



TRAINING FOR MEU FRUIT AND VEGETABLE SUPPLIERS

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Mondelēz
International
SNACKING MADE RIGHT

AGENDA

- 1 Mondelēz Documentation
- 2 Supplier Tiering, Risk Assessment and Approval Process
- 3 Hygienic Zoning
- 4 Pathogen Environmental Monitoring
- 5 Fruit and Vegetable Processing Expectations
- 6 Sensitive Materials
- 7 Extraneous Matter Management

A circular portrait of a woman wearing a pink headscarf and a patterned dress, holding several green and yellow cocoa pods.

MONDELÉZ DOCUMENTATION

Susana Cunquero

MONDELEZ SUPPLIER SITE

The screenshot shows a web browser window for the Mondelez International Supplier Site. The URL in the address bar is <https://www.mondelezinternational.com/procurement.aspx>. The page features a dark purple header with the Mondelez International logo and the tagline "SNACKING MADE RIGHT". Navigation links include ABOUT US, OUR BRANDS, SNACKING MADE RIGHT, and STORIES. A search bar and a "Buscar..." button are also present. The main content area displays a message to supply partners, mentioning their dream of creating delicious moments of joy through brands like Milka, Cadbury Chocolate, Oreo Biscuits, and Trident Gum. It encourages supply partners to commit to the same dream by driving value through innovative products and services. The footer contains a "Supplier Log In" link.

https://www.mondelezinternational.com/procurement.aspx

Mondelēz International, Inc. - ... X

NASDAQ: MDLZ \$49.56 USD -0.84 (0%)

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ABOUT US **OUR BRANDS** **SNACKING MADE RIGHT** **STORIES**

HOME /

SUPPLIER INFORMATION CENTER

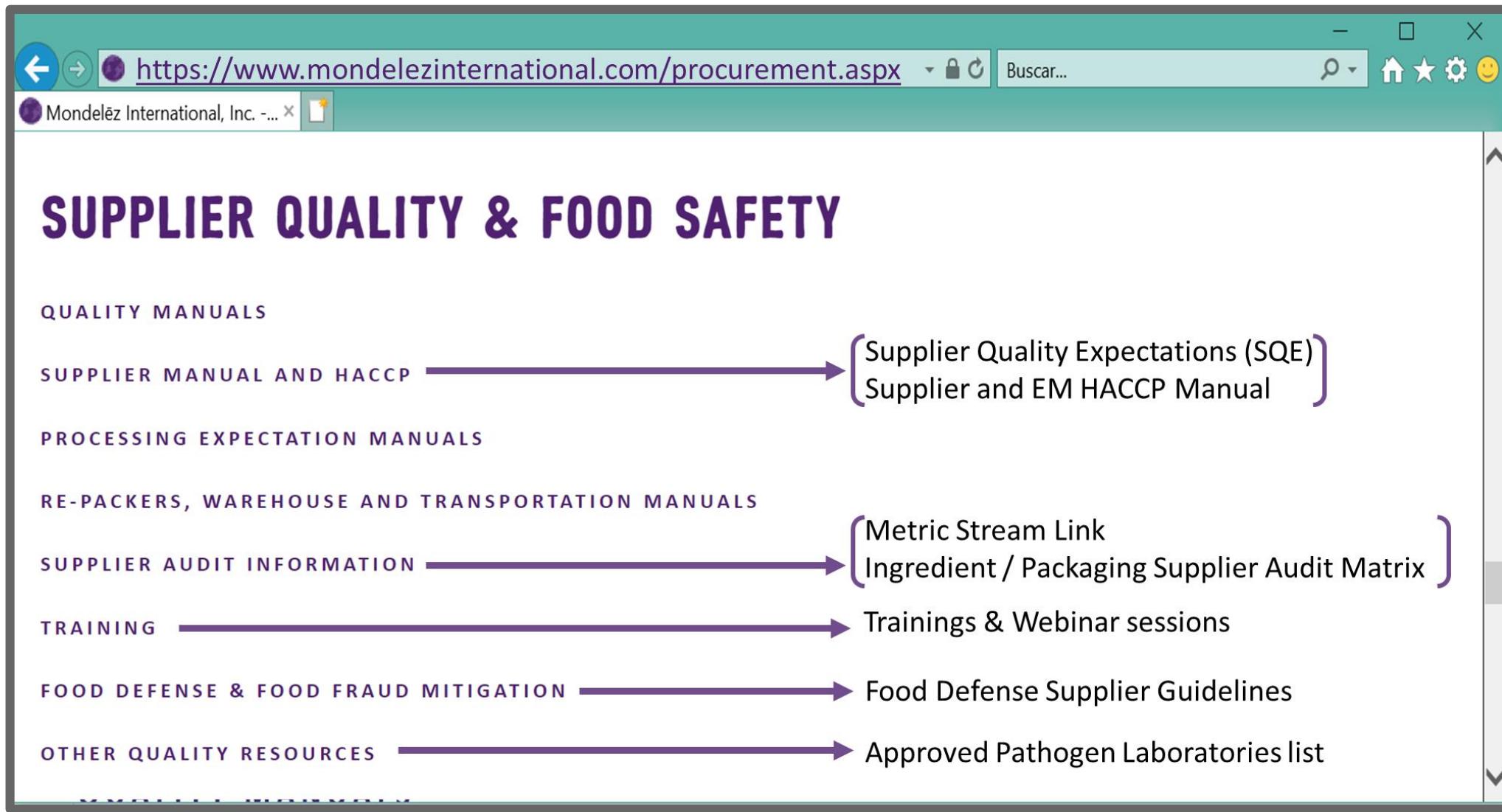
Dear Supply Partner,

At Mondelez International, our dream is to create delicious moments of joy. We are passionate about snacking and about driving growth through our much-loved Global Power Brands like *Milka* and *Cadbury Chocolate*, *Oreo Biscuits*, and *Trident Gum*, to name but a few.

We look to our supply partners to commit to the same dream by helping us drive extraordinary value through innovative products and services of the highest quality at competitive costs.

It's an exciting time to be working with Mondelez International. We want to form winning relationships that create opportunities for you to help build our brands, optimize our processes, and achieve mutual growth. We want to work with only the very best and look forward to our continued partnership.

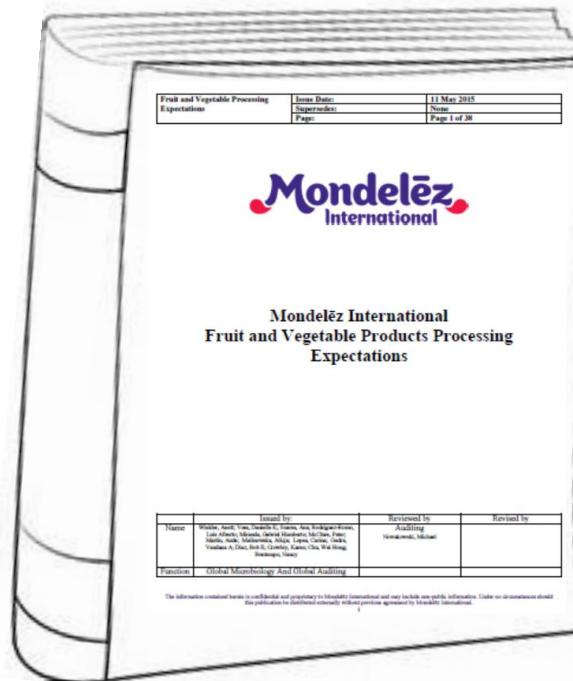
MONDELEZ SUPPLIER SITE



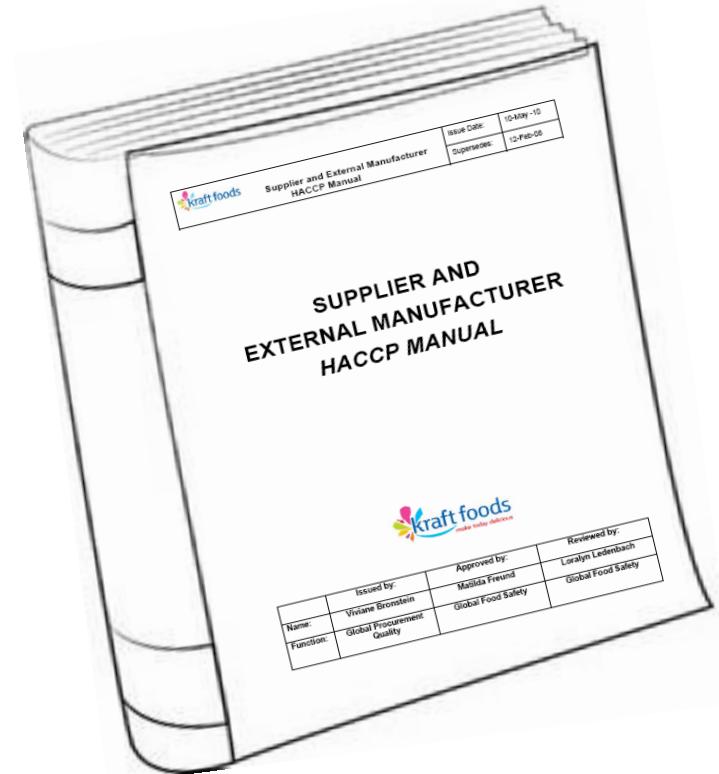
DOCUMENTS OF REFERENCE



Supplier Quality
Expectations



Fruit&Vegetable
products processing
expectations



Supplier HACCP
Manual

FRUIT AND VEGETABLE PROCESSING EXPECTATIONS

Fruit and Vegetable Processing Expectations	Issue Date:	11 May 2015
	Supersedes:	None
	Page:	Page 1 of 38

The current version is sent by
Mondelez Procurement Team

The current version issued:
11 May 2015

All Mondelez documentation
is confidential



Mondelēz International
Fruit and Vegetable Products Processing
Expectations

Name	Issued by:	Reviewed by	Revised by
Winkler, Anett; Voss, Danielle K; Soares, Ana; Rodriguez-Romo, Luis Alberto; Miranda, Gabriel Humberto; McClure, Peter; Martin, Aude; Malinowska, Alicja; Lopez, Carina; Gadre, Vandana A; Diaz, Bob E; Crowley, Karen; Chu, Wei Hong; Bentempo, Nancy	Auditing Nowakowski, Michael		
Function	Global Microbiology And Global Auditing		

A close-up, profile shot of a woman's face as she takes a bite out of a dark chocolate bar. She has dark hair and is looking down at the chocolate. The background is blurred.

SUPPLIER TIERING, RISK ASSESSMENT AND APPROVAL PROCESS

Covadonga Olay Lopez

THE CORPORATE QUALITY AUDIT PURPOSE

FEEDBACK

- Provide FEEDBACK to Mondelēz International Senior Management regarding the plant's compliance to QP's, manuals (e.g. HACCP, Pest control, GMP, Net Content, Sanitation, etc.), engineering standards and the microbiological programs

SUPPORT

- SUPPORT the plant's **journey and mindset of good quality culture** by identifying opportunities and providing technical expertise regarding Mondelēz International Company requirements

EDUCATE & SHARE

- EDUCATE through joint cooperation between the internal and external members of the team
- SHARE ideas from other locations in support of plant corrective actions

THROUGH THE PLANNING, COORDINATION AND PERFORMANCE OF ASSESSMENTS OF THE WHOLE MONDELEZ INTERNATIONAL VALUE CHAIN

DESIGN

PROCURE

Supplier Audits

CONVERT

Manufacturing Audits:
Mondelez External

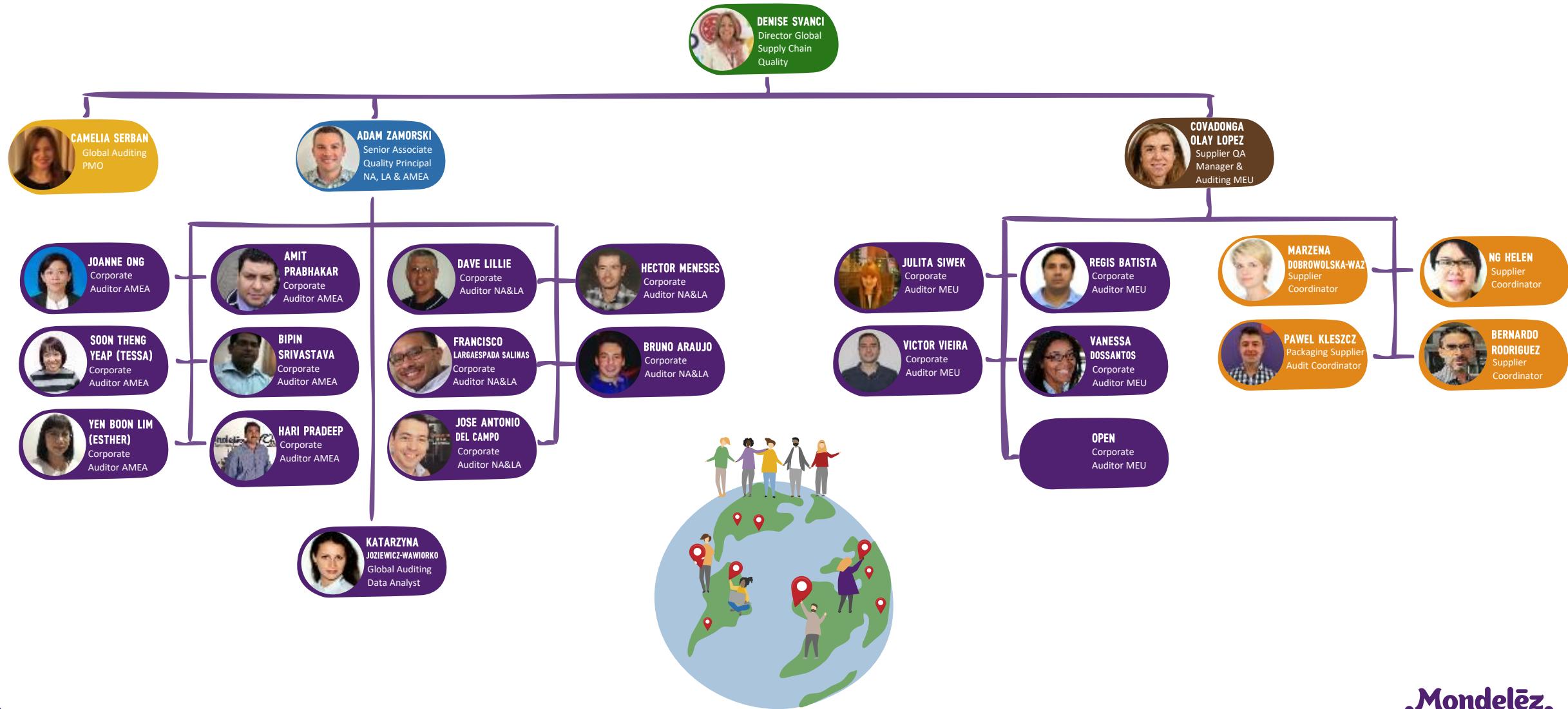
DISTRIBUTE

Supply Chain
Audits

CUSTOMER

CONSUMER

GLOBAL QUALITY AUDITING ORGANIZATION



Mondelēz International Regional Coordinators

North America

Bernardo Rodriguez – Regional Coordinator

Global Supplier Audit Manager

Covadonga Olay Lopez – based at Madrid

MEU

Marzena Dobrowolska-Waz, – Global Coordinator
Pawel Kleszcz – Global Packaging Coordinator

Latin America

Bernardo Rodriguez – Regional Coordinator

AMEA

Helen Ng – Regional Coordinator

AUDIT PROGRAMME: PLANNING AND FREQUENCY



Mondelēz International Quality Policy 8.2-02 “Corporate Quality Audit” details all the internal requirements for the corporate audits related to audit planning, risk assessments, auditor qualification, audit notification and execution, scope, reporting, deadlines and rating. These are also required by ISO 22000: 2018 (requirement 9.2.2)



The corporate quality auditing team prepares an annual audit schedule to include Suppliers, Mondelēz International plants and External Manufacturers



- ◆ The frequency and schedule for audit is based upon the risk criteria:
 - ◆ For Mondelēz International Plants and External Manufacturers, outlined in the Tier Classification Scheme (next slide)
 - ◆ For Suppliers, outlined in the Raw Material Risk Assessment. This risk assessment is done by Global Supplier Quality Team and takes into account the literature, past incidents, volume, number of suppliers, geographical area and the risk associated to the material. Each tier classification has a defined audit frequency according to the tiering classification matrix for suppliers (2 slides ahead)

TIERING CLASSIFICATION MATRIX AND AUDIT FREQUENCIES FOR SUPPLIERS

NEW AUDIT MATRIX (DEC 2015)

Tier	Ingredient Categories <i>(List is not all inclusive - refer to the Raw Material Tier Assignment list for details)</i>	Qualification Process (new)	Accepted Audits & Certifications (ongoing)	Target Freq. (years)
1	RTE Meats, RTE Cheese, RTE raw fruits and vegetables., RTE Seafood, (Strategic Tier 2 suppliers)	Mondelez SQE Audit, ¹ GFSI Certification and report	⁸ Mondelez SQE Audit every 2 years ¹ GFSI certifications and report	2.0
2	Coconut, Retorted & Aseptic Products including seafood (Low Acid Canned Foods), Sugar Confectionary, <u>Treated</u> Herbs/Spices/Seasoning, Treated Tea & Tea Products; Treated Egg & Egg Products; Dairy Products, Yeast (Non baking) Enzymes, Cultures, Treated Nuts and Seeds, Cocoa Chocolate confectionery, Vegetable Products (pH>3.5), Fruit & Fruit Products pH>4	Mondelez SQE Audit, ¹ GFSI Certification and report	¹ GFSI Certification and report, Supplier Food Safety Assessment	2.5 (SFSA 3 years)
3	As above (case by case decision ⁹) and Retorted & Aseptic Products including seafood (Low Acid Canned Foods), Sugar Confectionary; Yeast (Non baking) Enzymes, Cultures, dried fruits; flavorings	Mondelez SQE Audit, ¹ GFSI Certification and report	¹ GFSI Certification and report	GFSI 2.5year, SFSA Lethality review process: 3 Years
4	Grain & Grain Products, Emulsifiers; Prepared Sauces/Spreads/Condiments, Coffee & Coffee Products, Bread & Bakery Products; Salt Sugars & Sweeteners (Lactose); Starter Media/Culture; Fats & Oils; Food Additives; Raw Meat & Raw Meat Products, Food Chemicals Hydrocolloids & Gums, <u>Untreated</u> herbs/Spices/Seasoning; ⁴ Direct Contact Packaging Material (See packaging Audit matrix, Labeled and Unlabeled, Non-Contact Packaging Material Labeled); ⁵ Chemicals-Distillation ,Crystallization, Extraction, Talc , ² Cheese for processing, ² Liquid / Frozen Egg products, ² Yeast For baking/Further processing, Fruit Products pH<4; Vegetable Products pH<3.5	¹ GFSI Certification and report	¹ GFSI Certification and report	3
5	Raw Milk & Cream, ³ Nationally Branded Confections; Green Coffee Beans; Raw Cocoa, Compressed Gases; Raw Grains; Raw Nuts/Seeds/Coconut; Alcoholic Substances (Spirits, Liquors); Cream, Liquid Whey and Liquid Milk (Bulk Only), Sodium Hydroxide, Raw Agricultural Vegetables, Gum Base,	Audits may be required as result of a risk assessment by BU or Plant using the material. A Risk assessment or Audit must be on file for all approvals going forward.		4

SUPPLIER QUALIFICATION PROCESS

Process flow after procurement request a supplier qualification
*For packaging supplier please refer to the backup slides for more details

**WE APPROVE PER RAW MATERIAL,
ANY CHANGE ON THE LINE WHERE
MATERIALS ARE PRODUCED OR ON
THE PROCESS SHOULD BE NOTIFIED.**



NEW REQUEST IS PLACED IN MSI (METRIC STREAM) BY PROCUREMENT WHEN A NEW SUPPLIER NEEDS QUALIFICATION



SUPPLIER COORDINATOR REVIEWS THE REQUEST AND THE APPROVAL IS DONE BY DIFFERENT WAYS (GFSI OR PHYSICAL AUDIT, ACCORDING TO THE SQE AUDITING MATRIX)

**IF A SQE PHYSICAL AUDIT IS NEEDED:
SUPPLIER COORDINATOR CONTACT SUPPLIER QUALITY TO UNDERSTAND THE READINESS OF THE SUPPLIER**

**IF SUPPLIER IS READY:
SCHEDULER ASSIGNS THE AUDITOR TO THE AUDIT DEPENDING ON AVAILABILITY.**

AUDIT RESULT IS SHARED WITH DL, INCLUDING PROCUREMENT



Packaging suppliers are not physically audited but the main goal is to ensure that all food contact packaging suppliers are GFSI certified and that all the non-food contact packaging suppliers have at least ISO 22000 and ISO 9001 certification. Any supplier that does not meet this criteria shall be put on escalation list which could potentially lead to disapproval. **Packaging Suppliers certification completion rate is measured and targets are set for Food Contact and Non-Food Contact packaging suppliers (>99% certificated)**

SUPPLIER APPROVAL



- Mondelēz International audit requirements
 - All suppliers must be approved before a factory can produce with ingredients or packaging from that supplier
 - Approval is based on the specific supplier facility having passed an audit
 - The supplier site is approved, not the trader.
 - Traders must disclose the Manufacturing location
 - The type of audit that can be accepted is based on risk analysis of the material
 - Mondelēz International audit mandatory for some materials
 - All new suppliers must be GFSI certified and are willing to share full GFSI audit report
 - For new Tier 5 suppliers a Risk Assessment is needed
 - Packaging suppliers should receive documentation but only new primary packaging suppliers need an audit

SQE AUDIT FOLLOW-UP / CLOSE-OUT

METRIC STREAM (MSI) PROCESS



Escalation schedule:

- >14 Calendar days reminder - BU Director/Regional Audit Manager
- >21 Calendar days reminder - BU Director/Regional Audit Manager
- >30 Calendar days - Quality Auditing Management
- >45 Calendar days - VP Quality
- >60 Calendar days – VP Quality

Automatic email notifications with Metric Stream at the escalation dates

AUDIT RATINGS REVIEW

Approved – Satisfactory

- Effective controls and documentation are in place and comply with the expectations.
- Minor deviations may be present.

Approved – Needs Refinement

- Sound controls are in place.
- Minor deficiencies are present that impact the effectiveness of those controls.

Approved – Needs Improvement

- Deficiencies or absence of control pose a potential risk to product safety, or systematic program failure is identified.

Not Approved/Dis-Approved

- Deficiencies or absence of control presents a direct risk for significant product contamination or to the reputation of Mondelēz International.
- Implementation of additional control is necessary to achieve compliance and approval.

New suppliers need to have a minimum rating of **Needs Refinement** in order to sign a contract for purchasing



SQE AUDIT FOLLOW-UP / CLOSE-OUT

METRIC STREAM (MSI) – COMMON ISSUES

Internet Explorer
Is the most compatible
browser to MSI



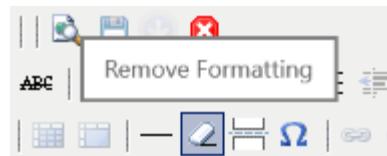
1

The system does not allow the upload of photos, tables, hyperlinks or other special characters.

Any additional evidence must be sent by e-mail



Only plain text is allowed



2

Auditee receives an error
Required Inputs: Actions

Auditee did not choose action in the drop down list at the bottom of the form



Action*
Select One
Request Clarification
Send for Corrective Actions Approval

Regional Manager*
Covadonga Olay Lopez

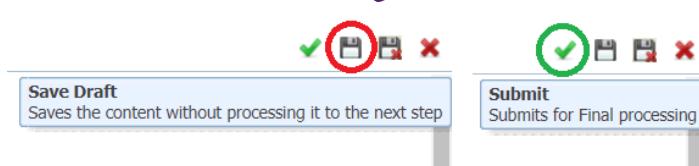
Comments History

In case of any MSI problems please contact the auditor for help.
Ensure that all the timelines can be respected!

3

When auditee sent CAPA but auditor did not receive the assignment

Most likely auditee saved the draft but did not submit for further processing





HYGIENIC ZONING

Yolanda Tong

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OBJECTIVES

1. What is zoning?
2. Why do we need zoning?
3. Zoning definitions
4. MDLZ requirements
5. Zoning assessment

WHAT IS ZONING?

Identification and differentiation of the processing areas within the manufacturing facility based on microbiological risk.

The purpose is to protect products from potential microbiological hazards originating from the manufacturing environment and its surroundings.

Microbiological cross contamination by relevant spoilage or pathogenic organisms may occur during the receipt, storage, processing and packaging of products.

Separation may include :

- Personnel and materials traffic
- Air handling
- Equipment
- Effluent, drains and waste systems
- Locker rooms
- Others, that could result in transfer of microorganisms

WHY DO WE NEED ZONING?

- To prevent **microbial cross contamination** and to assure product safety.
- Re-contamination of processed microbiologically sensitive products after the heat process, could be a major source of inadequate application of zoning principles e.g. re-contamination of material after pasteurisation.
- Therefore areas, where processed (e.g. heat treated) products are kept, shall be separated from the non-processed/ raw and/ or under processed product areas.

ZONES

Non-manufacturing zone

Raw zone

Controlled zone

High hygiene zone

ZONING DEFINITIONS

Non-manufacturing zone

- Areas where there is no product processed/ packaged
- May Includes areas such as utility rooms, offices, cafeteria, locker room, laboratory

Raw zone

- Areas containing raw agricultural materials e.g. fruit receiving, storage, washing, skin removal, slicing, entrance to heat exchanger
- May also include refuse/ recycling, restrooms (when in the manufacturing area), roof access and emergency door exits to processing
- These zones may have dedicated employees and shall be physically separated from controlled zones or high control zones

ZONING DEFINITIONS

Controlled zone

- Product of low to medium microbiological sensitivity and can be exposed to the environment and operators
- The controlled zone may also serve as transition from non-manufacturing zone or high risk zone to high control zone

High hygiene zone

- Product of high microbiological sensitivity can be exposed to the environment and/ or operators
- Additional GMP practices e.g. captive footwear, clothing may be required and more stringent equipment and building sanitary design requirements are followed
- When product of very high sensitivity are exposed, additional production practices e.g. preventing cardboard/ wooden pallets from this area may be implemented

MDLZ REQUIREMENTS

All facilities which manufacture or handle MDLZ International products shall have a Zoning programme to reduce the potential for environmental microbial cross contamination of materials and products through the application of proper controls.

Requirements



A Hygienic Zoning map must be documented and shall be reviewed in the event of changes to plant layout and/ or introduction of new lines and processes.

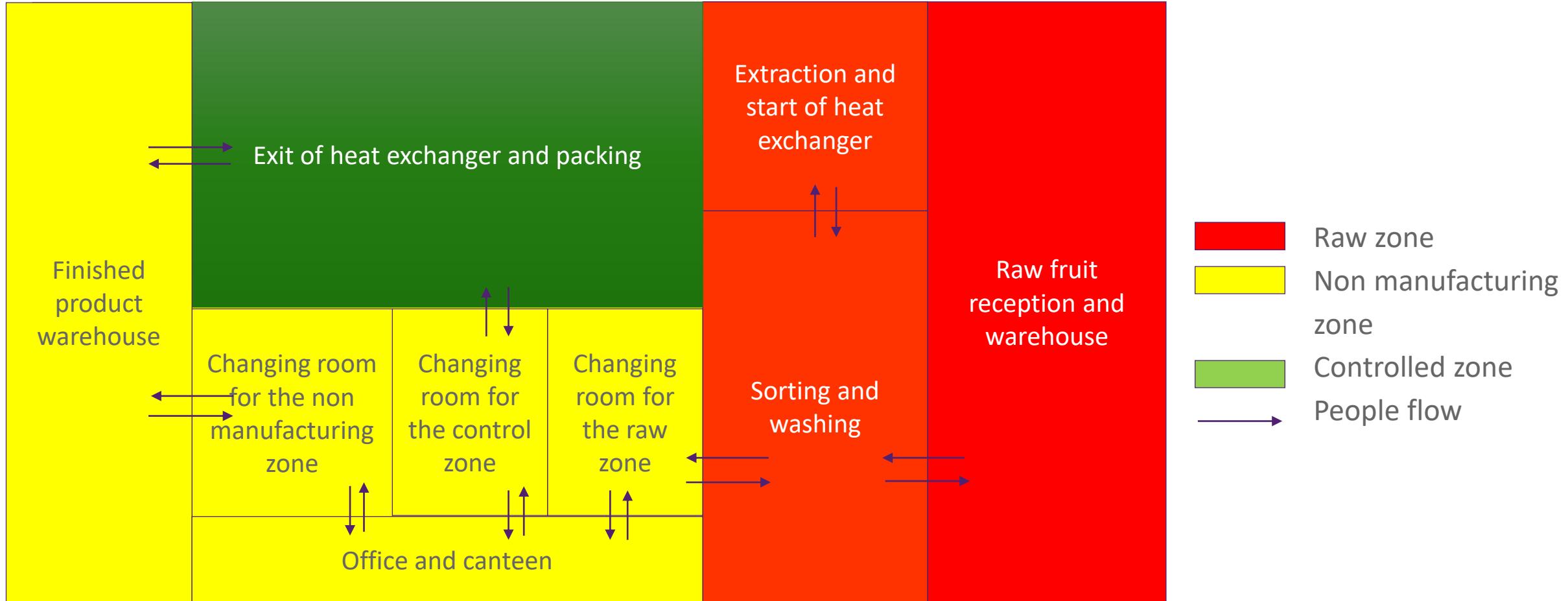
CONDUCTING A ZONING ASSESSMENT

Identification and differentiation of the processing areas within the manufacturing facility based on microbiological risk.

Categorise zones in the production facility taking into consideration:

- Use of closed systems
- Structural separation of the respective area by design
- Utilities control (air, water)
- Control traffic and movement of people, materials, forklifts and equipment
- Vestibule as entrance and exit with personnel hygiene and changing measures
- Sanitation control
- Personnel hygiene practices of employees
- Use of designated and/ or coded tools and equipment
- Filtration of the room air to protect the food against pathogens and/or spoilage organisms
- Packaging material treatment e.g. for clean cold filling or aseptic packaging
- Separation of effluent and water waste drains coming from zones with potentially higher contamination risk
- Consider refuse, recycling, restrooms, roof access and emergency door exits to processing areas that may be a risk

EXAMPLE OF ZONING MAP



HOW TO VERIFY THE EFFECTIVENESS OF ZONING MEASURES?

The following tools should be used:

Pathogen Environmental Monitoring

Air and Water Monitoring

GMP Audits

Sanitation Controls

A circular photograph on the left side of the slide shows a close-up of a young child's face. The child is holding an Oreo cookie with both hands, one above the other, and is about to take a bite. In the foreground, at the bottom, there is a glass of milk. The background is blurred.

PATHOGEN ENVIRONMENTAL MONITORING

Yolanda Tong

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OBJECTIVES

1. What is PEM?
2. Why do we perform PEM?
3. General approach to PEM
4. PEM sampling plan
5. Zone concept for PEM
6. Target organisms
7. Additional monitoring
8. Corrective actions

WHAT AND WHY?

PEM is a programme aimed at:

- Detection of pathogens
- Detection of organisms that indicate potential presence of pathogens in the processing environment

The purpose of PEM is to:

- Verify that the controls put in place for during the Hygienic Zoning assessment is effective at preventing cross-contamination
- Tool to provide information to improve environmental controls for prevention of potential cross-contamination
- Use data to correct problem areas before they pose a risk to product

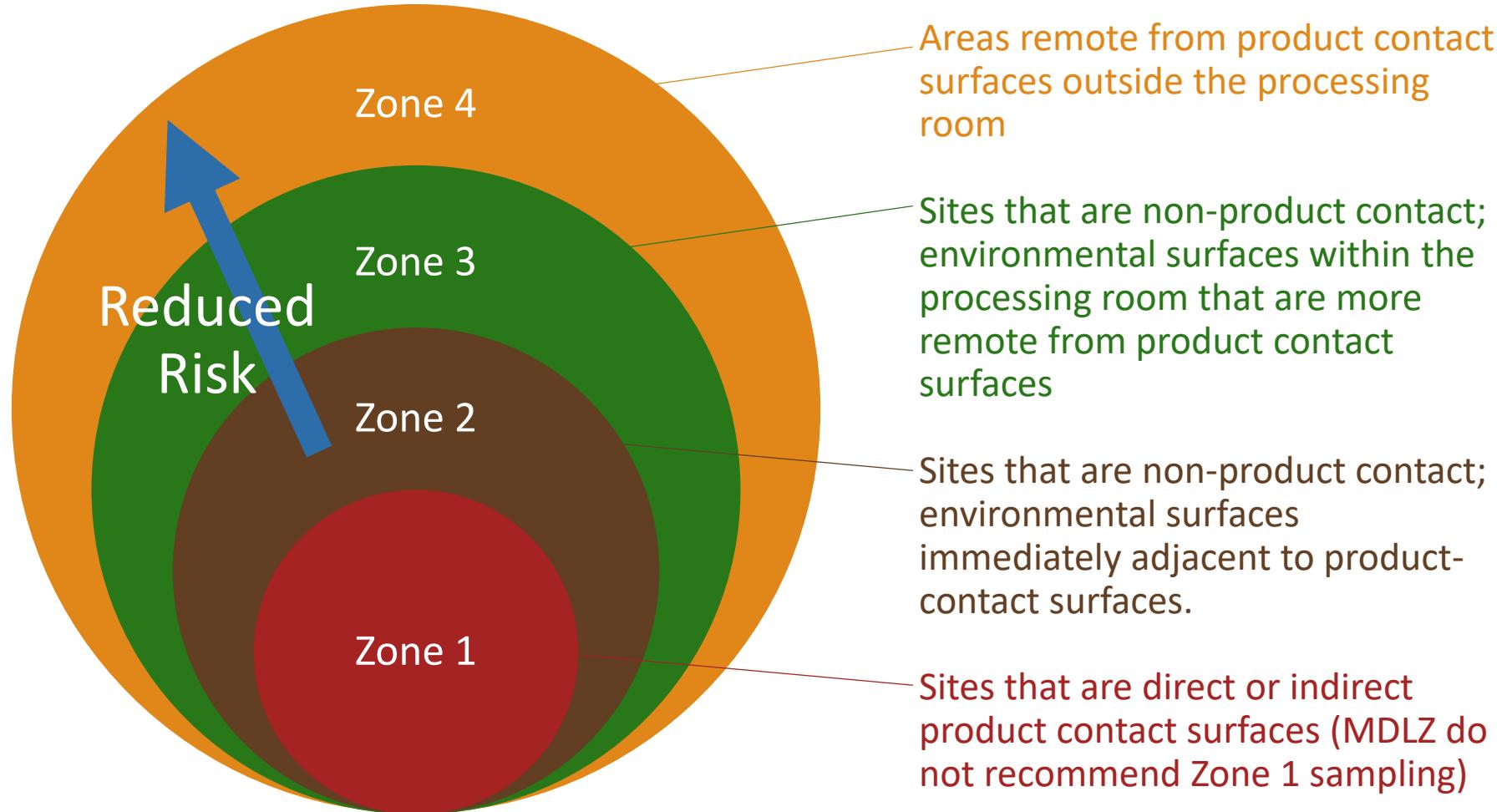
GENERAL APPROACH TO PEM

- PEM team (QA, Sanitation, Maintenance, etc) review layout and flow diagrams
- Assessment of controls of post processing environment
- Environmental testing requires a high level of sampling
- Sampling is randomised
- Sampling plans need to be flexible
- Review historical environmental and sanitation swab data
- Critical evaluation of process flow and identify areas of greatest risk
- Raw areas receiving further processing are not included
- Zone concept and sample site selection
- Unique events (e.g. construction) should be monitored

PEM SAMPLING PLAN

- Determine a site list for plant, ensure all critical swabbing locations have been identified
- Swabs should be taken during production and at least 3-4 hours into a run
- PEM sample size changes for large areas
- Composite – Take individual sponges for each site to form composite sample versus using same sponge (only when minimum one year history built up)
- Increase sampling focusing on water harbourage and high traffic areas and sites more likely to be a source, based on equipment and plant infrastructure conditions
- Raw areas not included
- Focus on cross-contamination after the kill step
- Sanitise the site after swabbing

ZONE CONCEPT FOR PEM



TARGET ORGANISMS AND TEST FREQUENCY

Table 8 PEM Reference Sampling Plans

Testing Plan	PEM Zone	Test organisms	Minimum Test Frequency*
Plan A RTE refrigerated products in which <i>Listeria monocytogenes</i> may survive or grow; typically in wet and cold environments. Typically applied to Meat and Meat products	1, 2, 3	<i>Listeria spp.</i>	Once per week
	4	<i>Listeria spp.</i>	Once per month
Plan B Low moisture products in which <i>Salmonella</i> may survive and/or grow; Typically applies to cocoa, nuts, and biscuit products.	2, 3	<i>Salmonella</i> only	Once per week
	4	<i>Salmonella</i> only	Once per month
	2, 3	<i>Listeria spp.</i> to monitor conditions that could lead to the presence of <i>Listeria monocytogenes</i> , or other type of conditions susceptible to support the survival of <i>Listeria monocytogenes</i> (typically where water / moisture may be present).	Once per month
Plan C	4	<i>Listeria spp.</i> and coliforms/total <i>E. coli</i>	Once per week

TARGET ORGANISMS AND TEST FREQUENCY

Products	Sampling Plan
RTE refrigerated and shelf-stable products that support pathogen survival; typically applies to Fruits and Vegetables products	E
Commercially Sterile Food & Beverage products – Aseptic, UHT, Retort	No testing required
Dips oil based, Dressings & Sauces	I
Dry Spice Blends	B
Flavors & extracts	B
Jams, Jellies and Honey (Aw<0.85)	I
Fermented / pickled products	I
Tea, powdered or leaves	B

TARGET ORGANISMS AND TEST FREQUENCY

Products	Sampling Plan
RTE refrigerated and shelf-stable products that support pathogen survival; typically applies to Fruits and Vegetables products	E

Table 8 PEM Reference Sampling Plans

Testing Plan	PEM Zone	Test organisms	Minimum Test Frequency*
Plan E RTE refrigerated and shelf-stable products that support pathogen survival; typically applies to Fruits and Vegetables products	1	Indicator organisms, coliforms [optional <i>E.coli</i>)	Once per week
	2, 3	<i>Listeria</i> spp. & <i>Salmonella</i> (or optional indicators to monitor conditions that could lead to <i>Salmonella</i> presence)	Once per week
	4	<i>Listeria</i> spp. & <i>Salmonella</i> (or optional indicators to monitor conditions that could lead to <i>Salmonella</i> presence)	Once per month

Table 9 PEM Guidance for Quantitative Indicator Organisms

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

ADDITIONAL PEM SAMPLING

- Investigation of positive findings
- In the event of a roof leak or water leak, PEM swabs should be taken immediately and before clean-up
- Environmental sampling after clean-up from floor drain back-ups in product exposed areas
- Construction or equipment (new line) installation
- Increased controls and monitoring should be implemented between construction and production areas in order to prevent possible cross contamination
- Dust and traffic should be controlled in the area
- Upon completion of construction activities; the area should be cleaned/ sanitised and swabs should be taken before production begins again
- Risk assessment of traffic patterns (supplementary swabbing)

POSITIVE PATHOGEN FINDINGS



- Root cause investigate within 24 hours of reporting results
- Corrective action plans, including increased control procedures and verification requirements
- A minimum of three consecutive negatives or in-standard results must be achieved prior to returning to the routine testing and sampling schedule within a 3-week time frame
- Root cause analysis and documented corrective action report must be provided to MDLZ, even if specific lot is not for MDLZ



FRUIT AND VEGETABLE PROCESSING EXPECTATIONS

Yolanda Tong

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FRUIT AND VEGETABLE PROCESSING EXPECTATIONS

- Two major sections:
 - Critical Control Points (CCPs)
 - Pre-requisite Programs (PRPs)
- Provides guidance values where available and applicable
- Reference to Scientific Literature
- Links to official documents added e.g. Health Canada, Chinese Regulations



PURPOSE

All fruit and vegetable suppliers and processing and bottling facilities, supplying MDLZ shall have effective processing conditions in place to ensure safe and wholesome processing and packaging.

Pathogens commonly associated with human outbreaks attributed to fruits/ vegetable products (raw/ processed) include *Salmonella* spp., *Campylobacter* spp., pathogenic *Escherichia coli*, *Listeria monocytogenes*, *Clostridium botulinum*, *Cryptosporidium parvum* and other parasites, and viruses. **Patulin** has been identified as a chemical hazard.

Yeasts, **molds**, and spoilage bacteria from fruits and vegetables have been shown to cause spoilage and negative quality attributes in fruit and vegetable products and need to be effectively managed to reduce spoilage.

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5.5 Fruit Filling and Sauces (pH < 4.6) – Heat Treatment

5.5.1 CRITICAL CONTROL POINT ID/PROCESS STEP:

Fruit filling/Fruit sauce heat treatment (pH less than 4.6)

5.5.2 HAZARD:

Biological (*E.coli* O157:H7, since considered most resistant)

5.5.3 CRITICAL CONTROL POINT PARAMETERS:

Time and temperature to reduce 5 logs of *E.coli* O157:H7

5.5.4 CRITICAL LIMIT:

Single-strength Juice (Brix \leq 16.5):

71.1°C (160°F) for min. 6.6 sec or equivalent process.

An equivalent time/temperature can be calculated using a z-value of 6.7 °C (12.05 °F). The lowest applicable temperature is 68.1 °C/154.6 °F.

Juice Concentrates (16.5 \geq Brix \leq 58)

71.1°C (160°F) for min. 1.5min or equivalent process.

An equivalent time/temperature can be calculated using a z-value of 10.3 °C (18.52 °F). The lowest applicable temperature is 62 °C/143.6 °F.

Equivalent time/temperatures. The following thermal process equation may be used to calculate equivalent time/temperatures (critical limits) when actual temperatures applied are different than those stated in the CCP Models:

$$F = F_R 10^{\frac{T_R - T}{z}}$$

T = temperature

F = the time required at actual applied temperature T

F_R = the time required at given T_R (i.e. the time/temp. stated in Model CCP)

z = the z-value is the increase/decrease in temperature required to increase/decrease time by a factor of 10.

PROCESS VALIDATION

5.9 Extrusion

If extrusion is used as a pathogen reduction step, then the Scientific Basis and validation for lethality must be provided and reviewed by Corporate Microbiology. The critical control parameters must be recorded and monitored.

5.10 Fruit Drying

If fruit drying is used as a pathogen reduction step, then the Scientific Basis and validation for lethality must be provided and reviewed by Corporate Microbiology. The critical control parameters must be recorded and monitored.

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6.7 Air Quality	30
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6.9 Prevention of growth by <i>Alicyclobacillus</i> spp.(ACB)	31
6.10 Heat Treatment to Prevent Spoilage in High Acid RTD Beverages.....	31

PRE-REQUISITE PROGRAMS (PRP)

6.4 Drying of vegetables as a Prerequisite Program (freeze dried, air dried, spray dried, oven dried, drum dried, crystallization)

Drying, like refrigeration, is not viewed as a pathogen reduction step, but is considered a means of microbial growth inhibition and product preservation

6.4.3 SPRAY DRYING

- All product contact air for product without further processing must be **filtered** to F7 unless air temperature is > 120°C, then coarse filtration is required.
- Routine **cracking testing** of spray dryers shall be performed at a frequency sufficient to demonstrate.
- The drying air heating system has the potential of being a source of **chemical contamination**. If burners are used for this purpose, a control mechanism shall be in place to prevent product contamination with hazardous chemicals.



SENSITIVE MATERIALS

Yolanda Tong

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BIOLOGICALLY SENSITIVE INGREDIENT CATEGORIES (APPENDIX B)

- 
- 
- Milk/ Dairy Products
 - Starter Media
 - Yeast/ Yeast Extracts
 - Enzymes/ Rennets
 - Meat/ Fish/ Poultry/ Seafood
 - Egg/ Egg Products
 - Soy Products
 - Fruit/ Fruit Products
 - Spices/ Herbs
 - Tea
 - Coconut
 - Vegetables/ Vegetable Products
 - Seeds/ Seed Products
 - Grains/ Grain Products
 - Cocoa Products
 - Natural Gums/ Thickeners
 - Green Coffee Beans
 - Nut/ Nut Products
 - Flavors

BIOLOGICALLY SENSITIVE INGREDIENT CATEGORIES

Biologically Sensitive Ingredient Categories		
Category of Biologically Sensitive Ingredient	Category includes (but not limited to):	Exclusions (only those listed):
Fruits/Fruit Products		Candied fruit, fruit in alcohol, jams/jellies, dried fruits having an Aw of ≤0.81 and a pH of ≤4.0, dried fruits having an Aw of ≤0.81 with an initial sulfite content of 100ppm minimum

SENSITIVE INGREDIENT POST-LETHAL PROCESS ADDITION

APPENDIX E: MODEL CRITICAL CONTROL POINTS AND PREREQUISITE PROGRAMS

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).

MONITORING:

Each lot of sensitive ingredient must have a supplier COA certifying ingredient negative for the target pathogen(s) or test results that indicate materials are negative for the target pathogen(s).



EXTRANEOUS MATTER MANAGEMENT

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OBJECTIVES

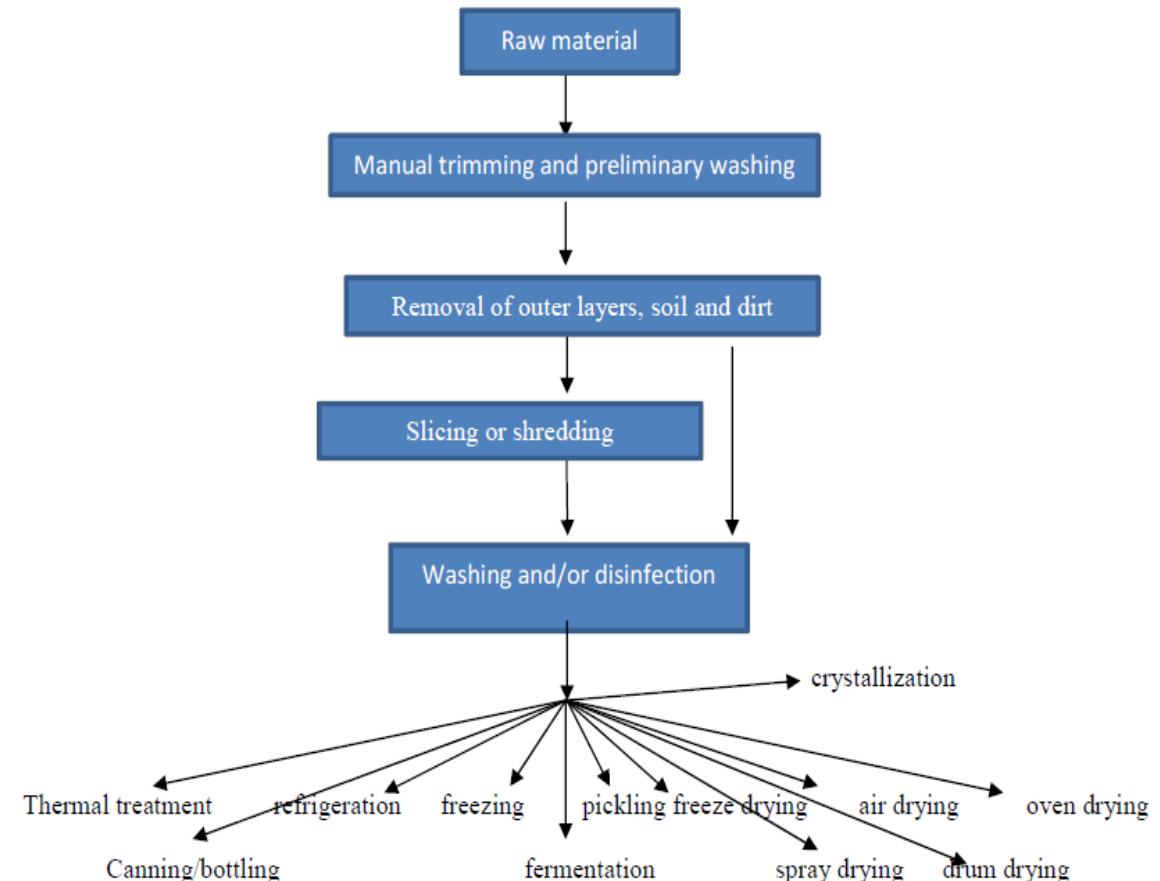
1. Focus on EM control
2. EM control programs
3. Control devices
4. Validation, calibration, verification, monitoring
5. Validation examples

FOCUS ON EM CONTROL

All Fruit and Vegetable materials in scope

High risk:

- Dried, sundried and dehydrated
- Frozen, freeze dried



WHY TO FOCUS AND WORK ON EM MANAGEMENT?

- Extraneous matter should not normally be found in food
- Consumers do not want to find EM in the product.
- Risk for consumers is hazardous.
- When review Quality Notifications and Customer Complaint we observe the trend is increasing.
- We observe more stones, glass, plastic related complaints.



EXAMPLES OF FINDINGS



This is really surprising
when open delivered boxes and find

Stalk

Stem

Leaves

Twigs

Pits

Stones

Sand

Hair

Wood

Metal

Glass

Plastic

Many of them are
HAZARDOUS



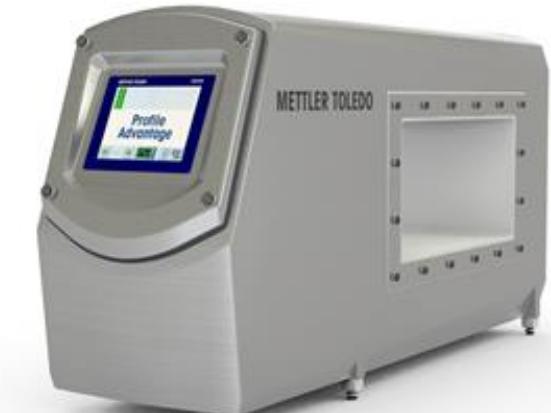
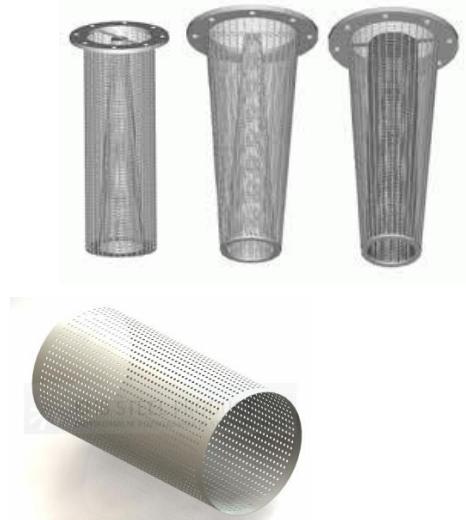
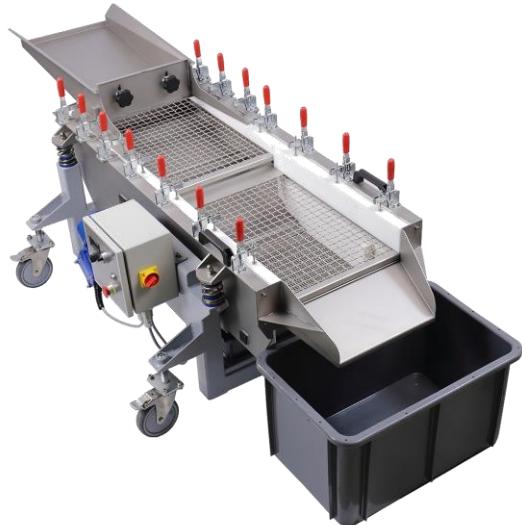
STRONG PRE-REQUISITES & EM CONTROL PROGRAM

Extraneous matter control
should be based on strong PRP
and linked to excellent people
practices: GAPs, GMP



The approach should be developed
in a program of EM Risk Assessment
and Management
(SQE section 7.6)

EM CONTROL DEVICES AND METHODS



VALIDATION – CALIBRATION – VERIFICATION - MONITORING

VALIDATION

Operational functionality

Can it consistently detect and reject
POD

Conducted before first production
and if any issues or after
maintenance

CALIBRATION

Technical functionality

Air pressure, Electrical integrity
Belt tracking. Sensor

Conducted usually annually

VERIFICATION

Are you actually doing what you we
say are going to do

Review and trending of results
Confirm devices operational
functionality 6mthly / yearly

MONITORING

Ensuring the system continues to
detect and reject in accordance
with the documented standard

Ongoing at a frequency to
demonstrate control - Can you hold
product if something goes wrong?

VALIDATION – KEY POINTS TO CONSIDER

Each equipment prior to use need to be validated

Confirm full functionality of the device

Use external expertise as support /producer/

Design validation protocol:

- Define product and target of extraneous matter /type and size/ on scope
- Methodology: [Consider process conditions: normal proces, standardized product flow i.e. belt speed and product layer, associated devices like aspiration system, EM separator, destoner, etc.]
- To be statistically sound
- Evaluate results for each extraneous matter type

SAMPLES OF EXTRANEous MATTER USED FOR VALIDATION

For metal, glass



For irregular materials
(collect real contaminants and
create a catalogue of E.M.)



VALIDATION OF METAL DETECTOR / X-RAY



Purpose:

To ensure Metal Detector is at its most sensitive detection limit with a

- Probability of Detection (POD) of 100%
- and False Reject Rate (FRR) <0.1%

Pass 30 times each Validation Sample

The POD limit is defined by the smallest dimension achieving a POD of 30/30 (detected & rejected)

POD
Calculation:- $POD = 100 \times \frac{\text{Rejected Test Samples}}{\text{Total Test Samples Inspected}}$

FRR
Measured during production by adding/ not adding known amount of contaminants with product amount equivalent to (200 – 2000 SKU). Evaluate each rejected product and classify it as a False

Reject or not

Recommended target: not more than 0.1%

Calculation:- $FRR = 100 \times \frac{(\text{Total Reject} - \text{Correct Reject})}{\text{Total Inspected}}$

EXAMPLE FOR VALIDATION REPORT FOR METAL DETECTOR:

Plant: _____		Product: _____		Contaminant: (Circle One)								
Date: _____		Line: _____		Ferrous	SS							
NUMBER OF TEST SAMPLES	ACCEPTED	10										
	ACCEPTED	9										
	ACCEPTED	8										
	ACCEPTED	7										
	ACCEPTED	6										
	ACCEPTED	5										
	ACCEPTED	4										
	ACCEPTED	3										
	ACCEPTED	2										
	ACCEPTED	1										
NUMBER OF TEST SAMPLES	REJECTED	1										
	REJECTED	2										
	REJECTED	3										
	REJECTED	4										
	REJECTED	5										
	REJECTED	6										
	REJECTED	7										
	REJECTED	8										
	REJECTED	9										
	REJECTED	10										
		mm	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0

* Contaminant sizes given here are intended to provide the minimum size requirements. However, smaller detection sizes may also be included in the verification (e.g 0.3mm)

INSTRUCTIONS:

- 1 Ensure detector is set at optimal settings for normal operation and all rejects and applicable verifications are functioning
- 2 Place the largest contaminant in the product
- 3 Pass through the metal detector or X-Ray 10 times
- 4 Record the accept or reject result for each pass by placing an "X" in the appropriate box
- 5 Repeat steps 3 & 4 for each contaminant size (reducing in size each time) and then review the data for the smallest contaminant with 10 successful rejects



Microsoft Excel
Worksheet

THE SUMMARY

- Consumers don't want to have foreign matters in product
- EM devices critically important to protect consumer and MDLZ brands reputation
- Devices must be validated to ensure they are effective



A circular inset photograph of a young woman with dark hair, wearing a white t-shirt and a pink hoodie. She is smiling and looking towards the camera while holding a small, round, orange-colored snack between her fingers.

QUESTIONS & ANSWERS

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QUESTIONS & ANSWERS

1

What is the Tiering for Aseptic Packed Product?

- *For Quality rated ingredients → Tier 4*
- *For other cases, ingredients shall be evaluated by Food Safety.*

2

You presented a table regarding PEM sampling planning according to products category. I cannot find the same table in your SQE version April 2013. According to the presented table Commercially Sterile Food & Beverage products - Aseptic NO TESTING REQUIRED. Can you send us the updated table? It is very important because we are supplying to Mondelez aseptic products.

- *Supplier Quality Expectations are under revision. More details about PEM table will be included in the new version.*
- *The aseptic process should be reviewed by Food Safety to assure sterilisation conditions are fulfilled in order to be exempt from PEM.*

For further information, please contact:

Fruit: Wiktor Szuszkiewicz : wiktor.szuszkiewicz@mdlz.com

Vegetables: Susana Cunquero : susana.cunquero@mdlz.com



QUESTIONS & ANSWERS

3

The list of approved/disapproved pathogen laboratories was last updated in Oct 2017. Would it possible to have this updated as we recently contacted some of these labs and was advised by 1-2 of the labs they were unable to perform Salmonella testing in 250g as per Mondelez Spec.

- The list of approved/ disapproved pathogen laboratories will be migrating to a new SharePoint system by the end of 2020. Suppliers will have access to the SharePoint system to check the live list. In the meantime, the list updated in Oct 2017 is still valid.*
- If you have any doubt about a specific laboratory/ method or if you have a query regarding additional laboratory in your area, please, contact your Supplier Quality Contact.*

4

Re the tiering process, I wanted to check re a product like tea extract. Which Tier would this fall under please?

- During the approval process, Procurement will inform you about Tiering and other specific requirements. Food Safety may be consulted for specific materials to determine the Tiering depending on the microbiological sensitivity of ingredient (included in Ingredient Specification).*
- If you need more information before approval process, please contact directly with your Supplier Quality contact.*

For further information, please contact:

Fruit: Wiktor Szuszkiewicz : wiktor.szuszkiewicz@mdlz.com

Vegetables: Susana Cunquero : susana.cunquero@mdlz.com

THANK YOU

MORE QUESTIONS?

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