Seminar on EU Rules on Food and Nutrition Labelling and Nutrition and Health Claims

Mr Basil Mathioudakis

Health Claims

Better Training For Safer Food

Initiative

Bangkok, Thailand
8 October 2015

Outline

1. Typology: Function claims, Reduction of a risk factor of a disease claim, claims for children's growth and development
2. Authorised claims
3. Non-authorised claims
4. Claims "on hold"
5. Problem areas

Types of claims

Claims referring to a function of the body (Function claims)

- Growth, development, function of the body
- Psychological, behavioural functions
- Slimming/weight control, hunger, satiety, reduction of available energy
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e.g. "Vitamin C contributes to the normal function of the immune system"

Types of claims

Claims referring to the reduction of a risk factor of a disease

e.g. "Plant stanol esters have been shown to reduce blood cholesterol. Blood cholesterol is a risk factor in the development of coronary heart disease"

Claims referring to children's growth and development

e.g. "Calcium is needed for normal growth and development of bone in children"

Procedure for adoption or rejection of claims

- Submission of a request to authorise a claim to a Member State (MS) ➔ transmission to EFSA
- Scientific assessment by European Food Safety Authority (EFSA) ➔ Opinion by Risk Assessor
- Preparation and adoption of legal act by European Commission with Scrutiny of European Parliament and Council ➔ Decision by Risk Manager

Procedure for adoption or rejection of claims

- MS to inform EFSA of application received and transmit application **without delay**
- EFSA-**5 months** from receipt of a valid application to deliver opinion (possible extension of 2 months)
- EFSA Opinion transmitted to European Commission, Member States and applicant and **published**
- Applicant and others may submit comments to the Commission within **30 days from publication**
- European Commission-**2 months** to submit draft decision

Criteria for substantiation of heath claims

Regulation – health claims should be substantiated by:

- "*Generally accepted scientific evidence*"
- "*Taking into account the totality of the available scientific data*"
- "*Weighing the evidence*"

EFSA criteria for scientific substantiation:

- Relevance to human health
- Causality of the relationship
- Food quantity required for claimed effect
- Representativeness of data for target population

Main issues addressed by EFSA

Defining the claim

1. Is the food/constituent defined and characterised ?
2. Is the claimed effect defined and is it a beneficial physiological effect ?

Substantiation

3. Is a cause and effect relationship established between consumption of the food/constituent and the claimed effect ?
   - for the target group and under the proposed conditions of use
   - Human data are central

➢ Scientific substantiation requires a favourable outcome to **all** three questions

Assessment of evidence - steps

1. Selection & review of **relevant human studies:** key element for substantiation

2. Review of studies on **biological plausibility** (e.g. mechanisms that explain the effect of the food)

3. **Weighing the evidence** - combining the relevant human studies + other studies **to conclude on substantiation**

History numbers for function claims

- 31 January 2008 - Member States submitted national lists (**44.000 entries**)
- 2008-2009 consolidation of national lists
- May 2010 – EFSA publishes consolidated database (**4637 main entry claims / IDs**)
- More than 300 claims withdrawn by FBOs during consolidation phase

High level of evidence for substantiation

- EFSA approach/criteria surprised many FBOs
- Criticised generally as not appropriate for claims on foods
- Challenged in Court that it was not intended to apply to function claims that were already in use in the market- **challenge was rejected**

History numbers for other claims

EFSA has received **434 applications** (162 withdrawn)

- **224 children's claims**
- **66 risk reduction claims**
- **170 newly developed science / proprietary data / modification conditions of use**

Commission has received **256 EFSA opinions**

- **75 positive opinions**
- **181 negative opinions**

For the majority, comments by applicant/public to the Commission

Scientific comments are transmitted to EFSA; response is provided

Comments and EFSA response to comments on SANCO's website:

http://ec.europa.eu/food/food/labellingnutrition/claims/comments_efsa_en.htm

Use of permitted claims

For all claims:

- If in compliance, all operators may use authorised claims, subject to principles and conditions:
  - Compliance with specific conditions of use AND
  - Compliance with other general principles and conditions
  - Limited flexibility for wording allowed
  - Compliance with nutrient profiles (if and when set)

- Possibility to protect data for 5 years-own data

Claims, where do we stand today?

- 30 permitted nutrition claims
- 260 permitted health claims
- 2020 non-authorised health claims
- 2o95 health claims 'on-hold'

http://ec.europa.eu/nuhclaims/?event=register.home

On-hold claims

Where we stand today:

2095 IDs remaining 'on hold'

- 2078 IDs (claims) on botanicals
- 17 IDs were put on hold in June 2013 either for further assessment by EFSA or for further consideration by risk managers (e.g. caffeine, foods with reduced lactose)

Claims 'on hold' are:

- Listed on SANCO website
- Allowed to remain on the market until finalisation of their consideration

EU register of claims

Interactive database

List of **permitted** claims with wording, condition of use, restrictions

List of **non-authorised** claims with **reasons,** e.g.

- Substance not characterised
- Claimed effect too general to be assessed
- Claim not substantiated

Useful **additional information** for stakeholders

http://ec.europa.eu/nuhclaims/

Enforcement of the rules

Member States are responsible for the enforcement of EU rules. To promote uniform application of the rules

- **Guidance of 2007**
- **EU guidelines for the implementation of specific conditions in Article 10 of Regulation (EC) No 1924/2006 (Decision 2013/63/EU)**

Member States' guidance document on flexibility of wording. European Commission not involved.

Health Claims on Botanicals

Reflection on claims on 'botanicals' became inevitable and is on-going in the EU;

- More than 500 claims on botanical received a negative EFSA opinion
- Similar ingredients in Food Supplements and Traditional Herbal Medicinal Products (THMPs)
- Different approach for allowing claims / therapeutic indications
- Evidence of ‘traditional use’ carries different weight

This difference in legislation has been questioned

Health claims on Botanicals

Option 1:

Resume evaluation under current rules on claims

Option 2:

Develop specific legislation on botanicals used in food, including food supplements

- "Traditional use" allowed as the sole source of evidence to substantiate botanical claims?
- Other aspects than claims to be regulated? Safety, Quality, Labelling (and Claims)

Health claims on Botanicals

Notification of national rules is on the rise (especially for botanical substances) in the absence of EU rules

- The BELFRIT initiative (BEL, FR, IT). Notified list includes indications of use
- Compilation of a list of botanicals by DE

Other EU Member States expressed interest

Reaction of stakeholders-Consumers

Claims attract attention of consumers **but**

Nutritional considerations are not the main criterion for choice. Higher ranking:

- Price
- Taste
- Convenience

But consumers fully support the Regulation

Reaction of stakeholders-FBOs

- **Companies with authorised claims are supportive**
- **Big companies- rather supportive**
- **SMEs- variable, maybe less supportive**
- **Specific sectors (examples):**
  - Probiotics- very disappointed
  - Food supplements:
    - Other substances (-/+)
    - Botanicals (awaiting decision on Options)

Reaction of stakeholders-FBOs

Marketing reactions

Adjust products within the rules

- Addition of nutrients/substances for which claims can be made

Reaction of stakeholders-FBOs

Label of a dairy product with live microorganisms

Before decision on relevant claims ➔

"Contains good bacteria that help protect us"

After ➔ ❽⑤*contains more than 10 billion microorganisms L. Casei defensis and Vitamin B6 which contributes to the good functioning of the immune system…"*

Reaction of stakeholders-FBOs

Regulatory "shopping"

- Marketing under food categories with indications not subject to the Regulation on nutrition and health claims

Claim: '*any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics*

Regulatory shopping-dietetic foods

Labelling requirements for dietetic foods

"The designation under which a product is sold shall be accompanied by an indication of its particular nutritional characteristics"

"The labelling of products for which no specific Directive has been adopted shall also include (...) the particular elements of the qualitative and quantitative composition or the special manufacturing process which gives the product its particular nutritional characteristics"

Regulatory shopping-FSMPs

Labelling requirements for (FSMPs) foods for special medical purposes

- "The labelling shall (…)include:

(a) the **statement 'For the dietary management of…**' where the blank shall be filled in with the diseases, disorders or medical conditions for which the product is intended (…)

(c) a **description of the properties and/or characteristics** that make the product useful in particular, as the case may be, relating to the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product"

Regulatory shopping-medical devices

Council Directive 93/42/EEC concerning medical devices

'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for **diagnostic** and/or **therapeutic purposes** and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

Regulatory shopping-examples

As dietetic food:

“A concentrated mix of folic acid, vitamin D, iron, iodine, DHA and EPA for pregnant or breastfeeding women”

As an FSMP:

“A combination of minerals and cranberry extract for the dietary management of recurrent bladder infections (cystitis)”

As Medical Devices:

Products claiming weight loss (fibres blocking fat absorption)

Products claiming treatment/prevention of cystitis

Generic descriptors

Article 1(4) of Regulation (EC) No 1924/2006 provides for an exemption from that Regulation, for generic descriptors (denominations) which have been traditionally used to indicate a particularity of a class of foods or beverages which could imply an effect on human health.

Generic descriptors

Examples of generic descriptors:

- **Tonic water**
- **Digestive biscuits**

"**probiotics**"???-Generic descriptor or not?

Generic descriptors

COMMISSION REGULATION (EU) No 907/2013

setting the rules for applications concerning the use of generic descriptors (denominations)

came into force on 11 October 2013

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:251:0007:0009:en:PDF

European Commission

Thank you for your attention

BTSF

ANY QUESTIONS?

Consumers, Health And Food Executive Agency

The contents of this presentation are the views of the author and do not necessarily represent an official position of the European Commission.

AETS - Application Européenne de Technologies et Services

17 Av. André-Marie Ampère
64140 Lons, France

Tel: +33 5 59 72 43 23
Fax: + 33 5 59 72 43 24
www.aets-consultants.com

Better Training for Safer Food
BTSF

European Commission
Consumers, Health and Food Executive Agency
DRB A3/042
L-2920 Luxembourg