

FOOD CLAIMS - TRUTH AND MYTH

OUR JOURNEY

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Introduction to our Australia New Zealand food regulatory system

A partnership between Australia and New Zealand since 1996

- two countries sharing a common set of food standards
- joint standards recognise interconnection of food businesses and trade between the countries
- collaboration in policy development, standard setting and enforcement



Food regulation framework

Standard setting

FSANZ (consistent with Codex)

Policy

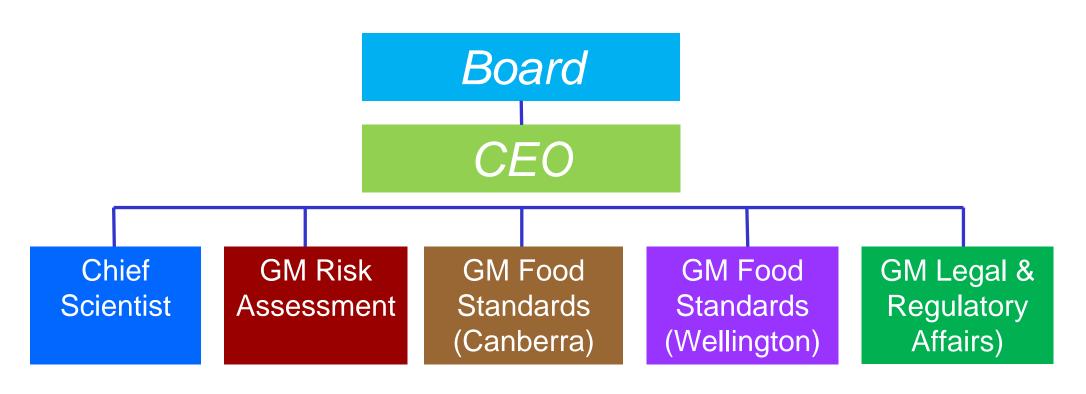
Ministerial Forum
(States/Territories/Aust/NZ)
(health/agriculture portfolios)
FSANZ Act

Enforcement

States/Territories/NZ
FSANZ (monitoring)
Biosecurity (imported foods)
Local government



FSANZ structure



Canberra, Australia Wellington, New Zealand 130 staff17 staff

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FSANZ approach to standards setting –CODEX model

RISK ASSESSMENT (Science) RISK
MANAGEMENT
(Policy)

RISK COMMUNICATION

Open process

Public consultation

Board approval

1.Assessment report

2.Approval report

(draft Standard)

3. Notified to Ministers



Chapter 1 – General food standards

Chapter 2 – Food Product Standards

Food Standards Code

Chapter 3 – Food Safety Standards (Australia only) Chapter 4 –
Primary Production
Standards
(Australia only)



HEALTH CLAIMS



Why do we need a new Standard?

- Existing transitional Standard narrow, lacks certainty
 - Permits claims related to folate and NTD
 - Prohibits claims relating to
 - disease or physiological condition
 - slimming, weight reduction, therapeutic, medical advice
- Industry wants to innovate
- Enforcement authorities seeking certainty
- Rest of world moving in this direction



Our journey starts with Policy guidance in 2003 and finishes in 2012





Why so long?

Complex project 8 years

6 rounds public consultation

>500 submissions

Diverse and divergent views

- Industry 'space' to innovate
- Jurisdictions enforceability (certainty, prescription), health protection, and costs
- Public health advocates health protection
- Consumers choice with confidence



Policy guidance (2003)

- Regulatory measure for voluntary use of nutrition and health claims
- Regulatory requirements for making health and nutrition claims in the one standard
- To allow certain disease risk reduction claims

Generally aims to

- permit health claims where they support healthy food choices
- not mislead consumers
- support innovation



Nutrition Content Claims

Presence or absence

Source of calcium





General Level Health Claims

Links to health function, not disease

Calcium builds stronger bones





High Level Health Claims

Links to serious disease - risk reduction

Calcium reduces risk of osteoporosis





Therapeutic Claims

Links to serious disease - prevention/cure

Calcium prevents osteoporosis

Not allowed on foods





Building a health claim - two principal elements

Food health relationship

Substantiated

Relationship between a food or property of a food and a health effect:

e.g. calcium and bone mineral density

e.g. vit C and iron absorption



Building a health claim - two principal elements

Food health relationship

Substantiated



Other requirements of Std 1.2.7



Claim

- Qualifying criteria property
- Food eligibilityNPSC
- Wording conditions
- Not misleading

 Wording prepared by manufacturer



Step – up approach (2008) – self substantiation

Step Up

Pre – market assessment and approval

Self substantiation

Qualifying criteria, some specific disqualifying criteria

Nutrition

content claims

Qualifying criteria, nutrient profiling scoring criteria (NPSC)

General level health claims

Qualifying criteria, nutrient profiling scoring criteria (NPSC)

as determined on a case-by-case basis

High level health claims

NPSC nutrient
profiling - for
foods carrying
health claims



Nutrient profiling scoring criteria (NPSC)

Baseline points

- Energy
- Sat fat
- •Sodium
- Sugars

Modifying points

- •FVNL
- •Fibre
- Protein

Score

- Beverages
 - Foods
 - Spreads
 - &cheese



Approval of food health relationships - GLHC

Step Up

Pre – market assessment and approval

Selfsubstantiation

Preapproval?

Qualifying criteria, some specific disqualifying criteria

Nutrition

content claims

General level health claims

Qualifying

criteria,

nutrient

profiling

scoring

criteria (NPSC)

Qualifying criteria, nutrient profiling scoring criteria (NPSC) or as determined on a case-by-case basis

High level health claims

2008 draft standard self substantiation

2010 pre-approval



Hybrid option (2012)

Step Up

Pre – market assessment and approval

Self-substantiation

Pre-approval

Qualifying criteria, some specific disqualifying criteria

Nutrition content claims

Qualifying criteria, nutrient profiling scoring criteria

(NPSC)
General level
health claims

Qualifying criteria,
nutrient profiling
scoring criteria
(NPSC)
or
as determined on a

High level health claims

case-by-case basis

2012
hybrid with both
pre-approval and
self
substantiation



Substantiation of food health relationships GLHC

Pre-approved

- Schedule in proposed Standard
- •200+ at gazettal
- Drawn from various sources
- •JHCI, EFSA, Health Canada
- Commitment to adopt more

And

By application – special process





Substantiation of food health relationships GLHC – structured process

Self substantiation

- Substantiation requirements in Standard
- Guidance to sit outside Standard
- Company to prepare dossier
- Dossier to be available to enforcement authorities
- Requirement to notify
 - Food health relationships to be on public listing
 - Responsible officer to authorise
 - Register to be held by FSANZ



Substantiation – principles - general

- ✓ Systematic review
- ✓ Broad evidence base favourable, unfavourable
- √ Tabulating evidence/studies
- ✓ Assessing power and quality of studies
- ✓ Some human studies required
- Causality to be shown
- ✓ Target population stated
- ✓ Weighing of evidence/conclusion
- ✓ Comprehensive documentation dossier
- Interaction with consumer law







Transition!

- Transition period 3 years proposed.
- Allow industry to adjust products, claims
- Consideration of existing claims in market food businesses to provide dossiers to FSANZ
- Guidance material to be available
- FSANZ further evaluating approved claims from

other jurisdictions.



Nearing the journey's end - have we achieved all our goals?

- Enormous challenge not possible to meet all needs of all stakeholders
- Standard reflects a range of stakeholder viewpoints
 - Flexibility for industry
 - Certainty for jurisdictions
 - Confidence for consumers
 - Supports healthier food choices for public health





Last steps?

- Consultation completed
- Finalise report and draft Standard
- Report to FSANZ Board Oct 31



- Notify Ministers by October 31, 2012
- Consideration within 60 days
 - Accept

- Amend

- Reject

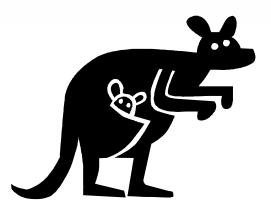


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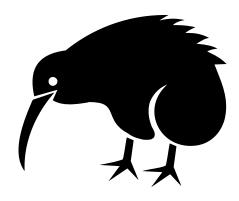


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Thank You



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