Joint FAO/WHO Technical Meetings

The Nature of Infectious Foodborne Disease Risk Associated with Lipid-Based Ready to Use Food for Severe and Moderate Acute Malnutrition

Copenhagen, 01-02 July 2015
Progress Since Last Meeting

- *Salmonella* and EB data on ~2 years of production
- Applied research on lethal processes
- Related CODEX Alimentarius discussions
Hazard Identification

- Many potential pathogens may be present in ingredients and the processing environment
- Hazard identification - start with broad consideration of possible pathogens
- Previously identified pathogens and ones associated with pediatric infections
- Criteria – syndrome, severity, low moisture foods as a vehicle

Gram negative bacteria
  - Nontyphoidal *Salmonella*
  - *Cronobacter*, *E.coli*, *Shigella*, *S. typhi*
  - *Klebsiella*, *Enterobacter*, *Citrobacter*

Gram positive bacteria
  - *Listeria*, *Clostridium* spp.
  - including *botulinum*, *Bacillus* spp., Toxigenic
  - *Staphylococcus*, *Enterococcus*

Viruses
  - Norovirus, Hepatitis A

Parasites
Salmonella – highest priority

- Common contaminant of ingredients that may be used
- Survives for months to years in dry ingredients, low water activity foods, and manufacturing environment
- Common cause of large outbreaks associated with similar foods
- *Salmonella* control program likely to control other pathogens as well
- Other pathogens could become important in some manufacturing environments
Exposure Assessment

- Microbiologic survey of past two years suggests on average less than 0.5% of lots contain *Salmonella* and concentrations are low
  - Represents good progress

- Inferences form this - if approximately five 25g samples in every 1000 (0.5% prevalence) contain one or more *Salmonella* cells and SD is 0.5% then,
  - 1 in 100,000 servings of 100g contains 10 cells
  - one in 10 billion servings contains 1000 cells of *Salmonella*.

- Variation between producers is much too high and must be addressed (<0.5 to 20%), inconsistency in achieving <0.5% of lots contaminated at <10 *Salmonella*/100 grams
Hazard Characterization

Susceptibility of Intended Consumers

Acutely malnourished children are more likely than other children in the community to become infected, ill, and die if exposed to Salmonella.
Susceptibility of Intended Consumers

- Body defenses disrupted by malnutrition and diarrhea increases risk of all-cause deaths

- *Salmonella* commonly identified in invasive infections among children with SAM

- Review of medical literature suggests children with SAM are 2.1 to 3.4 times more likely to have severe illness from *Salmonella* infection, on the same order as the effects of HIV (2.6 times)

- Based on same literature, unlikely to be more than 5.5 times more susceptible
Dose Response

- Best we have but still uncertainty
- At low levels of contamination – in linear part of curve

Examples of the predicted risk of gastrointestinal salmonellosis for SAM children receiving a full course of RUF (62 servings) based on different levels and frequencies of RUF contamination.

<table>
<thead>
<tr>
<th>CFU/serving</th>
<th>% Contaminated Servings</th>
<th>Probability of salmonellosis after 62 servings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&lt;0.2</td>
<td>&lt;0.0011</td>
</tr>
<tr>
<td>20.0</td>
<td>0.10</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>&lt;0.2</td>
<td>0.010</td>
</tr>
<tr>
<td>20.0</td>
<td>&lt;0.64</td>
<td></td>
</tr>
</tbody>
</table>

Calculations are based on the FAO/WHO (2002) dose response model, adjusted by 3.5 for SAM children susceptibility.
Relationship between the numbers of samples analyzed and the probability of accepting a contaminated lot

<table>
<thead>
<tr>
<th>Number of sachets analyzed</th>
<th>Estimated likelihood (%) that the lot would be accepted if it had ( \geq 1 ) Salmonella/serving in 2% of the servings (%)</th>
<th>Estimated likelihood (%) that the lot would be accepted if it had ( \geq 1 ) Salmonella/serving in 0.5% of the servings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>98.0%</td>
<td>99.5%</td>
</tr>
<tr>
<td>2</td>
<td>96.0%</td>
<td>99.0%</td>
</tr>
<tr>
<td>5</td>
<td>90.4%</td>
<td>97.5%</td>
</tr>
<tr>
<td>20</td>
<td>66.8%</td>
<td>90.5%</td>
</tr>
<tr>
<td>50</td>
<td>36.4%</td>
<td>77.8%</td>
</tr>
<tr>
<td>100</td>
<td>13.3%</td>
<td>60.6%</td>
</tr>
<tr>
<td>149</td>
<td>5.0%</td>
<td>47.4%</td>
</tr>
<tr>
<td>598</td>
<td>&lt;0.01%</td>
<td>5.0%</td>
</tr>
</tbody>
</table>
Risk Management

Not about microbiological testing and criteria

but

(1) maintenance of good hygienic practices (GHPs)
(2) raw ingredient sourcing controls
(3) inclusion of appropriate intervention technologies,
(4) prevention of re-contamination.
Role of microbiological testing of foods or food ingredients

- An integral part of most food safety systems
- Specific approach dependent on the type of food safety management system that is being implemented
- For this product: Codex code of hygienic practice for low-moisture foods – focus on GHPs and HACCP

Two approaches to micro testing

- Lot-based testing (LBT) of end products (or key ingredients) as part of a “test and release” program for the ingredients or finished product
- Process control verification (PCV) testing as part of a company’s HACCP verification program.
Role of microbiological testing of foods or food ingredients

• Same microbiological method may be used in both, BUT the means of sampling and the interpretation/response to the results is distinctly different.

• Traditional end product testing - originally designed to examine lots of food (typically at ports-of-entry) for which there was little information available on how the food was manufactured.

• Modern food safety systems - there is or can be a wealth of information available concerning the history and handling of foods.
BUT still many manufacturers use “test and release programs.” - testing becomes a *de facto* critical control point.

**limiting factor (see slide 10)**

the number of samples needed to have confidence that one has actually identified a contaminated lot becomes very large when the percentage of servings that are contaminated falls below 2%. e.g. to be 95% confident that < 2% of RUF servings were free of salmonellae approximately 150 serving would need to be tested and found negative.
Process control and verification

- Rely on preventive controls and intervention technologies to ensure that microbiological hazards are controlled to a desired level of protection.

- A number of key processing metrics are “monitored” to ensure that the system is functioning within specifications - physical (e.g., temperature) or chemical (e.g., pH, water activity) in nature and can be done in “real-time.”

- Verification protocols that are performed periodically to ensure that the food safety system has not changed and is under control.
Parameters related to the attributes of a fit-for-purpose PCV program that have to be considered in terms

- What microorganisms should be tested for in a PCV program?
- Who should do the testing?
- What should be the frequency of testing?
- Where along the production process should the testing be performed?
- What corrective actions should be taken if PCV testing exceeds established levels?
- What is the role of environmental testing in PCV testing programs?
- What actions should be taken if a performance criterion for a PCV testing program is repeatedly exceeded.
Approach for RUF

*That depends*

*For whom and for what purpose?*
   Purchaser vs Producer

*Type /Status of food safety management system?* GHP, HACCP, ingredients control, Env monitoring specific interventions, kill steps etc

*Testing for what?* Pathogen vs indicator and how you test for these

*Use of results and actions to be taken*
Derivation of MC

2 Approaches

**Approach 1.** Existing criteria for similar product for the general population taking into consideration target population susceptibility
n= 10 x 25 g samples, c = 0

Population 3.5 times more susceptible
n= 30 x 25 g samples, c = 0

**Approach 2**

*Link to risk and acceptable level of protection*

Then can use information on dose response and exposure

More complex - 2 examples are under development