AXON
science based lawyers

LEGAL & REGULATORY ASPECTS OF NOVEL FOODS AND HEALTH CLAIMS

Novel Foods & Health Claims
31 January 2013

health
food
technology

Karin Verzijden
www.axonadvocaten.nl

Agenda

- Rationale for this seminar
- Introduction to notions of novel foods and health & nutrition claims;
- Case study: market launch of innovative product in food sector;
- What's cooking?
- Conclusions

Rationale for this seminar

- Food is more and more in the center of interest: link with health
  - EFSA sets average requirements for energy intake
  - The Economist Dec. 2012: special report obesity
  - Bakas, *Future of Food*: new medicines = food!
- Health claims have become important tools for marketing food, including novel foods.
- Regulatory framework re. health claims has changed, whereas changes in novel food regulatory framework are still pending.
  - Consequences re. market access and marketing strategy?
  - Anticipation of changes?
  - Any open ends?

Introduction to novel foods (1) Regulation 258/97

Novel Foods are not:

- Medicinal products (Directive 2001/83, Regulation 726/2004)
- GM Food (Regulation 1829/2003)

- Food additives, food enzymes or food flavourings (so-called "*food improvement agents*", Regulation 1331–4 /2008)
- Food Supplements (Directive 2002/46)
- Vitamins / minerals / other substances (Regulation 1925/2006)
- Foodstuff for particular nutritional uses (so-called PARNUTS, such as infant formulae and baby food, Directives 89/398, 2006/141 and 2006/125)

Introduction to novel foods (2)

- Novel foods (Regulation 258/97): food and food ingredients that prior to 1997 have not been used for human consumption to a significant degree within the EU.
- 4 categories, namely food and food ingredients:
  - with a new or intentionally modified primary molecular structure: structured lipids;
  - consisting of or isolated from micro-organisms, fungi or algae: fungal lycopene;
  - consisting of or isolated from plants and food ingredients isolated from animals: nangai nuts, Baobab;
  - to which a new production process has been applied: high pressure treatment for fruit preparations.

Novel foods (3)

- Novel foods should in the first place be safe. Therefore, novel foods and novel food ingredients must not:
  - present a danger for the consumer
  - mislead the consumer → proper labeling!
  - be nutritiously disavantageous for the consumer (in comparison to food they intend to replace).
- Two types of authorisation procedures:
  - Full blown procedure based on new scientific evidence demonstrating that above criteria are met;
  - simplified procedure for products that are substantially equivalent to existing foods ("me too" products)

Novel Foods (4) granted authorisation

- Yellow fat spreads with added phytosterol esters (Unilever, UK, 2000)
- Fruit preparations pasteurized using a high pressure treatment process (Danone, France, 2001)
- Coagulated potato protein and hydrolysates thereof (Avebe, the Netherlands, 2002)
- Milk based beverage with added phytosterols (Novartis Consumer Health, Belgium, 2004)
- Arachidonic acid-rich oil from mortierella alpina (fungal oil, Abbott International, USA, 2008)
- Baobab dried fruit pulp (PhytoTrade Afrika, UK, 2008)
- Chia seeds (Salva hispanica, R Craig and Sons Ltd, UK, 2009)

Introduction to health & nutrition claims, Regulation 1924/2006

- Claim: any message stating that a food has particular characteristics
- Nutrition claim: any message stating that a food has particular beneficial 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?

Nutrition claims (1)

Nutrition claims are aimed at certain nutritional properties, due to: the energy (read: calorific value) the food:

- provides (10 kcal per 100 g)
- provides at a reduced or increased rate (low energy)
- does not provide (energy free)

the nutrients the food:

- contains (source of calcium)
- contains in reduced or increased proportions (light)
- does not contain (sodium free).

Nutrition claims (2)

- Nutrition claims are only permitted if listed in the Annex to Regulation 1924/2006 (24 + 5) and if certain conditions are met:
  - shown nutritional/physiological effect;
  - claimed nutrient is present in significant quantity;
  - claimed nutrient is present in suitable form for human body;
  - claim relates to food ready for consumption.

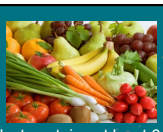
Health claims (1)

- 3 types of claims
  - general function claims (16 May 2012: 222 claims authorised persuant to Regulation 432/2012)
  - reduction of disease risk claims
  - children's development and health claims
- A general function claim:
  - relates to the growth, development and functions of the body: Lycopene helps to strenghten your body's natural defences
  - refers to physiological/behavioural functions: Helps refocus your mind and keeps you in relaxed but alert mental state
  - concerns slimming/weight control: Keeps you in shape

Health claims (2)

- A reduction of disease risk claim: states that the consumption of a food significantly reduces a risk factor in the development of a human disease: A low calcium intake is a risk factor in the development of osteoperosis. This product is rich in calcium.
- In children's development and health claims: Essential fatty acids are needed for normal growth and development of children.
- For (i) reduction of disease risk, (ii) children's development and health claims and (iii) general function claims based on newly available evidence → individual authorisation procedure.

Claim examples



- "High fibre" (claim allowed if product contains at least 6 g of fibre per 100 g or at least 3 g of fibre per 100 kcal.)
- "Vitamin D is needed for the normal growth and development of bone in children".
- "Plant stanol esters have been shown to reduce blood cholesterol. Blood cholesterol is a risk factor in the development of coronary heart disease."
- "Low fat" (claim allowed if product contains no more than 3 g. of fat per 100 g for solids or 1,5 g of fat per 100 ml for liquids)

Case study (1)

- Fully Berry B.V., a spin-out company from WUR, has innovated together with WUR a cranberry extract powder. Prior to 1997, this powder has not been used for human consumption within the EU to a significant extent.
  - Market access in EU?
  - Marketing strategy?
- Distinction should be made between requirements and options.
  - Novel foods legislation → safety = requirement
  - Claims legislation → voluntary information = optional

Case study (2)

- Does Fully Berry's cranberry extract powder qualify as a novel food under the EU Novel Foods legislation?
  - Yes: food ingredient isolated from (the fruit of) plants
- In that case, what is the designated route for market access?
  - Depends on whether substantially equivalent product was marketed before.
  - If so: simplified authorisation procedure
  - If not: full blown authorisation procedure
- What does the full blown authorisation procedure imply for Fully Berry B.V.?
  - Request for authorisation should be made to Medicines Evaluation Board (MEB) - assessment made by Committee on Safety Assessment of Novel Foods.

Case study (3) – novel foods

- What is actually evaluated?
  - Overall safety evaluation, taking into account toxicology, nutrition, microbiology, gastroenterology, epidemiology, molecular biology, statistics and allergology.
- And then?
  - MEB assessment report serves as scientific advice for Dutch Health Minister = so-called Initial Assesment → Commision
- What is the role of the Commission?
  - Portal for 27 Member States: comments / reasoned objections

Case study (4)

- When does the EFSA come into play?
  - If Dutch Health Ministry requires so-called Additional Assessment or if a MS makes reasoned objections, then the Commission will request an opinion from EFSA.
- Is this exceptional or rather customary?
  - Judge for yourself: of all 59 approvals for Novel Foods since 1997, for 45 an EFSA opinion was obtained.
- Any incidence on timing?
  - For sure: full blowns authorisation procedures for novel foods take between 1 – 6 years, average 3,5 years: 2 years without EFSA opinion, 4 years with EFSA opinion.
  - Substantial equivalence procedure only takes few months!

Case study (5) – health claims

- Assuming that Fully Berry managed to obtain an authorisation for its cranberry extract powder to be marketed as a novel food, what does this imply for any potential health claim?
  - Request for health claim should be made separately and in accordance with Regulation 1924/2006.
  - Any mandatory labeling associated with novel foods shall not be considered as health claims.
- In order to assess the relevance and contents of any health claim, Fully Berry should consider its target audience:
  - B2B?
  - B2C?

Case study (6) – health claims

- Scope of Regulation 1924/2006 is all commercial communications, whether in the labeling, presentation or advertising.
  - Includes: brochures, leaflets, internet, trademarks
  - Excludes: scientific communication as such (but scientific information on labels is in) and communication to health care professionals.
- NB Commercial communications re. food are also subject to:
  - Directive 2006/114 re. misleading and comparative advertising;
  - Directive 2005/29 re. unfair B2C commercial practices
  - Advertising Code for Foodstuff issued by Dutch Advertising Code Authority

Case study (7) – health claims

- What health claim would be appropriate for the cranberry extract powder Fully Berry wants to market?
  - *"Cranberries have proven to have a positive effect on the bladder. Therefore the consumption of cranberry extract powder reduces the chance of contracting bladder inflammation".*

OR

- *"Cranberries contain proanthocyanidins. These are potent antioxidants of which scientific evidence has shown to decrease bacterial adherence to the bladder epithelium cells. As a consquence, bacteria have less likelihood of grouping together to cause bladder infection"*

Case study (8) – health claims

- How should Fully Berry's intended claim be classified and what are the consequences?
  - Claim qualifies as a reduction of disease risk claim → reduction of risk is explicitly stated.
  - Intended claim is not contained in list of 222 authorised general function claims: individual authorisation procedure.
- Fully Berry should make an application for indiviual authorisation to Food and Consumer Product Safety Authority ("*admissibility check*"), cc EFSA containing:
  - Information on the characteristics for which claim is made;
  - Proposal for wording of health claim + specific conditions of use;
  - All pertinent data substantiating health claim ("studies")

Case study (9) – health claims

- What should the studies to be submitted by Fully Berry in particular demonstrate?
  - Claimed effect is relevant for human health;
  - Cause/effect relationship between consumption of the food and claimed effect in humans
  - Quantity of food + pattern of consumption required to obtain claimed effect
  - Study groups from which evidence was obtained is representative for target population.
- What guidance is available?
  - Regulation 353/2008
  - www.efsa.europe.eu/efsajournal

Case study (10) – health claims

- Is any protection offered for Berry's proprietary data?
  - Yes: scientific data in the application may not be used for the benefit of subsequent applicant for period of five years from authorisation date, where
    - such data were designated as proprietary;
    - prior applicant had exclusive right of reference to proprietary data;
    - claim could not have been authorised without submission of proprietary data.
- What is a realistic timing for Fully Berry to have its claim approved?
  - 9 – 12 months (excluding "stop the clock" requests for further info by EFSA)

What's cooking (1) ?

Health claims:
Regulation 1624/2006 contains prohibition on general, non-specific benefits of food for *overall good health* or *health-related well-being*.

- First EU Court case: Deutches Weintor vs. Land Reinland-Pfalz (ECJ C-544/10, date decision 06-12-12): "*easily digestible*" ("bekömlich") = health claim?
- Pending preliminary ruling before the European Court of Justice Spirituosen-Industrie vs. Sonnthurn (C-51/11, date request 04-02-11): It is consistent with Community law that prohibition *"beverages containing > 1,2% alcohol by volume of alcohol shall not bear health claims*" also applies to beverages that do not place a strain on or adversely affect the body or its functions?

What's cooking (2)?

Health claims
Regulation 1624/2006 lays down principle of so-called Nutrient Profiles (NP) → adoption due in 2010, but yet to be established.

- NP will restrict the use of claims which contain high levels of fat, sugars and salt.
- As long as NP are not defined, nutrition and health claims can get authorized without having to match a NP.
- When established, products bearing health claim must comply with NP within 2 years time.
- If such product fails one of the NP, the product will not be allowed to bear any health claim at all.

What's cooking? (3)

Health claims
- 24 January 2013: Commission issues guidelines for implementation of specific conditions for health claims (art. 10 Regulation 1924/2006).
- Guidelines are addressed to national control authorities and food business operators.
- Article 10 provides four pieces of mandatory information accompanying authorised health claims in the labeling, presentation or advertising of the food:
  - Labeling, presentation → Regulation 1169/2001 on the provision of food information to consumers (entry info force end 2014)
  - Advertising → Directive 2006/114
  - Further rationale for mandatory information: consumer safety

What's cooking (4)?

Health Claims
- List of 222 authorised general function claims still leaves open ends
  - Example: "Water contributes to normal regulation of the body's temperature" subject to restriction of compliance with Directives 2009/54 and/or 98/83. Consequences?

Novel Foods:
- Ongoing discussions >3 years on changes in Regulation 259/97
- Remaining hick-ups are:
  - Term for obtaining market approval
  - food produced from cloned animals
  - nano-foods (now not covered by Regulation 259/97)

Conclusions

1. Health claims have become vital marketing tools in attracting consumer's attention and to differentiate products from competing products.
2. Increased pressure on food business operators: providing accurate information to EU consumers + comply with regulatory framework.
3. When marketing Novel Foods, health claims are even more attractive to get innovative message across to target audience.
4. In order not to hamper innovation, regulatory framework should be streamlined → effective lobbying required!

niaba

Thank you for joining this Axon seminar today!

- Axon lawyers: niche firm dedicated to life sciences, focus on health, food & technology
- Started by Carine van den Brink, Erik Vollebregt and Karin Verzijden in 2011, based in Amsterdam.
- International alliance with similar niche firms in UK, Germany, France and Italy
- Services provided are all at the crossroads between law and innovation: IP licensing, regulatory advice and litigation, formation and growth financing of companies.