Insight, hindsight & foresight: functional foods, probiotics & the consumer

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Platform 4 is concerned broadly with the development of novel food concepts, processes and services based on integrating knowledge generated by all the CoRE research platforms and existing knowledge in the literature.
Overview

> Insight
  > Manufacturer’s point of view
  > Regulator’s point of view
  > Customer’s response

> Hindsight
  > The case of probiotic cheese

> Foresight
  > Recommendations for the future
Insight: manufacturers

Manufacturers want to sell product, preferably at a premium price.

> Label claims seen as valuable and can attract a premium

Regulatory is seen as a barrier:

> Cost and risks in getting approvals
  > Cost of compliance

But an approved claim is also a barrier to competitors
Insight: manufacturers – probiotic claims are trouble!

UK censors Danone probiotic TV ads
By Shane Starling, 14-Oct-2009

The voluntary UK advertising watchdog has told Danone to cease broadcasting TV adverts that stated its one-shot probiotic drinking yoghurt, Actimel, could boost the immune system of children.

Nestle and FTC Reach Agreement Regarding Probiotic Advertising
By Jodi L. Barrow Published on July 15, 2010

On Tuesday, an agreement was reached between Nestle HealthCare Nutrition Inc. and the FTC regarding the Company’s allegedly deceptive advertising concerning the health benefits of its drink “Boost Kid Essentials.”
Danone cautioned over UK Actimel adverts
The UK Advertising Standards Authority (ASA) has told French dairy giant Danone to remove or alter a "misleading" probiotic yoghurt drink TV advert.

Alternatively, can use vague claims in advertising of brand, e.g. “feel the difference”
Insight: regulators

> Food regulation has grown out of considerations of food safety
> There is an implied social contract between regulators and the public to ensure food is safe and healthy
> Functional food claims are new and go beyond nutrition – regulators are struggling to come to grips
FSANZ

FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act.

> the protection of public health and safety;
> the provision of adequate information relating to food to enable consumers to make informed choices; and
> the prevention of misleading or deceptive conduct.

Can be considered as:

> Safety
> Public Health
> Truth
FSANZ – three levels of claims

> Content claims

> General level health claims (function claims)

> High level health claims (disease reduction claims)

- Source of calcium
- Calcium builds stronger bones
- Calcium reduces risk of osteoporosis
More than 200 pre-approved food health relationships available (drawn from the EU for example and a UK Joint Health Claims Initiative) to underpin General Level Health Claims, and industry can make application to FSANZ for new food health relationships provided they have the evidence.
Building a health claim – two principal elements

**Food health relationship**
- Substantiated (some pre-approved in Standard)

**Other requirements of Std 1.2.7**
- Qualifying criteria - property
- Food eligibility
  - NPSC
- Wording conditions
- Not misleading

**Claim**
- Wording prepared by manufacturer

NPSC is a food compositional profiling scheme adapted from the UK

It assesses eligibility of food to make a health claim (but not nutrition content claims)

Both negative and positive nutrients considered, trialled on 10,000 foods
“A health claim is defined as any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.”
EFSA criteria for the scientific substantiation of claims

1. The food or food component to which the claimed effect is attributed should be characterised.

2. Substantiation of a claim should be based on human data, primarily from intervention studies, the design of which should include the following considerations: (8 considerations)...

3. When the true endpoint of a claimed benefit cannot be measured directly, studies should use markers.

EFSA criteria for the scientific substantiation of claims

4. **Markers** should be:
   - **Biologically valid** in that they have a known relationship to the final outcome and their variability within the target population is known.
   - **Methodologically valid** with respect to their analytical characteristics.

5. Within a study the target variable should change in a **statistically significant** way and the change should be **biologically meaningful** for the **target group** consistent with the claim to be supported.

6. A claim should be scientifically substantiated by taking into account **the totality of the available data** and by weighing of the evidence.

Scientific reasons for rejection by the European Food Safety Authority of health claim applications

> The foods/food constituents were **not sufficiently characterised**.

> **Effects of food matrix, processing and stability** information, bioavailability and content variability not sufficiently characterised.

> **A cause and effect relationship** was not established between the food/food constituent and the claimed effect.

> **Lack of systematic literature review** and no specific inclusion/exclusion criteria.

> **Criticism of study designs**, absence of power calculations, insufficient information on background diet and lifestyle, failure to describe target group, intervention trials lacking, no lowered risk factor/no measurable effect.

> **Patient (clinical studies) not used as evidence** for health effects in general population.
Insight: regulators

Probiotic health claims ruled unproven
guardian.co.uk, Tuesday 19 October 2010
European Food Safety Authority says claims regarding immune system and digestive health lack sound scientific basis

EFSA slams door on probiotic health claims (again); Prunes pass
Nutra Ingredients 6 June 2012
Hopes that the resubmission of 74 probiotic health dossiers would win a sector-first claim in the EU have been dashed after the European Food Safety Authority (EFSA) held its earlier line and unanimously rejected them all.

EFSA rejects Lactobacillus casei probiotic gut health claim
Nutra Ingredients 7 June 2012
The European Food Safety Authority (EFSA) this week rejected 74 probiotic health claim dossiers it had been sent for a second reading after many of them were initially turned down for reasons such as inadequate strain characterisation. Its rejection logic is outlined in its assessment of a gut health submission for Lactobacillus casei DG CNCM I-1572.
Insight: regulators

Reasons given:

The food constituent that is the subject of the health claim, Lactobacillus casei DG CNCM I-1572, is sufficiently characterised. ✓

The claimed effect, decreasing potentially pathogenic gastro-intestinal microorganisms, might be a beneficial physiological effect. ✓

The proposed target population is the general population.

No human studies were provided from which conclusions could be drawn for the scientific substantiation of the claim. ❌

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of Lactobacillus casei DG CNCM I-1572 and decreasing potentially pathogenic gastro-intestinal microorganisms. ❌

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Insight: consumers

- Quantitative research (surveys)
- Qualitative research (discourse analysis)
Quantitative consumer research - surveys

FSANZ commissioned two pieces of quantitative research from Roy Morgan research in 2008 (1060 respondents in Australia and NZ). They concluded:

> Content claims did not have a significant influence on nutrition attitudes
> Nutrition content claim did not contribute significantly to the prediction of purchase intention
> Type of nutrition content claim had no influence on consumer purchase intention, or product evaluations in terms of nutrition attitudes.
Quantitative consumer research - surveys
Results were re-analysed & confirmed by Monash University:
Quantitative vs. Qualitative Research

**Quantitative**
- Hypothesis driven
- Statistical, numerical data
- Deductive
- Misses contextual detail
- Structured

**Qualitative**
- Descriptive
- Verbal, transcribed data
- Inductive
- Aim is to understand the context
- Unstructured/semi-structured

The aim of the present research is to understand the context within which food is embedded, by applying the appropriate qualitative research methods to investigate how consumers understand the relationship between diet and health, and how functional food products are understood by older adults.
Qualitative research – critical discourse analysis

> Focus group interviews (4-6 people in each group)
> Semi-structured, with example products as stimuli
> Conversation recorded and transcribed at word-level accuracy
> Analysed and annotated using specialist software (NVivo)
> Insights developed
Insight: Nutritional altruism

“Eating is no longer a matter which merely foregrounds personal preference or taste but is itself a kind of personal management of risk for oneself and one’s family. It is ... managed by a ‘social appetite’, where the moral, nutritional and health-giving qualities of food are intimately involved in decisions about purchasing and consumption, and we are ... ‘shopping our way to safety’ – the safety of self and of others.”

Talk focused upon specific attributes of both functional and non-functional food products in relation to their relative fat, sugar and sodium content; ... dichotomising these attributes as being fundamentally ‘good or ‘bad’ nutrients...

‘fats’ and ‘sugar’ were pathologised ... as being an addiction.

H. Bunting, unpublished
Insight: function of probiotics

* The role of probiotic products ... associated with curative and medicinal purposes ... having a specific function in terms of dietary health and nutritional practice.

* Consumers ... associate the use of probiotic products with having to take antibiotic medications and as a means of restoring ‘balance’ to the gut.

H. Bunting, unpublished
Insight: nutritional idealism

> Consumers ... differentiate dairy products into ‘routine’ and ‘luxury’ products – with yoghurt ... routine and an intrinsically ‘good’ and ‘healthy’ product, an acceptable carrier for probiotic cultures.

> ‘Luxury’ dairy items such as cheese were considered ... to be problematic carriers of probiotics ... such products should be consumed in much smaller quantities as part of dietary intake due to them being considered relatively ‘unhealthy’...

H. Bunting, unpublished
Hindsight: the case of probiotic cheese

The curd way: is cheese the new yoghurt?

> The Agricultural Research Centre of Finland has produced a Swiss cheese called Festivo using cheese starter cultures in combination with *Lactobacillus acidophilus* and *bifidobacteria*.

> Belgium company Cosucra has reacted to the popularity of low-fat fresh cheese by adding fibre as a bioactive enrichment agent.

> Australia recently imported its first probiotic cheese from New Zealand, a low-fat cheddar called Mainland Inner Balance, containing the probiotic agent *L rhamnosus* DR20.

> Korean processed cheese manufacturers are enriching cheese with DHA to improve the learning ability of children.

Source: Landell-Mills Consulting, July 1 2005
Mainland Inner Balance Cheddar Cheese - Light
MANUFACTURER: Mainland Dairies CATEGORY: 056 - Cheese.(Abstract)(Product Announcement)
Article from: International Product Alert | September 17, 2001

Mainland Dairies has introduced Mainland Inner Balance Light Cheddar Cheese to consumers in Australia. According to trade literature, it contains additional lactobacillus cultures.
Hindsight: the case of probiotic cheese

Kraft: probiotic cheese is a disappointment  Nutra Ingredients 18-Feb-2009

Kraft US has confirmed what many market analysts have been saying for some time – probiotic cheese is not winning over the public.

Consumers going off probiotic cheese  Nutra Ingredients 7-Feb-2009

Probiotics have had a rapid rise to public prominence in North America since Danone launched probiotic drinkable and spoonable yogurts on the US market in 2005, but probiotic cheeses have won little favor, according to Euromonitor research.

Kraft to face functional food failure?  Nutrition New Business

Launched only two years ago, Kraft’s major attempt to extend probiotic benefits to snacking cheeses through its new LiveActive brand has failed to catch on with American consumers – even as sales of Danone’s Activia probiotic yogurt products have taken the US market by storm
Foresight: the future for probiotics and the digestive health proposition
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Thank you.
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