Functional drinks: an uncertain future

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www.practicallaw.com/3-201-2759

Functional drinks are shaping the soft drinks industry. Static sales in the traditionally dominant carbonates market have forced major players to look at new ways of maintaining their market position. Some reports value the current global functional food market (including drinks) at EUR53 billion (about US$65 billion) and predict growth to EUR138 billion (about US$170 billion) by 2010.

Functional drinks have, for the most part, escaped product specific EC-level regulation. Like all food products, they are currently subject to a range of horizontal (non-product specific) EC rules. However, EC legislative proposals look set to considerably restrict manufacturers' freedom to market position their drinks as functional products.

With this in mind, this chapter examines the implications for drinks manufacturers and, more specifically, analyses:

- The definition of functional drinks.
- The horizontal legislative proposals for the future, concerning both:
  - nutrition and health claims;
  - fortification.
- Relevant case law.
- Borderline products.
- The draft proposal on sports drinks.
- The implications for the future.

WHAT ARE FUNCTIONAL DRINKS?

There is no commonly accepted definition (in law or policy) of what constitutes a functional food. In its 1998 report on Functional Food Science in Europe, the Commission defined functional foods (which includes drinks) as those which are:

> "...satisfactorily demonstrated to affect beneficially one or more target functions in the body, beyond adequate nutritional effects, in a way which is relevant to either an improved state of health and well-being and/or reduction of risk of disease."

Market practice commonly refers to the following as comprising functional drinks:

- Sports and energy drinks (dominant in the functional drinks sector).
- Vitamin and mineral enriched drinks (for example, vitamin enriched juices, near water drinks with minerals added and calcium enriched milks).
- Herbal drinks.
- Certain neutraceuticals.
- So-called health and wellness drinks.
- Probiotics.

While the six categories listed above can overlap, they are distinguishable from the following:

- Food supplements – which are sold in dose form.
- Dietetic drinks (with the exception of sports drinks) – which are aimed at those with specific nutritional needs.

These are subject to distinct EC regimes under Directive 2002/46/EC on food supplements and Directive 89/398/EEC on foodstuffs intended for particular nutritional uses (as amended) respectively, and are not covered within the scope of this chapter.

A MORE RESTRICTIVE FUTURE

All six of the functional drink categories identified above will be affected by horizontal legislative proposals concerning both:

- Nutrition and health claims made on foods.
- The addition of vitamins, minerals and certain other substances to foods.

A vertical proposal on sports drinks (*see below, Sports drinks*) is also on the horizon.

Nutrition and health claims

The Commission issued its proposal for a Regulation on Nutrition and Health Claims (*COM (2003) 424 final*) (Claims Proposal) on 16 July 2003, as part of its drive for informed consumer choice. Currently, the European Parliament (Parliament) and the Council of Ministers (Council) have each given their first readings on the Claims Proposal. The Claims Proposal is to be adopted by the co-decision procedure, under which both the Parliament and the Council must agree on a final text. The two most controversial aspects of the Claims Proposal are:

- Nutrient profiling.

- Prior authorisation of new health claims.

Nutrient profiling. The Claims Proposal requires foods (including drinks) for which nutrition or health claims are made to comply with specified nutrient profiles. The profiles will be drawn up by the Commission. However, the basis on which it will do so remains vague, even at this fairly advanced stage in the legislative procedure. The latest Council text states that profiles will be established with particular reference to:

- The amounts of fats, sugars and salt in the product.
- The overall nutrition composition.
- The scientific knowledge about diet and nutrition and their relationship to health.
- The role and importance of the product in population diet, especially that of children.

Unfortunately, these criteria are not sufficiently precise for industry to ascertain in advance, with any degree of certainty:

- Whether all products will be subject to profiling (or only certain categories of products).
- If only certain categories are covered, which categories they might be.
- How widely or narrowly such categories will be defined.
- What conditions will need to be complied with before making a claim about a product.
- Crucially, which functional claims may not be permitted.

Under the procedures envisaged in the Claims Proposal, these questions could remain unanswered for up to two years after the final Regulation enters into force. What is clear is that the Commission's aim is to ensure that only healthy foods will be able to bear claims and that the EU Consumer Protection Commissioner, Markos Kyprianou, considers profiling to be a key method of tackling obesity (under the wider European Platform for Diet, Physical Activity and Health). One likely consequence of this is that functional drinks with a high sugar content, which currently bear claims, may not be able to do so in the future.

Health claims. The Claims Proposal regulates graphics and written claims in labelling or advertising. It establishes two distinct categories of health claim:

- Generally accepted and scientifically proven existing health claims. Those in the following categories must appear on a positive list in order to be used:
  - growth, development and functions of the body (such as "good for bones");
  - psychological or behavioural functions (for example, "improves memory");
  - slimming (for example, "reduces calorie intake");
  - reduction of hunger or reduction of available energy from the diet.

  EU member states will have to provide the Commission with a list of such claims, the relevant scientific justification and the conditions for their use within a year of entry into force of the regulation. There is, as yet, no firm indication of:
  - precisely which claims will feature on this list;
  - what level of scientific justification will be required to establish general acceptance;
  - what conditions will attach to claims.

  Each EU member state will have to devise its own procedure for collating its list of existing claims. For example, the UK Food Standards Agency is considering taking independent advice from the Joint Health Claims Initiative and has recently begun a stakeholder consultation.
- New health claims. Those not in the above category (for example, "wholegrain may keep your heart healthy") will be subject to prior approval through an authorisation procedure involving submission of a dossier to the European Food Safety Authority (EFSA) to prove the validity of the claim in question.

Additional restrictions. There are other equally important prescriptive requirements in the Claims Proposal, aimed at protecting the consumer from unsubstantiated and misleading marketing hype (*see box, Requirements relevant to functional drinks under the Claims Proposal*).

Ideological conflict. The nutrient profile debate between the EU institutions centres on the extent to which the average consumer, presumed to be "reasonably well-informed and reasonably observant and circumspect" (*Gut Springenheide (Case C-210/96) [1998] ECR I-4567*), needs to be protected. The stated aim of nutrient profiling is (*new Recital 6 of Proposal, as inserted by Council's Common Position*):

> "...avoiding a situation where nutrition or health 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."

An example of such a claim might be "containing vitamin C" on a chocolate bar. In contrast, the Parliament has defended industry concerns. Its approach (which is, perhaps, more proportionate) is to credit the consumer with being sufficiently alert to the general nutritional value of foods so as not to be swayed by claims. At the same time, it recognises that there are vulnerable groups (such as children) that need to be protected from targeted claims.

In relation to nutrient profiling, the Parliament's view is that the categorisation of "good" and "bad" foods is discriminatory and disproportionately prejudicial to certain manufacturers.

On prior authorisation, the Parliament suggested a less burdensome notification system for new claims. This would involve a nine-month default period for the Commission to prohibit the continued use of the health claim where there are serious

REQUIREMENTS RELEVANT TO FUNCTIONAL DRINKS UNDER THE EUROPEAN COMMISSION'S PROPOSAL FOR A REGULATION ON NUTRITION AND HEALTH CLAIMS (*COM (2003) 424 FINAL*) (THE CLAIMS PROPOSAL)

- Nutrition claims (such as "rich in vitamin C" or "fat free") must comply with certain conditions guaranteeing that they are scientifically justified. For example, the claim "source of/ with/added/enriched [certain] Vitamins or Minerals" is permitted only where the product contains at least a significant amount of the relevant vitamin or mineral as defined in Directive 90/496/EEC on nutrition labelling for foodstuffs.*
- Generally accepted scientific data must substantiate a beneficial nutritional or physiological effect of the claim.
- A nutrient must be contained in sufficient quantity to have the effect claimed, in an amount likely to be consumed and in a form directly available to the body.
- The so-called average consumer must be able to understand the claim.
- Health claims must be accompanied by information on how much of, or how often, the product has to be consumed to produce the beneficial effect.
- Mandatory nutrition labelling of "the Big 8" (energy value, protein, carbohydrate, sugars, fat, saturates, fibre and sodium) must accompany health claims.*
- Health claims referring to general, non-specific well being ("helps your body to resist stress") will be permitted only if accompanied by a more specific positive listed health claim.
- Health claims making reference to rate/amount of weight loss and on drinks containing more than 1.2% alcohol by volume will be totally prohibited.*
- Recommendations of doctors or health professionals or associations (such as "recommended by the British Heart Foundation") which are neither regulated by Community law nor relevant national rules will be generally prohibited (with limited exceptions).
- A trade mark or brand name which may be construed as a claim will only be permitted if accompanied by a related and scientifically justifiable claim.
- EU member states can require manufacturers or importers to notify national competent authorities of foods bearing nutrition or health claims by submitting product labels.*
- Reduction of disease risk claims (such as "reduces heart disease" or "may help lower cholesterol levels") will have to be authorised and accompanied by a clarificatory statement that altering one of multiple risk factors may or may not have a beneficial effect.

*Denotes the existence of a parallel provision in the Fortification Proposal (*see main text, A more restrictive future: Fortification Proposal*).

concerns with regard to its scientific substantiation. The Parliament's proposal was short lived, having been unanimously rejected by the Council. The Parliament's second reading is scheduled for the last quarter of 2005 and (if agreement between the EU institutions can be reached) a final Regulation may be adopted during the first half of 2006. Although it rarely occurs, if the institutions cannot reach a compromise, the Claims Proposal will fall by the wayside.

Fortification Proposal

The Commission issued its proposal on 10 November 2003 for a Regulation on the addition of vitamins and minerals and of certain other substances to foods (*COM 2003 671 final*) (Fortification Proposal). As with the parallel Claims Proposal, the Parliament and Council have both given their first readings on the text. The Fortification Proposal will also be adopted under the co-decision procedure.

The most recent Council text only permits fortified drinks (for example, calcium enriched orange juice or vitamin enriched milks) containing positive listed vitamins and minerals. It will also subject the levels of vitamins and minerals in those drinks to maximum and minimum limits (to be set up under subsequent legislation). The Fortification Proposal also establishes a transitional period for non-positive listed vitamins and minerals which have been included in a dossier submitted to EFSA for authorisation. Finally, it introduces additional restrictions similar to those found in the Claims Proposal (*see box, Requirements relevant to functional drinks under the Claims Proposal*).

A crucial point for the future of the marketing of functional drinks is the fact that the Fortification Proposal covers the addition of "certain other substances" to products. Where the addition of such substances would "result in the ingestion of amounts of this substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers" (*Article 10(1), Proposal*), the Commission can, either on its own initiative or, if asked by an EU member state, prohibit other substances or restrict them where a health risk is found (following risk assessment by EFSA).

In addition, substances for which "the possibility of harmful effects on health is identified but scientific uncertainty persists" (*Article 10(2)(b), Proposal*) may be placed on a list of "Substances under Community scrutiny". This reflects the precautionary principle which is now entrenched in EC food law under Regulation (EC) No. 178/2002 on the general principles and requirements of food law and establishing the European Food Safety Authority. Food manufacturers can submit a scientific dossier demonstrating the safety of these types of substances to

EFSA. Within four years from the substance being listed, the Commission will then decide, on the basis of any dossiers submitted, whether to prohibit the substance altogether, restrict it or allow its use.

The concept of substances under Community scrutiny is a worrying development for functional drinks manufacturers. It gives the Commission a *carte blanche* to rely on the precautionary principle in restricting or prohibiting any substance where only a suggestion (rather than conclusive evidence) of a health risk exists. It also places the onus on industry to provide convincing evidence of its safety, or face prohibition or restrictive conditions of use. The Council has suggested that amino acids and various plant and herbal extracts are likely other substances which may be restricted, prohibited or placed under Community scrutiny. In the preliminary draft proposal (*SANCO/329/03 17 June 2003*), taurine was listed as a substance under Community scrutiny and caffeine featured on the restricted list, suggesting that the latter's use might be restricted further (for example, by maximum permitted levels) than the current requirement, in Directive 2002/67/EC on the labelling of foodstuffs containing quinine and caffeine, to label high caffeine content and the caffeine levels if the drink contains more than 150 mg/litre. This is despite the fact that in two previous Opinions (*Opinion on Caffeine, Taurine and D-Glucorono - γ - Lactone as constituents of so-called "energy" drinks dated 21 January 1999* and *Opinion on Additional information on "energy" drinks dated 5 March 2003*) the EU Scientific Committee on Food found that caffeine consumption (in energy drinks) was not, in general, a cause for concern. It was also unable to say whether or not the amounts of amino acids in energy were unsafe or establish upper safety levels for daily intake of taurine. EFSA has been asked to give its views on these ingredients.

PROSPECTS FOR LEGAL CHALLENGE

A recent judgment in the European Court of Justice (ECJ) suggests that where positive lists and prior approval (both key elements in the proposals outlined above) are employed, the Commission is under a strict duty to ensure that minimum procedural standards are respected.

In the joined cases *The Queen, Alliance for Natural Health, Nutri-Link Ltd (C-154/04)* and *The Queen, National Association of Health Stores, Health Food Manufacturers Ltd (C-155/04)*, the UK High Court asked the ECJ, in a preliminary reference, whether certain articles in Directive 2002/46/EC on food supplements (Food Supplements Directive), which prohibited the marketing of non-positive listed food supplements, were lawful. In its judgment of 12 July, the ECJ confirmed the Food Supplements Directive's precautionary approach of restricting free movement of food supplements to those positively listed substances already deemed safe by European scientific authorities. However, it stated that (*joined Cases C-154/04 and C-155/04, paragraph 82*):

> "It is none the less the responsibility of the Commission .... to adopt and make **accessible** to interested parties, in accordance with the principle of sound administration, the measures necessary to ensure generally that the consultation stage with the European Food Safety Authority is carried out **transparently** and within a **reasonable time**." (Emphasis added.)

Although the ECJ did not follow Advocate-General Geelhoed's recommendation that the provision concerning modification of positive lists was unlawful, its judgment acknowledges his concern that the procedure for implementing such modification must fulfil "the minimum requirements of the legal certainty necessary in economic relations" (*paragraph 69, Opinion*). In the immediate wake of the judgement, the Commission acknowledged the ECJ's indication of the need for timely and transparent implementation procedures. This is somewhat ironic, given that the Commission previously brought successful infringement action against France (*Commission v France (Case C-24/00)*) for lack of transparency, inaccessibility and unreasonable time frames in its national prior approval system for additives (including amino acids) in products lawfully manufactured in other EU member states.

In the context of the Claims Proposal and the Fortification Proposal (and indeed any other food law proposal based on the precautionary principle), this leaves open the possibility of challenging on the basis of procedural impropriety.

BORDERLINE PRODUCTS

A major issue for functional drinks manufacturers is to ensure that their products are not categorised as medicines, as they would then be subject to the burdensome authorisation and licensing requirements under Directive 2001/83/EC on the Community code relating to medicinal products for human use (as amended) (Code for Human Medicines Directive). If a food is presented as having properties for treating or preventing disease in human beings, it will be classified as a medicine, irrespective of its composition. The borderline between claims which render a product a medicine and those that do not is not immediately obvious. For example, the claim "provides calcium which helps prevent osteoporosis" is a medicinal claim, whereas to say "provides calcium which is important for strong bones" is not.

In addition, functional drinks containing, for example, particular herbs or high levels of vitamins may be treated by the competent authorities as borderline products. National competent authorities have traditionally enjoyed some discretion in categorising certain products, which contain low levels of medicinal ingredients and which are not presented as medicines, as foods. Manufacturers may insert such de minimis quantities purely as a basis for using functional claims in marketing (which may be misleading if the quantities used do not have functional effect claimed). While many functional drinks "restore, correct or modify physiological functions" within the definition of medicinal products in the Code for Human Medicines Directive – for example, the drink might stimulate metabolism or boost the immune system – EU member states have, nonetheless, been able to regulate them under the less stringent regime applicable to foods.

However, Directive 2004/27/EC amending the Code for Human Medicines Directive (to be implemented in national laws from 30 October) adds a new "trump card" provision to the Code for Human Medicines Directive, which further threatens marketing of functional drinks. It requires that "in cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation", it should be classified as a medicine. The validity of that provision was recently

approved by the ECJ (*HLH Warenvertriebs and Orthica (Joined Cases C-211/03, C-299/03, C-316/03 and C-318/03)* 9 June 2005). The effect of this new article is to remove the classification discretion enjoyed by the national competent authorities of individual member states in certain cases and to mandate the reclassification of some functional drinks, such as herbal tea and other health store products, as medicines.

SPORTS DRINKS

In June 2000, the European Scientific Committee on Food adopted a Report on composition and specification of foods intended to satisfy the particular nutritional requirements associated with intense muscular effort, especially for sportsmen. This analysed which substances genuinely assist intense muscular effort. As a result, the Commission produced a draft Directive in April 2004 (*Working Document for Draft Commission Directive on foods intended to meet the expenditure of intense muscular effort, especially for sports people, Brussels SANCO D4/HL/mm/D440182*). This supplements the existing framework for sports drinks as dietetic foods under Directive 89/398/EEC on foodstuffs intended for particular nutritional uses and Directive 2001/15/EC on substances that may be added for specific nutritional purposes in foods for particular nutritional uses (both as amended).

While immediate progress on its adoption as a formal proposal has been stalled by the current focus on the Claims Proposal and the Fortification Proposal, the draft both:

- Limits the marketing of dietary drinks for physical activity to those containing significant carbohydrate or proteins.
- Establishes prescriptive requirements for their marketing.

For example, carbohydrate rich energy drinks must contain a minimum carbohydrate content of 10% weight by volume and metabolisable carbohydrates must provide at least 75% of their total energy. Similarly, drinks marketed as carbohydrate-electrolyte solutions (those claiming to both provide energy and restore or maintain hydration) must have an energy content of at least 340 kj/l, and a specified sodium content and osmolality range. Nutritional labelling will be mandatory, the word "isotonic" can only be used on the label if the osmolality is within certain permitted limits, and the use of creatine is limited to 3g daily intake and requires detailed instructions on the labelling. Generally accepted science must substantiate that the product meets the nutritional requirements of the intended recipient.

THE FUTURE

Current plans to regulate both labelling and composition promise an increasingly restrictive and prescriptive regime for the marketing of functional drinks in the next few years. At the same time, there has been a tangible increase in enforcement against misleading labelling and medicinal substances wrongly marketed as functional foods.

At the heart of the proposed legislation is a desire to protect the consumer from misleading and scientifically unsubstantiated marketing hype. Functional drinks currently on the market with unsubstantiated claims or containing substances in insignificant amounts, or which do not fit the Commission's future profile for healthy foods, may have to be withdrawn or risk being the focus of future enforcement action. Other products currently marketed as drinks may have to be withdrawn or be authorised as licensed medicines.

Some manufacturers may be in favour of such regulation insofar as it serves to level the competitive playing field. However, irrespective of whether undertakings support or resist such regulation, the lack of legal certainty arising out of these, as yet, undefined nutrient profiles and positive lists, and the delays inherent in submitting authorisation dossiers, are likely to be a problem for industry and may have the effect of stifling continued growth in the functional drinks market.

The recent ECJ judgment concerning the Food Supplements Directive indicates that the Commission's discretion in implementing food law based on the precautionary principle must respect minimum procedural standards. Insistence on full application of these procedural safeguards may offer industry a means of mitigating some of the most burdensome aspects of the forthcoming legislation.