

Older people and functional foods

The importance of diet in supporting older people's health; what role for functional foods?

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Foreword

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Diet and nutrition are key factors that impact on the health of older people and a healthy diet and lifestyle can help prevent disease, particularly chronic disease. In general, healthy eating advice for older people is similar to the rest of the population. However, the physiological changes associated with ageing result in older people having some specific nutritional needs that differ from the rest of the population. This report looks at older people's specific nutritional needs and examines the evidence behind current dietary recommendations for older people and looks into whether functional foods have a role to play.

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Chapter one – Executive Summary

Diet and nutrition have a role in supporting older people to remain healthy and preventing disease, particularly chronic diseases such as cardiovascular disease. Functional foods, defined here as "*conventional food products modified in some way to give a health benefit above and beyond basic nutrition*" are concentrated in the areas of bone health, cardiovascular health and gastrointestinal function, all of which are more likely health concerns for older people. Functional foods can therefore have a role to play in supporting older people's health, but they don't replace healthy eating; they supplement it.

Due to physiological changes associated with ageing older people can have different nutritional needs to younger people, for example, the over 75s are at greater risk from malnutrition than obesity and many over 60s would benefit from higher vitamin D intake. Current dietary recommendations do not distinguish between different age groups of older people, despite the fact that a 55 year old and an 80 year old can have some significantly different nutritional needs and there is very little research into what the oldest old (the over 80s) actually eat.

When examining consumer behaviour towards functional foods, the impact of socioeconomic factors is rather inconsistent, although many studies confirm that a consumer of functional foods is more likely to be older and female. There is a strong link between interest in health and perceived need for the health benefit of the functional food, both of which have been found more frequently in older consumers and as well as a propensity to consume functional foods. Taste, however, is more important than health benefit for consumers of all ages and people only buy functional food in the form of products that are already part of their diet. Healthy carrier products, for example, yoghurt, benefit from health claims, whereas unhealthy products such as mayonnaise do not. Consumers show cultural differences across Europe, for example, technology loving Finns being more receptive to functional foods than natural food oriented Danes.

This paper undertook three case studies to consider whether functional foods have a role in supporting older people's health and nutrition.

The first case study was probiotic yoghurts and drinks. The scientific literature found evidence for their effect on the body including the gastrointestinal microflora and gut related immunity. The strongest evidence of health benefits were found in preventing and treating antibiotic associated diarrhoea (AAD), a serious health problem often affecting older people and to a lesser extent for digestive discomfort and other gastrointestinal complaints.

The second case study looks at plant sterol and stanol containing functional foods, for which there is solid scientific data and approved health claims that 2g per day can lower Low Density Lipid (LDL) ("bad") cholesterol and total cholesterol by on average 10%. Given that older people are at greater risk of cardiovascular disease and high cholesterol

is a major risk factor, cholesterol-lowering functional foods present a strong case for being included in many older people's diets as part of a healthy lifestyle approach instead of or accompanying statins.

The third case study looked at the nutrients calcium and vitamin D, which are essential to bone health, a key concern for older people, especially postmenopausal women. There is also growing evidence for the role of vitamin D in immune health. Many older people experience calcium and particularly vitamin D deficiencies and current UK recommended daily amounts seem in need of revision in the light of current nutritional science. There is as yet no concrete answer as to how best older people should achieve increased intakes of calcium and vitamin D, although functional (fortified) foods could clearly play a role.

This paper has developed a number of recommendations in relation to older people's nutrition and functional foods, which include:

- The need for some age tranche-specific dietary recommendations for older people.
- Calcium and vitamin D screening for older people.
- Review the UK recommendations on calcium and vitamin D intake for older people (probably increasing daily intakes of vitamin D to 25mcg and calcium to 1200 mcg)
- Consider the routine inclusion of plant sterols/stanols into some older people's diets.
- Consider protocols for the use of probiotics in preventing and managing antibiotic associated diarrhoea, particularly in older people.

In relation to research gaps, this paper has found a need for further research into a number of areas including:

- The dietary habits of the oldest old.
- Older consumers and functional foods
- Compliance with functional foods.
- Randomised clinical trials looking at the effect of incorporating functional foods into older people's diets.

Chapter two – Aims and Objectives

This study seeks to understand the role of nutrition in supporting healthy older age including:

- The role of nutrition in maintaining health and preventing disease.
- The evidence which has led to current food and nutrition recommendations for older people.
- The development of functional foods to support specific health and nutritional needs.
- The role of functional foods in supporting older people to remain well-nourished and healthy.

In particular the study will:

- Focus on older people living independently in the community.
- Consider two age groups, older people aged 55-74 and the over 75s.
- Consider the general role of diet and focus on specific nutrients only where directly applicable to the health of older people.
- Acknowledge the role of social and behavioural issues connected to nutrition and healthy ageing.
- Consider nutritional status in its broadest sense from obesity to malnutrition.
- Define a functional food and consider whether it can be classed as a healthy food.
- Highlight the breadth of functional foods, but focus on a number of case studies.
- Consider the evidence for the inclusion of functional foods into older people's diets.
- Develop policy options and recommendations for the routine use of functional foods in older people's nutrition.
- Not focus on the role of macronutrients and dietary recommended values (DRVs).

Chapter three – Methodology

This study will not undertake primary research, but will be based on secondary research primarily through a literature review of peer reviewed journals mainly in the field of nutrition.

A comprehensive literature review was undertaken to look at:

- The link between nutrition and older people's health.
- Current dietary recommendations for older people.
- The development, definition, and scientific evidence for functional foods.
- Current trends in the use of functional foods including for older people.
- Whether there is evidence of a role for functional foods in older people's health.

A number of literature searches were undertaken. Initial literature searches were undertaken using the following terms:

- "elderly nutrition" (title)
- "older people AND nutrition" (title)
- "older people AND diet" (title)
- "functional foods AND older people" (title and abstract)
- "functional foods AND definition" (title and abstract)
- "regulation AND functional foods" (title and abstract)
- "functional foods" (title and abstract)
- "functional foods AND consumers" (title and abstract)

Subsequent literature searches looked for:

• "probiotics" (title)

- "probiotics AND older people" (title and abstract)
- "cholesterol-lowering AND functional foods" (title and abstract)
- "calcium AND functional foods" (title and abstract)
- "vitamin D AND functional foods" (title and abstract)
- "calcium AND older people" (title and abstract)
- "vitamin D" AND "older people" (title and abstract)

A number of peer reviewed journals were individually searched; these were:

- British Journal of Nutrition
- Clinical Nutrition
- European Journal of Clinical Nutrition and Metabolism (E-SPEN)
- Journal of the American Dietetic Association
- Journal of Human Nutrition and Dietetics
- Public Health Nutrition
- American Journal of Clinical Nutrition

In order to find relevant articles falling outside of the major peer reviewed nutrition journals a PubMed search was undertaken using the same search terms.

Many further articles were subsequently found via articles that turned up in the initial literature searches. In addition, certain ad-hoc searches were undertaken during the course of the review as and when topics or issues arose that required further investigation.

Articles were rejected on a number of grounds including:

- They were purely methodological.
- They referred to animal experiments relating to biological markers.
- They focused only on hospital and/or care home based older people.
- They focused only on parental nutrition.
- They reported only on dietary habits and nutritional status of very small groups of people for narrow nutrients/parameters.
- They were published before 1990

A number of websites were also searched for information on older people's nutrition (guidelines and recommendations) and functional foods (definition and regulation):

- UK Food Standards Agency
- European Commission
- European Food Safety Authority
- UK Department of Health

- European Food Information Council
- Functionalfoods.info

• World Health Organisation

• World Cancer Research Fund

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Chapter four - The role of diet in older people's health

Findings

- Literature and dietary recommendations do not take into account the fact that 55 year olds are likely to have different nutritional needs to 80 year olds.
- The 55-64 age group has, for the most part, similar nutritional needs than younger adults with the exception of paying extra attention to dietary risk factors for chronic diseases.
- The 65-74 age group also has similar nutritional needs to younger adults, except for those with higher risk of developing chronic disease or where slowing the progression of chronic disease may be necessary.
- There is insufficient research into the dietary habits of the oldest old.
- Health promotion to encourage better nutrition and appropriate levels of physical activity can work in older people and can bring health benefits.

Demographic trends

The United Kingdom's population is increasing and ageing at the same time. Population increases are due to the older sections of the population living longer, two post war "baby booms" and immigration. Over 25 years from 1983 to 2008, the population of the UK increased from 56.3 million to 61.4 million, an increase of 9% (ONS, 2010).

According to the latest demographic data (ONS, 2010), older people (aged 65-84) represented 14% of the population in 1983 at 7.8 million, rising to 8.6 million by in 2008 and predicted to rise to 13.1 million or 18% of the population by 2033. But the biggest change is the increase in the oldest old section of the population (the over 85s) which represented only 1% of the population in 1983 at 0.6 million individuals, but increased to 1.3 million people by 2008 and is forecast to rise to 3.3 million or 5% of the population by 2033 (ONS, 2010).

This ageing of society has drawn increased attention to the health needs of older people. While much of this debate focuses on the use of NHS resources to treat older people and how to provide social care, the healthy lifestyle agenda, including diet and nutrition, has also become more important for older people.

Diet, nutrition and health for older people

Supporting general health and well-being

A healthy diet is an important part of a healthy lifestyle for people of all ages. A healthy diet with adequate calories and appropriate levels of key nutrients is needed to meet basic metabolic and nutritional requirements in order to maintain physical and mental functioning and growth (FAO, 2007; Laparra and Sanz, 2009), whereas inadequate nutrition can lead to loss of functioning and development or progression of disease (Canella et al, 2009). Deficiencies in key nutrients can lead to health and development problems, for example, vitamin D deficiency, which can cause bone health problems (Horwath et al, 1999).

There is considerable evidence that some diets, for example, the Mediterranean diet (Hu et al, 2000; Masala, 2007), have a positive influence on health and can reduce the risk of developing certain diseases, for example, cardiovascular disease and some cancers (WHO, 2003; WCRF, 1997; Tyrovolas and Panagiotakas, 2010; Trichopoulou et al, 2009). A lifecourse approach to healthy eating and good nutrition means that they remain as important for older people as for their younger counterparts.

"Nutrition is recognised as one of the major determinants of successful ageing, defined as the ability to maintain three key behaviours: low risk of disease and disease related disability, high mental and physical function, and active engagement of life". (Krondl et al, 2008).

"A good diet and physical activity help to minimise potential health problems and accelerate recovery from illness" (Caroline Walker Trust, 2004, p.11).

There is now general agreement that a balanced healthy diet should:

- Be rich in complex carbohydrates, for example, wholemeal bread, wholegrain rice
- Include five servings of fresh fruit and vegetables per day
- Be low in salt and saturated fat

- Be low in sugar and refined carbohydrates
- Include "good" fats like olive oil, nuts and oily fish
- Include protein sources like lean meat, oily fish, low fat dairy products, eggs and vegetarian sources of protein (legumes, beans, tofu)

(WHO, 2002; Department of Health, 2004; Nutrition Australia, 2009; Food Standards Agency, 2010)

If a person is eating a healthy balanced diet, they should be able to get enough macronutrients such as carbohydrate, protein and fat, as well as sufficient quantities of micronutrients (Food Standards Agency, 2010, British Nutrition Foundation, 2010). The nutrients that are important and commonly deficient in older people are vitamin D, calcium,

folic acid, iron, vitamin B12, vitamin B6 and vitamin C (Food Standards Agency, 2010, British Nutrition Foundation, 2010).

Disease risk reduction

As well maintaining physical and mental capacity, the link between diet and the incidence chronic disease is now widely accepted (WHO, 2003). In particular, diet can play a role in reducing the risk of developing cardiovascular disease, some cancers, osteoporosis, inflammatory conditions (WHO, 2003; WCRF, 2007; Arvanitoyannis, 2005; Hu, 2000; Danini et al, 2009) and Alzheimer's disease (Gu et al, 2010).

For example:

- High cholesterol (largely diet influenced) is a risk factor for coronary heart disease (Chernoff, 2001)
- Adequate intake of calcium and vitamin D has been shown to help prevent or slow down the onset of osteoporosis (WHO, 2003; Ilich et al, 2003; Rosen 2003)
- A diet high in high glycaemic (usually refined) carbohydrates is associated with an increased risk of Type II diabetes (Hu et al, 2000)
- "Mediterranean" and "Asian" traditional diets (high in whole grains, fresh fruit and vegetables, low in red meat and high fat dairy products) are associated with lower rates of coronary heart disease than the typical American diet (Hu et al, 2000; Masala et al, 2007) and lower risk of mortality in general (Trichopoulou et al, 2005; Trichopoulou et al, 2009).

While inadequate or bad nutrition is a risk factor in the development and progression of many chronic diseases, good nutrition is not a guarantee of prevention or cure, but can significantly reduce the likelihood of developing a number of common chronic diseases and/or slow down their progression (WHO, 2003).

Ageing, health and nutrition

Physiological and social factors affecting older people's nutrition

Biological ageing results in physiological changes that make it more difficult for older people to get all the nutrients they need from a balanced diet (Gariballa et al, 1998; Department of Health, 1992). Nutrients considered particularly important for older people's health include vitamin D in combination with calcium, vitamin B12 and folic acid (folate) (Cannella, 2009).

As people age, particularly once they get into their 70s, physiological changes occur that have an effect on nutritional intake and needs. These changes include loss of taste and smell, changes in body composition and bone density, in the basal metabolic rate, to the

immune system (Martin, 2000; De Groot et al, 2001; Volkert, 2002; Wardwell, 2008; Stanga, 2009) and to the digestive system (Donini et al, 2009).

The loss of taste and smell accompanied by an increase in the taste buds which detect bitter or sour tastes (Gariballa et al, 1998; Volkert 2002) can result in older people finding food unappetising, which can put them off eating and reduce their overall food intake (Schiffman, 1997).

Older people's body composition changes through a decrease in lean body mass (muscle), known as sarcopenia, and an increase in body fat (Gariballa et al, 1998; Ritz, 2001), which has an effect on the basal metabolic rate (BMR), the rate at which the body uses up energy (Cannella, 2009). The BMR decreases proportionately with the decrease in muscle, which is the most metabolically active tissue (Cannella, 2009; Gariballa et al, 1998; Ritz, 2001). Studies show, however, that maintaining or increasing physical activity can reverse the decline in BMR in older people (Ritz, 2001; Gariballa et al, 1998; Chandra, 1990; JJ Reilly et al, 1993).

There are other physiological factors which can affect nutritional intake and status. These include disabilities, such as problems with eyesight and joints, which may affect the ability to prepare and eat food (Darmon et al, 2009; Gariballa et al, 1998) and problems with personal physical mobility can make food shopping difficult (Department of Health, 2004; Age Concern, 2006). Dental health and oral function are also of concern as dental status can affect nutritional status (Buttriss, 1999, Walls and Steele, 2004). For example, 58% of the over 75s wear dental prostheses and many wearers report difficulties in eating certain foods, particularly fruit and vegetables (Bradbury et al, 2006), which can lead to lower nutrient intake (Walls and Steele, 2004).

Older people are more likely than other ages to suffer from disease, some of which can increase energy expenditure due to factors like metabolic stress and fever, while reducing energy intake, through bed rest and physical inactivity, and lead to a negative energy balance, or weight loss (Ritz, 2001). In addition, where older people have chronic diseases, they will often need to take medication (prescribed and non-prescription), which can cause anorexia, nausea, diarrhoea, constipation and dry mouth, all of which can suppress food intake (De Groot et al, 2001; Gariballa et al, 1998; Volkert, 2002).

Some mental health problems are also highly correlated with malnutrition, in particular dementia (Vetta, 1997) and depression, which is one of the most important causes of weight loss in the very old (Vetta, 1999).

In addition, there are a number of socio-economic factors which can influence diet and nutritional intake making it difficult for older people to access, prepare and eat a healthy diet (Age Concern, 2006; Wilson, 2009). These factors include:

- Social isolation, for example, feeling lonely rather than merely living alone leading to depression, which is linked to decreased interest in food (Krondl et al, 2008)
- Living situation, for example, living alone increases the risk of malnutrition (Krondl et

al, 2008) and eating in company can result in higher energy intakes (Mathey et al, 2000).

- Bereavement, for example, a widower living alone who is not able or not used to cooking for himself (Krondl et al, 2008; Wilson, 2009).
- Low income in older age can result in older people having less money to spend on food (Wilson, 2009; Chernoff, 2001)
- Food accessibility including availability of transport (Age Concern, 2006).

Gariballa et al (1998) say that socio-economic factors can have more bearing on the person's health than nutritional status alone, but the two are interlinked.

Immune system

The responsiveness of the immune system decreases with age, a process known as immunosenescence (Wardwell, 2008). Immunosenescence is characterised by decreased proliferation of T lymphocytes and impaired T-helper activity which can lead to impaired cell mediated immune defence (Wardwell, 2008; Volkert, 2005). This can makes older people more susceptible to infection - the fourth most common cause of death in old age (Chandra, 1990; Chandra, 2004) - less able to fight disease (Wardwell, 2008; Martin, 2000; Volkert, 2005), and reduce the effectiveness of vaccination (Wardwell, 2008; Martin, 2000). Lower cholesterol levels have been associated with improved immune function (Tufts, 2003), thus giving people another reason to make dietary changes to improve their health.

Digestive system

Ageing related changes to the digestive system can lead to gastrointestinal disorders or simply digestive discomfort (Donini et al, 2009) such as bloating, flatulence, abdominal pain and altered bowel habits (Guyonnet et al, 2007). These changes can affect appetite as well as absorption of nutrients, for example, vitamin B12 absorption is impaired with age (Buttriss, 1999). Lactose intolerance, which occurs when a person is deficient in lactase, the enzyme which processes lactose (Lin, 2003), is more common in older people (Lin, 2003; Hamilton-Miller, 2004) and its symptoms include bloating, cramping and diarrhoea (Lin, 2003). As well as unpleasant symptoms, lactose intolerance can result in calcium deficiency through avoidance of dairy products (NIH, 2010).

Hypochlorydria (reduction in the secretion of stomach acid) is relatively common in older people (Hurson, 1990) often resulting from atrophic gastritis, and can decrease the bioavailability and absorption of some nutrients such as calcium, iron, folate and vitamin B12 (De Groot et al, 2001; Gariballa et al, 1998; Hurson, 1990). Atrophic gastritis is present in a large minority of older people, for example, a Dutch study found that 32% of 74-80 year olds in the Netherlands are affected by it (De Groot et al, 2001). In addition, medicines commonly prescribed to older people such as proton pump inhibitors can cause a reduction in gastric acid secretion (Logan et al, 2010; Ali et al, 2009).

Age related changes in the gastrointestinal tract combined with changes in diet and immune system reactivity affect the composition of gut microbiota, leading to increased numbers of facultative anaerobes, decreased number of beneficial organisms like anaerobic lactobacilli and bifidobacteria (Donini et al, 2009). The consequence of these changes can be an impaired digestive function with increased transit time, increased putrefaction of the colon and a greater susceptibility to disease (Donini et al, 2009). It is also worth pointing out that intestinal complaints such as constipation, flatulence and bloating are common in older people and can have a considerable impact on their quality of life (Donini et al, 2009; Gage, 2009). Increasing dietary fibre along with the use of probiotic or prebiotic supplements or functional foods, have been suggested to improve digestive and immune health in older people (Donini et al, 2009; Gage, 2009; Ouwehand, 2009).

Bone health

Older people, especially older women, are susceptible to bone health problems primarily osteoporosis due to loss of muscle and reduced bone density (Caroline Walker Trust, 2004; Phillips, 2000; Bonjour et al, 2009; Gennari, 2001).

Osteoporosis is a disease which is characterised by decreasing bone density and increasing fragility of bones due to micro-architectural deterioration (bones become porous), which increases the risk of fracture (Gariballa et al, 1998; WHO, 2003; Phillips, 2000; British Nutrition Foundation, 2003; Bonjour et al, 2009). Osteoporosis is a risk factor in 90% of fractures in the over 65s (Buttriss, 1999). Osteoporosis is exacerbated by malnutrition, low weight, poor intake of vitamin D and calcium, and in women, low levels of sex hormones (Stanga, 2009; Eisman, 1993).

There are two key nutrients that are essential to bone health: vitamin D and calcium (Phillips, 2000; Bonjour et al, 2009; Heaney, 2007; Gennari, 2001; Bischoff-Ferrari and Staehelin, 2008) Calcium is one of the main bone forming minerals (WHO, 2003; Bonjour et al, 2009; Phillips, 2000; Bischoff-Ferrari and Staehelin, 2008) and vitamin D is essential for bone health because it is required for calcium absorption (Buttriss, 1999; Bischoff-Ferrari and Staehelin, 2008). The efficiency of calcium absorption declines in older adults (British Nutrition Foundation, 2003; Gennari, 2001). It is therefore more important for older people, especially women, to have adequate intake of calcium and vitamin D to maintain bone health and help prevent osteoporosis (Rao and Alqurashi, 2003; Bonjour et al, 2009; Dawson-Hughes and Bischoff-Ferrari, 2007).

Older people are more vulnerable to vitamin D deficiency because their skin is less able to synthesise previtamin D3 and declining kidney function can impair the synthesis of active metabolites of vitamin D (BNF, 1996; Zochling et al, 2005; Gillie, 2004). As well as reduced ability to synthesise vitamin D from sunlight, older people spend less time in the sun (Cannella, 2009; De Groot et al, 2001; Gillie, 2004). Belgian research shows a high prevalence of vitamin D inadequacy in post-menopausal osteoporotic women, even among those taking vitamin D supplements (Neuprez et al, 2007).

Vitamin D can be obtained from the diet, but research shows that "Western" style diets typically provide around 25-50% of the required vitamin D, thus supplementation in older age might be desirable (De Groot et al, 2001). Clinical trials have shown that calcium and vitamin D supplementation reduces the risk of fracture in vulnerable older women (Buttriss, 1999). Research in Spain concluded that vitamin D supplementation would be advisable for sections of the population at risk of osteoporosis, such as older people and post-menopausal women (Del Campor et al, 2005).

Malnutrition

Malnutrition is: "a state of nutrition in which a deficiency, excess, imbalance of energy, protein, and other nutrients causes measurable adverse effects on tissue, body form (body shape, size and composition), body function and clinical outcomes" (ENHA/BAPEN, 2006).

Malnutrition in the form of undernutrition is a particular risk for older people (Gariballa et al, 1998; Ritz, 2001; Wilson, 2009; Stanga, 2009; ENHA/BAPEN, 2006), particularly those over the age of 75 (Volkert, 2002). Unless specified otherwise, this paper will examine the problems of malnutrition in the form of undernutrition for older people. Malnutrition does not only lead to nutrient deficiencies (Caroline Walker Trust, 2004), but can adversely impact recovery from illness (Ritz, 2001) and is associated with higher morbidity and mortality (Vetta, 1999). For example, inadequate nutrition can contribute to the progression of chronic diseases like cardiovascular disease and osteoporosis in older people with those conditions and malnourished older people are also at greater risk of infection (Volkert, 2005). In addition, older people are at greater risk of not being able to recover from malnutrition (Pirlich et al, 2003).

Protein energy malnutrition (consumption of too few calories and too little protein), which is rather common amongst older people with estimates that 1 in 10 people over 65 living in the community are malnourished (ENHA/BAPEN, 2006), has been shown to decrease immunity (Mazari and Lesourd, 1998; Cosquéric et al, 2006; Chandra, 1990).

Physiological changes to the digestive system affect appetite which can affect nutrient intake (Stanga, 2009; Gariballa et al 1998). Changes in dental status can also negatively affect nutrient intake as studies have shown that independently living older people who are edentulous (have dental prosthetics) consume lower quantities of non-starch polysaccharides, protein, calcium, iron, niacin, and vitamin C than those who still have their own teeth (Marcenes et al, 2003). In addition, socio-economic factors play a very important role in the development of malnutrition in older people (Wilson, 2009; ENHA/BAPEN, 2006) These factors include low income (Krondl et al, 2008), availability and accessibility of food shops, social isolation, depression, lack of cooking skills and motivation (Wilson, 2009; Age Concern, 2006).

Because of the increased risk of malnutrition for older people, the Department of Health have recommended that except in cases of obesity, older people should have energy intakes that "tend to the generous" in order to make sure they get enough calories and do

not lose weight unnecessarily (Department of Health, 1992).¹

In addition, older people may need higher quantities of some nutrients, for example, calcium, vitamin D and vitamin B12 (Tufts, 2003) due to physiological changes making absorption of nutrients more difficult. Studies show that calcium, vitamin D, folate, iron and vitamin B12 are the most important micronutrients in which deficiencies commonly occur in older people (Tufts, 2003; Biesalski et al, 2003). Eating less also means that there is a greater possibility that nutrient intake will be insufficient or even dangerously low (Caroline Walker Trust, 2004).

Obesity

Up to the age of 75, obesity and being overweight are more prevalent than malnutrition in the form of undernutrition (Volkert, 2002) and a higher BMI (body mass index) is correlated with morbidity and mortality (Stanga, 2009) because of disease risk factors linked to cardiovascular disease such as high cholesterol (WHO, 2003). Obesity is an increasing health problem for these younger cohorts of older people, typically those ages 55-70, which can lead to metabolic syndrome which has links to diabetes and cardiovascular disease (Krondl, 2008, Cabrera et al, 2007).

However, once people get even older, typically over the age of 70 (Darmon et al, 2009), being underweight poses greater health risk than obesity (Caroline Walker Trust, 2004, Wilson, 2009). This means that even when a person over 75 is overweight and would like to lose weight, eating less could result in nutrient deficiencies which may cause more health problems than being overweight (Caroline Walker Trust, 2004). Darmon et al (2009) say that exercise is probably more important than dietary restriction for the health of overweight and obese older people. It is around the age of 70 that low BMI starts to become more highly correlated with mortality than a high BMI (Stanga, 2009). Flegal et al (2005) point to a U-shaped mortality curve where the risk of mortality is higher with a very low BMI, then decreases with weight gain, as an underweight person attains a normal weight, then increases as BMI moves from normal to overweight or obese.

¹ The Department of Health Committee that set these guidelines has now been replaced by the Scientific Advisory Committee on Nutrition (SACN). SACN has not yet updated the 1992 recommendations on the nutrition of older people.

Calle et al (1999) present this u-shaped mortality curve:



Figure 2. Multivariate Relative Risk of Death from Cardiovascular Disease, Cancer, and All Other Causes among Men and Women Who Had Never Smoked and Who Had No History of Disease at Enrollment, According to Body-Mass Index.

The reference category was made up of subjects with a bodymass index of 23.5 to 24.9. It should be noted that there is no precise age at which malnutrition in the form of undernutrition overtakes obesity as a health problem; it is more of a gradual change. However, it is safe to conclude from the literature that generally speaking, obesity is more of a problem for the under 75s whereas malnutrition is a greater concern for the over 75s.

Cardiovascular health

Coronary heart disease and stroke are major causes of death and disability in older people (Howarth et al, 1999). 40% of deaths among the over 65s are caused by coronary heart disease or stroke, (Caroline Walker Trust, 2004) so any measures that can be taken to prevent or reduce the progression of such conditions should be welcomed.

Older people are more likely to develop "metabolic syndrome", a group of risk factors including abdominal obesity, high cholesterol, high blood pressure, and elevated fasting glucose levels, all of which are cardiovascular risk factors (Krondl et al, 2008; Bo et al, 2008; McNeill et al, 2005). Hypertension (high blood pressure), which a major risk factor for stroke (Stroke Association, 2010) and coronary heart disease (WHO, 2003), can be reduced by decreasing dietary sodium (salt). Interestingly enough, sodium reduction is more effective in lowering blood pressure in older hypertensive people, but attention must be paid to salt reduced food still being appetising to older people whose sense of taste has often diminished with age, as if not, this can lead to appetite reduction which brings its own health concerns (Darmon et al, 2009). Older women are also at greater risk of coronary heart disease due to losing the cardio-protective effect of oestrogen after the menopause (Korzen-Bohr and O'Doherty Jensen, 2006).

High cholesterol is risk factor for cardiovascular disease, including coronary heart disease, but one that can be improved through diet including in older people, for example, by reducing saturated fat intake and including "good" fats like olive oil and oily fish containing omega-3 fatty acids (Howarth et al, 1999; Caroline Walker Trust, 2004). Innovation in food science has also led to the development of functional foods that help lower cholesterol (Chen, 2008) such as margarine containing plant sterols. High cholesterol is also associated with increased long term risk for reinfarcation, death from coronary heart disease and all-cause mortality in patients who have had one myocardial infarction (heart attack) (Wong et al, 1991).

However, it is important to note that high cholesterol is a risk factor for cardiovascular mortality until after the age of 65, whereby the correlation between the two decreases as the person gets older (Darmon et al, 2009) and total cholesterol tends to decrease (Volpato et al, 2001). Volpato et al (2001) have undertaken clinical research which suggests that poor health status is responsible for lower cholesterol in people over 65 years old.

There is a common perception that changing dietary habits in older age (over 65) will not bring any health benefits (Howarth et al, 1999; Chernoff, 2001; Age Concern, 2006). But in many areas, including cardiovascular health, this is not true. Ellingsen et al (2008) demonstrated that an increased intake of fruit and berries was inversely associated with

carotid artherosclerosis (narrowing of the arteries due to fatty deposits) in older Swedish men at high risk of cardiovascular disease. Tyrovolas and Panagiotaka (2009) found that data from a number of European countries supports a Mediterranean diet being cardio-protective for older people.

Diabetes

There are two types of diabetes, type I, and type II. Type I diabetes usually begins in childhood or adolescence and is a result of the body not producing enough insulin, and although there is a strong genetic component, it is not yet known what triggers the condition (Diabetes.co.uk, 2010; Daneman, 2006). Type II diabetes is lifestyle related and more common in older people, with some countries reporting 10-20% of the over 65 population having the condition (Darmon et al, 2009). One of the reasons that type II diabetes is more prevalent in older people is that ageing is associated with a reduced ability to metabolise glucose from food (Howarth et al, 1999).

Obesity and in particular central adiposity (weight gain around the waist) are strongly associated with the development of type II diabetes. Increased abdominal obesity in older people can cause metabolic changes which lead to insulin resistance, a key risk factor in the development of type II diabetes (Ritz, 2001).

Type II diabetes can be prevented by lifestyle modification (WHO, 2003) and there is evidence that a healthier lifestyle can contribute to managing the condition. For example, studies have shown that replacing saturated fats with unsaturated fats improves glucose tolerance, even if total fat intake does not change (WHO, 2003). In addition, a good intake of non-starch polysaccharides, that is, wholegrains, legumes, fruit and vegetables may protect against type II diabetes (WHO, 2003).

Cancer

In both men and women, the likelihood of developing cancer increases with age.



Diagram one: cancer diagnoses in the UK by age group

Source: Cancer Research UK

Only a small proportion of cancers are known to be inherited; environmental factors including nutrition, physical exercise and body composition are far more important (WCRF, 1997). Obesity, in particular, is linked to several cancers including breast cancer (WCRF, 1997). There is significant data to show that a diet rich in fresh fruit and vegetables, unprocessed cereals and pulses reduces the risk of many cancers (WCRF, 1997). There is also evidence that diets high in red meat, processed meat (for example ham), refined carbohydrates and sugar is linked to higher risk of colon cancer in both men and women (Slattery et al, 1998).

Mental health

There has been a recent increase in research looking at mental health and diet, particularly in older people. A Mediterranean type diet (rich in nuts, fish and vegetables) has been shown to reduce the risk of developing Alzheimer's disease (Gu et al, 2010). A Mediterranean diet contains folate, which reduces homocysteine (an amino acid linked to Alzheimer's), vitamin E, which has an antioxidant effect, and is low in saturated fat, which can increase dementia risk by encouraging clot formation (Gu et al, 2010). It should be noted; however, that homocysteine has a stronger association with vascular disease as clinical studies have shown that even moderately increased homocysteine levels increase the risk of atherothrombotic vascular events (McCulley, 2007; Hankey and Eikelboom, 1999).

Current dietary recommendations for older people

As a preface to this section, it is important to note that there is no consistency in the literature as to at what age some dietary recommendations are supposed to apply. While the use of 65 as a benchmark age is more common than others, many studies merely refer

to "older people" or "elderly people" without actually specifying age (see annex 1 for more details).

In addition, there is very little data on the dietary habits of the sub-groups of older people, with many studies using "over 50" and "over 60" with no specified upper age limit, thus meaning the study is treating an age-group spanning more than 30 years as homogenous. This means that recommendations based on the dietary data and health status of a 55 year old are being applied to an 80 year old, whereas their nutritional needs and habits could be markedly different due to physiological, social and economic factors. Ritz (2001), points to a particular paucity of data on the dietary habits of the over 80s. This is no doubt linked to the fact that life expectancy has increased significantly in recent decades in a way that was not expected, that is, most researchers did not realise there would be so many 80 year olds around today whose dietary habits could be studied! However, it is clear from the literature that there is agreement that the oldest older people, that is, the over 75s, have some particular nutritional needs that differ from the rest of the population.

For the reasons outlined above, we have decided to further segment the age groups selected for this paper (originally 55-74 and over 75s) as follows:

- People aged 55-64
- People aged 65-74
- People over 75 years old

People aged 55-64

There are no special dietary recommendations for people aged 55-64, but instead they are expected to follow the same healthy eating guidelines that apply to younger adults. The importance of maintaining a healthy weight, and avoiding overweight and obesity are as valid for this age group as for younger adults (Krondl et al, 2008).

Nutritional guidelines for adults:

- Include plenty of complex carbohydrates, for example, wholemeal bread, wholegrain rice
- Include five servings of fresh fruit and vegetables per day
- Aim for a diet low in salt, saturated fat, refined carbohydrates and sugar.
- Include "good" fats like olive oil, nuts and oily fish
- Include protein sources like lean meat, oily fish, low fat dairy products, eggs and vegetarian sources of protein (legumes, beans, tofu)

(WHO, 2002; Department of Health, 2004; Nutrition Australia, 2009; Food Standards Agency, 2010)

However, the COMA² guidelines (Department of Health, 1992) does not set totally uniform energy (calorie) requirement for this age group:

- Aged 51-59 = 2550 calories for men, 1900 calories for women
- Aged 60-64 = 2380 calories for men, 1900 calories for women

Although the 55-64 age group does not have special nutritional needs as such, this age group would be well advised to start paying extra attention to healthy lifestyle including diet, in relation to the future risk of chronic diseases and to best prepare themselves for healthy older age. For example, once women are postmenopausal, as most are in this age group, there is an increased need to ensure appropriate vitamin D and calcium intake to maintain bone health and help to prevent osteoporosis (Gennari, 2001; Heaney, 2007) and an increased risk for cardiovascular disease due to lower levels of oestrogen (Korzen-Bohr and O'Doherty Jensen, 2006). Age is the most powerful independent risk factor for cardiovascular disease and the risk of stroke doubles every decade after the age of 55 (WHO, 2004). In men, reaching 55 means that their risk of cardiovascular disease increases (Pocock et al, 2001), so attention to risk factors including high LDL cholesterol, obesity and increasing blood pressure is highly desirable (Lloyd-Jones et al, 2006). Using the data from the Framington Heart Study, Lloyd-Jones et al (2006) found that the absence of established risk factors at 50 years old is associated with low lifetime risk for CVD and longer survival. This age group will, over the next decade of its life, be subject to physiological changes associated with ageing that could negatively impact their nutritional status and immune functioning (Wardwell et al, 2008), so now is arguably the time to focus on maintaining good health to prevent or limit potential future health problems.

Health promotion in older people both in relation to diet and keeping physically active can produce results (Chernoff, 2001). The main aim of healthy diet and lifestyle (including physical activity) in this age group would be to maintain good health, to reduce the risk of chronic disease and strengthen or maintain immune function to avoid health problems later.

People aged 65-74

The dietary recommendations for this age group are not hugely different to those for people aged 55-64, as long as people remain in good health. However, the risk of developing a chronic disease is higher for this age group than the previous one; studies in the USA show that 75% of the over 65s have one chronic disease and 50% have two or more (Hasler et al, 2000). Those individuals already suffering health problems, particularly those that increase the risk of chronic disease or people who already have a chronic disease, may need to make further more changes to their diet, for example:

• A person with high cholesterol may need to further reduce their saturated fat intake to

² The Department of Health Committee on Medical Aspects of Food Policy (COMA) is now replaced by the Scientific Advisory Committee on Nutrition (SACN). NB: SACN has not yet updated the 1992 COMA recommendations on the nutrition of older people.

reduce the risk of coronary disease or to prevent existing coronary heart disease from progressing.

• A person identified as having reduced bone density may need to increase their calcium and vitamin D intake to reduce the risk of osteoporosis or to prevent its progression.

The COMA energy requirements for this age group are the same as for 60-64 age group, namely 2330 calories for men and 1900 calories for women.

People aged over 75

The physiological changes associated with the ageing process and the associated health problems that can arise, which are discussed earlier on, start to have an effect on most people aged 75 and over. This means that a more age specific approach is required for this age group which could include:

- In general, consuming a more nutrient rich diet in order to obtain the nutrients needed from a lower calorie intake which results from both physiological and socio-economic factors.
- A switch of focus from the risk of obesity to the risk of malnutrition, especially given that in this age group, a lower BMI is more highly correlated with morbidity and mortality than a higher BMI.
- Additional nutritional support to ensure acceptable levels of key micronutrients due to lower intake and uptake, for example, vitamin D.

The COMA recommendations (from 1992) on energy intake for the over 75s, now appear to be in out of date in recommending a lower energy intake for this age group than their younger counterparts. More recent research does not recommend a lower energy intake for the over 75s, although there is acknowledgement that it often happens.

However, because there is very little data about dietary habits of specific sub-groups of older people for the later age groups of older people, that is, those over 80 (Ritz, 2001) and the nutritional recommendations for "older people" that differ from the rest of the population are not age specific, further research is clearly needed here.

Chapter five - Functional foods

What is a functional food?

Functional foods are generally considered to be those food products which provide a specific health benefit over and above their basic/traditional nutritional value (Abdel Salam, 2010; Buttriss, 2010). Functional foods were developed originally to identify and correct nutritional deficiencies, for example, breakfast cereals with folic acid, but many have now gone further to become food products that improve physical and mental well-being (Siro et al, 2008) and reduce the risk of chronic diseases (Abdel-Salam, 2010) or even manage disease (Hasler et al, 2000)

Functional foods:

Correcting nutritional deficiencies \rightarrow improving health \rightarrow preventing and managing chronic disease

Definition of a functional food

There are many definitions of a functional food, but as Arvanitoyannis (2005) informs us, there is no universal precise definition. However, it is possible to pick out a number of common themes which include providing an additional health benefit, containing specific ingredients to confer a health benefit, and looking like a conventional food product, that is part of a normal diet.

This paper will understand a functional food as:

"a conventional food product modified in some way to give a health benefit above and beyond basic nutrition"

Modification here would also include enhancement, for example, fruit juice with vitamin D. This definition would exclude some food products for which a functional claim is made, for example, soy products which make cholesterol reducing claims. Such products would not meet our definition as the soy protein referred to is naturally occurring in the soy beans used to make the product, and has not been modified, manipulated, or added to the product.

Some definitions that refer to providing additional health benefits include:

"A normal type of food with an additional ingredient that provides a health benefit beyond satisfying traditional nutritional requirements" (Food-info.net, 2010)

"it has beneficial effects on target functions in the body, beyond adequate nutritional effects, in a way, that is relevant to health and well-being and/or reduction of disease" (Katan, 1999)

"it offers the potential of reducing the risk of chronic disease beyond basic nutritional functions" (FAO, 2007, page 21)

Also see Arvanitoyannis et al (2005), Berner and O'Donnell (1998) EUFIC (2006), and Buttriss (2010).

The component or ingredient that the functional food contains that provides the additional health benefit (the "function") can be a non-nutrient, or a nutrient (FAO, 2007). An example of a non-nutrient would be plant sterols to reduce cholesterol. Where a micronutrient is a functional food ingredient, it should be in quantities that are higher than daily recommendations, should be directly linked to the health and well-being of the person including disease risk reduction (Roberfroid, 2000; FAO, 2007). For example, vitamin D, which is added to fruit juice to raise dietary vitamin D levels in a target population, such as postmenopausal women who are at risk of developing osteoporosis (Heaney, 2007).

In relation to the conventional nature and use of functional foods, Clydesdale (1997) says functional foods are "*similar in appearance to conventional foods that are consumed as part of a normal diet*" while Buttriss (2010) describes them as "*foods that are similar in appearance, smell and taste to a conventional food, that is consumed as part of a usual diet*" (Buttriss, 2010, p91). Other references include American Dietetic Association (2009) and EUFIC (2006).

In Japan, where functional foods have a legal definition as "Foods for specified health uses³", they are defined as per the regulation that governs them as:

"foods containing ingredients for health and officially approved to claim its physiological effects on the human body" (Japanese Ministry of Health and Welfare, 2010)

Nutraceuticals, food supplements and functional foods

Confusion can arise when it comes to other food products with functional roles such as nutraceuticals and food supplements.

Food supplements are clearly defined in a way that distinguishes them from functional foods in relation to their form and usage. In a number of jurisdictions food supplements are defined in law. For example, in the EU, a food supplement is defined in Directive 2002/46/EC (page 1, whereas 1), as a foodstuff whose purpose is to "supplement the normal diet" and which is made of "concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form", that is, capsules, pills, powders, drops, etc and taken in "measured small unit quantities".

In the United States, a food supplement is defined according to US Dietary Supplement Health and Education Act 1994 (cited in Zeisel, 1999) as a product in capsule, powder or pill form, that is not a conventional food product and is "*intended to supplement the diet to enhance health*" and contains "*a vitamin, mineral, amino acid, herb, or other botanical*".

³ The literal translation of the original Japanese language term (tokutei hokenyo shokuhin) is "food products for specific health preservation use".

It is therefore quite clear that a food supplement and a functional food are not the same.

However, when it comes to nutraceuticals, there is often confusion. "Nutraceutical" is a term first coined by Dr Stephen DeFelice of the Foundation for Innovation in Medicine in 1989 (Kalra, 2003) and is an amalgamation of "nutrition" and "pharmaceutical". Arvanitoyannis et al (2005) says that the definition of functional foods is "*occasionally confused with that of nutraceuticals*". Kalra (2003, page 1) points out that although the term "nutraceutical" is used in marketing, there is no regulatory definition and some people including Lang (2007) regard "nutraceutical" as another term for functional foods, whereas others imbue them with almost pharmaceutical type properties (Zeisel, 1999).

If one takes the view that a nutraceutical is different to a food supplement and a functional food, Health Canada's definition (cited in FAO, 2007, page 3) of a nutraceutical as: "*a product isolated or purified from foods that is generally sold in medicinal forms not usually associated with foods*" is the most sensible. An example of a nutraceutical under this definition would be black radish juice sold in ampoules for improving digestive functioning and Echinacea sold in several formats to prevent or treat common colds. To avoid confusion, this paper will not refer to nutraceuticals.

For further reading on definitions of nutraceuticals, please see Zeisel (1999), Adelaja and Schilling (1999) Fitzpatrick (2003), Kalra (2003) and Hasler (2005b).

Are functional foods healthy foods?

This paper understands healthy food in a broad sense as food products which have a desirable nutritional content and are usually recommended to be eaten as part of a normal healthy diet. This definition means that a healthy food product is not necessarily functional, but a functional food could be considered a healthy food.

According to the relevant EU legislation⁴, the starting point for regulatory approval of a functional food is that the food product must meet certain nutritional standards, known as "nutrient profiles". The European Commission advised by the European Food Safety Authority (EFSA), sets nutrient profiles for different types of food products and in doing so must take into account:

"fat, saturated fat, trans-fatty acids, salt/sodium and sugars, excessive intakes of which in the overall diet are not recommended, as well as poly- and mono-unsaturated fats, available carbohydrates other than sugars, vitamins, minerals, protein and fibre."

"the role of these foods in the overall diet" (Regulation 1924/2006, page 2)

This means that the starting point for submitting a request for approval of a health or nutritional benefit to EFSA is that the food product concerned meets the relevant nutrient profile. The rationale for establishing nutrient profiles was to prevent a food with an unhealthy nutrient profile being able to have a health or nutritional claim, or as a 2006

⁴ Regulation 1924/2006/EC on nutrition and health claims made on food

position on the draft regulation⁵ put it *"only foods that have a desirable nutrient profile and thus truly contribute towards a healthy diet should be allowed to bear claims"* (Eurocoop et al, 2006 page 1). It should be noted that complying with the nutrient profile does not ensure that a claim will be approved.

Common functional foods

It is important to remember here, that we are focusing on foods that are functional foods in accordance with the definition:

"a conventional food product modified in some way to give a health benefit above and beyond basic nutrition"

The most common functional foods are those which target the following health functions:

- gastrointestinal function
- cardiovascular disease
- bone health

(FAO, 2007)

Probiotic and prebiotic products

The most common type of probiotic functional foods are dairy products such as yoghurts and yoghurt/dairy drinks which have been modified by the addition of a particular strain of live microorganism in the form of lactobacteria such as *Lactobacillus* and *Bifidobacterium* and in some cases prebiotics such as inulin as well. The additional health benefits claimed by probiotic dairy products are related to the gastrointestinal functions and include improving digestion and immunity and managing digestive disorders such as IBS (irritable bowel syndrome) and diarrhoea. The most commonly used definition of probiotics is "living food supplements or components of bacteria that have been shown to have beneficial effects on human health" (Sheil et al, 2007; Weichselbaum, 2009). Probiotics are also available in food supplement form (pills or capsules).

Examples of probiotic dairy products on the UK market include:

- Activia yoghurt
- Yakult dairy drink
- Actimel dairy drink
- Müller vitality yoghurt and yoghurt drinks
- Sainsbury probiotic yoghurt
- Innocent thickie drinks

Recently, other probiotic functional food products have been created including probiotic

⁵ "Briefing note to members of the European Parliament: Nutrition and health claims – We need nutrient profiles and prior authorization for a healthier Europe"

fruit juice and cereal:

- Proviva fruit juice
- Kashi Vive breakfast cereal
- M&S probiotic fruit smoothies (non-dairy)

Prebiotics are non-digestible oligosaccherides added to food, the most common being oligofructose and inulin (Roberfroid, 2007). The health claim made for prebiotics is that they stimulate beneficial digestive activities including growth in the number of bifidobacteria (Roberfroid, 2007).

Examples of prebiotic functional foods include:

- Oatibix bites
- Rice Krispies multigrain breakfast cereal
- Alpen muesli bars

Cholesterol-lowering products

There is now a broad range of cholesterol-lowering functional foods available which contain added esterised fat soluble forms of phytosterols or stanols (plant extracts). The additional health benefit of these functional foods is to help lower cholesterol through the action of the added sterols/stanols.

Examples of cholesterol-lowering functional foods on the UK market include:

- Benecol margarine spreads and cream cheese
- Benecol yoghurt and yoghurt drinks
- Benecol dairy free drinks and dairy smoothies
- Flora pro.activ margarine
- Flora pro.activ milk and low-fat yoghurt and dairy drinks
- Tropicana fruit juice with Benecol

Omega-3 functional foods

Omega-3 fatty acids, which occur naturally in foods such as oily fish and some plant and seed oils, are the latest substance to be added to a variety of food products including margarine, milk, fruit juice and eggs to make functional foods. Omega-3 fatty acids can contribute to reducing the risk of cardiovascular disease, so the additional health benefit from omega-3 containing functional foods is to increase omega-3 fatty acids intake for cardiovascular risk reduction effect.

For example:

- Omega-3 eggs (various producers)
- Flora omega-3 margarine

- Omega-3 bread (various producers)
- Vitaquell margarine
- St Hubert omega-3 margarine
- So Good omega-3 soya milk
- St Ivel omega-3 milk

Calcium and vitamin D enriched functional foods

The food products which provide high levels of calcium and/or vitamin D are mostly fortified food products. Some are fortified only with calcium or vitamin D and others with both nutrients.

- Calcium enriched fruit juice, for example, Tropicana calcium containing orange juice
- Calcium and vitamin D enriched soya milk, for example, Alpro, So Good,
- Calcium fortified breakfast cereal (many varieties)
- Vitamin D and calcium fortified orange juice
- Vitamin D fortified milk
- Vitamin D enriched margarine⁶
- Calcium and vitamin D enriched yoghurt

The regulation of functional foods

EU/UK

In 1997, the UK set up a "Joint Health Claims Initiative⁷" (JHCI), an initiative which brought together consumer associations, public authorities and the food industry. The JHCI established and supervised a code of practice on health claims, which came into operation in December 2000. At this time, there was no European legislation on health claims.

Manufacturers wanting to use a health claim on their product had to submit a dossier to the JCHI showing that the product met with the requirements of certain generic health claims (functional ingredient rather than product specific), for example, Omega-3 polyunsaturated fatty acids (PUFA) and heart health. The JHCI code applied to any foodstuff or food product wishing to use a health claim including functional foods.

The JCHI was disbanded on 31 March 2007 in response to the coming into force on 1 July 2007 of the EU regulation on health and nutritional claims on food (JCHI press release, 22 March 2007). As of the implementation of the regulation, health and nutritional claims on food in the UK became subject to EU rules and assessment.

⁶ In the UK all margarine is required by law to be fortified with vitamin D. ⁷ www.jhci.org.uk

The European regulation on nutrition and health claims made on food (EC Regulation no 1924/2006) regulation establishes the conditions under which health and nutritional claims can be made and mandates the European Food Safety Authority (EFSA) to assess health and nutrition claims on a system of prior authorisation, that is, claims have to be approved before they can be used. Coppens et al (2006) note that the prior authorisation was not used by any EU Member State which had a previously established national system for the approval of health claims.

There are several different types of claims possible:

- Nutrition claims as listed in an annex to the regulation (anything not listed is not permitted).
 For example "high fibre", "low fat" or "source of vitamin C".
- Health claims which refer to the role of a nutrient or other substance on growth, development, functions of the body, psychological or behavioural functions, slimming or weight control, reduction in hunger or increase in satiety that are based on "generally accepted scientific data" and included in a list of permitted claims (Article 13.1 claims)

For example, vitamin D and immune system functioning, meal replacements for the maintenance of weight loss.

- Health claims based on newly developed scientific data which require the submission of a specific dossier to EFSA via the relevant competent national authority. (article 13.5 - similar to article 13.1 claims)
 For example, tomato extract lycopene and blood platelet aggregation.
- Reduction of disease risk claims, which require the submission of a specific dossier to EFSA via the relevant competent national authority. (Article 14 claims) Most claims approved here have been for vitamins and minerals, such as vitamin D and calcium for the prevention of osteoporosis, iron intake for the cognitive development of children and adolescents. The small number of other claims that have been approved include plant sterols/stanols which lower cholesterol and alphalinolenic acid and brain development.

(EFSA website/regulation 1924/2006).

The applications for health and nutrition claim approval have to specify the quantities that should be consumed to achieve the claim, the target population, any relevant health risks if consumed in excess, and warnings about unsuitability for individuals with certain profiles (Regulation 1924/2006).

All foodstuffs or food products bearing nutrition or health claims have to be assessed by the dietetic products, nutrition and allergies (NDA) panel of EFSA. The deadline for assessing all claims currently on the market is the end of 2011.

So far, in relation to health claims ESFA has mostly accepted:

• Article 13.1 health claims that refer to vitamins or minerals

• Article 14 disease risk reduction claims that mainly refer to specific nutrients, for example, iodine for children's' growth, as well as those that refer to plant sterols and stanols

(Buttriss, 2010)

There has been criticism of EFSA from some quarters in relation to how health claims have been assessed, while other actors back its stringent approach, believing it necessary for consumer protection (Starling, 28 June 2010).

Some of the complaints relate to specific applications for approval, others relate more generally to the way the agency has been operating, including a lack of communication with applicants and the length of time it has taken to process applications. In its early years, EFSA experienced problems in recruiting sufficient staff (Bureau van Dijk, 2005) and was heavily criticised for being "overcharged" by Herman Koëter who resigned as the agency's Science Director in 2008 (AllAboutFeed.net, 2008). EFSA has been subject to capacity problems and accusations of slowness on occasions since then partly, the agency explains, because it has consistently received a higher number of applications than expected (Heller, 26 July, 2010).

Some recent complaints include:

- Out of 22 article 13.5 applications, only one has been approved (Starling, 18 June 2010).
- EFSA acknowledged that participants in clinical trials of Gencor Pacific's weight management product showed a reduction in waist size and that a reduction in abdominal fat was of cardiovascular benefit, but did not accept that Gencor had sufficiently demonstrated causality (Daniells and Starling, 21 May 2010; Starling, 17 September 2010).
- A letter sent by the European Responsible Nutrition Alliance (ERNA), European Health Products Manufacturers (EHPM) and European Botanical Forum (EBF) accused the agency of:
 - blocking scientifically backed health communications
 - failing to qualify the level of evidence underlying a health effect by the totality of the evidence and weighing it
 - only issuing positive 13.1 claims on essential nutrients or on compounds that relate to disease risk reduction (Heller, 20 May 2010)
- French regulatory consultancy NutraVeris noted that huge discrepancies between the levels of scientific evidence required for black and green tea compared to vitamin C and selenium (Starling, 1 March, 2010).

It is important to explain that EFSA is processing the applications for claims in batches. Food companies have complained that this batch approach could distort the market by giving, for example, an advantage to a company whose claims is approved early on over competitors who have to wait for their application to be processed (Clarke, 2010). Equally, a company whose claim is rejected earlier than its competitors could be put at a disadvantage (Clarke, 2010).

Many health sector NGOs and consumer groups were very active during the development of the health claims regulation, but do not take a position on the way EFSA now undertakes the assessment of claims. The European Public Health Alliance (EPHA) has pointed out that many rejected applications were not approved because the evidence submitted did not clearly identify the substance responsible for the health/nutrition benefit (EPHA, 2009). Several European parliamentarians recently visited EFSA on the issue of health claims and their main concern was protecting consumers against misleading claims (Starling, 28 June 2010). The leader of the MEP delegation, Jo Leinen, Chair of the European Parliament's Environment Committee, said that EFSA should continue to reject claims not supported by strong science (Starling, 28 June 2010).

Japan

Japan has the longest standing regulatory regime for functional foods, the "Food for Specific Health Use" (FOSHU) system, which was established in 1991 (Katan, 2004). Under the FOSHU system, which is voluntary, products have to prove their safety as well as demonstrate their health value and show that the product contains sufficient quantities of the health benefit giving component (Katan, 2004). However, the evidence required is minimal by pharmaceutical standards and most manufacturers opt for the softer categories of claims that require less evidence (Katan, 2004).

Initially FOSHU foods could only make claims for health maintenance not for disease treatment (Lin, 2003). In 2001, the FOSHU system was expanded to cover "Foods with Nutrient Function Claims" (FNFC). Then in 2005, the system was further expanded to split FOSHU into three categories (1) standardised FOSHU (2) qualified FOSHU and (3) disease risk reduction FOSHU (Ohama et al, 2006).

USA

In the US, functional foods are not recognised as a regulatory category by the FDA, but are covered by the legislation on food supplements known as DHEA, the Dietary Supplement and Health Act of 1994 (Sanders, 2008; American Dietetic Association, 2009) and the NLEA, the Nutrition Labelling and Education Act of 1990 (American Dietetic Association, 2009). The NLEA allows nutrition claims for dietary substances or nutrients with an established daily value and health claims including disease risk reduction claims that are based on scientific literature reviews and structure function nutrition claims (Larsen and Berry, 2003; American Dietetic Association, 2009; Agarwal et al, 2009). Manufacturers of functional foods are not required to obtain premarket approval for claims of efficacy or safety (Sanders, 2008), but are responsible for ensuring their products are safe (Larsen and Berry, 2003). Although the FDA can challenge the labelling or safety of functional foods, in practice this only happens when the product has been represented as a drug when it does not have drug approval (Sanders, 2008).

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Chapter six - Consumer behaviour towards functional foods

Findings

- Although there are contradictory findings on the influence of most socio-economic factors on consumer behaviour towards functional foods, older consumers and in particular older women are more likely to consume functional foods than other consumers.
- Consumers of all ages with an interest in health are more likely to be positively inclined towards functional foods.
- It seems highly likely that older people with an interest in health and/or a perceived need for the health benefit offered by a functional food will be receptive to it.
- Consumers of all ages are most interested in the taste of the functional food, and then its health benefit.
- Consumers of all ages are most likely to purchase a functional food that belongs to a product category they usually consume.
- If the functional foods is more expensive than a conventional version of the product, older consumers are prepared to pay a price premium, but only if it is affordable.
- To be convinced to buy and consume functional foods, consumers of all ages want to sure that their perceived health need will be met by the product.
- Older consumers would be most likely to be convinced of the health benefit of a functional food by health professional endorsement.
- There is evidence suggesting significant cultural differences in attitudes towards functional foods.

Consumers of all ages

A review of the literature about consumer behaviour in relation to functional foods reveals a number of key factors that influence if and why consumers buy and consume functional foods, and what they think of them.

The first factor of influence is health and interest in health. Herath et al (2008) suggest that consumers who demonstrate concern about a wide range of health issues are more receptive towards functional foods. Many consumers are aware of the link between health and nutrition (Sanders, 2008) and therefore the trend in society is to demand healthy food with added health improving benefits (Bleiel, 2010), a demand which functional foods aim to meet. Healthiness is one of the most frequently mentioned motivations behind food choice in general (Saher et al, 2004), as well as functional foods. The health benefits mentioned by functional food consumers as reasons to buy are general well-being, ease of
following a healthy diet, and prevention of disease (Urala and Lähteenmäki, 2004; Urala and Lähteenmäki, 2003; Bhaskaran and Hardley, 2002, Frewer et al, 2003). Functional foods appear to have benefitted from increased consumer awareness and interest in healthy lifestyles, which includes healthy eating as well as alternative therapies and physical activity (Hasler, 2000).

Functional ingredients which are familiar to consumers, for example, vitamins or minerals, achieve higher rates of consumer acceptance (Siro et al, 2008); as do functional foods whose carrier products are viewed as healthy, for example, fruit juice and yoghurt (Ares and Gámbaro, 2007). Conversely, foods that are perceived as unhealthy, for example, mayonnaise, do not benefit from having an approved health claim (Miele et al, 2010). Siro et al (2008) believes that consumers who understand the benefits of functional foods are persuaded to buy them, something backed up by repeated Finnish studies by Urala (2005), who found that perceived reward from functional foods explained the decision to choose them. Bleiel (2010) believes that functional foods must meet a health need that the consumer identifies with.

Overall, there is limited agreement over the impact that knowledge of functional foods has on the consumer. There are studies showing knowledge contributes positively to success and studies showing knowledge decreases acceptance (Verbeke, 2005). Some studies report a lack of knowledge as a reason for not consuming, while others that find knowledge had no effect (Verbeke, 2005).

Knowing about the health claim that a functional food makes can play a role in guiding consumer purchasing decisions for functional foods, even if many consumers do not fully understand the claims (Pothoulaki and Chryssochoidis, 2009). The influence of different types of claims varies as Pothoulaki and Chryssochoidis (2009) report that consumers find disease risk reduction claims more appealing than other claims, particularly when the individual has experience of the disease concerned, whereas Verbeke et al (2009) found that health claims were more convincing than nutrition claims, and that disease risk reduction claims reduced credibility. Van Kleef et al (2005) showed that consumer evaluation of health claims varies according to how much the claim is personally relevant to the consumer in addressing a disease they have experienced. Bleiel (2010) believes that health claims such as digestive health are more appealing to consumers than disease risk reduction claims such as lowering cholesterol, because the consumer can more easily feel the benefits. This backs up what Urala (2005) found about perceived reward, and Siro et al (2008)'s findings about understanding the benefits of functional foods.

Socioeconomic factors such as education, as well as age and gender, have been explored, but there is little agreement as to their effect because different studies reveal different and sometimes contradictory influences (Verbeke, 2005). One common thread did emerge, however, namely that being female and/or older makes a consumer more likely to be positive towards functional foods (Frewer et al, 2003; Herath et al, 2008; Pothoulaki and Chryssochoidis, 2009; Verbeke, 2005; Korzen-Bohr and O'Doherty Jensen, 2006). Herath et al (2008) and Verbeke (2005) found that people with a lower level of education and income were more likely to buy functional foods, whereas Pothoulaki and Chryssochoidis (2009) found that individuals with higher socioeconomic status, particularly women were more likely to be functional food consumers. Verbeke (2009) and Urala and Lähteenmäki (2003) both found socioeconomic factors such as level of education and health status were insignificant determinants of functional food acceptance and use.

The price and/or perceived value of a functional food are important considerations in the decision to buy and/or consume (Bhaskaran and Hardley, 2002; Frewer et al, 2003). However, Bleiel (2010) reports that even in difficult financial times, consumers are willing to pay a premium for functional foods, that is, pay more for a probiotic yoghurt drink than a normal yoghurt drink. Verbeke et al (2009) reports that while consumers may reference price when rejecting a functional food, the underlying reason for rejection is non-economic.

Research suggests some cultural differences in consumer views:

- Swedish consumers think functional foods compensate for an unhealthy lifestyle and should only be used when it is not possible to improve one's health through lifestyle changes (Landstrom et al, 2009), whereas English consumers think that functional foods are an easy way to achieve healthy eating (Urala, 2005).
- Swedish consumers define healthy eating as eating fresh and natural foods, that is, not technologically developed, whereas Finnish consumers appear to trust technology to produce health enhancing foods (Landstrom et al, 2009) and Danish consumers are particularly suspicious of functional foods, regarding them as "unnatural and impure" (Verbeke, 2005).
- Finnish consumers accept functional foods more readily than their Danish or American counterparts (Bech-Larsen et al, 2007).
- US research showed the typical functional foods consumer to be in a higher socioeconomic class (Pothoulaki and Chryssochoidis, 2009), while Canadian research found the opposite (Herath et al, 2008) and Belgian and Finnish research found that socio-economic class had no effect (Verbeke, 2005; Urala and Lähteenmäki 2003 respectively).
- The Japanese regard functional foods as a separate food category, unlike European consumers (Korzen-Bohr and O'Doherty Jensen, 2006).

Some other interesting findings were:

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- Functional foods are first and foremost viewed as members of the food category to which they belong, for example, yoghurt, rather than as a functional food (Urala and Lähteenmäki, 2003; Urala, 2005; Korzen-Bohr and O'Doherty Jensen, 2006).
- Regardless of health benefit, consumers will not buy a functional food if they do not like the taste of it (Verbeke, 2005; Bhaskaran and Hardley, 2002).
- Communication on functional foods is mainly undertaken by the food industry (Frewer

et al 2003), which is not always a trusted source of information (Frewer et al, 2003; Pothoulaki and Chryssochoidis, 2009), unlike health professionals who are considered highly credible sources of information (Age Concern, 2006; Korzen-Bohr and O'Doherty Jensen, 2006).

• A number of studies have shown that perceived risk (safety or otherwise) does not seem to be a factor in consumers' acceptance or use of functional foods (Frewer et al, 2003; O'Conner and White, 2010).

Older consumers

There are factors that specifically influence how older consumers view and consume functional foods and those that apply to consumers of all ages, but are more marked in older consumers.

First of all, older people are more likely to be interested and/or concerned by health than their younger counterparts (Hasler et al, 2000; Saher et al, 2004; Hunter and Worsley, 2009) which reinforces the fact that interest in health positively influences acceptance and consumption of functional foods. Contrary to other research, studies in Poland showed that the over 65s were less likely to consume probiotic yoghurt drinks than their younger counterparts (Wadolowska et al, 2009). This could be due to what Korzen-Bohr and O'Doherty Jensen (2006) found in their research, namely that only functional foods that were part of a product category normally consumed were of interest to older consumers. So if older Polish consumers are less likely to consume probiotic yoghurt drinks, this might reflect their yoghurt drink consumption habits.

Some of the so-called "baby boomer" generations (born from 1946-63) have become increasingly proactive in relation to improving their health and well-being through lifestyle changes (Hasler et al, 2000; Hunter and Worsley, 2009), a phenomenon sometimes called the "self-care movement" (Hasler et al, 2000). Saher et al (2004) also report several studies that confirm that health interest in food and the healthiness of food increases with age and Verbeke (2005) specifically reports that acceptance of functional foods increases with age. Health interest has been found to be highly relevant in positively influencing the acceptance and consumption of functional foods in all consumers. Therefore, functional foods with their health promoting/health maintenance focus are likely to be of interest to the older consumer, who is more likely to be interested in health. However, this then raises the question of how to target functional foods at these consumers while respecting that many older consumers do not want to be considered old (Bleiel, 2010; Sinclair, 2010).

The baby boom generation is currently facing serious health challenges like obesity and cardiovascular disease (Bleiel, 2010; Hunter and Worsley, 2009) and disease threat, which increases with age, is a key driver of receptivity towards functional foods (Herath et al, 2008). Functional foods are increasingly targeted at specific health concerns, many of which are the chronic diseases whose likelihood increases with age (Hasler et al, 2000). For example, a US survey of consumers (of all ages) found that the most common health benefit consumers were trying to achieve through food was lowering cholesterol (Hasler et al.

al, 2000), a health problem far more commonly experienced by older people. This is confirmed by Urala (2005) who reports that 9% of Finns aged 64-74 years old used cholesterol-lowering margarine, compared to only 1% of 35-44 year olds. This seems to confirm Urala and Lähteenmäki (2004)'s findings that older respondents value the benefit of functional foods more than their younger counterparts, and Bleiel (2010)'s belief that people are more favourable towards functional foods if they believe they will experience their benefits. However, caution should be applied, as a UK study revealed that healthy diet was only the 7th most important reason for older consumers' general food buying decisions (Raats, 2005).

As well as being health and lifestyle focused, the current generation of 50 to 64 year olds are one of the wealthiest generations ever (Hasler et al, 2000), which has led to them being an increasingly targeted market (Leventhal, 1997; Hare et al, 1999) and one, that is attractive in terms of numbers and spending power (Mumel and Prodnick, 2005). This extends to the food industry (Hare et al, 1999; Leighton and Seaman, 1997; Meneely et al, 2008), although research in Northern Ireland undertaken by Meneely et al (2008) revealed that although food retailers wanted to appeal to older consumers and improve their shopping experience, appropriate measures were not always put into practice. A market analysis report highlights bone health, heart health and diabetes as "growth opportunities in healthy food and drinks for seniors" (Lewis, 2007).

However, not all older people are wealthy and there is considerable evidence about economic status influencing the amount of money older people spend on food, meaning that although poorer older people may spend a higher proportion of their income on food (Sinclair, 2010), they spend less than other sections of the population (Hunter and Worsley, 2009; Wilson, 2009), which can negatively impact their nutritional status (Wilson, 2009). This seems to indicate that the price of functional foods, which is usually higher than non-functional versions of the same products, may prevent some older consumers from purchasing them. Given what Michael Marmot's report on health inequalities (Marmot, 2010) calls the "social gradient" in health, that is, the higher your socioeconomic background, the better your health and vice versa, the issue of social exclusion is a factor that needs to be taken into account if functional foods are sold at a price, that is out of reach of low income older consumers (Frewer et al, 2003).

It is important to note that food prices have decreased over the last 30 years, for example, in the UK food and non-alcoholic drink made up close to 25% of household expenditure in 1975, but only just under 16% by 2003 (ONS, 2004). With the rise of supermarkets and an increasingly globalised food industry, it may be that many now expect food to be cheap and do not want to pay a premium even when they can afford to do so and when the product may bring additional health benefits.

As well as affordability, accessibility could be an issue if older people's food shopping habits mean that they do not use the retail outlets where functional foods can easily be purchased. There is no conclusive evidence on where older people prefer to shop, as age does not always dictate preference (Sinclair, 2010), although research by Raats (2008)

indicates that older people in the UK tend to use and prefer supermarkets more than their counterparts in other countries. The most common functional foods such as probiotic yoghurts and cholesterol-lowering margarines, for example, are widely available in major supermarkets and convenience stores. There is insufficient data available to make any further conclusions on availability.

There is very little research looking specifically at older consumers' views and use of functional foods. Messina et al (2008) undertook research in eight European countries looking at the perceptions of functional yoghurts held by consumers over 65 and found that likelihood of buying was strongly influenced by perceived need. Korzen-Bohr and O'Doherty Jensen (2006)'s research, which asked British and Danish women aged 50-59 about heart disease and functional foods, found that the women wanted certainty in relation to the efficacy of a functional food before being convinced to consume it. More than half the women interviewed did not trust manufacturers product labelling or advertising, but 85% would trust information from a doctor or nutritionist (Korzen-Bohr and O'Doherty Jensen, 2006).

Differences have been found in the views on functional foods held by older consumers and their knowledge and understanding. The Food in Later Life project revealed gender, age and living status differences including that women aged 65-74 and people living alone aged 65-74 viewed the health benefits of functional foods as positive, whereas the over 75s living alone considered them negatively (Raats, 2005). This seems to tie in with research showing that younger cohorts of older people are more likely to make changes to their diet for health reasons than the very old (Age Concern, 2006).

The Food in Later Life project revealed that few older people understood the term 'functional foods' although they had heard it used, and many showed confusion between functional ingredients and additives (Raats, 2005). Common functional food ingredients like probiotics and plant stenols were viewed with suspicion and less than 10% of respondents believed health claims used in advertising functional foods (Raats, 2005).

In conclusion, the factors that are likely to encourage a consumer to accept or consume functional foods are: perceived health benefit, perceived need for the product, pleasant taste and reasonable price. Lack of these aforementioned factors has a negative impact on a consumers' propensity to accept or consume functional foods. Older consumers, especially females and those with a strong interest in health are more likely to buy functional foods.

Chapter seven - functional foods and older people's nutrition

Selection of case studies

The following criteria were established to guide the selection of functional foods for the case studies:

- There is a clear link between the health benefit of the functional food product and older people's health needs.
- There is enough scientific literature (quantity and quality) on which to make an analysis of the potential contribution of the functional food in maintaining or improving an older person's health.
- A substantial majority of the scientific literature supports the health benefit of the functional food product⁸.

The following three case studies are considered below:

• Probiotic yoghurts/drinks

- Cholesterol-lowering margarine/yoghurt/drinks
- Vitamin D and calcium fortified products

The table on the next page explains how the case studies were selected against the criteria.

⁸ This would include here whether there are versions of the product that have had a health/nutritional claim approved by the relevant regulator, but this would not be decisive.

Table: Criteria for selction of functional food case studies

Product	Clear link between functional food health benefit and older people's health needs?	Sufficient scientific literature to analyse potential contribution of functional food to older people's health?	Majority of scientific literature supports functional food health benefit, where applicable, the product has regulatory approval?	Other observations
Probiotic yoghurts/dr inks	Yes – older people commonly suffer from digestive discomfort/disorders and weakened immune system.	Yes.	Yes. A majority of the literature supports the health benefit of probiotic yoghurt/drinks. A number of products have successfully obtained regulatory approval in Japan. None have yet obtained European regulatory approval, a situation which is raising many questions ⁹ .	

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⁹ The regulatory approval of probiotics is explored further in the next section of this paper.

Product	Clear link between functional food health benefit and older people's health needs?	Sufficient scientific literature to analyse potential contribution of functional food to older people's health?	Majority of scientific literature supports functional food health benefit, where applicable, the product has regulatory approval?	Other observations
Probiotic breakfast cereals	Yes – as above.	No	NA	
Probiotic fruit juice	Yes – as above.	No	NA	
Cholesterol -lowering products with plant sterols/sten ols	Yes – older people are a greater risk of cardiovascular disease and high cholesterol is a key risk factor for CVD.	Yes.	Yes. There is a great deal of literature supporting the disease risk reduction claims of plant sterols/stenols and many relevant products have obtained European regulatory approval.	

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Product	Clear link between functional food health benefit and older people's health needs?	Sufficient scientific literature to analyse potential contribution of functional food to older people's health?	Majority of scientific literature supports functional food health benefit, where applicable, the product has regulatory approval?	Other observations
Omega-3 products	No - older people need to have sufficient omega-3 fatty acids in their diet, but there is no evidence that older people's needs are different to people of other ages.	Not sufficiently (see next column for more details).	The scientific literature supports the health benefit of omega-3 fatty acids, but not specifically functional foods containing omega- 3s. This is probably due to the fact that omega-3 functional foods are fairly recent developments.	Omega-3 functional foods usually contain a significantly lower level of omega-3s than food products with naturally occurring omega-3s like oily fish. Many products in this category have been withdrawn from the market following poor sales (Starling, 1 August, 2008).

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Case study one - probiotic yoghurts and drinks

Probiotic yoghurts and drinks are marketed as a health promoting alternatives to nonprobiotic yoghurts or drinks. In particular they are marketed as improving gut health and general immunity (Sanders, 1999).

Among the health benefits that are claimed or targeted for probiotic yoghurts and drinks are:

- Improvement in general digestive comfort/functioning
- Improvement in immunity
- Improvement and management of various gastrointestinal disorders including antibiotic associated diarrhoea, *Clostridium difficile* associated diarrhoea, traveller's diarrhoea, irritable bowel disease syndrome (IBS), Crohn's disease and ulcerative colitis
- Prevention of colon cancer

There is currently further research underway into the health benefits mentioned above and other possible health benefits including respiratory and genito-urinary infections, allergic diseases like atopic dermatitis, energy metabolism and dyslipidaemia. Recent research includes diarrhoea risk in children (Sur et al, 2010) and food allergies (Schneider Chafen et al, 2010; Schouten et al, 2009). The two largest probiotics companies, Danone and Yakult, have come together under the Global Probiotics Council to fund probiotics research projects by young researchers (Food Navigator, 2009).

Probiotic yoghurts and yoghurt drinks and are seen by consumers, first and foremost as yoghurt products and secondly as probiotic functional foods (Urala and Lähteenmäki, 2003; Urala, 2005; Korzen-Bohr and O'Doherty Jensen, 2006). Yoghurts are generally seen by consumers as healthy, which helps the image of probiotic yoghurts (Korzen-Bohr and O'Doherty Jensen, 2007).

There are numerous branded and own-label probiotic yoghurts and drinks available in the UK today. The market leaders are Danone and Yakult (Lawrence, 2009). In Europe probiotic dairy products have been dominating the functional foods market for over a decade (Lin, 2003). According to Felicity Lawrence in the Guardian (2009) nearly 60% of UK households regularly buy probiotic drinks and the market is worth £164 million a year in the UK.

It should be mentioned that probiotics are also available in food supplement form, although this paper focuses on their use in functional foods, not food supplements.

Health benefit of probiotic yoghurts and drinks

This section will look at the general action of probiotics and then specifically at each of the claimed health benefits and the evidence for them.

Probiotic mechanism of action

The term "probiotic" first coined by Lilly and Stillwell (1965), refers to substances produced by one microorganism that stimulate growth of another, in other words the opposite of antibiotics (Salminen et al, 1999). Probiotics are naturally occurring microorganisms found in lactic acid bacteria (LAB), most commonly strains of lactobacilli or bifidobacteria and occasionally yeasts such as *Saccharomyces*, which it is claimed, have a beneficial effect on health by improving the intestinal microbial balance (Shanahan and McCarthy, 2000; Siro et al, 2008; Isolauri et al, 2004; Floch and Hong-Curtiss, 2001). Sanders (2008) goes further in saying that only products containing an adequate dose of live microbes that have been documented in target host studies as conferring a health benefit should be called probiotics.

Lactic acid bacteria strains, which are normal components of the intestinal microbiota, are the most commonly used in probiotic functional foods (Kociubinski and Salminen, 2006; Isolauri et al, 2004; Shanahan and McCarthy, 2000). Each probiotic manufacturer develops its own specific strain of a particular probiotic (Sanders, 2008) and different health benefits are claimed for different strains. For example, Iactobacilli and bifidobacteria strains have been selected as candidates for IBS due to their apparent lack of pro-inflammatory effect (Shanahan and McCarthy, 2000). This paper looks primarily at the lactobacilli and bifidobacteria strains as these are the ones used in probiotic yoghurts and drinks. Multiple strains of *Lactobacillus* and *Bifidobacterium* have been evaluated for probiotic effect, but while each study provides insight to the specific strain, the findings cannot currently be extrapolated to other strains, even if they are of the same species (Sanders, 2008). Reid (1999) points to a lack of emphasis in clinical studies on selecting specific probiotic strains which have shown to be effective in colonising the host and reacting against pathogens.

The rationale for probiotics is that many gastrointestinal dysfunctions are based on disturbances or imbalances of intestinal microflora (Salminen et al, 1999; Lin, 2003; Floch and Hong-Curtiss, 2001). Laparra and Sanz (2007) note that microbial imbalances are associated with metabolic and immune mediated disorders and that diet is considered a major driver for changes in the diversity of the microbiota (Laparra and Sanz, 2007). Some probiotic strains such as bifidobacteria are used to correct unbalanced intestinal microbiota (Isolauri et al, 2004, Floch and Hong-Curtiss, 2001). In order for these probiotic strains to have a beneficial effect on microbial balance, a number of actions are suggested as necessary including increased digestive capacity, enhanced mucosal barrier, reduced inflammation and lowered allergic sensitivity (German et al, 1999; Lesvos-Pantoflickova et al, 2007). Sanders (2008), however, notes that while probiotic strains have been shown to alter populations or activities of colonising microbes, it is difficult to say with accuracy that this improves the balance as there is no agreement on what is a healthy microbiota composition.

A role has also been suggested for the immunomodulatory effect of probiotics which is both immune system response enhancing and anti-inflammatory (Isolauri et al, 2004). A

number of studies show that probiotic strains act to prevent infection from pathogens that can cause diarrhoea by inhibiting the growth, metabolic activity and intestinal adhesion of enteropathogenic bacteria (de Vrese and Marteau, 2007; Matsuzaki, 2007), for example, *Lactobacillus casei* strain Shirota (Matsuzaki, 2007). It is important to note, however, that while many clinical trials support a strong role for probiotic strains in gastrointestinal health, the methods available to detect changes in human gastrointestinal function are still limited (Duggan et al, 2002).

If probiotic strains are to have the beneficial effects claimed, they need to survive the harsh environment of the gastrointestinal tract (Lin, 2003, Floch and Hong-Curtiss, 2001). Lin (2003) reports that numerous in-vitro and in-vivo studies have confirmed that lactobaccilli and bifidobacteria strains can survive inside the gastrointestinal tract, something confirmed by Floch and Hong-Curtiss (2001) in their review of studies on the effect of probiotics.

In addition, there are questions as to the quantity of probiotics that a functional food needs to contain in order to have an effect on the host. In Japan, the world's most advanced probiotic market, the Japanese trade association for probiotic dairy products requires a minimum probiotic content of 1×10^7 of viable probiotic per ml. Lee and Salminen (1995) propose a minimum concentration of 1×10^5 CFU¹⁰ per gram or ml.

It should be noted here that probiotic strains are considered to have an excellent safety profile (Gage, 2009) having been found safe in numerous clinical trials (Floch and Hong-Curtiss, 2001), and also through years of common use, for example, in Finland (Isolauri et al, 2004).

Digestive comfort

German et al (1999) note that it is: "hard to overstate the importance of intestinal health to an individual's overall sense of well-being" and Donini et al (2009) say that physiological changes to the gastrointestinal system experienced by older people can lead to digestive discomfort and more serious gastrointestinal disorders. Digestive discomfort in this context will be taken to mean "abdominal pain, altered bowel habits, flatulence and bloating" (Guyonnet et al, 2007), altered bowel habits referring to mild constipation and slow gastrointestinal transit time. Ageing is associated with changes to the intestinal microflora including a reduction in bifidobacteria (Ouwehand et al, 2009; Saunier and Doré, 2002; Gage, 2009) and an increase in bacteria with negative side effects such as *Clostridium difficile* (*C.difficile*) (Gage, 2009). Such changes can lead to digestive discomfort, which can be embarrassing and painful (Gage, 2009) and has a negative impact on the quality of life of older people (Donini et al, 2009).

A broad range of clinical (in-vitro and in-vivo) studies show that probiotic strains including *Lactobacillus acidophilus* have shown positive outcomes in relation to clinical markers, for example, increasing the levels of lactobacilli and bifidobacterium in study participants (Ouwehand et al, 2009; Spaanhaak et al, 1998) and improvements in digestive well-being

¹⁰ CFU = colony forming units

as assessed by study participants (Ouwehand et al, 2009, Gage, 2009). A double blind clinical study in which subjects over 65 years old were given a combination of three probiotic strains including *Lactobacillus acidophilus* for two weeks, showed that the treated group experienced improved microbiota composition, for example, levels of bifidobacteria increased to the level usually found in young healthy adults, and improved mucosal function (Ouwehand et al, 2009).

Some studies looking specifically at digestive discomfort have reported positive outcomes following the use of probiotics. For example, in a review, Gage (2009) reports on a number of studies including Bouvier (2001) and Marteau et al (2002), which showed *Bifidobacterium lactis* strains reducing transit time in healthy adults. Méance et al (2001) found that a fermented dairy drink with *Bifidobacterium animalis* strain DN 173-010 reduced gut transit time in older people aged 50-75. Slow transit time can cause digestive discomfort such as bloating and abdominal distension (Gage, 2009). Guyonnet et al (2007) went further, showing that older women with minor digestive discomfort receiving a *Bifidobacterium lactis* strain reported an improvement in symptoms following a randomised double blind controlled study.

Clinical studies looking specifically at constipation, which is common in older people, have reported positive outcomes (Hamilton-Miller, 2004). For example, Matsumoto (2001) found that a yoghurt with a *Bifidobacterium lactis* strain improved defecation frequency in healthy adults, and Ouwehand et al (2002) found that a *Lactobacillus rhamnosus* strain combined with *propionibacter freundreichii* increased defecation in older subjects by 24%. Ouwehand et al (2002), however, report in a review of the effects of probiotics that these effects are not fully substantiated in the literature.

Lactose intolerance, which can lead to gastrointestinal symptoms such as diarrhoea, bloating and flatulence (Shaukat, 2010), is more common in older people due to physiological changes associated with ageing that reduce lactase, the enzyme responsible for processing lactose in the body (Lin, 2003, Hamilton-Miller, 2004). Some studies have found evidence that probiotic strains help alleviate the symptoms of lactose intolerance (Salminen et al, 1999, de Vrese and Marteau 2007), for example, *Lactobacillus* GG (Floch and Hong-Curtiss, 2001). However, others such as Shaukat et al (2010) found that only one in four trials assessing strains of *Lactobacillus acidophilus, L.lactobacillus, L.bulgaricus* and *Bifidobacterium longum* found sufficient evidence of symptomatic improvement. Where improvement occurs, the mechanism is not totally clear; Lin (2003) suggests that the β -galactosidase present in probiotic products increases lactose digestion and delays food transit from the stomach to the small intestine, which allows for more effective digestion (Lin, 2003,). De Vrese and Marteau (2007) believe that probiotic bacteria may not improve lactose digestion in the small intestine, but avoid the symptoms of it in the large intestine.

General immunity

The ability of probiotics to encourage effective modulation of the immune system is well supported by the scientific literature (Lin, 2003; German et al, 1999; Calder and Kew,

2002), although Lin is more positive about the relationship to immunity than Calder and Kew. Probiotics positively affect the immune system in a number of ways including preventing the passage of an antigen through the epithelium (Lin 2003; Calder and Kew, 2002), providing a barrier effect by competing with an antigen for colonisation of the gastrointestinal tract (German et al, 1999; Lin, 2003; de Vrese and Marteau, 2007; Calder and Kew, 2002), enhancing the phagocytic activity of leukocytes, stimulating non-specific immune response to microbial pathogens (Lin, 2003; de Vrese and Marteau, 2007; Lopez-Varela et al, 2002), producing bateriocins that inhibit the growth of pathogens (Calder and Kew, 2002; Quigley and Flourie, 2004), and enhancing the humoral immune response, that is, immunoglobulin A production, which strengthens the intestinal immunologic barrier (Lin, 2003; Lopez-Varela et al, 2002). For example, Calder and Kew (2002) point to human studies including Schiffrin et al (1997) which found enhanced phagocytosis by neutrophils and monocytes following consumption of probiotics.

Establishment and maintenance of intestinal tolerance is dependent on suppressive cytokines such as interleukin 10 and transforming growth factor β produced by regulatory T cells and T helper cells characteristic of the intestinal immune system (Isolauri et al, 2004). Quigley and Flourie (2006) refer to a study demonstrating that a probiotic cocktail of *streptococcus thermophilus* combined with several species of *Lactobacillus* and *Bifidobacterium* has been shown to promote secretion of the anti-inflammatory cytokine IL-10 and suppress secretion of the pro-inflammatory cytokine IL-12 in humans and in other models. Improvement in non-specific phagocytic activity of granulocytes has been shown in blood levels of patients given lactobacilli and bifidobacteria based probiotics (Marteau et al, 2001, Schiffrin et al, 1995). A clinical study of over 65s using the probiotic strain *Lactobacillus* acidophilus showed a modest increase in PGE2, which has a role in immune modulation, in the treatment group, but no changes in IgA levels (Ouwehand, 2009).

Clinical trials have shown that functional foods containing lactobacilli increased intestinal mucosal lactobacilli and reduced pathogenic gram negative anaerobes, which are often involved in post-surgical infections (Lin, 2003). Probiotics protect the gut from undesirable microbes and encourage effective modulation of the immune system (German et al, 1999). Probiotic yoghurt has demonstrated an immunoprophylactic effect which stimulates immunoglobulin in rats (Abdel Salam, 2010). It is important to understand that there is a difference between showing that probiotic strains have mechanisms that may bring health benefits and demonstrating those benefits in randomised clinical trials. However, as Hoyles and Vulevic (2008) point out, studies looking at the role of functional foods in relation to the immune system are in their infancy.

Weichselbaum (2009) reviews a number of specific studies looking at the effect of probiotics on the common cold and flu infections, which reveals no significant difference in adults including older adults, but some reduction in fever for children. However, Guillemard et al (2009) report on a clinical trial which showed a decrease in the duration of respiratory infection in older people given *Lactobacillus casei*.

Gastrointestinal disorders

There is a great deal of scientific literature to show the positive effect of probiotics on gastrointestinal disorders (German et al, 1999; Lin, 2003; Shanahan and McCarthy, 2003; Zubillaga et al, 2001; Sheil et al, 2007).

Probiotic strains have been used effectively as part of the treatment regimen for abnormal intestinal microorganisms such as *Helicobacter pylori* (*H.pylori*) and rotavirus (German et al, 1999). Clinical studies using probiotic strains including lactobacilli have been shown to alleviate symptoms and shorten the length of acute diarrhoeal infections caused by rotavirus, although so far the evidence is stronger for children than adults (Nomoto, 2005, De Vrese and Marteau, 2007; Salminen et al, 1999; Asp et al, 2004). Nomoto (2005) reports on the success of a number of double-blind placebo controlled trials showing that probiotics reduce the duration of Rotavirus induced diarrhoea in children. However, probiotics were not shown to be consistently effective against traveller's diarrhoea (Marteau et al, 2001; Floch and Hong-Curtiss, 2001; de Vrese and Marteau, 2007).

Hylobacter pylori (*H.pylori*) is an infection responsible for peptic ulcers and atrophic gastritis (Lesbros-Pantoflickova et al, 2007; Asp et al, 2004; Floch and Hong-Curtiss, 2001), and is a common condition in older people. Atrophic gastritis can cause problems with absorption of nutrients (Zubillaga et al, 2001; Lesbros-Pantoflickova et al, 2007) and peptic ulcer can be life-threatening (Graham et al, 2002). Studies have shown that the composition of the intestinal flora is important for the establishment of *H.pylori* infection (Zubillaga et al, 2001). Children infected with *H.pylori* have been successfully treated with a combination of probiotics containing *Lactobacillus* and *Bifidobacterium* strains, and antibacterial therapy (Zubillaga et al, 2001).

In-vitro experiments have shown that strains of *Lactobacillus acidiophilus*, *Lactobacillus salivarius* and *Lactobacillus casei* can inhibit or kill *H.pylori*, possibly by producing lactic acid, lowering the PH or releasing a bacteriacidal factor (Lin, 2003). Clinical (in-vivo) trials, however, showed that strains of *Lactobacillus johnsonii* and *Lactobacillus gasseri* could only inhibit not eradicate *H.pylori* (Lin, 2003). A review of studies into the effects of lactic acid bacteria based probiotics on *H.pylori*, showed an in-vitro inhibitory effect on *H.pylori*, effectively reducing gastric inflammation in infected animals and showing an improvement in *H.pylori* gastritis in seven out of nine human trials (Lesbros-Pantoflickova et al, 2007). Asp et al (2004) reports on a human clinical trial that showed that a *Lactobacillus gasseri* strain reduced but did not totally eliminate *H.pylori*.

The mechanisms responsible for improvement following probiotic administration are thought to include the secretion of antibacterial substances, preventing a bacterial infection like *H.pylori* adhering to the epithelial cells, restoring the permeability of gastric mucosa and modulating the secretion of anti-inflammatory cytokines (Lesbros-Pantoflickova et al, 2007). It is important to note, however, that probiotics alone do not eradicate *H.pylori* infection, but when combined with antibiotics they improve eradication rates as well as reduce the unpleasant side of effects of antibiotic treatment (Lesbros-Pantoflickova et al, 2007).

Probiotics have also shown promise in the treatment of small bowel bacterial overgrowth (SIBO) (German et al, 1999; Schiffrin et al, 2009), a condition which is common in older people, particularly those taking medication that suppresses gastric acid secretion (German et al, 1999). Schiffrin et al (2009) report on a study of probiotic yoghurt containing a *Lactobacillus johnsonii* strain on older independently living people (median age 71) that showed normalisation of the response to endotoxin and modulation of activation markers in blood phagocytes, which may help to reduce low grade chronic inflammation. Quigley and Flourie (2006) suggest two possible mechanisms of action including qualitative changes to the microbiota and suppression of small intestine bacterial overgrowth. It is also worth pointing out that studies have generally been on small sample populations, so further research is needed (Asp et al, 2004).

Irritable bowel syndrome (IBS) leads to symptoms including abdominal pain, abdominal distension (bloating), diarrhoea, constipation, headaches, nausea, tiredness, and fluid retention (Lin, 2003; Asp et al, 2004; Quigley and Flourie, 2006). There are suggestions that changes in the intestinal microbiota might play a role and studies have shown higher numbers of facultative anaerobes and lower numbers of bifidobacteria and lactobacilli in people with IBS (Asp et al, 2004; Quigley and Flourie, 2006). Nobaek et al (2000) showed that IBS patients treated with a *Lactobacillus planatarum* probiotic had a significant decrease in symptoms. Clinical trials using different strains lactic acid bacteria probiotics have shown some success in relieving symptoms of IBS (Lin, 2003; Asp et al, 2004), but other studies have not confirmed these effects (de Vrese and Marteau, 2007). Weichselbaum (2009) reports differing results from studies, for example, a meta-analysis from McFarland and Dublin (2008) favoured the use of probiotics, whereas a study from Guyonnet et al (2007) showed no significant difference.

A recent study by Agarwal et al (2009) measured symptomatic relief from IBS following administration of a *Bifidobacterium lactis* strain and showed reduction in (measured) abdominal distension and in severity of symptoms. The UK National Institute for Clinical Excellence's clinical guideline on the management of IBS includes probiotics as a treatment option (NICE, 2008). The guideline recommends that IBS sufferers should take a probiotic product at the dose recommended by the manufacturer for at least four weeks while monitoring the effect on IBS (NICE, 2008).

However, it should be noted that many different treatments are used for IBS including acupuncture, peppermint oil, fibre tablets and anti-spasmodic drugs and most show inconclusive or inconsistent results (Hadley and Gardner, 2005).

Crohn's disease and ulcerative colitis, which are collectively referred to as inflammatory bowel disease (IBD) are chronic conditions (Sheil et al, 2007). Crohn's disease is a chronic inflammation of the intestine, mainly the lower ileum, but also involving the colon, which usually occurs in adults under 40 and results in abdominal pain, diarrhoea, weight loss, fever and anaemia (Lin, 2003). Although the cause of Crohn's disease has not been accurately pinpointed (Lin, 2003; de Vrese and Marteau, 2007; Asp et al, 2004), it is believed to be an immune response to imbalanced intestinal microflora in genetically

predisposed individuals (Lin, 2003). Ulcerative colitis is a chronic inflammation of the rectum and colon often characterised by bloody diarrhoea (Lin, 2003). For both forms of IBD, colonisation of the enteric flora is required for full expression of the condition, indicating that the composition of the flora may be important for IBD, but the functional activity of the bacteria should not be overlooked (Sheil et al, 2007).

Probiotics may counteract the inflammatory process of IBD by stabilising the gut microbial environment including the mucosal barrier (Isolauri et al, 2008, Sheil et al, 2007, de Vrese and Marteau, 2007), enhancing the degradation of enteral antigens and altering their immunogenicity (Isolauri et al, 2004) and modulating cytokine expression (Sheil et al, 2007; Quigley and Flourie, 2006). The normal microflora in the human gut vary in their capacity to drive mucosal inflammation, but lactobacilli and bifidobacteria are not proinflammatory hence their choice as candidates for managing inflammatory conditions (Shanahan and McCarthy, 2000).

There is evidence that normal intestinal flora drive the mucosal inflammatory response and that musosal inflammation in both Crohn's disease and ulcerative colitis occurs in areas of the gut with the highest bacterial count (Shanahan and McCarthy, 2000). In addition, both human and animal studies have consistently indicated loss of immunologic tolerance to the microflora in inflammatory bowel disease (Shanahan and McCarthy, 2000). A study undertaken on patients with acute Crohn's disease indicated that a Lactobacillus probiotic strain could offset the need for corticosteroids (O'Mahoney et al. 2000). Studies using *Lactobacillus* strains on teenage Crohn's patients showed significant relief of symptoms (Lin, 2003). Sheil et al (2007) report on a number of human clinical trials for IBD using various strains of probiotics, which showed promising results including increase in immunoglobulin A response, lower rates of relapse, and higher rates of remission. However, a review by Weichselbaum (2009) showed no significant improvements in three clinical studies which gave probiotics to Crohn's disease patients. Guslandi et al (2000) found that far fewer Crohn's patients receiving mesalamine and the probiotic S. Boulardii experienced relapse compared to those only received mesalamine. Asp et al (2004) signals caution about varying outcomes for studies on IBD and the fact the precise mechanism of anti-inflammatory activity attributed to probiotics is not fully understood.

Antibiotic associated diarrhoea

Various probiotic strains including *Saccharomyces* bourlardii and *Lactobacillus* rhamnosus have been shown to be effective against antibiotic associated diarrhoea (AAD) (German et al, 1999; Katz, 2006) and for re-establishing the equilibrium of the intestinal flora after antibiotic treatment (Shanahan and McCarthy, 2000). Older people are at greater risk of AAD (Ludlam et al, 1999) and it poses health risks as it can lead to malnutrition (undernutrition), which is associated with poorer clinical outcomes and slower recovery from illness in older people, as explained in further detail in chapter four of this paper.

Lin (2003) points to a review of 12 studies which demonstrated the effectiveness of probiotics in treating antibiotic associated diarrhoea and De Vrese and Marteau (2007) points to studies showing probiotics preventing AAD. Gao et al (2010) demonstrated that

adults receiving two capsules of a combined *Lactobacillus casei* and *Lactobacillus acidophilus* per day experienced lower rates of AAD (15.5%) than those receiving one probiotic capsule per day (28.2%) compared to those receiving only a placebo, 44.1% of which developed AAD. Hickson et al (2007) showed in a similar study that only 12% of patients receiving a probiotic drink containing *Lactobacillus casei*, *Lactobacillus bulgaricus*, and *Saccharomyces thermophilus* developed AAD, compared to 34% of those in the control group. A meta-analysis by McFarland (2006) using only randomised blind clinical trials found 25 studies showing a significantly reduced incidence of AAD for patients treated with *S.boulardii* and multi-strains of probiotics. Even the food journalist Felicity Lawrence (2009) who is often criticial of probiotics acknowledges the scientific evidence in relation to probiotics and AAD.

There is promising evidence for the role of probiotics in the treatment of *Clostridium difficile* (*C.difficile*) related diarrhoea. *C.difficile* is a bacterial infection spread by the faecaloral route and is the major identifiable cause of antibiotic associated diarrhoea (Starr, 2005). *C.difficile* associated diarrhoea is a serious condition in frail older people and can lead to death in up to 25% of cases (Starr, 2005). Gao et al (2010) showed that a combination of *Lactobacillus acidophilus* and *Lactobacillus casei* reduced incidence of *Clostridium difficile* associated diarrhoea, with 23.8% of the control group experiencing the condition compared to 1.2% of patients who had received 2 probiotic capsules per day and 9.4% of those who had received 1 capsule. Hickson et al (2007)'s study on AAD using a probiotic drink containing *Lactobacillus casei*, *Lactobacillus bulgaricus*, and *Saccharomyces thermophilus* revealed a 17% risk reduction for *C.difficile*. McFarland's meta-analysis found that only *Saccharomyces boulardii* strains were effective against *C.difficile*.

Probiotics have also been shown to improve compliance with antibiotic therapy by reducing unpleasant gastrointestinal side effects (Asp et al, 2004; Lin 2003). Given that unpleasant side effects are a major reason for non-compliance with medication regimes (Donovan and Blake, 1992; Dimou, 2000), the routine inclusion of probiotic strains in the treatment of infections requiring antibiotics offers a potential health benefit, particularly in older people, who may be more vulnerable to malnutrition as a result of treatment side effects such as AAD.

Malnutrition

It is suggested that undernutrition can lead to a damaged gut lining, which can reduce gut mediated immunity, reduced absorption of nutrients and loss of appetite (Hamilton-Miller, 2004). Clinical studies have shown that probiotic strains such as *Lactobacillus acidophilus*, *Lactobacillus delbrueckii var bulgaricus* and *Lactobacillus planatarum* can be helpful in normalising the nutritional status of children (Hamilton-Miller, 2004). Hamilton-Miller (2004) believes that it would be interesting to see if probiotic strains could help malnourished older people.

Prevention of colon cancer

There is strong evidence that links dietary factors to colon cancer risk, which is mainly seen in a consistent pattern that high intake of fat and protein increase colon cancer risk, while high intake of fruit, vegetables and wholegrains reduce the risk (Taylor, Steer and Gibson, 1999). A role has been suggested for probiotics in the prevention of colon cancer, which is linked to the role of diet in the metabolism of procarcinogens and carcinogens by the enteric flora (Shanahan and McCarthy, 2000; Taylor, Steer and Gibson; 1999), or more specifically through the binding and degrading of potential carcinogens, producing antitumourigenic or antimutagenic compounds in the colon (Lin 2003; Taylor, Steer and Gibson, 1999). Tests using the Ames assay have shown that lactobacilli, bifidobacteria and streptococcus thermophilus have been shown to prevent gene mutation (Lin, 2003). Murine models of enterocolitis have found that probiotic therapy reduces the rate of progression from colitis to dysplasia and then invasive colon cancer (Shanahan and McCarthy, 2000). Murine studies using a Lactobacillus casei strain have demonstrated recovery of host immune responses that were decreased by carcinogens, and increased natural killer and T-cell activity (Matsuzaki et al, 2007). Lin (2003), however, points out that epidemiological data on the effect of probiotics on colon cancer are inconsistent.

Regulatory Approval

EFSA has not yet approved any claims relating to probiotics, a fact sometimes cited by critics of probiotics to claim that there is no scientific basis for their mechanism of action (Lawrence, 2009). However, it is important to note that the majority of claims for probiotics submitted under article 13.1 were rejected without being assessed because the studies concerned were considered not sufficiently characterised in relation to strain specificity (Starling, 4 August, 2010). For example, EFSA's opinion on Biomed's application for a health claim on Lactoral (a combination of *Lactobacillus plantarum, Lactobacillus rhamnosus* and *Bifidobacterium longum*) was rejected on a number of grounds including that the human clinical studies did not identify which probiotic strains were responsible for the effect shown and at which consumption levels (EFSA Journal, no 859, 2008). Some applications were, however, rejected for not demonstrating any effect or for relying on invitro rather than in-vivo studies (EFSA Journal, no's 859, 860, 861 and 862, 2008). Following requests from probiotic companies for further guidance, EFSA is organising a workshop on gut health and immunity on 2 December 2010 (Starling, 4 August 2010).

Most probiotic companies are now awaiting further guidance from EFSA before submitting any more applications. However, in late August 2010, Finnish dairy company Valio, discussions are currently underway about the possibility of submitting health claims applications for probiotic products under article 13.5 (health claims based on new scientific evidence).

The two largest producers of probiotic yoghurts and drinks, Danone and Yakult have not yet had their claims assessed (Lawrence, 2009). Yakult has had regulatory approval for its probiotic dairy drink in Japan for more than a decade under the FOSHU regulatory regime, and by 2002 Japan had approved a total of 57 yoghurts or fermented milks as FOSHU

products (Asp et al, 2004). The claims allowed for probiotic products in Japan are along the lines of "promotes the maintenance of a good intestinal environment" (Asp et al, 2004). Danone has withdrawn its application for claim article 13.5 approval for its probiotic products twice citing a lack of clarity from EFSA as to what kind of scientific evidence and data the authority requires (Starling, 15 April 2010).

Table two: Established and suggested probiotic health effects

Probiotic effect	Validity of scientific	Examples of
	knowledge	relevant studies
Modulation of the intestinal microflora.	Well established effect, but correlation between probiotic action and health effect not totally clear.	Ouwehand et al (2009) Spaanhaak et al (1998) Bernet et al (1994)
General immunity - probiotic strains have shown a positive effect on the immune system including higher concentrations of immunoglobulin A and improved phagocytosis.	Clinical studies have shown the effect in healthy subjects, but have not demonstrated improved clinical outcomes. (strains included <i>Lactobacillus</i> <i>acidophilus</i>)	Ouwehand et al (2009) Schriffin et al (1995)
Prevention and alleviation of unspecific gastrointestinal complaints, that is, general improvement in gastrointestinal well- being.	Effects such as reduction in bloating and flatulence and reduced transit time are established in certain target groups, but more research is needed to better target which populations would benefit and under what conditions.	Guyonnet et al (2007) Méance et al (2001)
Prevention and/or reduction of duration and symptoms of rotavirus induced diarrhoea.	Well established in clinical studies. Paediatric data more conclusive than adult data.	Isolauri et al (2002) Marteau et al (2001) Shornikova et al (1997)

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Probiotic effect	Validity of scientific knowledge	Examples of relevant studies
Prevention and/or alleviation of antibiotic associated diarrhoea (AAD).	Lower occurrence well established in clinical studies. (probiotic strains included <i>Saccharomyces bourlardii</i> and <i>Lactobacillus rhamnosus</i>)	Katz JA (2006) McFarland (2006) Hawrelak (2005) D'Souza et al (2002) Hickson et al (2007) Gao et al (2010)
Alleviation of symptoms of lactose intolerance.	Some clinical trials provide evidence of alleviation, but this is not yet conclusive. (probiotic strains included <i>Lactobacillus acidophilus</i> , <i>Lactobacillus bulgaricus</i> and <i>Bifidobacterium longum</i>)	Shaukat et al (2010) McDonaugh et al (1987)
Reduction of <i>Helicobacter pylori</i> infection	In-vitro studies indicate probiotics have the potential to fight <i>H.pylori</i> and some clinical studies in animals and humans show reduction of the infection using probiotic strains, but not total eradication. (most frequently used strain was <i>Lactobacillus johnsonii</i> , but <i>Lactobacillus casei</i> and <i>Lactobacillus brevis</i> have also been used)	Asp et al (2004) Linsalata et al (2004) Michetti et al (1999)

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Probiotic effect	Validity of scientific	Examples of
	knowledge	relevant studies
Beneficial effects small	Effects are established in	Schiffrin et al
intestine bacterial	certain target groups, but	(2009)
overgrowth.	more research is needed to better understand which	Nobaek et al (2000)
	under what conditions.	Gionchetti et al (2000)
Occurrence or	Some studies show a	Gao et al (2010)
reoccurrence of <i>Clostridium difficile</i>	reduction in the reoccurrence of CDAD, others show no	Hickson et al (2007)
related diarrhoea (CDAD).	significant difference. (strains includes boulardii)	Plummer et al (2004)
		Surawicz et al (2000)
Reducing severity of	Clinical studies show better	O'Mahoney et al
Crohn's disease and	outcomes in children than	(2000)
preventing relapses.	adults for reducing severity. Most studies so far were not	Marteau et al (2006)
	achieving remission.	Guslandi et al
	(probiotic strains included S boulardii)	(2000)
Remission of ulcerative	Some evidence is available	Kato et al (2004)
colitis.	on maintenance of remission in adults.	Rembacken et al (1999)
Prevention of relapses of	Clinical studies show	Gionchetti et al
pouchitis (inflammation of	prevention, but data is	(2000)
ulcerative colitis patients).		Rembacken et al (1999)

	1	1
Probiotic effect	Validity of scientific	Examples of
	knowledge	relevant studies
Symptomatic relief for IBS	A number of clinical trials	Agarwal et al
sufferers.	have shown a symptomatic relief, but data is insufficient as yet to be conclusive, and	(2009)
		McFarland and
		Dubline (2008)
	a significant difference.	Guyonnet et al
	(probletic strains included	(2007)
	l actobacillus plantarum and	Quigley and
	Bifidobacterium lactis)	Flourie (2006)
		Nobaek et al
		(2000)
		Halpern et al
		(1996)
Treatment of the common	No significant effect founds in	De Vrese et al
cold and flu.	trials on adults, some studies	(2005)
	showing reduction in fever	Weizman et al
	days for children.	(2005)
Treatment of traveller's	Inconsistent results with	McFarland (2007)
diarrhoea.	some studies showing fewer	Larsen and Black
	or shorter episodes, and	(2005)
		Katelaris et al
		(1995)

Conclusions

The scientific evidence indicates that probiotics have a positive effect on the human body including modulating the intestinal microflora and positively stimulating the gastrointestinal immune response. Questions arise when it comes to linking the effect of probiotics, that is, the change the gastrointestinal microbial environment, with the health benefits that result. In addition, it is vital to remember that the beneficial effects can vary between different probiotic strains, and while some of the resulting health benefits, for example, prevention or reduction of antibiotic associated diarrhoea are well established, others, for example, symptomatic relief of IBS, have inconsistent results or currently show only promise.

A review of the scientific literature on the health benefits of probiotics shows strong evidence for reducing antibiotic associated diarrhoea and *Clostridium difficile* related diarrhoea, both of which are of concern in the health of older people (Ludlam et al, 1999) There is evidence in the area of improving general digestive well-being including lactose intolerance and irritable bowel syndrome. When it comes to gastro-intestinal infections, probiotics show promise in relation to *H.pylori* infection, small intestine bacterial overgrowth and rotavirus induced diarrhoea. Evidence exists, although is insufficient to be conclusive, relating to Crohn's disease, ulcerative colitis, pouchitis, related diarrhoea and irritable bowel syndrome. Some evidence, although rather inconsistent, also exists for traveller's diarrhoea and colds and flu in children.

Is there a role for probiotic products in supporting older people's health?

There is sufficient evidence that probiotic yoghurts and drinks can help support health in older people with certain health problems.

There are several ways that probiotic yoghurts or drinks could support some older people's health. Firstly, for those who suffer non-specific digestive discomfort, probiotic products may help, although outcomes can vary. Cannella (2009) points to several pieces of research indicating that functional foods which fortify gut microbiota can be beneficial to older people. Current evidence seems to suggest that probiotic products could be one option for older people with digestive discomfort to try. Symptoms of digestive discomfort can sometimes signal more serious health problems such as irritable bowel syndrome (Gage, 2009) or even colon cancer (AGS, 2005). It may therefore be appropriate to undertake clinical investigation of such symptoms occurring for the first time in order to exclude serious digestive disorders.

The strongest arguments relate to the use of probiotics to treat antibiotic associated diarrhoea, which is a greater health risk for older people (Ludlam et al, 1999) and can lead to malnutrition (undernutrition), which according to Calder and Kew (2002) can weaken the immune system. The evidence here suggests that older people with AAD could benefit from certain probiotic strains in their diet.

In addition, the role of probiotics in treating and managing irritable bowel syndrome shows potential, which if confirmed in the future may make probiotics and appropriate addition to the treatment of IBS in older people.

Recalling the literature on older consumers and functional foods, functional products must be ones that an older consumer normally eats and they must affordable.

When it comes to health problems such as AAD or IBS, an older person will normally be receiving medical advice most commonly from a GP, but also possibly from a consultant. Although the role of doctors and their views on functional foods was outside the scope of this paper, preliminary literature searches indicate limited research in this area. Older people (like their younger cohorts) are more likely to believe and act upon dietary and health recommendations from a health professional than advice received another way.

Related to this point and linked to the previous point about cost is the fact that an NHS doctor might be able to recommend an older patient try a probiotic yoghurt or drink for health reasons, but cannot prescribe a functional food, although could on the contrary prescribe a food supplement. Although this paper did not look at food supplements, it can be pointed out that probiotics are available also in food supplement format.

Case study two - cholesterol-lowering functional foods

Current use and trends of cholesterol-lowering products

Plant stanol/sterol containing margarines were first developed in the mid-1990s, (Kamal-Eldin and Moazzami, 2009) and pioneered in Finland where the first products were launched in 1995 (Hasler et al, 2000). Initially, plant stanols/sterols were used only in fat containing products like margarines, oils and salad dressings (Law, 2000), but further development led to them being emulsified in lethicin and added to non-fat or low fat foods like yoghurts, yoghurt drinks, bread and cereals (Volpe et al, 2001; Ortega et al, 2006).

Two companies, Rasio of Finland, which produces the Benecol range, and Unilever in the Netherlands which produces the Flora pro-activ range, are market leaders (Kamal-Eldin and Moazzami, 2009). Despite the availability of a variety of different functional food products containing plant sterols/stanols, cholesterol-lowering margarines dominate the market in the five biggest European countries (Brockman, 2010).

It is also worth pointing out that plant sterol margarines are more expensive than ordinary margarine or butter, with Law (2000) reporting in 2000 that the price difference was £2.50 versus £0.60 and £0.90 respectively leading to an annual additional cost of around £70. Law (2000) believes this could put poorer people off buying cholesterol reducing margarine, despite the fact that they are at higher risk of heart disease.

Research undertaken in Finland where plant sterol margarine was first sold, showed that it to be more popular amongst older consumers than younger on consumers; 9% of 64-74 year olds used plant sterol margarine compared to only 1% of 35-44 year olds (Urala, 2005).

Health/nutritional benefits of cholesterol-lowering functional foods

Cholesterol-lowering functional foods do just what they claim; they lower cholesterol, specifically they lower low density lipoprotein (LDL) cholesterol ("bad cholesterol") and total cholesterol while not affecting levels of high density lipoprotein (HDL) cholesterol ("good cholesterol") or triaglycerol (Kamal-Eldin and Moazzami, 2009; Hasler et al, 2000; Law, 2000; Ortega et al, 2006). High LDL cholesterol is a major risk factor for coronary heart disease and a significant risk in ischaemic stroke, (WHO, 2004). In addition, Wong et al (1991) found that increased total cholesterol levels in coronary heart disease patients who had already has one myocardial infarction were associated with a greater risk of reinfarction and death from coronary heart disease.

Mechanism of action

Plant stanols and sterols, also known as phytosterols and phytostanols, are compounds found in plant foods whose chemical structure resembles cholesterol except for the addition of an extra methyl or ethyl group (Kamal-Eldin and Moazzami, 2009; Jones and AbuMweiss, 2009; Kuhlman et al, 2005; Hasler et al, 2000; Law, 2000). The term "sterol" is often used to refer to phytosterols and stanols (Law, 2000). In functional foods, phytosterols or phyostanols are generally esterified with long chain fatty acids to increase their lipid solubility allowing them to be incorporated into food products (Hasler et al, 2000, Law, 2000; Sirtori et al, 2009).

Plant stanols and sterols are consumed as part of a normal healthy diet, but average consumption is between 150mg and 400mg per day, which is insufficient to have any benefit (Katan et al, 2003; Hasler et al, 2000). It is worth noting that vegetarian and Japanese diets contain higher levels of plant stanols and sterols at between 345mg and 400mg per day (Rudowska, 2010), compared to only 250mg per day for the typical American diet (Hasler et al, 2000). In addition, sterols are poorly absorbed in the intestine, with only about half of the dietary intake being absorbed (Chen et al, 2008).

Plant sterols lower cholesterol absorption, although the exact mechanism is not clear (Jones and AbuMweiss, 2009), despite the effect having been first discovered in the 1950s (Kamal-Eldin and Moazzami, 2009). It is suggested that sterols compete with cholesterol during its absorption into the digestive tract (Hasler et al, 2000), more precisely by displacing cholesterol in mixed micelles (Rudowska, 2010; Sirtori et al 2009). Mixed micelles are small aggregates of mixed lipids, cholesterol and bile acids, which enable lipids to be absorbed into the body via the gastrointestinal tract (John et al, 2007).

Long term studies from the Netherlands indicate that sterol and stanol enriched margarines results in stabilisation of total cholesterol levels over five years, which although modest, can reduce the risk of coronary heart disease and provide health benefits for the general population (De Jong et al, 2007).

Over forty phytosterols have been identified, although the common ones are beta sitosterol, campersterol and stimasterol, which are also the most efficient at reducing cholesterol (Ortega et al, 2006; Chen et al, 2008). Stanols are less abundant in nature (Law, 2000). Saturated phytosterols are more efficient at reducing cholesterol than unsaturated phytosterols (Ling and Jones, 1995). There is some evidence that sterols are more effective in the short term, whereas stanols maintain their efficacy in the long term (Chen et al, 2008). However, comparative studies of the cholesterol-lowering effect of sterol and stanol enriched margarine at a 2g daily dose have not found any difference in efficacy (Sirtori et al, 2009).

There is some evidence that certain types of sterol enriched functional foods are less effective than others; Clifton et al (2004) report on a study that showed that phytosterol enriched milk was three times more effective in lowering cholesterol than bread and cereal containing sterols. The results of a study into phytosterol intake by Demonty et al (2009)

showed a larger cholesterol-lowering effect at high dosage for solid enriched foods compared to liquid foods with the same level of phytosterol. However, Volpe et al (2001)'s study on sterol containing yoghurts had similar cholesterol-lowering outcomes to the study on stanol margarines by Miettinen et al (1995), but slightly better outcomes than the study using margarine undertaken by Hendriks et al (1999).

Plant sterols and stanols have been extensively tested for their safety and their effect on nutritional status and the evidence is that apart from beta-caratinoids, they have no negative impact (Rudowska, 2010; Law 2000; Ortega et al, 2006) except for some evidence that hyperabsorption of sterols can lead to premature coronary heart disease in patients with rare genetic defects (Chen et al, 2008). Law (2000) reports that randomised clinical trials have shown that stanols and sterols can lower blood concentrations of beta carotene by around 25%, concentration of alpha carotene by around 10% and vitamin E by around 8%. However, studies show that this deficiency is easily reversed with adequate fruit and vegetable intake and does not cause health problems (Ortega et al, 2006; Rudowska, 2010; Law, 2000).

Table three: Clinical trials of plant sterols/stanols

Study details	Cholesterol-lowering	Reference(s)
	effect shown	
Cholesterol-lowering effects of stanol esters in hypercholesterolaemic subjects.	7.5-10% reduction in LDL	Vanhanen (1993)
Reduction of cholesterol with plant stanol margarine in subjects with moderately high cholesterol.	10-14% reduction in LDL	Miettinen et al (1995)
Reduction of cholesterol	13% reduction in total	Gylling et al (1997)
in post-menopausal	cholesterol	
women with previous myocardial infarction.	7% reduction in LDL	
Reduction of total and	8-13% reduction in total	Weststrate and Meijer
LDL cholesterol by plant sterol margarines in subjects with normal and moderately high cholesterol.	and LDL cholesterol	(1998)
Cholesterol-lowering	4.9-6.8% reduction in	Hendriks et al (1999)
spreads in subjects with		
normal and moderately high cholesterol.	6.7%-9.9% reduction in LDL	

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Study details	Cholesterol-lowering effect shown	Reference(s)
Effect of plant stanol margarine on cholesterol of subjects with elevated cholesterol.	3-11% reduction in total cholesterol 2.7%-10.4% reduction in LDL	Hallikainen et al (2000)
Effect of plant sterol enriched yoghurt on patients with moderately high cholesterol	Total cholesterol reduction 6.7-11.2% LDL reduction 11.1- 15.6%	Volpe et al (2001)

It should, however, be pointed out that many studies report great variance in relation to the cholesterol-lowering effect of sterols/stanols, for example, Li et al (2007) report that a study on the effect of plant sterol enriched milk tea only resulted in a 3% reduction in LDL cholesterol in Chinese adults with high cholesterol, whereas most studies show 10% reduction. However, the reasons for this are unclear, as Li et al (2007) point out that ethnospecific effects and the impact of a lower fat diet have been discounted by other studies, and there is no agreement as to whether beverage format is a less effective delivery mechanism. On an anecdotal basis, the consumer association Which? reported a case of a member who experienced no decrease in cholesterol at all when using a cholesterol-lowering margarine in the appropriate quantities (Which, 2008). Li et al (2007) indicate that research on this issue does not currently present a clear picture.

Regulatory approval

The European Food Safety Authority has approved a number of plant sterol and stanol related health claims under article 14 of the relevant Regulation, which refers to reduction of disease risk. For example, EFSA's positive opinion no 2008-085 found that evidence had been provided to support a cholesterol-lowering effect of plant sterols added to spreads and low fat milk and yoghurt products of around 9% with a daily intake of 2-2.4g (EFSA, 11 July 2008). EFSA allowed the claim to be worded as follows:

"Plant sterols have been shown to lower/reduce blood cholesterol. Blood cholesterollowering may reduce the risk of coronary heart disease".

(EFSA, 11 July 2008).

Statins and cholesterol-lowering functional foods

Some consumers consider cholesterol-lowering functional foods to be an attractive

alternative to taking statins (cholesterol-lowering drugs) (Howe, 2000), although it should be pointed out that statins do not only lower cholesterol, but also have anti-inflammatory effects as measured by an increase in proteins such as C-reactive protein (CRP) (Blake and Ridker, 2000; Jain and Ridker, 2005). It is also worth pointing out that many statin users show decreasing compliance within one year of initial prescription (Howe, 2000), so if compliance was better with cholesterol-lowering functional foods, their attraction as an alternative could be even greater. However, because of their anti-inflammatory effect, replacing statins with cholesterol-lowering functional foods may not always be clinically appropriate.

Eussen et al (2010) conclude that there is substantial evidence that adding plant sterols and/or stanols to statin therapy further reduces total and LDL cholesterol by roughly 6% and 10% respectively. Larkin (2000) reports on Finnish studies that show that adults who take statins will see additional benefits from plant stanol margarine, as the two compounds work via different mechanisms; statins decrease cholesterol synthesis, whereas plant stanols decrease absorption.

According to Katan et al (2003) sterols reduce the cholesterol in patients taking statins more effectively than doubling the statin dose. De Jong et al (2008) report on a study that demonstrated that plant sterol or stanol containing margarine reduced the LDL cholesterol of patients on stable statin treatment by 8.7% and 13.1% respectively.

With regard to cost, statins are three times more expensive than plant sterol margarines, but lower cholesterol by about three times as much (Law, 2000). In the UK anyone using prescribed statins will pay only the standard prescription charge or no charge at all if they benefit from free prescriptions. However, some statins are also available from pharmacists in the UK without prescription and would have to be paid for.

Use of plant stanols and sterols

With regard to dosage, many studies confirm that the optimal intake of stanols or sterols for cholesterol-lowering purposes is 2 grams and that increasing the dose does not bring significant further reductions (Law, 2000, Volpe et al, 2001, Ostlund, 2004, Patch et al, 2005). Katan et al (2003) highlight a meta-analysis of 41 studies showing that a daily intake of 2g of stanols or sterols reducing low density lipoprotein (LDL) by on average 10%. An intake of 2g of sterols would require around 20-25g of cholesterol-lowering margarine a day (Law, 2000).

Rudkowska and Jones (2007) review the use of functional foods for the treatment of CVD including those containing plant sterols and conclude that they should be seen as an addition to other current lipid lowering recommendations for reducing CVD risk. Changes in diet, for example, lowering intake of saturated fat and cholesterol, can reduce cholesterol by 20% and the effect of sterols and stanols are additive to diet (Katan et al, 2003). Katan et al (2003) points to studies that show that the addition of plant stanols doubles the cholesterol-lowering effect of a low fat diet. This suggests that cholesterol-lowering functional foods are not stand alone and should form part of a dietary approach to

managing cholesterol (Larkin, 2000; Ortega et al, 2006). The American Heart Association (AHA) warn that people at risk of CVD cannot rely only on plant stanol containing foods to reduce their risk without doing anything else to change their lifestyle (Larkin, 2000). In addition the AHA stresses that plant stenol margarine must be used instead of and not in addition to other fats, for example, butter (Larkin, 2000).

A study of cardiac rehabilitation patients showed that an education programme on heart healthy functional foods, including cholesterol-lowering margarine, led to a significant increase in the consumption of those functional foods as well as positive changes in attitude towards diet and heart health (Pelletier et al, 2003). This further emphasises the case for cholesterol-lowering functional foods being part of a broad lifestyle approach to cardiovascular disease.

Conclusions

The scientific literature is overwhelming when it comes to the effectiveness of a daily intake of 2g of plant sterols and stanols in reducing LDL and total cholesterol in people with normal and high cholesterol. As Ortega et al (2006) point out "in few areas of nutrition is there such consensus". The question that then arises is how best people can incorporate plant sterols or stanols into their diet.

Is there a role for cholesterol-lowering functional foods in supporting older people's health?

First, it is worth recalling that the risk of cardiovascular disease increases with age, beginning to become significant at around 55 for men and post-menopause for women, and that managing LDL and total cholesterol levels is a key part of managing the risk of cardiovascular disease (WHO, 2004). Given the overwhelming evidence for the effectiveness of cholesterol-lowering functional foods, it would seem that they have a role to play in supporting older people to reduce the risk of cardiovascular disease. Indeed, Radowska (2010) specifically recommends that plant sterols and stanols be included in older adult's diets to help prevent cardiovascular disease and Patch et al (2005) recommend their use in the management of hypercholesterolaemic patients.

Given that the risk of cardiovascular disease and the role of cholesterol as a risk factor both change with age, the following would seem the most sensible recommendations:

- 1. Both men and women aged 55-64 would benefit from the inclusion of 2g of plant sterol/stanols via cholesterol-lowering functional foods in their daily diet, as part of a healthy lifestyle focused approach to reduce the risk of developing cardiovascular disease. This should be strongly encouraged for those already experiencing hypercholesterolaemia and could prevent or delay the need for statins.
- 2. Both men and women aged 65-74 would also benefit from the inclusion of 2g of plant sterol/stanols via cholesterol-lowering functional foods in their daily diet, again as part of a healthy lifestyle focused approach to managing the risks associated with cardiovascular disease. For those taking statins, cholesterol-lowering functional foods

can be considered as an addition to statin treatment, which has shown to be more effective than increasing the statin dosage.

3. As the role of high cholesterol as a risk factor in cardiovascular disease gradually becomes less significant after the age of 65, it would not seem necessary, although it would not be harmful to include cholesterol-lowering functional foods in the diets of the over 75s. Other aspects of nutrition are more important for this age group.

There are, however, a few points to take into consideration when developing a lifestyle approach which incorporates plant sterol/stanol containing foods into the diet of older people. The first is that plant stanol/sterol containing functional foods are considerably more expensive, than their non-functional varieties, which could inhibit some older people from consuming them due to financial constraints. This is of particular concern for cholesterol-lowering foods because cardiovascular disease is more prevalent in people of lower socio-economic status (Marmot, 2010; Law, 2000).

Secondly, it is important to remember that daily intake of plant sterols/stanols via functional foods should form part of a lifestyle approach to reducing the risk of cardiovascular disease which would cover healthy eating and physical activity. Changes to the diet such as decreasing saturated fat intake and increasing fruit and vegetables should go hand in hand with cholesterol-lowering functional foods and if necessary statins. Care should be taken that older people do not think that by incorporating cholesterol-lowering functional foods into their diet, they no longer need to make other lifestyle changes.

Thirdly, functional foods are more attractive to consumers when they are a food product usually consumed, which in the case of plant stenols/stanols may mean that different functional foods are relevant for different consumers. This paper has not looked in detail at the purchasing habits of older consumers for individual products, but one would imagine that margarine/butter is more widely used by older consumers and therefore more easily replaceable with a cholesterol-lowering version, than other food products for which cholesterol-lowering versions exist.

Finally, a small number of people do not respond to plant stanols/sterols and the reasons why are not currently fully understood. For older people with cholesterol problems who do not respond to plant sterols/stanols, even more attention to diet is needed and statin use may be required.

Case study three: calcium and vitamin D

Case study three: calcium and vitamin D

It is not possible to undertake a case study on calcium and/or vitamin D functional foods in the same way as the two previous case studies. However, the importance of these nutrients to older people's health and the recent increase in literature supporting this importance indicated that not covering them would be a lacuna in the study. This fits with the initial aims and objectives of the study, which stated that specific nutrients would only be focused upon "where directly applicable to the health of older people".

This case study is therefore slightly different to the two previous ones, as it takes a nutrient rather than product specific approach. The reasons for this approach here are:

- There are a plethora of functional foods containing calcium and/or vitamin D as well as many food supplements.
- There is insufficient product specific literature.
- There is sufficient literature focusing on the role of the two nutrients in older people's nutrition.

This case study will therefore be structured as follows:

- A mini-review of the literature on the role of calcium and vitamin D in older people's nutrition including recent new scientific developments in this area.
- A mini-review of functional food products containing calcium and/or vitamin D and their potential role in supporting older people's health.
- A mini-review of the use of calcium and vitamin D food supplements to support older people's health.

Calcium and vitamin D in older people's nutrition

As explained in section four of this paper, both calcium and vitamin D are essential for bone health (Bonjour et al, 2009) and older people need a higher intake of both calcium and vitamin D for a number of reasons including that they are more likely to suffer from deficiencies of both calcium and vitamin D (Phillips, 2000). According to Fujita (2000) calcium deficiency is a global problem and is linked to osteoporosis as bones get calcium depleted when intake is too low. Calcium deficiencies in older people can be partly linked to age related decrease in the efficiency of calcium absorption (Phillips, 2000; Gennari, 2001). The Survey in Europe on Nutrition and the Elderly: a Concerted Action (SENECA) studv¹¹ which looked at the diets of older people in 10 European countries revealed that a third of study subjects had very low intakes of calcium (Gennari, 2001). Older people often experience vitamin D deficiency (Buttriss, 1999; Zitterman, 2010; Gillie, 2004; Gennari, 2001; Bischoff-Ferrari and Staehelin, 2008) and are more susceptible to it because their skin is less able to synthesise vitamin D from sunlight and they tend to spend less time in the sun (Canella, 2009; De Groot, 2001; Gillie, 2004), and that declining kidney function can impair vitamin D synthesis (Canella, 2009). Data on the quality of women's diets in the UK shows that women, including older women have inadequate calcium and vitamin D intakes (Ruxton and Derbyshire, 2010) and Danish research shows that the population has a lower than recommended intake of vitamin D (Rasmussen et al, 2000).

Older people are more susceptible to bone health problems especially osteoporosis (Gariballa et al, 1998; WHO, 2003; Brouns and Vermeer, 2000; Bischoff-Ferrari and Staehelin, 2008), which is a risk factor in 90% of fractures in the over 65s (Buttriss, 1999). Calcium and vitamin D deficiency are risk factors in the development of osteoporosis

¹¹ Survey in Europe on Nutrition and the Elderly; a Concerted Action

(EUFIC, 2005; Dawson-Hughes and Bischoff-Ferrari, 2007; Bonjour et al, 2009). Specifically, insufficient calcium can result in reduced absorption of the nutrient, higher bone remodelling and increased bone loss while insufficient vitamin D is associated with reduced muscle function and an increased risk of falls (Dawson-Hughes and Bischoff-Ferrari, 2007; Bischoff-Ferrari and Staehelin, 2008). There is unsurprisingly good evidence that adequate vitamin D can prevent falls and osteoporotic fractures in older people (Zitterman, 2010; Bischoff-Ferrari et al, 2005; Bischoff-Ferrari, 2007; Bischoff-Ferrari and Staehelin, 2008).

Gennari (2001) also reports that calcium supplementation in postmenopausal women reduces bone loss by 1% on average and that women with low to moderate calcium intakes benefit more, but that calcium alone is insufficient to treat osteoporosis. Boonen et al (2007) also suggest that oral vitamin D only reduces the risk of hip fractures only when calcium supplementation is added. In relation to calcium supplementation, a very recent meta-analysis published by Bolland et al (2010) in the British Medical Journal found that the cardiovascular risks associated with calcium supplementation (when not accompanied by vitamin D supplementation) outweighed the benefits and thus the use of calcium supplements alone in the treatment of osteoporosis should be reassessed.

Women over 50 are at particular risk of osteoporosis because the menopause leads to lower levels of oestrogen, a sex hormone which conserves bone (Phillips, 2000). Postmenopausal osteoporosis mainly affects trabecular bone tissue during the 15-20 years after the menopause (Brouns and Vermeer, 2000). So far, hormone replacement therapy (HRT) has proved highly effective in retarding and delaying bone loss in postmenopausal women (Brouns and Vermeer, 2000), but the cardiovascular risks associated with HRT can outweigh the benefits to bone health (Compston, 2004; Schnitzer, 2002). Although osteoporosis is often seen as a female problem because it affects more women than men (Gennari, 2001), older men are also at risk of senile osteoporosis, which tends to affect cortical bones (Brouns and Vermeer, 2000)

There is therefore considerable agreement on the need to ensure that older people, in particular older women, receive adequate levels of calcium and vitamin D to protect and promote bone health and to prevent osteoporosis (Caroline Walker Trust, 2004; Bischoff-Ferrari and Staehelin, 2008; Dawson-Hughes and Bischoff-Ferrari, 2007). Gennari (2001) points to studies demonstrating that vitamin D supplementation of 400-800 IU per day alone or with calcium can reverse vitamin D deficiency, prevent bone loss and improve bone density in older people. The European Food Safety Authority (EFSA) has approved several health claims in relation to vitamin D, calcium and bone health:

- An article 14 health claim on reducing the risk of osteoporotic fractures by reducing bone loss in postmenopausal women for a food supplement providing 1000 mg of calcium and 800 IU of vitamin D (EFSA, 2010).
- An article 13.1 health claim on calcium and vitamin D and the maintenance of bone (EFSA, 2009)

It is important to note that there is no data as yet to show that improving calcium intake and absorption alone reduces the risk of osteoporosis; calcium and vitamin D are needed (Brouns and Vermeer, 2000). Given that vitamin D stimulates osteoblastic function (bone formation) (Phillips, 2003; Gennari, 2001), this is not surprising.

There is solid clinical evidence that vitamin D supplementation increases bone turnover and bone mineral density (Lips, 2001) and significantly reduces the risk of fracture in at risk older people (Buttriss, 1999; Reid, 1996; Bischoff-Ferrari, 2010). There is evidence that combined calcium and vitamin D supplementation helps in the same way (Buttriss, 1999; Chapuy et al, 1992; Prince et al, 2006; Gennari, 2001; Dawson-Hughes and Bischoff-Ferrari, 2007). Research in Spain concluded that vitamin D supplementation would be advisable for sections of the population at risk of osteoporosis, such as older people and post-menopausal women (Del Campor et al, 2005).

There is also increasing evidence concerning the role of vitamin D in immune health. Urashima et al (2010) report on a trial that showed that vitamin D supplementation reduced the incidence of seasonal flu in schoolchildren, with 11.7% of the supplement group developing flu compared to 18.6% in the placebo group. The European Food Safety Authority (EFSA) has also approved an article 13.1 health claim that vitamin D contributes to the normal functioning of the immune system and in particular the inflammatory response (EFSA, 2010). Essen et al (2010) suggest that that vitamin D's effect on the immune system is due to activating T cells, which become either "killer cells" that attack and destroy pathogens or "helper cells" that assist in the development of immune system memory. The immune system weakens with age (Wardwell, 2008) so vitamin D may have another potential benefit to older people, although as Bischoff-Ferrari (2010) points out, the evidence is still weak on immune system modulation.

In addition, there is some evidence that vitamin D may have a role in protecting older people from cardiovascular disease including reduced incidence of hypertension and reduced cardiovascular mortality (Bischoff-Ferrari, 2010). Parker (2010) reports on a metaanalysis conducted by the University of Warwick looking at the link between vitamin D levels and cardiometabolic disorder. Researchers found that high levels of vitamin D were associated with lower levels of cardiovascular disease, type II diabetes and metabolic syndrome (Parker, 2010). However, EFSA (2010) did not accept an article 13.1 health claim that vitamin D helped maintain a normal cardiovascular function. There is also some evidence that calcium deficiency is an important factor in the development of hypertension (Fujita, 2000).

The questions that then arise are:

- What are adequate levels of calcium and vitamin D for older people?
- How best can older people obtain the calcium and vitamin D they need?
Adequate levels of calcium and vitamin D for older people

There is currently considerable discussion in the nutrition world as to the appropriate levels of calcium and vitamin D for older people. Below are tables listing different dietary intake recommendations for calcium and vitamin D for older people.

Source	Details
Consensus development conference on optimal calcium intake (USA, 1994 cited in Gennari, 2001)	1500 micrograms of calcium per day for postmenopausal women not receiving HRT 1500 micrograms for people over the age of 65
COMA (Committee on the medicinal aspects of food) recommendation "Nutrition and bone health with particular reference to calcium and vitamin D" (1998)	700 micrograms of calcium per day for men and women aged over 50
Institute of Medicine (1997)	1200 micrograms of calcium per day for men and women aged 50-70 and over 70
Expert Committee of the European Community in the Report on Osteoporosis Action (cited in Gennari, 2001)	700-800 micrograms per day
Nieves (2003)	Older people should consume 1200 micrograms of calcium a day
EFSA (2010)	Women over 50 should consume 1200 micrograms of calcium a day.

Table four: Calcium recommendations for older people

There is a movement towards, although not yet a consensus, that older people need a daily intake of 1200 micrograms of calcium per day. The COMA guidelines (which have not been updated recently) recommend only 700 micrograms of calcium per day, something which now seems to warrant revision.

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Source	Details
COMA/Department of Health (1992) " <i>Report on</i> <i>Health and Social</i> <i>Subjects 31 - The</i> <i>Nutrition of Elderly</i> <i>People</i> "	10 micrograms of vitamin D per day for men and women aged over 65.
Institute of Medicine (1997)	10 micrograms of vitamin D per day for men and women aged 50-69.
	15 micrograms of vitamin D per day for men and women aged over 70.
Nieves (2003)	At least 600 and up to 1000 IUs of vitamin D per day for older people.
2005 Dietary Guidelines for Americans	25 micrograms (1000 IU) of vitamin D per day for older people.
Standing Committee of European Doctors (2009)	600-800 IU of vitamin D per day for people over 75 years old.
2010 recommendation of the National Nutrition Council of Finland	20 micrograms of vitamin D per day for older people.
International Osteoporosis	Older people need to consume on average 20-25 micrograms (800-1000 IU) of vitamin D per day.
Foundation (2010)	Older people at risk, including those with osteoporosis and those with limited sun exposure may need to consume up to 50 micrograms (2000 IU) of vitamin D per day.
EFSA (2010)	Women aged 50 and over should consume 800 IU of vitamin D per day.
Zitterman (2010)	Older people should consume 25 micrograms of vitamin D per day.

Table five: Vitamin D recommendations for older people

There is a near agreement that the recommended daily intake of vitamin D in older people needs to rise from the current UK recommendation of 10 micrograms per day to 25 micrograms per day. This increase is probably most easily available via dietary sources (fortified foods or food supplements) although changes to sunlight policy could also

contribute where practicable.

As might be expected, the reasons given for increasing recommended vitamin D intake for older people relate to reducing the risk of osteoporosis, which is cited by Raija Kara, Secretary General of Finland's National Nutrition Council (Byrne, 6 April 2010) and by EFSA's Panel on Dietetic Products, Nutrition and Allergies (NDA panel) (EFSA, 2010).

It should also be noted that as well as a need to improve vitamin D intake in older people, older people with vitamin D deficiency may need higher remedial doses of the nutrient. In relation to vitamin D deficiency, a recent study showed that remedial doses of vitamin D for people over 65 with a deficiency should be 125 micrograms (5000 IU) compared to 50 micrograms (2000 IU) for younger people (Whiting and Calvo, 2010). Bischoff-Ferrari et al (2010) conducted a risk-benefit analysis of vitamin D supplementation looking at randomised clinical trials on falls and fracture prevention and found that there was a significant dose-response relationship. Optimal benefits were found at a level of 700-1000 international units per day (Bischoff-Ferrari, 2010).

There is also a cost argument to improving vitamin D intake in general. A Europe wide study (Grant et al, 2009) estimated the direct and indirect costs of inadequate vitamin D levels to be €187 billion a year for the EU. Using the European study as a basis, Professor Zitterman calculated that Germany could save around €38 billion a year by ensuring sufficient vitamin D intake in the population (Zitterman, 2010). So not only does vitamin D deficiency impair health, it can be expensive as well.

How best can older people obtain calcium and vitamin D?

Calcium is obtained from the diet in a number of forms including:

- Dairy products
- Green vegetables
- Fish (soft bones)
- Fortified foods such as soya milk, orange juice

It is important to recall that older people are more likely to suffer from lactose intolerance due to physiological changes associated with ageing that reduce lactase (Donini et al, 2009, Lin, 2003). Osler and Heitmann (1998) report that a longitudinal study of Danish adults showed that associations between food and vitamin D intake were weak except for fish consumption.

Vitamin D has two biologically active precursors, vitamin D3 known as cholecaliciferol, which can be found in food and vitamin D2 known as ergocaliferol which is produced by the action of sunlight on the skin (Gillie, 2003).

Vitamin D3 is obtained through diet and can be found most commonly in:

• Vitamin D fortified margarine

• Oily fish like salmon, mackerel and sardines

• Fortified breakfast cereals

(Gillie, 2004; Phillips, 2000; Caroline Walker Trust, 2004)

However, many older people do not obtain sufficient vitamin D from their diet (Gillie, 2004; Phillips, 2000; Zitterman, 2010; Caroline Walker Trust, 2004) or from sunlight (Gillie, 2004; Gennari, 2001). Even those in at risk groups such as older women in Spain (Rodríguez et al, 2008) are often vitamin D deficient.

Gillie (2003) is particularly critical of the UK's sunlight policies, which he says are inappropriately adapted from Australian sunlight policies and result in people not spending enough time in the sun for their skin to generate sufficient vitamin D. Gillie (2004) suggests revising the UK's sunlight policies to improve vitamin D through skin synthesis. Gennari (2001) points to a US study suggesting that older people can obtain adequate levels of vitamin D by having 15-30 minutes of sunlight exposure per day. However, it is worth nothing that even in Southern Europe, as Rodríguez et al (2008) found, older people do not make enough vitamin D from sun exposure, so changing sunlight policy alone may not be sufficient.

Recent research from Terushkin et al (2010) points to the difficulties of determining the time needed in the sun to obtain sufficient vitamin D due to considerable variations relating to geography, season and skin type. Terushkin et al (2010) go on to recommend vitamin D supplements over UV exposure because of its "practical difficulties".

Rodríguez et al (2008) reported on the results of the EU funded OPTIFORD (towards a strategy for optimal vitamin D fortification) study on older women in Spain. Many of the older Spanish female population were vitamin D deficient and there was a noticeable difference between vitamin D deficiency in summer, when 28% of the study group were deficient and winter when nearly twice as many subjects were deficient, indicating that time spent in the sun was a factor (Rodríguez et al, 2008). Rodríguez et al (2008) recommend that vitamin D deficiency among older Spanish women be corrected with appropriate sun exposure and an increase in dietary vitamin D using supplements if needed.

Calvo et al (2004) note that cross-sectional studies suggest that vitamin D fortification of food products (milk, breakfast cereals and margarine) in the USA and Canada are not effective in preventing vitamin D deficiency, whereas the use of supplements seems to be more effective. However, Lips (2001) notes that vitamin D deficiency amongst older people is less common in the USA than elsewhere due to the fortification of milk and the use of supplements.

Functional foods containing calcium and/or vitamin D

A number of papers suggest that the use of functional (fortified) foods is a reasonable approach to increasing both calcium and vitamin D intake in a target population. Buttriss (1999) reports on data showing that older people suffer from vitamin D deficiency and suggests that this points to the need to consider fortification (Buttriss, 1999). Zitterman

(2010) also recommends more efficient vitamin D food fortification for Germany in order to make sure that the population receives adequate levels of the nutrient. A longitudinal study in Denmark showed that the removal of mandatory fortification of flour with calcium increased the number of adults with calcium deficiency from 6-22% (Osler and Heitmann, 1998). A systematic review of nine randomised clinical trials on vitamin D fortified foods showed a significant beneficial effect on concentrations of serum 25 hydroxyvitamin D in adults (O'Donnell et al, 2008).

When it comes to calcium and/or vitamin D containing functional or fortified foods, there are a number of issues that arise. Firstly, it is important to know whether the products are effective at providing calcium and vitamin D to the target population in appropriate, but not excessive amounts. The Institute of Medicine sets an upper limit of vitamin D of 50 micrograms or 2000 IU, but some clinicians are now in favour of a higher upper limit (Peregrin, 2002).

Biancuzzo et al (2010) undertook research comparing the effectiveness of calcium and vitamin D enriched orange juice with vitamin D3 supplements and found that the orange juice was as effective as the supplements in maintaining vitamin D status in adults. Tangpricha et al (2003) also found that fortifying orange juice with vitamin D was a safe and effective way to increase vitamin D levels in adult subjects. As yet unpublished data on vitamin D fortified bread from Professor Lamberg-Allardt of Helsinki University has shown that the fortified bread matches food supplements for vitamin D intake in human subjects (Daniells, 22 June 2010). Bonjour et al (2009b) and Wagner et al (2008a and 2008b) demonstrated that vitamin D is just as bioavailable from fortified hard cheese and fortified low fat soft cheese as from supplements.

Even more interesting are the results of a study of older women consuming vitamin D and calcium fortified soft cheese, which shows potential improvement in bone health through inhibition of bone reabsorption as demonstrated by relevant biomarkers (Bonjour et al, 2009b). Two servings of 100g of the cheese provided women with 17-25% of their daily vitamin D recommended intake and 25% of the calcium intake (Bonjour et al, 2009b).

Calcium bioavailability can vary according to the food product that is fortified (Heaney et al, 2005, Fairweather-Tait and Teucher, 2002). Heaney et al (2005) report that calcium enriched soya milk showed calcium absorbability of about 25% less than cow's milk, but this is superior to calcium enriched orange juice, where up to 50% of the calcium sediments on centrifugation.

The question of appropriate intake of vitamin D from fortified foods is somewhat problematic. Despite studies mentioned above showing that various types of vitamin D fortified foods increase vitamin D intake and uptake in human subjects, Rao and Alqurashi (2003) say that so far the impact of fortifying milk and dairy products to prevent vitamin D depletion has been less than satisfactory, raising questions of bioavailability and dosage. Hirvonen et al (2007) examine this matter in detail in relation to vitamin D and come to the conclusion that a wide variety of foods fortified to a low concentration is more efficient than a few products which are highly fortified. Rasmussen et al (2000) claimed that combining milk and margarine fortification would work best in Denmark. This is clearly an issue of contention, which leads onto the next question, which relates to dietary preferences.

A second point to consider is if the functional food products are liked and consumed by the target population. Older people cannot be seen as a homogenous group in relation to diet and as this paper has found out, there is insufficiently precise research into the dietary habits of different age tranches of older people. Some research has been undertaken, for example, a study of older people living in the community in Romania showed good compliance with fortified bread, with around 75% eating the product every day (Costan et al, 2008). At the moment it seems that there is unlikely to be a single functional food that would appeal to all those who could be considered as targets, and given what Hirvonen et al (2007) say with regard to effective dosage, there may not be.

Thirdly, as with all food products, it is important to look into whether there are any cost or availability barriers that might prevent (some of) the target population from being able to improve their calcium and vitamin D levels by consuming them.

Calcium and/or vitamin D food supplements

Raija Kara, Secretary General of Finland's National Nutrition Council says that increased vitamin D intake in older people will probably require the over 60s to take a daily vitamin D supplement (Byrne, 6 April 2010).

Rasmussen et al (2000) point to studies by Dawson-Hughes et al (1997) and Ooms et al (1995) which demonstrate that vitamin D supplements can stabilise or even increase bone mass in older women. As mentioned above, Terushkin et al (2010) believe that vitamin D supplementation is more effective for improving intake than increasing sunlight exposure (Terukshin et al, 2010).

However, there is research showing that vitamin D supplements may not be enough, for example, Belgian research showed a high prevalence of vitamin D inadequacy in postmenopausal osteoporotic women, even among those taking vitamin D supplements (Neuprez et al, 2007). This seems to indicate that there may be issues with compliance. It is reasonable to suggest that compliance with food supplements amongst older people living in the community may be lower than those in hospital for practical reasons.

Findings

The role of both calcium and vitamin D in bone health in undisputed as is the particular importance of both nutrients to older people, especially postmenopausal women. There is increasing evidence for the role of vitamin D in immune health, but this is not yet conclusive.

There is considerable evidence that vitamin D deficiency in particular is a problem among older people, especially postmenopausal women who are most at risk of osteoporosis. There is some evidence of calcium deficiency in older people as well, although the data is not as compelling as for vitamin D.

There is agreement that older people need higher intakes of vitamin D than current dietary guidelines to maintain bone health and prevent osteoporosis. There is agreement that calcium is important for bone health including in older people, but less evidence that calcium deficiency alone (that is, without vitamin D deficiency) linked to bone health problems. Current UK nutritional recommendations for calcium and vitamin D intake for older people appear out of date and are therefore in need of revision. Comparing various suggested revised calcium and vitamin D intakes for older people indicates that there is almost a consensus in relation to what revised recommended dietary intake might be; namely 1200 micrograms of calcium per day and 25 micrograms of vitamin D per day.

There is no agreement as to which is the best way to provide appropriate levels of calcium and vitamin D to older people. In relation to vitamin D, some argue for vitamin D supplements, whereas others would prefer increasing exposure to sunlight. Functional foods containing vitamin D and calcium have not yet been sufficiently examined for their potential in this respect, except on a clinical level in relation to uptake from functional foods, which so far show good results. In addition, the questions of which vitamin D and calcium enriched functional foods older people might prefer and how to ensure sufficient but not excessive dosage, are not yet satisfactorily answered.

Is there a role for functional foods containing calcium/vitamin D in supporting older people's health?

There is clearly a need to particularly improve vitamin D intake to support older people's bone and possibly immune health, and some evidence of the need to improve calcium intake, particularly in older women. Despite vitamin D being available in fortified margarine and food supplements, problems with intake remain even in at risk older people. This suggests a need to review vitamin D and calcium strategies in older people, a review that should definitely cover relevant functional foods including their ability to provide sufficient quantities of vitamin D and calcium.

Given that most people obtain their calcium and vitamin D intake from a variety of sources and there are many calcium and vitamin D functional foods, it must be quite confusing for an individual to work out if they are getting their recommended intake. This is surely an area for further research.

Chapter eight - Is there a role for functional foods in supporting older people's health?

Is there a general role for functional foods in supporting older people's health?

A balanced nutritious diet is the best way for older people to avoid nutrient deficiencies and maintain health. However, that is not always possible due to physiological changes associated with ageing (see chapter four of this paper for more details). In addition, the increase in the risk of chronic disease and/or the emergence of chronic disease in older people can mean that more radical dietary changes are needed in order to prevent or manage chronic conditions. It is worth noting that the most common health or disease problems that functional foods target, namely gastrointestinal function, cardiovascular disease and bone health (FAO, 2007), although not exclusively affecting older people, are conditions or problems that are more likely to occur in older age.

Due to the age related changes that can make it more difficult for older people to obtain the nutrients they need from their diet (see chapter three of this paper for more information) functional foods can have a role to play in improving nutrient intake (Cannella, 2009) and may help to slow down some of the degenerative changes associated with ageing (Shatenstein et al, 2003). Functional foods can play a role in reducing the risk of a number of chronic diseases associated with ageing including cardiovascular diseases, diabetes, and osteoporosis. Hasler and colleagues even go as far as positioning functional foods as having the potential to help reduce the healthcare costs associated with chronic diseases of ageing (Hasler et al, 2000). This disease risk reduction or disease prevention focus strengthens the positive or pro-active healthy eating paradigm (Shatenstein et al, 2003).

Older people are not always keen to make changes in their dietary habits even if for health reasons (Frewer et al, 2003), unless they have experienced serious health problems, for example, a heart attack (Age Concern, 2006). According to Ferrari (2007), health promotion in older people should focus on diet and regular physical activity and diet can include appropriate functional foods. Healthy lifestyle messages are considered more credible and are more likely to be acted upon if coming from a health professional (Age Concern, 2006; Korzen-Bohr and O'Doherty Jensen, 2006). Messina et al (2008) suggest that functional foods might be an alternative way to incorporate health giving nutrients into older people's diets. This is backed by Holm (2003) who sees functional foods being able to bring desired results to older people's health without the struggle of persuading them to make significant changes to their overall diet.

It would seem therefore that there is a case for functional foods playing a useful role in older people's diets. Sieber (2007) raises a note of caution pointing out that although functional foods clearly have a role to play helping older people achieve adequate nutrition, there is a lack of evidence based studies showing the benefit of this approach.

In a number of areas, older people have specific health needs/disease prevention needs for which there are functional foods that can help meet these needs, although cannot be seen as a sole or only solution, but should instead be seen as a way to reinforce the health improvement/disease prevention aims of a healthy lifestyle approach.

Consumer research suggests that older people can be more receptive to functional foods than younger people, even more so if they are female and/or have a strong interest in health. The health interest is increased still further when the health benefit of the functional food is one for which the person has a perceived need. This could lead older people to be more vulnerable to unsubstantiated health claims.

Is there a role for specific functional foods in supporting older people's health?

Cholesterol-lowering functional foods

This paper has reviewed the evidence on the effectiveness of cholesterol-lowering foods containing plant stanols and sterols and their suitability for older people. Strong evidence was found that on average, the inclusion of a cholesterol-lowering functional food in the diet reduces LDL and total cholesterol by 10%. Many older people in the age groups 55-64 and 65-74 are either at risk from cardiovascular disease due to normal elevated or high cholesterol or have already developed a form of cardiovascular disease. For such people, there is a strong evidence base for the benefits of replacing a regular food product such as margarine or yoghurt with a cholesterol-lowering version. This even extends to people already taking cholesterol-lowering statin medication as the effect of plant stanols and sterols has been shown to be additive to statins, something that would be of particular use to those who cannot take full doses of statins.

Probiotic yoghurts and drinks

This paper has reviewed the evidence on the health claims of probiotic yoghurts and drinks. Evidence has been found that probiotic yoghurts and drinks have a potential role to play in the management of certain health conditions, particularly antibiotic associated diarrhoea and general digestive discomfort, which older people often experience. However, it is important to point out that clinical studies sometimes show that some strains of probiotics are more effective than others and that response varies on an individual basis. Despite the growing evidence for probiotic effect on the immune system, it is not yet conclusive enough to be recommended for improving general immunity in older people, although this could change in the future.

The scientific evidence available thus far does, however, indicate a role for probiotic yoghurts and drinks as part of the management of AAD, and a possible role in improving general digestive discomfort in some older people.

Calcium and vitamin D

Obtaining sufficient vitamin D and calcium intake is of great importance to older people and functional foods providing these nutrients in higher quantities than normal food products, which could be one solution to improving intake of these nutrients for older people. There are, however, other solutions including food supplements and for vitamin D, increasing exposure to sunlight. The jury is still out as to the best way to improve calcium and vitamin D in older people's diets, despite agreement that improvement is needed.

While the range of functional foods products providing high levels of calcium and vitamin D can be confusing, one advantage is that many older people should surely be able find a product that suits their dietary habits and tastes. It would be desirable, however, to be able to present older people with evidence about which products lead to clinically significant increases in vitamin D and in what quantities.

Chapter nine - Recommendations

Recommendations for action

1. Consider establishing some age specific dietary recommendations for different age groups of older people, particularly those over 75

Current dietary recommendations for older people tend to consider the older population as a homogenous group of anyone over 60 or over 65. This does not take into account that nutritional needs can change with physiological ageing, so that there are some differences between the dietary needs and health concerns of the average 85 year old and those of the average 60 year old, although many healthy eating messages remain valid for older people of all ages. Therefore some form of age tranche-specific dietary recommendations would be welcome, for example the fact that malnutrition in the form of undernutrition presents greather health risks for the over 75s than obesity. Age tranche-specific recommendations should be accompanied by appropriately targeted healthy eating messages as and when appropriate. This could form part of the updating of the COMA recommendations on the nutrition of older people, which remain unchanged since 1992.

2. Review of calcium and vitamin D strategies for older people

This review should consider:

- Establishing routine screening for vitamin D and calcium deficiency in older people at particular risk of osteoporosis/other bone health problems
- Revising current recommended intakes of calcium and vitamin D for older people in line with current nutritional science
- 3. Consider how best to incorporate cholesterol-lowering foods into a healthy lifestyle approach for older people

There is strong evidence that many older people, particularly those considered at greater risk of cardiovascular disease, could benefit from incorporating cholesterol-lowering functional foods into their diet as part of a healthy lifestyle approach.

4. Consider the development of probiotic treatment protocols for older people at risk of AAD

There is strong evidence that some probiotic strains can prevent or reduce the severity or duration of antibiotic associated diarrhea (AAD). AAD is unpleasant and of greater concern in the case of older people, particularly frail older people, because of the risk of malnutrition in the form of undernutrition and nutrient deficiency.

Development of such protocols would need to consider:

• Risk assessment of older people for AAD and malnutrition

- Identification of probiotic strains with the best outcomes in relation to preventing/better managing AAD
- Personal preferences for probiotic administration, for example, food supplement or probiotic yoghurt
- Identification of factors that influence compliance and how to assess patients for such factors

Recommendations for further research

1. Research into older consumers and functional foods

There is a need for further research into the views of older consumers on buying and using functional foods and their buying and consumption patterns.

2. Research into the effectiveness of nutritional advice and messages for older people

There is a need for further research into how we can convince or nudge people to make the right decisions in relation to healthy eating. There is evidence that older people listen to health professionals and are unsure about nutritional advice/messages that accompany food products.

3. Randomised clinical trials on the use of functional foods

The functional foods sector does conduct randomised clinical trials (RCTs) to demonstrate the effect of functional foods on the body, for example, those supplied to EFSA to obtain health claim approval for cholesterol-lowering products and the clinical trials that show probiotic strains preventing or lessening AAD.

However, it would be interesting to see RCTs examining the impact on health and clinical outcomes of including specific functional foods into older people's diets. For example, cholesterol-lowering margarine has a well-documented effect on cholesterol, but what is the impact of this lowering of cholesterol on incidence of cardiovascular disease or on cardiovascular outcomes?

4. Research examining compliance with functional foods

During a RCT of a functional food, trial participants' consumption of the relevant functional food is highly controlled, but without the rigour of a study, it is quite possible that there are compliance problems. It would be interesting and useful to look into compliance of older people with functional foods that have been identified as potentially beneficial to their health. Such research could look at whether people follow the recommended daily intake and what influences their consumption patterns.

5. Examine the case for "normalising" cholesterol-lowering margarine

Given the strong evidence for cholesterol-lowering margarine, is there a justification for making all margarines cholesterol-lowering? This links to arguments over compulsory fortification of foods, which this paper did not examine in detail.

6. Research into the opinions of GPs and health professionals on functional foods

There is a need for research to ask GPs and other health professionals advising older people on diet and nutrition, what they think about functional foods and if/how they speak to patients about them.

This paper did not look into detail at this topic, but a simple PubMed search ("health professionals AND functional foods", "doctors AND functional foods" and "physicians AND functional foods" for title and abstract) revealed 12 articles, of which only two were specifically addressing the opinions of health professionals towards functional foods.

7. The potential of probiotics in helping to manage malnutrition (undernutrition) in older people

It would be interesting to take up Hamilton-Miller (2004)'s suggestion of investigating the potential of probiotic strains in undoing the gut damage attributed to malnutrition (undernutrition), which can further impair the nutritional status of older people.

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Annex 1 – Examples of age definition in literature on older people's nutrition

Authors	Publication	Age specification
Department of Health	"National Diet and Nutrition Survey (NDNS)" (age definition for the purpose of examining the diets of older people)	Older person = 65 and over
Age Concern (2006)	"Fit as a butcher's dog"	Older person = 65 and over
Krondl et al (2008)	"Helping older adults meet nutritional challenges", Journal of Nutrition for the Elderly	older person = 65 and over
Masala et al (2007)	"A diet rich in olive oil and raw vegetables is associated with lower mortality in Italian elderly subjects", British Journal of Nutrition	Elderly = 60 or older
Department of Health	Report on dietary reference values (COMA)	Older people = over 50
Tufts University (2003)	"Growing older presents new nutrition challenges" Health & Nutrition Letter	Older person = over 50
Cannella et al (2009)	"Nutrition, longevity and behaviour" Archives of Gerontology, Geriatric supplement	No age specified.
De Groot et al (2001)	"Meetingt nutrient and energy requirements in old age", Maturitas	No age specified
Ritz et al (2001)	"Factors affecting energy and macronutrient requirements in elderly people"	No age specified
Chernoff (2001)	"Nutrition and health promotion for older adults", Journal of Gerontology	No age specified



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