Infant and Medical Nutrition

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International Code for Marketing of Breast-Milk Substitutes

The International Code of Marketing of Breast-Milk Substitutes and other global nutritional principles set forth by the World Health Organization, the Codex Alimentarius, and UNICEF.

Breastmilk is the best source of nutrition for infants under 6 months. It is recommended that breastfeeding is continued along with appropriate complementary foods up to 2 years of age or beyond.
Infant and Medical Nutrition
Introduction

What is Medical Nutrition?

- Medical Nutrition comprises Total Parenteral (TPN) Infant + Special formula (IF), Enteral (EMN)
- Only the latter two segments utilize intact (dairy) protein
- EMN products can be oral/sip or tube feeds
- EMN and IF markets are of similar size allowing direct comparison of these two high added value markets
What is Infant Nutrition?

<table>
<thead>
<tr>
<th>Age (Months)</th>
<th>0</th>
<th>6</th>
<th>12</th>
<th>18</th>
<th>24</th>
<th>30</th>
<th>36</th>
</tr>
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<tbody>
<tr>
<td>Pregnancy</td>
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<td>Lactation</td>
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<td>Infant</td>
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<td>Older Infant</td>
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<tr>
<td>Young child</td>
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</tbody>
</table>

• Different countries define infant as 0-6 or 0-12 months
• Inconsistent naming of formula for different age groups
  — Infant (0-6 mths): Stage 1, Step 1, Infant
  — Older Infant (6-12+ mths): Stage 2, Step 2, Follow On/Up
  — Young Children (12-36+ mths): Stage 3, Step 3, Toddler/Growing Up Milk

Similarities between Infant and Enteral Medical Nutrition

• Global Infant Formula and Enteral Formula are similarly sized segments of Medical Nutrition
• Both segments are considered ‘high added value’
• Many shared market drivers
• Asia-Pacific is an important market for infant and enteral nutrition products
• Highly dependent on high quality protein – specifically dairy protein
• Importance attached to scientific support for formulations
• Segments share trends in new functional ingredients
• Growth in ‘developing’ markets dependent on imported product and know-how from established markets
Infant and Enteral Medical Nutrition Market Drivers

Shared Market Drivers of Infant and Enteral Medical Nutrition

<table>
<thead>
<tr>
<th>Driver</th>
<th>Infant</th>
<th>Enteral</th>
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</thead>
<tbody>
<tr>
<td>Population demographics</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Increased incidence of diagnosed disease</td>
<td>✔️</td>
<td>✔️</td>
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<tr>
<td>Convenience</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Increased costs of healthcare</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Importance of protein quality</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Links between nutrition and health</td>
<td>✔️</td>
<td>✔️</td>
</tr>
</tbody>
</table>
Threat Posed by Sarcopenia in Ageing Populations

- **Normal Sarcopenia**
  - 3-8% reduction in muscle mass/decade from 40 yrs
- **Advanced Sarcopenia**
  - Physical frailty
  - Increased risk of falls
  - Impairment of ability to perform routine activities
  - Loss of independence and free living
- BCAA especially Leu plays a critical role on muscle protein synthesis
- Whey protein is rich in Leu

<table>
<thead>
<tr>
<th>Bed Rest (d)</th>
<th>Age (y)</th>
<th>Muscle loss (kg)</th>
<th>Rate of Loss (g/d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young</td>
<td>28</td>
<td>38±8</td>
<td>-0.4±0.10</td>
</tr>
<tr>
<td>Middle aged</td>
<td>14</td>
<td>52±4</td>
<td>-1.1±0.14</td>
</tr>
<tr>
<td>Elderly</td>
<td>10</td>
<td>67±5</td>
<td>-0.9±0.15</td>
</tr>
</tbody>
</table>

Source: Paddon-Jones & Leidy, 2014

Infant and Enteral Medical Nutrition Market Characteristics
2016 Global Medical Nutrition Market

- Global Medical Nutrition market 2016 value ~ US$ 35Bln. (CAGR ~ 5.8%)
- Infant (0-6 mth + Special) largest segment at $15.9 Bln. (ca. 700,000 MT).
- Enteral valued at US$ 13Bln. (~ US$ 2 bln. retail sales; ~ 15% of market)
- Segments EMN & IF share major producers: Abbott, Danone, Nestlé, Mead Johnson, (Fresenius-Kabi)

2016 Infant Nutrition Market

- Global Infant Nutrition market valued at US$ 43.4 billion
- Infant $12.8 bln.; FOF $9.4 bln; GUM $17.4 bln
- NA accounts for 14% and China 40% of Infant Nutrition Market by value
Infant and Enteral Medical Nutrition
Similarities and Differences

Dairy ingredients critical in EMN and IF products

<table>
<thead>
<tr>
<th>Dairy Ingredient</th>
<th>Enteral</th>
<th>Infant</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid Milk</td>
<td>✓</td>
<td>✓</td>
<td>Must be of appropriate quality</td>
</tr>
<tr>
<td>Skimmed Milk Powder</td>
<td>✓</td>
<td></td>
<td>Often used in IF, less so in EMN</td>
</tr>
<tr>
<td>MPC/MPI</td>
<td>✓</td>
<td></td>
<td>Preferred over caseinate in new products</td>
</tr>
<tr>
<td>Caseinate</td>
<td></td>
<td></td>
<td>No lactose and heat stable</td>
</tr>
<tr>
<td>WPC/WPI</td>
<td>✓</td>
<td>✓</td>
<td>In 50% of IF; fastest growing ingredient in EMN</td>
</tr>
<tr>
<td>Demineralized Whey</td>
<td></td>
<td>✓</td>
<td>Alternative to WPC in IF; Demand and Supply</td>
</tr>
<tr>
<td>Lactose</td>
<td></td>
<td></td>
<td>Needed in WPC-based IF recipes</td>
</tr>
<tr>
<td>GOS</td>
<td></td>
<td>✓</td>
<td>Trending functional ingredient</td>
</tr>
<tr>
<td>Hydrolyzed Dairy Protein</td>
<td></td>
<td></td>
<td>Technical and nutritional benefits</td>
</tr>
</tbody>
</table>

- Most standard IF is based on skimmed milk (liquid or powder) with added whey (demineralized whey powder or WPC)
- Most standard EMN is based on MPC/MPI or caseinate often supplemented with WPC/WPI and/or SPI
Summary of Key Similarities and Differences

**Infant Nutrition**

- **Similarities**
  - Market size - Infant & Enteral
  - Mostly based on milk protein
  - Complete or supplemental Nutrition

- **Differences**
  - Prescriptive, strict regulation
  - Nutrient requirement for IF NOT met by cow’s milk
  - 90% powder, 10% RTF

**Medical Enteral Nutrition**

- **Similarities**
  - Market size - Infant & Enteral
  - Mostly based on milk protein
  - Complete or supplemental Nutrition

- **Differences**
  - Generally less regulated
  - Nutrient requirement met by cow’s milk
  - ~75% RTF, 25% powder

Infant Nutrition Regulations

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<td>EC2016-127 Annex II</td>
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<td>21CFR106, 107</td>
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2019 ADPI Dairy 360
Primary Dairy Ingredients differ between IF and EMN

**Infant Formula (0-6 mths)**
- Adjusted whey:casein ratio from 20:80 of cow’s milk to 60:40 of breast milk
- Base = fluid milk or SMP/NFDM
- Mineral content of added whey must be low: WPC50+ or DWP 70/90.
- WPC widely available; DWP limited - mostly produced in Europe; demand vs supply

**Standard Enteral Formula**
- EMN formerly predominantly caseinate-based but new products now mostly use better tasting MPC/mpi
- Caseinate persists in lactose-free & high protein formulations
- Increasingly WPC/WPI included in new products, replacing soy
- Whey protein preferred:
  - Protein quality DIAAS
  - High BCAA & Leucine content
  - Scientific evidence

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**Analysis of EMN new product ingredients**

- Ingredient information was analyzed in 640 oral and 237 tube feed new product launches
- Milk protein preparations (MPC, MPI and micellar casein) were the most frequently listed proteins followed by caseinate
- WPC/WPI occurred almost as frequently as caseinate in oral and was the most common protein in tube feed
- Soy protein was listed 128 times but only as secondary protein
- The trend is clearly towards MPC and WPC

Source: US Dairy Expert Council; Innova
### Rough Estimates of Dairy Protein Requirement Infant vs. Enteral

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<tr>
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<th>IF + FOF</th>
<th>Enteral</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016 Global Volume (YOY) MT</td>
<td>1,300,000 (88,500)</td>
<td>1,320,000 (77,000)</td>
</tr>
<tr>
<td>2016 Global Protein req’d (YOY) MT</td>
<td>156,000 (10,600)</td>
<td>111,900 (6,500)</td>
</tr>
<tr>
<td>Demin 90 - DWP req’d (YOY) MT</td>
<td>351,000 (24,000)</td>
<td></td>
</tr>
<tr>
<td>WPC80 req’d (YOY) MT</td>
<td>47,000 (3,100)</td>
<td>35,000 (2,000)</td>
</tr>
<tr>
<td>Lactose req’d (YOY) MT</td>
<td>293,000 (20,000)</td>
<td></td>
</tr>
<tr>
<td>SMP req’d (YOY) MT</td>
<td>73,500 (5,000)</td>
<td>56,000 (3,300)</td>
</tr>
</tbody>
</table>

**Assumptions:**
- Infant: 2.4-2.5g/100kcal (av. 12% protein; 52:48 split DWP:WPC recipes; CAGR = 6.8%; 100% powder
- Enteral: Volume based on retail having 15% share; 60:40 RTD/RTM; RTD @ av. 9g protein/250mL serving; protein split 25:40:25 WPC80:MPC80:Caseinate; CAGR 5.84%

Source: Industry Experts; Euromonitor

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### Infant and Enteral Medical Nutrition Innovations and Trends
Trends in Functional Ingredients
Infant & Enteral Medical Nutrition

<table>
<thead>
<tr>
<th>Functional Ingredient</th>
<th>Infant</th>
<th>Enteral</th>
<th>Claimed Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrolysed protein</td>
<td></td>
<td></td>
<td>Easy to digest/reduced viscosity</td>
</tr>
<tr>
<td>GOS/FOS</td>
<td></td>
<td></td>
<td>Prebiotic/Immune support</td>
</tr>
<tr>
<td>ARA/DHA/Omega lipids</td>
<td></td>
<td></td>
<td>Immune support</td>
</tr>
<tr>
<td>Lactoferrin</td>
<td></td>
<td>?</td>
<td>Mimic breast milk, Immune support</td>
</tr>
<tr>
<td>Phospholipids (WPPC, MFGM)</td>
<td></td>
<td>?</td>
<td>Immune support/cognitive function</td>
</tr>
<tr>
<td>α-lactalbumin</td>
<td></td>
<td></td>
<td>Mimic breast milk, catch up growth</td>
</tr>
<tr>
<td>Probiotics</td>
<td></td>
<td></td>
<td>Immune support</td>
</tr>
<tr>
<td>Sialic acid</td>
<td></td>
<td>?</td>
<td>Cognitive function/Immune support</td>
</tr>
</tbody>
</table>

- EMN and IF show similar trends in inclusion of functional ingredients
- Product differentiation is an important driver for manufacturers
- Mimicking breast milk is a guiding light for functional ingredient choice in IF

Innovations and Trends
Infant Nutrition

Convenience – Single Serving RTF

Organic Formula

Convenience – Formula Machine

Month Specific Formula Capsules

Photos: FoodBabe.com; Gerber.com; survivemag.com; amazon.com
Innovations and Trends
Enteral Medical Nutrition

Appealing – More like real food

To appeal to senior adult consumers, medical nutrition products must be:

- Available in a range of:
  - dosages
  - flavors
  - textures
  - nutritional values

- As “foodly” as possible
- Easy to integrate at meal times

Convenience – Single Serve YOcrème

Plant Protein-based Products

Photos: Nutrition Insight; Fresenius Kabi

Innovations and Trends
Infant and Medical Nutrition
Closing Remarks

Photos: AXS Imaging

2019 ADPI Dairy 360
Concluding Remarks

• Enteral Medical and Infant Formula (0-6 mths) are similarly sized markets; ageing population is growing faster than infants
• Many shared attributes: market drivers, critical dairy ingredients, importance of protein quality, scientific efficacy, functional ingredient trends
• There are differences in base dairy ingredients - fluid milk/SMP/NFDM vs. MPC/MPI/caseinate - in infant and medical enteral formulations
• Whey protein is a common and critical component in both value-added segments
• Infant is highly regulated compared to Enteral Medical

Thank you for your attention!

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