

Europe puts health claims to the test

For the past two decades food manufacturers have grown fat selling “functional foods” that claim to make you healthier. Now regulators in Europe are asking manufacturers to provide scientific evidence to support those claims. Mireia Bes reports.

The emergence of so-called functional foods – foods that have been modified to promote better health in one way or another – has done wonders for food company balance sheets over the past 20 years. Probiotic dairy products are a prime example. Starting in the 1990s with Yakult, a bacteria-enriched yogurt drink made by a Japanese company of the same name, sales of such products took off along with that of others, such as French food group Danone’s probiotic product, labelled Activia.

By launching such products, companies were anticipating consumer trends. As Sue Davies, chief policy adviser at Which? a not-for-profit consumers’ organization based in the United Kingdom, puts it: “People embraced food products offering health benefits because there’s a natural tendency to go for the quick fix rather than cut down on saturated fat, sugar or salt, or eat more fruits and vegetables.”

Fast forward to today and you can’t walk down the aisle of a supermarket in any developed country without seeing ads touting the benefits of additives, such as omega-3s/DHA, lycopene or antioxidants. Even sugar-packed fizzy drinks proclaim their “electrolytic value” and call themselves “sports drinks”. But

does adding vitamins to sugar water make it any healthier? And what about adding extra bacteria in yogurt?

Back in 2004, monthly journal *Drug and Therapeutics Bulletin* asked that very question and came to the conclusion that the evidence that probiotics improved intestinal flora was “patchy”, while the broader claim that such products increased consumers’ well-being and helped them fight allergies was “unreliable”. Drinking lots of Activia didn’t make much difference to a healthy person, they found, although it did not have any harmful effects. But that didn’t mean, of course, that other products that proclaim healthy properties couldn’t have harmful effects.

“Adding vitamins to a sweet doesn’t make the sweet healthier,” says Dr Francesco Branca, director of WHO’s department of Nutrition and Health Development, adding that if the addition of vitamins encourages people to overindulge in sweets it can be said to be harmful.

It is this issue of whether such products mislead people into unhealthy choices that is at the heart of the European Union’s regulation No. 1924/2006 on nutrition and health claims, which became applicable in July

of 2007 and is only now starting to deliver results. In the words of Davies: “Prior to 2007 there wasn’t enough control in the EU to ensure that health claims actually promoted healthier choices rather than undermining some of the healthy eating advice that was given by independent nutritionists and government authorities.”

The idea behind the legislation is that claims made in relation to health benefits need to be backed by scientific evidence. The body that decides whether such claims are indeed backed by credible data is the European Food Safety Authority (EFSA), which provides scientific advice to the European Commission. In July 2008 the Commission asked EFSA to prepare a scientific opinion on health claims that were permissible in the European Union and provided EFSA with a draft list containing 4185 entries that had been boiled down from the 44 000 claims supplied by the Member States. To date EFSA has asked for clarifications on more than half of the draft list, and in the words of Branca, the authority is “drowning in paper”.

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Part of the problem is the indigestible nature of the inputs it is trying to assess. Says Branca: “In some cases you only have incomplete information as the potential effects have been obtained under experimental circumstances. But then the dose might vary, the compound might vary, and the circumstances of absorption might vary. It will be difficult to evaluate the complexities of the interactions in real diet situations.” Based on the new regulation, EFSA says it approved the first



WHO/Mireia Bes

Many ads for food products tout the value of additives.

batch of opinions on Article 13 health claims in July and that it will be releasing opinions on 1024 health claims by September this year. Meanwhile, the final deadline for all opinions, set for 31 January 2010, looms.

Nutrient profiles are being developed by the European Commission and EU Member States; these are the nutritional requirements that food products must meet to make certain health claims. The system is designed to keep consumers from being misled as to the product's overall nutritional value. The World Health Organization (WHO) is also working in this area hoping to develop an international standard for nutrient profiles that could be used by many countries: "Currently, we have different systems in different countries: for example, one in France, one in New Zealand, a couple in the United States of America and two in the United Kingdom."

Susanne Döring, director of consumer information diet and health issues of the Confederation of Food and Drink Industries of the European Union (CIAA), believes that uncertainty over the European Commission's nutrient profiles and the list of generic claims that food products are permitted to make, which the Commission and EU Member States are preparing, will "hinder innovation" and lead to fewer products in the market and less choice for the consumer. The regulation has put food companies in a state of limbo, as they cannot design new products until they know which health claims are permissible. Furthermore, Döring says, the regulation places small to medium-sized companies at a competitive disadvantage because – unlike large, cash-rich multinationals – they can not afford to do the research required to design a food product that makes specific as opposed to generic claims, as a full scientific dossier is required.

Döring argues that the regulation is too strict, with repercussions for both industry and consumers: "It's also a problem for the consumer, because if the consumer can't read information on the food packaging he or she is not informed about that product."

Some companies may decide to pull out of the process altogether, anticipating that their products will not



Breakfast foods often claim additives will make you healthier.

fulfil EFSA's requirements for either generic or specific health claims.

Other companies plan to resubmit their data when it is clear what EFSA requires. For example, Danone withdrew its applications for approval of the health claims it makes for its probiotic products, Actimel and Activia, in April 2009. EFSA has yet to give an opinion on the leading specific probiotic brands, but while it has published comment in general terms, it has on no less than five occasions dismissed health claims related to these products.

The health claims made by Activia are backed by scientific studies, summaries of which can be found on the Activia web sites, according to Michael J Neuwirth, senior director of public relations for Danone in the United States of America. "Not only are Activia and DanActive scientifically substantiated, but also they are enjoyed by the millions of highly satisfied consumers who eat them regularly."

And Danone is not the only company to have reasons for concern. In July, EFSA caused a considerable stir by announcing that its scientists, having assessed some 70 claims, had rejected 54 of them. Industry players say EFSA is being too strict, but the European Commission is not swerving. According to a Commission policy officer dealing with the claims: "EFSA

has been subject to criticism by parts of the industry concerning the level of evidence required to reach a favourable opinion. But no Member States have expressed dissatisfaction about the way EFSA proceeds in the scientific assessment of the applications."

Health claims regulations are also being enforced in the USA. In May of this year, the Food and Drug Administration (FDA) ordered food giant General Mills to withdraw specific claims that suggested Cheerios cereal had been "promoted for conditions that cause it to be a drug". General Mills had claimed that the cereal could reduce cholesterol levels by 4% in six weeks. Bruce Silverglade, director of legal affairs at the Center for Science in the Public Interest (CSPI) in Washington, DC, welcomed the move. "I hope that it represents a new commitment by the FDA to enforce the law."

While industry groups say the food claims regulation is too strict, consumer groups say it doesn't go far enough. For example, Davies says that while EFSA gave an initial opinion on nutrient profiles, these are now being developed by the Commission with Member States. "Consumer organizations are concerned that the most recent draft was very weak – allowing foods such as doughnuts to make claims, for example." ■