Review of Nutrition & Health Claims Regulation in Europe and the World – Lessons Learned for Probiotic Claims

Lina Paulionis, MSc, MHSc, RD
Senior Scientific and Regulatory Consultant
Food and Nutrition Group

February 7, 2012
Sheraton Brussels Hotel, Belgium
Overview of Presentation

- Background – Canada *versus* the United States (U.S.) *versus* the European Union (EU)
  - Claim categories
  - Claim approval requirements
  - Scientific standard for claim substantiation
- Lessons Learned about Probiotic Claims - Canada *versus* U.S. *versus* Japan *versus* EU
What is a Probiotic?

- Probiotics are "live microorganisms which when administered in adequate amounts confer a health benefit on the host" (FAO/WHO, 2001)
## Health Claim Categories - Foods and Supplements - in 3 major jurisdictions

<table>
<thead>
<tr>
<th>Country</th>
<th>Health Claim Categories</th>
</tr>
</thead>
</table>
| Canada  | 1. Disease Risk-reduction (DRR) Claims*  
2. Therapeutic Claims*  
3. Function Claims*  
4. Nutrient Function Claims  
5. General Health Claims |
| USA     | 1. Structure/Function (S/F) Claims**  
2. Authorized Health Claims (NLEA; FDAMA – foods only)  
3. Qualified Health Claims |
| EU      | 1. Article 13 (1) Claims  
2. Article 13 (5) Claims  
3. Article 14 (1)(a) Claims (Reduction of disease risk factor)  
4. Article 14 (1)(b) Claims (Children’s Health and Development) |

*Although all 5 categories apply to food, only categories 1 to 3 apply to Natural Health Products (NHPs); ** Not considered “health claims” in the U.S.

NLEA=Nutrition Labeling and Education Act; FDAMA=Food and Drug Administration Modernization Act
## Do Claims Require Approval?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Foods</strong>: DRR Claims, Therapeutic Claims</td>
<td></td>
</tr>
<tr>
<td><strong>NHPs</strong>: DRR Claims, Therapeutic Claims, S/F Claims</td>
<td><strong>Foods</strong>: Function Claims, Nutrient Function Claims, General Health Claims</td>
</tr>
<tr>
<td><strong>Authorized Health Claims, Qualified Health Claims</strong></td>
<td><strong>S/F Claims</strong>*</td>
</tr>
<tr>
<td><strong>Article 13(1), 13(5), 14(1)(a), 14(1)(b) claims</strong></td>
<td><strong>Not applicable</strong></td>
</tr>
</tbody>
</table>

DRR=Disease Risk Reduction; S/F=Structure/Function  
* For dietary supplements, a notification to the FDA is required no later than 30 days following market introduction.
### Does More than One Scientific Substantiation Standard Exist?

<table>
<thead>
<tr>
<th>Scientific Standard</th>
<th>Applicable Claim Category</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Foods</strong></td>
<td>DRR, Therapeutic, Function claims</td>
</tr>
<tr>
<td>High level of certainty</td>
<td></td>
</tr>
<tr>
<td><strong>NHPs</strong></td>
<td>DRR, Therapeutic, S/F claims</td>
</tr>
<tr>
<td>Relevant and mostly of high quality</td>
<td></td>
</tr>
<tr>
<td><strong>Foods and Dietary Supplements</strong></td>
<td>S/F claims</td>
</tr>
<tr>
<td>Competent &amp; reliable scientific evidence</td>
<td>Authorized Claims (NLEA, FDAMA)</td>
</tr>
<tr>
<td>Significant Scientific Agreement (SSA)</td>
<td>high level of confidence in claim validity</td>
</tr>
<tr>
<td>&lt;SSA</td>
<td>Qualified Claims</td>
</tr>
<tr>
<td><strong>Foods and Food Supplements</strong></td>
<td>Article 13(1), 13(5), 14(1)(a), 14(1)(b) claims</td>
</tr>
<tr>
<td>Highest possible standard &amp; generally accepted scientific evidence</td>
<td></td>
</tr>
</tbody>
</table>
• Lesson # 1 – There are probiotic health claim opportunities in Canada for both foods and natural health products (NHPs)
<table>
<thead>
<tr>
<th>Product Category</th>
<th>Eligible Microorganisms</th>
<th>Eligible Claims*</th>
<th>Conditions for Use</th>
<th>Substantiation Requirements</th>
<th>Approval Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foods</td>
<td><em>B. adolescentis; B. animalis subsp. animalis; B. animalis subsp. lactis; B. bifidum; B. breve; B. infantis; B. longum</em> &lt;br&gt; L. acidophilus; L. casei; L. fermentum; L. gasseri; L. johnsonii; L. paracasei; L. plantarum; L. rhamnosus; L. salivarius</td>
<td>“Probiotic that naturally forms part of the gut flora.” &lt;br&gt; “Provides live microorganisms that naturally form part of the gut flora/contribute to healthy gut flora.” &lt;br&gt; “Probiotic that contributes to healthy gut flora.”</td>
<td>At least 1.0 x 10⁹ cfu of one or more eligible microorganisms per serving &lt;br&gt; Must declare genus, species and strain in labelling</td>
<td>None</td>
<td>No</td>
</tr>
<tr>
<td>Others (i.e., not mentioned above)</td>
<td>Any – so long as claim is valid and claim wording is specific</td>
<td>Based on strain-specific human efficacy evidence &lt;br&gt; Must declare genus, species and strain in labelling</td>
<td>Yes – strain-specific human efficacy evidence required</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B. = Bifidobacterium; L. = Lactobacillus; cfu = colony forming units  
* The word ‘gut’ can be replaced with ‘digestive tract’
### Canada – NHPs

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Eligible Microorganisms</th>
<th>Eligible Claims</th>
<th>Conditions for Use</th>
<th>Substantiation Requirements</th>
<th>Approval Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHPs</td>
<td><em>B. adolescentis; B. animalis</em> subsp. <em>animalis; B. animalis</em> subsp. <em>lactis; B. bifidum; B. breve; B. infantis; B. longum</em>&lt;br&gt;<em>L. acidophilus; L. casei; L. fermentum; L. gasseri; L. johnsonii; L. paracasei; L. plantarum; L. rhamnosus; L. salivarius</em></td>
<td>“Probiotic that forms/contributes to a natural healthy gut flora.”&lt;br&gt;“Probiotic to benefit health and/or to confer a health benefit.”&lt;br&gt;“Provides live microorganisms that form part of a natural healthy gut flora/that contribute to a natural healthy gut flora/benefit health/confer a health benefit.”</td>
<td>1.0 x 10^7 cfu to 1.0 x 10^{11} cfu of one or more eligible microorganisms per day</td>
<td>Strain identification using genotypic and phenotypic methods&lt;br&gt;Safety data</td>
<td>Yes</td>
</tr>
</tbody>
</table>

B. = Bifidobacterium; L. = Lactobacillus; cfu = colony forming units; NHPs = Natural Health Products
# Canada – NHPs cont’d

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Eligible Microorganisms</th>
<th>Eligible Claims</th>
<th>Conditions for Use</th>
<th>Substantiation Requirements</th>
<th>Approval Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHPs</td>
<td><em>L. amylovorus</em>; <em>L. reuteri</em>; <em>Saccharomyces boulardii</em></td>
<td>“Probiotic to benefit health and/or to confer a health benefit.” “Provides live microorganisms to benefit health and/or to confer a health benefit.”</td>
<td>1.0 x 10^7 cfu to 1.0 x 10^11 cfu of one or more eligible microorganisms per day</td>
<td>Strain identification using genotypic and phenotypic methods Safety data</td>
<td>Yes</td>
</tr>
<tr>
<td>NHPs</td>
<td><em>L. Johnsonii La1</em> or <em>L. Johnsonii Lj1</em></td>
<td>“An adjunct to physician-supervised antibiotic therapy in patients with Helicobacter pylori infections.”</td>
<td>1.25 x 10^8 to 3.6 x 10^9 cfu/day Must declare genus, species and strain in labelling</td>
<td>Strain identification using genotypic and phenotypic methods Safety data</td>
<td>Yes</td>
</tr>
</tbody>
</table>

B. = Bifidobacterium; L. = Lactobacillus; cfu = colony forming units; NHPs = Natural Health Products
## Canada – NHPs cont’d

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Eligible Microorganisms</th>
<th>Eligible Claims</th>
<th>Conditions for Use</th>
<th>Substantiation Requirements</th>
<th>Approval Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHPs</td>
<td><em>L. Rhamnosus GG</em></td>
<td>“Helps to manage acute infectious diarrhoea.”</td>
<td>6.0 x 10^9 to 1.2 x 10^{10} cfu/day</td>
<td>Strain identification using genotypic and phenotypic methods</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“Helps to manage antibiotic-associated diarrhoea.”</td>
<td>1.0 x 10^{10} to 2.0 x 10^{10} cfu/day</td>
<td>Safety data</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>“Helps to reduce the risk of antibiotic-associated diarrhoea.”</td>
<td>1.0 x 10^{10} to 2.0 x 10^{10} cfu/day</td>
<td>Safety data</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Must declare genus, species and strain in labelling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NHPs</td>
<td><em>Saccharomyces boulardii</em></td>
<td>“Helps to reduce the risk of antibiotic-associated diarrhoea.”</td>
<td>1.0 x 10^{10} to 3.0 x 10^{10} cfu/day</td>
<td>Strain identification using genotypic and phenotypic methods</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Must declare genus, species and strain in labelling</td>
<td>Safety data</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NHPs</td>
<td>Others – i.e., not mentioned above</td>
<td>Any – so long as claim is valid</td>
<td>Based on strain-specific human efficacy evidence</td>
<td>Efficacy evidence, strain identification, safety data</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Must declare genus, species and strain in labelling</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B. = Bifidobacterium; L. = Lactobacillus; cfu = colony forming units; NHPs = Natural Health Products
• Lesson # 2 - Guidance exists to understand the evidence requirements for health claim substantiation and/or health claim approval – generally and for probiotics
• Food

  • Guidance Document – Use of Probiotic Microorganisms in Food (Health Canada, 2009)
  
  • Accepted Claims about the Nature of Probiotic Microorganisms in Food (Health Canada, 2009)
  
  • Guidance Document for Preparing a Submission for Food Health Claims (Health Canada, 2009)
  
  • Guidance Document for Preparing a Submission for Food Health Claims Using an Existing Systematic Review (Health Canada, 2011)
• NHPs
  • *Product Licensing Guidance Document* (Health Canada, 2006)
  • *Evidence for Safety and Efficacy of Finished Natural Health Products* (Health Canada, 2006)
  • *Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats* (Health Canada, 2010)
  • *Product License Applications for Natural Health Products Containing Probiotics* (Health Canada, 2010)
  • *Product Monographs – Probiotics* (Health Canada, 2011)
Lesson # 3 – There is a tolerance for health claims based on “emerging evidence” in Canada
• Lesson # 1 – There are probiotic claim opportunities in the U.S. for both foods and dietary supplements; however, there does not exist a list of acceptable claims
• There is no list of acceptable/approved probiotic claims in the U.S.
  
  • No NLEA-authorized, FDAMA-authorized or Qualified claims exist for probiotics (all these claims would be publicly listed if they were approved)
  
  • S/F claims in the U.S. do not require FDA’s approval (manufacturers of dietary supplements must, however, notify FDA of these claims); as such, these claims are not publicly listed
Lesson # 2 - Guidance exists to understand the evidence requirements for substantiation in the U.S. for some but not all claim categories (e.g., lacking for S/F claims made on foods)
• **Dietary Supplements**
  
  • **Guidance for SSA claims**
    
    
    • 21 CFR 101.14
  
  • **Guidance for S/F claims**
    
    
    
    • Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act
U.S. - Lesson # 2 cont’d

• **Foods**
  
  • **Guidance for SSA Claims**
    
    
    • *Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body* (U.S. Food and Drug Administration, 2009)
    
    • 21 CFR 101.14
  
  • **Guidance for S/F claims**
    
    • None exists!
    
    • Learn from Federal Trade Commission case orders ([www.ftc.gov](http://www.ftc.gov)) – see The Dannon Company, Inc. cases regarding DanActive and Activia
Lesson # 3 - There is a tolerance for claims based on "emerging evidence" in the U.S.

- Structure/Function claims
- Qualified Health Claims
Japan – Lesson # 1

• Lesson # 1 – There are probiotic health claim opportunities in Japan (FOSHU)
Japan - Lesson # 1 cont’d

• **FOSHU** = Foods for Specified Health Uses
  • Approval required and conducted by the Consumers Affairs Agency
  • Approval is product-based/product-specific
  • As of August, 2010, there were 954 products with FOSHU status in Japan
<table>
<thead>
<tr>
<th>Product /Manufacturer</th>
<th>Eligible Microorganisms</th>
<th>Eligible Claim</th>
<th>Conditions for Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yogurt (Meiji)</td>
<td>Lactobacillus delbrueckii subsp. bulgaricus 2038 and streptococcus salivarius subsp. thermophilus 1131</td>
<td>The lactobacillus in this yogurt helps regulate the balance of intestinal microflora to maintain a good GI condition.</td>
<td>This product is effective if you drink more than 100 mL by the indication.</td>
</tr>
<tr>
<td>Yogurt/Lactic Acid Drink (Morinaga)</td>
<td>Bifidobacterium longum BB536</td>
<td>Since this product includes live bifidobacteria it helps increase the bacteria in the intestines, and maintains a healthy GI environment.</td>
<td>This product is effective if you eat more than 100 g by the indication.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>This yogurt contains living bifidobacteria (bifidobacterium longum BB536) and helps increase intestinal bifidobacteria. It helps maintain a good intestinal environment and regulate the GI condition.</td>
<td>One day is the indication of 100 g, but you can eat more than the indicated amount by your pleasure.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bifidobacterium longum BB536, which migrates to the intestine alive, helps increase bifidobacteria in the intestine, and maintains a healthy GI environment.</td>
<td>Please drink based on the indication of 1 bottle per day.</td>
</tr>
</tbody>
</table>
## Product / Manufacturer
- **Fermented milk (Takanashi)**
- **Yogurt (Fukusima)**
- **Fermented milk drink/Yogurt (Yakult)**

## Eligible Microorganisms
- **Lactobacillus GG**
- **Bifidobacterium lactis FK120**
- **Lactobacillus casei Shirota**

## Eligible Claim
- With the activity of Lactobacillus GG which reaches in the intestine alive, this product is a food which increases good bacillus, decreases bad one and makes up the stomach condition designed to makes the environment in the intestine satisfactory.
- The bifidobacterium in this yogurt is alive when it arrives in bad ones, and regulates GI condition.
- Yakult's lactobacillus casei Shirota is still alive when it arrives in our intestines. The Shirotta strain helps increase good bacillus and decrease bad ones. This improves the GI environment and keeps the intestines healthy.

## Conditions for Use
- Please drink based on the indication of 30 mL per day.
- Please take based on the indication of 100 mL per day.
- One day does as the indication of 100 mL (about half of glass) per day, but you can eat more than the indicated amount by your pleasure.
- Please drink based on the indication of 1 bottle per day.
<table>
<thead>
<tr>
<th>Product /Manufacturer</th>
<th>Eligible Microorganisms</th>
<th>Eligible Claim</th>
<th>Conditions for Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fermented Milk (Kyodo Milk Industry)</td>
<td>Bifidobacterium lactis LKM512</td>
<td>This Yakult contains Bifidus germ being alive, increases the Bifidus in the intestine, improves the enteral environment and maintains the stomach condition.</td>
<td>Please take based on the indication of 1 cup (100 g) per day.</td>
</tr>
<tr>
<td>Lactic Acid Bacteria Drink</td>
<td>Lactobacillus acidophilus CK60 and Lactobacillus helveticus CK60</td>
<td>Lactic acid bacteria CK92 and CK60 maintain your good GI condition.</td>
<td>Please drink based on the indication of 1 bottle (100 mL) per day.</td>
</tr>
<tr>
<td>Lactobacillus beverage (Nissin York Company)</td>
<td>Lactobacillus Casei (NY 1301)</td>
<td>With the action of Lactobacillus Casei (NY 1301), this product is a beverage suited to the person who worries about the daily stomach healthy as it improves the environment in the intestine and keeps the stomach condition satisfactory.</td>
<td>This product is effective if you take based on the indication of 65 mL per day.</td>
</tr>
<tr>
<td>Product /Manufacturer</td>
<td>Eligible Microorganisms</td>
<td>Eligible Claim</td>
<td>Conditions for Use</td>
</tr>
<tr>
<td>---------------------------</td>
<td>--------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Fermented milk (Nestle)</td>
<td>LC1Lactobacillus</td>
<td>LC1Lactobacillus reaches up to the intestine alive, binds to the intestine wall, decreases the destructive fungus such as Clostridium perfringens of stomach competitively and increases the useful germ such as Bifidus. With the action of the LC1lactobacill</td>
<td>Please take based on the indication of 1 cup (120 g) per day.</td>
</tr>
<tr>
<td>Azumino Food Co., Ltd.</td>
<td>Bifidus Bb-12 (Bifidobacterium lactis)</td>
<td>According to the activity of Bifidus Bb-12 which reaches in the living condition, it improves the enteral environment and maintains the stomach condition.</td>
<td>80 g (1 cup), 240 g (80 g x 2 cups), 320 g (80 g x 4 cups)</td>
</tr>
<tr>
<td>Fermented milk (Yakult)</td>
<td>Bifidobacterium Breve Yakult</td>
<td>With the activity of B. breve Yakult which reaches in the intestine alive, it increases good bacillus, decreases bad one, improve the environment in the intestine and protects the stomach health</td>
<td>1 bottle</td>
</tr>
</tbody>
</table>

Japan – Lesson # 1 cont’d
Lesson # 2 - FOSHU approval in Japan requires a Japanese contact – all essential guidance documents are in Japanese
Lesson # 3 – There is a tolerance for health claims based on “emerging evidence” in Japan

• Individual, Standard, or Qualified routes of approval exist for FOSHU, which differ in the scientific standard required for claim substantiation (Rank A vs. Rank B vs. Rank C, respectively)
EU – Lesson #1

• Lesson #1 – EFSA’s Scientific Opinions are evidence that it is indeed implementing European Commission regulations
• Commission Regulation (EC) No 1924/2006 of 20 December 2006 - Nutrition and health claims made on foods

  • “A claim should be substantiated by taking into account the totality of the available scientific data, and by weighing the evidence” (Point 17)

  • “Health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard.” (Point 23)
EU- Lesson # 1 cont’d

• Commission Regulation (EC) **No 353/2008** of 18 April 2008 – *Implementing rules for health claim applications*
  
  • 5-part organization of the application**
  
  • Comprehensive, systematic and transparent review of the totality of evidence – favourable and unfavourable
  
  • Weighing of evidence – hierarchy of study types and designs, consideration of study quality
  
  • Human studies (central to substantiation)

**1. Administrative and technical data; 2. Food/constituent characteristics; 3. Overall summary of pertinent scientific data; 4. Body of pertinent scientific data identified; 5. Annexes to the application**
EU – Lesson # 1 cont’d

  
  • Demonstration of causality and generalisability
  
  • “Defined” and “beneficial” claimed effect (physiologically relevant outcome and magnitude of effect)
  
  • Feasible consumption of food/constituent, in a balanced diet, to obtain effect
  
  • “Defined” and “characterised” food/constituent
EU – Lesson # 2

• Lesson # 2 – To date, EFSA has published several essential guidance documents pertaining to health claims
• Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim (revision 1) (EFSA, 2011)


• 6 guidance documents on: i) Bone, joints and oral health; ii) Appetite ratings, weight management and blood glucose concentrations; iii) Neurological and psychological functions; iv) Gut and immune function; v) Antioxidants, oxidative damage and cardiovascular health; vi) Physical performance
EU – Lesson # 3

• Lesson # 3 – There is NO tolerance for health claims based on “emerging evidence” in the European Union
Three criteria must be met for a favourable Scientific Opinion:

1. The food/constituent is defined and characterized

2. The claimed effect is defined and is a beneficial physiological effect (“beneficial to health”)

3. A cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use) - - rigorous data needed for health claims that are made for non-nutrients
Current Status of Article 13.1, 13.5, and 14 Claims*

*As of January 27, 2012

Favorable
Unfavorable

Type of Claim (Article)

13.1
12.9%
87.1%

13.5
11.9%
88.1%

14 - Adult
43.3%
56.7%

14 - Children
28.3%
71.7%
Lesson # 4 – EFSA has issued their requirements regarding what constitutes the “sufficient characterisation” of bacteria and yeasts
EU – Lesson # 4 cont’d

• “Sufficient Characterisation” of Bacteria (2 criteria)

1. **Species** identification by DNA-DNA hybridisation on 16S rRNA gene sequence analysis

   **AND**

2. **Strain** identification by DNA macrorestriction followed by pulsed-field gel electrophoresis (PFGE), randomly amplified polymorphic DNA analysis (RAPD) or other internationally accepted genetic typing molecular methods

   **Other:** Strains should be named according to the International Code of Nomenclature and strains should be adopted in an internationally recognized culture collection (with access number)
• “Sufficient Characterisation” of Yeast (2 criteria)

1. **Species** identification by restriction fragment length polymorphism analysis (RFLP) (e.g. RFLP of PCR products of the 5.8S rDNA internal transcribe spacer [ITS] region) or by sequencing analysis of DNA taxonomic markers (e.g. the D1 and D2 domains of 26S rDNA or ITS regions).

AND

2. **Strains** identification by chromosome length polymorphism analysis by PFGE, RAPDs, microsatellite DNA polymorphism analysis or other internationally accepted genetic typing molecular techniques.
Sufficient Characterisation of Probiotics – Per # of EFSA Opinions

- 30/37 (81%) Microorganisms sufficiently characterised.
- 8/11 (73%) Microorganisms sufficiently characterised and cause and effect established.
- 1/37 (3%) Microorganisms insufficiently characterised.
- 2/2 (100%) Cause and effect established.

Type of Claim (Article):
- 13.1
- 13.5
- 14 - Adult
- 14 - Children
Sufficient Characterisation of Probiotics – Per # of EFSA Claims

- Microorganism not sufficiently characterised
- Microorganism sufficiently characterised

Number of PROBIOTIC Health Claims

<table>
<thead>
<tr>
<th>Type of Claim (Article)</th>
<th>Number of Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.1</td>
<td>47/128 (37%)</td>
</tr>
<tr>
<td>13.5</td>
<td>8/11 (73%)</td>
</tr>
<tr>
<td>14 - Adult</td>
<td>2/2 (100%)</td>
</tr>
<tr>
<td>14 - Children</td>
<td></td>
</tr>
</tbody>
</table>

www.cantox.com  www.intertek.com
• Lesson # 5 – EFSA has issued one favourable Scientific Opinion on a probiotic, which represents 1/57 (1.8%) of all EFSA opinions (13.1, 13.5, 14 – adult, 14 – children) related to probiotics
<table>
<thead>
<tr>
<th>Claim Category</th>
<th>Food constituent</th>
<th>Claimed Effect</th>
<th>Proposed Claim Wording</th>
<th>Quantity</th>
<th>Target Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 13(1)</td>
<td>Live yoghurt cultures: <em>Lactobacillus delbrueckii</em> subsp. <em>Bulgarianus</em> and <em>Streptococcus thermophilus</em></td>
<td>Lactose maldigestion</td>
<td>“Live yoghurt cultures in yoghurt improve digestion of lactose in yoghurt in individuals with lactose maldigestion”.</td>
<td>Yoghurt should contain at least $10^8$ CFU live starter microorganisms (<em>Lactobacillus delbrueckii</em> subsp. <em>Bulgarianus</em> and <em>Streptococcus thermophilus</em>) per gram</td>
<td>Individuals with lactose maldigestion</td>
</tr>
</tbody>
</table>
## Conclusions

<table>
<thead>
<tr>
<th></th>
<th>Canada</th>
<th>U.S.</th>
<th>Japan</th>
<th>EU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific standards for claim substantiation can vary according to claim category</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Guidance for claim substantiation exists</td>
<td>Yes</td>
<td>Yes</td>
<td>Not in English</td>
<td>Yes</td>
</tr>
<tr>
<td>There is a tolerance for claims based on “emerging evidence”</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Examples of approved probiotic claims exist</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Characterisation of probiotics is critical in claim substantiation</td>
<td>Yes</td>
<td>Assumed to be yes</td>
<td>Not known</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Thank you!

Lina Paulionis
Senior Scientific and Regulatory Consultant
Email: lpaulionis@cantox.com
Telephone: 905-286-4164