



Health claims & functional foods

How will EU regulation shape our choices?

A report of the Business Forum
meeting on 17th March 2009

Contents

Introduction.....	1
Key points.....	1
Health claims on food	2
EU regulation	3
How is the regulation working?	4
Problems for industry	5
Problems for consumers	6
Industry vs. consumers?	6
Qualified claims	7
Innovation and public health	8
Innovation, freedom and fairness.....	9
Conclusion.....	9
Speaker biographies.....	10
About the Business Forum.....	11

Introduction

Health claims underpin one of the most prominent food industry trends of the past decade: developing and marketing 'functional foods'. While this trend has been most evident in manufacturing, it has in fact extended all the way from the supermarket shelf through to agricultural inputs.

Reports in 2008 claimed that consumer scepticism was dampening the market for functional foods and demanding more robust evidence to back up health claims. With the European Commission (based on the stringent scientific advice of the European Food Safety Authority) set to pronounce which health claims will be allowed in future, the market is due to get tougher still.

The March meeting of the Food Ethics Council's Business Forum discussed the challenges and opportunities that the new regulation poses to businesses and to consumers. We are very grateful to our two speakers: Nigel Baldwin, Senior Scientific & Regulatory Consultant at Cantox and a recognized expert on functional foods and health claims; and Sue Davies MBE, the Chief Policy Adviser at Which?, the UK consumer association, working on food issues. The meeting was chaired by Christopher Ritson, Professor of Agricultural Marketing at the University of Newcastle and a trustee of the Food Ethics Council.

This report outlines points raised during the meeting. Contributions are not attributed. The report was prepared by Tom MacMillan. It does not necessarily represent the views of the Food Ethics Council, the Business Forum or their members.

Key points

- **Consumers** like health claims on food products as long as they feel the claims can be trusted.
- **Businesses** have an incentive to claim health benefits even where these claims may not be of benefit to consumers.
- **EU rules** currently being implemented are designed to crack down on health claims for which there is insufficient evidence, and to prevent health claims on products that have little place in a health diet.
- The European Food Safety Authority (EFSA) has until **January 2010** to publish an initial list of approved claims that businesses can use.
- So far, EFSA has **approved seven** claims, **rejected 35** and has around **4,000 left** to review.
- Businesses and consumer groups **broadly support** the EU regulation.
- However, businesses are deeply **frustrated by the uncertainty** surrounding the EFSA assessments.
- Consumer groups support EFSA's approach but are concerned that low nutrition benchmarks and special exemptions will mean that health claims will be permitted on products that **undermine healthy eating advice**.
- Some businesses argue that EFSA should permit **qualified health claims**, for which the body of evidence is less substantial, whereas consumer groups disagree.
- Prohibiting qualified claims poses an immediate **barrier to R&D** on functional foods and health claims by small and medium-sized businesses.
- There is little evidence that this constraint on research will be detrimental to **public health** or that allowing qualified claims would promote **consumer freedom**.

Health claims on food

Consumers and food businesses can both benefit from health claims, at least in principle. A survey by Which?, in January 2009, found that four in five people are actively trying to eat a healthy diet but want more help in choosing what to eat. Previous Which? research had found that people like health claims on food products, as long as they feel they can trust them.

Businesses like health claims because consumers like them. Health claims can distinguish a product, making it stand out from its competitors, increasing sales or margins. However, the same factor that makes health claims attractive to consumers – that consumers are not always easily able to assess the healthiness of food themselves – also makes it difficult for consumers to distinguish between foods that are or are not useful for them.

Businesses face a strong commercial incentive to make health claims that extend beyond those that may be of benefit to consumers. In practice, this has resulted in two areas of concern:

- Claims for which there is limited evidence.
- Claims that highlight a potential health or nutrition benefit on one count (e.g. added vitamins) when products contain levels of fat, saturates, sugar or salt that are at odds with healthy eating advice.

So, to protect the consumer interest and ensure consumers can trust health and nutrition claims – which is also in the long-term interest of the food sector – the evidence behind health claims should be

subject to expert scrutiny and health claims should only be allowed on products that support the overall advice consumers receive on healthy eating.

To date, in the UK and the rest of Europe, protection of this kind has been limited. Scrutiny in the UK has been retrospective by making a challenge via the Advertising Standards Authority (ASA), which has often proved too little, too late. Nutrient profiling – setting agreed minimum nutritional standards that any product has to meet – has not been required of products carrying health or nutrition claims.

For example, Which? complained to the ASA about Kellogg's Nutri-Grain Soft Oaties (Oat & Chocolate Chip), which were claimed to be "Wholesome Cookie Goodness", stating that they were "made with oats and wheat, source of fibre, 6 B vitamins and iron" and to "enjoy as part of a healthy balanced diet". However, the products were high in sugar, salt and saturated fat.

The ASA upheld Which?'s complaint, concluding that the health claim was misleading because it referred only to those ingredients that could convey a nutritional benefit without also referring to those that might have a negative impact on health. However, the advertising campaign was over by the time the ruling came.

Which? research for its recent 'Hungry for Change' report also identified a number of foods highlighting health or nutritional benefits that contained high levels of saturated fat or sugar:

- Dairylea Lunchables Chicken 'n' Cheese Crackers claim to contain "half kids'

recommended daily calcium intake per serving” and come “with vitamin D to aid calcium absorption”. However, they contain over half the amount of salt a child under six should eat in a day in a serving and are also high in saturated fat.

- Nestlé Golden Nuggets claim to contain “wholegrain goodness” and “vitamins and minerals” prominently on the front of the packet, but contain 34% sugar.
- ASDA “Good for You” Banana and Toffee Cereal Bars with prebiotic, claim to be “high in fibre, healthier for your digestion”, yet contain around a quarter sugar.
- Snack a Jacks popcorn advertises the fact that it has “less than 10% fat”, though it would have to have less than 3% fat to be considered low fat and is also high in sugar (30%).
- McVities Jaffa Cakes highlight the fact that there is “only 1g fat per cake” on the front of pack but not that each cake is also over half sugar (53%).

EU regulation

Whilst any manufacturer using a health claim is legally obliged to be able to substantiate any claim made about a food, new rules currently being implemented in the European Union are intended to address these problems, requiring regulatory approval of up-front evidence to support health claims and linking claims to nutrient profiles so products with high levels of saturates, sodium and sugar cannot carry

health claims, simply because the product scores well on one aspect of nutritional content, and will face greater restrictions for making nutrition claims. The Nutrition and Health Claims Regulation ((EC) No 1924/2006) will thus affect both (a) what health claims can be made and (b) what nutrition benchmarks a product needs to meet in order to carry any health claims at all.

The regulation applies to any claim a business might make to consumers in a commercial communication, including a website, advertorial or a nutrition leaflet. It is not confined to claims on packets or attached to specific products. Others including Governments and health professionals can make statements about health and food, but food companies may not do so unless those claims have been formally approved. Businesses may make health claims that have not been through the approval process in material that specifically targets other businesses (for example an ingredients company advertising to food manufacturers). The regulation applies to all claims made to EU consumers including, for example, on the packets of imported products. Whether terms such as ‘increases energy’ or ‘gives you wings’ count as health claims is a grey area.

The regulation requires that all health claims are vetted by the European Food Safety Authority (EFSA) before they are used. It distinguishes between two main types of claim:

- Article 14 claims are health claims which refer either to children’s development and health or to reductions in the risk of

disease. Up until the regulation, products making disease-risk claims were effectively considered as medicines, and therefore could not be sold as food.

- Article 13 claims are all other health claims. Article 13.1 covers health claims which were already on the market based on “generally accepted scientific evidence” at the time the Regulation was introduced. Article 13.5 covers similar claims that are new and claims based on newly developed scientific evidence or on proprietary data.

The regulation has been in place since the end of 2006. By January 2010, EFSA is due to publish a list of approved health claims.¹ Until then the Annexes of the Regulation will only contain approved Article 13.5 and 14 claims. The procedure in has been different for Article 13 and 14 claims.

Under Article 14, companies have submitted dossiers of evidence for specific claims to EFSA, which has then to review the dossier and publish an opinion: if positive the claim goes on the list of approved claims; if negative it goes on the rejected list. The procedure is similar for Article 13.5.

Under Article 13.1, member states were required to gather a list of existing health claims and submit them to the European Commission, supported only by references rather than with full dossiers of evidence. The Commission consolidated these claims – reducing the total of around 20,000 that it received to about 4,200 – and passed them to EFSA. Some 2,000 of these claims have been sent back to the member states for

clarification. Even within the remaining 2,000, there is likely to be considerable duplication and it is expected that a significant number of claims will not withstand scrutiny.

How is the regulation working?

EFSA has so far announced assessments of only a few Article 13 claims. It is expected to release most of its opinions on the full list passed to it by the Commission in one announcement, rather than publishing the decisions one by one. Opinions on subsequent health claims under Article 13 (Article 13.5 claims) are being announced as they are reviewed (all have been negative so far).

So far the focus has been on Article 14 claims. EFSA has announced 43 opinions in total, of which seven have been positive. The seven approvals related to phytosterols, omega 6 and omega 3 helping children’s health, calcium, vitamin D, calcium and vitamin D in combination, and Docosahexaenoic acid (DHA) and arachidonic acid (ARA).

Examples of the positive and negative opinions EFSA has expressed so far include:

- “Follow-on formulae with a fixed combination of short-chain galactoligosaccharides, acidified milk, nucleotides and beta-palmitate” and intestinal ailments (Article 14). Opinion: a cause and effect relationship has not been established.
- Algatrium® (derived from fish oil) “promotes your antioxidant response” by

“stimulation of the own cells” (Article 13). Opinion: a cause and effect relationship has not been established.

- Kinder Chocolate® “helps to grow” (Article 14): a cause and effect relationship has not been established.
- Ocean Spray Cranberry Products® “helps reduce the risk of urinary tract infection in women by inhibiting the adhesion of certain bacteria in the urinary tract” (Article 14). Opinion: a cause and effect relationship has not been established.
- Docosahexaenoic acid (DHA) and arachidonic acid (ARA) and “visual development” in formula (Article 14): wording reflects the scientific evidence – “DHA contributes to the visual development of infants”.
- Melgaço mineral water and reduction of glycaemia “reduce body hyperglycaemic levels” (Article 14): Opinion: a cause and effect relationship has not been established.
- Dairy fresh cheese “contributes to healthy bone growth” (Article 14). Opinion: the following wordings reflect the scientific evidence – “calcium/vitamin D is needed for the normal growth and development of bone in children”.

Problems for industry

While many food businesses are broadly in favour of the European Commission’s attempt to reach a list of approved health and nutrition claims, the regulatory process

has so far proved deeply frustrating for the industry.

The main cause of these frustrations is uncertainty. The first source of uncertainty is a lack of transparency. Since the regulatory process is something of a ‘black box’, it has proved difficult for businesses to prepare dossiers that address the questions regulators are seeking to answer. The concern is that the box was actually pretty empty to begin with, and the regulators are having to make the rules up as they go.

The to-ing and fro-ing that arises from this opacity gives rise to delays – already a problem due to the sheer volume of claims that were submitted – which in turn is a second source of uncertainty. What will happen, for example, if EFSA does not succeed in reaching an opinion on all claims by the January 2010 deadline? At the moment, nobody seems to know.

Businesses are also concerned at the high proportion of claims rejected so far. Behind this pattern is a third source of uncertainty: over the level of evidence required for a claim to be accepted. EFSA has required the claims it has assessed under Articles 13.5 and 14 to demonstrate cause and effect, rather than just association, between the food or component and the health benefit. It follows that it should require the same level of evidence for Article 13.1 claims, yet it seems unlikely that the list of references required to support such claims could offer such evidence even where a cause and effect relationship exists. The less burdensome data requirements for Article 13.1 claims were the result of political horse-trading in the final stages of the regulation’s adoption,

and the compromises made then are now coming back to bite.

The result is that companies seeking to make health claims are in limbo. It is difficult for them, in the circumstances, to plan and develop strategies for the future. Being snowed under by the assessment process, EFSA is unable to offer much by way of further guidance.

Problems for consumers

Consumer groups welcome the regulation. They support EFSA's insistence that claims should only be approved if they are supported by evidence of a cause-effect relationship. That a high percentage of claims has been rejected underlines the importance of the regulation: up until now, consumers had been having to make such judgements themselves.

Yet, like businesses, consumer groups have also been frustrated by how the regulation is being implemented. In particular, they are concerned that the nutrient profiling that is central to the regulation – the benchmarks supposed to ensure that products high in saturates, sugar or sodium cannot carry health claims – is being eroded.

The nutrient profiles that have been drafted are permissive when compared with the criteria developed by the UK Food Standards Agency (FSA). Products that were badged entirely red and amber under the UK's traffic light labelling scheme would not be excluded from carrying health claims according to the current draft profiles.

This calls into question whether the EU benchmarks are high enough to perform their function of excluding products that

might reasonably be considered less healthy from carrying health claims. It also raises the more specific difficulty in the UK and other member states with differing nutrient profiling standards that consumers will be directly exposed to contradictory health messages on food packaging, undermining trust in health claims and, more importantly, healthy eating advice. Whether more achievable nutrient profiles would strengthen or limit the incentives for businesses to reformulate their products, for example in the way that the FSA has worked with the industry to reduce the salt content of foods, is hotly debated.

This problem of low standards is further exacerbated by moves to exempt some categories of product from nutrient profiling requirements, such as some 'traditional products'. For some foods this appears to be an attempt by member states to protect their national industries, and it is particularly worrying because it may include products that are widely eaten and can be produced in significantly more or less nutritious ways.

In considering whether such exemptions are justified, it is important to recall that the issue is not whether such products can be on the market or be promoted for their traditional qualities, but whether they need to meet basic standards of nutrition before they can make health claims. In any case, it will also be important to monitor the overall effect of the new regulations on the nutritional profiles of diets across the EU.

Industry vs. consumers?

Food businesses and consumers share in both a general enthusiasm for the nutrition

and health claims regulation in principle, and also deep frustrations about its implementation in practice. Yet their frustrations are not the same and, in some respects, they seem at odds: food businesses are not simply concerned by the uncertainty surrounding the EFSA assessments, but also by the high proportion of negative opinions that the 'black box' has spat out so far; consumer groups, by contrast, support EFSA's tight requirements on evidence yet are concerned that weakened nutrient profiles will undermine this benefit.

Yet it would be a mistake, on two counts, to see the purpose of the regulation as being to arbitrate between the competing interests of the food industry and consumers.

First, the food sector has a long-term interest in ensuring that consumers trust health claims. Consumers, meanwhile, will never be guaranteed a level of regulatory enforcement that eliminates the need for them to trust food companies. Even if the regulatory system in Europe ends up relatively robust, ambiguity over what counts as a health claim will leave some loopholes. So, even when regulatory systems work well, consumers still rely on a relationship of trust with the people who produce their food. In those respects, at the very least, the interest of consumers and the industry are intertwined.

Second, there is also a more fundamental issue of principle. The purpose of regulation is to promote and protect the public interest. The protection, health and wellbeing of members of the public, as consumers, is directly and immediately in the public interest. By contrast, promoting

particular institutions or sectors of industry can only be an objective of regulation insofar as such action can be shown to be in the wider public interest: what are the knock-on benefits for health through innovation, for example, or would such action promote fairer markets and freedom of choice? So the regulation should not be judged on how well it arbitrates between the interests of consumers and the food industry, but on how well it promotes aspects of the public interest that relate to both.

Qualified claims

A key area of contention between some food businesses and consumer groups is whether EFSA should permit 'qualified claims', such as "there is scientific evidence to suggest DHA/AHA *might* benefit eye development in small children". At the moment, the Commission is not permitting such claims, and allowing them would lower the standard of evidence required for health claims. What are the pros and cons of allowing qualified claims from a public interest perspective?

One concern is that EFSA's current approach pushes the evidence barrier so high that it will end up being detrimental to public health. Critics argue that this problem could arise in two ways. First, the high standard of evidence creates research requirements that might act as a direct cost barrier to useful new products reaching consumers. The cumulative effect of this, second, might be to undermine science and innovation in health more widely.

EFSA's insistence that health claims are supported by robust evidence of cause and

effect certainly raises the bar for companies preparing dossiers. Claims are rejected if they rely simply on 'good evidence of a relationship' or 'the balance of evidence'. Yet it may cost in the order of \$500,000 in research for a company to undertake the work necessary to assess cause and effect. While regulatory costs of this order or higher may be normal in pharmaceuticals, they are prohibitive for many small and medium-sized businesses working in the food sector, especially given the risk that they may not result in a new product. An alternative, lower-cost approach, might be to allow conditional health claims that clearly state the level of uncertainty and the nature of the research behind the claim, similar to the current situation in the USA.

Innovation and public health

If small and medium businesses were deterred from investing in research to develop functional foods that carry health claims, would that stop products that offered significant public health benefits from reaching the market?

How important are functional foods in addressing the major food-related problems in public health? These include: that over 60% of men and 50% of women in the UK are overweight or obese; that diet-related diseases including cancers, heart disease and strokes are the biggest killers; and that overall we eat too much fat, sugar and salt and not enough fruit and vegetables.

So far, the majority of health claims on food have not sought to contribute to addressing these public health problems. Furthermore,

functional food marketing conventionally targets the 'healthy wealthy', rather than groups at highest risk of diet-related health problems.

Indeed, functional food promotion is not a priority for public health initiatives, even among those directed at food marketing. Higher priorities identified by public health programmes include traffic light labels, reformulation and the advertising of unhealthy foods to children. The primary public health challenge relating to health claims is to ensure that they do not confuse wider public health messages – that they are not a barrier to healthy eating – rather than to ensure that they can be used to promote the consumption of specific functional foods.

Would it be bad for health product research more generally if health claims-related functional foods research by small and medium-sized businesses was deterred by the regulation? While this possibility was raised at the meeting, no evidence was known of whether research relating to health claims and functional food development played a major role in supporting wider research relevant to public health. It was suggested that tighter regulation on health claims might even push additional R&D investment into pharmaceuticals. Also, the possibility was raised that small and medium businesses might adopt the approach taken by their counterparts in the pharmaceutical sector, where small start-up companies play a prominent role in innovation, selling the intellectual property that derives from their research.

Innovation, freedom and fairness

A second possibility that critics raise is that allowing qualified claims might strike a better balance between consumer freedom and consumer protection. Do you have a right to know about plausible but unproven health benefits associated with a food? Even if 'right' is too strong a word, might consumers not at least have an interest in such information, so long as a product could be shown to be safe? After all, the risk of consumers overdosing with the active ingredient of a functional food is generally considered low.

Critics of EFSA's approach also ask whether it is fair, to people who depend on the food industry for a living, to expect food businesses to back up the claims they make to consumers with a higher standard of evidence than is required for other products, such as consumer electronics or cosmetics. If products are safe and conform to strict nutrient profiles, should they be allowed to carry qualified claims?

While some people might be interested in qualified claims supported by detailed information, research by the US Food and Drug Administration suggests that it is the basic connection made between a product and a health outcome that resonates with most consumers, leaving qualifications to that connection largely irrelevant. This is not a matter of whether consumers have the capacity to understand qualified statements

containing scientific evidence; it is about the practicalities of doing your food shopping in a hurry.

Conclusion

Food businesses and consumer groups in Europe appear generally to agree that having a list of approved health and nutrition claims is better than relying on retrospective challenges to root out misleading marketing.

Food businesses have been severely frustrated and concerned by the implementation of the regulatory process. Transparency and a clear forward programme for the regulatory process are crucial in mitigating this problem.

Consumer groups support the approach EFSA is taking to assessments and there is little evidence to suggest that lowering standards to allow qualified claims would be in the public interest. The major concern for consumer groups is that the benchmarks for nutrient profiling are being weakened, raising the prospect that foods with a marginal place in a healthy diet could be permitted to carry health claims.

However the ongoing uncertainties relating to the regulatory process end up being resolved, enforcement will always be a challenge, both because marketing can be very indirect and because what counts as a health claim is not always clear cut.

Speaker biographies



Christopher Ritson is Professor of Agricultural Marketing in the School of Agriculture, Food and Rural Development, University of Newcastle upon Tyne. He is author or co-author of 17 books and monographs, and many more articles, most recently concerned consumer attitudes to food quality and safety. He has advised numerous official bodies on food and agricultural issues and is currently a member of the Food Standards Agency Advisory Committee on Novel Foods and Processes, with responsibility for Ethical Issues. He is a trustee of the Food Ethics Council.



Nigel Baldwin is Senior Scientific & Regulatory Consultant at Cantox, and a recognized expert on functional foods and health claims. Prior to joining Cantox in 2003, Nigel worked in technical and regulatory affairs for over 15 years, encompassing nutritional and chemical microbiology, analytical chemistry, food science, quality management and toxicology. He was previously Corporate Regulatory Affairs Manager for a major international food ingredient company working on regulatory strategies for food additives and novel food ingredients. In addition to having been an active participant of the International Life Sciences Institute (ILSI), he is also a member of the Institute of Food Science and Technology, and Society of Cosmetic Scientists.



Sue Davies is the Chief Policy Adviser at Which?, the UK consumer association, working on food issues. She is also a member of the Management Board of the European Food Safety Authority (EFSA) and the recently established Council of Food Policy Advisers. She was until recently Chair of EFSA's Stakeholder Consultative Platform and is also the EU co-chair of the Trans-atlantic Consumer Dialogue (TACD) Food Working Group, a policy forum for EU and US consumer organisations. She was awarded the MBE in 2003 for services to food safety.

About the Business Forum

Ethical questions around climate change, obesity and new technologies are becoming core concerns for food businesses. We have launched the Business Forum to help senior executives gain expert insights into the big issues of the day. Membership is by invitation only and is strictly limited.

The Business Forum meets six times a year for in-depth discussion over an early dinner at a London restaurant. The forum members shape the meeting agenda.

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