Verification of the control of microbiological, chemical and physical hazards in food processing

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Driscoll’s of the Americas
Challenges with verification programs

- Statistical limitations of detecting contaminant in finished product and raw materials
- Distribution of contaminant may limit ability to detect non-conformance
- Environmental monitoring represents a point in time
- Sensitivity of methodology may limit effectiveness in monitoring to standard
- Cost of verification testing may limit application
Limitations to testing

Sampling by presence / absence testing for pathogens

<table>
<thead>
<tr>
<th># samples</th>
<th>Prob. accept.</th>
<th>Prob. reject</th>
<th>Proportion of lots rejected</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>10 % defective units in lot</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>59%</td>
<td>41%</td>
<td>1 / 3</td>
</tr>
<tr>
<td>10</td>
<td>35%</td>
<td>65%</td>
<td>2 / 3</td>
</tr>
<tr>
<td>60</td>
<td>0.5%</td>
<td>99.5%</td>
<td>199 / 200</td>
</tr>
<tr>
<td><strong>2 % defective units in lot</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>90%</td>
<td>10%</td>
<td>1 / 10</td>
</tr>
<tr>
<td>10</td>
<td>82%</td>
<td>18%</td>
<td>1 / 6</td>
</tr>
<tr>
<td>60</td>
<td>30%</td>
<td>70%</td>
<td>2 / 3</td>
</tr>
</tbody>
</table>

- Constraints for sampling and examining a sufficient number of samples
- The constraints of time and cost to obtain results
- Testing only identifies effects and often neither identifies nor controls causes

Source: ICMSF, 1986
Tools for developing sampling strategies

Operating Characteristic Curve

\[ n = 10, \, c = 2 \]

\[ P_{(rej)} = 0.32 \]

\[ P_{(acc)} = 0.68 \]

\[ p = \text{Percent of Defective Sample Units Comprising Lot} \]

\[ P_r = \text{Probability of rejecting such a lot if offered} \]
Example of a decision tree for categorizing raw material risk to determine verification activities

Example of a decision tree for categorizing raw material risk to determine verification activities

Table 7. Example of a raw material verification program based upon raw material risk and supplier confidence.

<table>
<thead>
<tr>
<th>Material risk</th>
<th>Supplier confidence</th>
<th>COA</th>
<th>Pre-shipment possible</th>
<th>Testing upon receipt</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>High</td>
<td>Each lot</td>
<td>Yes</td>
<td>Each lot</td>
</tr>
<tr>
<td>High</td>
<td>Medium</td>
<td>Each lot</td>
<td>No</td>
<td>Each lot</td>
</tr>
<tr>
<td>High</td>
<td>Low</td>
<td></td>
<td>Disqualify vendor</td>
<td></td>
</tr>
<tr>
<td>Medium</td>
<td>High</td>
<td>Each lot</td>
<td>Yes</td>
<td>First 15 lots, then quarterly</td>
</tr>
<tr>
<td>Medium</td>
<td>Medium</td>
<td>Each lot</td>
<td>Yes</td>
<td>Increase frequency (e.g., monthly)</td>
</tr>
<tr>
<td>Medium</td>
<td>Low</td>
<td>Each lot</td>
<td>No</td>
<td>Each lot</td>
</tr>
<tr>
<td>Low</td>
<td>High</td>
<td>Quarterly</td>
<td>Yes</td>
<td>First 10 lots, then quarterly</td>
</tr>
<tr>
<td>Low</td>
<td>Medium</td>
<td>Each lot</td>
<td>Yes</td>
<td>Monthly</td>
</tr>
<tr>
<td>Low</td>
<td>Low</td>
<td>Each lot</td>
<td>Yes</td>
<td>Increase frequency</td>
</tr>
</tbody>
</table>

### Environmental sampling modification based upon risk

<table>
<thead>
<tr>
<th>Environment priority rating</th>
<th>Control level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Minimum</td>
</tr>
<tr>
<td>First</td>
<td>Once / week</td>
</tr>
<tr>
<td>Second</td>
<td>Once / month</td>
</tr>
<tr>
<td>Third</td>
<td>None</td>
</tr>
</tbody>
</table>
Methods for verification of allergen control

- Surface swab for detection of protein (3-20 µg)
- ATP bioluminescence
- PCR (2.5-10 mg/kg)
- Lateral flow, dipstick, ELISA (5 ppm)
- Proteomic Mass Spectrometry
Developments in allergen detection

- LC/MS/MS has unique advantages of multiple allergen detection and quantification
  - High sensitivity and specificity allow detection of multiple allergens in one analysis
  - Suitable for evaluation of cooked foods:
    - Not dependent on proper folding of proteins
    - Internal standard improves precision and reliability
  - No need for antibody production
  - Multiplexing saves time and cost
Developments in allergen detection

- Selection of “marker proteins”
  - Specific for milk proteins from different species (cow, buffalo) but not specific for other food ingredients (e.g. egg)
  - Ideally 2-3 marker proteins per allergenic compound
  - Good extraction properties and solubility (no membrane proteins)
  - None to few posttranslational modifications, modifications during food processing

Developments in allergen detection

- LC/MS/MS multiplex allows the combination of allergen targets based upon needs:
  - Confectionery set:
    - tree-nuts, sesame, peanut
  - Culinary set:
    - lupine, mustard, celery, soy, gluten, egg
  - Infant nutrition set:
    - whey, casein, soy, gluten
Methods for foreign body verification

- Visual inspection
- Separation systems (sieves, filtration)
- Magnets
- Optical sorting
- Metal detection
- X-ray
In-line monitoring systems

Sources: Foodengineeringmag.com; Unitec, ipinimg.com; bbctechnologies.com
Glass in spinach recall

DiGiorno pizzas, Stouffer's meals recalled for glass in food

Nearest, which makes DiGiorno frozen pizzas, issued a recall for 3.2 million boxes of pizza, Stouffer's lasagnas and Lean Cuisine meals after customers said they found pieces of glass in their food. (Pub File/Chicago Tribune)

By Tribune news services · Contact Reporter

Nearly three million boxes of frozen DiGiorno pizzas, Stouffer's lasagnas and Lean Cuisine meals are being recalled after customers said they found pieces of glass in their food.

Nestlé USA, the company behind the brands, said no injuries have been reported.
Whole Genome Sequencing is increasingly used in food safety microbiology

GenomeTrakr: > 35 sequencing labs in and outside US providing to the FDA sequence information of foodborne pathogens

ECDC SCIENTIFIC ADVICE Oct 2015
Expert Opinion on the introduction of next-generation typing methods for food- and waterborne diseases in the EU and EEA

Whole Genome Sequencing: The Future of Food Safety
Bacterial Source Tracking By WGS Is More Discriminatory than other methods

- API: Enzyme
- Maldi-TOF: Chemical
- Serotyping: Antigens

DNA-Based Typing Methods:
- DGE, HRM
- PCR-RFLP
- MLVA
- Rep-PCR
- RAPD
- AFLP
- RFLP
- PFGE

WGS
WGS – It Requires Technical Competencies Beyond Traditional Microbiology

The Whole Genome Sequencing (WGS) Process
WGS is a laboratory procedure that determines the order of bases in the genome of an organism in one process. WGS provides a very precise DNA fingerprint that can help link cases to one another allowing an outbreak to be detected and solved sooner.

1. DNA Extraction
2. DNA Shearing
3. DNA Library Preparation
4. DNA Library Sequencing
5. DNA Sequence Analysis

'Dry' Processing WGS

'Wet' Processing WGS
WGS – It Requires Technical Competencies Beyond Traditional Microbiology

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‘Traditional’ Microbiology

‘Dry’ Processing WGS

‘Wet’ Processing WGS
Opportunities and barriers for Whole Genome Sequencing and Metagenomics

Opportunities

• Investigation of recurrent issues in factory environment
• Evaluation of spoilage issues
• Economic adulteration
• Characterization of micro-organisms to develop effective interventions
• Characterization of cultures for use in validation studies

Barriers

• Cost
• Time for results / interpretation
• Expertise to interpret results
• Evolving interpretation understanding of context of findings
• “Data lives forever”
Sampling locations in the factory are marked with red dots.

Line 12 and line 16 are in zone A.
Sample "59" was not received

Numbers correspond to location places indicated by the factory
Considerations for WGS in Food Safety Management

- Quality assurance - Standards P- Test
- WGS is not just another typing tool - Robust Underpinning Science
- Protocol Harmonization Stakeholder Guidelines on Decision-making /Interpretation
- Technical competence: authorities, industry, labs, academia
- WGS is ONE tool: epidemiology must also be used
- Sharing of data: legal, political, psychological constraints

Food safety is global – WGS will be a global tool
HACCP study of raw material / ingredient

Microbiological hazard is reasonably likely to occur and must be controlled at the supplier or at the food processor by CCP or CP / OPRP

Control measures at the supplier (CCP or CP / OPRP) are capable of controlling the hazard?

Control measure (CCP or CP / OPRP) is in place at the food processor sufficient to control the hazard?

Factors are in place that elevate the material risk?*

Microbiological hazards may be introduced by handling / transportation?

Control measure (CCP or CP / OPRP) is in place at the food processor sufficient to control the hazard?

Testing only if necessary to evaluate material quality or initial load prior to processing

CCP = Critical Control Point
CP = Control Point
OPRP = Operational Pre-requisite (ISO 22000:2005)

Low risk material

No material risk identified

Material not fit for purpose. Source new material or from supplier that has adequate control measures, or implement process control measure at food processor.

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

High risk material

Medium risk material

*Such as:
-Frequent history of hazard in material type
-Will be consumed by sensitive population
-Will be used in a product in which the pathogen can grow during processing, storage or distribution
-Risky origin

Jackson, T. 2014.