Overview of FSANZ's international engagement

On behalf of Australia:
• Committee/Taskforces of the Codex Alimentarius
  • CCFA, CCNFSDU, CCCF, AMR, CCFH
• Biototechnology Taskforce of the OECD
• APEC – Food Safety Co-operation Forum

Bilateral relationships – on behalf of ANZ
• MOUs/LOUs – e.g. Malaysia, Canada, UK etc.
• International visits e.g. South Korea
• International Liaison Groups
• Capacity Building, where extra budgetary funds available

Expertise based invitations
Invited Experts to FAO/WHO workshops & consultations eg. JECFA

Codex CAC/GL 23-1997

Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable. Health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, provide truthful and non-misleading information to aid consumers in choosing healthful diets and be supported by specific consumer education.

Vehicle related “profiling”

Substantiation
Before we start

Variation in business rules affect how profiling and substantiation can be implemented e.g.

- what is covered by “food”
- what is covered by health claims
- what language is used
- existing labelling rules that can be drawn on
- case-by-case or blanket rules

What is the universe?

- Do the food regulations include vitamin and mineral supplements etc as “food”?  
- Are special purpose foods to be included in the health claims regulation or not (e.g. infant formula, sports foods, medical foods)?
- What about alcoholic beverages?
- What about traditional foods with prescribed composition?

Our universe

What is food varies.....

<table>
<thead>
<tr>
<th>Authorised EU claim</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melatonin contributes to the reduction of time taken to fall asleep</td>
<td>Melatonin requires a prescription; regulated by the Therapeutic Goods Administration in Australia</td>
</tr>
<tr>
<td>Supplemental folic acid intake increases maternal folate status. Low maternal folate status is a risk factor in the development of NTDs in the developing foetus.</td>
<td>Vitamin and mineral supplements are complementary medicines; regulated by the Therapeutic Goods Administration in Australia</td>
</tr>
</tbody>
</table>
Foods have health “claims”

Complementary medicines, e.g. vitamin supplements, have “indications”

Getting Your Claims Right

Authorised EU claim | Comment
---|---
DHA intake contributes to the normal visual development of infants up to 12 months of age. | Health claims prohibited on infant and follow-on formula in ANZ.
Glucosamine contributes to the maintenance of normal blood cholesterol levels | Not permitted to be added to food in ANZ
Guar gum contributes to the maintenance of normal blood cholesterol levels | Permitted food additive at GMP levels in ANZ. EU recommended levels to achieve the health effect much higher than GMP levels; safety assessment needed

What is a health claim - Codex

Any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health.

Nutrient function claims – describes the physiological role of the nutrient in growth, development and normal functions of the body.

Other function claims – concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body.

Reduction of disease risk claims – relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition… means significantly altering a major risk factor(s) for a disease or health-related condition.

A different set of words

High level claim (ANZ)
a health claim that refers to a serious disease or biomarker of a serious disease

Serious disease
disease, disorder or condition which is generally diagnosed, treated or managed in consultation with or with supervision by a health care professional

General level claim
a health claim that is not a high level health claim

EU authorised claims | Pre-approved relationships in ANZ
---|---
Article 13 | General level | High level | Not listed
Not listed | (low) sodium or salt reduces blood pressure

Reducing consumption of sodium contributes to the maintenance of normal blood pressure
**Substantiation**

Food or property of food $\rightarrow$ Specific health effect $\rightarrow$ Evidence

**Food-health relationship**

Will you allow both food and property of food to be the subject of a claim e.g.

“Wholemeal bread contributes to digestive health”

Or only

“Fibre contributes to digestive health”

A claim is what appears on a label

The claim might say “digestive health” but this is not measureable

A measureable health effect has to be specified to look at the scientific evidence
Will all relationships need pre-market approval?

- If yes, then
  - specify the type of literature to be submitted in the request for approval
  - can specify claim wording
  - could have claim-specific vehicle criteria
- If no, then
  - need to describe how to substantiate
  - need to describe enforcement process
  - cannot prescribe claim wording tightly
  - difficult to define claim-specific vehicle criteria
  - generic criteria needed, at least for the “all other” group

“Sound and sufficient”

“Health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim”

Sound:
- relevant, well-conducted
- unbiased collection of the literature

Various places moving to systematic reviews:
- USFDA for health claims
- FSANZ for health claims
- WHO, EFSA for various topics

Can an existing review be used?

World Cancer Research Fund – 2007 review:

Refined cereals and cereal products

Cereals (grains) and their products have an extensively disrupted structure ...includes products made from white wheat flour or from “wholemeal” flour that has been made from blending finely milled grain fractions. Also includes ready-to-eat breakfast style cereals ... disrupted to such an extent that the endosperm is readily accessible to digestive processes. Some examples include bread made from white or finely ground wholemeal flour, ... dehulled oat flakes, cornflakes, popped corn ...”


Sufficient

How certain do you have to be that the relationship/claim is true?

Will different degrees of certainty be allowed for function and risk reduction claims?

What sources of evidence? Different types of evidence permitted for function and risk reduction claims?
"Sufficient"

A number of schemes to describe the degree of certainty in a relationship which might be useful: e.g.

**GRADE:**
- High
- Moderate
- Low
- Very low

**WCRF/AICR:**
- Convincing
- Probable
- Limited evidence
- Limited – suggestive
- Limited- no conclusion
- Substantial effect on risk unlikely

http://www.gradeworkinggroup.org/

https://www.wcrf.org/dietandcancer/resources-and-toolkit

**Study synthesis:**
looking at the totality of evidence, the conclusions are weighted towards the higher quality studies.

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Studies with favourable effect                  Studies with an unfavourable or null effect
significant               NS                  significant               NS
Study Quality
Higher quality  Lower quality  Higher quality  Lower quality  Higher quality  Lower quality  Higher quality  Lower quality
or
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- "self-substantiation" of the relationships is permitted for general level claims – see Schedule 6
- Notified to FSANZ so the enforcement agencies know what is coming

**FSANZ does not** assess these, the dossiers are **not** submitted to FSANZ
Various decisions about goals need to be made:

- Are you going to have any sort of vehicle-related criteria?

If yes, is the purpose

- To guide people to the “best” choice among similar foods or to include all foods which pass some criterion even if not the “best” choice?
- To include only the “basic foods” or to include pre-prepared multi-ingredient foods?
- To encourage manufacturers to modify formulations to improve fairly “good” foods or to include “fairly good” foods at the start?
- To rule out certain foods that are popularly regarded as “bad” even if manufacturers have reformulated extensively?

What is your underlying premise?

- That products are excluded unless they are ruled in
  Or
- That products are included unless ruled out
Different nutrients are mandatory in different countries

A system needs to be enforceable

- If there are categories, then the boundaries between categories
  - must be uncontestable if decision is made by judge in court
  - can be looser if a committee can make case-by-case decisions

- The ANZ Food Standards Code has very few identity standards
  → A category-based system was tested but...
  → All other things being approximately equal, an across-the-board system would be the preferred option in the ANZ context

How will enforcement agencies be able to assess whether a food is correctly classified?

**Decision we made:**

- That all the information an enforcer needs to determine whether a product gets through the disqualifying criteria **must** be on the label
  - → various consequences

What focus for the defining characteristics?

- Risk increasing components – saturated fat, sugar and sodium are clearly defined in the dietary guideline
- On micronutrients?

- Our decision: primary focus on “chronic disease” & reducing the overconsumption of risk increasing components while not ignoring the micronutrients
### Parsimony

Should the system have the least number of criteria needed to achieve the classification or do all the criteria have to make “nutritional” sense?

- E.g. % wholegrain not included – this might be seen as not supporting the dietary guidelines
- E.g. trans fats even though it does not alter the classification (in ANZ where intakes are very low)

### Will the system have to serve more than one purpose?

- Are you going to use it e.g. for nutrition education as well as disqualifying criteria?
  
  **Our decision**
  - Not looking to use the criteria for any other purpose and they have not been examined with any other focus in mind
  - Algorithm subsequently expanded and modified to use for the Health Star Rating System

### Whose cutoffs/targets for the selected characteristics?

a progressive system that becomes more rigorous over time or not?

- Population-weighted average values? Or values from a particular age-sex group?
  - UK basis very similar to those for moderately active woman or sedentary man in ANZ
  - Yet to do the work to adopt our new Nutrient Reference Values into the ANZ regulations; so would not wish to pre-empt any decisions
  - adopt UK steps as is

### Any important non-nutrition criteria?

- Should the salt content of e.g. processed cheese be discounted because it is there for microbiological reasons (so the cheese does not need refrigeration)
**Per 100g or per serve?**

In ANZ, we do not regulate serve size given on the label
- Strong criticism of the initial model on this point
- Current model is per 100g: criticised because “unfairly penalises foods eaten in smaller quantities”

The goal of the system is the classification
- per 100g or per serve is just the means to the end
- another country might regulate serve sizes and have a different view

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**Testing the algorithm**

- What database?
  - Food composition tables are averages – but a Nutrition label is generally brand-specific
- G or mL
- As sold or as consumed
- Definitions as per food regulations

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**Public health messages &**

- the changing composition of food
  - ‘Hot’ chips that have been extensively renovated to remove saturated fat and sodium
- the changing focus of messages
  - Yeast spreads (an icon food in Australia) – still contain high levels of sodium

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What are you trying to do?
How do your goals match those of the system you are looking at?

How will you enforce it?
What restrictions are imposed by the local enforcement system?

Do the enforcers think the proposed system is implementable and enforceable?