



ASSOCIATE PARLIAMENTARY FOOD & HEALTH FORUM



The EU Regulation on Nutrition and Health Claims

4-5.30pm, Tuesday 26 February 2008

Committee Room 2A, House of Lords

Minutes

Introduction

Lord Rea introduced the Forum's guest speakers: Noel Griffin, who leads the FSA unit within the Nutrition Division responsible for the nutrition and health claims legislation, and Claire Hughes, Marks & Spencer's Company Nutritionist.

Noel Griffin was one of the negotiators for the UK at official level in the European Council and is now heading the team faced with implementing the claims regulation. Noel also briefed UK MEPs for the European Parliament's scrutiny of the regulation and supported Health Ministers for the Committee debate during the scrutiny of the measure in Parliament.

Noel Griffin, Head the FSA unit within the Nutrition Division responsible for the nutrition and health claims legislation

Noel explained that in talking about the EU regulation (1924/2006) on nutrition and health claims, he had been asked to make the distinction between nutrition and health claims, to describe the UK Article 13 process and next steps and the impact of Article 10 laying down specific conditions for health claims.

The European Commission (EC) proposal was made in July 2003. A rolling consultation followed until the text was adopted in October 2006. The regulation was published on 30 December 2006 and came into force on 19 January 2007. The regulation applied from 1 July 2007, although transitional periods apply in order to give food businesses time to adjust to the requirements of the regulation. Transitional periods were also necessary to enable the authorities to collect and verify health claims on the market for the Community list of authorised health claims.

The European regulation on nutrition and health claims was introduced to harmonise legislation in this area across Europe in order to facilitate trade and to help protect consumers from misleading claims. It may not solve all the problems, but it should help consumers to make healthier food choices. In the future foods will not be allowed to carry claims unless scientific evidence to justify them has been verified by the European Food Safety Authority (EFSA).

The regulation is a pre-market authorisation process, so if a claim has not been given approval by EFSA it will not be able to appear on food in the EU. Having a list of authorised claims should give consumers confidence and support enforcement.

The claims are not made in isolation. The EU has imposed conditions of use for claims which have transparent criteria, so, for example, if a food is described as "low fat" it must be less than 3% fat.

The regulation distinguishes between nutrition claims and health claims and both are subject to general conditions as well as specific criteria, so for example, any claim must be made within the

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context of a healthy and balanced diet. The general requirements for all claims are set out in Article 3 (general principles), Article 4 (nutrient profiles), Article 5 (general conditions), Article 6 (claims must be substantiated) and Article 7 (nutrition labelling).

Nutrient profiles are to operate to ensure foods high in fats (particularly saturated fats), sugars and salt do not appear healthier than they are by bearing claims. A food failing the nutrient profile may have a nutrition claim, but with disclosure of the failed nutrient ("high in"), but it will not be allowed to carry a health claim. The EC must establish nutrient profiles by 19 January 2009. EFSA is about to publish its opinion on the feasibility of nutrient profiles and conditions under which they may be established.

Nutrition claims include any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to: energy or nutrients/other substances it does/does not provide/contain or that are present at a reduced or increased level.

Nutrition claims are listed in an annexe to the regulation with criteria so, for example, "high fibre" must contain 6g/100g fibre. Another example would be that foods carrying the claim "no added sugar" would need to highlight any naturally occurring sugar in the product. There are additional criteria for comparative claims in Article 9 (such as "reduced salt"). It was always intended that the nutrition claims listed in the Annex could be amended and added to. When the regulation was published, it was pointed out that some nutrition claims already agreed in Codex had different criteria, so the EC will look at these again. The FSA expects the EC to begin to introduce amendments in the next few months, starting with polyunsaturated fatty acids.

Health claims include any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its ingredients, and health. "Helps maintain a healthy heart" is an example of a health claim. There is as yet no list of authorised health claims. The authorised list is being put together now and there are three routes for establishing health claims.

The FSA has been collating a list of UK health claims under the Article 13.1 process which involves national lists of candidate health claims being compiled by Member States. Two other routes for health claims are provided. Article 13.5 provides a route for a claim that could not be included on a national list either because it involved substantiating evidence that is either proprietary data which could afford exclusivity of use of the claim to the submitter, or because the evidence is new (perhaps unpublished and not peer reviewed), but worthy of consideration. Article 14 provides a route for reduction of disease risk claims which, being closer to medicinal claims (which are still prohibited), require particular attention. At a late stage, the European Parliament decided that claims referring to children's development and health should also receive the same close attention.

Article 13.1 claims cover growth, development and functions of the body, including psychological and behavioural functions, slimming and weight control. The criteria for Article 13.1 health claims must be based on generally accepted scientific evidence and be capable of being well understood by the average consumer.

The Commission asked Member States to submit national lists of candidate health claims by 30 January 2008. The FSA opened its list as soon as possible after the regulation text was agreed in October 2006, but had to close it in September 2007 in order to be able to meet the EU deadline of 30 January. The FSA published the draft list of candidate claims on 14 December, informed submitters of failed claims before Christmas and reflected on the list before submitting it to the EU at the end of January. The FSA produced a standard, simple, logical format for candidate health claims (see slide 11), following discussions with stakeholders. This format sets out clearly the core component of a health claim (the active ingredient and the effect on health), the suggested conditions of use, the nature of the evidence (peer reviewed article, etc) and enables the submitter to provide references for the scientific evidence. This format was devised to enable submissions to be made without the need for lengthy dossiers of scientific papers and to allow some flexibility when making a claim. It did not require submitters to seek authorisation of an exact formulation of words.

The FSA developed an Access database to help facilitate manipulation of the data, which will be useful in tracking claims as the EU list of authorised list is compiled. The EC has asked Member States to apply a classification system to their national lists which will allow their database to merge claims, along lines similar to the UK list.

The FSA screened all the claims submitted to it to ensure that they were eligible claims and that they provided evidence which would enable EFSA to assess them. The FSA excluded duplicate claims, claims that were not in fact “health claims”, medicinal claims (which are still prohibited), ingredient claims and claims submitted without any scientific evidence. The FSA looked for human evidence, as that being most likely to be acceptable to EFSA, but it did not reject claims that rested on other evidence because human evidence might be supplied by another Member State and other evidence could be used to support a claim. It reduced some 2500 submitted claims to 2100 candidate claims that were submitted to the EU.

EFSA has now published guidance for the A14 claims and, in terms of the type and quality of science required, it is similar to the guidance given by the FSA when it invited A13 claims. The EC is now collating the national lists of health claims and will send them to EFSA for an opinion on their scientific validity.

Article 10 of the regulation lays down specific requirements that health claims must meet or be prohibited. The labelling must have a statement about the importance of a varied and balanced diet and healthy lifestyle. The quantity of food and pattern of consumption to achieve the benefit must be made clear and warnings must be given if excessive consumption is unsafe or if a population group should avoid the food. In addition to these labelling requirements, general, non-specific claims such as “good for you” cannot be made without a relevant authorised health claim, from the list, also appearing to support the claim.

Certain prohibitions continue to apply on specific types of health claims. Claims cannot suggest health is affected by not consuming a food; they cannot refer to a rate or amount of weight loss; claims cannot make reference to recommendations of individual doctors or health professionals; and medicinal claims will continue to be prohibited.

Lord Rea introduced Claire Hughes, Marks & Spencer’s company nutritionist. Claire joined Marks & Spencer in 2005 and her responsibilities include developing nutrition and health policy, including communicating to and educating customers and engaging with the FSA on nutrition issues. She also sits on the Nutrition Working Group at the British Retail Consortium. Prior to joining Marks & Spencer, she previously worked in food retail and has also worked in nutrition research.

Claire Hughes, Company Nutritionist, Marks & Spencer

Claire said she would speak briefly about some of the practical challenges facing food businesses as they seek to comply with the EU regulation on nutrition and health claims.

Marks & Spencer (M&S) supported the proposal for an EU regulation on nutrition and health claims because it welcomed the creation of a level playing field in terms of responsible health claims. M&S have always had lots of internal discussions about any claims they have made and have imposed strict limits on the claims they will use. For example, they only refer to omega-3’s and heart health benefits (based on the strength of the science); they make no other claims for it.

M&S does, however, have some concerns about the EU regulation which it has raised with the FSA through various working groups. Much of the regulation has yet to be scoped and, as Noel described, we do not yet have a final list of authorised health claims or nutrient profiles. The regulation also lacks clarity in relation to nutrition and health claims. For example, it is not clear how the provision of factual information about ingredients which does not include a health claim will be treated. Could, for example, “contains probiotics” on an ingredients label be regarded as implying a health claim?

One of the major challenges facing the food industry, given concern about obesity and other health issues, is food reformulation. M&S has been using marketing material to support the FSA salt reduction campaign, but this could be difficult in the future once the regulation applies. M&S does not want to be prohibited under the regulation from promoting messages about healthy eating to its customers.

M&S has been using packaging on its food to draw its customers' attention to changes in its standard food products. Last year, for example, it replaced the oil it was using in its crisps so that they now contain 70% less fat, which is mentioned on the pack. M&S believe communicating this information to its customers is helpful and encouraging to them, but the regulation will prohibit M&S from drawing attention to changes between its new and old recipes. M&S believes this is counter-productive and provides no incentive for food reformulation, which the UK Government has encouraged.

It is not clear whether the scope of the regulation, which refers to "commercial communications" includes communication with customers via websites and in-store magazines. M&S hopes the final guidance from the FSA to be published soon will confirm that it does not. M&S knows from customer feedback that it has an important role in providing information about healthy eating to its customers and it wants to be able to continue to use its magazines and website to give advice about healthy eating. M&S does not make any claims on its website that cannot be substantiated.

M&S is also concerned about the lack of clarity as to whether colour-coded front of pack labelling - as recommended by the FSA and which it has strongly supported - will be regarded as a health claim. It is possible that under Article 14 a colour-coded front of pack label which has two red lights and one green light could be prohibited because two "red" ingredients" would rule out making a health claim about the "green" ingredient. If this is the case it will undermine support for colour-coded front of pack labelling, which customers find helpful in making healthy choices.

Questions

Professor Jack Winkler asked Noel Griffin (NG) whether Claire was right to suggest that the new regulation may constitute a disincentive to food reformulation and whether there was a way of avoiding this problem by re-wording statements. **NG** said that when new legislation is introduced it is always susceptible to varied interpretations and we may have to wait for the courts to clarify the legislation. He agreed that, as it is written, Article 4 certainly has the potential to clash with front of pack labelling schemes depending on the format of the labelling. The EC has recognised this problem and has responded in its labelling proposal on "food information for consumers", so there is an opportunity to address it. **Lord Rea** asked whether there would be further discussion on this point or an "edict from on high". **NG** said he thought that as part of the new proposal, there would be further discussion on this during the negotiation.

Earl Baldwin of Bewdley asked NG to clarify whether the regulation only applied to food for sale and asked if he anticipated problems arising given the lack of a clear boundary between medicinal claims and claims of disease risk reduction. **NG** said that the Regulation applies to labelling, advertising and presentation of food, in a commercial context, to the final consumer. On the boundary between medicinal and disease risk claims, there could be scope for these to be blurred; currently there was sometimes a grey area between ordinary claims and medicinal claims – such that there is a unit within the UK Medicines control authority dedicated to looking at this issue. The regulation certainly provides an opportunity for food businesses which want to promote claims in this area to take them further.

Bryan Hanley of Martek Biosciences referred to the requirement that claims must be capable of being understood by consumers and asked if the speakers thought companies such as M&S have a role to play in educating consumers about healthy eating. **NG** said there is an important role for food businesses to play because consumers get a lot of information about their food when they go into shops to buy it. Claire Hughes (**CH**) agreed businesses have an important role to play. M&S

have done a lot of work with their customers, but she said customers' information is highly dependent on topical media reports. CH does not believe it is important that customers understand the evidence on which health claims are made so long as they are confident that the claims have been audited by people who do understand it.

Paul Berryman of Leatherhead Food International commented on the large number of claims submitted to the FSA and asked if many of them had been duplicate claims. **NG** said there had been some duplicate claims and many submissions making similar claims. The FSA did not exclude similar claims because they wanted to be as flexible and inclusive as possible.

Michael Hunt of the Food and Drink Federation (FDF) said the FDF's understanding is that front of pack labelling will not be construed as a claim if the ingredients are expressed in terms of percentages, but if colour-coding is used it may be construed as a claim.

Alan Long of Vega Research wondered whether too much attention has been devoted to the minutiae of this regulation. He emphasised the importance of an overall healthy diet and warned that too much focus on certain issues diverted attention from other important factors. He cited as an example the claims made about calcium derived from milk, when vitamin D deficiency in the UK may be a more important issue. He also expressed support for flexibility in implementing the regulation given that some food producers appear to be inhibited from making valid claims and he cited as an example soya milk producers who do not claim it is a good source of vitamin D. **NG** responded by saying the purpose of the regulation is to regulate voluntary claims made in a commercial setting, while the FSA tries to communicate general messages about a healthy diet.

Michael Hunt of the FDF said that the food industry welcomed the level playing field that the regulation will provide by harmonising legislation across the EU, but it is concerned about the complexity of the process for implementing it.

Bryan Hanley of Martek Biosciences welcomed the regulation saying that if health claims have to be clearly made and defended, it provides something concrete for consumers.

Lord Rea asked if the discussions at the EU level were a fraught process and whether the FSA had a strong influence on the outcome. **NG** said he thought the FSA had influenced the outcome of discussions on the regulation in a constructive way. He emphasised that because 27 Member States, the Commission and the European Parliament had been involved in the process, which was subject to considerable lobbying, compromises were required to ensure the passage of the legislation and NG thought this had contributed to some lack of clarity in the legislation.

Professor Jack Winkler asked whether M&S have a policy on when they make health claims. **CH** said M&S make very few health claims and any claims that they do make are substantiated by evidence because they want to retain their customers' trust in their brand. CH made the point that because M&S is reducing packaging on its food there will be fewer opportunities on packaging to convey helpful information to customers, so conveying messages about healthy diets on their website and magazine will become more important.

David Adams of the Health Food Manufacturers Association asked who the FSA would consult over the next couple of years about health claims. **NG** said the EC would be working on the authorised list of health claims until 2010 and they had said it would be a consultative exercise. He believes the EC will speak to EU umbrella organisations. The FSA have suggested to them that they may need to have further discussions with industry about health claims and they seem to accept this.

Conclusion

Lord Rea thanked the speakers and expressed the hope that the meeting had been useful in providing clarification on an important and complex issue. He also reminded members that the next meeting would take place on Tuesday 1st April, when we would be discussing the Foresight

report on obesity. Our guest speakers will be Dr Susan Jebb, Head of Nutrition and Health Research at the Medical Research Council, and Professor Klim McPherson, Visiting Professor of Public Health Epidemiology at Oxford University.

CLC, February 2008