New Biomarkers and Parameters for Evaluating Health Benefits

Dr Judy Cunningham
Australia
This presentation will:

1. Describe the health claims system in Australia and New Zealand
2. Outline the substantiation process used
3. Provide some general guidance on the use of biomarkers for health claims
4. Consider some new biomarkers
Australia New Zealand Food Standards Code

STANDARD 1.2.7

NUTRITION, HEALTH AND RELATED CLAIMS
Three main claim types

• Nutrition content claims
  *This whey powder is a good source of protein*

• High level health claims
  *Diets high in calcium improve bone density*

• General level health claims
  *Calcium for normal healthy bones*
Substantiation of health claims

General level
- Pre approved by FSANZ
- Self substantiation + notification to FSANZ
- Application to FSANZ

High level
- Pre approved by FSANZ
- Application to FSANZ
Substantiation requirements

Key differences to other countries:
• Systematic review required for both general and high level claims
• No qualified claims

High degree of certainty is required:

Would one more high quality study lead us to change our minds?
Substantiation requirements

- Schedule 6 of Standard 1.2.7 sets out requirements of a systematic review
- Also information in the Application Handbook
- Guidance for self-substantiation of general level claims
Relationship vs Claim

Food health relationship + Other requirements of Std 1.2.7 = Claim

Substantiation process

Food business
Relationship vs Claim

Relationship:

Protein contributes to the growth of muscle mass

Claim:

Protein to help build muscles!
Current health claims activity

• No applications received
• Four general level health claims notified
• Updating existing high level relationships
• Assessing around 30 new food health relationships
Notified relationships

• Wheat bran fibre increases stool weight and reduces intestinal transit time
• Green kiwifruit can contribute to normal bowel function
• Green Tea Catechins (GCTs) with caffeine contribute to modest weight loss in overweight and obese adults
• Combination of ingredients in Aspire drink ... thermogenic effect ...
What is a biomarker?

- Many types and many terms
- Measurable biological parameter that predicts biological processes including risk of disease

Not all biomarkers are relevant to health claim substantiation
Australia New Zealand definition: “a measurable biological parameter that is predictive of the risk of a serious disease when present at an abnormal level in the human body”
Why are biomarkers used?

• Simplify and shorten clinical trials
• Help understand mechanisms of action and establish plausibility of a food health relationship
• Objective not subjective
• Assess compliance
• Well established biomarkers may be the subject of health claims
## Permitted biomarker claims

<table>
<thead>
<tr>
<th>Biomarker</th>
<th>Related serious disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum cholesterol</td>
<td>Cardiovascular disease incl. coronary heart disease</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>Cardiovascular disease incl. stroke</td>
</tr>
<tr>
<td>Bone mineral density</td>
<td>Osteoporosis</td>
</tr>
</tbody>
</table>
New areas for biomarkers

Future:
• Nutrigenomics?

Now:
• Weight control and sports performance
• Many other areas?
“3% of global food & beverage launches in the year to March 2014 were for products marketed as high protein or source of protein” (Food Australia, Oct/Nov 2014)
Muscle biomarkers

... calf-raise exercise induced ... muscle damage symptoms which were accompanied by increases in both serum creatine kinase and aldolase activities, but ... (no) changes in examined markers of organ damage, inflammation and oxidative stress. Further research is needed to determine other more sensitive biomarkers and the underlying mechanisms of exercise-induced muscle damage.”

Kanda et al (2014)
Biomarkers for weight control

Gastro intestinal hormones as biomarkers for hunger or satiety:

• *Cholecystokinin* – *appetite rating*

Other possibilities:

• *C-reactive protein?*
• *Intracellular adhesion molecules?*

“No baseline biomarker profile was associated with weight loss success.” (Polsky et al, 2013)
High quality studies needed

• Substantiation requires high quality studies in humans, of all available evidence
• One study is not enough!
• Useful guidance is available on how to assess study quality
• Evidence must be relevant to the food and health outcome being claimed
Conclusions

• MUST understand health claims regulation in your market
• Most regulators require a high degree of certainty but few biomarkers provide this
• New biomarkers likely to provide only supportive evidence
References


