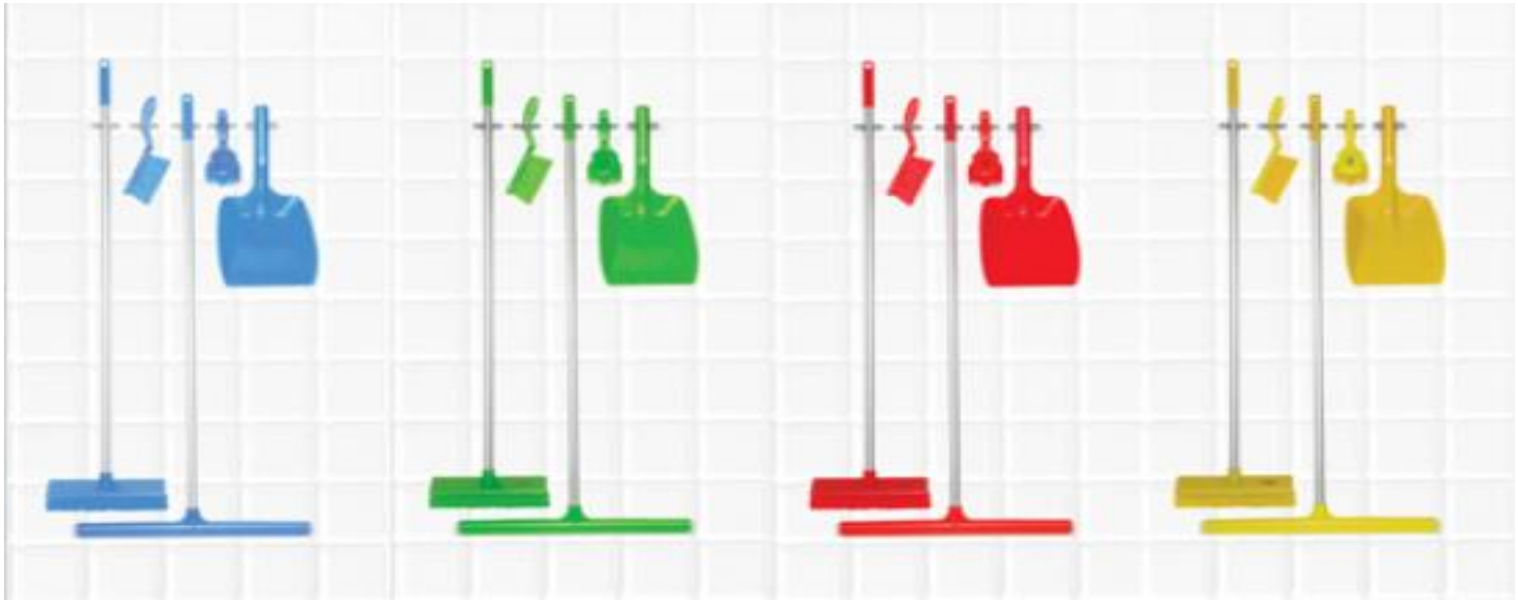
CLEANING TOOLS AND COLOR CODING



FOOD CONTACT TOOLS

DRAIN CLEANING TOOLS



RAW PILOTPLANT CLEANING TOOLS

CHOCOLATE PILOTPLANT CLEANING TOOLS

NON MFG. AREA CLEANING TOOLS

RB PILOTPLANT CLEANING TOOLS

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THANK YOU

Anuja Bagal