MICROBIAL SAFETY OF READY-TO-USE LIPID-BASED THERAPEUTIC AND SUPPLEMENTARY FOODS

Conclusions and Recommendations of an FAO/WHO Technical Meeting
Low moisture foods: Microbiological hazards

- RUTF and RUSF are categorized as low moisture foods
- Low water activity
  - Inhibits microbial growth
  - Does not kill microbial contaminants
  - May preserve them in a metabolically dormant state
Microbiological hazards associated with low moisture foods

• Many low moisture foods associated with outbreaks of foodborne disease, e.g.
  ▫ Peanut butter – salmonellosis, botulism
  ▫ Chocolate – salmonellosis
  ▫ Milk powder - salmonellosis
  ▫ Powdered infant formula – salmonellosis, Cronobacter
  ▫ Cereals (toasted or puffed) – salmonellosis
Purpose of meeting
FAO/WHO technical meeting in Rome, December 2012.

• Implications of finding *Cronobacter* in RUTF/RUSF
• Potential hazards of concern in these commodities, considering the intended consumer
• Guidance on the management of these hazards, including appropriate microbiological specifications
• Areas where further work/data are required
## Pathogens of greatest concern

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Potentially in ingredients</th>
<th>Potentially in processing environment</th>
<th>Potential will survive processing</th>
<th>Potentially pathogenic at low doses</th>
<th>Potential severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-typoidal <em>Salmonella</em></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>Serious</td>
</tr>
<tr>
<td><em>Salmonella</em> serovars</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Enterobacteriaceae</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>Variable</td>
</tr>
<tr>
<td><em>C. botulinum</em></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>Severe</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+/-</td>
<td>Serious</td>
</tr>
<tr>
<td><em>Bacillus cereus</em></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>Moderate</td>
</tr>
<tr>
<td><em>Enterotoxigenic Staph aureus</em></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>Moderate</td>
</tr>
<tr>
<td><em>C. perfringens</em></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>Moderate</td>
</tr>
</tbody>
</table>
Pathogens of greatest concern

- **Salmonella** – highest priority
  - Can persist in low moisture foods for months/years
  - No validated kill step in the process
  - Can cause illness at low doses (a few cells)
  - Causes severe illness in infants and young children (and elderly)
Salmonella - highest priority

• Recommendation: End product specifications for *Salmonella* should be enhanced
Pathogens of greatest concern

- *Cronobacter*
  - Can persist in low moisture products for years
  - No validated kill step in the production process
  - Susceptibility of consumers?
Cronobacter and population of concern

- Found in a wide range of foods
- Likely that most people ingest Cronobacter on a regular basis
- Clear attribution to food borne illness in high risk infants consuming reconstituted PIF held at temperatures which allow growth
*Cronobacter* and population of concern

- Few epidemiological studies on *Cronobacter* related illness
- Difficult to extrapolate to malnourished populations but
  - Risk of invasive illness is greatest in premature, very low birthweight babies and typical infants during the first two months of life
  - Meningitis risk linked to age-related development of blood brain barrier
  - Bacteraemia decreases with increasing age after age 1
Cronobacter and population of concern

- Very little information on infectious dose – Data suggest a high dose is needed
- Infection related to species and subtype
- Small number of reported cases compared to salmonellosis
- So lack of information
  - Still need to control
Cronobacter

• Conclusion: Probably does not present a greater risk than some other EB

• Recommendation: Control for the larger group of Enterobacteriaceae
Challenges in moving forward

- No evidence of illness attributed to RUTF/RUSF
  - Surveillance?
- Limited end product testing
  - Statistically insensitive sampling plan
- General increased susceptibility of malnourished populations
  - Implications for Cronobacter?
- Other potential pathogens
  - Data to quantify relative risk?
General conclusions

- RUTF and RUSF considered together – no specific data to warrant different approaches at the moment
Food Safety Control - Conclusions

- Existing microbiological criteria (MC) are inadequate
  - But MC do not in any way replace control during processing
  - MC serve a monitoring and verification purpose
- Manufacturers must maintain control of microbiological hazards
- No kill step thus dependent on microbiological quality of ingredients and implementation of GHPs throughout process
Recommendations to manufacturers

- Review existing control programmes
  - Facility design
  - Prerequisite programmes (environmental monitoring, zoning, training, management of airflow, water use and flow (including drainage), cleaning/sanitizing and maintenance procedures) GMP, GHP)
  - HACCP
Recommendations to manufacturers

- Undertake ingredient, environment, in-line and end-product surveillance
  - Establish baseline statistics
  - Monitor process control by reviewing trends
  - Continue to look into potential kill steps
  - Establish operational goals and plan reaction to marginal or non-conforming results.
  - Single use sachets
Revision of specifications

• Recommended a snapshot study to get some idea of the quality of the product
  ▫ Priority – Salmonella and EB (50 samples from 5 days of production)
## RUSF Results

<table>
<thead>
<tr>
<th>No of products tested</th>
<th>No of samples tested</th>
<th>Salmonella positive</th>
<th>EB (&lt; / \geq 10) cfu/g</th>
<th>EB (&gt; 10) cfu/g</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>401</td>
<td>2</td>
<td>394</td>
<td>7</td>
</tr>
</tbody>
</table>
### RUTF

<table>
<thead>
<tr>
<th>No of products tested</th>
<th>No of samples tested</th>
<th>Salmonella positive</th>
<th>EB $\leq 10$ cfu/g</th>
<th>EB $&gt; 10$ cfu/g</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>660</td>
<td>0</td>
<td>644</td>
<td>16</td>
</tr>
</tbody>
</table>

All those $> 10$ cfu/g were also positive for *Cronobacter sakazakii*.
Conclusions

• *Salmonella* can be present in such product
• As a serious pathogen in the consuming population controlling for *Salmonella* is critical
• Existing criteria for PIF indicate absence in 60 samples of 25 g (opportunity for growth after reconstitution)
• No growth in RUTF/RUSF so could consider a less stringent criterion – e.g. 30 samples
Conclusions

• Results of up to $10^4$ found in some samples – lack of control

• But many facilities can achieve levels of <10cfu/g

• Reasonable target
Establishing an MC for Salmonella

<table>
<thead>
<tr>
<th>Microorganism of concern</th>
<th>Non-typhoid <em>Salmonella</em> spp</th>
</tr>
</thead>
</table>
| Reason                  | Can persist in low moisture foods for months – years  
No validated kill step in the process  
Can cause illness at low doses  
Causes severe illness in infants and young children, ie consumer group of concern |
| Method                  | ISO 6579                     |
| No of samples           | 30 samples (analytical sample size of 25g) |
| Limit                   | Absence in 25g of all 30 samples |
| Food                    | RUTF and RUSF (end of processing) |
| Action for non conforming samples | Discard |
Application of an MC

- Apply to a lot/batch
- Clear definition of a batch
- One positive means all batch is discarded
- Reflection of control of ingredients and process
- As no kill step same criterion should apply to ingredients as end product.
Establishing an MC for EB

<table>
<thead>
<tr>
<th>Microorganism of concern</th>
<th>Enterobacteriaceae</th>
</tr>
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<tbody>
<tr>
<td>Reason</td>
<td>Can persist in low moisture foods for months – years</td>
</tr>
<tr>
<td></td>
<td>No validated kill step in the process</td>
</tr>
<tr>
<td></td>
<td>Opportunistic pathogens</td>
</tr>
<tr>
<td></td>
<td>Can cause illness in infants and young children, ie consumer group of concern</td>
</tr>
<tr>
<td>Method</td>
<td>ISO 21528</td>
</tr>
<tr>
<td>No of samples</td>
<td>???</td>
</tr>
<tr>
<td>Limit</td>
<td>10 cfu/g</td>
</tr>
<tr>
<td>Food</td>
<td>RUTF and RUSF (end of processing)</td>
</tr>
<tr>
<td>Action for non conforming samples</td>
<td>Discard</td>
</tr>
</tbody>
</table>
EB criteria

- Snapshot study highlighted relevance of such criteria
- Stringency of such criteria related to number of samples and type of sampling plan (2 or 3 class)
- Need to evaluate performance of different approaches
- Objective is to drive towards continual improvement.
Next steps.....

- More data will be useful (env monitoring, trend analysis etc)
- Finalise criteria that will drive continuous improvement – on-going improvement of ingredient and process control
- On-going review and revision including re-evaluation of MC in a year or so
Questions and discussions

Thank you