Associate Parliamentary Food & Health Forum

Report of the FHF Spring Conference 2009

"Food fortification – a necessary option in a junk food society?"

19 May 2009

House of Commons, London, SW1A OAA

Associate Parliamentary Food & Health Forum
Church House, Great Smith Street
London, SW1P 3AJ
Tel: 020 7222 1265 Fax: 020 7222 1250

Please note: it is not possible to circulate the speakers' PowerPoint presentations with this report because of their file size, but members may like to refer to them on the Forum's website at: www.fhf.org.uk

Introduction

Lord Rea – Chairman of the Associate Parliamentary Food and Health Forum

Lord Rea welcomed members and the guest speakers to the meeting on food fortification. He said food fortification had long been of interest to dietitians and nutritionists. It could play a useful role in times of food insecurity and in areas where nutrients are lacking in the soil.

Food fortification – a valuable option in a junk food society

Jenny Walton, Senior Nutritionist, Kellogg's UK & Ireland

Jenny works for Kellogg's in Manchester where she specialises in scientific and regulatory affairs. She manages the in house research programme for all of Kellogg's brands in the UK and Ireland. She has been working especially closely with the European Health Claims regulation and various activities on nutrient profiling.

Jenny studied for her first degree in nutrition, then studied for a further qualification in Nutrition and Exercise Science, and is now currently studying for her master's degree in public health nutrition at the University of Chester.

A registered nutritionist and member of the IFST, Jenny has ten years experience as a nutritionist in industry gaining experience at the Co-op, Jacobs Biscuits and Danone.

Presentation summary

Illness through nutrient deficiency is rare in the UK today. There is an abundance of nutritious food available. Life expectancy statistics show we are living longer, if not healthier. Our consumption of fruit and vegetables is increasing and, thanks to the work of the Food Safety Agency, our salt intake is decreasing. Consumers are now more interested in nutrition and the quality of their food. However, we have illnesses associated with dietary problems and lack of exercise, such as obesity, and we know that there is less home cooking and that many people are skipping breakfast.

The British population's diet is not far off the recommended nutrient levels (see slide 2), but iron levels among women are especially low and the level of some vitamins, such as folate and riboflavin, are of possible concern. Iron deficiency is the most commonly reported nutritional disorder during early childhood in the UK. The NDNS of British children found 1 in 8 toddlers to be anaemic. Calcium levels are also lower than is ideal (see slide 3).

Food fortification is the addition of of nutrients to a food to levels above those normally present in that food. Restoration is the replacement of nutrients lost during some stage of food production or distribution.

Some foods are very commonly fortified, such as breakfast cereals, but even water is fortified in some areas – with fluoride. Legislation requires the fortification of margarine. Research shows that 66 % of consumers in Ireland consume fortified foods, but fortified foods only provide 1.3% of the energy in the diet.

Kellogg's was built on a foundation of concern about health and nutrition. There is a misconception that much food is fortified simply to enable companies to make health claims for marketing purposes, but this is not true. Kellogg's only fortifies food where some nutrients are lacking. The first food fortified by Kellogg's was Special K, which was intended for people on a low calorie diet. Food fortification was subsequently extended to other foods – to include folic acid - at the request of MAFF in the 1980s. Kellogg's fortified foods are aimed at people on a low calorie diet and are designed to help them meet their nutritional needs. Special K is now fortified with 6 B vitamins, vitamin D, vitamin C and iron since NDNS statistics showed that many girls aged 11-14 are deficient in iron (see slide 10).
The impact of food fortification on diet has been measured by the National Diet and Nutrition Survey (NDNS). It has been demonstrated that breakfast cereals make a significant contribution to the amount of iron consumed in the average diet, but a small proportion to the amount of energy (sugar) and salt. The FSA has recognised the contribution that breakfast cereals make to

increasing the population intake of folic acid and thereby to reducing the number of cases of neural tube defects (NTDs). Children who eat breakfast cereals are more likely to meet their dietary needs (see slide 11 and 14). Increasing the consumption of fortified foods is associated with a lower percentage of food energy intake from total fat and a higher percentage of food energy intake from total carbohydrate. It appears that fortified food consumption is a marker of both better dietary quality and healthy lifestyle behaviours.

If we remove fortified foods from the diet it would have a profound effect on nutrient status as illustrated by American research (see slide 15), which showed that removing folic acid–fortified foods from the diets of women who consumed such foods at least once weekly reduced had a profound effect on their nutrient status in 12 weeks. This magnitude of change in folate status in women is predicted to have a significant, although not optimal, effect in preventing neural tube defects.

As we look to the future, we need to continue working to ensure that we do not consume excess calories. However a significant proportion of the population are still at some risk of nutrient deficiencies and as calorie intake decreases, there are fewer opportunities to take in micronutrients, so the nutrient density of our food is becoming ever more important. The evidence shows that children who eat fortified breakfast cereals are more likely to reach nutrient targets and are less likely to have deficiencies. Food fortification (including voluntary fortification) can, and does, make a significant contribution to mitigating this risk and foods fortified with folic acid can even save lives.

A healthy diet rather than food fortification?

Dr Anne Mullen, Lecturer in the Nutritional Sciences Division, King's College London

She works in the Diet and Cardiovascular Research Group led by Professor Tom Sanders, where her main research interests are in fish oils and the metabolic syndrome. Before moving to KCL, Anne worked on a complementary feeding project in Lusaka, the capital of Zambia. The on-going Chilenje Infant Growth, Nutrition & Infection Study is led by Professor Suzanne Filteau at the London School of Hygiene and Tropical Medicine. The study is trialling a micronutrient fortified porridge among infants in a HIV-endemic community where micronutrient deficiencies and malnutrition are prevalent. As well as research in public health nutrition, Anne has a background in nutrigenomics and dietetics.

Anne's PhD was from the Nutrigenomics Research Group of Trinity College Dublin – funded through Lipgene, an EU 6th Framework study of diet, genomics and the metabolic syndrome. She studied Human Nutrition and Dietetics in Trinity College Dublin and the Dublin Institute of Technology.

Presentation summary

Food fortification is not always necessary. Our food system is diverse so we could manage without food fortification. However food fortification is a complex issue and I'm not "anti" food fortification.

A healthy diet is well defined in the UK and we are moving towards a comprehensive system of labelling to help consumers make healthy choices. The key question is whether the population is taking in the messages about a healthy diet that are being sent out.

The UK population's diet has a wide range of energy intake, as illustrated by the National Diet and Nutrition Survey (NDNS). The NDNS also shows that the UK population's energy intake fell between 1970 and 1990, and other research (Swan 2004) found it fell between 1986 and 2001. Our overall fat intake is roughly at the recommended level, but our carbohydrate intake falls just short of the 50% recommended level and worryingly we eat still eat too much saturated fat. The evidence also shows that some young adults fall below the recommended levels of some nutrients such as vitamin A and Riboflavin. Our salt intake is far in excess of recommended levels and on average we eat well below the recommended levels of fruit, vegetables and oily fish. At the same time, 60% of men and 40% of men exceeded the recommended level of alcohol consumption on at least one day a week.

The experts know what the UK population should be eating and that information has been communicated to the public. We know they have some surmountable problems in acting on this information. We also know that a proportion of the population is obese, but these problems can be overcome with a better understanding of the barriers to a healthier diet.

There are socio-economic barriers to a healthier diet. Research (see slide 16) has shown that income levels are related to poor diet. Poor fruit and vegetable intakes are also associated with views such as "I don't really care what I eat". Attitudinal research has shown that 70% of consumers in the European Union did not think they needed to make major changes to their diet.

Research shows that consumers are aware of the healthy eating messages but they do not regard them as personally relevant. Have we done enough to explore the barriers to healthy eating in the UK? More resources should be directed at healthy eating messages and ensuring they have an impact rather than on food fortification.

Recent research (see slide 18) shows that we have a high incidence of over-weight and obesity in the UK as well as iron deficiency anaemia. There are four main approaches to tackling these problems: iron supplements, food fortification, nutritional information and horticultural practices to increase the amount of iron in the food that we eat. The most sustainable approach must be improving the healthy eating messages.

The NDNS also found low plasma vitamin D levels in the UK population. We have long known that vitamin D is important for bone health, but we now know that it is important for heart disease, diabetes and other conditions. The UK's latitude and advice on sun protection has contributed to vitamin D deficiency, but vitamin D insufficiency is fundamentally the result of sun deprivation. Small amounts of exposure to the sun and a healthy diet should be effective in dealing with any deficiency.

A recent article in *The Lancet* promoted iodised salt as a method for dealing with iodine deficiency, but only 5% of households in the UK and Ireland use iodised salt. However, although iodine deficiency is not a problem for the UK population as a whole, it does matter for pregnant women living in certain areas of the UK. A sensible solution if they do not have adequate iodine levels would be for pregnant women to take iodine supplements. A healthy diet can be achieved for most people, but other approaches are necessary for certain parts of the population, as for example, more sun exposure for those with vitamin D deficiency.

If folic acid is taken early in pregnancy it can remarkably reduce the risk of neural tube defects (NTDs). In the US food fortification (with folic acid) was introduced without population-wide consultation and it has created some problems. For example, fortifying foods with folic acid can mask vitamin B12 deficiency, it may have associations with cognitive function in older people and, although the WCRF said there was only suggestive evidence of a link with colorectal cancer, one study (Mason 2007, see slide 22) has shown epidemiological evidence of an association between mandatory fortification and incidence of colorectal cancer in the US and Canada. Moreover the long term effects of fortifying food with folic acid are not known. So, while fortifying food with folic acid has a role in dealing with the risk of NTDs, it has been a contentious issue.

One positive example of food fortification is the mandatory fortification of wheat flour with niacin, thiamin, riboflavin and iron in 1940s, which led to the virtual eradication of Pellagra in the US by 1950. Another positive example of food fortification is the mandatory fortification of margarine with vitamins A and D in the UK.

In many developing countries food fortification has taken place to deal with widespread nutritional deficiencies. It is useful where people have few food choices, poor diets, low incomes and access to food is limited so that fortified foods reach their target audience. However, the situation in the UK is different; here other problems – such as obesity and diabetes are more important. As a result, the most important response in the UK must be healthy eating messages, especially given the possible risks associated with blanket action. Other actions can also be considered to address specific nutritional deficiencies, but food fortification should be regulated, monitored and the public should be consulted.

The criteria for responsible food fortification

Dr Alison Tedstone, Head of Nutrition Science, the Food Standards Agency

Alison is a registered public health nutritionist. She has been a member of the Nutrition Society since about 1985. Alison graduated from London University with a BSc in physiology from Queen Elizabeth College and a PhD from St. George's Medical School. Her postdoctoral work was in Oxford in the MRC's Metabolic Research Laboratory. She joined the London School of Hygiene and Tropical Medicine 1992 as a lecturer in human nutrition, where she became heavily involved in the nutrition masters teaching and organisation. Sequentially she became course director responsible for the all post graduate course in the Department of Epidemiology and Population Health. While at the School her research focussed on children's diets with most recent projects on food security in refugee families in London, vitamin A status in mother and infants in rural Kenya and breastfeeding support in Brazil.

Alison left the School and academic life in 2001 to join the Food Standards Agency as a principal scientist in the Nutrition Division. Alison is now Head of Nutrition Science and also Head of Profession for Nutrition in the Agency. She is responsible for expert advice on nutrition, nutrition research, surveys, policy and consumer advice. She also leads UK Government work on folic acid fortification.

Presentation summary

Alison said that any consideration of food fortification has to take account of the U-shaped risk-benefit curve of nutrient intake, where the risk of deficiency of inadequate intake has to be balanced against any adverse effects associated with excess nutrient intake (see slide 2). Between the two sides of the curve there is a safety margin – in some cases this is very broad, but in others it can be very narrow. For example, if we consume too few calories we will be stunted and malnourished, but if we consume too many we will become obese. Very low levels of vitamin A are associated with night blindness, but very high levels are associated with an increased risk of bone fracture and even higher levels are associated with an increased risk of birth defects. So there is a risk continuum that policy makers must work within.

Folic acid is needed for healthy cell division and inadequate levels of folic acid are associated with many impaired bodily functions. Folic acid is found in foods, supplements and fortified foods. The reference nutrient intake (RNI) for folic acid is 200 µg for adults and lower levels for children. There is also a well established upper safe limit of 1000 ug for adults (with lower values for children), while women who might get pregnant need an extra 400 µg folic acid until the 12th week of pregnancy.

Babies need folic acid in the first weeks of life if they are to develop healthily. If they do not receive adequate levels the neural tube may fail to develop which, depending on the severity, may result in a failure of brain development or spina bifida, which may result in lifelong serious disability. We have very good data to show that increasing folic acid intake can reduce the risk of neural tube defects (NTDs) by up to 75% - a huge positive benefit that is very unusual for one nutrient.

Some countries have already adopted mandatory folic acid fortification, leading to a reduction of between 20% and 50% in NTD levels. But the picture is complicated because folic acid can mask vitamin B12 deficiency and may be associated with an increased risk of colorectal cancer. There are many difficulties in interpreting the new evidence that is emerging in this area, but in addition to the study referred to by Anne Mullen (Mason, 2007) there is a randomised controlled trial which suggests an increased colorectal cancer risk.

We know that levels between the RNI of 200 µg level of folic acid for adults and a higher level of 600 µg for pregnant women, will be enough to prevent significantly the risk of NTDs. After that we approach the upper safe limit for adults (see slide 8). The appropriate levels for children will be lower and it is possible that children are exceeding their upper safe limit simply by eating a normal diet.

Currently a wide range of foods are fortified with folic acid and it is quite difficult for consumers to calculate how much they are eating. The FSA's research shows that 23% of people have folic acid intakes below the RNI, but this varies between 35% for young and 50% for older women. We know that at the moment, only about 25% of pregnant women are taking a folic acid supplement as recommended, not least because approximately half of the pregnancies in the UK are unplanned. It is quite difficult, however, to persuade pregnant women to take supplements – even in a second pregnancy when the benefits of folic acid are known. At the same time, about 127,000 people (about 0.2% of the population) in the UK exceed the upper limit for folic acid.

Some years ago the Government asked SACN for advice on folic acid given the evidence that was emerging in other countries that folic acid consumption could reduce the number of cases of NTDs. SACN looked at all the evidence and also conducted a risk-benefit analysis. They produced a dual recommendation: that mandatory fortification of flour should be introduced to help people achieve the RNI, but voluntary fortification should be controlled to reduce the risk of people exceeding the safe upper limit (SUL).

In 2007 the FSA recommended the mandatory fortification of flour with folic acid, controls on voluntary fortification of food with folic acid and the provision of guidance on the use of supplements containing folic acid. The objective of this combined approach is to reduce the number of NTD-affected pregnancies by 11-18%, to ensure that we do not increase the number of people with intakes above the SUL for folic acid and to reduce the proportion of people with intakes below the RNI to 5% (see slide 13).

In 2008 the evidence of an increased colorectal cancer risk associated with higher folic acid intakes became more established and the FSA was asked by the Chief Medical Officer for further advice. Since then the FSA has been undertaking modelling – a very tricky exercise. It is very difficult because the food chain in the UK is so complex and products come and go all the time with no external restraints. In the UK we have more data than most countries because of the NDNS, so we can at least try to undertake this modelling exercise. We also have a nutrient database, which has helped, through cooperation with the food industry.

Early modelling indicated that there should be a status quo on voluntary fortification, a reduction in folic acid levels in fat spreads and controls on high dose supplements. Recent analysis has assessed the effect of current levels of voluntary fortification and supplement use, modelled changes in levels of voluntary fortification of the main food sources and modelled the effect of capping the level of folic acid in supplements.

Folic acid is found in many food groups, but the main sources are breakfast cereals, fat spreads, Marmite, Bovril and supplements. It is also found in Ovaltine, Horlicks, milkshake powders, cereal bars and soya milk. Around 20% of people eat Marmite or Bovril and about 40% of the population take a food supplement. Multi-vitamins tend to contain folic acid and there are also a lot of high dose supplements; 62% of supplements containing folic acid contain more than the RNI.

The FSA looked at various different levels of folic acid in a wide range of foods and supplements because we did not want to increase the number of people consuming more than the SUL. The FSA found that they could achieve what they wanted by capping levels in supplements at

400μg/day (800μg/day for women aged 14-49 years and reducing the levels in fat spreads from 25% to 15% of the RNI per portion (see slide 21).

The FSA's work on folic acid is currently on hold pending further work on the evidence of cancer risk, but margarine producers have reduced the level of folic acid in their spreads on a voluntary basis. At the moment, the only restraints are voluntary, but the EU has a proposal which would change this because of their recognition of the need to protect consumers. Proposals to set maximum levels of vitamins and minerals in supplements and fortified food are expected to be finalised in September 2009. They are intended to harmonise legislation to allow for the free movement of fortified foods, to protect consumers by producing lists of approved vitamins and minerals (and sources) and maximum safe levels and to create a procedure for review and control of other substances on safety grounds.

Responsible food fortification requires some controls and we need a clear risk-benefit analysis of the effects of food fortification to achieve the best decisions. This requires: science on the effects of nutrients on health (benefits and risks); nutrition survey data on food consumption patterns, nutrient intake from foods and supplements; composition data on foods (also market share information and overage); careful modelling of the effects on high and low level consumers; being alert to changes in science, food supply and consumption patterns; good communication with and between different parts of the food industry; and mechanisms to allow frank discussions that allow innovations while safe guarding consumers.

In summary, food fortification is very common in the UK. It can be of benefit to some (reducing the risk of deficiency), but it can put others at risk. Something like folic acid fortification was thought to be risk free until we discovered the association with an increased risk of cancer very recently. We need to keep up to date with emerging scientific evidence on the risks and benefits of nutrients. The risk/benefit balance can also change as science develops and products come on and off the market. We need to monitor the emergence of "me-too" products. When only Unilever was fortifying its spreads, it may not have presented a significant problem, but as other food producers followed suit the case for intervening became stronger. It is very difficult to manage food fortification in a modern food chain and the overall impact of food fortification is difficult to assess. Composition data was easy 50 years ago because foods did not change very much, but now foods change very quickly. Food fortification is not currently tightly controlled by legislation or voluntary agreement, but we need to be able to control the voluntary fortification of foods. For example, people consume large quantities of drinks and it would be a matter for concern if these became fortified, raising the risk of people exceeding SULs.

Taking advantage of technical innovations to produce healthier food

Nigel Baldwin of Cantox on behalf of the Food Additives and Ingredients Association

Nigel Baldwin heads Cantox's European Office. He is a recognised scientific and regulatory expert in the area of health claims and novel food ingredients and supplements. Mr. Baldwin is well-versed in European food regulations and has extensive experience with their practical implementation across the EU.

Prior to joining Cantox in 2003, Mr Baldwin worked in technical and regulatory affairs for over 15 years, encompassing nutritional and chemical microbiology, analytical chemistry, food science, quality management, and toxicology. He has had responsibility for regulatory strategies for food additives and novel food ingredients and has worked extensively on novel foods, food supplements, health claims, infant formula and feed regulatory approvals and strategies. He therefore has first hand experience of the technical, time, and cost pressures facing new product development.

Mr. Baldwin received his B.Sc. with honours in biochemistry and physiology in 1987 from the University of Central Lancashire, majoring in microbial biotechnology and pharmacology and is a Chartered Scientist in the UK. 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 the Society of Cosmetic Scientists.

Presentation summary

Nigel explained that the Food Additives and Ingredients Association (FAIA) represents both large multinational food ingredients producers as well as many UK based small and medium-sized enterprises. He chairs their Functional Foods Group. Nigel also works for a consultancy that prepares dossiers for submission to the European Food Safety Authority (EFSA). Trade associations and consultants work together to help steer food manufacturers through the maize of legislation they have to deal with if they are bringing new products to market. He emphasised that without commercial benefits for food producers we will not see the benefits that could be achieved through innovation in the food industry. The food ingredient industry is a very, very innovative industry. It is also responsible for producing the science on food ingredients and the value of this work to the British and European economy, or indeed the research institutions it funds, should not be underestimated.

The food industry is working to improve the nutrition, texture, taste and quality of our food. The negative side of the food industry is the exploitation by operators working in a legal vacuum on such issues as health claims especially via the internet. Problems have occurred chiefly because of a lack of enforcement as much as lack of legislation and legislators are now over-compensating for this with new laws.

One positive example of innovation is the development of a vegetarian omega-3 oil, as a replacement for fish oil, which has been made possible by new techniques for fermenting algae and extracting the omega-3 from it. This has huge benefits because algae are a sustainable source of omega-3, but novel food legislation has delayed "time to market". It can take at least two years to complete the legally required novel food processes under the current procedures which involve 27 member states all reviewing the dossier instead of mutual recognition.

Proposed new novel foods legislation designed to speed up and centralise the approval process for new ingredients appears to have been hijacked from its original purpose by MEPs intent on turning it into a moral debate on nanotechnology and cloned animals, resulting in further long delays. Nanotechnology can be used to make vitamins more readily absorbable, or better

distributed so that they have less impact on the taste of a food. However, work on the definition of nano-technology remains on-going and is different to that used in cosmetic products. Cloned animal technology is apparently ready for use in the USA and the RSPCA are concerned that it may be used in Europe unless the legislation is put in place. Discussions on this have held up the novel food discussions for more than a year.

Another example of innovative practice is enzyme technology, which can be used to reduce environmental impact, by requiring less energy for bioconversion, for example, in alcohol production and by creating functional lipids. The recent EU enzymes regulation will mean legislation is harmonised across Europe, which is good but smaller companies may well need more safety studies and thus investment, which is difficult to come by these days. It may also increase the time lag between developing new products and bringing them to market.

The slow progress of legislation is the main obstacle to food industry innovation. The revenue that accrues to companies in the food industry is very small in comparison with the pharmaceutical industry, but it is approaching a level where it is regulated as heavily.

Nutrition and health claims legislation was adopted with a regulatory compromise based on a two tier system, which distinguished between existing health claims on the market (the "Article 13 list"), where a relatively simple demonstration of efficacy is required via submission of references; and the more extensive requirements for new health claims and those aimed at children which require full scientific dossiers (these are very expensive to produce). This was the result of inadequate consultation with scientists who can only apply the rules of science, based on the balance of the totality of available data, to all claims. EFSA was subsequently asked to apply similarly high standards to all submissions, nearly a year into the process. This means that some 4,000 claims on the Article 13 list may have inadequate data submitted for EFSA to evaluate them properly, even though the applicants have followed the instructions in the legislation. If at the outset full dossiers were required for all submissions it is highly unlikely so many claims would now be sitting on EFSA's desk with only slim chances of approval. Given that all of these claims must be reviewed before the end of the year and after January 2010 only approved claims can be used, many products may disappear from health food stores next year. The industry itself is understandably extremely worried about what will happen over the next 6 months

In some cases there is a difficult compromise between the legislation and science. The legislation on health claims includes claims which refer to a reduction in disease "risk factors", but in some cases we do not have reliable factors (ie biomarkers) for a disease. Often this is fine, for example spreads like Benecol lower your cholesterol level, which is a risk factor for heart disease. But in some cases we have problems, for example the totality of the data on fish consumption shows that it reduces the risk of death from heart disease and there are likely biomarkers for this that have been demonstrated in controlled trials, but the main data that supports recommendations comes from population surveys and epidemiological data. So we could argue that simply saying that consuming fish reduces your risk of death by heart disease, which is entirely valid and understandable based on the totality of the data, but the legislation may not strictly permit such direct wording, at least without debate over interpretation of the regulation.

Overall the industry realises that it needs to discourage the "cowboys", but we should also encourage an innovative food industry based on sound scientific evidence by making the legislation more clear and by minimising the delays in the approval process. We also need to defend a reasonable return on the investment in scientific research that the food additives and ingredients industry makes by protection of proprietary data and even licensing of claims. Efficient management of the non-scientific aspects should also be a reasonable expectation and there are terrible delays already in the system because of the administrative and political processes involved in getting new claims adopted and published into law, even after scientific

agreement. The review of nutrition and health claims process undertaken by EFSA is entirely fair within the mandate they have been set, but it is placing a very heavy burden on EFSA experts and its staff who need to be of the highest calibre to ensure protection of consumers and industry alike. This country leads the world in research and development and the food sector will continue to play an important part in the future, but it needs a fair and clear regulatory environment to be able to prosper. The next six months or so will be critical to the food industry.

Food fortification and health claims

Bridget Benelam, British Nutrition Foundation

Bridget initially studied biochemistry at the University of Manchester and later went on to complete a Masters in nutrition at Kings College London. She then joined the Food Standards Agency (FSA) in their chemical safety division dealing with consumer enquiries (relating to food safety issues such as the risks and benefits of consuming soya, and safe levels of oily fish consumption for women) and research management. She was also part of the secretariat for the FSA's Committee on Toxicity.

Bridget moved to The British Nutrition Foundation in 2006 as a Nutrition Scientist. As part of this role she has travelled extensively via her work on behalf of the Foundation on EC funded projects on food composition, including recent visits to the International Food Science and Technology World Congress in Shanghai and to the European Food Safety Authority in Italy. She has also provided guidance on nutrition science, for schools, health professionals and consumers in the UK. The British Nutrition Foundation runs a media enquiry service and Bridget has featured in a number of newspapers and magazines and has been interviewed for radio and television about nutrition and health. In addition, she has recently written a Briefing Paper for the Foundation's journal *Nutrition Bulletin* entitled 'Satiation, satiety and their effects on eating behaviour'. She will speak at a conference to launch the paper next month.

Presentation summary

The nutrition and health claims legislation (Regulation 1924/2006) came into force July 2007. Nutrition claims concern claims about what a product contains and health claims concern claims about a product's effect on health. The regulation runs along side Regulation 1925/2006 on the addition of vitamins and minerals to foods.

The aim of the legislation is to protect the consumer from misleading claims and to encourage the food industry to produce healthier products. Claims must be understood by the "average consumer", although the legislation defines the average consumer as being "reasonably well informed and circumspect" consumer understanding is difficult to prove. FSA research has found that some consumers find claims useful and are influenced by them, but consumers are also sceptical that claims are used for marketing and the FSA found that reaction to a claim is affected by familiarity with the nutrient. Nutrition claims tend to be simpler, for example that a product is "low in fat". Consumers like these simple claims and respond to them. "Source of" claims enjoy quite high consumer confidence. If a consumer has a high understanding of the benefits of a nutrient – for example the link between vitamin D and healthy bones – they tend to equate "source of" claims with health claims. Consumers are more likely to be confounded by health claims, which is not surprising because they are usually not as simple. They are more readily understood if there is prior knowledge of, or interest in the health relationship and they are regarded as more plausible if the product is already viewed as healthy.

For many nutrition claims there are certain conditions of use, including threshold limits so claims cannot be made where insignificant amounts of a nutrient are present in, or added to, a food.

Making a health claim on a product has a "halo" effect so consumers will assume it is a healthy product even if, for example, if includes a high level of sugar. For this reason nutrient profiles have been established to prevent inappropriate health claims being made. Nutrient profiles define whether a product can be the subject of a nutrition or health claim. If it exceeds one threshold, a health claim cannot be made. A nutrition claim can still be made about it, but the product must clearly identify the threshold which it exceeds. If it exceeds more one threshold neither a health claim nor a nutrition claim can be made.

Nutrient profiles have been delayed to accommodate various changes that have been suggested, for example, to take into account additional categories and possible exemptions. Donuts, for example, were found to exceed only one threshold, so a nutrition claim could potentially be made if it conformed to the conditions of use of an approved nutrition claims. This could be damaging because it could lead to a lack of trust in the nutrient profiling system.

There are three thresholds for most food categories (sodium, saturated fat and sugar) and if a food passes all the thresholds both a nutrient and health claim can be made for it. Most food producers will probably not make nutrition claims about products where they fail one threshold because they will not want to draw attention to that fact. Not many products pass all the thresholds with flying colours (see slide 14). The thresholds have been raised as a result of some recent decisions, which have annoyed many health campaigners and consumer groups.

Before health claims can be made about fortified foods, conditions of use have to be satisfied, for example, there must be a significant amount of the nutrient present in the product, often 15% of the recommended daily amount. The nutrient profiling system should prevent foods with a less healthy profile making claims and all nutrition and health claims must be on an approved list.

EFSA is responsible for examining the Article 13 claims, where a full scientific dossier is not required. These claims are thought to be at the level of that described in nutrition text books. However, if the claim is based on new evidence then a dossier is required, as with the Article 13.5 and Article 14 health claims. Two EFSA opinions illustrate the approval process: claims that “vitamin D is essential for the bone growth of children” (see slides 17 and 18).

In the case of the vitamin D and bone development claim, studies showed good consensus on the role of vitamin D in bone growth, the cause and effect relationship is well established, there is evidence of low vitamin D status in subgroups of target population and it was agreed that the food making the claim should be at least a ‘source of’ vitamin D (15% RDA). On this basis the claim was approved by the EC.

A less obvious claim is that “a dairy product enriched with milk peptide and magnesium can help to moderate signs of anxiety in mildly stress-sensitive adults due to its milk peptide and magnesium content.” EFSA found that the target group of “mildly stress sensitive adults” is not well defined, no positive effect was seen in human RCTs, other human studies used endpoints not relevant to the claim (for example, blood pressure, sleep duration and doses higher than that of the product). This claim has not yet been considered, but is less likely to be approved.

The nutrition and health claims legislation should ensure that claims made on fortified foods are robust, but the nutrient profiles need to be finalised for the regulation to work well.

Questions

Earl Baldwin of Bewdley asked Anne Mullen to clarify the colorectal cancer risk associated with the fortification of food with folic acid. Anne said there had been a "blip" – a rise in the number of cases of colorectal cancer in 1996 and 1997 - that coincided with the introduction of folic acid fortification in the US and Canada. In 2007 the World Cancer Research Fund (WCRF) had said the evidence was only "suggestive". **Lord Rea** said it had subsequently gone up in one country and down in the other. **Alison** said experts were looking at this evidence, but it is very difficult to interpret because America also changed the way it screened for colorectal cancer at the same time and this could have explained the changes. It is not surprising if, when better screening is introduced, the number of cases identified increases. Anne said the evidence suggested that at very low and very high levels of folic acid intake there was an increased colorectal cancer risk.

Alan Long of Vega Research said Vega Research has been looking at the implications of a plant based diet and it could be argued that the Neanderthals had died out because of a vitamin B deficiency and because they did not eat enough fish. We do not get enough vitamin D in the UK over the winter to meet our needs, but this is not surprising if you think that man developed closer to the equator. Last year 250 people died of malnutrition in our hospitals, but many of these patients entered hospital in a malnourished state. Alcohol can also reduce our vitamin levels.

Professor Jack Winkler of London Metropolitan University asked Jenny Walton to comment on the apparent contradiction that in the UK we are eating less in energy terms but obesity levels are increasing. **Jenny** said physical activity levels have dropped in the UK over the same period. There is also a wide range of energy intake in the UK and she had been referring to the mean intake. Around 70% of the people in the UK do not reach the recommended levels of physical activity. We also tend to eat too much saturated fat. **Alison** said that the UK population is consuming enough calories (as it is getting fatter) and they are not taking enough exercise. **Lord Rea** suggested the problem was exacerbated because many young men consume "empty calories" – food high in energy but with a low nutritional value.

Bridget Benelam of the British Nutrition Foundation asked if Jenny knows what proportion of the UK population skip breakfast and what the barriers are to eating breakfast. **Jenny** said that Kellogg's often carry out surveys and the results vary, but it is usually about 1 in 5 people who skip breakfast each day. Two key barriers are time and not feeling hungry in the morning. People who are overweight do not appear to feel hungry in the morning. Some people do not like breakfast cereals. Lifestyle changes are also relevant – fewer families eat breakfast together. Kellogg's tries to encourage people to eat breakfast as part of a healthy diet.

Earl Baldwin of Bewdley asked if our levels of selenium in the UK are satisfactory. **Alison** said that levels of selenium consumption in the UK are relatively low, but the level required is not well established. The Scientific Advisory Committee on Nutrition (SACN) are undertaking work in this area. High levels of selenium consumption have been associated with higher rates of some cancers.

Dr Orla Kennedy of the Nutrition Society suggested a balanced approached to food fortification was needed. It can help tackle specific nutritional deficiencies, but food fortification should not mean that we do not need to worry about eating a balanced diet even if a balanced diet alone is insufficient. She suggested food fortification should be considered on a nutrient by nutrient basis. **Lord Rea** suggested that is a very complicated task and **Alison** agreed, saying it is a difficult challenge but it is exactly what is needed.

Lord Rea referred to the fact that we do not eat enough oily fish and asked if there was a case for fortifying foods with essential fatty acids. **Anne Mullen** said before fortification was considered we should try to ensure that people eat up to the dietary guidelines. She expressed personal concern that omega-3 fortification would be used simply as a marketing tool. We are on average consuming a third of a portion of oily fish a week, when the guideline is one portion. She suggested the healthy eating message on oily fish was not being well communicated. **Nigel Baldwin** suggested that the message was clear but many people do not like eating oily fish and so the healthy eating message is not working. **Tracy Forward of Efamol** said there is a clear need for food fortification, but it needs to be carefully considered. One company is cancelling its fortification policy because consumers do not want to eat yoghurts fortified with essential fatty acids in it. **Nigel** suggested that if the goal is to ensure the population achieves recommended nutrient intakes then the food industry should be encouraged to fortify food and policy makers should work positively with industry.

Eileen Steinbock of Brakes raised the dilemma that if we were all to eat the recommended levels of oily fish it would have a negative impact on fish levels. **Alison** agreed and said the FSA had just closed a consultation on the balance of fish sustainability against dietary guidelines on fish

The Countess of Mar suggested the public are becoming increasingly resistant to being told what they should eat. One speaker had distinguished between clinical nutrition and public health nutrition, but she is concerned that public health nutrition is resulting in blanket recommendations for all which are not suitable for every person. For example, she had reduced her salt consumption, as recommended, but this had had an adverse affect on her heart. We all have individual health needs and should be cautious about public health messages. **Anne** said that a lot of attitudinal research shows that consumers will respond to personal and targeted advice, but public health nutritionists have to respond to population needs. Public health messages should be refined so that they become more effective.

Professor Jack Winkler of London Metropolitan University asked whether, if the public are fed up with being told what to eat, the Countess of Mar concluded that we need food fortification rather than public health messages. The Countess did not support food fortification, which she regards as mass medication. Her suggestion was that young children in school should be taught about a healthy diet and encouraged to cook. **Anne Mullen** agreed, but said this did amount to giving young people targeted health information and skills at a local level.

Alison Tedstone of the FSA said there is evidence of low nutrient intake in the UK, but there is little evidence of actual nutritional deficiencies and we should be careful not to confuse the two. We have evidence that many older people who can cook are not doing so, so there are some very complex issues to deal with. Her experience is that single good ideas need to be absorbed in a much bigger jigsaw if positive results are to be achieved.

Alan Long of Vega Research expressed support for the NICE guidelines which have resulted in GPs measuring the BMI of their patients and, if necessary, referring them to specialists for help. He hopes this will catch older people in danger of becoming malnourished as well as anorexic young girls.

Earl Baldwin of Bewdley suggested it would be a difficult task to ensure the SULs for folic acid are not exceeded, while ensuring that the average person does reach the RNI. **Alison** agreed and said the FSA had recommended bread or flour for fortification because bread consumption tends to be very even across the population. At the moment folic acid fortification tends to be in premium products, which may not be consumed by the people who most need to be reached. The best way of reaching the low folic acid consumption group is to fortify a staple food.

The Countess of Mar drew attention to the fact that one of the slides had shown a margarine contained 500% of the RDA for folic acid and asked if this could be a problem, for example for a person who ate a lot of toast with margarine. **Alison** said that it was that amount in 100g of spread; she agreed it could be a problem and said the FSA had been concerned about it and they had asked margarine producers to reduce the amount of folic acid in their products, which they are doing.

The Countess of Mar asked why we think humans should eat less saturated fat, when we know the best way to fatten up animals and help them maintain a healthy weight. Alison said that the evidence shows that people eating diets high in fruit and vegetables, with moderate intakes of meat and whole grain carbohydrates will have healthier lives than those with higher amounts of saturated fat in their diets. We tend to kills animals young, so we do not have evidence about the long term effect of their diet on them.

Lord Rea asked for clarification of the current status of the EU health claims legislation. **Bridget** confirmed that the legislation is now in force, but is a work in progress as the nutrient profiling system is finalised and the dossiers are being scrutinised by EFSA. Transitional periods were built into the legislation, but the 2010 deadline may slip. **Alison** said that much work was involved in implementing this legislation.

Dr Orla Kennedy of the Nutrition Society asked what evidence is currently available with regard to the possibility that folic acid can mask vitamin B12 deficiencies in adults. **Alison** said that this issue had been considered by SACN. **Lord Rea** asked if the possible risk was associated with levels in excess of the SUL of 1000 ug or whether it might occur at lower levels. **Alison** said clinical cases showed people who take 5000 ug (ie 5g) are at risk of a vitamin B12 deficiency diagnosis being delayed, which could cause some problems. The 1000 ug SUL was safe in relation to masking vitamin B12 deficiency because it includes a large safety margin. The serious risk occurs at higher levels of folic acid consumption. But the FSA are not sure about the reality of the cancer risk or the threshold at which it may arise. **Anne** asked whether if mandatory folic acid fortification is introduced in the UK, the FSA would still advise pregnant women to take folic acid supplements. **Alison** said they would because you could not reduce the risk of NTDs to the lowest possible levels without supplementation. Otherwise the mandatory folic acid fortification would have to be set at levels that would be unacceptable in terms of the risks to older people (of vitamin B12 deficiency being masked) being too high..

Lord Rea asked Alison to comment on the supposedly protective link between high folic acid intakes and a reduced risk cardiovascular disease, which had been taken seriously in the US some time ago. **Alison** said this thesis had been disproved.

Professor Jack Winkler of London Metropolitan University said that Nigel had identified three policy issues: licensing as a means of ensuring that companies derive a decent benefit from investment in research; administrative delays; and the overload on EFSA. He asked Nigel had any suggestions for tackling them. **Nigel** said he believed science should determine the amount of work necessary. The original decision by the EU not to require dossiers for Article 13 claims was flawed and this is now recognised. Scientific dossiers to substantiate claims should always have been required. Proprietary data to substantiate claims could have been protected for 5 years and then released. EFSA will issue their opinions on 31 July and most of them will be negative because insufficient evidence has been submitted to substantiate them.

Lord Rea asked whether EFSA should employ more scientists to speed up the process of approval. **Nigel** said that if dossiers had always been required it would have deterred those who did not have robust evidence from submitting claims, allowing the remaining dossiers to be considered more quickly, thereby supporting the responsible parts of the food industry. **Alison** said the system had been simplified by manufacturers producing joint “category claims” for some products, such as milk products and breakfast cereals.

Conclusion

Lord Rea thanked the guest speakers and announced the date of the next Forum meeting: on 23 June, when we will be discussing the links between diet and asthma.

CLC, May 2009