Safety controls for the production of safe dry food products
Introduction

Mondelēz International
A Global Snacks Powerhouse With $36 Billion In Revenue (2)

- Nearly 75% of revenues in fast-growing snacks categories

Biscuits (1) 30%
Chocolate 27%
Gum & Candy 16%
Beverages 17%
Cheese & Grocery 10%

North America 19%
Europe 37%
Developing Markets 44%
Latin America
CEE
MEA
Asia Pacific

(1) Biscuits includes salty/other snacks
(2) Based on 2011 reported net revenues; includes accounting calendar changes and 53rd Week.
Our Categories & Global Power Brands

Biscuits
- OREO
- CLUB SOCIAL
- TUC
- belVita
- Barni

40% of Biscuit Revenue

Gum & Candy
- Trident
- HALLS
- Chiclets
- Stride
- Dairy Milk Eclairs

60% of Gum & Candy Revenue

Chocolate
- Cadbury Dairy Milk
- Milka
- LACTA
- Toblerone

50% of Chocolate Revenue
Objectives

• Introduction to HACCP
• Emphasis on Dry Products
• The importance of Product, Process and People
• Mondelēz International journey towards food safety A look at specific programs: Supplier selection (Specifications, Auditing, Supplier Food Safety Assessment, Material Monitoring), Product Design (Microbiological Risk Assessment, Control points, Design Safety Analysis, Specifications), Manufacturing (Hygienic Zoning, Control Point Validation, and Periodic Equipment/Infrastructure cleaning)

Identify the risks for the consumers, determine what you will do (identify the controls and have your scientific basis), verify if you do what you intended to
Introduction to HACCP
Why & How HACCP was developed..


Need to be sure that food sent into space would not cause illness
Why don’t we just test everything?

• If you test all batches, there is nothing left to send...how many batches do you test???

  – If 1 batch out of 1000 batches was defective (0.1%)...
  – If 60 negative batches are tested (6%)...

  ...There is still a 94% chance a defective batch could be released!!!
And so there was a need for HACCP…

“Hazard Analysis And Critical Control Point”

• Identifies Hazards in the Process

• Identifies Critical Points for Control and Monitoring

• Focus is on Food Safety and not Quality

• Program of Prevention rather than Inspection

• Science Based and systematic approach

• And today a Legal Requirement in many countries
HACCP
(Hazard Analysis Critical Control Point)

is a systematic approach to the identification, risk assessment, and control of biological, chemical and physical hazards associated with a particular food production process or practice.
HACCP

• Is a system for food safety control
• Is preventive, not reactive
• Is a management tool to protect against biological, chemical and physical hazards
• Is designed to minimize, not eliminate, the risk of food safety hazards
What is a Hazard?

A biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control (NACMCF, 1997)

Three types of hazard:
- Biological
- Chemical or
- Physical
Biological Hazards

Bacteria

Viruses

Parasites

Protozoans

Moulds and Yeasts
Vegetative Bacteria

- Salmonella
- E. coli
- Staphylococcus aureus
- Campylobacter
- Listeria
Spore Formers

- Clostridium botulinum
- Clostridium perfringens
- Bacillus cereus
- Clostridium botulinum
# Chemical Hazards

<table>
<thead>
<tr>
<th>Point of Use</th>
<th>Types of Chemicals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Growing crops</td>
<td>Pesticides, herbicides, defoliants</td>
</tr>
<tr>
<td>Crop storage</td>
<td>Mycotoxins</td>
</tr>
<tr>
<td>Production</td>
<td>Food additives, processing aids, <strong>allergens</strong></td>
</tr>
<tr>
<td>Plant maintenance</td>
<td>Lubricants, paints</td>
</tr>
<tr>
<td>Plant sanitation</td>
<td>Cleaners, sanitizers, pesticides</td>
</tr>
</tbody>
</table>
Physical Hazards

- Glass – pieces of bottles, lights, equipment, etc.
- Metal – nuts, bolts, screws, wire, tacks, needles, fragments from equipment, etc.
- Plastic – equipment, packaging materials, etc.
- Natural materials – twigs, grass seed, shell, stones, etc.
- Others – buttons, jewelry, etc.
Initial Tasks In Developing A HACCP Plan

1. Assemble the HACCP team
2. Describe the food product and its distribution
3. Describe the intended use and consumers of this product
4. Develop a flow diagram for this product’s processing operation
5. Verify the flow diagram “on the ground”
Seven Principles of HACCP

1. Conduct a hazard analysis for each product’s production process
2. Determine the Critical Control Points (CCPs) where the process can be managed
3. Establish critical limits for the CCPs
4. Establish monitoring procedures for the process
5. Establish corrective actions in case of a deviation
6. Establish verification procedures to be sure the plan is working properly
7. Establish record keeping and documentation procedures for each process
What is a Hazard Analysis?

The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.
Conducting a Hazard Analysis

Step 1 – HAZARD IDENTIFICATION

• For each unit operation in the flow diagram, develop a list of all potential biological, chemical or physical hazards that are reasonably likely to cause injury or illness to the consumer, if they are not controlled.
# Hazard Analysis

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Hazard (B, C or P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving Shelled Peanuts</td>
<td>Biological – <em>Salmonella</em></td>
</tr>
<tr>
<td></td>
<td>Chemical – pesticide, aflatoxin</td>
</tr>
<tr>
<td>Refrigerated Storage</td>
<td>Biological – <em>Salmonella</em></td>
</tr>
<tr>
<td>Cleaning</td>
<td>Physical – foreign material (glass)</td>
</tr>
</tbody>
</table>
Step 2 – Hazard Analysis

- Decide which hazards identified in Step 1 must be addressed by the plan, based on
  - Severity
  - Likelihood of occurrence (risk assessment)
Factors to Consider in Risk Assessment

- Has the problem happened before and how often
- Shelf-life of the food product
- Product sensitivity to organism growth
- Numbers of organism required to cause disease
- Virulence of organism
- Susceptibility of population
  - Immuno-compromised
Each Hazard Analysis is Unique

• Not possible to find in a book or to copy from a similar operation.

• A hazard at one plant might not be a hazard at another plant with a nearly identical line because of different ingredients, plant design, equipment, etc.
Hazard Analysis

• **Significant** food safety hazards are managed by the HACCP plan
  – i.e. pathogen or allergen risks

• **Non-significant** hazards are managed by prerequisite programs.
  – GMPs
CCP Determination

Critical Control Point:

A point, step, or procedure in a process at which control can be applied to prevent, eliminate or reduce a food hazard to an acceptable level.

NACMCF, 1997
Defining CCPs

• CCPs are product and process-specific.
• They are only used to control significant hazards.
• They must be measurable and controllable.
• Use the CCP Decision Tree to identify whether a step is a CCP or not.
What are Critical Limits?

**Critical Limit:** A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.

NACMCF, 1997
Frequently Used Criteria For Critical Limits

• Temperature/Time
• Moisture level
• Water activity ($a_w$)
• Presence of screen
• pH
• Viscosity
• Metal detector sensitivity
Setting Critical Limits

1. HACCP team must determine criteria that must be met at CCP to control the hazard

2. Examine scientific/technical publications, government regulations, processing authorities, etc., for published criteria

3. If no limits have been published, experiments (heat penetration/ thermal death time studies, microbial challenge studies) should be performed to establish criteria
What is Monitoring?

... a planned sequence of observations or measurements to assess whether a CCP is under control, and to produce an accurate record for future use in verification.

NACMCF, 1997
Monitoring

Who will monitor?
- Trained, designated employee

What will be Monitored?
- Temperature*
- Time and temperature*
- Flow rate
- Moisture
- Visible residue
- Belt speed
- Belt depth
- Acid addition
- PH
- Water activity
Monitoring (continued)

When will critical limits be monitored?
- Continuous
  - Recorders
- Non-continuous
  - Batch basis
  - Visual

How Critical Limits and Preventive Measures will be Monitored, e.g.
- Calibrated thermometer
- Calibrated pH meter
- Visual
- Calibrated chart recorder
- In-line analyzers
- Laboratory analyses
Example: Metal Detector

- **What is monitored?**
  - Calibrated metal detector
- **How is it monitored?**
  - Visually
- **When is it monitored?**
  - At start-up, and every 30 minutes during operation
- **Who monitors it?**
  - Production line employee
What are Corrective Actions?

**Corrective Action** shall be immediately taken when monitoring indicates there is a deviation from an established critical limit.

NACMCF, 1997
## Corrective Action Records

<table>
<thead>
<tr>
<th>IF deviation:</th>
<th>Product (e.g., hot-filled juice) does not reach required internal temperature for the required time</th>
</tr>
</thead>
<tbody>
<tr>
<td>THEN corrective action:</td>
<td><strong>Isolate</strong> affected product AND <strong>Reprocess or destroy</strong> product AND Determine the <strong>reason</strong> for the deviation; make necessary <strong>adjustments</strong>; AND <strong>record</strong> deviation and actions taken</td>
</tr>
</tbody>
</table>
## Corrective Action Log

<table>
<thead>
<tr>
<th>Time</th>
<th>Product Involved</th>
<th>Label</th>
<th>Amount of Product Involved</th>
<th>CCP Exceeded</th>
<th>Person Who Identified Problem</th>
<th>Person Informed</th>
<th>Action Taken on Product/Process</th>
<th>Product Disposal</th>
<th>Person Verifying Disposition</th>
</tr>
</thead>
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</tbody>
</table>

### Comments:

Verified by: ___________________________  Date of Review: ____________________
What are Verification/Validation Procedures?

**Verification:** those activities other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

NACMCF, 1997

**Validation:** the element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the identified food hazards.

NACMCF, 1997
Verification vs. Validation

• **Verification** asks whether the HACCP system is being implemented according to the plan
  – “Are you doing what you say?”

• **Validation** asks whether the hazard analysis was complete and if the control measures are effective
  – “Are you doing the right thing?”

HACCP Principle 6
Elements of Verification

CCP verification activities include:

- Regulatory inspections/audits
- CCP record reviews
- Calibration of monitoring instruments
- Targeted sampling and microbiological testing
On-Site Verification Audit

- Checks the accuracy of the product description and flow chart
- Checks that CCPs are monitored as required by the HACCP plan
- Checks that CCPs are operating within established critical limits (CLs)
- Checks the accuracy of all record keeping procedures and the time intervals required
- Processor review of customer complaints
CCP Record Review

• Monitoring activities have been performed at the locations specified in the HACCP plan
• Monitoring activities have been performed at the frequencies specified in the HACCP plan
• Corrective actions have been performed whenever monitoring indicated deviation from critical limits
• Equipment has been calibrated at the frequencies specified in the HACCP plan
Calibration of Instruments

• On equipment and instruments used in monitoring or verification
• At a frequency to ensure accuracy of measurements
• By checking accuracy against at recognized standard at or near the condition that the instrument or equipment will be used
Targeted Sampling/ Microbial Testing

Purpose: Vendor compliance may be checked by targeted sampling / microbial testing when receipt of raw material is a CCP and purchase specifications are relied on as critical limits.
Initial HACCP Validation (new plans)

- Include scientific basis for control
- Assure that the plan is adequate for controlling food safety hazards
- Determine control parameters can be adhered to
- Confirm plan is being implemented properly
- Adjust plan if deficiencies are found
Who, When and How?

• Who does the validation of the HACCP plan?
  – HACCP team
  – Individual qualified by training or experience

• When does validation occur?
  – Initially
  – When factors warrant
  – Annually or Every 2yrs

• What does validation involve?
  – Scientific and technical review of the rationale behind each part of the HACCP plan from hazard analysis through each CCP’s verification strategy
Factors for Validation Review

- Changes in raw materials
- Changes in product
- Changes in processing methods
- On-line observations
- Adverse review findings

- Recurring deviations
- New information on hazards or control measures
- New distribution or consumer handling
Record Keeping and Documentation

- Establish effective record keeping procedures that document the HACCP system, including:
  - Summary of the hazard analysis, with rationale
  - Supporting documentation, such as validation records
  - Records generated during operation of the plan
  - Schedule of verification (audit) activities and person responsible for monitoring

NACMCF, 1997
Reasons for Keeping Records

• Documents all CCPs within CLs to ensure product safety
• Documents corrective actions taken when CLs are exceeded
• Provides monitoring tool so process adjustments can be made to prevent loss of control
• Only reference available for product traceability
Reasons for Keeping Records: (continued)

• Provides data for review during regulatory compliance and HACCP auditing

• Provides irrefutable evidence that procedures and processes were followed in strict accordance with HACCP requirements

• Filing all records in a designated location prevents accidental loss of key information.
Types of HACCP Records

- Critical control point records
- Records establishing critical limits
- Records of CCP monitoring
- Records associated with deviations
- Records of verification activities
- HACCP plan and support documentation used in developing plan

Document even your HACCP team meetings!
HACCP Plan & Support Documentation:

- HACCP team list and assigned responsibilities
- Description of product and intended use
- Flow diagram of entire manufacturing process indicating CCPs
- Hazards associated with each CCP and preventive measures
- Rational developed for determining hazard significance
HACCP Plan and Support Documentation (continued)

- Critical limit(s) for each CCP
- Monitoring system, including sampling procedures and test methods
- Corrective action plans for deviations from CLs
- Record-keeping procedures, including copies of forms and instructions
- Procedures for verification of the HACCP system
Emphasis on Dry Products
Why so much focus on dry/low moisture foods?

Understanding Moisture and Water activity

• Defined as the vapor pressure of a liquid divided by that of pure water at the same temperature;

• As the temperature increases, \( a_w \) typically increases, except in some products with crystalline salt or sugar.
Water Activity and Food Design and Safety

- Food designers use water activity to formulate products that are shelf stable (inhibition of microorganisms).
- Can also help limit moisture migration within a food product made with different ingredients (example raisins and bran cereal)
- Used to determine application of CCPs
- Relationship between water activity and bacterial growth (1953)
- Low water activity (aw) is a barrier to growth for many vegetative pathogens, including *Salmonella* spp.
- Organisms can still survive
<table>
<thead>
<tr>
<th>Food</th>
<th>Salmonella serotype(s)</th>
<th>Inoculum (log cfu/g)</th>
<th>Water activity</th>
<th>Length of Survival</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dried milk products</td>
<td>Naturally contaminated with 3 serotypes</td>
<td></td>
<td></td>
<td>Up to 10 months</td>
<td>Ray et al., 1971, cited by Bell and Kyriakides, 2002</td>
</tr>
<tr>
<td>Pasta</td>
<td>Infantis, Typhimurium</td>
<td></td>
<td>0.12% moisture</td>
<td>Up to 12 months</td>
<td>Rayman et al., 1979, as cited by Bell and Kyriakides, 2002</td>
</tr>
<tr>
<td>Milk chocolate</td>
<td>Eastbourne</td>
<td>8.0</td>
<td>0.41</td>
<td>&gt; 9 month at 20°C</td>
<td>Tamminga et al., 1976</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.0</td>
<td>0.38</td>
<td>9 months at 20°C</td>
<td></td>
</tr>
<tr>
<td>Bitter chocolate</td>
<td>Eastbourne</td>
<td>7.0</td>
<td>0.51</td>
<td>9 months at 20°C</td>
<td>Tamminga et al., 1976</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.0</td>
<td>0.44</td>
<td>76 days at 20°C</td>
<td></td>
</tr>
<tr>
<td>Peanut butter</td>
<td>A composite of Agona Enteritidis Michigan Montevideo Typhimurium</td>
<td>5.7</td>
<td>0.20-0.33</td>
<td>Up to 24 weeks held at 5°C or 21°C</td>
<td>Burnett et al., 2000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.5</td>
<td>0.20-0.33</td>
<td>Up to 24 weeks at 5°C</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Up to 6 weeks at 21°C</td>
<td></td>
</tr>
<tr>
<td>Paprika powder</td>
<td>Multiple serotypes</td>
<td></td>
<td></td>
<td>&gt; 8 months</td>
<td>Lehmacher et al., 1995</td>
</tr>
</tbody>
</table>
The importance of Product, Process and People
Product Design

Key factors to consider

• Intended consumer
• Product use
• Shelf life
• Package integrity
• Manufacturing conditions
• Transportation and Storage
• Ingredients and Suppliers

Robust product and package (supplier quality program) meeting consumer needs for foreseeable shelf life before and after opening
Process Design

Key factors to consider:

- HACCP – Design and monitor a robust process
- Manufacturing equipment
- Cleaning method and frequency
- Maintenance
- Facility structure
- Traffic flow

Controllable process that consistently eliminates hazards and an environment that prevents recontamination
People

Key factors to consider

• Regular education and training
• Zones of separation (Raw to RTE)
• GMPs
• HACCP

Motivated and educated team who understand and care about food safety
Food Safety Journey

More recent events that shaped our approach and increased our focus on design; the creation of new programs and their implementation
Food Safety Journey

- Pre-requisite programs, such as GMP, Sanitation, Pathogen Environmental Monitoring implemented for many decades
- Supplier and internal Quality audits implemented for many decades
- HACCP Implemented in the early 1990

- Recalls / Near misses
  - Chicken strips and Maple Leaf
  - Pistachio, Peanut Corporation of America, Skim Milk Powder from Eastern Europe
  - Melamine

- Changes
  - Periodic Equipment Cleaning and increased focus on execution of Pathogen Environmental Monitoring
  - Divide suppliers in tiers and Supplier Food Safety Assessment
  - Material Monitoring
A Look at Specific Programs

Supplier selection and Management (Specifications, Auditing, Supplier Food Safety Assessment, Material Monitoring)

Product Design (Microbiological Risk Assessment, Control point and validation, Specifications)

Manufacturing (Hygienic Zoning, Control Point Verification, and Periodic Equipment/Infrastructure cleaning)
Supplier Selection / Management

A comprehensive approach to managing supplier quality

Policy/Contract Requirements
- Quality Policy
- WW Supplier Quality Expectations
- Supplier HACCP Manual
- Material Specifications

Continuous Improvement
- Supplier QI Program
- Supplier Quality Partnerships
- Supplier Development
- Industry Benchmarking

Selection/Approval
- Risk Assessments
- Supplier Pre-Assessment
- Quality Audit Approval

Monitoring
- WW Quality Audit Program
- Materials Monitoring Program
- COA Verification
- Supplier Performance Monitoring
- Certificate of Conformance (COC)
Supplier Selection / Management

Examples from European Confectionery (Verification Testing Results)

Since 1991:
- 22 salmonella positive in dairy powders
- However, of those positives most were detected before the implementation of our supplier control programs and before the implementation of HACCP at our suppliers

Since 2000:
- Mondelēz International Supplier Quality expectations are focused on process control e.g. Pasteurization to deliver food safety rather than testing for pathogens

Testing is a step to verify that process controls are effective
### Supplier Selection / Management

Impossible to audit all our suppliers at the same frequency – need to be risk based

<table>
<thead>
<tr>
<th>Tier</th>
<th>Ingredient Categories</th>
<th>Qualification Process</th>
<th>Accepted Audits &amp; Certifications</th>
<th>Target Freq. (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>RTE Meats, Cheeses, RTE Raw_Fruits/Vegetables</td>
<td>MDLZ Audit</td>
<td>MDLZ Audit</td>
<td>1.5</td>
</tr>
<tr>
<td>2</td>
<td>RTE Nuts/Seeds/Coconut, Retorted &amp; Aseptic Products (Low Acid Canned Foods), Cocoa/Chocolate/Confectionary, Treated Herbs/Spices/Seasoning; Tea &amp; Tea Products; Egg &amp; Egg Products; Dairy Products &amp; Substitutes; Yeast; Enzymes</td>
<td>MDLZ Audit</td>
<td>GFSI Certifications or 3rd Party SQE + Supplier Food Safety Assessment (frequency determined by Food Safety Group)</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>Fruit &amp; Fruit Products, Vegetable &amp; Vegetable Products, Flavoring Ingredients (material assigned to tier 2 or 4 - refer to the Raw Material Tier Assignment list for details)</td>
<td>3rd Party SQE or 1st Certifications</td>
<td>3rd Party SQE or 1st Certifications</td>
<td>3</td>
</tr>
<tr>
<td>5</td>
<td>Grain &amp; Grain Products, Emulsifiers; Prepared Sauces/Spreads/Condiments, Coffee &amp;Coffee Products, Bread &amp; Bakery Products; Sugars &amp; Sweeteners; Starter Media/Culture; Fats &amp; Oils; Food Additives; Raw Meat &amp; Raw Meat Products, Food Chemicals Hydrocolloids &amp; Gums, Wafers; Untreated Herbs/Spices/Seasoning; Raw Milk &amp; Cream, Nationally Branded Confections; Green Coffee Beans; Compressed Gases; Raw Grains; Raw Nuts/Seeds/Coconut; Raw earthen materials (e.g., unprocessed materials mined from the earth); Alcoholic Substances (Spirits, Liquors)</td>
<td>Audits may be required as result of a risk assessment by BU or Plant using the material</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>
Supplier Selection / Management – Supplier Food Safety Assessment

Provide a proactive means of identifying and controlling microbiological and food safety risks across existing suppliers to Mondelēz International

• Zoning (adequate separation between raw and RTE)
• Pathogen Environmental Monitoring
• HACCP
• Validation of the kill step (CCP)
  – Review of the technical data
  – Review of production records
• Environmental Monitoring (non-pathogen)
  – Sanitation indicators
  – Air Handling
  – Water monitoring program
Summary

• Design is key to food safety
• Food safety management system is HACCP built on foundation of prerequisite programs
• Verification and validation are aggressive and used to identify potential issues (e.g. kill step validation)
Questions???