Making and Justifying Health Claims

Dr Fiona Lalor
Food for Health Ireland
University College Dublin
Fri 7th September 2012

Global Functional food market expected to reach nearly $30 bn by 2014, according to Leatherhead Research

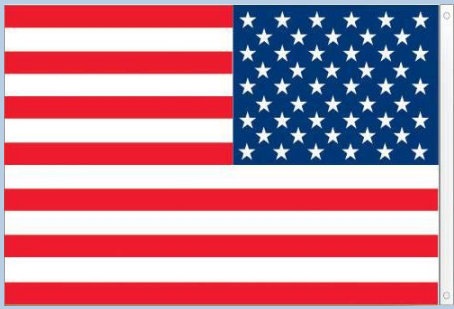
Functional Food Market Challenges

- Overcoming consumer scepticism
- Providing additional value that compensates for increased product cost
- Improving product quality, especially texture and flavour, so they compare favourably to regular products
- Regulatory limits on health claims made by Functional Food and Drinks

What are the Regulatory Limits?

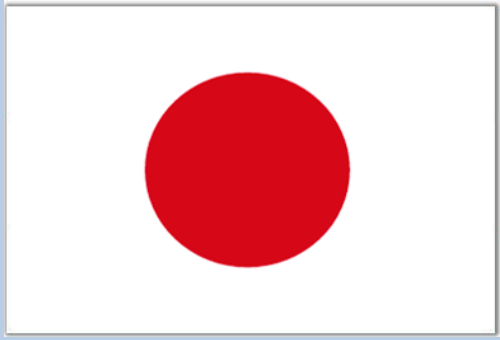
- Japan – 1990 – Ministry for Health and Welfare published a policy approving commercialisation of functional foods – FOSHU
- USA – 1990 – FDA published the Nutrition, Labelling and Education Act – health claims permitted but scientific substantiation required
- EU – health claims prohibited until EU Regulation 1924/2006 came into force.
- Aus/NZ – draft standard currently under consultation
- China – increased focus on substantiation

Requirements in USA



- NLEA Fully authorised claim – significant agreement from suitable experts that the claim is supported by ‘totality of publicly available scientific evidence’.
- Claim based on authoritative statements from a scientific body of the US government
- *Qualified Health claim* - quality and strength of evidence falls short of that required for NLEA claim but, with qualifying statement, claim still permitted
- USDA and Federal Trade Commission are stepping up enforcement of regulations and raising sanctions placed on companies for making unsubstantiated health claims

Requirements in Japan



- Effectiveness based on scientific evidence (including clinical evidence)
- Safety of product (including safety studies in human subjects)
- Analytical determination of the effective components.
- *Qualified FOSHU* permitted since 2005

Australia/New Zealand

- Currently working on a Draft Standard
  - *May* be published before end 2012
- Claims will only be permitted if food-health relationship is scientifically substantiated
- When published, standard will include more than 100 pre-approved food health relationships manufacturers can use
- Additional relationships will require submission of dossier for approval

Requirements in China

- In 2009, the Food Safety Law was passed which included 27 permitted health claims
- August 2011, a draft amendment was published which reduced this to 18
- Have an increased emphasis on human clinical data – ‘improves sleep’, ‘reduces fatigue’ will need human data

Requirements in EU

- Strict adherence to process under EU Regulation 1924/2006
- Positive opinion required from EFSA
  - Is the food sufficiently characterised?
  - Is the claimed effect beneficial for health?
  - Is a cause and effect relationship established between the consumption of the food and the claimed effect?

EFSA Opinions

- 3 categories
  - Article 13.1. – generic claims
  - Article 13.5 – those based on newly developed scientific evidence
  - Article 14 – those targeting children or disease risk reduction claims

EFSA Opinions

- First opinions on Art 13 (5) and 14 published in August 2008
- Article 13 (5), 6.5% are positive (8/52)
  - No positive opinions for probiotics
  - No positive opinions for antioxidants
- Article 14 – reduced risk reduction/children's growth and development claims
  - 23 positive opinions to date
    - 7 in cholesterol reduction and reduced risk of CHD
    - 4 in bone growth/strength
    - 3 in teeth and dental

Approval for claims within EU

- Article 13.1 claims register received final approval from European Commission in May 2012
  - Industry has 222 health claims to play with
  - Industry has until December 2012 to comply with the register
  - Botanicals still to be reviewed.

European Commission

EU Register on nutrition and health claims

Claim type	Nutrient, substance, food or food category	Claim	Conditions of use of the claim / Restrictions of use / Reasons for non-authorisation	Health relationship	EFSA opinion reference	Commission regulation	Status	Entry Id
Art.13(1)	Alpha-linolenic acid (ALA)	ALA contributes to the maintenance of normal blood cholesterol levels	The claim may be used only for food which is at least a source of ALA as referred to in the claim SOURCE OF OMEGA 3 FATTY ACIDS as listed in the Annex to Regulation (EC) No 1924/2006. Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 2 g of ALA	maintenance of normal blood cholesterol concentrations	2009;7(9):1252, 2011;9(6):2203	Commission Regulation (EU) 432/2012 of 16/05/2012	Authorised	493, 568
Art.13(1)	Activated charcoal	Activated charcoal contributes to reducing excessive flatulence after eating	The claim may be used only for food which contains 1 g of activated charcoal per quantified portion. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with 1 g which should be taken at least 30 minutes before and 1 g shortly after the meal	reduction of excessive intestinal gas accumulation	2011;9(4):2049	Commission Regulation (EU) 432/2012 of 16/05/2012	Authorised	1938
Art.13(1)	Barley grain fibre	Barley grain fibre contributes to an increase in faecal bulk	The claim may be used only for food which is high in that fibre as referred to in the claim HIGH FIBRE as listed in the Annex to Regulation (EC) No 1924/2006	increase in faecal bulk	2011;9(6):2249	Commission Regulation (EU) 432/2012 of 16/05/2012	Authorised	819

http://ec.europa.eu/nuhclaims/resources/docs/euregister.pdf

Article 13.1 claims

- Most positive opinions for vitamins, minerals and plant stanols/sterols
- All negative for probiotics
- Flexibility within this still unclear across EU – different Member States likely to demonstrate different degrees of flexibility –
- UK Health Food Manufacturers Association has published guidance

Article 13 (1)

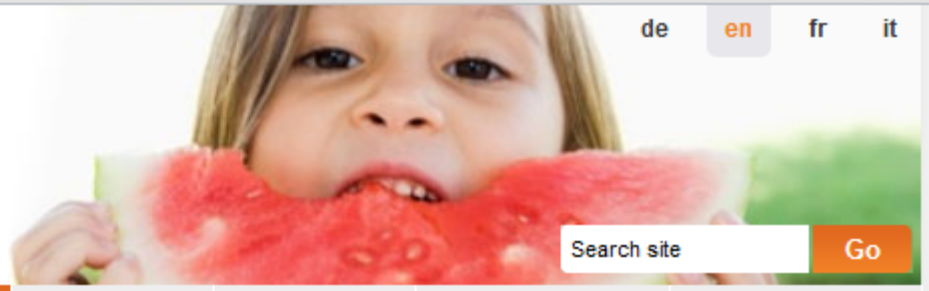
- 80% of them rejected because:
  - Companies failed to supply enough data
  - Assumptions were made about ingredients
  - Imprecise framing of claims e.g. energy, health, etc
  - ‘food groups’ e.g. fruit & veg, too broad

EFSA Guidance

- Guidance for health claims related to gut health and immunity
- Guidance on health claims related to antioxidants, oxidative damage & cardiovascular health
- Guidance on the scientific requirements for health claims related to appetite ratings, weight management and blood glucose concentration

EFSA Guidance

- Guidance on the scientific requirements for health claims related to bone, joint, skin and oral health
- Guidance on the scientific requirements for health claims related to physical performance
- Guidance for the scientific requirements for health claims related to functions of the nervous system, including psychological functions



de en fr it

efsa

ropean Food Safety Authority

ted *since 2002* to ensuring that Europe's food is safe

Search site Go

ut EFSA | News & events | Topics A-Z | Publications | Panels & units | Cooperation | Applications helpdesk | Calls & consultations

> Publications > EFSA Journal > Guidance on the scientific requirements fo...

Print

. Journal
: Published
st Issue
ssues
ut the Journal
orting publications
orate publications

EFSA JOURNAL

Search EFSA Journal Search

Advanced Search

Guidance on the scientific requirements for health claims related to gut and immune function

EFSA Journal 2011;9(4):1984 [12 pp.]. doi:10.2903/j.efsa.2011.1984

EFSA Panel on Dietetic Products, Nutrition and Allergies

Panel Members
Acknowledgment
Contact

Type: Guidance of the Scientific Committee/Scientific Panel

On request from: EFSA

Question number: EFSA-Q-2010-01139

Adopted: 28 January 2011

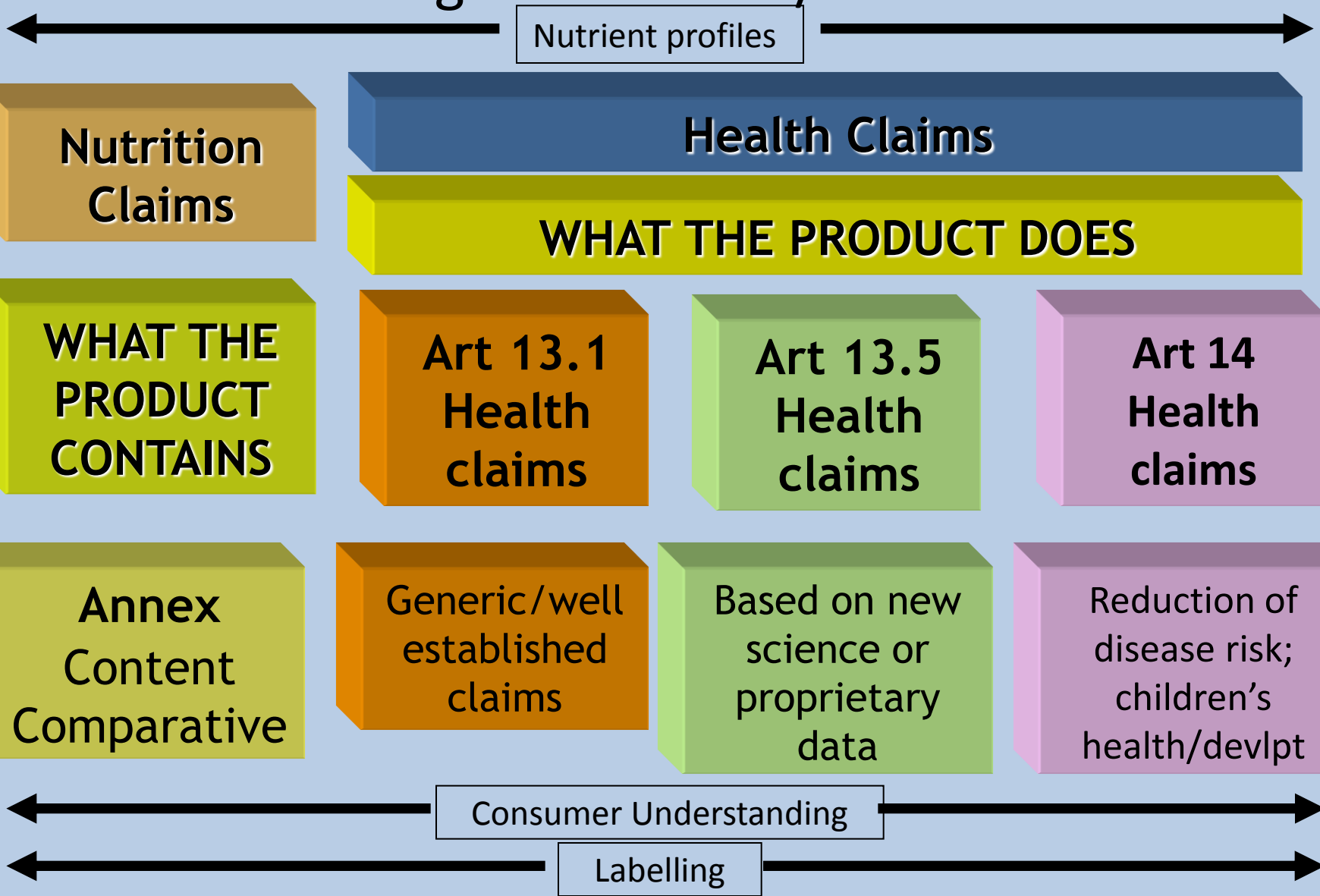
See also

- Nutrition and health claims homepage
- Panel on Dietetic Products, Nutrition and Allergies (NDA)
- Mandate

What is the difference between a nutrition and a health claim?

What's all the fuss about?

Nutrition and Health Claims Regulation 1924/2006



Nutrition Claims

Nutrition Claims

WHAT THE PRODUCT CONTAINS

- Conta… …ioxidants
- Conta… …biotics

Annex

= Health Claims

Nutrition Claims

- Clearly outlined in the Annex to the Regulation
  - E.g. 'Low fat' – no more than 3g fat per 100g for solids or 1.5g fat per 100 ml for liquids
  - 'High protein' – At least 20% of energy value of the food is provided by protein
- Amended by Regulation 116/2010 to include conditions of use for 'source of omega 3 fatty acids', 'high in omega 3 fatty acids', 'high in monounsaturated fat', 'high in unsaturated fat'

Key Elements of EFSA Assessment for Health Claims

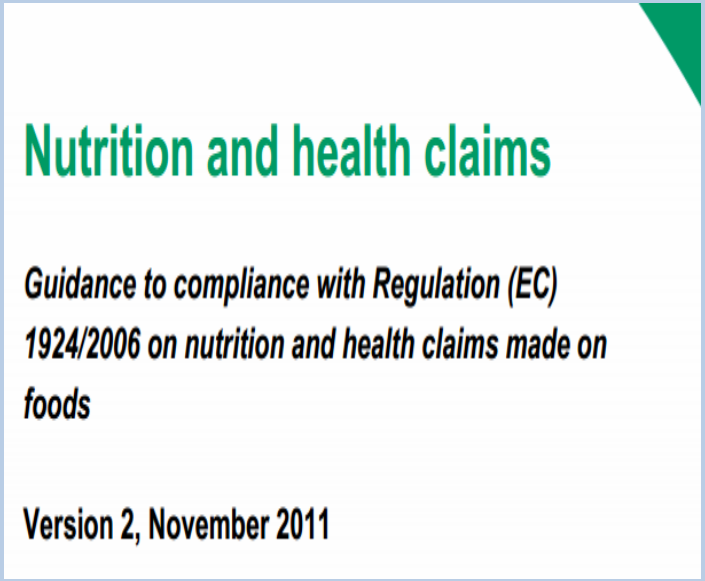
- Characterisation
- Relevance (benefit) to human health
- Substantiation of the claim
- Proposed wording
- Conditions of use
- http://www.youtube.com/watch?v=3zNL21gjwuo

EFSA Guidance

- No pre-established formula for approval but…
- HUMAN STUDIES ARE CENTRAL FOR SUBSTANTIATION OF HEALTH CLAIMS
- Studies must have been carried out with the food/constituent for which the claim is made
- Design and quality (incl. duration) of studies must allow conclusions to be drawn
- Studies must have been conducted in a study group representative of the population group for which the claim is made.

Guidance from Member States

- UK Dept of Health Guidance
- http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_131531.pdf



- Gives guidance on use of the term ‘healthy’
- Guidance on brand names and trade marks
- Guidance on recommendations from health professionals
- V useful Q & A
- Most practical and useful guidance

Glucosamine & Joint Health

- EFSA rejected Merck's original 13.1 claim in 2009 – 'glucosamine does not benefit the normal function of joints'
- EFSA subsequently rejected the 13.5 claim application in April 2012
- Merck challenged this stating that EFSA did not consider the bioavailability and efficacy data
- EFSA rejected arguments relating to healthy versus diseased populations and biomarkers used
- EFSA rejected the application again in August 2012

Probiotics rejected by 13.1 process

- Products incl. yoghurts, currently making claims about probiotics will have to cease by December 2012.
- Reformulation or alternative marketing strategies will be required.

Why do Probiotics continue to fail?

- Probiotics strains of bacteria were not sufficiently characterised.
- Additionally, because the claims were non-beneficial
  - *EFSA: "Just because you increase the number of any group of micro-organisms, including lactobacilli, is not considered in itself a beneficial effect. "*
- Lack of cohesive, conclusive biomarkers and clinical end points is a limiting factor

Health Claims options

1. Submit a new application with stronger science carrying out new studies if necessary
2. Already-approved generic health claims e.g. for vitamins and minerals, must ensure products contains at least ‘a source’ of the vit/mineral
3. For other nutrients, more specific conditions
   - E.g. glucomannan and weight loss: *“at least 3g of glucomannan should be consumed daily in 3 doses of at least 1 g each together with 1-2 glasses of water before meals in the context of an energy restricted diet”*

Products with EFSA approved health claims

Barley beta-glucans have been shown to lower/reduce cholesterol. High cholesterol is a risk factor in the development of coronary heart disease."

"Helps maintain normal platelet aggregation which contributes to healthy blood flow"

Phytosterols have been shown to lower/reduce cholesterol. High cholesterol is a risk factor in the development of coronary heart disease

"Supports energy yielding metabolism"

Thank-you

Fiona.lalor@ucd.ie