ILSI Meeting on Maternal and Infant Nutrition - New Australian Research and More

Quality and safety of food products in maternal and infants nutrition

Melbourne, August 19, 2014

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Sen. Vice President Nutrition Science & Advocacy
From maternal to infant nutrition: Each phase requires adequate nutrition

The first 1,000 days and beyond:
A window of opportunity for nutrition to set the stage for life-long health
Tailored products are available for the different phases
Safety and quality is a sensitive topic
Consumers are concerned ...

• But concerned also means interested in knowing more, even paying more
• Consumers want the information on how food is produced, where, by whom, …
• Reassurance on food safety & quality from
  • Scientific and political authorities
  • Reliable food brands & companies
  • Key opinion makers (NGOs)
  • Media

Parents are most concerned about the well-being of their children – every time and everywhere!
The food chain is complex: safety & quality matters everywhere

...and different stakeholders have to be taken care of...
Quality Management at an Infant Food Ingredient Manufacturer has to take care of

- Regulatory Environment, which gets more and more demanding
- Increasing number of markets, requiring proof of effect for new ingredients
- In many countries, laws and regulations require food chain stakeholders to have systematic structures and standard process controls in place
A number of risks have to be managed continuously to guarantee product safety

- Allergen risks
- Dry process: avoidance of water
- Hygiene: constant hygiene and hygienic training
- Zoning concept for people, material, waste, areas
- Extended testing for contamination
- ....
The big eight allergens to consider

Allergy is a growing issue globally!
Integrated approach for allergen management

- Identification and segregation (raw material check, “may contain..”)
- Prevention of cross contamination
- Confirm cleaning efficacy by testing
- Product label review
- Personal awareness and training
Allergic life starts at the earliest age and is related to diet

...and is a life long topic!
Why all the concern about hygiene?

- Dust and dirt are carriers for bacteria and viruses
- A visual clean area is to 80% a microbiological clean area. The remaining 20% is removed by sanitization
Examples for lack of quality: From inconvenient to dangerous

- **Vitamin E**
  - Ease of handling

State-of-the-art

Lumps
Poor flowability

- **Enterobacter cloacae**
  - Found in 25g

- **Bacillus Cereus**
  - Found in 1g

- **Bacillus Subtilis/Bacillus Licheniformis**
  - Already found in 0.01g!

- **Enterobacter Sakazakii**
  - Found in 10g

- **Bacillus Cereus**
  - Found in 1g

- **Enterobacter Sakazakii**
  - Negative in 10g

- **Bacillus Cereus**
  - Negative in 1g

- **No counts (<100 CFU/g)**

State-of-the-art
Examples for lack of quality: From inconvenient to dangerous

**Vitamin E**
**Ease of handling**
- State-of-the-art
- Lumps Poor flowability

**Vitamin E**
**Microbiological purity**
- No counts (<100 CFU/g)
- Bacillus Cereus Found in 1g
Examples for lack of quality: From inconvenient to dangerous

**Vitamin E**
**Ease of handling**
- State-of-the-art
- Lumps
- Poor flowability

**Vitamin E**
**Microbiological purity**
- No counts (<100 CFU/g)
- Bacillus Cereus
- Found in 1g

**Vitamin A**
**Microbiological purity**
- Bacillus Cereus
- Negative in 1g
- Enterobacter Sakazakii
- Negative in 10g
- Enterobacter cloacae
- Found in 25g
- Enterobacter Sakazakii
- Found in 10g
- Bacillus Cereus
- Found in 1g
- Bacillus Subtilis/
- Bacillus Licheniformis
- Already found in 0.01g!
The requirements develop further to encompass integrated approaches

- **Goal of European Commission's Food Safety Policy:**
  
  ⇒ *ensure a high level of protection of human health and consumers' interests in relation to food.*

- **European Commission's guiding principle:**
  
  ⇒ *apply an integrated approach from farm to table covering all sectors of the food chain, including feed production, primary production, food processing, storage, transport and retail sale.*
A systematic implementation of quality-related legal and regulatory requirements is needed

- To ensure a systematic implementation of quality-related legal and regulatory requirements, certifications towards well-known standards are useful.

- The ISO 9001 standard is a generic industry-independent standard that is further derived into different industry-specific standards to facilitate, e.g., food chain companies to comply with the various applicable regulatory and industry-specific requirements.
The impact of quality issues: loosing trust at consumers and stock market

Product recall due to melamine contamination…
…50% drop in share price!

Source: Google Finance

MENU FOODS (supplier of Wal-Mart, Safeway and other retailers in USA)
Quality over the full value chain is our commitment

DSM Nutritional Products

- Raw material sourcing
  - Verification of traceability certificates
  - Vendor audits

- Production
  - Full traceability with Quality systems and processes
  - Recall and tracking exercises

- Distribution
  - Full traceability with SAP and bar coding systems

![DSM Nutritional Products diagram](image-url)
A quality issue can start small and generate a huge impact.

Quality is a key differentiator and the responsibility of the industry.
Example: Quality certificates

<table>
<thead>
<tr>
<th>Quality management</th>
<th>ISO 9001/14001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food</td>
<td></td>
</tr>
<tr>
<td>✓ EU food safety regulation</td>
<td></td>
</tr>
<tr>
<td>✓ Kosher/Halal</td>
<td></td>
</tr>
<tr>
<td>✓ NSF</td>
<td></td>
</tr>
<tr>
<td>✓ HACCP</td>
<td></td>
</tr>
<tr>
<td>✓ FDA (infant formula)</td>
<td></td>
</tr>
<tr>
<td>✓ Japan Food Additive Reg.</td>
<td></td>
</tr>
<tr>
<td>Feed</td>
<td></td>
</tr>
<tr>
<td>✓ EU food safety regulation</td>
<td></td>
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<tr>
<td>✓ FAMI -QS</td>
<td></td>
</tr>
<tr>
<td>✓ HACCP</td>
<td></td>
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<tr>
<td>✓ GMP+</td>
<td></td>
</tr>
<tr>
<td>✓ GRAS</td>
<td></td>
</tr>
<tr>
<td>Personal Care</td>
<td></td>
</tr>
<tr>
<td>✓ EU Cosmetic directive</td>
<td></td>
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<tr>
<td>✓ EFfCI</td>
<td></td>
</tr>
<tr>
<td>✓ FDA (21CFR210/211-UV filter)</td>
<td></td>
</tr>
<tr>
<td>Pharma</td>
<td></td>
</tr>
<tr>
<td>✓ ICH Q7A, IPEC</td>
<td></td>
</tr>
<tr>
<td>✓ CEP, DMF</td>
<td></td>
</tr>
<tr>
<td>✓ GMP certificates by authorities</td>
<td></td>
</tr>
<tr>
<td>✓ Japan Pharmacopoeia</td>
<td></td>
</tr>
<tr>
<td>Sustainability</td>
<td></td>
</tr>
<tr>
<td>✓ ISO 14001 – Environment protection</td>
<td></td>
</tr>
<tr>
<td>✓ Dow Jones Sustainability Index leader</td>
<td></td>
</tr>
<tr>
<td>✓ CSR – Social Accountability</td>
<td></td>
</tr>
<tr>
<td>✓ Global Safety Program</td>
<td></td>
</tr>
<tr>
<td>✓ JAS – Agricultural Standard</td>
<td></td>
</tr>
</tbody>
</table>
Example: GMP Milestones

- GMP for all vitamins
- Successful inspections by authorities (Pharma and Food): FDA, NVWA, Swiss Medic, UNISA...
Example: Care for safety & traceability in all DSM food plants

FS22000 Certification

Certificate

The Food Safety Management System of

DSM Nutritional Products France SAS
Boulevard d'Alsace
FR-68305 Saint-Louis Cedex

has been assessed and complies with

FSSC 22000:2009

This certificate is applicable for:

Category L: Ingredients

Field of activity
Production of customized Blends for Human Consumption

This certificate is provided based on the FSSC 22000 certification scheme. The certification system consists of an annual audit of the food safety management system and an annual verification of the PRP elements as included in the scheme and the PAS 220.

Swiss Association for Quality and Management Systems SQS
Breisgauer Str. 170, CH-5522, Zollikfen
Issue date: July 16, 2016

This SQS Certificate is valid up to and including July 29, 2018
Scope: Location, Site 12
Registration number 30835
We also care for societal and cultural diversity: example Halal

We are committed to offer products respectful of Halal rules:

- Halal Certification Audits
- Use of Halal raw material

...and got Halal Certification

DNP works with 3 different organisations to for Halal certification:

- HFCE (Halal Food Council of Europe)
- IFANCA (Islamic Food and Nutrition Council of America)
- MUI (Majelis Ulama Indonesia)
We also care for societal and cultural diversity: example Kosher

We are committed to offer products respectful of Kosher rules:

- Kosher Audits
- Schedule of Kosher Production Campaigns: cleaning according to Kosher rules and presence of a Rabbi.
- Kosher for Passover on request.
We engage for nutrition as an important element to ensure a healthy for pregnant mothers and infants

- Folic acid and NTD is the classical case
- PUFAs are important for brain development
- Vitamin A is essential for organogenesis -/ differentiation
- Lutein is a critical nutrient in infant formulas
- Vitamin D deficiency is common, and newborns and their mothers are at high risk.

Inadequate (micro) nutrient status is considered a risk factor for development of chronic diseases later in life
Lutein is the predominant carotenoid in human milk

Compared to plasma lutein and zeaxanthin are the major carotenoids in human milk

References:
Jackson, JG et al 1998
Lutein is positioned in the infant brain

- Infant brain doubles in size in the third trimester
- 75% of brain growth occurs during first year
- L & Z make up approximately 66-77% of the total carotenoid concentration in the brain.
- L and Z are positioned in regions of the brain that are specialized for:
  - Visual processing
  - Memory
  - Learning
  - Language

References:
Lutein is the predominant carotenoid in infant brain

Vishwanathan, R., et al. (2014). "Lutein is the predominant carotenoid in infant brain: Preterm infants have decreased concentrations of brain carotenoids." Journal of Pediatric Gastroenterology and Nutrition. accepted

Results:
in all brain regions tested the amount of lutein was up to 3-4 fold higher than the other carotenoids present

Conclusions:
These data reveal a preferential accumulation and maintenance of lutein in the infant brain despite under-representation in the typical infant diet.
LZ content drops in unfortified formula fed infants

Formula- and breast-fed infants start with similar L&Z plasma concentration at birth.

After one month, L&Z increases in breast-fed infants, declines in unfortified infant formula-fed.

Implies that retinal levels in formula-fed infants may be low (see xanthophyll-deprived monkeys by Leung et al., 2004).

Similar trends observed for other infant plasma carotenoids (β-carotene, lycopene, cryptoxanthin).

Similar trends observed for all infant plasma carotenoids: Increasing over time in breast-fed, decreasing in formula-fed infants.

Plasma lutein and zeaxanthin concentrations at birth and one month of age for breastfed and formula-fed infants.

References:
Zimmer and Hammond, 2007
Preterm infants are highly susceptible to retinopathy of prematurity (ROP), an eye disease which may result in ocular abnormalities, deficits in visual function and blindness.

Breast-fed preterm infants have a lower incidence of ROP.

Human milk has many antioxidant constituents including Lutein, vitamin E, and beta-carotene that may protect against the development of ROP.

Preterm infants fed lutein-supplemented formula have healthier vision as measured by rod sensitivity.

<table>
<thead>
<tr>
<th>Human milk</th>
<th>ROP absent (%)</th>
<th>(n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>64.7 (11)</td>
<td></td>
</tr>
<tr>
<td>80–99%</td>
<td>53.6 (15)</td>
<td></td>
</tr>
<tr>
<td>20–79%</td>
<td>60.0 (23)</td>
<td></td>
</tr>
<tr>
<td>&lt;20%</td>
<td>62.5 (10)</td>
<td></td>
</tr>
<tr>
<td>Formula</td>
<td>36.5 (27)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>49.4 (86)</td>
<td></td>
</tr>
</tbody>
</table>

Percentage of Infants with ROP by Human Milk Groups
Four categories of human milk feedings and formula by the four stages of ROP. There were no cases of stage 3 or 4 ROP among VLBW infants who were exclusively human milk-fed or who were fed at least 80% human milk. Adapted from Hylander et al., 2001

References:
Hylander et al, 2001; Rubin et al, 2011
Safe use of Lutein for infants and young children

Below the age of 2 years, lutein appears to be the major pigment.

16-week prospective, randomized, controlled, and double-blind study in 232 healthy term infants fed either control formula or experimental formula fortified with lutein at 200 mcg/l.

Safety was assessed through monitoring of study events (SEs) throughout the study and evaluation of selected blood chemistry tests performed at Week 16.

The lutein-fortification level of 200 mcg/l corresponds to the high end of the range of observed breast milk values and potentially could maximize functional effects to infants without any safety risk.

References:
As science-based company we stimulate science, consensus meetings and communication

Expert workshop in Singapore:

- Current information and Asian perspectives on long chain polyunsaturated fatty acids in pregnancy, lactation and infancy
- Systematic review and practice recommendations from the Early Nutrition Academy workshop in press

Participants:

- B Koletzko, Germany
- C Boey, Malaysia
- C Campoy, Spain
- S Carlson, USA
- N Chang, S. Korea
- Y Su, China
- S Joshi, India
- S Quak, Singapore
- D Rusli Sjarif, Indonesia
- S Supapannachart, Thailand
- Y Yamashiro, Japan
- S Osendarp, Netherlands
- M Guillermo-Tuazon, Philippines
Recommendations for DHA intake during pregnancy have increased

- Pregnant women should consume at least 300 mg of DHA per day.
- Higher doses of 600-800mg DHA per day may provide greater protection against early preterm birth.
- The need for LCPUFAs begins before pregnancy.

(Presented by B Koletzko at the Early Nutrition Academy Meeting Munich 2014)
Practice recommendations from the Early Nutrition Academy workshop: Lactation

Breast feeding is recognized as the preferred choice for infant feeding

**Recommendation for the breast feeding women**
- get a minimum of 200 mg of DHA per day to achieve a breast milk content of 0.3% of fatty acids

**Recommendation for the term infant**
- 100 mg of DHA + 140 mg of ARA per day and thus at least 0.3% of fatty acids as DHA along with ARA

**Recommendations for the very low birth weight infant**
- **Reasonable intakes:**
  - 18-60 mg DHA per day and 18-45 mg per day ARA;
  - EPA should not exceed 20 mg
- **Higher intakes of DHA and ARA appear preferable**
  - 55-60 mg/kg/d DHA (≈1% TFA) + 35-45 mg/kg/d ARA (≈ 0.6-0.75% TFA)

(Presented by B Koletzko at the Early Nutrition Academy Meeting, Munich 2014)
Every child has the right to healthy, nutritious and safe food. 

Especially during the critical first 1,000 days
In summary: We are committed to making a difference

- Pioneer in developing nutritional ingredients
- 100+ scientific publications (2008-2013)
- Partner in World Food Programme
- Not-for-profit nutrition think-tank and humanitarian initiative
Thank you!

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