LEGAL AND REGULATORY ASPECTS OF FUNCTIONAL & MEDICAL FOODS

What are medical foods?

Product characteristics food for special medical purposes (Reg. 609/2013)

- Food specially intended for dietary management of patients
- Which cannot be achieved by modification of normal diet alone
- To be used under medical supervision
- Type of use: total diet replacement or partial food
- Intended for patients that do not digest/excrete ordinary food

What are functional foods?

Product characteristics functional foods

- Hippocrates (nearly 2,500 years ago): “Let food be thy medicine and medicine be thy food”
- Japan: only country having regulatory approval process for so-called FOSHU - Food for Special Health Use
- Institute of Medicine’s Food and Nutrition Board (1994): any food or food ingredient that may provide a health benefit beyond the traditional nutrients it contains

Examples:
- oats ➔ fiber b-glucans lowering cholesterol,
- tomato’s ➔ lycopene lowering cancer risk
- fish ➔ omega-3 fatty acids (PUFA’s) reducing CVD risk

(source: IFT, 1998)

Agenda

- Rationale for this seminar
- Legal framework of functional and medical foods
- Focus on Health and Nutrition Claims
- Focus on Food Information
- Expected developments

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Functional foods in context

- food
- functional food
- food supplements
- foodstuffs intended for particular nutritional uses
- medicinal products

Legal framework medical foods (1)

Highly regulated both at EU/national level

- Regulation 609/2013 dated 12 June 2013 re. foods for special medical purposes i.e. Entry into force: 20 July 2016 / 19 July 2013
- Warenwetregeling Dieetvoeding voor medisch gebruik
- Informative leaflet of Dutch Food Safety Authority "Beoordelingskader t.b.v. dieetvoeding voor medisch gebruik"
- NVWA Infoblad # 77 “Dieetvoeding voor medisch gebruik”

Requirements

- Composition of medical food is appropriate for satisfying nutritional requirements of persons for whom it is intended.
- Medical foods should be safe: do not contain any substance in such quantity as to endanger the health of target group.

Legal framework medical foods (2)

Further EU/national requirements

- If a medical foods ingredient qualifies as a Novel Food, requirements of Novel Foods Regulation (258/97) should be met as well.
- This should be established by food business operator on the basis of generally accepted scientific data.
- Mandatory labeling as "food for special medical purposes" (dieetvoeding voor medisch gebruik) and "to be used under prescription".
- No pharmacological: no misleading information attributing to the food preventing, treating or curing properties re. human disease.
- Detailed composition requirements: present in product:
  - EU: Union list re. vitamins / minerals / amino acids etc.
  - NL: min / max quantities of spec. vitamins / minerals /

Legal framework medical foods (3)

Market access

- No pre-market authorisation.
- Usually clinical trials for validation of safety, toleration and efficacy is medical foods are responsibility of food business operator.
- And also: prior to first marketing manufacturer / importer should send label specimen to Dutch Food Safety Authority ➔ flow chart

Assessment re ➔ qualification (is product medical food or not?)
- compliance (does the effect and composition of the product meet the needs of target group and the Commodity Act requirements)
Legal framework functional foods (1)

Requirements re. composition and labeling / specific categories
• No specific requirements for functional foods as such, but all applicable legislation re. (i) food information to consumers and (ii) health / nutrition claims applies
• Specific categories include food supplements / Novel Foods / medical foods

Requirements re. market access
• Depending on the qualification of the functional food as one of above categories ➔ functional food follows applicable market access legislation.

Focus on health & nutrition claims (1)
Relation between claims and medical foods regulations
• Regulation 1924/2006 establishes rules and conditions for use of nutrition and health claims on food ➔ these apply as a general rule to medical foods, unless otherwise specified in Regulation 609/2013 or delegated acts adopted pursuant thereto (Cons. 28 Reg. 609/2013).
• Medical foods shall comply with any requirement of EU food law. However, 609/2013 requirement prevail over any conflicting EUR food law requirements (art. 6 Reg. 609/2013).
Likewise, the 1924/2006 framework on nutrition and health claims equally applies to functional foods.

Focus on health & nutrition claims (2)
Regulation 1924/2006
• Claim: any message stating that a food has particular characteristics
• Nutrition claim: any message stating that a food has particular nutritional properties
  • What is in the product?
• Health claim: any message stating that a relationship exists between the consumption of a food and health
  • What does the product do?
Focus on nutrition & health claims (3)
Regulation 1924/2006
Both nutrition and health claims can only be used if:

• The presence of a nutrient in a food in respect of which the claim is made has shown to have a beneficial nutritional or physiological effect;
• The nutrient for which the claim is made is contained in the final product in a quantity that will produce the claimed effect;
• The nutrient covered by the claim is available to be used by the body;
• The quantity of the food that can be reasonably expected to be consumed provides a significant quantity of the nutrient to which the claim relates.

Focus on nutrition claims (4)
Regulation 1924/2006
• Nutrition claims are aimed at certain nutritional properties, in terms of the energy the food provides and the nutrients the food contains.
• Currently: 29 authorised nutrition claims, subject of specific conditions of use – for example:
  Claim: High fiber
  Condition of use: product should contain at least 6 g of fibre per 100 gram or at least 3 g of fiber per 100 kcal.
  Claim: Source of protein
  Condition of use: at least 12 % of the energy value of the food is provided by protein

Focus on health claims (5)
Regulation 1924/2006
3 types of health claims:
(1) General function claims
(2) Disease risk reduction claims
(3) Claims re. children's health and development
Examples
Ad (1) "Carbohydrates contribute to the maintenance of normal brain function."
Ad (2) "Plant stanol esters have been shown to lower/ reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart diseases."
Ad (3) "Essential fatty acids are needed for normal growth and development of children."

Focus on health claims (6)
Regulation 1924/2006
"Help Replenish Bifido Lost with Age" "Restores natural balance of good bacteria in digestive tract"
**Claims and medical foods (1)**

Prohibition to attribute to medical foods the property of preventing or curing a human disease or imply such properties (art. 9.5 Reg. 609/2013)

- Use of disease risk reduction claims practically ruled out

However, targeted audience of medical foods (or their medical staff) is usually interested in the mere maintenance of certain body functions

- Use of general function claims of particular interest for this type of products, for example:

  **Claim 1:** Calcium contributes to the normal muscle function
  **Claim 2:** Calcium is needed for the maintenance of normal bones

  **Condition of use:** food should contain significant amount of calcium

**Claims and functional foods (1)**

For functional foods, any type of claim could be of interest - example:

**Claim:** "Activated charcoal contributes to reducing excessive flatulence after eating"

**Condition of use:** food should contain 1 g of activated charcoal per quantified portion.

**Focus on Food Information (1)**

**Relation between food information and medical foods Regulations**

- Regulation 1169/2011 on the provision of food information to consumers (Food Information Regulation) will enter into force on 13 December 2014 and lays down general labelling requirements.

- These requirements apply, as a general rule, to all categories of food including medical and functional foods.

- However, Medical Foods Regulation may provide for additional requirements to / derogations from Food Information Regulation to meet the specific objectives of the Medical Foods Regulation (cons. 24)

**Focus on Food Information (2)**

**Regulation 1169/2011 replaces i.a the following Directives that needed to be updated:**

- Directive 2000/13 re. labelling, presentation and advertising of foodstuffs
  - Community rules of a general nature applicable horizontally to all foodstuffs.

- Directive 90/496 on nutrition labelling for foodstuffs
  - Caters to growing public interest in relationship between diet and health: appropriate nutrition labelling helps making healthy choices.
Focus on Food Information (3)

Scope of Food Information Regulation:
- applies to food business operators in all stages of the food chain responsible for compliance;
- applies to all foods intended for the final consumer;
- deliberately includes food supply via internet.

Relation with other food legislation
- Novel Foods / Medical Foods (consideration)
- Health and Nutrition Claims (art. 49 new wording art. 7 Health Claim Regulation: nutrition labelling of products for which a nutrition / health claim is made is mandatory declaration of nutrients in accordance with art. 31 to 34 Food Information Regulation)

Focus on Food Information (4)

What’s new as per 13 December 2014 (selection)?
- Additional requirements to list of ingredients (allergens, nano).
- Detailed legibility requirements.
- Nutrition declaration (required as per 13 December 2016).

Focus on Food Information (5)

Mandatory particulars (art. 9) NB exceptions for packaging < 10 cm²:
(a) Name of the food
(b) List of ingredients listed in descending order of weight
(c) Ingredients/processing aids causing allergens/intolerances emphasised through clearly distinguished typeset
(d) Quantity/category of ingredients
(e) Net quantity of the food
(f) Date of minimum durability or “use by” date
(g) Special storage conditions or conditions of use
(h) Name and address of FBO
(i) Country of origin/place of provenance if required as per art. 26
(j) Instructions for use
(k) Alcoholic strength by volume if > 1.2%
(l) Nutrition declaration

Focus on Food Information (6)

Legibility (art. 12 and 13)
Where should mandatory food information be stated?
- prepacked food: directly on product or label attached thereto;
- non-prepacked food: MS may adopt national measures to define the communication and content of mandatory info. (art. 44).

How should mandatory food information be shaped?
- Easily visible and clearly legible;
- Minimum font size 1.2 mm or 0.9 mm if packaging is smaller than 80 cm².
Focus on Food Information (7)

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Nutrition declaration (1/2)

- As of 13 December 2016, a nutrition declaration is mandatory for most of the food products.
- Such declaration includes (art. 30):
  - the energy value (calories) and
  - the amounts of fat, saturates, carbohydrates, sugars, protein and salt.
- Exceptions apply to food supplements i.a. Instead: specific regime for supplements (art. 8 Dir. 2002/46).

Focus on Food Information (8)

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Nutrition declaration (2/2)

Energy value and amount of nutrients (art. 31 – 33):

- shall relate to food as sold or food as prepared, if sufficient detailed preparation instructions are given;
- Shall be expressed per 100 g or 100 ml;
- May only be expressed per portion/consumption unit in addition thereto; also state quantity per portion and no. of portions.

Presentation (art. 34 and 35):

- in tabular format (when space does not permit: linear format);
- Different forms of expression allowed when meeting specific conditions.

Expected developments

- Flexibility in wording re. nutrition / health claims: differences between various MS are likely to increase
- Case law: more and more cases on borderline products, e.g.:
  - District Court Rotterdam 6 March 2014: qualification food supplement as pharmaceutical
  - Advertising Code Committee 28 April 2014: idem
- Graphic representation of nutrition tables: preferred standard? Traffic light or otherwise?

Conclusions

1. Medical foods are highly regulated, whereas legal framework for functional foods is less clear.
   - Does not mean there are no requirements for functional foods
2. Claims offer an opportunity but in the same time a challenge
   - Consumer focuses on obtaining health benefits from food.
   - However, does food product meet conditions for use?
   - How much flexibility in wording?
3. Food information Regulation brings along many changes, of which the most important ones are (i) many new mandatory particulars, (ii) nutrition declaration and (iii) requirements re. legibility.
   - Also medical foods and functional foods need to comply.
Extra: Claims and medical foods

Other examples of claims to be used for medical foods related to iron

Claim 1: Iron contributes to the normal cognitive function
Claim 2: Iron contributes to the normal formation of red blood cells and haemoglobin
Claim 3: Iron contributes to the reduction of tiredness and fatigue

Condition of use: product should contain significant amount of iron

→ Is calculated on basis of Reference Intake (RI) of iron: 14 mg (see Annex XIII to Regulation 2011/1169)
→ Depends on type of product: beverage (7.5 % RI), non-beverage (15 % RI) or single portion (15 % RI)

Extra: Claims and functional foods

Further examples of claims to be used for functional foods:

Claim: creatine increases physical performance in successive bursts of short-term, high intensity exercise.
Condition of use: mention that beneficial effect is obtained with a daily intake of 3 g creatine

Claim: protein contributes to a growth in muscle mass
Condition of use: At least 12 % of the energy value of the food is provided by protein

Legal stuff

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