

Dietary Supplements and Functional Foods

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Preface

I decided to submit the proposal for this book in 2002 after writing a short commissioned article on dietary supplements for a nursing journal. This was the first time that I had given concentrated thought to the use of supplements as a whole. The low word limit of the article forced me to identify general concepts and principles relating to dietary supplements. Previously, I had only considered the use of individual supplements such as fish oils or evening primrose oil, or the use of supplements in particular circumstances such as during pregnancy or in housebound elderly people.

The easiest option when writing this book would have been to make an alphabetical list of substances to include and then write something about each of these under a series of common subheadings. Such an approach is useful, especially as a resource for reference, but good books that use this approach already exist. In this book I have identified common themes and principles that apply to all supplements or to particular categories of supplements. This is most obvious in Chapter 1 where I have overviewed the reasons for using supplements and how these have changed over time; the ways in which supplements can be categorised; the legal regulation of supplements; the market for supplements and the quality of the products available; and a critical review of the ways in which their efficacy and safety are tested. I have put supplements into groups and then discussed these groupings in subsequent chapters.

As far as possible, I have carried the 'strategic overview' approach of the first chapter through to the rest of the book. Chapter 2 overviews the likely micronutrient adequacy of various age groups and other subgroups of the population – the general validity of the case for taking micronutrient supplements to ensure adequacy. Individual vitamins and minerals are then discussed in Chapters 3 and 4. One consequence of my grouping together of vitamin and mineral supplements is that the overlap between this book and a standard nutritional text becomes more obvious than if they were distributed throughout the book in alphabetical order. In Chapter 5, there is a general review of the oxidant theory of disease and the possible role of antioxidants in preventing disease, as well as evidence of the safety and efficacy of particular antioxidant supplements. In Chapter 6, the lipids are discussed as a group and the effects of different oil supplements upon essential fatty acid metabolism and eicosanoid production reviewed. This is followed by a discussion of the safety and efficacy of individual lipid supplements.

Most of the substances covered in Chapters 3 to 6 are recognised essential nutrients, but in Chapter 7 are found a group of substances that, whilst not normally considered to be essential nutrients, are none the less almost all normal body constituents and are often vitamin-like in their biochemical roles. Unlike established vitamins, however,

endogenous synthesis is generally considered to be sufficient to prevent deficiency of these substances although their use as supplements implies that endogenous synthesis is considered not always sufficient for optimal health or increases in some disease states. In a few cases, there is clear evidence that some of these substances become essential in some people or under some circumstances (conditionally essential).

In Chapter 8, I have briefly reviewed and classified the thousands of secondary metabolites found in plants, some of which are established drugs and others of which may be responsible for the claimed benefits of taking supplements of herbal preparations for improving health and treating disease. I have overviewed some of the potential mechanisms by which plant secondary metabolites might help prevent chronic diseases such as cancer or heart disease. A selected list of some of the most commonly used plant extracts sold as dietary supplements are then discussed individually; in the main I have selected substances where there is a history of authentic culinary use although I have also been guided in my selection by the popularity of particular supplements.

Chapter 9 gives a brief overview of some important categories of functional foods and the evidence for their usefulness and safety. Many experts in this area may feel that, given the title of the book, this section is too short or even that functional foods do not belong in this book. There is, however, considerable overlap between dietary supplements and functional foods: probiotic organisms that have long been used in functional foods are now also available in pill form as supplements; plant sterols, such as β -sitosterol, that started out as supplements taken in pill form are now the active components of a major group of functional foods. Both supplements and functional foods are an attempt to produce dietary improvement without necessarily making the structural changes in the diet that would make it conform to current dietary guidelines. They are often marketed as short cuts to health and dietary improvement for people unwilling to ensure that their overall diet is 'healthy'.

The number of substances and extracts marketed as dietary supplements is enormous and is constantly changing so I have had to be selective about which substances to include. I have also had to make choices about which suggested benefits of each supplement to discuss. I may well have made some inclusion or exclusion decisions that some readers will disagree with. This is inevitable, especially with herbal products where the already indistinct dividing line between herbal medicines and dietary supplements is further blurred by legal regulations that offer major advantages to marketing a herbal preparation as a supplement rather than as a drug.

Relatively few primary trials of supplements are referenced in this book and those that are tend to be trials that have had a major impact upon scientific opinion. When evaluating evidence of the safety and efficacy of individual supplements or functional foods, I have relied heavily upon systematic reviews, meta-analyses and the conclusions of expert working groups. Quoting the results of many and often contradictory individual trials can be unhelpful to readers who want an evaluation of where the current consensus is and how strong the supporting evidence is. Selecting examples of trials can also bias the reader's view of the total literature. Primary sources can be found in the reference lists of the reviews and reports that are referenced.

Finally, I have tried to make the book accessible to people from varied scientific and clinical backgrounds and so have assumed only limited nutritional and biochemical

knowledge. I have, for example, explained the systems of dietary standards which people from a nutrition or dietetics background would already be familiar with. I would thus hope that the book will be accessible to those interested in dietary supplements but who have limited specialist nutritional background.

Geoffrey P. Webb

Chapter 1

An overview of dietary supplements and functional foods

The evolving rationale for supplement use

Adequacy and the prevention of deficiency diseases

Traditionally, dietary supplements such as cod liver oil, iron tablets and multivitamins were taken to ensure the adequacy of the diet. They were taken to ensure that our diet contained enough essential nutrients to prevent overt deficiency disease and to ensure that we did not suffer other more subtle adverse effects of marginal nutrient inadequacy. Whilst this remains an important motivation for many people, others now also take supplements in the hope that they will have additional health benefits, such as:

- To reduce the risk of developing a chronic age-related disease such as cancer, heart disease, osteoporosis or type 2 diabetes
- To compensate for some (perceived) individual idiosyncrasy that may increase requirement for an accepted nutrient or make another substance an essential nutrient for that person
- To ‘boost the immune system’
- To treat or lessen the symptoms of a non-deficiency disease such as clinical depression or arthritis
- To boost intake during periods of (perceived) increase in requirement such as in pregnancy, illness or old age
- To boost athletic performance.

One ironic consequence of these new circumstances is that the high levels of vitamins A and D in cod liver oil, the traditional reason for taking it, may actually be seen as a disadvantage. These vitamins are toxic in excess and may prevent us safely taking large doses of the essential polyunsaturated fats that are now regarded as the most important active ingredients of fish and fish liver oils (see Chapter 6).

During the first half of the twentieth century, it was found that certain foods and essential nutrients extracted from these foods could prevent or cure several common, serious and frequently fatal diseases such as those listed below.

- Vitamin C cures scurvy, a frequently fatal disease experienced by those undertaking long voyages by sail or expeditions where they were required to live for long periods without access to fruit or vegetables. It is characterised by bleeding gums, excessive bruising and a tendency to haemorrhage internally.

2 *Dietary supplements and functional foods*

- Niacin (vitamin B₃) cures pellagra, a fatal disease associated with a subsistence diet composed largely of maize. It is characterised by the '4 Ds': diarrhoea, dermatitis, dementia and ultimately death.
- Thiamin (vitamin B₁) cures beriberi, another potentially fatal disease associated with a diet heavily dependent upon polished (white) rice. It is characterised by degeneration of sensory and motor nerves, loss of peripheral sensation, paralysis, brain damage, oedema and heart failure.
- Iodine supplements cure goitre and the iodine deficiency diseases which are still endemic in many areas where the soil iodine content is low. They are characterised by low metabolic rate and mental deterioration in adults (myxoedema), severe and irreversible impairment of mental and physical development in children (cretinism), and high risk of miscarriage, stillbirth and birth defects.
- Vitamin D cures rickets, a disease once prevalent amongst children in the northern industrialised cities of Europe owing to a combination of a poor diet and low exposure of the skin to summer sunlight. Rickets leads to characteristic abnormalities in the skeleton such as bow legs (which may not be entirely reversible) as well as poor growth, muscle weakness and increased susceptibility to infection.
- Vitamin A prevents xerophthalmia and can reverse some cases in which there is a progressive deterioration of the eyes leading ultimately to permanent and irreversible blindness. Vitamin A deficiency also increases susceptibility to, and death from, infectious diseases. Deficiency occurs in populations subsisting largely upon starchy foods where the staple diet contains practically no animal fats and few brightly coloured fruits or vegetables.

Some of these diseases are still prevalent in some parts of the world. Vitamin A deficiency (xerophthalmia) causes hundreds of thousands of children in developing countries to go blind each year and is a major contributory factor to the high child and infant mortality rates in some countries. Iodine deficiency and goitre still affect hundreds of millions of people around the world. Iodine deficiency is the most common preventable cause of mental deficiency in the world.

Most people who now live in one of the wealthy industrialised countries will have had no direct experience of any of the classical dietary deficiency diseases with the possible exception of iron deficiency anaemia. This was not true in the nineteenth century and the first half of the twentieth century when these diseases were not confined to developing countries; some, such as the examples below, were prevalent even in countries that are now part of the industrialised world.

- Pellagra (niacin deficiency) caused tens of thousands of deaths in the southern states of the USA in the early twentieth century and epidemics also occurred in parts of southern Europe where maize was a staple food.
- In the first decades of the twentieth century, beriberi (thiamin deficiency) exacted a heavy toll in the countries of the Far East such as Japan and the Philippines where white rice was the dietary staple.
- In the early decades of the twentieth century, the majority of children from poor families living in the northern industrialised cities of Britain would have been affected by rickets (vitamin D deficiency).

- Goitre (iodine deficiency) was once common in the states bordering the Great Lakes in the USA and in the Cotswolds and the Peak District in England.

As the dietary origins of these diseases were unravelled it became common knowledge that simple dietary changes could prevent and cure these serious and frequently fatal diseases. As the active components of the diet were identified and purified they were found to be equally effective when taken as supplements in pill or liquid form. Such observations must have encouraged the belief in nutritional ‘magic bullets’ that might be able to cure or prevent all sorts of diseases. The dramatic and demonstrable benefits of taking small amounts of these nutrient supplements would surely have encouraged the use of larger supplements to ‘optimise’ intakes and perhaps prevent other more subtle adverse effects of deficiency. Dietary supplements were thus proven to have major benefits for some people and were thought to be a useful safety net for anyone concerned about the adequacy of their own or their family’s diet.

The notion of widespread use of dietary supplements was born. It was reinforced by scientific advisers who persuaded governments to fortify common foods with extra vitamins and minerals which seemingly gave official confirmation that ordinary food could not guarantee nutrient adequacy. For example, the British government made it mandatory to fortify white bread and flour with iron, calcium and some B vitamins, and to fortify margarine with vitamins A and D.

Diet as a means to prevent chronic, age-related and wealth-related diseases

In the latter decades of the twentieth century, the nutritional focus, and the health focus generally, changed in the industrialised countries. As affluence increased, the focus shifted away from the problems associated with poverty and deprivation (such as infectious and deficiency diseases) towards the chronic diseases that afflict middle-aged and elderly people in affluent populations – cancer, heart disease, diabetes and osteoporosis. These chronic diseases now cause most of the deaths and chronic ill-health in long-lived populations. The reasons for this change of emphasis are illustrated by the British mortality statistics listed below.

In Britain in 1901:

- Average life expectancy was only around 47 years.
- Less than half of people lived to see their 65th birthday.
- A fifth of all deaths were due to infectious diseases.
- Less than a quarter of deaths were due to cancer and heart disease combined.

A hundred years later:

- Average life expectancy had increased by about 30 years.
- Most people lived beyond their 65th year.
- Only around one in 200 of all deaths was due to infection.
- Three-quarters of all deaths were now due to cancer and cardiovascular diseases.

Dietary advice and guidelines these days are aimed not just at ensuring adequacy and preventing deficiency but also at preventing or delaying the onset of these ‘diseases of

industrialisation' or 'diseases of longevity'. Most nutritionists and dieticians would agree that a prudent diet should be built around starchy staples such as potatoes, bread and other cereals. It should have substantial amounts of fruit and vegetables (at least five portions a day), moderate amounts of lean meat, fish and low fat dairy produce (or vegetarian alternatives) with only sparing inclusion of sugary and fatty foods. This diet is visually represented in the USA by a 'food guide pyramid' (Figure 1.1) and in Britain by a 'food guide plate' (Figure 1.2). This is not the diet that most affluent people choose to eat when guided just by preference and convenience. Fats and sugars improve the palatability of foods whereas starchy foods are essentially bland. As populations become more affluent and the economic and supply constraints upon food selection are loosened, populations tend to replace much of the starchy food in their diet with more expensive and more palatable foods. They tend to choose diets that are rich in fat and sugar but low in starch. In a poor population, starch may provide three-quarters of the daily calories consumed, whereas in Britain and the USA it provides only around a quarter. Increasing affluence and industrialisation generally lead to a sharp decline in the consumption of cereals and potatoes and increased consumption of meat, dairy foods, sugar and sugary products, and fats and oils. Figure 1.1 also shows in 'food guide pyramid' form what the diet that Americans (and Britons) actually choose to eat is like.

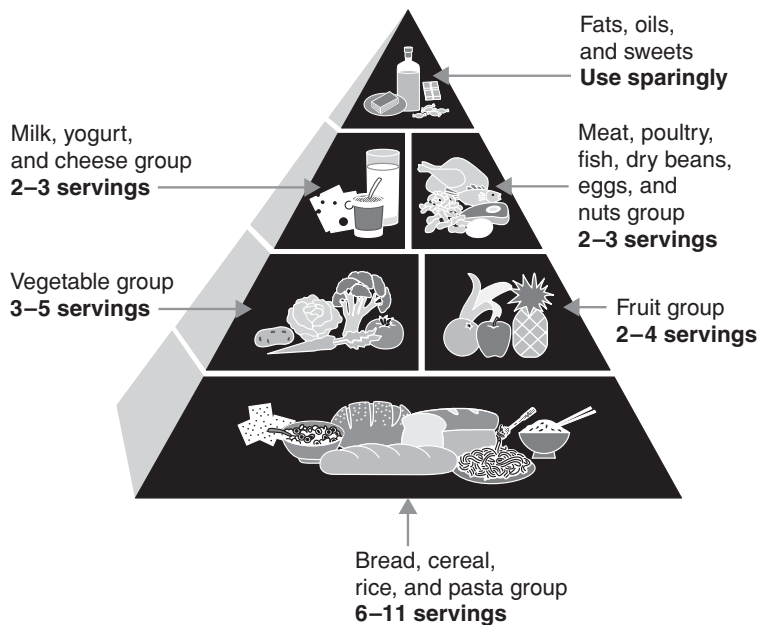
Supplements versus dietary change for the prevention of chronic disease

It is sometimes argued that health promotion and dietary guidelines are pointless because people ignore advice about diet and health. This does not seem to be consistent with the health-driven changes in the British diet that have occurred in the past few decades. Despite their preferences, many people have been prepared to make changes in their diet in order to improve their weight control and long-term health prospects. Some aspects of the typical British and American diet have been transformed by health promotion. Table 1.1 charts some of these health-driven dietary changes in Britain in the last 25 years of the twentieth century.

Most people nowadays are aware that deficiency diseases can be cured, and that adequate intakes of essential nutrients can be assured either by taking purified nutrients as supplements or in fortified foods. By analogy, perhaps some of the benefits of a modern recommended diet could be obtained by taking supplements that contain the active ingredients of foods that may help to prevent diseases such as cancer, heart disease and osteoporosis. This would allow us to eat our preferred 'unhealthy' fat- and sugar-rich diet but still enjoy at least some of the health benefits of eating a more prudent diet. Most of the dietary changes listed in Table 1.1 involve simple substitution of a traditional and perhaps preferred product by a similar product that is perceived to be healthier. Many people are prepared to make these relatively simple and painless substitutions for health reasons but may be less willing to make more complex and far-reaching structural changes to their diet. 'Popping a pill' or buying a modified functional food could be seen as the ultimate example of this willingness to make changes that are easy, convenient and painless. For example:

- Instead of eating five daily portions of antioxidant-rich fruit and vegetables we could take the substances that have antioxidant properties in pill form.

Food Guide Pyramid



Food Consumption Pyramid The Average American Diet

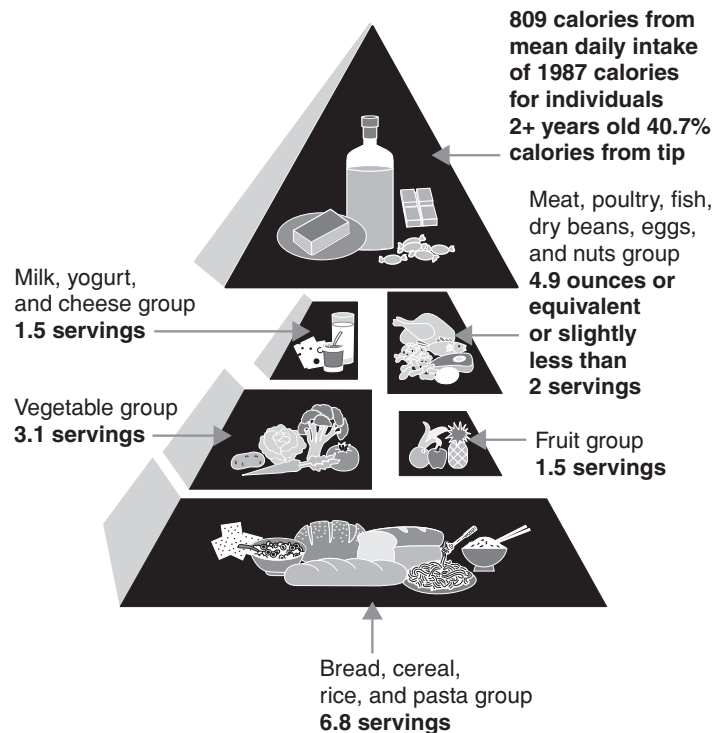


Figure 1.1 What Americans really eat. Redrawn with permission from figures previously published by the Cattlemen's Beef Board and National Cattlemen's Beef Association, 2003. Source: US Department of Agriculture and the US Department of Health and Human Services.

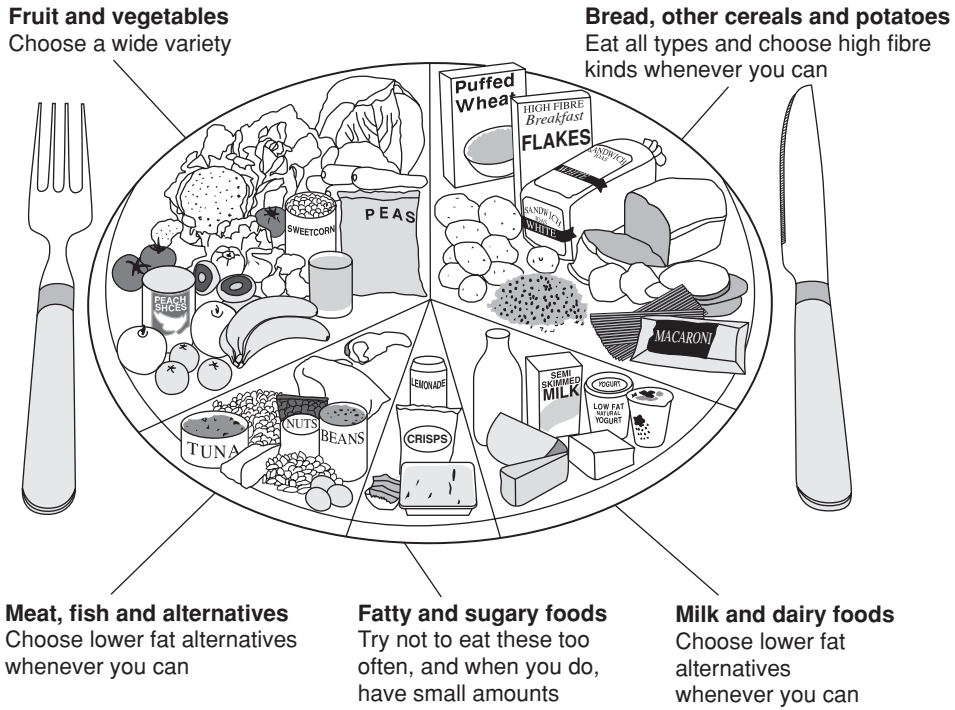


Figure 1.2 The UK National Food Guide – the tilted plate model. Redrawn with permission from the Health Education Authority/Food Standards Agency, London.

Table 1.1 Health-driven changes in the British diet in the last quarter of the twentieth century.

<ul style="list-style-type: none"> • Butter has decreased from around 70% of the 'yellow fat' market to around 25%. • Low fat spreads have increased from zero to capture over half the yellow fat market. • Vegetable oil has increased from less than a quarter of the cooking fat market to more than three-quarters. • Animal fats have decreased from over three-quarters of the cooking fat market to under a quarter. • Low fat milk (skimmed and semi-skimmed) has increased from almost zero to around two-thirds of milk sales. • Low calorie soft drinks have increased from very little to over 20% of the soft drink market. • Sales of sugar <i>per se</i> have decreased by around two-thirds. • Sales of wholemeal bread have risen from very small to almost a fifth of bread sales. • Around a third of men and half of women take some dietary supplements.

- Rather than eating one or two portions of oily fish each week we could swallow capsules containing fish oil.
- Rather than eating foods naturally rich in dietary fibre we could sprinkle wheat bran onto our preferred low-fibre foods or buy a fibre-enriched breakfast cereal.

- Rather than eating a diet that is low in saturated fat and cholesterol, to lower our blood cholesterol we could use margarine that contains a plant sterol that reduces blood cholesterol concentration by interfering with cholesterol absorption.

Dietary supplements and natural remedies as a safer alternative to modern medicine?

In recent decades, major scientific and engineering advances have led to increasing development of expensive, high technology medical and surgical procedures and drug therapies. Paradoxically, recent decades have also seen increased numbers of people turning to alternative medical therapies which often have little or no formal scientific basis and may be based upon traditional folk medicine or upon theories put forward before the explosive growth of scientific knowledge in the twentieth century. Many alternative therapies emphasise the importance of a 'good diet' in maintaining and restoring health. The perceived 'naturalness' of many of these therapies contrasts sharply with the high technology image of modern medicine. The media provide us with an endless stream of stories about iatrogenic (physician-induced) problems, which may undermine confidence in the safety of modern medicine. Stories abound about medical accidents, untoward side-effects of common treatments, hospital acquired infections, and patients being infected by infected health workers, surgical instruments or contaminated therapeutic products.

In these circumstances, people may see diet therapy, dietary supplements and non-invasive alternative therapies as a safer, less technological and more natural way of maintaining health and treating illness. If something is naturally present in the diet and is perhaps even an essential nutrient then surely it must be safer to take than an artificially manufactured or genetically engineered drug? Self-selected supplements or alternative therapies also allow people to play a more active role in their own health management rather than being passive recipients of whatever treatment the health 'expert' decides to administer. These alternatives may be seen as empowering the individual patient/consumer and shifting the locus of control away from the medical establishment.

People may also turn to these alternatives when orthodox medicines or surgery 'fail'. Despite the undoubted advances in conventional medical and surgical therapy they still have limits; many of the fatal or chronically disabling conditions which are responsible for most deaths and disability are, by definition, still incurable.

It would be unwise to assume that high doses of purified nutrients, food extracts or herbal products are always harmless. Overdoses of several nutrients have well-known toxic and potentially fatal effects, such as vitamins A and D and iron. Indeed, iron poisoning is the most common cause of accidental poisoning in children. It is also believed that there may be adverse long-term consequences associated with other supplements such as large β -carotene supplements taken to prevent cancer and heart disease, which may actually accelerate development of these conditions in some groups (see Chapter 5). Many common foods contain natural toxicants and these may become hazardous if unusually large amounts or concentrated extracts of a food are consumed regularly. Many conventional medicines are derived from substances present in plants. These may be harmful in excess. Some potent poisons are also of plant origin (for a list of examples see the section on alkaloids in Chapter 8).

In this book I shall look at the suggested effects of particular supplements and any scientific rationale for these effects, and overview the evidence of their effectiveness. I shall also deal with safety issues and any evidence of harmful effects. If supplements have the potential to improve health and alleviate illness it would be illogical not to consider that they also have the potential to do harm.

Defining dietary supplements

The definitions that are taken for dietary supplements and functional foods in this section will determine the scope of the book. The broadest definitions of dietary supplements and functional foods would make the scope of this book impossibly large. Dietary supplements could include food preparations designed to meet all or part of the nutritional and energy needs of invalids, sports drinks, slimming foods and hundreds of herbal medicines that can be marketed as dietary supplements. The term functional foods could include every fortified food and every food for which some sort of health claim has been made, such as most breakfast cereals (see Chapter 9 for definition of functional foods).

There are many formal definitions of dietary supplements which attempt to specify what is and what is not covered by the term. Some of the important elements of these definitions are listed below and in general only substances that satisfy these criteria have been included. I have not attempted to produce a contrived definition but rather to specify what is and what is not covered in the book and also to produce a logical classification of the types of supplements in common use.

- They are taken orally and in specified doses in the form of pills, capsules, powders or liquid preparations.
- They are intended to be additional to the normal diet.
- They are not the sole source of energy or fluid or a major contributor to the energy or fluid intake.
- They usually carry some health claims either on the label or in other promotional material (for example in sales brochures or press advertisements).
- They may be classified into the following three broad categories.
 - Substances that are accepted by nutritionists as essential nutrients, such as vitamins, minerals, trace elements, essential fatty acids and amino acids are dealt with in Chapters 2–6. Antioxidants are also dealt with in Chapter 5. Some vitamins and minerals have important antioxidant functions, but some substances not considered essential nutrients may nevertheless have useful antioxidant effects and so are included in this discussion.
 - Substances that are natural body metabolites and/or are naturally present in the diet but which are not considered to be essential nutrients, at least for most people under normal circumstances, are dealt with in Chapter 7. Additional intakes of these supplements may be claimed to have health benefits or even the potential to alleviate disease.
 - Some supplements of plant or occasionally animal materials or extracts that contain substances in the above categories or other pharmacologically active substances are

claimed to have health enhancing properties (such as garlic, ginseng, *Ginkgo biloba* and royal jelly). A selected list of some of the most commonly used of these substances and those with the most claim to be derived from potential foods are dealt with in Chapter 8.

Legal regulation of dietary supplements (UK perspective)

Medicines

A medicine is a substance that is used to cure, treat or prevent a disease. The EU further decrees that a substance ‘administered . . . with a view to making diagnosis or restoring, correcting or modifying physiological functions’ is also considered to be a medicinal product. In the UK, and in many other countries, only substances licensed as medicines are permitted to make medicinal claims, – claims that they can cure, prevent or treat a disease. In the UK, control and licensing of medicines is the responsibility of the Medicines and Healthcare Products Regulatory Authority (MHRA). In order to obtain a product licence, medicines must satisfy this authority as to their safety and effectiveness. Some medicines can be sold over the counter at a variety of retail outlets (GSL, general sales list medicines), some can be sold only in pharmacies (P) and some are prescription only medicines (POM), which can be provided only if prescribed by a medical practitioner or sometimes another health professional.

A few of the substances used as dietary supplements are also licensed medicines: some generic vitamins (vitamins A and D, folic acid and cyanocobalamin, vitamin B₁₂); a multi-vitamin preparation designed to meet the needs of children (Abidec); a fish oil preparation (Maxepa); and an iron and folic acid supplement intended for pregnant women (Pregaday). It is permissible to make medicinal claims for these products, for example that Maxepa lowers raised plasma triacylglycerols and so helps to prevent heart attacks and pancreatitis. Other fish oil preparations marketed as dietary supplements are not allowed to make such claims. Similarly, it is permissible to refer to Pregaday’s role in reducing the risk of babies being born with a neural tube defect but such claims are not allowed for other dietary supplements that contain folic acid. This difference between medicines and dietary supplements is highlighted by the recent withdrawal of medicinal licences for two preparations of evening primrose oil, Epogam and Efamast. These have been widely used and prescribed to treat eczema and mastalgia (breast pain), but more recent evidence has persuaded the licensing authority that the evidence for their efficacy does not meet the current standard required for licensing for the treatment of these conditions. Evening primrose oil was freely available as a dietary supplement (whilst these two products were licensed as medicines) and continues to be available, but claims that it is effective in treating these conditions are not now legal for any evening primrose preparations.

Some herbal remedies are exempt from licensing if they consist solely of a dried or crushed part of the plant which is sold under its botanical name with no written recommendations for use on the packaging and provided they are made by a person who holds a special manufacturing licence. This so-called ‘section 12 exemption’ (of the Medicines Act) was intended to be used by herbalists who produce their own remedies for supply to

their patients. It is also possible for manufacturers to sell products under this exemption. The MHRA has indicated that it proposes to repeal this latter category of section 12 exemptions; there are also moves to review the legal regulation of herbalists (see <http://medicines.mhra.gov.uk/>).

Non-medicinal supplements

To get a medicine licensed can take up to a decade and cost many millions of pounds; this is why many manufacturers of nutrients, ‘natural substances’ and herbal preparations choose to market them as dietary supplements instead. This means that they are subject to legal regulations relating to food rather than to medicines. Anything which is taken orally and not classified as a medicine is, by default, classified as food. This has major commercial advantages for the manufacturer who not only bypasses the expensive and slow process of getting the product licensed but is also subject to the much less stringent legal regulations relating to food. It is illegal to sell food which is harmful to health and it is illegal to dishonestly describe or advertise a food. This means that although it is illegal to make false health claims for a dietary supplement it is the prosecution that must ‘prove’ a claim to be false, whereas a medicine must be shown to be safe and effective before it is licensed. In the UK, there has been no agency similar to the MHRA to oversee the regulation of dietary supplements; enforcement of food safety laws and advertising claims has been the responsibility of environmental health officers and trading standards officers employed by local authorities.

Health claims

Even though medicinal claims for foods and dietary supplements are not permitted, more general health claims that do not imply that the supplement prevents or treats a specific disease are permitted in the UK. Some examples are listed below.

- Not acceptable
 - ‘contains calcium which helps to prevent osteoporosis’
 - ‘prevents heart disease’
 - ‘helps to prevent cancer’
 - ‘helps to prevent or treat arthritis’
 - ‘prevents colds and flu’
 - ‘treats eczema’
- Acceptable
 - ‘contains calcium which is important for strong bones’
 - ‘helps to maintain a healthy heart’
 - ‘helps to mop up excess cell-damaging free radicals (these may contribute to many of the diseases of old age)’
 - ‘helps to maintain healthy joints’
 - ‘helps to maintain a healthy skin’
 - ‘helps to maintain an effective immune system’
 - ‘helps to maintain normal blood cholesterol levels’

In the UK, the Joint Health Claims Initiative is a joint venture between consumer organisations, enforcement authorities and industry trade associations set up to establish a code of practice for health claims (JHCI 1997). They were set up in 1997 in response to the growth in the functional foods market. Their stated aim is to ensure that health claims on food are:

- Scientifically true
- Legally acceptable in the UK
- Meaningful to consumers and not confusing.

Legal regulation – the European (EU) dimension

There have recently been initial steps taken towards harmonisation of the legislation relating to food supplements within the European Union (EU). Currently each individual member state has its own regulations which vary enormously from country to country. The first stage in this process was the Food Supplements Directive which was passed into EU law in 2002 and has now been integrated into the national laws of the member states (in the UK as the Food Supplements (England) Regulations 2003). These regulations are due to come into force on 1 August 2005. They define a food supplement as any food the purpose of which is to supplement the normal diet and which:

- (1) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination
- (2) is sold in dose form.

Dose form means substances sold as pills or capsules, sachets of powder, or liquids or powders designed to be taken in small measured unit quantities. These regulations contain two positive lists which may be seen in the Food Supplements (England) Regulations 2003. These two positive lists are:

- A list of vitamins and minerals which may be used in the manufacture of food supplements
- A list of the forms in which these vitamins and minerals may be used in the manufacture of food supplements.

The ultimate intention is that any substance not present in these positive lists cannot be used in food supplements. The first list does not contain, for example, boron or vanadium which have in the past been included in some dietary supplements. Several forms of vitamins and minerals that have been widely used are also not present in the second list. The three-year delay in implementing these regulations was intended to allow manufacturers to modify their products in order to comply with the new regulations. Substances that are not on these lists may still be legally sold until 1 January 2010 if:

- The substance was on sale in the EU in July 2002.
- A dossier has been submitted by an agency from a member state supporting the use of the substance by July 2005.
- The European Food Safety Authority has not given an unfavourable opinion of the substance.