

A close-up, blue-tinted photograph of a microscope's objective lenses and eyepiece, positioned on the left side of the slide.

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FOOD INFORMATION AND CLAIMS: IMPLICATIONS OF CONTROLLED ADVERTISING FOR THE FOOD INDUSTRY

Craig Simpson, Attorney

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NUTRITION AND HEALTH CLAIMS: SCOPE AND PURPOSE

- Regulation 1924/2006 covers:
 - ✓ Words (including trade marks/brand names), symbols or graphics
 - ✓ In commercial communications (labels, presentation, advertising (websites))
- Removes trade barriers for foods arising from national claims rules
- Scientific substantiation of beneficial claims
- Stop beneficial claims on “bad” foods (nutrient profiles)
 - ✓ “Avoid that claims mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet” (Recital 11)

NUTRITION AND HEALTH CLAIMS: ISSUES AND CONTROVERSIES

- Demonising “unhealthy foods” despite role in balanced diet
- Role of the Regulator? Information to consumer or make choice for consumer?
- Are natural products a special case?
- Effect on competitiveness of Food Industry (probiotics, functional products)

NUTRITION AND HEALTH CLAIMS: UNCERTAINTIES

- Current regulatory limbo because:
 - ✓ Nutrient profiles undecided (deadline 19.1.09);
 - ✓ Which claims qualify as ‘generally accepted’ or subject to authorisation (borderline issues)?
 - ✓ Extent of evidence needed to support claims (particularly ‘generally accepted’ claims)
- Hinder food industry competitive strategies:
 - ✓ Reformulate to legally bear claim (regulator’s intention)
 - ✓ Remove claim (kills marketing / product positioning)
 - ✓ Use ‘disclosure’ exemption

NUTRITION AND HEALTH CLAIMS: NUTRIENT PROFILING

- Food must comply with nutrient profiles to bear claim (e.g. not exceeding certain levels of fat, sugar or salt)
- Commission to establish by 19.1.09
- February 2008 EFSA scientific advice to Commission re profile setting:
 - ✓ Industry criticises as vague and inconclusive (no mention of acceptable levels for fat, salt or sugar)
 - ✓ Good news? : Tailored profiles for certain categories of foods

NUTRITION AND HEALTH CLAIMS: NUTRIENT PROFILING

- Commission Working Document on the setting of Nutrient Profiles (October 22, 2008)
 - ✓ Exemptions: food supplements, dietetic foods, fruits and vegetables
 - ✓ Categories with specific, different profiles
 - ✓ Suggested profiles (which ingredients, which levels)

REDUCTION OF DISEASE RISK AND CHILDREN'S DEVELOPMENT CLAIMS (ARTICLE 14)-PROCEDURE

- Most strictly controlled: full authorisation procedure
 - ✓ Dossier to MS authority with supporting scientific studies and any proprietary information claim
 - ✓ MS sends to EFSA for Opinion
 - ✓ EFSA to produce public Opinion with 5 months of receipt (review scientific substantiation and wording)
 - ✓ Final Commission decision whether included in positive list by Member State experts in SCFCAH (Commission not bound to follow EFSA Opinion)

REDUCTION OF DISEASE RISK AND CHILDREN'S DEVELOPMENT CLAIMS (ARTICLE 14)-EVIDENTIAL BAR?

- August 2008 EFSA rejects 7 of first claims evaluated, including National Dairy Council Ireland Claims
- “Three portions of dairy foods every day ... may help promote a healthy weight during childhood and adolescence” (on milk, cheese and yoghurt)
 - ✓ EFSA Opinion
 - Insufficient data on nutritional composition and its variability between products
 - Insufficient evidence of cause and effect
 - Insufficient study sample given (50 – 90 subjects)
 - Age range of study subjects too limited

REDUCTION OF DISEASE RISK AND CHILDREN'S DEVELOPMENT CLAIMS (ARTICLE 14)-EVIDENTIAL BAR?

- “Milk and cheese prevents dental caries in children”
 - ✓ EFSA Opinion:
 - Studies fail to address dietary pattern or other lifestyle factors
 - Insufficient characterisation of nutritional composition and variability between products
- Similar strict approach in pending EFSA review of ‘generally accepted’ claims?

REDUCTION OF DISEASE RISK AND CHILDREN'S DEVELOPMENT CLAIMS (ARTICLE 14)-EVIDENTIAL BAR?

- Dossier preparation a significant burden on industry (Regulation 353/2008):
 - ✓ Human studies mandatory
 - ✓ Non-peer reviewed articles/books aimed at consumers insufficient
 - ✓ “All scientific data, published and unpublished, in favour and not in favour”
 - ✓ 3 clinical trials = €500,000
- Chilling effect on industry?
 - ✓ Example of food supplements
 - ✓ Rejection of insufficiently detailed dossiers

GENERALLY ACCEPTED HEALTH CLAIMS (ARTICLE 13(3))

- Member State submitted lists of “generally accepted” claims to Commission pre 31.1.08
- Final positive list by 31.1.2010
- Lighter EFSA ‘review’ (no authorisation procedure) with ‘references to scientific justification’
 - ✓ EFSA Guidance: same evidence needed as for Article 14 claims
 - ✓ Legally incorrect to apply same evidence standard?
 - ✓ Impractical (2,800 claims before 31.1.2010)
 - ✓ Commission (not EFSA) finally decides whether evidence is sufficient

NUTRITION AND HEALTH CLAIMS: BORDERLINE DAIRY CLAIMS

- Is it Article 14 or generally accepted claim - authorisation procedure or not?
- Irish Food Safety Authority:
 - ✓ ‘Helps maintain a healthy blood pressure’ (milk) – 13(1) or 14?
- Generally accepted claim can mention disease risk provided does not suggest reduction of disease:
 - ✓ Maintains [normal vital function of body] (Article 13(1))
 - ✓ Lowers incidence of [risk factor] (Article 14)

NUTRITION AND HEALTH CLAIMS: BORDERLINE DAIRY CLAIMS

- Generally accepted claim can refer to children if does not solely refer to health/development of children or appear on products aimed solely at children and scientific substantiation covers entire life span
 - ✓ “Calcium is good for children’s growth” (Article 14)
 - ✓ “Calcium is good for children’s growth and pregnant women” (Article 13(1), provided adequate substantiation)

NUTRITION AND HEALTH CLAIMS: INNOVATIVE CLAIMS/PROPRIETARY DATA (ARTICLE (13(5)))

- Claims based on new scientific evidence: (not so!)
‘fast track’ authorisation procedure
- Threatened delay on submission of innovative claims (with proprietary data) until 2010
- Proprietary information claim in application:
 - ✓ 5 year data protection period from authorisation date
 - ✓ Use of health claim by others restricted without authorisation (anti free-rider provision)

NUTRITION AND HEALTH CLAIMS: NUTRITION CLAIMS

- Must be on positive list/Annex to Regulation and comply with conditions stated claims
 - ✓ **Low fat:** “where the product contains no more than 3 g of fat per 100 g for solids or 1,5 g of fat per 100ml for liquids (1,8 g of fat per 100 ml for semi-skimmed milk)”.
 - ✓ **Low-saturated fat:** “if the sum of saturated fatty acids and trans-fatty acids in the product does not exceed 1,5 g per100 g for solids or 0,75 g/100 ml for liquids and in either case the sum of saturated fatty acids and trans-fatty acids must not provide more than 10 % of energy”.

NUTRITION AND HEALTH CLAIMS: NUTRITION CLAIMS

- ✓ **Saturated fat-free:** “where the sum of saturated fat and trans-fatty acids does not exceed 0,1 g of saturated fat per 100 g or 100 ml”.
- ✓ **Source of protein:** “where at least 12 % of the energy value of the food is provided by protein”.
- ✓ **High protein:** “where at least 20 % of the energy value of the food is provided by protein”.
- ✓ **Light/Lite/Reduced:** “where the reduction in content is at least 30 % compared to a similar product, except for micronutrients where a 10 % difference in the reference values as set in Council Directive 90/496/EEC shall be acceptable and for sodium, or the equivalent value for salt, where a 25 % difference shall be acceptable”

NUTRITION AND HEALTH CLAIMS: MAIN TRANSITIONAL PERIODS

ISSUE	DATE UNTIL PERMITTED
Non compliant foods labelled/placed on market prior to 1 July 2007	31 July 2009
Non-compliance with nutrient profiles	19 January 2011
Trade mark/brand names constituting claims existing before 1 January 2005	19 January 2022
Nutrition claims not on positive list and legally used in MS before 1 January 2006	19 January 2010
Health claims referring to growth, development and bodily functions legally used in a MS	Establishment of Community positive list of established claims (31 January 2010 at latest)
Health claims previously evaluated and authorised by a MS (other than growth, development and bodily function and reduced risk claims) and transferred to Commission	6 months after adoption of any Commission decision not to include positive list

FOOD INFORMATION PROPOSAL – DOES IT ACHIEVE ITS AIMS?

- Harmonisation (Article 95 measure)
 - ✓ ‘...ensuring smooth functioning of internal market’ (Article 1(1))
 - ✓ Remove trade barriers
- Informed consumers
 - ✓ ‘... high level of consumer protection in relation to food information’ (Article 1(1))

FOOD INFORMATION PROPOSAL – FONT SIZE

- 3 MM font size for mandatory information
- Increased packaging since in combination with:
 - ✓ More mandatory information (on top of brand information)
 - ✓ Multilingual labelling requirements (for example, Belgium)
 - ✓ Conflicts with ethos of environmental requirement to minimise packaging (Directive 94/62)
 - ✓ Food supplements: small packaging but largest surface larger than 10 cm² (no Article 18(2) exemption).
 - ✓ 30 tablets in 1 litre container?
- EuroCommerce “ ... considerable costs for consumers without any benefit for consumers”.
- Community proportionality principle: least restrictive measure to achieve aim?

FOOD INFORMATION PROPOSAL – NATIONAL SCHEMES

- Voluntary national schemes (Article 44):
 - ✓ alternative forms of expression of mandatory nutritional declaration (energy, fat, saturates, carbohydrates (specific reference to sugars and salts))
 - ✓ use of graphics or symbols for presentation of nutrition declaration
 - ✓ Traffic lights, instead of guidelines daily amounts
- De Facto mandatory rules?
- No prior check on whether schemes constitute trade barriers?
 - ✓ ‘The application of national schemes shall not give rise to obstacles to the free movement of products’ (Article 45(2)).

FOOD INFORMATION PROPOSAL –ISSUE: NATIONAL FITNESS

- ✓ Commission may ask MS to appeal or amend national scheme if considers scheme a trade barrier (Article 46(1))
- ✓ Really harmonising? Encouraging, not removing differing national requirements
- At same time: DG Enterprise initiative (High Level Group) on competitiveness in Food Industry:
 - ✓ moratorium on new food legislation
 - ✓ ban on national labelling initiative in interest of single market
 - ✓ Focus on big issues: Lisbon Agenda v. 3 MM font size!

FOOD INFORMATION – ORIGIN LABELLING

- Voluntary country of origin statements must include provenance of main ingredient if different from where food finally processed
 - ✓ ‘produced in Belgium from Danish milk’
 - ✓ ‘produced in Belgium from Spanish pigs’
- Practically difficult:
 - ✓ Manufacturers regularly change source of ingredients (seasonal for fruits, for example)
- Why not ‘made in EU’? (but reflects EU hygiene standards not regional strength/patriotism!)

FOOD INFORMATION PROPOSAL ISSUE: CONCLUSION

- Much uncertainty remaining = difficult for food industry to plan product positioning/anticipate viability of current products
- Effect on competitiveness of food industry still to be seen
- Significant burden on industry to scientifically substantiate all claims (i.e. including ‘generally accepted claims’)
- Look on the bright side: the rules will eventually be clear – no more EU trade barriers!

FOOD INFORMATION PROPOSAL ISSUE: CONCLUSION

- Not achieving stated aims
- Disproportionate measures
- Study purely a recast, not harmonisation?
- DG Enterprise route more promising?