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Food Control 12 (2001) 99–107

FOOD CONTROL

www.elsevier.com/locate/foodcont

Functional foods. Part 1: the development of a regulatory concept

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Received 25 September 1999; received in revised form 6 July 2000; accepted 6 July 2000

Abstract

As a number of functional foods have been already introduced into the international market, their claims of health benefits may challenge the traditional border between food and medicine. As a result the position of functional foods within existing categories in the regulatory system is vague. The regulatory concept of functional foods on the basis of Japanese and international concepts has been examined in view of the approaches in other countries. From the examination, it is generally agreed that functional foods should provide health benefits over and above their normal nutritional values within daily dietary patterns. In order to clarify the scope of functional foods their relationship with food and drugs is also examined. © 2000 Elsevier Science Ltd. All rights reserved.

Keywords: Functional foods; Dietary supplement; Regulatory concept

1. Introduction

As society has become more complex and life changes swiftly, and the environment has become more polluted, people often show symptoms of tiredness, depression, and irritation, or more generally, a form of weariness (Hue and Kim, 1997). In addition, many parts of industry have been mechanized, physical work at home has been reduced by automation, and public transport systems have been developed. The result is that many people do not regularly obtain physical exercise from their daily activities and need to take exercise for their health. An additional consideration is that the use of chemical fertilizer and abundant processed food may cause an imbalance in nutrition intake – an excess of macronutrients and possible shortage of micronutrients or other beneficial non-nutrients.

Over half a century ago, the founders of the World Health Organisation defined health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (Anon., 1998f). This implies that people should be in perfect condition – not that they do not need any medical treatment. This concept of health status can be displayed in the form of a continuous graph (Fig. 1), on which health can be classified into three levels (Hue and Kim, 1997). At the highest level, classified as the 'health state', people are in good condition and work freely and they do not have any symptoms relating to weariness or disease. In the 'disease state', people have explicit symptoms relating to disease which require treatment. In the 'semi-health state', between the health state and the disease state, people feel generally weak and can display various symptoms (tiredness, depression, irritability) and these symptoms can affect their ability to manage life.

As chemical and biological sciences have developed and the cost of treating chronic disease has increased, the focus of medicine has moved from the treatment of disease to its prevention (Hue and Kim, 1997). This change means that not only patients in the 'disease state' but also potential patients, who are in the 'semi-health state' should be managed in the health service sector. It is this sector which is the main market for functional foods. Arai (1996) stated that "any functional food should be used for the prevention of a disease at the stage when it is premonitory, not as a remedy for a disease at the stage of development." It is this approach which has established the concept of functional foods in Japan.

The concept of functional foods is not a totally new concept. In the countries of the Far East, influenced by Chinese culture, food and drugs have, by many, been thought of as materials from the same source (KoJima, 1996). In some cases, they are referred to as

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PII: S0956-7135(00)00028-1

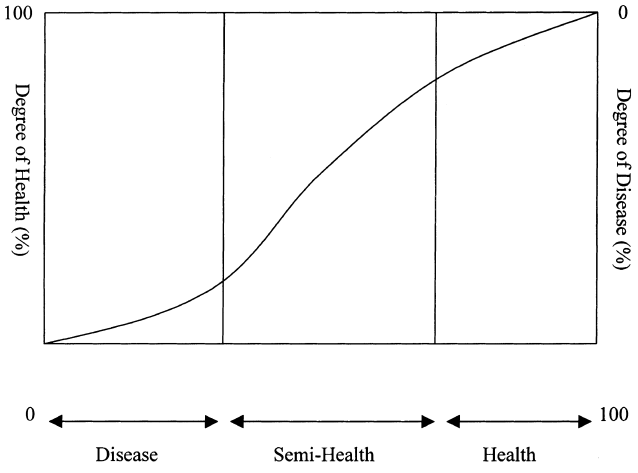

Fig. 1. Concept of health and disease.

isogenous. 365 different animals, plants, and minerals were recommended as sources of medicine in the old Chinese medicine book 'Shinongbonchokyung' (Hue and Kim, 1997). These were divided into three classes: 'High Class' containing medicine used for chronic disease, 'Middle Class', and 'Low Class' containing medicine used for acute disease because of their strong toxicity. The medicines classified as High Class includes conventional foods, such as glutinous rice, wheat, sesame, jujube, ginger, and leek. This shows that the staple diet was considered a major part of the prevention and treatment of chronic disease. Building on this concept, many conventional foods are now being considered health foods in Korea, Japan, and China.

So far a large number of functional foods in various forms have already been introduced into the market. Many of them contain a number of characteristic functional ingredients. They include dietary fibre, oligosaccharides, sugar alcohols, peptides and proteins, prebiotics and probiotics, phytochemicals and antioxidants, and polyunsaturated fatty acids (Stark et al., 1994). Roberfroid classified substances which can lead to production of functional foods (Roberfroid, 1997):

(i) an essential macronutrient having specific physiological effects, such as resistant starch or omega-3 fatty acids;
(ii) an essential micronutrient if it confers a special benefit through the intake over and above recommended daily intake (RDI);
(iii) a non(essential)-nutrient giving specific physiological effects, such as some oligosaccharides and phytochemicals.

Unlike functional ingredients, the target functions of functional foods are quite diversified, while reflecting regional trends of nutrition policy and research. It would be difficult to classify them at this stage. In the case of the EU, International Life Science Institute (ILSI) Europe summarised the situation as follows (Diplock et al., 1999):

(i) growth, development and differentiation (e.g., maternal adaptations during pregnancy and lactation);
(ii) substrate metabolism (e.g., maintenance of appropriate body weight);
(iii) defense against reactive oxidative species (e.g., preservation of structural and functional activity of DNA);
(iv) cardiovascular system (e.g., lipoprotein homeostasis);
(v) intestinal physiology (e.g., optimal intestinal function and stool formation);
(vi) behavioural and psychological functions (e.g., cognitive performance).

With the change of nutrition concept, from essentiality to optimality, several factors have contributed to the development of functional foods. One of the factors may be the increase of health-consciousness of consumers who desire to improve the quality of their life and are significantly influenced by mass media. According to the market report published by Leatherhead Food Research Association, consumers were of the view that, "the three most important factors contributing to health are diet, exercise, and genetic factors" (Hilliam, 1996). Among those factors, "diet was perceived to be the most important factor, cited by 70% of German respondents, 68% of UK respondents, and 55% of French respondents". Responding to the demand of consumers, industry has conducted research on nutrition as well as food technology. As a result, many types of functional or health foods have been introduced into the market.

From the governmental point of view, functional foods also have a significant implication. The increase in the average span of people's life has resulted in an increase in the number of elderly people. The average life expectancy of birth of total WHO member states has increased from 46 years in the 1950s to 65 years in 1995, and is estimated to be above 70 years by 2020 (Anon., 1998f). Therefore, the rising cost of healthcare is of primary concern in many parts of the world. The cost of healthcare in European countries in 1995 was, for example, estimated to be, on average, around 8% of the gross domestic product, approximately one percentage point higher than it was a decade ago (Diplock et al., 1999).

In this regard, the government has been concerned about the aging of the country's population and the resultant cost of healthcare in Japan, where the life span is the longest in the world (Ichikawa, 1994). As one of possible means of reducing the cost, the government has encouraged the development of functional foods. This is considered to be one of the reasons for the popularity of functional foods in Japan.

2. Definition of functional foods

Although the present concept of functional foods originated in Japan it has been evolving internationally and the concepts vary at the national level since they have been influenced by various national factors. These include national differences in culture, the differences in approach to nutrition science, and the different market situation found in countries. The concept of functional foods originated from the traditional concept in Far Eastern countries that a food can function like a drug. While this concept has now spread to other countries, including Western countries, it has to be considered within the context of their own national diet and culture. To date a number of national authorities, academic bodies and industry have proposed definitions for functional foods.

The lack of an agreed terminology may not seem to be a direct obstacle to the development of a mature market since consumers are more attracted by a health message rather than the use of a particular legal term. In addition, it may appear unnecessary for scientists to spend their time discussing the definition of functional foods (Pascal, 1996).

However, in order to achieve adequate regulatory control, an explicit definition of functional foods is crucial. Common terminology must be the basic requirement on discussing the relating issues among academy, industry and government. Without it, it is possible that what one person calls a functional food can be considered by other people only more nutritious (Schmidt et al., 1998).

In addition, although the techniques used by national authorities to control foodstuff by legislation vary greatly, one of the key issues in the establishment of a new legal control or the revision of existing controls, is the clear recognition of the objects affected by the new or revised regulations. The clear definition of the targeted products or sectors is always important. Failure to provide such clarity leads to legal uncertainty and confusion.

A detailed consideration of the various definitions of functional foods (and of related terms) used or proposed by countries or market sectors can also demonstrate what regulators, scientists, and businessman think about functional foods and other similar products. This paper therefore will first consider the definitions of functional foods used in various places and will then discuss the terms, food and drugs with a close relationship to them.

2.1. Japan

The term 'functional foods' was first introduced in the reports on ''Systemic Analysis and Development of Food Functions'' sponsored by the Ministry of Education, Science and Culture during 1984–1986 (Hue and Kim, 1997). In these reports, the functions of food were divided into three categories based on the history of food consumption patterns in Japan (Arai, 1996). They stated that, ''Since any food is basically a supplier of nutrients to the body, its nutritional function is naturally understood to be of primary importance. This can probably be recognised as true in almost any part of the world in any period of history.'' This adequate supply of nutrients therefore defines a 'primary function'. After meeting this primary function, people's choice is then based on preference including matters of sensory satisfaction such as taste and flavour – this can be considered the 'secondary function'.

During the 1980s people began to seriously recognize the potential problems which were likely to arise with the rapidly advancing age of the population. Consideration was then given to the possible prevention of adult and geriatric disease through improved daily dietary practice. Many studies which have considered the role of foods in disease prevention have demonstrated, ''there are variety of substances originating in food with tertiary functions that can be expected to be involved in preventing disease by modulating the immune, endocrine, nerve, circulatory and digestive systems.'' This therefore provides the 'tertiary function' which functional foods seek to develop.

In 1988 the Japan Ministry of Health and Welfare (MHW) established a Meeting for Functional Foods in order to propose how to control these foods (Hue and Kim, 1997). In its interim report, functional foods were defined as foods designed and processed in order to sufficiently express the functions relating to the body defense mechanism, control the body rhythm, the prevention and recovery from disease (Anon., 1994a). It should also satisfy the following conditions:

(i) it should consist of conventional ingredients or compositions and be consumed in the conventional form or method of food;
(ii) it should be consumed as part of staple diet;
(iii) it should be labelled as having body control function.

It should be emphasized that this role of food incorporates functions which had previously been permitted only for drug, although, as food, it is required to work within the context of a staple diet.

In 1990 a Review Body of Functional Foods was established by the MHW so as to incorporate functional foods into the Nutrition Improvement Law (Hue and Kim, 1997). However in its report, the term 'foods for specified health use' (FOSHU) was used instead of functional foods. There was concern that the primary (nutrition) and secondary (preference) functions may be neglected by the emphasis of the tertiary function (Anon., 1991b). In addition, the term 'function' in functional foods might be confused with the term 'function' in medicine. Based on this report, the MHW

in 1991 laid down the guidelines on FOSHU permission, where FOSHU is officially defined as a sub-group of the category, foods for special dietary uses and where the labelling suggests that people who consume it in the diet may achieve the intended health benefits (Anon., 1991a). In addition, it should satisfy the following criteria:

(i) the food should be expected to contribute to the improvement of one's diet and the maintenance/enhancement of health;
(ii) the health benefits of the food or its constituents should have a clear medical and nutritional basis;
(iii) based on medical and nutritional knowledge, an appropriate daily intake should be definable for the food or its constituents;
(iv) based on experience, the food or its constituents should be safe to eat;
(v) the constituents of the food should be well defined in terms of physicochemical properties and qualitative/quantitative analytical determination;
(vi) there should be no significant loss in nutritive constituents of the food in comparison with those contained in similar types of food;
(vii) the food should be of a form normally consumed in daily dietary patterns, rather than consumed only occasionally;
(viii) the product should be in the form of a normal food, not in another form, such as pills or capsules;
(ix) the food and its constituents should not be those exclusively used as a medicine.

The final requirement was added at the stage of establishing guidelines whereas, other requirements were already set up by the Review Body of Functional Foods. It would be done so as to minimise possible confusions between food and drugs in the implementation of the guidelines.

2.2. ILSI

In 1995 the First International Conference on East–West Perspectives on Functional Foods was held by ILSI. By the agreement of several panels from several countries, the meeting defined functional foods as "foods that improve or affect body functions over and above their normal nutritional values" (Anon., 1996). This can be considered as the first definition that has been internationally agreed. The meeting also agreed the following:

(i) functional foods should be distinguished from vitamins, minerals, and other dietary supplements;
(ii) these foods should not be allowed to be included in medical claims;
(iii) The altered functional effects of the foods must be substantiated and scientifically proven through laboratory and human studies.

The approach adopted at this meeting was broadly in agreement with that adopted in Japan. Taking into account the original and international perspectives, approaches to the definition in other countries will be compared to those of Japan and ILSI.

2.3. UK and EU

In August 1995, the UK Ministry of Agriculture, Fisheries, and Food (MAFF) temporarily defined a functional food as "a food that has had a component incorporated into it to give a specific medical or physiological benefit, other than a purely nutritional effect" (Richardson, 1996). Although medical benefit is involved in the definition it is recognised in the code of practice on health claims on foods that the labelling on medical benefit is prohibited by law (Anon., 1998d).

As a working definition, ILSI Europe proposed that a food can be regarded as 'functional', "if it is satisfactorily demonstrated to affect beneficially one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either an improved state of health and well-being and/or reduction of risk of disease" (Diplock et al., 1999).

It also required the functional foods to:

(i) remain as foods;
(ii) demonstrate their effects in amounts that can normally be expected to be consumed in the diet;
(iii) be consumed as part of a normal food pattern (i.e., not as pills or capsules).

Both of these definitions do not seem to differ from the definitions of Japan and ILSI. In 1996, at an IBC conference entitled "Functional Food, Nutraceutical or Pharmaceutical?" Potter (1996) stated that "functional foods can be interpreted in many different ways and can lead to confusion since after all, is not all food functional?" It was here that the concept of *positive nutrition* was used instead of the direct introduction of their concept. Positive nutrition was defined as "the consumption, as part of the normal diet, of everyday food and drink products that can provide positive health benefits". Positive health effects include a reduction in blood cholesterol levels, the promotion of a healthy digestive system, increased resistance to disease, the promotion of healthy teeth and bones, provision of energy, and perhaps even reducing the risk of contracting some forms of cancer. Positive nutrition may be conceptually similar to the Japanese and ILSI definitions although it does include, in addition, some normal nutritional health benefits such as energy.

2.4. USA

In the USA a number of health claims have been already permitted under the rules of the Nutrition Labelling and Education Act 1990 (Anon., 1997a). Functional foods can be sold with a health claim on the label once permission from the USFDA has been obtained. Although a legal definition in the USA does not exist,

the Institute of Medicine of the US National Academy of Sciences defined functional foods as those that, to encompass potential healthful products, ''include any modified food or food ingredient that may provide a health benefit beyond the traditional nutrients it contains'' (Anon., 1994b). This is consistent with the definitions of Japan and ILSI in that they should have a health benefit beyond traditional nutritional values. It however seems to be wider than the definitions of Japan and ILSI in that a food ingredient itself can be considered a functional food. In other words, dietary supplements, which are composed of only food ingredients and which are in the form of a tablet or something similar, can be considered as functional foods. Even the term 'functional food pill' is mentioned in a paper from the USA (Schmidt et al., 1998). This approach may reflect a unique policy on dietary supplement in the USA.

2.5. Australia

In the preliminary definition by the Australia New Zealand Food Authority, functional foods were defined as ''Functional foods are similar in appearance to conventional foods and are intended to be consumed as part of a normal diet, but have been modified to serve physiological roles beyond the provision of simple nutrient requirements'' (Preston and Lawrence, 1996).

This does not seem to be different from the definitions of Japan and ILSI.

3. Food and drugs

In western countries, a clear distinction between food and drugs has been incorporated into their regulatory system for a long time (Preston and Lawrence, 1996). This tendency can also be found in many eastern countries where many parts of their regulatory system have been imported from western countries with certain minor exceptions. As stated earlier it is generally agreed that functional foods are food and not drugs. Functional foods may however challenge the clear distinction between food and drug, which could lead to confusion. Therefore it is necessary to review the relationship between food and drugs so as to clarify the scope of functional foods.

This distinction will be considered in two ways:

(i) national or international definitions of food and drugs,

(ii) practically recognised concepts of food and drugs.

3.1. From the viewpoint of the national or international definitions of food and drugs

For the purposes of the international Codex Alimentarius, food is defined as follows (Anon., 1995):

> Any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of 'food' but does not include cosmetics or tobacco or substances used only as drugs.

In the EU, most member states have already established their own definitions of foodstuffs. For example, in the UK the definition of food is laid down in Food Safety Act 1990 as follows (Anon., 1990):

> Food includes (a) drink, (b) articles and substance of no nutritional value which are used for human consumption, (c) chewing gum and other products of a like nature and use, and (d) articles and substances used as ingredients in the preparation of food or anything falling within this subsection. Food does not include ... (d) subject to such exceptions as may be specified in an order made by the Ministers – (i) medicinal products within the meaning of the Medicines Act 1968 in respect of which product licences ... are ... in force; or (ii) other articles or substances in respect of which such licences are ... in force ...

However, a legal definition of foodstuffs does not exist at the EU level, which suggests that the implementation of EU legislation in member states may vary depending upon the various national interpretations of the word. At the request of the European Parliament, the European Commission has been initiated the development of a more structural approach to food law which would incorporate a definition (Anon., 1997b). A definition, based on that in the Codex Alimentarius, was proposed by the Commission in a discussion paper as follows:

> 'Foodstuff' means any substance or product, whether processed, partially processed or unprocessed, intended to be ingested by humans, with the exception of tobacco ..., medicinal products ..., and narcotic or psychotropic substances controlled by member states pursuant to the relevant international conventions.

In the USA, the term 'food' is defined in the Federal Food, Drug, and Cosmetic Act as ''(i) articles used for food or drink for man or other animals, (ii) chewing gum, and (iii) articles used for components of any such article'' (Anon., 1998a).

The term 'food' in Korea is defined as all kinds of food and drinks excepts those ingested as medicine (Anon., 1998e). It would be a concise definition reflecting the above definitions of food or foodstuffs. In this context, the definition of drug or medicine is crucial to

determine the scope of foodstuffs. It can be noted that, although the definition of food in the USA does not mention the term 'medicine' or 'drug', it may be because food and drugs are separately defined within the same act, the Federal Food, Drug, and Cosmetic Act. The definitions of drug or medicine seem to be more sophisticated and explicit.

In the USA the term 'drug' means (Anon., 1998b):

(a) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;

(b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

(c) articles (other than food) intended to affect the structure or any function of the body of man or other animals;

(d) articles intended for use as a component of any article specified in clause (a), (b), or (c). A food or dietary supplement for which a claim, ..., is made in accordance with the requirements of section [relating to nutrition levels and health-related claims] is not a drug solely because the label or the labelling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section [relating to a statement for a dietary supplement] is not a drug ... solely because the label or the labelling contains such a statement.

In the EU, medicinal products are defined as follows (Anon., 1965):

(i) any substance or combination of substances presented for treating or preventing disease in human beings or animals;

(ii) any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is like wise considered a medicinal product.

In Korea, medicinal products are defined as (Anon., 1998g):

(i) articles recognized in the official Korea Pharmacopoeia, except sanitary products;

(ii) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals, except apparatus and machinery;

(iii) articles intended to affect the structure or any function of the body of man or animals, except apparatus, machinery and cosmetics.

In addition, Chinese medicine is also defined as natural medicine derived from animal, plant, or minerals and dried, cut, or refined in the original form.

The above definitions of drug or medicine are more similar to each other than is the case of with the definitions of food. This is understandable taking into account that the control of drug or medicine has been more internationally harmonised. The conditions of drugs or medicines reflected in the above definitions can be summarised as follows:

(i) treatment and prevention of disease;

(ii) administration to make medical diagnosis;

(iii) restoring, correcting or modifying physiological functions in human beings.

Of these three conditions, the first and third have implications for functional foods whereas the second provides only a medical meaning.

With respect to the first condition, a product which might reduce the risk of a disease would not be considered as a drug is generally considered as an alternative to escape the existing conflict of legal requirements between food and drugs. It is considered possible that if people place an excessive belief in the potential of food to prevent disease, they may fail to obtain medical treatment in time and thus allow the disease to go untreated. However, health benefits by foods – including the reduction of disease risk – should be informed consumers of for the improvement of diet. This approach was proposed in the Codex Committee on Food Labelling in 1999 by the delegations of France, CIAA, Canada and ILSI (Anon., 1999a,b,c,d). Through this approach, the legal distinction between food and drugs becomes clearer although the actual implementation may not be as simple.

The third condition listed above has a more complicated implication. The present knowledge of disease development is not sufficient to clarify the role of a large number of functional ingredients. A series of complex research, which spend enormous resources, is therefore required for the substantiation of any proposed claim. Even pursuing the fully agreed substantiation would prevent the investment to the research. In this regard, ILSI Europe has proposed 'enhanced function claims', which concern "specific beneficial effects of nutrients and non-nutrients on physiological, psychological functions or biological activities" (Diplock et al., 1999). This was also proposed in the Codex Committee on Food Labelling in 1999 by the delegations of France, the CIAA, and ILSI (Anon., 1999a,b,d). A sort of claims – nutrient function claims – have been already agreed in the Codex, (e.g., calcium aids in the development of strong bones and teeth). These claims are based on generally agreed scientific evidence, which have been produced for a long time. Claims on the function of substances relating to functional foods are usually based on new scientific evidence, which is often controversial, in many cases not internationally agreed. Despite this, certain claims for the function of substances are being used in the market and may be misleading consumers.

In the USA, where health claims and nutritional statements for a dietary supplement have already been

permitted, these two difficult issues (i.e., the relationship with disease and the function of substances) are addressed in the fourth condition of the definition of a drug. The issue of the relationship with disease seems to be properly controlled since the US FDA has the power to review proposed claims before they are used (Anon., 1998c). Claims for the function of substances are however raising more difficult issues. This is because manufacturers of dietary supplements do not need to go through the US FDA's approval under the DSHEA 1994 and no guidelines has yet established in terms of the claims for foodstuffs. In order to cope with this turmoil the US FDA has proposed regulations on statements made for dietary supplements concerning the effect of the product on the structure or function of the body in 1998 (Anon., 1998h). However, it has not proposed any regulations on the claims for ordinary foodstuffs.

In most countries, medicines are divided into a number of categories for the purpose of retail sale or supply. For example, in the UK, medicines for human use are categorised into the following (Anon., 1997c):

(i) *General sale list* (GSL): "medicinal products which can be sold with reasonable safety without the supervision of a pharmacist, for example in a supermarket."

(ii) *Pharmacy* (P): "medicinal products which do not require a prescription and may be sold or supplied only in a registered pharmacy by or under the supervision of a pharmacist."

(iii) *Prescription only medicine* (POM): medicinal products which "may be sold or supplied only from a registered pharmacy and in accordance with a prescription issued by a doctor or dentist .... [It is] due to the condition being treated requires diagnosis by a doctor or dentist and because they may produce toxic reaction or physical or psychological dependence, or may be a hazard to the health of the community."

Of these, the issues involved in establishing controls on the GSL (called over-the-counter (OTC) in some other countries) would be closest to the issues involved in establishing control strategies for functional foods. This is because GSL products are nearest to food among medical products and could be sold simultaneously with functional foods in a supermarket.

3.2. From the viewpoint of practically recognised concepts of food and drugs

To distinguish between the regulatory approaches to food and drugs, Clydesdale has suggested three criteria as follows (Clydesdale, 1997):

(i) *Targeted effect*: foods, unlike drugs, yield a future benefit rather than an immediate effect.

(ii) *Target population*: foods "provide a broad-brush treatment approach to an entire population [whereas] conversely, drugs are consumed by a targeted population of those who are ill or have medically accepted indicators of disease (e.g., abnormal lipid levels)".

(iii) *Safety*: "foods have a presumption of safety ... and are not allowed to have a benefit-risk equation applied to them, whereas the benefit-risk equation of drugs is an accepted part of their regulatory approval. ... The level of proof for drugs is well established ... internationally and does not include a presumption of safety."

He particularly emphasised that a basic criterion to distinguish between food and drugs should be their intended use. As an example, ascorbic acid can be a food or a drug depending on whether it is added with the specific intention of curing a disease or the more general improvement of a food's nutritional value. A component of a drug can be extracted from a food which is consumed daily and, in addition, a number of drugs have a caloric value. Therefore, he has suggested, "it would be logical to deal with the effects of food and its relationship to health at a level that ascribes to a food reduced risk of disease or improved biologic function, rather than prevention or cure."

This opinion exactly matches the concept originated in Japan as well as the approach proposed in the Codex described earlier.

Of the three criteria mentioned by Clydesdale, the timing of targeted effect and specificity of target population can be related to the concept of intended use. They would clarify some of the confusion between the concepts of food and drug. Several questions do however arise when considering intended use. For example, what is the relationship between foods for special dietary uses and drugs or medicinal foods? All of them have been developed for, or to target, a certain group of people. More specific discussion of these issues is provided in a separate paper (Kwak & Jukes, 2000).

With respect to final criterion, it is generally consented that food should be safe. The safety of food is considered as most important issue in a series of food chains. It is generally presumed through the national and local authorities in any country based on long history of use or an approval process (Clydesdale, 1996). Besides, taking into account foods cannot be perfectly free from harmful chemicals or microorganisms such as pesticides or *Listeria*, the level of those chemicals or microorganisms in foods are strictly controlled in order not to place people in any apparent danger. Conversely, the concept of risk/benefit ratio is applied to the approval criteria of drugs. According to the medicinal control agency, "a completely safe medicine will probably never exist. Even aspirin can occasionally cause problems so that safety is a relative term. All medicines that are effective have some side-effects and should be used only when needed" (Anon., 1997c).

4. Conclusion

On the basis of the traditional concept of the relationship between food and drugs the concept of functional foods originated in mid-1980 in Japan. With the consumers' demand to manage healthy life, the development of nutrition research has introduced a number of functional food products into the market place. Up to date, only the Japanese food laws were established so as to cope with this situation. The introduction of functional foods into the present regulatory system has been pursued nationally and internationally. However, without common terminology it is impossible to discuss this matter.

Generally speaking, the definitions of Japan and ILSI agree with those proposed in other approaches, although some of the approaches by industry and academy may tend to involve additional products beyond the scope of functional foods in Japan and ILSI – such as energy drink or dietary supplements. Especially, the approaches by national authorities in the UK and Australia are very similar to those of Japan and ILSI in a number of aspects.

In this regard, international agreement on the scope or definition of functional foods would appear to be feasible. From the definitions of functional foods discussed to date, the key requirements are as follows:

(i) a functional food should provide health benefits over and above its normal nutritional values and preference;

(ii) it is a food in the same form as ordinary food and should be consumed within daily dietary patterns. Therefore, it should keep its own normal nutritional values. This can be a character to distinguish functional foods from dietary or food supplement.

Although functional foods are regarded as food and not drugs, it is necessary to review the relationship between food and drugs so as to clarify the scope of functional foods. Food can be briefly defined as all kinds of food and drinks except those ingested as medicine. Medicine can be characterised as follows: (i) treatment and prevention of disease; (ii) administration to make medical diagnosis; (iii) restoring, correcting or modifying physiological functions in human beings. The first and third characters would especially have significant implication for functional foods. Only risk reduction, but not risk prevention would be claimed for functional foods. Physiological functions of components in a food are also claimed for functional foods. At the moment claims on the function of a nutrient are only restrictively permitted for foods in the Codex. The scope of claims relating to the function of substances in food has not been properly addressed nationally or internationally.

Food can be distinguished from medicine based on the differences of practical concepts applied in a regulatory system. One of the criteria is intended use, such as timing of targeted effect and the specificity of target population. It would clarify some of the confusion between the concepts of food and drug. Another criterion is the different approaches to safety between food and medicine. Whereas foods are generally presumed safe considering that they are daily consumed, absolute safety is not applied to medicine. This is evaluated and permitted on the basis of a benefit/risk ratio.

In conclusion, although functional foods challenge the regulatory concepts of food and drugs they seem to be clearly distinguishable in a number of aspects.

Acknowledgements

The authors would like to thank the support from Kwak, No-Seong's parents to undertake research in the United Kingdom.

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