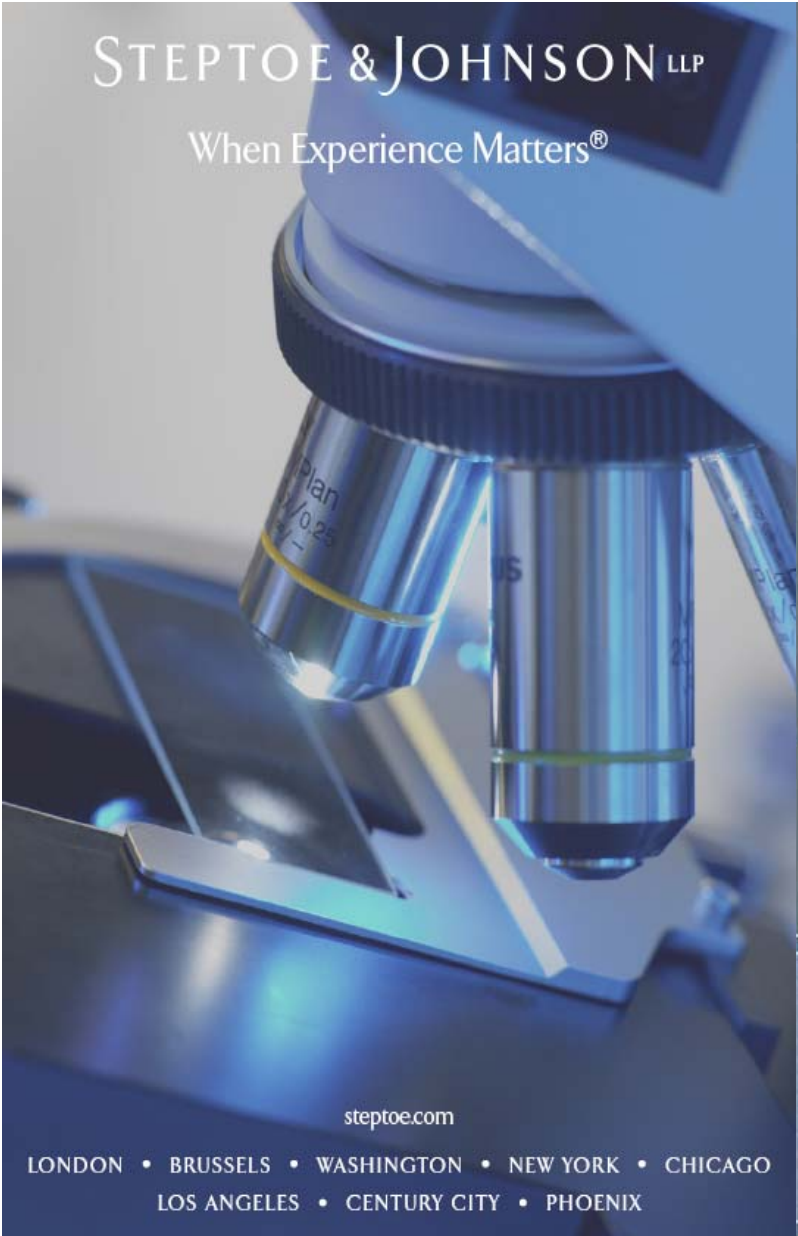


A close-up, blue-tinted photograph of a microscope's objective lenses and eyepiece, positioned over a slide. The lighting creates a soft glow on the lenses.

STEPTOE & JOHNSON ^{LLP}

When Experience Matters[®]

step toe.com

LONDON • BRUSSELS • WASHINGTON • NEW YORK • CHICAGO
LOS ANGELES • CENTURY CITY • PHOENIX

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

Craig Simpson, Attorney

Functional and Healthy Drinks
28-29 April, 2009

STEPTOE & JOHNSON ^{LLP}

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?
- Effect on competitiveness of Food Industry (probiotics, functional products)
 - ✓ FT: ‘... the end of the so-called functional foods movement of the past few years.’
 - ✓ Exaggerated? More question of economic downturn?

NUTRITION AND HEALTH CLAIMS: UNCERTAINTIES

- Current regulatory limbo because:
 - ✓ Nutrient profiles undecided
- Confusion over:
 - ✓ 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)
- Deadline for Commission decision on nutrient profiles (19.1.09) long past
- February 2009: Third Commission (DG SANCO) draft proposal:
 - ✓ Few exemptions: food supplements, dietetic foods, fruits and vegetables
 - ✓ Specific nutrient profiles (sodium, saturate and sugar thresholds) and conditions of use, generally and for food specific categories, in order to bear claim
 - ✓ Criticism from other DGs that levels too high/forgiving

NUTRITION AND HEALTH CLAIMS: NUTRIENT PROFILING

➤ March 2009: Barroso proposal

- ✓ Watered down due to political pressure
 - Yakult lowering minimum content of dairy ingredients in dairy products to 40%
 - German bread (salt) exemption
 - BEUC: ‘... putting industry and political interests before consumer health.’
- ✓ Thresholds levels too high and too many exemptions
- ✓ Contradicts supposed aim of Regulation:
 - Traditional foods exempted, even if unhealthy
 - Reformulation of many ‘unhealthy foods’ not now necessary – including those banned from advertisement on UK TV
- ✓ Strategy?: previous proposal suddenly looks acceptable

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 through Member State experts in SCFCAH (Commission not bound to follow EFSA Opinion)
 - ✓ 3 month scrutiny by European Parliament (limited 'all or nothing' veto powers)
- Yet faster than Article 13 procedure (delay in Art. 13 in positive list)?!

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

- August 2008, EFSA rejects 8 of first 9 claims: rejects significantly more than accepts
- February 2009, SCFCAH agrees to authorise first health claims
 - ✓ 14 children's claims rejected
 - ✓ 2 disease risk reduction claims approved
 - ✓ 5 children's health claims approved
- EFSA Opinions accept:
 - ✓ Benecol: 'plant stanol esters have been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of coronary heart disease.'
 - ✓ Yoplait: 'calcium and vitamin D are needed for normal growth and development of bone in children.'

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

- EFSA Opinions find no cause and effect relationship between:
 - ✓ Pharma Consulting Industries: Fish oil/Omega 3 and development of children
 - ✓ Ocean Spray: Cranberry juice and reduced risk of urinary tract infection in women
 - ✓ Valio: LLG Max (probiotic) and reduced abdominal comfort
- Reasons for negative EFSA Opinions (no cause and effect relationship established):
 - ✓ Studies not representative of target population (for example, wrong age range)
 - ✓ Variable quality of studies
 - ✓ Insufficient study sample given
 - ✓ Insufficient characterisation of nutritional composition

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

- Similar strict approach in pending EFSA review of 'generally accepted' claims?
- 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 now unlikely – consequences?
- 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)
 - (DG SANCO now saying:
 - 'X [directly] reduces risk of Y disease' – not acceptable
 - 'X reduces risk factor in development of Y disease' – acceptable)

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 per 100 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) – now unrealistic
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
 - ✓ EP push for reduced font size, combined with background contrast requirement
 - ✓ Industry against; Commission strongly supports
- 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: NATIONAL SCHEMES

- ✓ 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!)

NUTRITION AND HEALTH CLAIMS: CONCLUSION

- Much uncertainty remaining = difficult for food industry to plan product positioning/anticipate viability of current products
- Latest Nutrient Profile proposal: not achieving stated aims
- 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?