FUNCTIONAL FOODS

M.Sc., FOODS AND NUTRIONAL SCIENCE
First Year, Paper - III

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FOREWORD

Acharya Nagarjuna University, since its establishment in 1976, has been moving ahead in the path of academic excellence, offering a variety of courses and research contributions. The University achieved recognition as one of the eminent universities in the country by gaining A grade from the NAAC 2016. At present Acharya Nagarjuna University is offering educational opportunities at the UG, PG levels to students of 447 affiliated colleges spread over the two districts of Guntur and Prakasam.

The University had started the Centre for Distance Education in 2003-04 with the aim to bring Higher education within the reach of all. The Centre has been extending services to those who cannot join in colleges, cannot afford the exorbitant fees as regular students, and to housewives desirous of pursuing higher studies to study B.A., B.Com, and B.Sc., Courses at the Degree level and M.A., M.Com., M.Sc, M.B.A. and LL.M. courses at the PG level.

For better understanding by students, self-instruction materials have been prepared by eminent and experienced teachers. The lessons have been prepared with care and expertise. However constructive ideas and scholarly suggestions are welcome from students and teachers. Such ideas will be incorporated for the greater efficacy of the distance mode of education. For clarification of doubts and feedback, Weekly classes and contact classes are arranged at UG and PG levels respectively.

I wish the students who pursue higher education through Centre for Distance Education will not only be personally benefited by improving their qualifications but also strive for nation's growth by being a member in Knowledge society I hope that in the years to come, the Centre for Distance Education will grow in strength by introducing new courses, catering to the needs of people. I congratulate all the Directors, Academic coordinators, Editors, Lesson - Writers, and Academic Counsellors and Non-teaching staff of the Centre who have been extending their services in these endeavours.

Prof. KOONA RAMJI
Vice-Chancellor I/C
Acharya Nagarjuna University

M.Sc., FOODS AND NUTRITIONAL SCIENCE (Course Code-139)

Paper – III: FUNCTIONAL FOODS

SYLLABUS

UNIT I

- Functional foods: Definition, Current market scenario of the health foods, public demand and Indian market potential.

UNIT II

- Hyper nutritious foods: Protein powders, Sources, Types, Method of extraction of proteins of Oil seed and legume cakes-Nutritional implications
- Fat free foods: Types of fats, PUFA oils n3, n6 fatty acids, Fat free milk powder, Low cholesterol oils and Cholesterol free foods.

UNIT III

- Nutraceuticals: Definition, Need, Importance, classification \ types, sources, processing of nutraceutical products, Role in health and therapeutic applications.
- Pharma foods: Diabetic nuts, Confectionaries, Sodium free, Lactose free, phenylalanine free and fibre rich foods - Nutritional implications.

UNIT IV

- Dietary supplements - Fortification of nutrients in the processed foods & other dietary supplements – Role in health.
- Non nutritive sweeteners: Definition, Need, importance, Types, Development of sugar free products - Nutritional implications current market trend - Artificial sweeteners therapeutic applications.

UNIT V

- Biotechnology: Definition, need, importance of technologies and organisms for food biotechnology, food processing improvements through biotechnology - genetically modified foods - nutritional implications

CONTENTS

UNIT—I

INTRODUCTION

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Objectives

After going through this unit, students will be able to:

- discuss the concepts pertaining to functional foods (Definition, Basic concepts and its primary sources);
- state the importance of functional foods in human life;
- understand functional food sector as well as its current market scenario;
- explain the demand and supply chain of functional foods.

STRUCTURE

1.1 Introduction

This is an emerging field in food science in which such foods are usually accompanied by health claims for marketing purposes, for example, a certain "cereal is a significant source of fiber. Studies have shown that an increased amount of fiber in one's diet can decrease the risk of certain types of cancer in individuals."

The general category includes processed food or foods fortified with health-promoting additives, like "vitamin-enriched" products. Fermented foods with live cultures are considered as functional foods with probiotic benefits.

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The term was first used in Japan in the 1980s where there is a government approval process for functional foods called Foods for Specified Health Use (FOSHU). Some countries, such as Canada and Sweden, have specific laws concerning the labeling of such products.

Definition

Functional food or medicinal food is any fresh or processed food claimed to have a health-promoting and/or disease-preventing property beyond the basic nutritional function of supplying nutrients, although there is no consensus on an exact definition of the term.

The tenet "Let food be thy medicine and medicine be thy food," espoused by Hippocrates nearly 2,500 years ago, is receiving renewed interest. In particular, there has been an explosion of consumer interest in the health enhancing role of specific foods or physiologically-active food components, so-called functional foods *(Hasler, 1998)*.

Clearly, all foods are functional, as they provide taste, aroma, or nutritive value. Within the last decade, however, the term functional as it applies to food has adopted a different connotation — that of providing an additional physiological benefit beyond that of meeting basic nutritional needs. This Scientific Status Summary reviews the literature for the primary plant and animal foods that have been linked with physiological benefits. Although a plethora of biologically-active compounds have been identified in this regard *(Kuhn, 1998)*, this review focuses on foods, rather than specific compounds isolated from foods.

1.2 The Concept of Functional and/or Health-Enhancing Foods

Functional foods have been developed in virtually all food categories. Dairy, bakery products, beverages, and confectionery are among the more popular. From a product point of view, the functional property can be included in numerous different ways *(Ashwell 2002; Fogliano et al 2005; Roberfroid 1997)*, as illustrated in *Table 1*.

Innovations in functional foods can be based on new functional components (either those not previously found in foods or those for which new functional properties are discovered) or special processing technologies. In either case, the initial development work entails significant research efforts, whether the focus is on elaborating physiological mechanisms and beneficial effects of traditional foods products or developing entirely new process technologies. Market development often includes additional clinical studies, since in many markets this type of support is required by governments for making health claims in marketing.

Conceptually, functional foods fall in the grey area between conventional foods and medicine (see Figure 1): they are primarily foods and in food form, but as discussed above offer specific health-enhancing properties. In most countries a suitable regulatory category for these hybrid products is missing and individual products are forced under an existing category of either foods or medicines, which usually have separate and very distinct legislation.

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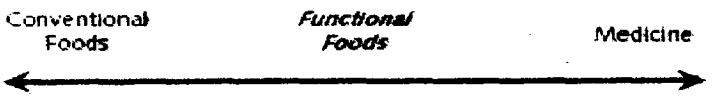
Table 1. Selected Examples of Functional Foods

Type of functional food	Example	Benefit to health and well-being
A food that naturally contains sufficient amounts of a beneficial nutrient or nonnutrient component	oats (beta-glucan)	heart health
A food in which one of the components has been naturally enhanced through special growing conditions, new feed composition (animals), genetic manipulation, or otherwise	eggs with increased omega-3 content achieved by altered chicken feed	heart health
A food with a modified recipe formulation that incorporates a functional ingredient	margarine fortified with plant sterols	improved cholesterol levels
A food in which the nature of one or more components or their bioavailability in humans has been modified by means of specialized food processing technologies	fermentation with specific bacteria to yield bioactive peptides	for example lowers blood pressure
A food from which a deleterious component has been removed, reduced or replaced with another substance with beneficial effects	chewing gum sweetened with xylitol instead of sugar	helps prevent dental caries

Source: Authors.

Figure 1. The concept of functional foods in relation to conventional foods and medicines



Source: Authors.

Most complications in marketing functional foods arise from this lack of a suitable legal framework. Typically, the distinction is based on intended use: *Products that are used to treat or prevent a condition are considered medicine, while those used to improve health and reduce a risk of developing a disease could be classified as functional foods if they are presented in the form of food or drink, and meet other safety and quality conditions set for this category.*

Distinguishing functional foods from dietary supplements and natural or herbal medicine is especially difficult, and cultural perceptions on this vary.

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Although functional foods have been a new topic in the food and nutrition field for years, a shared expert understanding of what is covered by the term is still lacking. Selected definitions used by different institutional bodies are listed in Table 2.

Table 2. Selected Definitions of "Functional Food"

FUFOSE[a]: A functional food 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 improved stage of health and well-being and/or reduction of risk of disease. A functional food must remain food and it must demonstrate its effects in amounts that can normally be expected to be consumed in the diet: it is not a pill or a capsule, but part of the normal food pattern. *(Diplock et al., 1999)*

IFT[b]: Foods and food components that provide a health benefit beyond basic nutrition (for the intended population), including conventional foods, fortified, enriched or enhanced foods, and dietary supplements. They provide essential nutrients often beyond quantities necessary for normal maintenance, growth, and development, and/or other biologically active components that impart health benefits or desirable physiological effects. *(MacAulay et al., 2005)*

ADA[c]: functional foods are foods that have health benefits beyond the nutrients they contain. *(ADA, 2005)*

IFIC[d] foundation: Any food or food component that may provide a health benefit beyond basic nutrition *(IFIC, 2002)*

Food and Nutrition Board of the National Academy of Science (US): "potentially healthful products that may include any modified food or food ingredient that may provide a health benefit beyond the traditional nutrients it contains" *(Food and Nutrition Board 1994)*

(a) *FUFOSE* = The European Commission Concerted Action on Functional Food Science in Europe, coordinated by the International Life Sciences Institute (ILSI Europe)

(b) *IFT* = Institute of Food Technologists

(c) *ADA* = American Dietetic Association

(d) *IFIC* = International Food Information Council

As shown, the definition ranges from general to highly elaborate even among professional organizations. Some definitions include only products that have been manipulated in some way, which would exclude the so-called "naturally functional foods" such as oats and carrots. Others emphasize the importance of the totality of scientific support for the physiological function as inclusion criteria. In the latter case, new emerging functional foods would potentially not be included in this category in years until sufficient scientific evidence is collected. Views of nutrition and/or health experts, the government and the consumers are typically divergent.

It should also be noted that from a scientific point of view, not all functional foods are functional for the entire population. They may only provide beneficial effects in individuals with specific risk factors. An intake at a certain threshold

level may also be necessary for a physiological effect. Many functional foods may thus be functional only under specific conditions of usage.

Some national views consider functional foods a distinct product category (for example Japan—Foods for Specific Dietary Uses (FOSHU); China— "health foods"). For others, the question is more about a concept—small improvements in the properties of existing food products *(Hilliam 1998)*. In most countries, the general consensus suggests that functional foods must be in the form of regular food or drink that can be incorporated in a regular diet. However, some cultures also include certain products in the form of capsules, extracts, and so forth, that are elsewhere classified as dietary supplements or even drugs *(Verschuren 2002)*. In China and Japan, functional foods may be in a form that would be considered a supplement in other countries, while in the U.S., a product in food form can be sold as a supplement (provided safety and quality regulations are met), with the only distinction being the place of purchase and product labelling.

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Further complications are the large number of terms often used interchangeably and in a confusing manner such as health foods, nutraceuticals, designer foods, pharma foods, and so forth. None have clear and generally accepted definitions.

For the purposes of this report, functional or health-enhancing foods are food-type products that influence specific physiological functions in the body, thereby providing benefits to health, well-being or performance, beyond regular nutrition, and are marketed and consumed for this value added property. Other definitions will be provided when discussing the differences in "functional foods" definition in the selected countries.

1.3 Background of Functional Foods

The term functional foods was first introduced in Japan in the mid-1980s and refers to processed foods containing ingredients that aid specific bodily functions in addition to being nutritious. To date, Japan is the only country that has formulated a specific regulatory approval process for functional foods. Known as Foods for Specified Health Use (FOSHU), these foods are eligible to bear a seal of approval from the Japanese Ministry of Health and Welfare *(Arai, 1996)*. Currently, 100 products are licensed as FOSHU foods in Japan. Functional Foods: Their role in disease prevention and health promotion In the United States, the functional foods category is not recognized legally. Irrespective of this, many organizations have proposed definitions for this new and emerging area of the food and nutrition sciences.

The Institute of Medicine's Food and Nutrition Board (IOM/FNB, 1994) defined functional foods as "any food or food ingredient that may provide a health benefit beyond the traditional nutrients it contains." Health-conscious baby boomers have made functional foods the leading trend in the U.S. food industry *(Meyer, 1998)*. Estimates, however, of the magnitude of this market vary significantly, as there is no consensus on what constitutes a functional food. Decision Resources, Inc. *(Waltham, 1998)* estimates the market value of functional foods at $28.9 billion. More significant, perhaps, is the potential of functional foods to mitigate disease, promote health, and reduce health care costs.

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1.4 Functional Foods from Plant Sources

Overwhelming evidence from epidemiological, in vivo, in vitro, and clinical trial data indicates that a plant-based diet can reduce the risk of chronic disease, particularly cancer. In 1992, a review of 200 epidemiological studies *(Block et al., 1992)* showed that cancer risk in people consuming diets high in fruits and vegetables was only one-half that in those consuming few of these foods. It is now clear that there are components in a plant-based diet other than traditional nutrients that can reduce cancer risk. Steinmetz and Potter (1991a) identified more than a dozen classes of these biologically active plant chemicals, now known as "phytochemicals."

Health professionals are gradually recognizing the role of phytochemicals in health enhancement *(ADA, 1995; Howard and Kritcheveky, 1997)*, aided in part by the Nutrition Labelling and Education Act of 1990 (NLEA). The NLEA required nutrition labelling for most foods and allowed disease- or health-related messages on food labels.

Oats: Oat products are a widely studied dietary source of the cholesterol-lowering soluble fiber *b-glucan*. There is now significant scientific agreement that consumption of this particular plant food can reduce total and Low Density Lipoprotein (LDL) cholesterol, thereby reducing the risk of coronary heart disease (CHD). For this, the Food and Drug Administration (FDA) awarded the first food-specific health claim in January 1997 (DHHS/FDA, 1997), in response to a petition submitted by the Quaker Oats Company (Chicago, Ill.).

In its health claim petition, the Quaker Oats Company summarized 37 human clinical intervention trials conducted between 1980 and 1995. The majority of these studies revealed statistically significant reductions in total and LDL-cholesterol in hypercholesterolemic subjects consuming either a typical American diet or a low fat diet. The daily amount of oat bran or oatmeal consumed in the above studies ranged from 34 g to 123 g. Quaker Oats determined that 3 g of *b-glucan* would be required to achieve a 5% reduction in serum cholesterol, an amount equivalent to approximately 60 g of oatmeal or 40 g of oat bran (dry weight). Thus, a food bearing the health claim must contain 13 g of oat bran or 20 g oatmeal, and provide, without fortification, at least 1.0 g of *b-glucan* per serving. In February of 1998, the soluble fiber health claim was extended to include psyllium fiber.

Soy: Soy has been in the spotlight during the 1990s. Not only is soy a high quality protein, as assessed by the FDA's "Protein Digestibility Corrected Amino Acid Score" method, it is now thought to play preventive and therapeutic roles in cardiovascular disease (CVD), cancer, osteoporosis, and the alleviation of menopausal symptoms.

The cholesterol-lowering effect of soy is the most well-documented physiological effect. A 1995 meta-analysis of 38 separate studies (involving 743 subjects) found that the consumption of soy protein resulted in significant reductions in total cholesterol (9.3%), LDL cholesterol (12.9%), and triglycerides (10.5%), with a small but insignificant increase (2.4%) in high density lipoprotein (HDL) cholesterol *(Anderson et al., 1995)*. Linear regression analysis indicated

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that the threshold level of soy intake at which the effects on blood lipids became significant was 25 g. Regarding the specific component responsible for the cholesterol-lowering effect of soy, recent attention has focused on the isoflavones (Potter, 1998). Isoflavones, however, were not effective in lowering cholesterol in two recent studies *(Hodgson et al., 1998; Nestle et al., 1997)*. The exact mechanism by which soy exerts its hypocholesterolemic effect has not been fully elucidated.

On May 4, 1998, Protein Technologies International *(PTI, St. Louis, Mo.)* petitioned the FDA for a health claim on soy protein containing products pertaining to reduced risk of CHD. Based on an effective daily level of 25 g soy protein, PTI proposed that the amount of soy protein required to qualify an individual food to bear the health claim is 6.25 g with a minimum of 12.5 mg of total isoflavones (aglycone form) per reference amount customarily consumed. On August 12, the FDA accepted PTI's petition and is in the process of formulating a proposed rule.

Several classes of anticarcinogens have been identified in soybeans, including protease inhibitors, phytosterols, saponins, phenolic acids, phytic acid, and isoflavones *(Messina and Barnes, 1991)*. Of these, isoflavones (genistein and daidzein) are particularly noteworthy because soybeans are the only significant dietary source of these compounds. Isoflavones are heterocyclic phenols structurally similar to the estrogenic steroids. Because they are weak estrogens, isoflavones may act as antiestrogens by competing with the more potent, naturally-occurring endogenous estrogens *(e.g., 17b-estradiol)* for binding to the estrogen receptor

This may explain why populations that consume significant amounts of soy (*e.g.*, Southeast Asia) have reduced risk of estrogen-dependent cancer. However, the epidemiological data on soy intake and cancer risk are inconsistent at the present time *(Messina et al., 1997)*. To date, there are no published clinical intervention trials investigating the role of soy in reducing cancer risk.

Soy may also benefit bone health *(Anderson and Garner, 1997)*. A recent clinical study involving 66 post menopausal women conducted at the University of Illinois *(Erdman and Potter, 1997)* found that 40 g isolated soy protein (ISP) per day (containing 90 mg total isoflavones) significantly increased (approximately 2%) both bone mineral content and density in the lumbar spine after 6 months.

The theory that soy may alleviate menopausal symptoms was prompted by the observation that Asian women report significantly lower levels of hot flushes and night sweats compared to Western women. Most recently, 60 grams of ISP daily for 3 months reduced hot flashes by 45% in 104 postmenopausal women *(Albertazzi et al., 1998)*. Although these observations are exciting, there is a significant placebo effect in these studies, and it is too premature to suggest that soy may substitute for hormone replacement therapy.

Flaxseed: Among the major seed oils, flaxseed oil contains the most (57%) of the omega-3 fatty acid, *a*-linolenic acid. Recent research, however, has focused more specifically on fiber-associated compounds known as lignans. The two primary mammalian lignans, enterodiol and its oxidation product, enterolactone, are formed in the intestinal tract by bacterial action on plant lignan precursors. Flaxseed

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is the richest source of mammalian lignan precursors. Because enterodiol and enterolactone are structurally similar to both naturally-occurring and synthetic estrogens, and have been shown to possess weakly estrogenic and antiestrogenic activities, they may play a role in the prevention of estrogen-dependent cancers. However, there are no epidemiological data and relatively few animal studies to support this hypothesis. In rodents, flaxseed has been shown to decrease tumors of the colon and mammary gland as well as of the lung.

Fewer studies have evaluated the effects of flaxseed feeding on risk markers for cancer in humans. Phipps demonstrated that the ingestion of 10 g of flaxseed per day elicited several hormonal changes associated with reduced breast cancer risk. *Adlercreutz et al. (1982)* found that the urinary lignan excretion was significantly lower in postmenopausal breast cancer patients compared to controls eating a normal mixed or a lactovegetarian diet. Consumption of flaxseed has also been shown to reduce total and LDL cholesterol as well as platelet aggregation.

Tomatoes: Selected by Eating Well magazine as the 1997 Vegetable of the Year, tomatoes have received significant attention within the last three years because of interest in lycopene, the primary carotenoid found in this fruit *(Gerster, 1997)*, and its role in cancer risk reduction.

In a prospective cohort study of more than 47,000 men, those who consumed tomato products 10 or more times per week had less than one-half the risk of developing advanced prostate cancer *(Giovannucci et al., 1995)*. Interestingly, lycopene is the most abundant carotenoid in the prostate gland. Other cancers whose risk have been inversely associated with serum or tissue levels of lycopene include breast, digestive tract, cervix, bladder, and skin and possibly lung. Proposed mechanisms by which lycopene could influence cancer risk are related to its antioxidant function. Lycopene is the most efficient quencher of singlet oxygen in biological systems. The antioxidant function of lycopene may also explain the recent observation in a multi-center European study that adipose tissue levels of carotenoids were inversely associated with risk for myocardial infarction.

Garlic: Garlic *(Allium sativum)* is likely the herb most widely quoted in the literature for medicinal properties. Thus, its not surprising that garlic has ranked as the second best selling herb in the United States for the past two years. The purported health benefits of garlic are numerous, including cancer chemopreventive, antibiotic, antihypertensive, and cholesterol-lowering properties.

The characteristic flavour and pungency of garlic are due to an abundance of oil-and water-soluble, sulfur-containing elements, which are also likely responsible for the various medicinal effects ascribed to this plant. However, intact, undisturbed bulbs of garlic contain only a few medicinally active components. The intact garlic bulb contains an odorless amino acid, alliin, which is converted enzymatically by allinase into allicin when the garlic cloves are crushed. This latter compound is responsible for the characteristic odor of fresh garlic. Allicin then spontaneously decomposes to form numerous sulfur-containing compounds, some of which have been investigated for their chemopreventive activity.

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Garlic components have been shown to inhibit tumorigenesis in several experimental models *(Reuter et al., 1996)*. However, additional reports have shown garlic to be ineffective. Inconclusive results are likely due to differences in the type of garlic compounds or preparations used by various investigators. Considerable variation in the quantity of organosulfur compounds available in fresh and commercially available garlic products has been demonstrated *(Lawson et al., 1991)*.

Several epidemiologic studies show that the garlic may be effective in reducing human cancer risk. A relatively large case-control investigation conducted in China showed a strong inverse relationship between stomach cancer risk and increasing allium intake *(You et al., 1988)*. More recently, in a study of more than 40,000 postmenopausal women, garlic consumption was associated with nearly a 50% reduction in colon cancer risk *(Steinmetz et al., 1994)*.

Not all epidemiological studies, however, have shown garlic to be protective against carcinogenesis. A 1991 review of 12 case-control studies *(Steinmetz and Potter, 1991b)*, found that eight showed a negative association, one showed no association, and three studies showed a positive association. A more recent review of 20 epidemiological studies *(Ernst, 1997)* suggests that allium vegetables, including onions, may confer a protective effect on cancers of the gastrointestinal tract.

Garlic has also been advocated for the prevention of CVD, possibly through antihypertensive properties. According to Silagy and Neil (1994a), however, there is still insufficient evidence to recommend it as a routine clinical therapy for the treatment of hypertensive subjects. The cardioprotective effects are more likely due to its cholesterol-lowering effect. In a meta-analysis, *Warshafsky et al. (1993)* summarized the results of five randomized, placebo-controlled clinical trials, involving 410 patients. They showed that an average of 900 mg garlic/day (as little as one half to one clove of garlic) could decrease total serum cholesterol levels by approximately 9%. In a second meta-analysis involving 16 trials, Silagy and Neil (1994b) reported that 800 mg garlic/day reduced total cholesterol levels by 12%. The validity of both of these reports, however, is reduced by methodological shortcomings, including the fact that dietary intake, weight, and/or exogenous garlic ingestion was not always well-controlled. In a recent multicenter, randomized, placebo-controlled trial in which dietary assessment and supervision were strictly controlled, 12 weeks of garlic treatment was ineffective in lowering cholesterol levels in subjects with hypercholesterolemia *(Isaacsohn et al., 1998)*. It is currently unclear which component in garlic is responsible for its cholesterol-lowering effect.

Broccoli and other Cruciferous Vegetables: Epidemiological evidence has associated the frequent consumption of cruciferous vegetables with decreased cancer risk. In a recent review of 87 case-control studies, *Verhoeven et al. (1996)* demonstrated an inverse association between consumption of total brassica vegetables and cancer risk.

The percentages of case-control studies showing an inverse association between consumption of cabbage, broccoli, cauliflower, and brussels sprouts and

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cancer risk were 70, 56, 67, and 29%, respectively. Verhoeven attributed the anticarcinogenic properties of cruciferous vegetables to their relatively high content of glucosinolates.

Glucosinolates are a group of glycosides stored within cell vacuoles of all cruciferous vegetables. Myrosinase, an enzyme found in plant cells, catalyzes these compounds to a variety of hydrolysis products, including isothiocyanates and indoles. Indole-3 carbinol (I3C) is currently under investigation for its cancer chemopreventive properties, particularly of the mammary gland. In addition to the induction of phase I and II detoxification reactions, I3C may reduce cancer risk by modulating estrogen metabolism. The C-16 and C-2 hydroxylations of estrogens involve competing cytochrome P-450-dependent pathways, each sharing a common estrogen substrate pool. Studies suggest that the increased formation of 2-hydroxylated (catechol) estrogen metabolites relative to 16-hydroxylated forms, may protect against cancer, as catechol estrogens can act as antiestrogens in cell culture.

In contrast, 16-hydroxyestrone is estrogenic and can bind to the estrogen receptor. In humans, I3C administered at 500 mg daily (equivalent to 350—500 g cabbage/day) for 1 week significantly increased the extent of estradiol 2-hydroxylation in women *(Michnovicz and Bradlow, 1991)*, suggesting that this compound may be a novel approach for reducing the risk of breast cancer. However, since I3C has also been shown to enhance carcinogenesis in vivo, caution has been urged before proceeding with extensive clinical trials *(Dashwood, 1998)*, although such phase I trials are currently ongoing *(Wong et al., 1998)*.

Although a wide variety of naturally occurring and synthetic isothiocyanates have been shown to prevent cancer in animals (Hecht, 1995), attention has been focused on a particular isothiocyanate isolated from broccoli, known as sulforaphane. Sulforaphane has been shown to be the principal inducer of a particular type of Phase II enzyme, quinone reductase. *Fahey (1997)* recently demonstrated that 3-day-old broccoli sprouts contained 10-100 times higher levels of glucoraphanin (the glucosinolate of sulforaphane) than did corresponding mature plants. However, in view of the importance of an overall dietary pattern in cancer risk reduction, the clinical implications of a single phytochemical in isolation has been questioned *(Nestle, 1998)*.

Citrus Fruits: Several epidemiological studies have shown that citrus fruits are protective against a variety of human cancers. Although oranges, lemons, limes, and grapefruits are a principal source of such important nutrients as vitamin C, folate, and fiber, *Elegbede et al. (1993)* have suggested that another component is responsible for the anticancer activity. Citrus fruits are particularly high in a class of phytochemicals known as the limonoids *(Hasegawa and Miyake, 1996)*.

Over the last decade, evidence has been accumulating in support of the cancer preventative effect of limonene. *Crowell (1997)* showed this compound to be effective against a variety of both spontaneous and chemically- induced rodent tumors. Based on these observations, and because it has little or no toxicity in humans, limonene has been suggested as a good candidate for human clinical chemoprevention trial evaluation. A metabolite of limonene, perrillyl alcohol, is

currently undergoing Phase I clinical trials in patients with advanced malignancies *(Ripple et al., 1998).*

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Cranberry: Cranberry juice has been recognized as efficacious in the treatment of urinary tract infections since 1914, when Blatherwick (1914) reported that this benzoic acid-rich fruit caused acidification of the urine. Recent investigations have focused on the ability of cranberry juice to inhibit the adherence of Escherichia coli to uroepithelial cells *(Schmidt and Sobota, 1988).* This phenomenon has been attributed to two compounds: fructose and a nondialyzable polymeric compound. The latter compound, subsequently isolated from cranberry and blueberry juices *(Ofek et al., 1991),* was found to inhibit adhesins present on the pili of the surface of certain pathogenic E. coli.

Avorn et al. (1994) published the results of the first randomized, double-blind, placebo-controlled clinical trial designed to determine the effect of a commercial cranberry juice beverage on urinary tract infections. One hundred-fifty three elderly women consuming 300 mL cranberry beverage per day had significantly reduced (58%) incidence of bacteriuria with pyuria compared to the control group after six months. Based on the results of these studies, prevailing beliefs about the benefits of cranberry juice on the urinary tract appear to be justified.

Tea: Tea is second only to water as the most widely consumed beverage in the world. A great deal of attention has been directed to the polyphenolic constituents of tea, particularly green tea *(Harbowy and Balentine, 1997).* Polyphenols comprise up to 30% of the total dry weight of fresh tea leaves. Catechins are the predominant and most significant of all tea polyphenols *(Graham, 1992).* The four major green tea catechins are epigallocatechin-3-gallate, epigallocatechin, epicatechin-3-gallate, and epicatechin.

In recent years, there has been a great deal of interest in pharmacological effects of tea *(AHF, 1992).* By far, most research on health benefits of tea has focused on its cancer chemopreventive effects, although the epidemiological studies are inconclusive at the present time *(Katiyar and Mukhtar, 1996).* In a 1993 review of 100 epidemiological studies *(Yang and Wang, 1993),* approximately 2/3 of the studies found no relationship between tea consumption and cancer risk, while 20 found a positive relationship and only 14 studies found that tea consumption reduced cancer risk. A more recent review suggests that benefits from tea consumption are restricted to high intakes in high-risk populations *(Kohlmeier et al., 1997a).* This hypothesis supports the recent finding that the consumption of five or more cups of green tea per day was associated with decreased recurrence of stage I and II breast cancer in Japanese women *(Nakachi et al., 1998).*

In contrast to the inconclusive results from epidemiological studies, research findings in laboratory animals clearly support a cancer chemopreventive effect of tea components. In fact, *Dreosti et al.(1997)* stated that "no other agent tested for possible chemoprevention effects in animal models has elicited such strong activity as tea and its components at the concentrations usually consumed by humans."

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There is some evidence that tea consumption may also reduce the risk of CVD. Hertog and coworkers (1993) reported that tea consumption was the major source of flavonoids in a population of elderly men in the Netherlands. Intake of five flavonoids (quercetin, kaempferol, myricetin, apigenin, and luteolin), the majority of which was derived from tea consumption, was significantly inversely associated with mortality from CHD in this population. Although several other prospective studies have demonstrated a substantial reduction in CVD risk with tea consumption, the evidence is not presently conclusive.

Wine and Grapes: There is growing evidence that wine, particularly red wine, can reduce the risk of CVD. The link between wine intake and CVD first became apparent in 1979 when St. Leger found a strong negative correlation between wine intake and death from ischemic heart disease in both men and women from 18 countries. France in particular has a relatively low rate of CVD despite diets high in dairy fat *(Renaud and de Lorgeril, 1992)*. Although this "French Paradox" can be partly explained by the ability of alcohol to increase HDL cholesterol, more recent investigations have focused on the non-alcohol components of wine, in particular, the flavonoids.

The high phenolic content of red wine, which is about 20—50 times higher than white wine, is due to the incorporation of the grape skins into the fermenting grape juice during production. *Kanner et al. (1994)* showed that the black seedless grapes and red wines *(i.e., Cabernet Sauvignon and Petite Sirah)* contain high concentrations of phenolics: 920, 1800, and 3200 mg/L, respectively, while green Thomson grapes contain only 260 mg/kg phenolics. *Frankel and coworkers (1993)* attributed the positive benefits of red wine to the ability of phenolic substances to prevent the oxidation of LDL, a critical event in the process of atherogenesis.

Although the benefits of wine consumption on CVD risk reduction seem promising, a recent prospective study of 128,934 adults in Northern California concluded that the benefits of alcohol consumption on coronary risk were not especially associated with red wine. Moreover, a note of caution is in order, as alcoholic beverages of all kinds have been linked to increased risk of several types of cancer, including breast cancer. Moderate wine consumption has also been associated with a decreased risk of age related macular degeneration.

Those who desire health benefits of wine without potential risk may wish to consider alcohol-free wine, which has been shown to increase total plasma antioxidant capacity. Furthermore, Day showed that commercial grape juice is effective in inhibiting the oxidation of LDL isolated from human subjects. Red wine is also a significant source of trans-resveratrol, a phytoalexin found in grape skins. Resveratrol has also been shown to have estrogenic properties which may explain in part the cardiovascular benefits of wine drinking, and it has been shown to inhibit carcinogenesis in vivo.

1.5 Functional Foods from Animal Sources

Although the vast number of naturally occurring health-enhancing substances are of plant origin, there are a number of physiologically-active components in animal products that deserve attention for their potential role in optimal health.

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Fish: Omega-3 (n-3) fatty acids are an essential class of polyunsaturated fatty acids (PUFAs) derived primarily from fish oil. It has been suggested that the Western-type diet is currently deficient in n-3 fatty acids, which is reflected in the current estimated n-6 to n-3 dietary ratio of 20:25, compared to the 1:1 ratio on which humans evolved *(Simopoulos, 1991)*. This has prompted researchers to examine the role of n-3 fatty acids in a number of diseases — particularly cancer and CVD — and more recently, in early human development.

That n-3 fatty acids may play an important role in CVD was first brought to light in the 1970s when *Bang and Dyerberg (1972)* reported that Eskimos had low rates of this disease despite consuming a diet which was high in fat. The cardioprotective effect of fish consumption has been observed in some prospective investigations *(Krumhout et al., 1985)*, but not in others *(Ascherio et al., 1995)*. Negative results could be explained by the fact that although n-3 fatty acids have been shown to lower triglycerides by 25-30%, they do not lower LDL cholesterol. In fact, a recent review of 72 placebo controlled human trials, showed that n-3 fatty acids increased LDL cholesterol *(Harris, 1996)*.

Although eating large amounts of fish has not unequivocally been shown to reduce CVD risk in healthy men, consumption of 35 g or more of fish daily has been shown to reduce the risk of death from nonsudden myocardial infarction in the Chicago Western Electric Study *(Daviglus et al., 1997)*, and as little as one serving of fish per week was associated with a significantly reduced risk of total cardiovascular mortality after 11 years in more than 20,000 U.S. male physicians *(Albert et al., 1998)*.

Dairy Products: There is no doubt that dairy products are functional foods. They are one of the best sources of calcium, an essential nutrient which can prevent osteoporosis and possibly colon cancer. In view of the former, the National Academy of Sciences recently increased recommendations for this nutrient for most age groups. In addition to calcium, however, recent research has focused specifically on other components in dairy products, particularly fermented dairy products known as probiotics. Probiotics are defined as "live microbial feed supplements which beneficially affect the host animal by improving its intestinal microbial balance" *(Fuller, 1994)*.

It is estimated that over 400 species of bacteria, separated into two broad categories, inhabit the human gastrointestinal tract. The categories are: those considered to be beneficial (e.g., Bifidobacterium and Lactobacillus and those considered detrimental (e.g., *Enterobacteriaceae* and *Clostridium* spp.). Of the beneficial microorganisms traditionally used in food fermentation, lactic acid bacteria have attracted the most attention *(Sanders, 1994)*. Although a variety of health benefits have been attributed to probiotics, their anticarcinogenic, hypocholesterolemic and antagonistic actions against enteric pathogens and other intestinal organisms have received the most attention *(Mital and Garg, 1995)*.

The hypocholesterolemic effect of fermented milk was discovered more than 30 years ago during studies conducted in Maasai tribesmen in Africa *(Mann et al., 1964)*. The Maasai have low levels of serum cholesterol and clinical coronary heart disease despite a high meat diet. However, they consume daily 4 to 5 L of

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fermented whole milk. Although a number of human clinical studies have assessed the cholesterol-lowering effects of fermented milk products (Sanders, 1994), results are equivocal. Study outcomes have been complicated by inadequate sample sizes, failure to control nutrient intake and energy expenditure, and variations in baseline blood lipids.

More evidence supports the role of probiotics in cancer risk reduction, particularly colon cancer *(Mital and Garg, 1995)*. This observation may be due to the fact that lactic acid cultures can alter the activity of fecal enzymes *(e.g., b-glucuronidase, azoreductase, nitroreductase)* that are thought to play a role in the development of colon cancer. Relatively less attention has been focused on the consumption of fermented milk products and breast cancer risk, although an inverse relationship has been observed in some studies *(Talamini et al., 1984; van't Veer et al., 1989)*.

In addition to probiotics, there is growing interest in fermentable carbohydrates that feed the good microflora of the gut. These prebiotics, defined by *Gibson and Roberfroid (1995)* as "nondigestible food ingredients that beneficially affect the host by selectively stimulating the growth and/or activity of one or a limited number of bacteria in the colon and thus improves host health," may include starches, dietary fibers, other non-absorbable sugars, sugar alcohols, and oligosaccharides *(Gibson et al., 1996)*. Of these, oligosaccharides have received the most attention, and numerous health benefits have been attributed to them *(Tomomatsu, 1994)*. Oligosaccharides consist of short chain polysaccharides composed of three and 10 simple sugars linked together. They are found naturally in many fruits and vegetables (including banana, garlic, onions, milk, honey, artichokes). The prebiotic concept has been further extended to encompass the concept of synbiotics, a mixture of pro- and prebiotics *(Gibson and Roberfroid, 1995)*. Many synbiotic products are currently on the market in Europe.

Beef: An anticarcinogenic fatty acid known as conjugated linoleic acid (CLA) was first isolated from grilled beef in 1987 *(Ha et al., 1987)*. CLA refers to a mixture of positional and geometric isomers of linoleic acid (18:2 n-6) in which the double bonds are conjugated instead of existing in the typical methylene interrupted configuration. Nine different isomers of CLA have been reported as occurring naturally in food. CLA is unique in that it is found in highest concentrations in fat from ruminant animals *(e.g., beef, dairy, and lamb)*. Beef fat contains 3.1 to 8.5 mg CLA/g fat with the 9-cis and 11-trans isomers contributing 57—85% of the total CLA (Decker, 1995). Interestingly, CLA increases in foods that are cooked and/or otherwise processed. This is significant in view of the fact that many mutagens and carcinogens have been identified in cooked meats.

Over the past decade, CLA has been shown to be effective in suppressing forestomach tumors in mice, aberrant colonic crypt foci in rats, and mammary carcinogenesis in rats *(Ip and Scimeca, 1997)*. In the mammary tumor model, CLA is an effective anticarcinogen in the range of 0.1-1% in the diet, which is higher than the estimated consumption of approximately 1 g CLA/person/day in the United States. These results are not due to displacement of linoleic acid in

cells, suggesting that there may be unique mechanism(s) by which CLA modulates tumor development. Thus, there has been research designed to increase the CLA content in dairy cow milk through dietary modification *(Kelly et al., 1998)*.

More recently, CLA has been investigated for its ability to change body composition, suggesting a role as a weight-reduction agent. Mice fed CLA-supplemented diets (0.5%) exhibited 60% lower body fat and 14% increased lean body mass relative to controls *(Park et al., 1997)*, possibly by reducing fat deposition and increasing lipolysis in adipocytes.

Safety Issues

Although "increasing the availability of healthful foods, including functional foods, in the American diet is critical to ensuring a healthier population" *(ADA, 1995)*, safety is a critical issue. The optimal levels of the majority of the biologically active components currently under investigation have yet to be determined. In addition, a number of animal studies show that some of the same phytochemicals *(e.g., allyl isothiocyanate)* highlighted in this review for their cancer-preventing properties have been shown to be carcinogenic at high concentrations *(Ames et al., 1990)*. Thus, Paracelsus' 15th century doctrine that *"All substances are poisons . . . the right dose differentiates a poison from a remedy"* is even more pertinent today given the proclivity for dietary supplements.

The benefits and risks to individuals and populations as a whole must be weighed carefully when considering the widespread use of physiologically-active functional foods. For example, what are the risks of recommending the increased intake of compounds *(e.g., isoflavones)* that may modulate estrogen metabolism? Soy phytoestrogens may represent a "double-edged sword" because of reports that genistein may actually promote certain types of tumors in animals *(Rao et al., 1997)*. Knowledge of toxicity of functional food components is crucial to decrease the risk: benefit ratio.

1.6 Description of the Functional Foods Sector

Although functional foods have been a topic of considerable interest in the food and nutrition field for years, a shared expert understanding of what is covered by the term is still lacking.

For the purposes of this report, functional or health-enhancing foods are food-type products that influence specific physiological functions in the body, thereby providing benefits to health, well-being or performance, beyond regular nutrition, and are marketed and consumed for this value added property.

Conceptually, functional foods fall in the grey area between conventional foods and medicine. In most countries, a suitable regulatory category for these hybrid products does not exist and most complications in market development arise from a lack of a clear definition and the consequent legal framework for functional foods. The confusing classification and terminology also make it difficult to estimate the size of this sector: global functional foods market size has been estimated at approximately US$30 to US$60 billion, depending on the definition. Regardless of the large range in estimates, it is clear that the global

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functional foods sector has experienced phenomenal growth over the past years with approximately 10 per-cent annual increase in value.

The development and marketing of functional foods require significant research efforts. This involves identifying functional compounds and assessing their physiological effects; developing a suitable food matrix, taking into account bioavailability and potential changes during processing and food preparation; and clinical trials on product efficacy in order to gain approval for health-enhancing marketing claims.

At the global level, the approach to regulating functional foods and their marketing is heterogeneous. This is largely due to the challenges in classifying these products and to the varying views on what is considered sufficient scientific evidence to determine functionality. Common concerns in all legislation are ensuring product safety and public health. Regulation of functional foods differs from that of conventional foods mainly with respect to labelling and advertising. In Japan and China, a manufacturer can apply for product approval and a "functional food" symbol can be displayed on the food label. In some European countries and the United States, a health benefit can be conveyed to the consumer using "nutrient-function claims" or "health claims". The regulatory aspects are an important consideration in bringing new functional foods to market.

Besides a well-defined regulatory framework, factors that enable a successful market for functional foods include consumer awareness of health issues and the role of diet in them; consumer acceptance of active components and food solutions to health issues; sufficient disposable income level; organized retail sector; and mature markets for processed foods.

1.7 Current Market Scenario of the Health Foods

Functional foods have been the topic of considerable interest in the food and nutrition industry for years, but the term currently lacks a common definition. A practical definition adopted here includes products, in food or drink form, that influence specific functions in the body and thereby offer benefits for health, well-being, or performance beyond their regular nutritional value.

These functional food products result from: technological innovation at the processing level, such as cholesterol lowering spreads, xylitol-sweetened chewing gum, and dairy products fermented with specific lactic acid bacteria; technological innovation at the production level such as genetically modified crop seeds *(e.g., Golden rice)* and planting materials derived through conventional breeding *(e.g., orangefleshed sweetpotato)*; or crops that naturally contain components that have a physiological function *(e.g., soy bean and oats, which are good for cardio-vascular health)*. See Table 3 for examples.

Economic Opportunities from Functional Foods

Functional foods entered the global markets with force in the past decade and rapidly gained market share conservatively estimated to exceed that for organic foods. Thus, in addition to the health benefits, functional foods present new economic opportunities. Functional foods sell at higher prices and contain larger profit margins than conventional foods, which make the sector attractive for the

players in the supply chain. Retail prices of functional foods are typically 30 to 500 percent above the comparable conventional foods. Confusion over the definition of functional foods makes it difficult to estimate the exact size of this sector—global market size has been estimated between US$30 and US$60 billion depending on the definition, with Japan, the United States, and Europe as the biggest markets. Regardless, the global functional foods sector grew exponentially over the past years with an approximately 10 per-cent annual increase in value. As a result, developing countries have started to emerge as exporters to cater to the increasing demand in the developed countries *(see Box 1 for examples)*.

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Moreover, demand for functional foods within the developing countries is growing, presenting a lucrative opportunity to develop domestic markets *(see Box 2 for examples)*. The economic returns from functional foods can offer improved opportunities for all members in the supply chain: from raw material producers and processors to retailers.

Functional foods can be an opportunity for economic growth for many developing countries endowed with rich biodiversity and traditional knowledge of the health effects of certain indigenous plant species. Some developing countries can also be competitive in production due to lower labor costs (e.g., 10 per-cent lower soybean production cost in China's northeast region than in mid-west U.S. *(Ford et al. Forthcoming))*.

Besides the opportunity for diversified and high-value production, farming for the functional foods industry can benefit primary producers and rural communities in other ways. Poorer communities can benefit from growing functional food markets through domestication of wild plant species; enhanced links to the private sector, for example, through contract farming; employment or business opportunities from processing functional foods; and employment on plantations *(see Box 3 for examples)*.

Moreover, some of the crops with health-enhancing features may be native to marginal areas, where more traditional farming is difficult and returns are low. Lastly, functional properties can increase the value of otherwise rare plant species, which can aid in biodiversity conservation if their sustainable use is carefully managed.

Table 3. Selected Examples of Functional Foods

functional food	*benefit to health and well-being*
Oats (beta-glucan)	Heart health
Eggs with increased omega-3 content achieved by altered chicken feed	Heart health
Margarine fortified with plant sterols	Improved cholesterol levels
Fermentation with specific bacteria to yield bioactive peptides	Lowers blood pressure

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Chewing gum sweetened with xylitol instead of sugar	Helps prevent dental caries
Golden rice	Pro-vitamin A
Orange-fleshed sweetpotato	Pro-vitamin A

Still, relatively little is known about the current status of functional food production, products, and market development in most developing countries. A recent study *(Kotilainen et al., 2006)* sought to narrow this knowledge gap by reviewing the status of the functional foods sector through a literature review, in-depth studies of India and China, and an assessment of the sector in five countries—China, India, Brazil, Peru, and Russia.

Challenges and Success Factors in the Sector

Even though developing countries are a rich source of raw materials for functional food products because of their vast biodiversity and cost advantages in crop production, developing a functional foods industry in these countries faces significant barriers. The cost of bringing a new product to the market can be significant, especially the upfront costs associated with high-value food processing and exporting (search for markets, product research and certification, meeting regulatory demands, consumer research, and public relations).

Below are some of the major challenges and recommendations for how a country might tackle them.

The Regulatory Framework: Most countries lack a suitable regulatory category for these 'hybrid' functional food products, which makes market development much more complicated. A clear regulatory system for production, sales, certification, and advertising of functional foods, together with consistent enforcement are critical factors in building consumer trust in functional foods. A credible system can also help to provide a level playing field that fosters competition and encourages innovation. In many cases, development of institutional capacity is necessary. These institutions include food research centers, advisory services for producers, educators in food sector marketing and management, and authorities approving health claims for functional foods.

The Underlying Science: The development and marketing of functional foods require significant research efforts because most markets require scientific evidence and proof of functionality. Even though certain foods may have been used for a long time for health-enhancement purposes, the definitive scientific support for claims as a functional product is often lacking. This involves identifying functional compounds and assessing their physiological effect, taking into account bioavailability in humans and potential changes during processing and food preparation and clinical trials on product efficacy in order to gain approval for health-enhancing marketing claims. This research requires time, financing, and skilled labour, especially for products destined for export markets. Lastly, innovation and research capacity is required to screen local biodiversity to uncover potential new sources for functional foods. This is also a management culture challenge for researchers because the best results can be obtained through partnerships between formal science institutions and indigenous communities.

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Box 1. *Emerging Functional Foods from Developing Countries*

- ***Brazil:*** Manufacturers in Japan and the U.S. obtain plant-based physiologically active ingredients such as antioxidant compounds from acaiberry, guarana, and yacon.
- ***Kenya:*** There is a potential to develop the camel milk sector for the domestic market and to respond to the demand from South America. Camel milk has medicinal properties, especially in management of diseases such as diabetes, high blood pressure, heart disease, allergies, and peptic ulcers. Camel milk can be found in a number of supermarkets in Nairobi.
- ***Peru:*** Purple corn, yacon, maca, and cat's claw are exported to Japan and the U.S. The export value of just two plants, purple corn and yacon, grew at an average annual rate of 467 percent and 335 percent, respectively, from 1998 to 2002. Dozens of companies are involved in export.

Source: EMBRAPA; BioTrade Peru 2004; Gitonga 2006.

Box 2. *Small but Growing Functional Food Market in Developing Countries*

- ***China:*** The total functional foods market is approximately US$6 billion per year, which is expected to double by 2010.
- ***India:*** With its strong tradition of eating healthy foods, India ranks among the top ten nations in buying functional foods and the market size is expected to nearly double in the next five years.
- ***Brazil:*** The sector is relatively young, growing rapidly and has significant room for further growth. Sales value is projected to reach US$1.9 billion by 2009, which translates into a growth rate of 29 percent per capita spending on functional foods during this period.
- ***Peru:*** The sector for health foods, in general, is still in early stages, but has potential for growth because of rich biodiversity in roots and tubers containing diverse sugars and carbohydrates, which can respond to the demand for low-fat and sugar-free products.
- ***Russia:*** The value of functional foods market was estimated at US$75 million in 2004, with an annual growth of 20 percent expected. The dairy industry took the lead in the functional foods movement and the largest growth is expected in this sector.

Source: Sun 2006; Ismail 2006; Benkouider 2005; Gutierrez 2004; Drujinina 2005; Spiridovitsh 2005.

Understanding Demand: As implied above, the requirements of the market will define what regulations, actions, and science are needed in the producing/exporting country. This market information needs to permeate through the entire value chain of the product from producer to retailer. This would enable improved strategic decision-making and better coordination and collaboration between the players in the supply chain. As market demand and the associated regulations differ in different markets, transaction costs in the export market are significant for individual companies. Specialized market development and export promotion

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services might offer a way to address this challenge. Moreover, policymakers need to concentrate on harmonizing regulations with those of major export markets to reduce potential trade barriers and unnecessary duplication of work for different markets.

Producers, processors, and retailers need to pay attention to both domestic and export markets. While in 2003, Japan, the United States, and Europe comprised 90 percent of global demand for functional foods *(Datamonitor, 2004)*, increased incomes in developing and transitional economies—especially China, Russia, and Brazil—currently feed a growing domestic market for functional foods.

Understanding Supply: As mentioned before, developing countries often have a wealth of biodiversity to develop their functional foods sector. However, a sustainable management plan for these resources is important so as to avoid dramatic reductions in plant populations and interference in the dynamics of local biodiversity. On the regulatory level, it is also important to have intellectual property rights protection for new products developed in country with equitable benefitsharing between local communities and developers of the products.

Besides a well-defined regulatory framework, factors that enable a successful market for functional foods include: consumer awareness of health issues and their linkage to diets; consumer acceptance of food solutions to health issues; sufficient disposable income level; organized retail sector; and mature markets for processed foods.

Box 3. Peru: Farmers Gain in Cultivating and Processing Functional Products

The Asociación de Productores de Yacon de Oxapampa (APYEDO), a producers' association, with the assistance of the International Potato Center in 2002, started producing syrup, juice, marmalade, and dehydrated flakes utilizing yacon, which contains an oligofructose, utilized for low caloric beverages and known to be beneficial for diabetic patients. Since 2003, several supermarkets in Peru have offered yacon syrup, juice, marmalade, and tea leaves. Although small scale production predominates, exports of yacon products have reached markets in Japan, the European Union, and the U.S. High demand for information on yacon indicates that there is considerable interest in this crop in various parts of the world.

Source: International Potato Center (CIP) 2004.

Concluding Remark

Developing countries can enjoy the benefits of the functional food sector to expand options for producers and to promote growth in the sector through partnerships between research centers, private entrepreneurs, and indigenous communities. However, the success requires sufficient proof to establish the health claim and capacity to accurately market functional foods to consumers in high-end markets.

Countries that are interested in this sector should also assess the opportunities at the national level because functional foods cover such a broad

group of products and production systems that some can find demand in the domestic market, while others can be targeted for export.

Identification of specific export markets, certification and other regulations, and consumer demand are product and/or ingredientspecific, and largely dictate the possibilities for development. Further studies could establish the most critical bottlenecks in production systems and identify opportunities with the greatest potential for rural employment creation and competitive advantage for small-scale farmers as producers of functional foods.

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1.8 Global Picture of the Nutraceutical Industry

Functional foods have entered the global market with force in the past decade and continue to gain market share as value added products at a rapid pace. Although the term "functional foods" currently lacks a common definition, this category is generally thought to include products that influence specific functions in the body and thereby offer benefits for health, well-being or performance, beyond their regular nutritional value. These products result from technological innovation, such as cholesterol lowering spreads, xylitolsweetened chewing gum and dairy products fermented with specific lactic acid bacteria, or are naturally functional foods including soy, oats and grains high in fiber. Functional foods have been developed in most food categories and even by conservative estimates, the global market size already exceeds that for organic foods. In addition to providing consumers options for improving their health and well-being, functional foods as an attractive market sector, provide new economic opportunities.

The rapidly growing market of functional or health-enhancing foods has emerged as a response to global trends in demographics, patterns of health and disease, innovation in food and health related research, and globalization. In developed countries, with increases in the ageing population and the increasing prevalence of lifestyle related diseases, many use functional foods and diet to reach and maintain optimal health.

In developing countries, similar demographic and public health trends are evolving among higher socio-economic groups, and functional foods have entered these markets. Growing domestic markets and the possibility of exports to the dominant markets of the United States, Europe and Japan provide economic opportunities in this sector. Many developing regions have vast biodiversity that can be tapped for new sources of functional foods or functional ingredients. This potential source and the increased economic value from functional foods can offer new or improved opportunities for all in the supply chain, starting from primary producers. However, while many developing countries could potentially benefit from investing in the production and development of functional foods, relatively little is known about their current status.

The functional food and nutraceutical industry represents in excess of a $75.5 billion U.S. industry (Just-food, 2007) with prospects of growing to $167 billion by 2010 (Just-food, 2004). Operationally, the industry relies upon a network of supportive stakeholders *(Fig. 2)* with a vested interest, in one form or another

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in providing consumers with alternative health products with potential to prevent diseases resulting from nutrient deficiencies or with products that have beneficial physiologic effects beyond those simply attributed to their nutrient content. Support from groups within the network is essential to development and maintenance of a strong popularized consumer base within the industry and is one of the key factors behind establishment, ongoing operation, expansion and commercialization of the global functional food and nutraceutical industry. Although popularity of products marketed as functional foods and nutraceuticals is highly variable and often dependent upon historical if not local allegiances, the industry as a whole has an international presence and operates in many countries and has potential to grow in a major way in some *(Fig. 2)*.

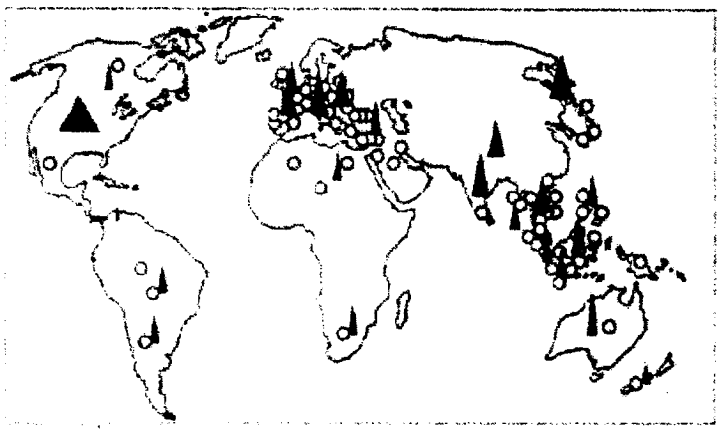

Fig. 2: Global nutraceutical and functional food markets (map not to scale). Countries playing a major role in nutraceutical and functional food industries are identified in the map. Each circular dot represents a niche market in the globe. The triangles represent the areas with most rapid expansion. The size (width and length) of the triangles indicates projected proportional expansion of the key nutraceutical markets within the next ten years.

The United States of America (USA) currently possesses the largest and most rapidly expanding functional food and nutraceutical market in the world (World Nutraceuticals, 2006). In 2006 value of the industry was $21.3 billion (Datamonitor, 2007). Its strong domestic market supports major imports from Japan, North and South Korea, China, India, Brazil, the European Union (EU), Australia, New Zealand and other parts of the world *(World Nutraceuticals 2006)*. For the USA it has been suggested that about 50% of its multi-billion dollar food market can be related to use of nutraceuticals and functional food products *(Belem, 1999)*. By comparison the Canadian nutraceutical and functional food market is relatively young and is growing. In 2003 Canadian trade in nutraceuticals and functional foods represented 3% of the global market compared to the USA (35%) and EU (32%) *(D'Innocenzo, 2006)*. According to a Statistics Canada survey (2003) conducted in 2002, the majority of Canadian functional food and nutraceutical exports are to the USA, Japan and the EU. Elsewhere, in Central, Latin and South

America, functional food and nutraceutical markets are still developing and lack popularity. Still, scattered markets have been recognized in Mexico, Brazil, Uruguay and Argentina *(World Nutraceuticals, 2006).*

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Nutraceutical and functional food markets in the EU have grown over the past eight years, from about $1.8 billion out of a $5.7 billion global market in 1999 *(Kleter et al., 2001)* to $8 billion (Datamonitor, 2007) out of a global market of $75.5 billion (Just-food, 2007) in 2006. While growth in this market has been significant, it appears to be trailing in growth seen in other parts of the world; i.e., world market share in 1999 was about 30% but, in 2006 only represented about 10% of total estimated world expenditures. While growth of functional food markets within the EU was estimated to be only 2-5 fold in 2001 *(Kleter et al., 2001),* it reached more than 10 fold in 2006 *(World Nutraceuticals, 2006).* A number of factors have contributed to restricted growth within the industry throughout the EU. Strict regulations governing food labelling, product formulation, food processing, packaging, marketing, registration and licensing details are all strictly monitored in the EU and have been identified as restricting the size of the consumer market in these countries *(Breithaupt, 2004; Kleter et al., 2001; Moon & Balasubramanian, 2003; World Nutraceuticals, 2006).* Major trading partners with the EU are the USA, Japan, south, south-east, far east and middle east Asia and Pacific regions *(Japan's Nutarceuticals, 2003; World Nutraceuticals, 2006).*

Eastern cultures have a long history of use of traditional medicines associated with health foods in forms of recognized nutritional foods, food supplements, medicinal herbs, and crude powdered drugs derived from plant, animal and marine sources *(Datta Banik and Basu, 2002; Dhanukar, Kulkarni and Rege, 2000).* India and China are the two most important countries known for their production of traditional functional food products and nutraceuticals. Both of these countries have large populations, in particular in rural, remote and inaccessible areas which are totally dependent upon herbal remedies and other naturally available bioresources which they use to treat common ailments, and as general preventive and protective medications *(Dhanukar, Kulkarni and Rege, 2000).*

In India the most common forms of functional foods and nutraceuticals are available as traditional Indian Ayurvedic Medicines (IAM); these are marketed under different brand names *(Patwardhan et al., 2005).* India is the home of a large number of medicinal herbs, spices and tree species that have a substantially large domestic market with no major foreign competition at present *(Datta Banik and Basu, 2002; Patwardhan et al.,2005).* However, it is important to note that there are no strict pharmaceutical regulations on Ayurvedic and nutraceutical health products in India. Most of these products are available to consumers directly over the counter without need for a medical prescription *(Patwardhan et al., 2005).* India has a large share of the international functional food and nutraceutical market, and exports products to the far east, south-east, west and middle east Asia as well as to parts of north Africa and the EU. However, India's major export destination is the USA and Japan *(Patwardhan et al., 2005).* Labelling, and strict control over formulations and branding are still not required for most products.

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In addition cost of production typically is low, making this produce highly competitive in Asian and African markets *(World Nutraceuticals, 2006)*. Estimated value of the industry is $10 billion per annum with exports of $1.1 billion per annum making a significant contribution to the he export market *(Singh and Khanuja, 2003)*.

A similar profile for the industry can be developed for China. Both functional foods and nutraceuticals are part of the traditional Chinese diet and are also a large component in Traditional Chinese Medicine (TCM). The industry is represented by around 1000 small to medium sized enterprises located throughout China *(AAFC, 2002; Patwardhan et al., 2005)*. There is a steady demand for functional foods and nutraceuticals in the country and a friendly business environment.

Branding and labelling are not under stringent control and ironically, foreign-made preparations of Chinese medications have been reported to have better health and nutritional qualities than those produced in China. However, because of less stringent regulations, cheap labour, lower production costs and the enormous market involved, China has the potential to emerge as a leader in the international market *(AAFC, 2002; Patwardhan et al., 2005)*. Japan, Hong Kong, Korea and Singapore are major importers of TCMs and represent 66% of Chinese plant drug exports *(Report of the Chinese Ministry of Commerce, 2003)*. The annual Chinese herbal drug production is estimated at $48 billion, with estimated exports of $3.6 billion *(Handa, 2004)*.

Japan is the second largest market in the world for nutraceutical products after the United States. Its nutraceutical market has exhibited a steady average growth rate of 9.6% per annum for the past decade, and in 2006 its functional food industry was estimated to have a value of $27.1 billion *(Functional Food Japan, Project Report, 2006)*. The Japanese people invented use of modern functional foods in the early 1970's and ever since the Japanese functional foods' industry has been a leader within the global marketplace. The percapita consumption of nutraceuticals by the Japanese is actually higher ($166.00 per annum) than that seen in the USA ($136.00 per annum) and in the EU ($92.00 per annum). Two types of functional foods have been approved by the Japanese government; *i.e.*, those with approved health claims or FOSHU (Foods for Specified Health Use) and foods that may provide health benefits (without any health claims). .

Other large, emerging international markets in south and south-east Asia are seen in Taiwan, Sri Lanka, Thailand, the Philippines, Vietnam, Lagos, Kampuchea, Indonesia, Malaysia, North and South Korea *(World Nutraceuticals, 2006)*. In addition Australia and New Zealand are emerging quickly as international competitors. Investment in research and development of high quality functional food and nutraceutical products along with promotional support from both the industry and government has helped in rapid establishment of the industry in these two countries and in their catching a share of the expanding global market *(Heasman, 2004; FRST, 2003)*.

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Potential markets also can be found in oil rich middle-eastern or gulf countries like Saudi Arabia, the United Arab Emirates, Qatar, Oman and Kuwait *(World Nutraceuticals, 2006)*. It is estimated that demand for functional food and nutraceutical products will grow internationally by about 6% per annum through 2010, and that China and India will be the fastest growing markets, while the USA will continue to be the largest, followed by Japan. African markets are still not well organized, although functional food and nutraceuticals are part of the African diet and culture. Scattered opportunities also have been identified in parts of northern and sub-Saharan Africa and in some southern African nations *(Global Market Review of Functional Food, 2005)*.

Increasing Prospects for the Functional Food Industry

Production of functional foods is being recognized as the number one global food industry as changing trends in population demography, consumer affluence, increased education, life expectancy and improved healthcare give rise to a rapidly emerging diet and health conscious consumer clientele *(Belem, 1999, Childs 1999; Dillard and German, 2000; Drouin & Gosselin 2002)*. Increasing health consciousness has been one of the most important stimulating factors for rapid global growth of the nutraceutical and functional food industry *(Hasler, 2000)*. In a survey of public opinion conducted in 1998 by the International Food Information Council (IFIC), about 95% of the participants expressed a view that some foods are capable of reducing health risks and that consumption of these foods can result in an improved quality of life (Schmidt, 1999). In another survey the American Dietetic Association / ADA (2000) reported that 85% of participants believe that nutrients and diet are important to them. Moreover, personal use of Alternative Medicines (AM) in the United States of America (USA) doubled (to 40%) during a period of seven years from 1990 - 1997 *(Hasler, 2000)*. Nutraceuticals and functional foods have been reported to have significant biological actions and their use across the globe continues to increase due to historical and more recent reports of clinical success through use of these products *(Acharya and Thomas, 2007; Hardy, Hardy and Ball, 2003)*.

Primary factors associated with increased popularity of nutraceuticals and functional foods that have generated interest within the public have been reported by a number of different scientific groups as well as government agencies (Belem, 1999; Breithaupt, 2004; Childs, 1999; De Felice, 1995: DellaPenna, 1999; Drouin and Gosselin, 2002; Elliott & Ong, 2002; Govt of Canada, 2003; Hardy, Hardy & Ball, 2003; Hasler, 2000; LFRA, 2001; McNamara, 1997; Peterson and Dwyer, 1998). Some of the most important are:

An Increase in Public Health Consciousness

Increased access to information through education and an enquiring media has resulted in a rapidly emerging self-care movement among consumers. As well, our understanding of the mode of action, health promoting effects and value added properties of food and non-food products is increasing rapidly. When coupled with increased economic prosperity, health awareness is driving more

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consumers to take a more proactive role in managing their health; people are less willing to simply wait and implement health care advice provided by a medical community in response to health problems.

An Aging Population

Increase in age of the baby-boomer birth cohort and recognition of their limited mortality is precipitating need for a more responsive, if not sympathetic health care system that promises to help them manage the vast array of age-related maladies that this group now is facing.

Escalating Health Care Costs

Exponential increase in expenditures within the health care system and concern for maintenance and sustainability of the system is forcing many consumers to seek out more cost-effective alternatives to those being provided by traditional forms of high cost professional and structured medicine.

Recent Advances in Research and Technology

Advances in the areas of food technology, food biochemistry and the nutritional sciences (including nutritional genomics) are providing consumers with access to fresh and often supplemented produce with recognizable health benefits that previously were not available. New methods being used by the functional food industry to isolate, characterize, extract and purify nutraceuticals from bacterial, plant and animal sources are resulting in decreased costs to the industry as well as providing new options for use of functional food products.

Changes in Government Regulations and Accountability

Changes in policies and laws governing distribution and marketing of food are recognizing the current shift in attitude towards consumer awareness and accountability of government to the people it represents. Increased Recognition of Functional Food Benefits: increased numbers of reports now recognize health and clinical benefits associated with access to high quality and nutritional foods.

Expansion of the Global Marketplace

Better communications and transport for marketable goods is resulting in a more accessible global marketplace and an increase in international business opportunities. This, coupled with increased recognition for proprietary patented products is resulting in a more business-friendly environment for expansion of industry.

A Sympathetic Media

A supportive and promotional environment is being generated by the media in response to significant advances being made in research and development of food, its processing, packaging and transportation.

Together these changes are resulting in sweeping global acceptance and demand for functional foods and nutraceutical derivatives.

Science-based Evidence is Contributing to the Popularity of Functional Foods

There is increasing recognition of the need for scientific evidence to support nutritional and medicinal claims being made within the functional food and

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nutraceutical industry *(Acharya and Thomas, 2007)*. In 1997 Clydesdale called for development of an international dialogue on the types of validation required to recognize health claims being made for functional foods and food components. Since then there has been considerable discussion on the need for better characterization of functional foods and food products as well as need for clinical trials demonstrating medicinal claims, and better labelling of products whose active agents may vary considerably in concentration due to genotypic variation, response to environment and/or processing during preparation of a product.

According to Dillard and German (2000) the health promoting effects of phytochemicals and nutraceuticals and/or functional foods likely are due to a complex mix of biochemical and cellular interactions which together promote overall health of the individual. They suggest that these agents may function as substrates in metabolic reactions or cofactors of key metabolic enzymes; as ligands that promote or compete with biochemical interactions at the cell surface or with intercellular receptors which can enhance absorption and assimilation of important macro and micro nutrients; and as agents which selectively promote the growth of bacteria with health benefits in the gastrointestinal system and compete with or partially eliminate the growth of harmful bacteria. In addition these agents may act as enzyme inhibitors, absorbents or toxicant scavengers that can associate with and help remove damaging substances or toxins from the body. Major chemical groups now recognized as having potential health promoting effects, at least under some circumstances are the phenolics, flavonoids, alkaloids, carotenoids, pre- and pro-biotics, phytosterols, tannins, fatty acids, terpenoids, saponins, and soluble and insoluble dietary fibres *(Burt, 2004; Dahanukar et al., 2000; Datta Banik & Basu, 2002; Patwardhan et al., 2005)*. A list of important phytochemicals (nutraceuticals) commonly promoted and sold in the global market is presented in *Table 4*. While this list seems to expand on a daily basis, considerable more work is required to support claims that often times have been made locally in support of herbal or other traditional medicines but cannot be supported globally due to biological variation in genotype and ecotypic responses *(Acharya and Thomas. 2007)*. While considerable research may have been done with individual biological isolates, this same research often fails to recognize the vast diversity of biological organisms and consumer products derived from them.

Table 4. Important phytochemicals (nutraceuticals), their corresponding plant sources and medicinal properties

phytochemicals: chemical groups	*plant sources*	*medicinal property*
Alkaloids		
Quinine	Cinchona	Anti-malarial
Tropane alkaloids	Solanaceous members: Deadly night shade, Datura	In treatment of heart ailments
Morphine	Opium poppy	Antidepressant, pain killer
Ergot alkaloids	Fungus: *Claviceps purpurea*	Abortifacients

Vincristine	Periwinkle	Antineoplastic
Vinblastine	Periwinkle	Antineoplastic
Coumarin,	Fenugreek	Hypoglycaemic
Scopoletin	Fenugreek	Hypoglycaemic
Fenugreekine	Fenugreek	Hypoglycaemic
Trigonelliine	Fenugreek	Hypoglycaemic
Carotenoid terpenoids/ Isoprenoids		
α-carotene	Carrots	Antioxidants, anticarcinogenic
β-carotene	Fruits & vegetables	Antioxidants
β-cryptoxanthin	Oranges & tangerines	Antioxidants, anticancer
Lutein	Vegetables (kale, spinach, watercress, parsley)	Reduce risk of macular degeneration, protect against colon cancer
Zeaxanthin	Corn, avocado	Protects eye from macular degeneration and cataracts
Lycopene	Tomatoes, pink grapefruit, watermelon, guava, papaya	Reduces risk of prostrate cancer in males
Non-carotenoid terpenoids		
Perillyl alcohol	Cherries & mints	Anticancer
Saponins	Legumes (Chicks, peas, fenugreek, all pulse crops)	Reduces cholesterol levels in blood
Terpenol	Carrots	Anticancer
Terpene	Peels and membranes	Anticarcinogenic
limonoids	of citrus fruits	
Flavonoid polyphenolics		
Anthocyanins	*Stawberries*, raspberries, cherries, cranberries, pomegranate, apples, red grapes	Antioxidants
Betacyanins	Beet root	Antioxidant
Catechins	Tea	Antioxidant
Flavonones	Citrus fruits	Antioxidant
Flavones	Fruits & vegetables	Anticancer
Isoflavones	Soybean	Anticancer
Hesperetin	Citrus fruits	Antioxidant
Naringin	Grapefruit	Reduces cholesterol
Rutin	Asparagus, buckwheat & citrus fruits	Protects against cardio vascular ailments
Quercitin	Red onions, buckwheat, red grapes,	Anti-sitaminic, antioxidant

	green tea, apple skins	
Silymarin	Artichoke & milk thistle	Anti-atherosclerotic
Tangeretin	tangerines	Anticancer
Tannins	Cranberries, pomegranate, cocoa & tea	Reduces blood cholesterol,
Phenolic acids		
Ellagic acids	Strawberries & raspberries	Prevents colon cancer
Chlorogenic acids	Blueberries, tomatoes, grapes & bell peppers	Antioxidant
p-coumaric acids	Red and green ball peppers, legumes	Antioxidant, anticancer
Phytic acids	Legumes and whole seed grains	Lowers blood glucose
Ferulic acids	Seeds of brown rice, whole wheat and oats, apple, artichoke, orange, peanut & pine apple	Antioxidant, anticancer
Vanillin	Vanilla bean	Antioxidant, anticancer
Cinnamic acid	Cinnamon, balsam tree resins	Antibacterial, antifungal
Hydroxycinnamic acid	Grapes, blueberries & blackberries	Antioxidant, anticancer
Non-flavonoid polyphenolics		
Curcumin	Curcuma	Anti-microbial, anticancer, antioxidant
Resveratrol	Grapes	Anti-inflammatory, anticancer
Lignans	Plant cell walls	Reduces skin cancer
Glucosinolates		
Isothiocyanates	Horseradish, radish & mustard	Anticancer
Phenethyl isothiocyanate	Watercress	Anticancer
Sulforaphene	Broccoli	Anticancer
Indoles	Broccoli	Anticancer
Thiosulfonates	Garlic & onions	Anticancer, antimicrobial, reduces blood pressure and blood cholesterol
Phytosterols (plant sterols)	Peanuts, cashews, almonds, peas, kidney beans & avocados Anticancer, blocks cholesterol absorption	

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Anthraquinones		
Senna	Legumes and pulses	Purgative,
Barbaloin	Aloe	Laxative, anti-helminthic
Hypericin	St. John's wort	Analgesic
Capsaicin	Capsicum (hot peppers)	Anticancer, anti-inflammatory, anti-apoptotic
Piperine	Black peppers, jalapeno peppers	Helps in digestion
Terpenes		
Menthol (Monoterpene)	Plants of mint family	Topical pain reliever & anti-pyretic
Borneol (Monoterpene)	Pine oil	Disinfectant
Santonin (Sesquiterpene)	Wormwood	Photosensitizer
Gossypol (Sesquiterpene)	Cotton	Contraceptive

Recognition of variation in functional food and nutraceutical composition will provide opportunity for the industry to give consumers a variety of new products that can be developed for niche or specialized markets. Development of new products with distinctive genetics, ecotypic response and reliable health benefits also could provide local producers with access to more stable and specialized markets similar to those already seen in the coffee and wine marketplace where regionally produced variants of these products have been successfully marketed based on their unique regional attributes. In any case, as scientific studies which reveal new discoveries with potential health benefits are identified by potential consumers and the media, more support, credibility and demand for functional foods and nutraceuticals is being generated. This is resulting in a marketplace with considerable potential for growth and many new opportunities within the industry both internationally and at a regional level.

The Stakeholders of the Industry

A conceptual portrait of the stakeholders dealing with the global functional food and nutraceutical industry and the inter- and intra-relationships is presented in this section. The stakeholders can be grouped under two core groups: primary (inner circle) and secondary (outer circle). The primary stakeholders include the producers (farmers/growers) of the plant products, food processing and pharmaceutical companies who manufacture products and byproducts, the consumers who directly or indirectly buy them for the purpose of willful consumption, the government and regulatory agencies who have the responsibility to assure proper development of the industry and scrutinize and/or certify the quality of food for human consumption, university and research institutes for developing innovative ideas, approaches and techniques to survive in an environment of intense global competition and physicians to help patients

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to make the right choice to take appropriate food as a life style change rather than going for conventional and expensive medications each time that they fall ill. This core group is responsible for survival and well being of the industry. The secondary group consists of stakeholders that help in further expansion of the industry. This includes dieticians, alternative health practitioners, naturopathists, and herbalists who advocate for nutraceutical and functional food products making them acceptable and desirable to the common public, insurance companies who provide security to the manufacturing companies, retailers who help in the rapid sale and distribution of the manufactured products and environmentalists who promote the industry by supporting use of these products. The two core groups of stakeholders rotate around the central industrial pivot for this emerging industry. Some stakeholders have tight linkages while some work independently. However, all of them influence the center of this circle and ultimate success of the industry.

With Scientific Acceptance there is Need for Vigilance in Use of Terminology

With increasing consumer awareness, there is need for those within the industry to become more vigilant in their use of terminology as it applies to terms such as nutraceutical, functional, medical and novel foods. A list of important definitions is included in *Table 5*. In simple terms, nutraceuticals and functional foods are those foods or parts of foods that provide health and/or medical benefits to the target consumers, including prevention, protection and treatment of a disease *(Belem, 1999)*. It is important to the development of consumer confidence that functional foods and nutraceuticals are properly categorized. Formal characterization of products provides government and other regulatory agencies with the opportunity to implement controls such as labeling and verification within the industry. While movement in this direction has been taken in some countries *(Health Canada, 1998)*, it is important that those involved in the science and industry be proactive in order to avoid unnecessary conflict and to provide consumers with produce that they can both trust and depend upon.

Table 5. Important Definitions Associated with the Nutraceutical and Functional Food Industry

terminology	*definition*	*source*
Bioactive compounds	Naturally occurring chemical compounds contained in, or derived from, a plant, animal or marine source, that exert the desired health/wellness benefit.	Shambrock Consulting Group Inc. & Kelwin management Consulting (AAFC bulletin, 2006)
Functional ingredients	Standardized and characterized preparations, fractions or extracts containing bioactive	-

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	compounds of varying purity, that are used as ingredients, by manufacturers in the food (human and pet) and fractions or extracts containing bioactive compounds of varying purity, which are used as ingredients by manufacturers in the cosmetics and pharmaceutical sectors.	
Industrial ingredients	Standardized and characterized preparations, fractions or extracts of agri-commodities of varying purity that are used as ingredients by manufacturers of non-food products.	-
Natural Health Products (NHP)	Includes homeopathic preparations, substances used in traditional medicines, minerals or trace elements; vitamins; amino acids; essential fatty acids; or other botanical, or animal or microorganism derived substances. These products are generally sold in medicinal or "dosage" form to diagnose, treat, or prevent disease; restore or correct function; or to maintain or promote health.	-
Traditional Food Ingredients (TFI)	Standardized and characterized preparations, fractions or extracts of agri-commodities of varying purity, that originate from plant, animal or marine sources.and are used as ingredients, by manufacturers in the food (human and pet) and NHP sectors.	-
Traditional Processed Foods (TPF)	Conventional foods that have been manufactured by the traditional food processing industry and sold to the public through established distribution systems for generations	-

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Traditional Whole Foods (TWF)	Conventional foods that have been grown by agricultural producers for generations	-
Designer Foods	Foods that naturally contain or are enriched with cancer-preventing substances such as phytochemicals (Coined in 1989 by National Cancer Institute, USA)	-
Novel Foods	Products that have never been used as food; foods that result from a processes that has not previously been used for food; or, foods that have been modified by genetic manipulation	Health Canda (1998)
Nutraceuticals	A product isolated and purified from foods that is generally sold in medicinal forms are usually associated with food. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease (Coined originally by Stephen DeFelice in 1989, founder and chairman of the Foundation for Innovation in Medicine, USA)	-
Functional Foods	A functional food is similar in appearance to. Or may be, a conventional food, is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond the basic nutritional functions	-
Phytochemicals / phytonutrients	nonnutritive bioactive plant substance, A such as a flavonoid or carotenoid, considered to have a beneficial effect on human health.	American Heritage® Stedman's Medical Dictionary (2004)
Medical Foods	Special dietary food intended for use solely under medical	Food Technol (1992). 46:87—96.

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	supervision to meet nutritional requirements in specific medical conditions (Coined in 1992 by the Institute of Food Technologists Expert Panel on Food Safety and Nutrition).	
Phyto-pharmaceuticals	Chemicals in their natural from isolated from medicinal plants with potential benefits in human health and disease prevention.	Association of Saskatchewan Home Economists (2006)
Dietary Supplements	A product that is intended to supplement the diet that bears or contains on or more of the following dietary ingredients: a vitamin, a mineral, a herb or other botanical, an amino acid, a dietary substance, for use by man to supplement the diet by increasing the total daily intake, or concentrate. Metabolite, constituent, extract or combinations of these ingredient; intended for ingestion in pill, capsule, tablet, or liquid form; not represented for use as conventional food or as a sole item of a meal or diet; labelled as dietary supplement; includes products such as approved new drug, certified antibiotics, of licensed biologic that marketed as a dietary supplement or food before approval, certification, of license (unless a product is redefined through regulatory government agency)	Mueller (1999)

Future Directions

Explosive growth in use of nutraceutical and functional food products has made it necessary for the industry to develop new more global supply chain relationships *(Hobbs, 2002)*. Access to "credible quality" produce is needed to deal with rising consumer scepticism and to promote international growth within the industry *(Hobbs, 1962)*. Application of modern approaches in genomics, proteomics and metabolomics to the study of genetics and the biochemistry of

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functional foods derived from plants and animals has potential to allow us to characterize these products better. Moreover, these approaches will enable us to modify product characteristics with precision. Using marker assisted breeding and the application of genetic engineering new products with potentially better characterized and optimized benefits to human and animal health can be developed over relatively short periods of time *(Baima, 2006; Laroche, 2007)*.

Considerable attention now is being paid to characterization of the natural organismal diversity found throughout the planet. Natural diversity in growth and biochemical makeup of organisms presents us with unique opportunities to expand the product base within the functional food and nutraceutical marketplace. Plants in particular, present us with opportunities to alter their biochemical makeup to adapt to new applications and challenges, as well as providing us with a diverse array of growth responses that can be exploited to allow their use under many different regional ecotypic conditions.

A number of research groups in Canada, have been working in this direction. For example, we have been working with fenugreek *(Trigonella foenum-graecumL.)*; an annual legume commercially grown as a spice in India, but also possessing medicinal properties with potential for use in lowering blood glucose and cholesterol levels in humans, in particular in diabetics *(Acharya, Thomas & Basu, 2006)*. The plant is well adapted for growth in arid regions such as those found in the southern part of western Canada, but normally requires about 120 days to mature. As these regions of Canada only exhibit about 90 to 100 frost free days, the plants often do not have sufficient time to set commercially viable amounts of good quality seed. To address this problem we used a combination of selection and mutation breeding *(Acharya, Thomas & Basu, 2007)* to optimize the plants for growth in prairie regions of western Canada, and now are working to identify plants with unique biochemical properties for commercialization *(Bandara et al., 2007)*. Because different plant cultivars can respond to local soil and climatic conditions by significantly altering their biochemical content *(Taylor et al., 2002)* this is allowing us the opportunity to provide local producers with specialty crops that have limited capacity for exploitation outside the region. These crops will possess distinctive genetic and ecotype traits with reliable health and nutritional benefits. Development of niche markets based on these types of plants has potential to allow countries like Canada to compete effectively within the global marketplace by appealing to both local and international consumers by providing them with biochemically uniform produce with highly predictable health and nutritional properties. This approach also will benefit local producers by providing them with more stable markets similar to those seen in the coffee and wine industry. Moreover, by selecting plants with uniform performance over a wide range of environments, marketing agencies can label their products reliably and consumers can benefit from more predictable health and nutritional effects.

Development of better characterized and research proven products will help enhance consumer confidence in functional food and nutraceutical products produced in Canada and elsewhere and this will help these products in the global marketplace.

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Functional foods have entered the global markets with force in the past decade and have rapidly gained market share as value added products. Although the term "functional foods" currently lacks a common definition, this category is generally thought to include products that influence specific functions in the body and thereby offer benefits for health, well-being or performance, beyond their regular nutritional value. These products result from technological innovation, such as cholesterol lowering spreads, xylitolsweetened chewing gum and dairy products fermented with specific lactic acid bacteria, or are from a naturally functional food such as soy, oats and grains high in fiber. Functional foods have been developed in most food categories and the global market size is conservatively estimated to exceed that for organic foods. In addition to providing new options for improving health and well-being, the functional foods sector offers potential for new economic opportunities.

Functional foods sell at higher prices and contain larger profit margins than conventional foods, which makes the sector attractive for all. Retail prices of functional foods are typically 30 to 500 percent above the comparable conventional foods. For developing countries, economic opportunities in this sector are likely to result from growing domestic markets and from export possibilities to the dominant markets of USA, Europe and Japan. Many developing regions host vast biodiversity that can be tapped for new sources of functional foods or ingredients. The economic returns from health or performance-enhancing functional foods in consumer markets can offer improved opportunities for all members in the supply chain: from raw material producers to retailers. Besides the opportunity for diversification of production and the increased unit prices, farming for the functional foods industry can benefit primary producers and rural communities in other ways.

Firstly, contract growing and long-term partnerships benefit both suppliers and buyers; secondly, some of these crops may be native to areas, where more traditional farming is difficult and returns low; and thirdly, functional properties increase the value of otherwise potentially marginal plants, which can aid in biodiversity conservation if their sustainable use is carefully managed.

Although many developing countries could potentially benefit from investing in functional foods, relatively little is known about the current status of functional food production, products, and market development in most developing countries. The objective of this study was to review and assess the status of the functional foods sector in developing countries. Reviewing the available literature provides a general picture and assists in identifying gaps in knowledge of the sector. More details on two target countries, India and China, were collected in a concurrent study that will be reported separately.

The present report includes a general literature review of the potential generated by functional foods and an assessment of the sector in five countries *(China, India, Brazil, Peru, and Russia).*

1.9 Opportunities and Challenges for the Functional Foods Sector in Developing Countries

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The five target countries in this study are at different evolutionary stages in the development of the sector. China and Brazil have advanced regulatory frameworks for the approval of functional foods and their advertising, although these differ in the specifics. Russia has recently introduced regulations, while Peru and India still need to formulate regulations. Consumer demand for health-enhancing foods tends to be high and now the increasing levels of disposable income, especially in China, Brazil and Russia, provide a market for new value-added food products. Several target countries represent global biodiversity hotspots, and the potential this natural resource provides in functional food development is both recognized and embraced.

Functional foods represent a broad and heterogeneous food sector. The role of different supply chain players depends on the type of product and its physiologically functional characteristics. Additionally, cultural and regulatory factors influence the potential success of each type of product in different markets. However, there are many common issues that concern most functional food supply chains and products. Factors critical to success include existing scientific support for products; institutional capacity issues relating to research and regulation; and market-related aspects outlined above. In relation to these, the following challenges (although preliminary at this stage due to the limited data) in this sector in developing countries were identified as follows:

1. Legislation and regulatory frameworks require further clarification and strengthening. A clear regulatory system for production, sales, and advertising of functional foods, together with consistent enforcement are critical factors in building consumer trust in functional foods. Moreover, building institutional capacity may be necessary to better meet the demands. A credible system can also help to provide a level playing field to foster competition within the industry and encourage innovation. And, harmonization of still-evolving regulations with major export markets could help reduce potential trade barriers and reduce unnecessary duplication of work for different markets.
2. Continued presence in the functional foods market requires scientific evidence for product effectiveness. Even though certain foods may have been used for a long time for health-enhancement purposes, the definitive scientific support for claims as a functional product is often lacking. This necessary research requires time, financial and human resources, especially for products into the export markets, and for home markets as local regulations become stricter. Research investments are also needed for discovering new functional foods or ingredients in local sources.
3. Knowledge of end-market demand and regulatory requirements is lacking especially at the level of primary producers and ingredient processors. As

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this information is often available among the food sector experts, its distribution to all involved in the functional foods sector would enable better strategic decision-making and better coordination and collaboration within supply chains.

4. Producers, processors and exporters need market intelligence and knowledge of regulatory processes to create successful market development strategies. As market demand and the associated regulations differ in different markets, transaction costs in the export market are significant for individual companies. Specialized market development and export promotion services might offer a way to address this challenge.
5. Unique local biological resources may provide, much raw material for the functional foods industry and there are specific issues relating to this resource that need to be addressed. These are ecological and environmental sustainability, and intellectual property rights protection.

Opportunities in the functional food sector for developing countries exist in capitalizing on local knowledge on health-enhancing properties of foods and local resources, provided there are sufficient research, market development and institutional capacity in the sector.

Because functional foods cover such a broad group of products and production systems, an assessment of the specific opportunities at the national level is necessary as increased benefits for farmers and food manufacturers need to be assessed on product-byproduct basis. Specific export markets; regulations and consumer demand are product and/or or ingredient specific and largely dictate the possibilities for development. Further studies could establish the most critical bottlenecks in production systems and identify opportunities with the greatest potential for competitive advantage for small-scale farmers as producers of functional foods. This review has indicated some critical success factors in the functional foods sector and suggested some of the common challenges faced by the sector in developing countries. Although further research is needed to identify specific entry points in each target country, this assessment has indicated the areas where there are needs, and where assistance might help strengthen the sector.

The overall attitude towards the sector in the reviewed countries seems enthusiastic and promising functional food research areas and potential production systems were evident during this initial study.

1.10 Role of Diet and Foods in Human Health and Well-Being

Countries worldwide are going through a nutritional transition and are now affected by double burden of nutritional problems. Undernutrition and specific nutrient deficiencies continue to present a problem, and simultaneously imbalanced diets and chronic diseases are becoming alarmingly common. Non-communicable conditions (cardiovascular diseases (CVD), diabètes, obesity, cancer, and respiratory diseases) account for 59 percent of the 56.5 million deaths annually and 45.9 percent of the global burden of disease (WHO fact sheets).

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The problem of chronic diseases and malnutrition is more serious in developing countries. About 79 percent of all chronic disease-related deaths globally are taking place in the developing world. Lack of access to health services and sufficient income needed to buy healthy and nutritious foods characterize majority of poor people in developing countries. This poverty malnutrition nexus provides a strong case for improving income of the poor to help in reducing disease and malnutrition burden.

Globally, it is estimated that up to 80 percent of CHD, 90 percent of type-II diabetes, and 1/3 of cancers can be avoided by changing lifestyle, including diet (WHO fact sheets). Diet-related high cholesterol, high blood pressure, obesity and insufficient consumption of fruits and vegetables are among the significant risk factors that cause the majority of this disease burden (WHO fact sheet). Change in diet could reduce four of the risk factors and thus reduce the chronic disease prevalence.

In recent years, there has been growing consumer awareness about health, nutrition and the food safety (often triggered by specific food incidents) especially in developed countries and high-income groups in developing countries. In the food industry there have been two broad trends. There has been recognition that hazards and contaminants can enter the food chain and can cause sickness, death and diseases, and so governments, often to deal with consumer and industry concerns, establish regulations and standards on food hazards including standards on pesticides, antibiotics, microbiological hazards and other chemical and physical contaminants. There is also a growing awareness of the health-enhancing properties for prevention and treatment of health concerns beyond the basic nutritional component of many foods.

In the past century, the link between nutrition and human health has also been strongly established by modern science (WHO 2003). Examples include the role of nutrients in curing clinical deficiency status was discovered and more recently, the role of either suboptimal or excessive consumption of certain nutrients in the development of chronic diseases (heart disease, cancer, diabetes and dental diseases) that are a major public health burden in both developed and developing countries (*see Table 6*). As scientific evidence for these linkages has accumulated, the possibility of foods to influence more specific physiological functions in a beneficial way has become a growing area of interest.

Table 6. Selected Statistics on Non-communicable Diseases and Role of Nutrition

- Heart attacks and strokes kill 12 million people annually.
- An estimated 177 million people have diabetes, mostly type II. Two thirds of the cases are in the developing world.
- Over 1 billion adults worldwide are overweight.
- High blood pressure affects approximately 600 million people worldwide, and is estimated to cause 13 percent of deaths and 4.4 percent of disease burden. Two thirds of strokes and half of heart disease could be attributable

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to high blood pressure. High blood pressure is associated with risk of stroke, heart disease, and renal failure.

- High cholesterol levels increase the risk of heart disease, CVD and stroke. 18 percent of stroke events and 56 percent of heart disease are attributable to high blood cholesterol levels. High cholesterol thus causes 7.9 percent of total deaths and 2.8 percent of total disease burden globally.
- Low fruit and vegetable intake increases the risk of cancer, heart disease and strokes. Mechanisms of action behind this could involve various components in these foods, including antioxidants, flavonoids, carotenoids, vitamins and dietary fiber.

Sources: WHO Chronic Disease fact sheet and Global Strategy fact sheet.

However, dietary habits are notoriously difficult to change and even more difficult to sustain, even if the positive health effects are known. Functional foods can offer a means of providing some health or well-being benefits in a way that requires smaller behavioural changes by the individual consumer. Improved products may also provide dietary components that would otherwise be difficult to obtain in sufficient amounts from normal diets.

As more is understood about food components and physiological mechanisms, foods can be manipulated to reap the greatest benefits from their properties. The focus is moving beyond disease prevention to optimal health, optimal performance and maximum well-being. In addition to staying healthy, consumers seek to enhance functions such as mental or physical performance, perceived energy level, appearance, and even mood. Some experts suggest that in mature markets, these non-nutritional benefits ("softer benefits") are in fact taking over ground from the earlier focus on disease prevention.

Functional foods can, thus, have two general types of beneficial effects: to reduce the risk of a disease, and to enhance a specific physiological function *(Roberfroid, 2002)*. Disease reduction examples include reducing the risk of cardiovascular disease or dental caries, while physiological benefits include enhanced intestinal function, and mental performance. In reducing the risk of chronic health problems, foods exert their effect incrementally, over years and decades while for physiological functions foods and food components can offer benefits that are immediately evident, such as improved mental alertness, normal gut functions, or feeling of higher energy state.

Currently, cost-effectiveness of functional foods in reducing disease burden and lost productivity is an important research gap. The popularity of functional foods is increasing and the effect on the food industry is evident. Functional foods offer new options for consumers interested in improved dietary behaviour, which may use dietary components from functional foods.

Goldberg (1994) suggested the following trends in developed countries that will drive the success of functional foods:

- Accumulating clinical evidence;
- Age wave, demographic changes;

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- Health care cost containment;
- Media, access to more information;
- Nutritional labelling;
- Growing emphasis on healthy diet and overall prevention of chronic disease;
- Food technology innovations; and
- Brand differentiation.

Functional foods have displayed an annual growth in sales value at around 10 percent in global markets and this is expected to continue. Some listed trends are inevitable (demographic changes) but with others, systematic market development must involve many stakeholder groups from policy makers and food manufacturers to educators and the consumers. In addition, the relative strength of the driving factors varies as for example, some national governments have actively pursued the issue of functional foods as a response to growing public health problems. In other countries, the main driving factor comes from consumers or from emerging food science research.

1.11 Potential Benefits of Functional Foods to Developing Countries

With prevalent poverty and high rates of malnutrition and escalating rates of diet-related diseases in developing countries, growing functional foods markets provide opportunities for developing countries through improvements in public health, and for generating employment and income in the development of functional foods and their supply chains.

At present, demand for functional foods is concentrated in developed countries and high-income groups in developing countries. Functional foods are still considered expensive, although research has been carried out to cover issues of affordability and access, especially by the poor. Moreover, there is growing research on the potential of biotechnology in the development of functional foods for improved health effects of the staple foods in developing countries including high-iron rice, high vitamin A rice, improved oil content in legumes, improved protein content in legumes and soybean and orangefleshed sweet potato (Niba, 2003). To date, however, none of these genetically modified products have reached large-scale production. A few developing countries have been considering functional foods as part of their plan to tackle malnutrition. For example, in China, the Center for Public Nutrition and Development has proposed that essential consumables such as salt, flour, edible oils, baby foods and soy be fortified to help reduce malnutrition especially in poverty-stricken regions (Japan Development Institute, 2006). In India's rural areas, food companies have introduced specific products with high vitamin A at affordable prices (Japan Development Institute, 2006). At present, there is a weak case for functional foods to be used as an instrument to improve public health in developing countries, as development of traditional agriculture is likely to produce more affordable supply of food to cater to the basic nutrition and health needs of the public. There is,

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however, a stronger case supporting the development of functional foods and their supply chain needs for employment and incomegeneration opportunities. Demand for functional foods in both developed and developing countries is growing and there are increasing examples of supply chain development of functional foods in developing countries to meet these growing demands.

1.12 The Demand for Functional Foods

The global functional foods sector has experienced phenomenal growth over the past years. Since the late 1990s, the rapid expansion (approximately 50 percent to 60 percent growth in value sales over a five year period) is expected to continue only at a slightly slower pace over the next five years *(Benkouider, 2004; Datamonitor, 2004)*. The indicated growth rates are significantly higher compared with the approximately two percent growth annually for the food sector as a whole *(Menrad, 2003)*. Growth forecast for main emerging markets as a group (Hungary, Poland, Russia, Mexico, Brazil, China, and South Korea) is similar to the global forecast *(Benkouider, 2005)*.

In dollar terms, the estimates of total market value of functional foods currently range from US$31 billion to nearly US$61 billion *(Datamonitor, 2004; Benkouider 2005)*. In Europe, the market share of functional foods was less than 1 percent of total food market (which is valued at about US$1 to US$1.5 trillion) in the late 1990s *(Menrad, 2003)*. In the US, functional foods account for approximately 3 percent of food sales valued at more than US$500 billion, and percentage is expected to double by 2008. *(Benkouider, 2004)* More conservative forecasts suggest that even though the market share of functional foods will continue to grow, it will not surpass a 5 percent share in the near future *(Menrad 2003; Hilliam, 1998)*.

For comparison, the size of the global organic foods market was estimated at approximately US$36 billion in total revenues in 2005 *(Datamonitor, 2005)*. In organic foods, compound annual growth rates in revenues have been over 15 percent globally in 2001–2005 and are expected to continue at nearly 13 percent until 2010 *(Datamonitor, 2005)*.

Globally, dairy products represent the highest value sales (39 percent to 56 percent of total in 2003, depending on the source); functional confectionery, soft drinks and bakery and/or cereal groups (not in order) follow in popularity *(Benkouider, 2004; Datamonitor, 2004)*. The three main markets exhibit somewhat different characteristics and focus areas. In both Japan and Europe, gut health forms the most prominent area; in the U.S., heart health and cancer prevention are emphasized *(Arai et al, 2002)*. Globally, segments with most promise include probiotic products, cholesterol-lowering segment, and cosmeceuticals (Benkouider, 2004); gut and bone health *(Euromonitor, 2003)*; and heart health, weight management, and physical and mental *(Weststrate et al, 2002)*. Consumer health concerns and product preferences between markets vary.

Statistics on international trade of functional foods are not directly available as functional foods are traded in the tariff code categories of "among other foods". Similarly, a large portion of botanical ingredients are funnelled into the pharmaceutical, natural medicine or dietary supplement markets, along with the

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portion used in the production of functional foods making commodity trade figures of limited informational value. In trade reports, the ingredient markets for cosmetics, dietary supplements as well as functional foods are examined together because, at least in the major destination of the U.S., many or most of the natural ingredient manufacturers and distributors have positioned themselves as suppliers to manufacturers of all these sectors. *(Brinkmann, 2003)*

Growth in Functional Food Demand in Japan, Europe, and United States

The United States, Japan and Europe are dominant global markets, contributing over 90 percent of total sales (see Figure 3).

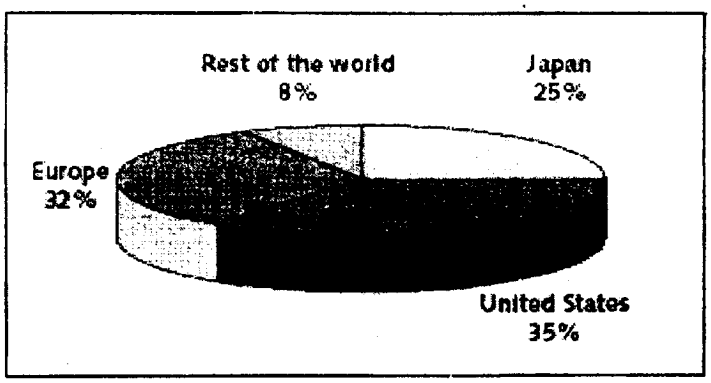

Fig. 3 Share of global functional foods market in 2003

Source: Datamonitor, 2006.

Japan

With an estimated demand for nutraceuticals and functional foods of between US$4 and US$15 billion annually, Japan represents the most sophisticated market in the world for this industry *(SWMI, 2002)*. The industry is expected to grow at a rate of about 12 percent per year through 2005 *(SWMI, 2002)*.

In Japan, functional food products have been sold since the 1930s. The sector's world leadership began in 1980s, driven by major forces from demographic and public health trends, strong government involvement as a response to these changes, and favourable characteristics in local demand.

The government push into functional food research programs in the mid 1980s was a response to the ageing population with its increasing health problems and the expected increases in health care costs as a result. The purpose of the government-initiated research was to investigate, in-depth, the role foods can play in reversing and preventing the prevalent chronic health conditions. Following these national research efforts, legislation was soon crafted to bring newly developed functional foods onto the market. In 1991, a distinct category, Foods for Specific Health Use *(FOSHU)* was created for products, which may improve specific health conditions. The key reason for this distinct product category and labelling system was to curb misleading marketing of non-proven products *(Arai, 2002)*.

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The FOSHU regulations recognize various health conditions, for which food products can be approved (see Table 7). In 2001, this regulation was expanded and a new category of "foods with health claims" was created to include both FOSHU and a group of "foods with nutrient-function claims". This latter type of claim has now been approved for twelve vitamins, five minerals and beta-carotene *(Ohama et al, 2006)*. FOSHU approval is determined on a case-by-case basis while nutrient-health claims are generic for any product meeting the stipulated requirements. Since 2005, disease risk reduction claims are also allowed, and a possibility for "qualified FOSHU" products based on emerging scientific evidence has been included *(Ohama et al, 2006)*.

Table 7. FOSHU* functions and functional food components

FOSHU function	*Approved products (#)*	*Main functional ingredients*
Foods for gastrointestinal health	254	Oligosaccharides, Lactobacillus, Bifidobacterium, Psyllium husk, indigestible dextrin, wheat bran, low molecular sodium alginate, partially hydrolyzed guar gum
Foods for people with high cholesterol/ triglyceride level and body fat	117	Soy protein, chitosan, low molecular sodium alginate, peptides, diacylclycerol, plant sterol/ stanol (esters), green tea catechin, middle chain fatty acid, Drug and Health Administration, Environmental Protection Agency, degradation products of globin protein, Psyllium husk
Foods for those with high blood glucose	71	Indigestible dextrin, L-arabinose, wheat albumin
Foods for those with high blood pressure	64	G A B A, peptides
Foods for dental health	34	Xylitol, polyols, tea polyphenols, CPP-ACP
Foods for bone health	26	Soy isoflavone
Foods for those prone to anemia	3	Heme iron

Source: Ohama et al., 2006.
**Foods for Special Use.*

Since 2001 FOSHU products can take the form of capsules and tablets (that is dietary supplement form) in addition to food and drink, although a great majority of products are still in more conventional forms *(Ohama et al., 2006)*.

Even with the clear category of functional foods and the possibility of obtaining government FOSHU certification, many companies choose to use other

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means of promoting products. This is partly because relying on consumers' awareness of nutritional components may be equally effective. In the late 1990s, it was reported that 90 percent of functional food products do not have a health claim on their packaging *(Farr, 1997)*.

The FOSHU label may allow for higher pricing of the product but even without it, functional foods present a lucrative business sector. FOSHU approved products constitute only approximately 18 percent of all functional food revenues in Japan *(Hayes, 2004)*.

At the end of 2005, more than 569 products had been approved as FOSHU *(Ohama et al, 2006)*. Since 1990, an estimated 5,500 or more new functional foods (FOSHU or non-FOSHU) have been introduced in Japan. At anyone time there are 1,500 to 2,000 functional foods on the market, of which approximately 400 qualify for FOSHU status *(Mine, 2005)*. At the present time, the Japanese spend US$126 per person annually on functional foods compared with US$67.9 per person per year in the U.S., US$51.2 for Europeans, and an estimated US$3.20 for other Asians *(Mine, 2005)*.

Japan has pioneered functional foods and remains the world leader. The factor driving this market's emergence and continued thriving include purposeful government involvement that regulates the field, but does not overly restrict it. In addition, the demographic shift and population health trends create demand. The Japanese culture also is receptive; innovation is appreciated and consumers are willing to try new products and even demand them *(Heasman, 2001)*.

Europe

The functional food market in Europe is estimated in excess of US$15 billion, and is growing quickly, expected to increase by as much as 16 percent annually *(SWMI, 2002)*.

From the European perspective, functional foods are more a concept than a distinct product category. The approach is function rather than componentand or product oriented. The European taskforce FUFOSE has set the following six physiological functions as focus areas in research: growth, development, and differentiation; substrate metabolism; defense against reactive oxidative species; cardiovascular system; gastrointestinal physiology and function; and behaviour and psychological functions *(Diplock et al, 1999)*.

Common legislation regarding health claims and labelling among EU countries is still missing. EU-wide regulations on types of claims approved and the necessary conditions for them have been under intense debate in the past years. Until the EU regulations have been written, national regulations have different rules regarding the acceptability of structure or health claim *(Hawkes, 2004)*.

In the heterogeneous European markets, there are large regional differences in use and acceptance of functional foods *(Menrad, 2003)*: traditionally, southern Europeans have appreciated natural, fresh foods and consider those good for health, in northern Europe many food technology innovations have experienced remarkable market success such as the daily dose probiotic dairy products which

have been the most popular product category across Europe *(Menrad 2003; Arai 2002)*. European consumers tend to use functional foods mostly for their health-promoting or disease risk preventing properties *(Arvanitoyannis 2005)*.

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United States

Similar to Japan, the American functional foods market tends to be product, component, and marketing driven *(Diplock et al., 1999)*. The food labelling regulations in the United States are complex, constantly evolving, and disagreements about content and wording issues have been even resolved in court *(Heasman & Mellentin, 2001)*. The two pieces of legislation relevant to functional foods are 1990 National Labelling Education Act (NLEA) and the 1994 Dietary Supplement and Health Education Act (DSHEA) and are administered by the Food and Drug Administration (FDA).

In the U.S, two types of claims related to health and/or well-being are allowed for foods: health claims and structure-function claims. Health claims describe a relationship between a substance in food and a disease or health condition and are generic in that any food that contains an indicated level of the respective nutrient can use them. (*See table 8* below for a list of currentlyapproved health claims.) Health claims must be supported by the all publicly available scientific evidence and there must be significant scientific agreement among qualified experts that this support exists *(IFT, 2005)*.

The current regulations also recognize "qualified" health claims for products that currently do not meet the extensive demands for supporting scientific evidence. The FDA, however, reserves the right to formulate the wording on these claims. The results in many cases have been poor; the claims are seen as confusing by consumers and they may unintentionally even placed the quality of the product in bad light. Health care claims are one of the most significant areas of the U.S. functional foods regulations *(Burdock et al., 2006)*.

Table 8. Generic Health Claims Approved in the United States

- Calcium and Osteoporosis
- Dietary Lipids (Fat) and Cancer
- Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease
- Dietary Non-cariogenic Carbohydrate Sweeteners and Dental Caries
- Fiber-containing Grain Products, Fruits and Vegetables and Cancer
- Folic Acid and Neural Tube Defects
- Fruits and Vegetables and Cancer
  - —Fruits, Vegetables and Grain Products that contain Fiber, particularly Soluble fiber, and Risk of Coronary Heart Disease
- Sodium and Hypertension
- Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease
- Soy Protein and Risk of Coronary Heart Disease
- Stanols and/or Sterols and Risk of Coronary Heart Disease

Source: U.S. Food and Drug Administration website, http://www.cfsan.fda.gov/~dms/lab-ssa.html. Accessed: Jan. 25, 2006

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Structure-function claims, which describe the role of a nutrient in the maintenance of a normal physiological function, do not have to be preapproved. These claims may only refer to normal physiological processes or states and follow the format such as "calcium helps maintain healthy bone structure." Using structure-function claims requires notification to the FDA 30 days prior launching the product.

In contrast to foods, dietary supplements also regulated by the FDA can be marketed more freely with various structure-function claims, although labelling must also identify the product as a dietary supplement. Functional food additives can be used in supplements with fewer restrictions compared to foods.

Skilful marketing and consumer oriented product development are key features of the American market. Marketing possibilities created by the healthy eating trends have been fully utilized for example in marketing traditional foods such as oats and tomatoes as functional, once their health benefits have been established (Heasman & Mellentin, 2001). Although the labelling regulations are complex, consumers do use label information as sixty-four percent of North American (U.S. and Canada) consumers report "mostly" understanding nutritional information on food packaging (Nielsen, 2005b). In a recent survey, food product labels were found to be one of the three most common reasons for change of diet, along with information from health professionals and family and friends *(IFIC, 2006a)*.

The most interest in functional foods has been in reducing the risk of cancer and heart disease *(Arai, 2002)*. In 2005, the most discussed functional foods or food components in the media were: general fruits and vegetables and omega-e fatty acids *(IFIC, 2006b)*. After these came garlic, fiber, foods with antioxidants, lycopene, plant estrogens, and unspecified functional foods *(IFIC, 2006b)*. While the top five health benefits from functional foods were: reduced risk of cardiovascular diseases, reduced risk of cancer, weight loss/management, improved general health, and improved memory *(IFIC, 2006b)*. The biggest health concerns, reported by consumers, have been heart health (heart disease, blood pressure, and cholesterol level) and cancer *(IFIC, 2000)*.

Small but Growing Demand in Developing Countries

The demographic, economic, and cultural changes that have driven the development of functional food markets in developed countries are occurring also in developing countries. Small ageing populations and the continuing and increasing prevalence of chronic diseases are producing interest in the benefits of improving dietary habits. With the increasing globalization of the marketplace, especially in the food and pharmaceutical sectors, there has been an increase in the demand for new innovative products including in the functional foods sector.

Developing countries are currently at very different stages of market maturity. In Southeast Asia, Latin America and Africa, traditional knowledge has always been appreciated with considerable knowledge of the functional, preventative or even curative properties certain foods. As a result, the idea of health promoting foods is readily acceptable and welcomed, even though the term "functional food" is unknown to consumers. A further element in the use of

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traditional methods, such as functional foods for health maintenance, is the high costs of pharmaceuticals.

Although disparities in income are great in most countries in the regions, increasing numbers have income levels that enable the purchasing higher priced food items, including functional foods. High prices exclude low income people buying these special products and this is the population group that could potentially gain the most from products.

While the domestic market environment and demand sophistication a factors in the opportunities available for companies developing countries, export markets may offer profitable opportunities to overcome their limited domestic demand of functional foods. Commercial export opportunities exist in value-added raw materials, functional ingredients, and even in consumer products for the functional food sector in the more mature markets. The following section examines the functional foods sector in the five case study countries, China, India, Brazil, Peru and Russia. For a more in-depth review, *see Annex 3.*

China

China's functional foods market is approximately US$6 billion per year, and this is expected to double by 2010 (Sun, 2006). It is still heavily influenced by Traditional Chinese medicine, even though western influences are moving in. All types of functional foods are increasing in popularity and increasing numbers of consumers can afford to use them.

China's "health food" industry experienced rapid growth from late 1980s to late 1990s, with fastest increase among the urban higher income population. Continued expansion in the functional foods market is predicted with per capita spending on functional foods expected to grow two-fold or more between 2004 and 2010. *(Benkouider, 2005; U.S. Commercial Service, 2006)* Currently, it still a small fraction of that in the developed markets.

The Chinese health food market will be driven by: economic growth, nutrition awareness, efforts to extend health food markets to rural areas, and the ancient tradition in herbal medicine that provides a platform for the development of the functional foods market (U.S. Commercial Service, 2006a). Increasing health care costs to deal with chronic diseases and an increasingly aging population may act as an incentive for using self-care methods such as health foods.

Table 9 sets out the claims made for functional foods. The regulations for the past decade involve 27 classes of claims.

Table 9. Functions Approved for Functional Foods in China

• Enhanced immunity	• Help in lowering blood pressure	• Eliminate acne
• Sleep improvement	• Increase bone density	• Eliminate chloasma
• Enhance tolerability to oxygen deficiency	• Help in the protection against liver damage caused by chemicals	• Help in the protection against the damage caused by radioactive matters

• Relief of physical fatigue	• Relieve eye fatigue	• Improve oil content of skin
• Weight loss	• Improve moisture of skin	• Improve growth and development
• Help in lowering blood glucose	• Anti-oxidation	• Improve nutritional anemia
• Lactation improvement	• Help in memory improvement	• Adjust enteric bacteria colony
• Promote lead excretion	• Promote digestion	• Clear the throat
• Help in the protection of gastric mucosa	• Promote lactation	• Catharsis

Source: Xie, 2005.

Between 1995 and late 2005, approximately 7000 domestic and 500 imported products had received government functional food approval (Xie, 2005). Overall, according to a locally conducted survey (not original report), 89 percent of all health foods are functional foods, while 11 percent are in a supplement form. Imports account for 40 percent of health food (including supplements) sales, although imported products fall mainly in the dietary supplement category. Approved products primarily target enhancement of the immune system (34 percent), combating fatigue (18 percent) and regulating cholesterol levels (16 percent) *(U.S. Commercial Service, 2006a).*

India

India's health foods history dates back centuries. Developments of the last few decades, have taken the traditions of ancient medicines and natural health foods to a new stage. With its strong tradition of healthful eating, India ranks among the top ten nations in buying functional foods *(Watson, 2006).* India's nutrition industry is generating US$6.8 billion in annual revenue, and that number is expected to nearly double in the next five years *(Ismail, 2005).*

The functional food industry in India is strong and growing with aims of becoming a major force in the international health foods market *(Japan Development Institute, 2006).* The government is working hard and fast at shoring up its intellectual property rights laws and food legislations; productivity is growing; and investment in research and development infrastructure continues to increase year-over-year *(Ismail, 2005).* This ambitious state of affairs is due to cooperation at all levels. Unanimity of purpose exists between major companies and in the government, where both ministers and the substantial state research organization are behind the idea *(Shrimpton, 2004).* In addition, the functional food market has met with popular acceptance from consumers at large.

Robust growth is expected to continue in the functional food industry. India's population is large and predominantly young, with 516 million people between the ages of 20 and 55 today, this number is expected to increase to 800 million within the next 40 years. As the younger generation moves toward middle age and disposable income increases, the need to maintain and/or establish a healthy diet will drive functional food consumption increasingly higher.

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However, despite all the positive support for functional food there are problems within the food industry including the low level of organization in the retail sector, inadequate infrastructure, and lack of capacity in valueadded processing. In addition, while the internationally recognized Central Food Technological Research Institute in Mysore has extensive research facilities and activity in this sector, food laboratory capacity in general is currently insufficient for the industry needs especially considering the need to regulate and implement international standards.

Brazil

The income gap in Brazil is large, but even with only 2.4 percent share affluent families amount to 1.16 million families creating a sizable target market for value-added foods, including functional foods. The size of the middle class is estimated at a significant 61.9 million. More than half of wealthy families are concentrated in Sao Paulo state. These affluent consumers follow international trends and are demanding in their purchase decisions *(Fonseca 2005a; Fonseca 2005b)*.

The market for functional foods in Brazil is relatively young, but growing. Despite the narrow target consumer segment, the total population size, developed retail network and local demand increase the attractiveness of this market. Currently products are mainly focused on micronutrient fortification, probiotic products, and cholesterol lowering spreads.

Regardless of the needs, health foods have a limited presence in the Brazilian market but the sector is relatively young, growing rapidly and has significant room for further growth. The small size of domestic target market has discouraged local companies from stronger market development efforts *(Fonseca, 2005)*. The Brazilian functional foods market is currently a small niche market that, however, has been forecasted to reach value sales of US$1.9 billion by 2009. However, the growth of 29 percent in per capita spending on functional foods during this period is considerably lower than forecasts for some other emerging markets *(Benkouider, 2005)*.

Dairy products present clearly the largest category of Brazilian functional foods sales. Functional dairy accounts for 73 percent of total functional foods sales, and 11 percent of all dairy sales in Brazil *(Nutraceuticals World 2005)*. From a functional ingredient point of view, the currently available functional foods are products fortified with vitamins and minerals, dietary fibers or probiotics. Recently, probiotic products have been receiving increasing media attention. Cholesterol-lowering spreads are also available; the first product with an approved health claim in the Brazilian market was in this category. Supermarkets are becoming the mainstream distribution channel for functional food products in Brazil *(Benkouider, 2005)*.

Since 1999, over 200 products with labelling claims have been approved with 14 different functional property claims (see Table 10). There are 25 types of substances or microorganisms to which these functions have been attributed. To date, no products with a disease risk reduction claim had been approved *(ANVISA, 2005; Bellaglia, 2006; Cleber Ferreira dos Santos, 2006)*.

Several challenges in developing the domestic functional food market include: most functional ingredients must be imported; previously emphasis on low-level processing of bulk commodities, and high cost of ingredients and meeting regulations.

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Table 10. Brazil Food Components and Related Functions Approved for Health Claims

- Omega 3 and the maintenance of healthy blood triglyceride levels
- Lutein and the protection against cellular damage from free radicals
- Lycopene and the protection against cellular damage from free radicals
- Dietary fiber and intestinal function
- Lactulose and intestinal function
- Bifidobacter animallis and intestinal function
- Fructo-oligosaccharides and balanced intestinal flora
- Inulin and balanced intestinal flora inulin Probiotics (9 species specified) and balanced intestinal flora
- Beta-glucan—helps reduce absorption of cholesterol
- Psyllium—reduces the absorption of fats
- Quitosan—reduces the absorption of fats and cholesterol
- Plant sterols—reduce the absorption of cholesterol
- Soy protein and reduction of cholesterol

Source: ANVISA, 2005.

Peru

The market for healthful products in Peru, in general, is still in early stages, but has potential for growth. As in the entire region, demand for better-foryou type low-fat and sugar-free products is increasing, but mainly among high-income consumers with rising health consciousness *(Gutierrez, 2004; EIU, 2005).*

Local demand for more specific functional food products seems to be directed at products made with local edible plants traditionally believed to have functional or even therapeutic properties, even though the effects have often not been substantiated by scientific studies. These fruits and vegetables can be purchased and used raw, home cooked, or processed (personal interview).

Processed functional or health-enhancing foods are also sold in Peru by at least the local branches of the largest multinational companies. Consumer attitudes regarding functional foods in Peru is a research gap.

Barriers to the growth of the functional foods market in Peru include lowincome level of consumers, lack of organized retailing, absence of clear regulations especially in labeling. Lack of analytical laboratory capacity, and the need to meet stringent quality demands for export would require more resources.

Russia

The Russian functional foods market is still relatively small but shows promise; improving nutrition awareness combined with the large population with

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rising incomes result in an increasing demand for health-promoting foods. The current market is mainly concentrated in the functional dairy sector.

Diet-related issues have recently gained publicity for Russia; the most prominent public health problem in Russia is cardiovascular disease (CVD), which accounts for over 50 percent of deaths. In large part because of CVD,9 life-expectancy in Russia is 12 years lower than in the U.S., and 5 years lower than in China. Inappropriate diet is a major determinant of CVD risk factors.10 About 60 percent of Russian adults have blood cholesterol levels above recommended levels and 20 percent need medical attention. Overall, death rates from non-communicable diseases are three times higher in Russia compared with the EU average *(World Bank, 2005).*

Although the Russian functional foods market is still undeveloped, numerous new products have been introduced in the past few years, and the demand for functional foods is high among the higher income population. A trend towards healthy lifestyle and healthier eating is evident *(Spiridovitsh, 2005; Taybakhtina, 2005b).*

The value of Russian functional foods market was estimated at US$75 million in 2004, and annual growth of 20 percent is expected *(Patton, 2005).* However, the definition for functional foods behind this figure was not explained. Growth in certain sectors, such as enriched products has been extremely rapid *(Drujinina, 2005c).*

The dairy industry has taken the lead in the functional foods movement and the largest growth is expected in this sector *(Spiridovitsh, 2005).* Probiotic products currently hold a noteworthy 35 percent market share in kefirs and 25 percent in drinking yogurts *(Drujinina, 2005c).* Functional properties are also becoming popular in the bakery and beverage sectors and functional foods differentiation strategies are used in oils, dietary fats, and confectionery, and even in spirits *(Drujinina, 2005a).* The main driver for the functional food market is consumer demand that comes from rising affluence and increasing health awareness, partly induced by public health education efforts and aggressive advertising of functional foods. In the dairy sector, 80 percent of advertising expenses in 2004 went into marketing functional products *(Spiridovitsh 2005).* Consumer awareness has improved particularly about the role diet can play in reducing the extremely high prevalence of CVD in the country. The government and business climate is supportive of companies investing in functional foods.

Russian consumers read product labels carefully and are ready to pay more for branded products *(Taybakhtina, 2005a).* The concept of functional foods is best understood in the dairy sector, while some product segments, such as high fiber foods, suffer from low consumer awareness *(Taybakhtina, 2005a).* In addition to still lagging consumer awareness in some aspects, challenges for the sector are the limited retail distribution, especially in rural areas, and lack of quality ingredients and technology from domestic suppliers. Expansion of functional foods market is likely to remain urban based for years *(Benkouider, 2005).*

Concluding Remark

There is an increasing demand of functional foods in developed countries. The rapidly growing market of functional or health-enhancing foods has emerged

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as a response to demographics, patterns of health and disease, innovation in food and health related research, and globalization. The ageing population, increasing prevalence of lifestyle related diseases, and the generally improving nutritional status has shifted the focus from nutrition issues to using diet to reach and maintain optimal health. This sizeable demand of functional foods provides important export opportunities for developing countries.

Demand for functional foods in the developing countries is small but growing and is an opportunity to develop local markets to supply this demand. Key concerns that may require public support include: underdeveloped infrastructure; unorganized and fragmented retail network; lack of resources for research and little cooperation between academic research and the industry; emphasis on low-level processing of bulk commodities; the high cost of ingredients, and the high costs in meeting food safety and quality regulations. The future of functional food markets will depend on how these concerns will be addressed by governments and how international organizations and the private sector can participate and facilitate this process.

1.13 Supply Chains in Functional Foods

Functional foods sell at higher prices and carry larger profit margins than conventional foods. Despite the higher initial research and development (R&D) costs, this makes it an attractive sector for all: from raw material producers to retailers. Price premiums for functional foods over similar conventional products are reported between around 30 percent and over 500 percent, depending on the product *(Hilliam, 1998; Heasman & Mellentin, 2001; Menrad, 2003)*. The main question, however, is who captures the price premium and how it affects the primary producer, especially the more marginalized ones. Despite limited research on quantifying the net benefit to primary producers and other actors along the supply chain, there are a number of studies that show how poor communities would benefit from having a viable alternative source of income.

Figure 4 illustrates the main stages involved in the functional foods supply chain from primary producers of raw materials to the end consumers. This generic supply chain representation does not factor in the various specific characteristics of different markets, nor the differences between the numerous types of functional foods. The detailed form of an individual supply chain may be very different from this representation.

The individual steps in *Figure 4* can be contained within the same company or can be conducted by separate parties, or even broken down into several sub-steps. In international markets, trade across national borders may take place at any stage of the chain. The ultimate destination (domestic versus. foreign market) could dictate how the activities from the very beginning (raw material cultivation or collection) are conducted.

The role of research distinguishes functional foods from the general food sector. Both basic and applied research can occur in public institutions, in private in-house research centers or through collaboration in various partnership arrangements. It is often incorporated into other supply chain activities and holds an integral place in the entire concept of functional foods, although in *Figure 4* shown as a separate group of activities. The top two research areas have applications

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in many related industries. Integral areas of research include basic biochemical and physiological research, combined with food technology. Research required for market development involves clinical studies on safety and efficacy and consumer research.

Developing countries, from the primary producers to retailers and consumers, can potentially benefit from developing functional foods for domestic consumption. The main challenge is producing affordable products for the poorer population. Functional foods for export markets can benefit mainly the primary producers and processors depending on the level of participation among supply chain actors in developing countries. There is, however, a need to assess the competitiveness of individual developing countries to ascertain the level of involvement (for example, primary production and/or processing) and the most economically attractive products for developing countries to participate in the growing demand for functional foods.

Figure 4.1 Supply Chains in Functional Foods

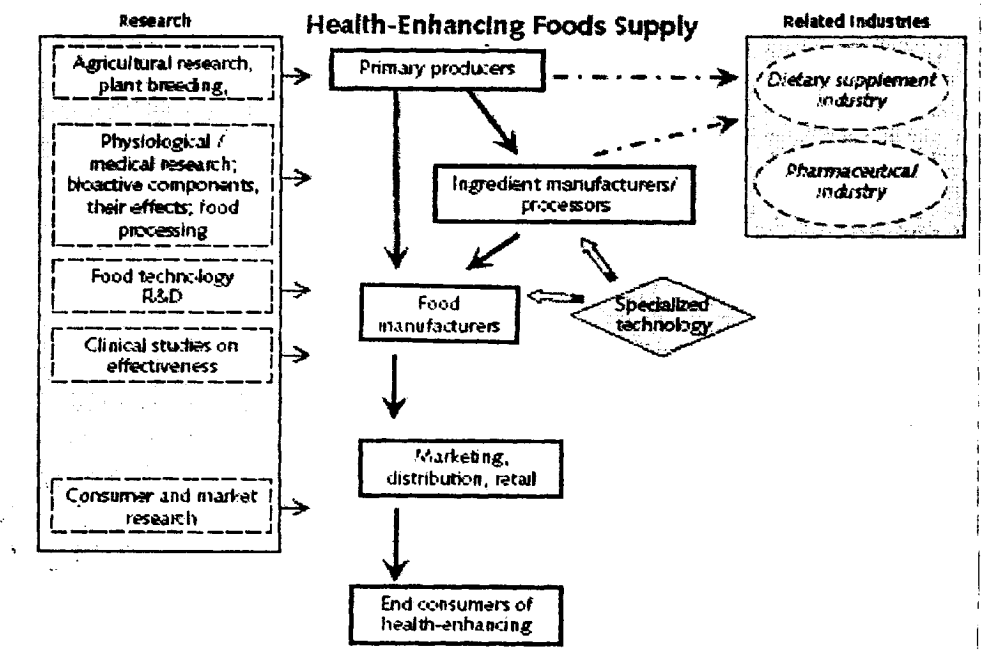

Fig. 4. Supply Chains in Functional Foods

Source: Authors.

Note: The bold black arrows indicate material flows (dashed lines flows into related industries). Small arrows from the research section indicate places in the supply chain where this type of activity is most used. Levels of research in product development have also been included.

Primary Producers

The functional foods sector has the potential to provide product diversification for producers and an alternative source of income. Primary agriculture is traditionally viewed as a bulk products industry, and competition

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based mainly on price and quality. Product differentiation is a key feature of successful competition in today's food industry. Health benefit claims are an example of an adding value to a product in order to differentiate this product from other similar products. Product differentiation affects production and often at the beginning of the supply chain with production of raw materials of improved quality and meeting strict buyer specifications. Such functional foods can result in higher value primary products, both plant- and livestock-based. Developing countries' poorer communities may benefit from growing functional foods which include sustainable harvesting and or production of wild plants; enhanced links to the private sector, for example, through contract farming; employment or business opportunities from processing ingredients or producing high-value products for functional foods; and employment in plantation farming.

Crops grown specifically for the functional food industry may include those with especially high content of applicable nutrients or bioactive nonnutrient components such as specific fatty acids, insoluble fiber, and so forth. These crops might include nontraditional plants with beneficial nutrient composition or improved varieties of traditional crops. Crops may be used naturally in nonprocessed form as functional foods or may only be used after processing.

Medicinal plants for functional foods, dietary supplements, pharmaceuticals and cosmetics, are a growing export sector for developing countries. In 2000, the leading developing country suppliers of medicinal and aromatic plants to the EU were China, India, Egypt, Morocco, Chile, Turkey, and Albania (UNCTAD (Peru) 2004). Almost two thirds of the EU imports of medicinal and vegetable saps and extracts originated in Madagascar, China, and Congo and more than 80 percent of vegetable alkaloids from Congo, Turkey, China and Brazil (UNCTAD (Peru), 2004). Trade activity in Uganda in dried/ground leaf/bark/root plant materials to the domestic and regional markets for food, cosmetics and pharmaceutical use increased and while its export market is relatively small, with a few companies transforming the plant material into powders, extracts and essential oils, the potential exists for further development (Biotrade Uganda website).

In addition to agricultural production, raw materials functional foods can be harvested wild, as is the case with many medicinal plants. However, the inability to standardize the concentration of active ingredients in wildcollected plants may present a problem in their commercial use (FAO 2005). If sufficient demand exists, systematic cultivation of these species could be a viable option (De Silva 1997). There are examples of where harvesting plants from forests for processing of healthy food products have benefited ethnic groups in some developing countries including the Philippines *(see Box 4)*. Moreover, health-enhancing properties increase the value of otherwise marginal crops and their potential use, if carefully managed, can aid in sustainable biodiversity conservation.

Box 4 Philippines: Processing of Healthy Food Products from Indigenous Forest Species by Ethnic Groups

Since 1994, the Ikalahans in the northern Philippines have been processing jams and jellies labeled as healthy food products from indigenous forest species. Their first products were guava jelly, guava jam and guava butter and their

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commitment to quality and good taste attracted people from outside the reserve to buy their products. Leading supermarkets in Manila also took notice. Their products were entirely natural with no chemical additives. Quality control measures ensure proper cooking and sterilization. To prolong the shelf life of the preserved products marketed under the "Mountain Fresh" label, jars are sealed airtight.

Encouraged by the favourable acceptance of their first products, the Ikalahans started processing other products from indigenous plants in 1980. These products include dagwey *(Saurauia subglabra)* preserves, dagwey jelly and spread; dikay *(Embelia philippinensis)* jelly; ginger *(Zingiber officinale)* jelly; passion fruit *(Passiflora edulis)* jelly; roselle *(Hibiscus sabdariffa)* jelly; and santol *(Sandoricum koetjape)* jelly and spread. Today, their products are sold in 10 major shopping centers in Manila and are exported to the United States of America, Japan and Australia.

Source: Dolom and Serrano, 2005.

Functional foods can also be based on animal products. For example, eggs have been promoted as nature's own functional foods and eggs with added benefits from increased omega-3 fatty acid content have been developed and marketed. A recent study on the supply chain of the value-added Omega-3 eggs in Canada found the return to egg farmers was 45 percent while the egg processor/concept marketer return was 29 percent *(SWMI, 2002)*. Other potential animal sources for functional foods include fish oil due to its high omega-3 content. Dairy products in health-enhancing forms of kefirs and drinking yogurts in Russia and camel milk in Kenya are leading functional foods *(see Box 5)*.

The rich biodiversity and traditional knowledge in developing countries of the health effects of certain indigenous plant species provide good potential cost competitive sources as primary producers for raw materials for functional foods *(see Box 6)*.

Box 5 Russia and Kenya: Dairy-Based Functional Foods

Dairy industry in Russia has taken the lead in the functional foods movement and the largest growth is expected in this sector *(Spiridovitsh, 2005)*. Probiotic products currently hold a noteworthy 35 percent market share in kefirs and 25 percent in drinking yogurts *(Drujinina, 2005c)*. The leading functional food company in Russia is the dairy and juice manufacturer Wimm-Bill-Dann (WBD). WBD together with Danone are the market leaders Fifteen percent of Danone's products belong in the Activia® health-enhancing product family *(Drujinina, 2005b)*. Local firms Ochakovo and Petmol have also launched probiotic product lines, although research and development costs as well as production and marketing investments are significantly higher than in traditional products, representing a barrier to entry into this sector *(Drujinina, 2005b)*. Still, most dairy processing companies have probiotic products in their product line *(Spiridovitsh, 2005)*.

In Kenya, there is a potential to develop the camel milk sector to respond to the demand from South America. Camel milk has medicinal properties, especially in management of diseases such as diabetes, high blood pressure, heart

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disease, allergy and peptic ulcers. A Peruvian hospital that specializes in allergy-related conditions has placed a large order for camel milk from a Kenyan company. Vital Camel Milk Ltd, which has been retailing the commodity in some selected outlets in Nairobi, says the clinic wants a supply of 1,000 liters of camel milk per week. The company's main marketing approach has been the fact that camels feed exclusively on diverse vegetation in the virgin savannah, far from pollution of urban centers. The animals browse more than 200 different plant species that make camel milk a unique organic product, according to Vital Camel Milk (VCM) Managing Director, Holger Marbach. Stakeholders from the Kenya Dairy Board Kenya Bureau of Standards and VCM are currently working on quality standards for camel milk. A cooling plant was inaugurated for camel milk in Isiolo town, where residents will be selling their milk and being paid promptly for milk deliveries at the rate of Sh 40 a liter. VCM handles 6,000 liters per day from some selected herders who meet its hygienic and herd management standards. There is an estimated one million camels in Kenya, and camels and dairy goats account for 16 per cent of the total milk production. Camel milk was a non-commercial commodity until VCM started processing it mid-2005. Since then, the commodity is found in some supermarkets (Gitonga 2006).

Sources: Spiridovitsh, 2005; Drujinina, 2005c; Gitonga, 2006.

To date, however, the promoted health effects of many local plants typically lack substantial scientific validation. In Peru, farmers are too far away from the functional food market and are mostly unaware of how their crops are finally sold or the health claims made by processors and concept marketers and sometimes these claims match with their traditional knowledge (personal communications with Thomas Bernet of the International Potato Center (CIP). Scientific substantiation of health effects would be necessary for gaining a stronger foothold in mature markets as illustrated by the Brazil and Peru cases (see Box 6). In other parts of the world, increasing research activities have been undertaken for substantial scientific validation of several local species including green tea in the Himalayan region in India, and various medicinal plants in Chattisgarh, India and Chiloe, Chile *(Durst, 2005)*. Moreover, as conservation and sustainability issues are included in the efforts to increase the cultivation and export of some of the non-traditional commodities *(BioTrade Peru, 2004)* functional foods market development warrants further research.

In addition to the rich reservoir of wild and exotic plants, developing countries may offer cost advantage in crop production as raw materials for functional foods due to generally lower labour and land costs. For instance, a recent study indicates that China and India have cost advantage over U.S. in soybean production (see Box 7).

Box 6 Peru and Brazil: Growing Production and Export Activities for Functional Foods

The vast biodiversity of Brazil, Peru and of the Amazon and the Andes holds remarkable potential for the discoveries of new health-enhancing ingredient.

In Brazil, manufacturers in Japan and the U.S. obtain plant-based physiologically active ingredients such as antioxidant compounds. Of these, acai-

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berry, guarana, and yacon have received global media attention. Currently products are mainly focused on micronutrient fortification, probiotic products, and cholesterol lowering spreads. The Brazilian functional food market is currently a small niche market that, however, has been forecasted to reach a sales value of US$1.9 billion by 2009. However, the growth of 29 percent in per capita spending on functional foods during this period is considerably lower than forecasts for some other emerging markets *(Benkouider, 2005)*. Investments in biodiversity related research have been described as inadequate. The Brazilian Agricultural Research Corporation (EMPRABA) investigates numerous plants with potential uses in this sector, including tubers, tropical fruits and medicinal plants (EMPRABA web site). Overall, functional foods related research is primarily conducted in public institutions.

Functional food activities in Peru focus strongly on the possibilities of utilizing its exceptionally rich biodiversity. In these efforts, functional foods are one sector among others including dietary supplements, cosmetics, and pharmaceuticals, all of which use natural ingredients. A natural ingredients sector assessment from 2004 identified ten species for further analysis on the basis of their potential in world markets. Of these, at least maca, camu camu, maize morado (purple corn), and yacon have health-enhancing applications. The value of exports of healthenhancing plants purple corn and yacon have boomed, growing an average of 467 percent and 335 percent annually, respectively, in the years 1998-2002 *(BioTrade Peru, 2004)*. The website of Peruvian Institute of Natural Products (IPPN), lists 16 plants under investigation for commercial use, some of which are at this stage more suitable for dietary supplements and natural medicines than functional foods. The main export destinations for maca and cat's claw, for which statistics are provided, are Japan and the United States, with 52 percent and 19 percent share of maca exports, respectively (2002 statistics). Dozens of companies are involved in export.

Source: Biotrade Peru 2004; IPPN website; Lima 2006; Benkouider 2005; EMPRABA website; Authors.

Box 7 Soybean Farming Cost Comparison between China, India, and United States

Soybean has now become one of the world's most valuable agro-products and by some estimates it is the most valuable crop in international trade. Soybeans are rich in edible oil and protein - around 60 percent of the protein food consumed in the world is provided by soybeans. Soybeans are the most nutritious food among all the beans and some even call it the "king of beans." A dry soybean is 38 percent protein, which is twice the protein average of pork, three times more than an egg and 12 times more than milk. It has an 18.4 percent fat content, which is basically unsaturated fatty acid. Soybean byproducts include soy meal, which is the most valuable, and range from 50—75 percent of its value (depending on relative prices of soybean oil and meal). According to the United States Department of Agriculture (USDA) soybean meal is the world's most important protein feed, accounting for nearly 65 percent of world supplies.

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Today, China is the fourth largest producer of soybeans in the world and after Argentina and Brazil. Based on a recent study by Japan Development Institute (2006), soybeans are 10 percent less costly to produce in China's northeast region and 2 percent less costly to produce in India than in mid-west U.S. As cost-efficient producers of soybeans, China and India have the potential to develop their soybased processing industry to cater to the increasing demand in the domestic and export markets for soy based functional foods.

Source: Japan Development Institute, 2006.

The distribution of value added benefits along the supply chain varies greatly among product types. The health-enhancing property that differentiates a food product may reside in the raw ingredient composition, for example oats or soy, or be entirely created in specialized processing, for example fermenting bacteria for yogurts. In the latter case, most of the value added benefits beyond a conventional product accrues to the company responsible for processing and market development. With a naturally health-enhancing product, a larger share of the profit could be expected to return to the primary producer, although in this category basic research and market development play an equally prominent role. A value-added chain analysis of functional foods and nutraceuticals in Canada more closely resembles that for highly processed foods with the share of value received by agricultural producers estimated between 5 percent and 25 percent of total value added, in comparison to 10 to 70 percent in the conventional food sector (SWMI, 2002).

Because functional foods return a higher value than conventional foods, the reduced percentage received by raw material suppliers reflects the other value added components in the value chain. Despite the fact that most functional foods provide higher price, there may be no additional value in chain for suppliers of raw materials than there is under the conventional food model (SWMI, 2002). While these circumstances may also be true for some supply chains in developing countries, the untapped demand may offer a potential source of income especially for those communities that are struggling to earn a living.

There is a growing literature on the success stories of developing countries tapping the export markets for high-value products, which have been the source of economic development in many poor communities. These range from fruits and vegetables in Kenya and Zimbabwe; and fish in Bangladesh to farmers' organizations supplying supermarkets in Brazil, Argentina and Chile.12 Farmers' associations have been effective in helping smallholders participate directly in supply chains through a variety of contractual arrangements to market their products and to access inputs at better terms as illustrated by the case of tea production in Vietnam initiated by the Making Markets Work for the Poor (MMW4P) project *(ADB, 2004)*. Moreover, the same study suggested strategic orientations for the tea value chain with emphasis on strong private sector and foreign direct investment (FDI), diversification into new products and markets, strengthening partnership with research bodies for improved quality, and strengthening linkages within the supply chain which could potentially make higher contribution to overall income, given that the current tea sector income, US$100 million, is far below its potential *(ADB, 2004)*.

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Associations can also help organize producers, negotiate contracts, improve market information systems, promote products, coordinate research, enforce quality standards, and pool risks as in the case of medicinal plants cultivation in India (see Box 8). These functions have become increasingly important with the rise of global sourcing of products and private or company grades and standards.

Additional trends in the area of raw materials, applying also to ingredients, include the value-added from ecologically friendly and ethical production, for which demand has been growing. Marketing advantage may be gained further from functional foods by offering, for example, products that are "certified organic" *(Brinkmann 2003)*. These innovations through differentiated strategies and certification can be crucial to some developing countries to enable them to gain niche markets internationally as in the case of Ecuador's medicinal plant sector (see Box 9).

International donor organizations, including the World Bank, have supported several schemes to foster small-scale farmers' participation in global supply chains, especially for higher value products. Despite these successes, small scale farmers' organizations for high-value exports are still very challenging to scale up and sustain. The case of the Asumpal farmers' cooperative in Guatemala is a good example. Farmers received technical assistance, technology, and market access, but they eventually failed in the market because they could not sustain the quality of the produce, supply it regularly, or resolve conflicts over side-selling *(Dugger, 2004)*. In Kenya and Zimbabwe, small holders grew nearly 75 percent of fruits and vegetables in 1992, but by 1998 four of the largest exporters were sourcing only 18 percent of produce from small holders *(Dolan and Humphrey 2000)*. Where markets are not competitive, contract farming and vertical integration (in which the same entity controls some or all of the steps in the supply chain, for example, from the seed and other inputs used to grow a crop to the processing and sale of the final product) threaten to make farmers overly dependent on one agribusiness company.

Simultaneous increases in production and exports in several countries can drive down world prices, posing a major risk for new suppliers into the markets. Price trends for avocados, green beans, green peas, mangoes, and pineapples already demonstrate this risk *(FAO, 2004)*. Similar to other high value crops, functional foods may run the risk of a "price crash" as many producers may simultaneously shift production as a result of strong government or non governmental organization (NGO) support as a result of media attention to these crops with praise for their nutritional and health benefit. This is already creating some concerns in Peru's functional food market where producers are potentially on the losing side when underutilized crops take off because of evidence related to health benefits (personal communications with Thomas Bernet). This provides a case for strengthening market intelligence to small-scale producers to aid them in decision-making and encouraging contract farming and private sector linkages to reduce the risk for small-scale producers by providing them a certain level of assurance for the market of their products. It also points to the importance of continuous innovation and diversification among producers and processors in order to be competitive in the market. The public sector also has a role in supporting the overall development of the functional foods sector as developing

the sector as a whole limits the risk of 'picking winners' and provides conditions for functional food innovations to develop and thus expand farmers food production choices.

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Box 8 India: Farmers Quickly Respond to New Market Opportunities

The Agricultural Technology Management Agency (ATMA), through a World Bank-financed National Agricultural Technology Project established in the Patna District of Bihar, became the lead agency that orchestrated and facilitated a series of development activities resulting in a sustainable supply chain being established for selected medicinal plants in that district. The lead crop and focus of this case study, is Vinca Rosa, the most common flowering plant in India. Studies have shown that this plant contains about 65 alkaloids, of which Indol, Robesin and Serpentine are most prominent. The leaves of Vinca Rosa contain alkaloids, like Vincristine and Vinblastine, which are used to treat certain types of cancers. The roots of Vinca Rosa also have alkaloids, like Azmalicine and Risprine, which can help reduce high blood pressure.

The first company to enter into a formal contract with producer groups to produce Vinca Rosa was M/s Ayurveda Shri Herbals Ltd. This firm had recently established a traditional drug manufacturing facility in the state of Gujarat, with a subsidiary office situated in Patna. The second company identified by the ATMA during its initial assessment of potential markets for medicinal plants was Baidyanath Ayurved Bhawan. This firm has four factories and produces over different 86 products requiring a significant range of herbs and medicinal plants.

When this activity was launched in 2000, there were five Farmer Interest Groups (FIGs) with a combined membership of about 60 farmers who began with the cultivation of Vinca Rosa in Patna district. By April 2003, the ATMA had established a network of 50 FIGs who were pursuing medicinal plants cultivation. The number of new members and FIGs in this network is expected to increase rapidly as farmers become interested in medicinal plant cultivation. At the state level, there is already a farmer association that is promoting medicinal plants cultivation as a means to increase farm income and to enhance rural livelihoods. Based on a cost-benefit analysis, estimated net income per hectare per annum is US$1,516.

The ATMA was instrumental in helping these farmers get organized and in learning how to produce and market Vinca Rosa and other medicinal and aromatic crops to buyers' specifications. In addition, the ATMA played a central role in coordinating and mobilizing the expertise of other organizations, including scientists from universities and research organizations, private sector firms, banks and nongovernmental organizations to develop and test the production technologies, to train the farmers and farm leaders, to arrange for the needed inputs and so forth.

As a result of these extension activities, the participating farm families substantially increased their farm income, which improved their rural livelihoods through better nutrition and expanded schooling for their children, especially girls; in addition, rural employment was generated due to the need for postharvest handling and processing of these crops.

Source: Singh and others, 2005.

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Box 9 Ecuador: Differentiated Strategy Based on More Exotic and Innovative Products for Competitiveness

Most of plant species for functional foods demanded in EU markets are not commercially produced in Ecuador or the entry barriers or competitiveness requirements are too high to warrant consideration in the country's development strategy. Based on expert opinion, a late entry by Ecuador into the functional foods and pharmaceutical products market in EU would be a mistake. Instead, Peru needs to concentrate on a differentiated strategy based on more exotic, rare, innovative plant products. In some cases, exporters have proved successful with non-native products such as cardamom, where the competitive edge is based on the competitiveness of the sustainable supply chain, its efficiency and the quality of the extraction process that makes Peru a global competitor.

In some cases, it is not sufficient to offer new and innovative products, as ecological and/organic certifications are important. Ecuador could develop a competitive edge, positioning itself as a reliable supplier of biodiversity based products (from extraction or domesticated harvests), with a system of sustainable supply chains organized around networks of small businesses or community based enterprises as long as these obtain sustainability and fair trade certification, and work with global quality standards.

Source: UNCTAD (Ecuador), 2004.

The experiences of many producer organizations that successfully participated in these export markets have demonstrated the importance of the private sector's role otherwise private entities will not invest in functional food production *(World Bank, 2005)*. As noted above, public support remains critical, however, for establishing a conducive legal, regulatory, and policy framework for example, in contract law and grades and standards; for promoting the organization of small-scale producers with good leadership which understands market requirements; and for helping to provide training, technology, and quality control systems *(World Bank, 2005)*. Moreover, there is need to promote interaction and strengthen linkages among producers, traders and processors.

In addition to the potential direct linkage of smallholder farmers to markets, there can be a significant employment effect from agribusiness, especially for women, and often at higher wages than traditional agriculture can offer *(Dolan and Sorby, 2003; Minot and Ngigi, 2003, Singh et al., 2005)*. These backward and forward linkages from the development of functional food markets potentially create opportunities for employment and additional income for producers of inputs, (middlemen, retailers, and exporters and service providers (private laboratory services, training, scientific and market researches, and other related services).

Processors (Food Ingredients and End Products)

Low-level processing at or near the production site could offer a feasible means to add value to raw materials with processing limited to general initial processing such as milling or involve specialized value-added processing. The output of initial processing could be channelled into further processing, or directly

serve as health-enhancing ingredient for the industry. In developing countries, most innovations come from the low-level processing (for example extracts, ingredients, and so forth.) whereas high-level processing often remains a constraint as in case of Brazil and Peru (see Box 10).

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Box 10 Brazil and Peru: Limited High-Level Processing of Functional Foods

In Brazil, most innovation in the food industry is occurring incrementally at the ingredient level. Processing equipment suppliers are not flexible enough to generate innovative solutions for the evolving food industry needs (Lima, 2006). From food industry point of view, the still low awareness of functional foods among Brazilian consumers limits the market. Research on consumer attitudes and behaviour with respect to functional foods presents a research gap (Lima, 2006). High cost of obtaining functional ingredients and scientific substantiation also present barriers for expanding markets. Other market challenges to manufacturers are posed by regulations on the use of certain ingredients and strict health claim regulations. Because of the regulatory hurdles concerning labelling, products may be launched under alternative names instead of as functional foods *(Lima, 2006)*, or by relying on consumers' previous knowledge of ingredients, which can be listed in packaging. Laboratory capacity is described as a barrier for development of functional food markets in this region. A major task of food laboratories in recent years has been creating a food composition database for Brazil. This task was necessary to enable companies to comply with the mandatory nutritional label legislation.

In Peru, biotrade-related activities often involve low level processing. Higher processing and the technology required for it are concentrated in Lima. The natural ingredients sector as a whole involves approximately 170 companies, out of which 80 companies are involve in exporting extracts for functional foods. Natural ingredients producers, mainly private, total around 20,000. (UNCTAD Peru 2004). For local consumer markets, some of the native functional fruits and vegetables are sold fresh, but also processed. Especially tubers maca and yacon1 are available in various forms (flours, extracts, syrups, chips, juices, and so forth), and also used as additives in many types of foods *(Hermann & Heller 1997; interviews)*. Statistics on how much of these consumer-ready products are exported or whether the export market is mainly at the ingredient level were not available. Dietary supplements, such as capsules containing these functional ingredients, are exported as end-products (IPPN website).

Sources: Lima, 2006; IPPN website; UNCTAD (Peru) 2004; Hermann & Heller 1997; key informants' interviews.

Medicinal plants are primarily processed into extracts, which can be used in the production of health foods, drinks, and dietary supplements. Ecuador, Columbia, Peru and Brazil have established and are expanding activities for harvesting and production of medicinal plants. While private companies are involved in the processing into extracts, the supply chain is dependent on business support services and technical assistance from international organizations. For

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instance, developing the medicinal plant industry in Ecuador with the aim of providing a source of livelihood and improving the quality of life of poor communities have been supported by international organizations for financial and technical assistance (see Box 11).

Box 11 Ecuador: The Jambi Kiwa Project

This project started in 1998 as a pilot project for the Guayabamba community in the Chimborazo province of Ecuador. Its legal status is similar to a community based company with the objective of improving the quality of life of the families through income generated by the production of the medicinal plants, and improving their knowledge of alternative medicine and management of their natural environment. The final goal of this project is to allow Jambi Kiwa to enter international markets. Jambi Kiwa brings together 600 families of 62 related communities of the province, with 80 percent of the women included. The company regularly supplies a product mix of about 44 different herbs, spices, medicinal plants and aromatic plants. Depending on the customer, it delivers the products as fresh, dried or processed. In some cases, it produces formulated mixes, each with a particular health claim: expectorant, digestive, carminative, fat burners, parasite control, and so forth.

Typical income for a partner family, of Jambi Kiwa is about US$60 per month, which is significant for these families living below poverty conditions. The income depends on the size of the plots of land assigned to the program; however on average a partner's income has increased by approximately 25 percent.

This project has received international support at different stages since its conception. Today, Canadian Centre for International Studies and Cooperation; International Solidarity Center Alma Quebec, Canadian International Development Agency, and the Dioceses of Riobamba are supporting the organization with technical and managerial services, constant technical assistance, financial support and infrastructure. Other previous supporters have included German Technical Cooperation, Comart Foundation and United Nations Development Programme. Recently, Export and Investment Promotion Corporation (CORPEI) joined with Jambi Kiwa to present a project to the Organization of American States , which has been accepted for a second round of support and should be the subject of final decisions in July 2006. This project requests funding for organizational, managerial and commercial support. It also includes some funds for infrastructure and equipment.

CORPEI is already helping Jambi Kiwa with its competitive funding (matching grants) for organic certification of 300 producers, commercial contacts and market information. For instance, Jambi Kiwa will need additional services from the BTFP such as joint venture formation, additional certification requirements, quality assurance, technical support, packaging design, export audit and integral business plan definition. The current goal is to increase average family income to at least US$200 per annum.

Source: UNCTAD (Ecuador) 2004.

Functional ingredients for food fortification are a rapidly growing market within the functional food sector. Staple foods have traditionally been fortified with vitamins and minerals in an effort to combat and alleviate nutrient deficiencies on a population-wide level such as the iodization of table salt. Much of this basic fortification is no longer considered "healthenhancing" but new possibilities for functional food fortification to help attain optimal health and reduce the chronic disease burden have emerged. Extraction of new functional ingredients for fortification may be highly specialized and the core innovation can in certain cases reside at this level.

The better-established functional ingredients for food product fortification include dietary fibers, plant stanols and sterols and probiotics. In addition, active research is conducted on other components including, but not limited to, fatty acids, various antioxidant compounds, and phytoestrogens. These compounds could be ingested naturally in, for example, fresh fruits, berries and vegetables, but are increasingly also processed for the ingredient market.

Genetic engineering has also been applied to modify plant metabolism to enhance nutritional or health enhancing properties. A famous case is Golden rice containing the Pro-vitamin A. Biotechnology offers opportunities for functional foods sector, however, none of the genetically modified products with health-enhancing food properties have, reached large-scale production yet (see Box 12).

Box 12 Genetic Engineering and Functional Foods

Genetic engineering of crops through gene transfer offers great potential for developing health-enhancing properties in foods. Research on these enhancements has included improving fatty acid profiles in oil seed crops, in modification of protein quality in potato, and anti-oxidant content in different crops, to mention a few *(see table below).*

Examples of Genetically Modified Crops with Health-Promoting Properties

Substance	*Benefit*	*Crop*	*Transgene*
Provitamin A	Anti-oxidant vitamin A supplement	Rice	Phytoene synthase (daffodil); Phytoene desaturase (Erwinia); Lycopene cyclase (daffodil)
Vitamin E	Anti-oxidant	Canola	γ-tocopherol methyl transferase (Arabidopsis)
Flavonoids	Anti-oxidant	Tomato	Chalcone isomerase (Petunia)
Fructans (indigestible polysaccharide)	Low calorie	Sugarbeet	1-sucrose:sucrose *fructosyl* transferase *(Helianthus tuberosus)*
Iron	Iron supplement	Rice	Ferritin (Phaseolus); Metallothionein (rice); Phytase (mutant, Aspergillus)

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A famous case in nutritional enhancement is 'Golden Rice' in which pro-vitamin A pathway has been engineered into rice, which does not naturally have it. However, a distinction is made here between health-enhancing properties inherently in a crop species and in biofortification applications, where a totally new metabolic pathway has been engineered into a crop. Thus, Golden rice, while an interesting example of the potential of agricultural biotechnology, falls into the latter category and is not included in this study. In addition to engineering specific nutritional and functional traits, where the genes governing the different properties are already known, there is also a new systems biology community applying genomics to explore bioactive properties of crops called nutrigenomics (Nutrigenomics is the application of the sciences of genomics, transcriptomics, proteomics and metabolomics to human nutrition, especially the relationship between nutrition and health wikipedia (Ruth and Wrick, 2005). It is evident that there is much dynamism and interest in applying the tools of molecular biology to identify new nutritional and functional foods properties in foods, and it is important for the development community to be informed on these developments. However, none of the genetically modified organism crops with functional foods properties have reached large-scale production. It is also worth noting, that engineered foods are more complicated from the regulatory point of view and require significant research to ensure the necessary approvals associated with food safety risk assessments and this is likely to delay their approvals for large scale production in developing countries.

Sources: Kleter, 2001(Table above); Ruth and Wrick, 2005; Authors.

Basic research aims to identify physiologically active components and investigate their effect on human health and disease, and discoveries may benefit several related industries (dietary supplements, pharmaceuticals and cosmetics). Additional research on product-specific applications must also be conducted. Economic analysis of the profits from producing for the functional food industry in comparison to dietary supplements or pharmaceuticals has not been presented in this report, but it would offer valuable insight into the potential and the associated tradeoffs in each segment of the industry.

While developing countries are the main source of raw materials due to vast biodiversity and cost advantage in crop production, developing a high-value processing of these materials may pose barriers to these countries. Because functional foods are conceptually defined at the consumption level, the development of suitable food solutions to deliver the health benefit to its ultimate target function is critical. On the other hand, functional foods are first and foremost foods and beverages, and in addition to health benefits, consumers expect to derive pleasure from consuming them *(Goldberg, 1994; Sloan, 2000)*. Therefore, the task faced by food technology is to transfer biological discoveries into organoleptically and conceptually acceptable consumer products, while ensuring that the health-enhancing properties are maintained throughout the process.

Building consumer awareness is critical in the case of new functional foods or ingredients or newly found health benefits of functional foods. Acceptance of products is linked to prior knowledge and understanding of the healthenhancing

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ingredients and the associated health benefits (Menrad 2003). Typically the product and its marketing must be adjusted to meet both the local regulatory environment (standards, scientific support for health claims when applicable) and deliver preferences to local consumer. Thus, the costs of bringing a new product on the market can be significant, and especially the magnitude of transaction costs associated with exporting (information search, registrations, meeting regulatory demands, consumer research, public relations and so forth) can present a barrier. The R&D and marketing costs of Nestle's probiotic LC1 product and Becel Proactive spread have been estimated at over US$ 50 million each (Menrad 2003).

Because of these challenges in developing functional food end-products, intermediate products and raw materials may present a more easily approachable area in international trade, especially for companies with limited resources (at least at the entry level to the market). Once capacity (for example, physical and market infrastructure, and institutional and regulatory framework including standards and certification) of developing countries is improved, high-level processing could be expected to start. Especially for smaller producers and processors, there is a need for public support to deal with the regulatory system through time-limited technical and market assistance, especially at the entry level (see World Bank 2005).

There are a few examples of producers' organizations that successfully found a niche in producing and processing functional foods such as the case of yacon products in Peru (see Box 13). International research organizations have also been active in providing technical assistance to producers' organizations as in the case in Peru. The biggest challenge still remains on how to sustain and scale up these few ventures of small-scale producers and processors involved in functional foods.

Box 13 Peru: Processed Yacon Products by a Producers' Association

Asociación de Productores de Yacon de Oxapampa (APYEDO) is a producers' association of limited economic resources, located in the eastern Andean foothills, which acquired legal status in 2002, with International Potato Center's (CIP) technical assistance. In order to generate greater and better income opportunities from the association, CIP promoted and co-financed research on a processing technology to produce yacon syrup. This product is similar to maple syrup, and other natural sweeteners. It is made up of oligofructose, a sugar with fewer calories that does not increase the blood glucose level. For this reason, it can be positioned well in market niches for people who suffer from diabetes and wish to lose weight.

In 2004, three new products, using yacon roots as raw material, were developed at CIP: juice, marmalade and dehydrated flakes. At present, the juice and the marmalade are produced in APYEDO. CIP has co-financed the development of labels and legal transactions, required to obtain the licenses for marketing of the products in order to obtain greater market opportunities. The Dirección General de Salud Ambiental, entity of the Ministry of Health, which authorizes the marketing of beverages and processed food in Peru, has assigned to APYEDO several marks to authorize the marketing of their products.

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Because of the high perishability of the roots, processed yacon products provide an alternative to the traditional marketing of fresh roots. Since 2003 several supermarkets in Peru have offered syrup, juice, marmalade and tea leaves made of yacon. Although small-scale production predominates, exports of yacon products have been exported to Japan, the European Union and the U.S.

High demand for information on yacon indicates that there is considerable interest in this crop in various parts of the world.

Source: CIP 2004.

At present, even in processing functional foods for domestic consumption, several developing countries face difficulties in supplying demand and in face competition with imported products. For instance, a recent study indicates that the growing demand of functional foods in China face strong competition from imports (see Box 14).

Box 14 China: Strong Competition of Local and Imported Products

China has a growing demand of functional foods and with a huge population base, the country has a strong economic incentive to develop the market for functional foods. In its current stage, however, the production and processing of functional foods face strong international competition. With the attractiveness of the market, there has been an increased number of participants. Depending on the source of statistics, domestic competitors in the functional foods industry number anywhere from "more than 3,000" to "some 4,000." Although the market is growing rapidly, bankruptcies among domestic manufacturers have occurred due to a lack of a variety of products, short product lifecycles for certain approved brands, and the low level of investment in research and development. Data also show that foreign functional food products occupy over 40 percent of market share. It is estimated that sales of foreign products have grown 12 percent per annum over the last five years and the prospect for their continued growth and expansion is positive.

Foreign companies compete on the basis of strong management, financial resources, investment in research and development, and marketing techniques. Additionally, many consumers believe that foreign products are of higher quality than the domestic products; thus, they are more willing to try foreign products and to pay high prices for them.

Source: Japan Development Institute, 2006.

In Brazil, the lack of research on food processing and lack of institutional and physical infrastructure are barriers to strengthening the high-value processing sector (see Annex 3).

Moreover, the development of functional foods for domestic consumption is threatened by the high costs of imported specialized raw materials, which is bulk of the components of the end product processing in Brazil and Russia (see Box 15). Soymilk processing in India shows a negative benefit to processors compared to processing loose milk (Japan Development Institute, 2006).

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Box 15 Brazil and Russia: Dependence on Imported Materials for Processing Functional Foods

Multinational companies are dominant in the sector in functional foods production (Nutraceuticals World 2005). In the food ingredients sector in general, importers hold an important position as Brazilian manufacturers depend on foreign ingredients especially in special products such as colorings, flavorings, vitamins, (Hirata 2004) and functional food ingredients. According to a local source, an informal survey in 2004 suggested that approximately 80 percent of ingredients for functional foods are imported. The high prices of special ingredients drive up the prices of end products; health foods and organic foods are sold at prices 40-300 percent over comparable conventional products (Fonseca 2005).

The expanding food industry in Russia relies on imports of special ingredients. Multinationals and domestic food processors source food ingredients from foreign suppliers in order to provide competitive quality products. At this stage, local suppliers are not able to match foreign quality ingredients (Evdokimova 2005; EIU 2005). Similarly, domestic food processing equipment does not meet modern criteria in terms of quality, but is competitively priced (U.S. Commercial Service 2006c).

Source: Nutraceuticals World, 2005; Hirata, 2004; Fonseca, 2005; U.S. Commercial Service 2006c.

It is important for developing countries to devise strategies to find niches in functional food markets. Proper targeting of consumer segments combined with adequate investment in R&D to meet the needs of these targeted segments will contribute to continued industry growth and this will provide more opportunities, including foreign joint ventures. In China, for example, based on an interview done by Japan Development Institute (2006), one of the world's leading natural food ingredients suppliers (Chr. Hansen) has formed a strategic alliance with Mengniu Dairy, China's leading milk producer, to promote probiotics, and the concept of healthy bacteria in the dairy market (Japan Development Institute, 2006). There is a crucial need to assess the competitive advantage of developing countries participation in the functional food market especially in the functional food processing and value adding sectors.

Concluding Remark

There are numerous examples of activities related to the development of functional foods in developing countries. All studies refer to a strong potential in the market with primary producers, middlemen, retailers, processors and exporters directly benefiting from the development of functional foods markets. The backward and forward linkages potentially create opportunities for employment and additional income for the population from production and supply chain activities and may increase demands for private laboratory services, training, scientific and market researches.

Production of certain raw materials for functional foods can have a cost competitive advantage in developing countries as their rich biodiversity and

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traditional knowledge of the health effects of certain indigenous plant species offer good source for raw materials for functional foods. In addition to the rich reservoir of wild and exotic plants, developing countries offer cost advantages in crop production due to lower labour and land costs. Poorer communities can benefit from growing functional foods through sustainable harvesting and or production of wild plants; enhanced links to the private sector, for example, through contract farming; employment or business opportunities from processing ingredients or high-value processing for functional foods; and employment on plantation farming.

While developing countries are the main source of raw materials due to vast biodiversity and have cost advantages in crop production, developing a functional foods industry producing high-value food products face significant barriers. The costs of bringing a new product on the market can be significant, and especially the magnitude of transaction costs associated with exporting (information search, registrations, meeting regulatory demands, consumer research and public relations) can present a barrier. Because of these challenges in developing health-enhancing food products, intermediate products and raw materials may present more opportunities in international trade, especially for companies with limited resources (at least at the entry stage to the export markets). The public sector role relates to building infrastructure, establishing regulatory frameworks and developing research capacities to take advantage of the emerging functional food sector. The experiences of many producer organizations that have successfully participated in exporting functional foods into high value markets offer lessons in developing the functional products and markets and improving links to primary producers especially the more marginalized ones. The importance of having the private sector fully involved was critical investment by private entities. Public support for functional foods remains critical, for establishing a legal, regulatory, and policy framework (for example, contract law and grades and standards); for promoting the organization of small-scale producers with good leadership and understanding of market requirements; and for helping to provide training, technology, and quality control systems. In addition, there is need to promote interaction and strengthen linkages between producers, traders and processors.

The participation of developing countries in the development of functional foods and the benefits obtained vary depending on the geographical, sociocultural, economic, and resource endowment of each country. There is, however, a need to assess the competitiveness of individual developing countries to ascertain their level of involvement (for example, primary production and/or processing) in the growing demand for functional foods.

Recommendations

Functional foods present a broad and heterogeneous sector. The role of different supply chain members depends on the type of product and the characteristics that render it physiologically beneficial to health. Cultural and

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regulatory factors influence the potential of each type of product in different markets. More detailed assessments at the country level or with specific production systems are needed to clearly identify specific opportunities and the associated challenges.

While there should be awareness of the differences in both functional food product characteristics and cultural perspectives, there are many common issues relating to: the production-related capacity; the demand and market development in home markets; the demand in export markets, and the associated regulatory requirements and marketing needs; and the need for research on product effectiveness. In domestic markets, market development involves increasing consumer awareness and demand for functional foods, providing infrastructure (which also influences the development of other processed or value-added food products), and on the supply side, supporting product development that targets the most pressing health needs, and establishing a clear regulatory environment for this product. For international markets, market development could focus on areas of potential competitive advantage, such as native plants, local traditional knowledge of health effects, and unique food applications and the need to comply with international food safety standards.

The five target countries are in different evolutionary stages with respect to the above-mentioned factors. China and Brazil have advanced regulatory frameworks for the approval of functional foods and their advertising, although these differ somewhat in the specifics. Russia has recently introduced regulations, while in Peru and India there is still a need to formulate and clarify the regulatory frameworks. Consumer demand for functional foods tends to be high in all of the countries as foods have traditionally been used for health-enhancement purposes and increasing levels of disposable income enable the purchase of new value-added products. However, the lack of organized retail chains and the poor physical infrastructure in some countries limits both the domestic market penetration of functional foods and export capacity.

New market opportunities exist in capitalizing on local knowledge to aid scientific investigations and the local biodiversity is a potential target for development of functional foods in many developing countries (including transition economies). However, the increased benefits for farmers and food manufacturers from this sector need to be assessed on product-by-product basis and with specific export markets in mind to find the most promising opportunities. Regulations and consumer demand are product and/or ingredient specific and largely dictate the possibilities.

Due to the limited published literature and the small number of interviewees, this study was not able to comprehensively describe the situation in target countries. It would be necessary to examine these issues more closely to better identify specific opportunities and constraints. In further research, a key issue is the varying definition for functional foods. In many developed countries the definition between foods and medicine is clear; there is less clarity on whether a

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product is considered a functional food, a dietary supplement, or a drug. For practical purposes, "functional foods" is primarily a marketing term and its meaning becomes relatively less clear going closer to the producers along the value. For the World Bank purposes, it might be beneficial to create one definition for "functional food" or "health-enhancing foods" that would be used consistently in further studies.

More country-to-country studies on the competitive and comparative advantage in functional foods would assist in understanding the potential for participation in the functional foods product development. Benefits will vary depending on the geographical, socio-cultural, economic, and resource endowment of each country. There is, a need to assess the competitiveness of individual developing countries by ascertaining the level of involvement (for example, primary production and or processing) and the products that can participate in the growing demand for functional foods.

There is a need to further assess the role of private and public sector in assisting the sector. A growing literature on experiences in the development of high value products, including functional foods, suggest some potential forms of public support in assisting supply chain development, especially for the small-scale producers, in these high value markets. Possible entry points for public sector support include:

(a) **Creating a regulatory atmosphere to ensure product safety and support the industry:** Legislative aspects of functional foods are complex, as the product group can be considered to display properties of both food and drugs. Food labelling is an important tool in the market success of functional foods. A clear regulatory system for nutrition and health claim use and its enforcement are critical factors in building consumer trust in functional foods. They also help provide a level playing field to foster competition within the industry and encourage innovation. In many developing countries, legislation and regulatory frameworks require further clarification and strengthening.

(b) **Building institutional capacity of sector participants:** Capacity to meet higher regulatory requirements may present a bottleneck in the market development for functional foods. Assistance to build this capacity could be made available to producers, processors as well as the government regulatory bodies, as necessary. Support to producers and processors could include technical assistance on potential technologies, improved understanding of quality standards, establishment of producer organizations that are often better capable of meeting complex quality requirements and provide economies of scale, or enhanced access to financial services. Specific needs for each should be identified in further assessments.

(c) **Research and innovation:** Biodiversity in many developing regions and the beneficial health effects of food crops have been traditionally recognized, but very few of the foods or bioactive compounds have been scientifically studied to the extent required for functional food uses in the

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markets. This lack of scientific evidence for proposed health effects presents a major challenge for the countries in this study; scientific evidence for safety and functional effectiveness of these compounds is essential in order to realize their potential in the production of high market valued products. New value-added components could also come from local food crops, medicinal plants or non-food sources.

(d) **Providing information and support for strategic decision-making:** For raw materials and ingredient providers, the target markets of functional foods, dietary supplements, and sometimes natural medicines are closely related. It would be important to assess the relative profitability of each possible sector, case by case, and select the most promising areas for intensive functional foods programs. The possibility to diversify activities to reach all these sectors could expand the potential markets. The public sector could encourage this by facilitating the interaction between the various disciplines and participants, including public and private research, industry, primary producers, and so forth.

Regulations in export markets have been identified as a challenge for the functional foods industry that is aiming at export activities. Both novel food legislation and the strength of scientific support for health benefits are involved in this. It could be useful to consider the likelihood of market acceptance and the resource intensiveness of the process in advance, on a market-by-market basis, when product and/or ingredient decisions are made. To this end, market and regulatory information could be made available to the entire supply chain, so that each member has the opportunity to make informed decisions.

At primary producer level, domestication of selected wild plants with functional properties and promotion of their cultivation could be encouraged, if a closer assessment indicates that they present benefits for farmers. Well coordinated value chains could also be included as a goal, as these would help to reduce uncertainty related to returns in this sector, increase commitment by all parties involved and maximize the proportion of value added received by the farmers.

In addition to health enhancement, other market value properties, such as "certified organic" could be promoted for both ingredients and end products. Assistance to upgrade facilities to meet standards or to certify products or processes could be provided, as necessary and appropriate.

(e) **Emphasizing and supporting marketing, both domestic and export markets:** Market intelligence, especially on export markets, is critical for producers, processors and exporters to create successful strategies. The lack of market information was indicated as a challenge in the supply chain in some countries studied. Market demand and associated regulations are diverse between major market areas, and the transaction costs in engaging in export are consequently significant, thus suggesting a need for export promotion services, particularly for smaller companies. Other supporting activities related to market development include marketing

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and consumer education, when applicable. Collaboration in these areas could be fruitful, as many stakeholder groups stand to benefit from them.

(f) **Other considerations:** Although not emphasized here, factors critical in broader general areas must be considered. These relate to processed food markets in general, food exports, and the use of natural resources for botanical ingredients. With respect to the latter, ecological issues, environmental sustainability, intellectual property rights protection should be considerations with respect to primary production of raw materials for functional foods. In general, level of organization in food retail and infrastructure development need to be at a sufficient level for domestic market to grow.

Appendix 1. Regulation and Labelling of Functional Foods

The approach to regulating functional foods and their marketing is notably heterogeneous on the global level. This is largely due to the challenges in classifying these products, as explored in Annex 3, but there are also varying views on what is considered sufficient scientific substantiation to conclude functionality *(Verschuren, 2002)*.

Common concerns behind all legislation involve ensuring product safety and public health implications. In most countries, general agreement exists that functional foods are first and foremost foods and must be safe *(Hasler 2002; Diplock et al 1999)*. Food safety and quality demands may influence this market even more than conventional foods, as often the innovative aspects of products include novel and/or non-traditional ingredients or new processes. As an example of the challenges posed by novel food regulations, a Finnish baking company, Fazer, obtained an approval to market rye bread fortified with plant sterols in 2006, after an application process that spanned more than five years *(Kehittyvä Elintarvike, 2006)*. Both rye bread and plant sterols have been in the market before, in other combinations. By one estimation, the cost of registering a dietary supplement for the Chinese market is around $US 70,000 to US$100,000 and for a functional food product US$2,500 to US$10,000. The time demanded by this process is up to one year and up to six months for supplements and functional foods, respectively *(Habiger, 2005)*. In the less developed countries, with often rather ambiguous or non-existent regulatory systems, the approval processes might take even longer time, and thereby, pose significant challenges and/or bottlenecks for product development and marketing.

Regulation of functional foods differs from that of conventional foods mainly with respect to labelling and advertising. In Japan and China, a manufacturer can apply for product approval and a "functional food" symbol can be displayed on the food label. Elsewhere, for example in some European countries and the U.S., a health benefit can be conveyed to the consumer using "nutrient-function claims" or "health claims" when specified conditions are met. As outlined in the International Codex Alimentarius Guidelines for Use of Nutrition and Health Claims *(CAC, 2004)*, any reference to cure or prevention of a disease state should not be permitted. Approved health claims must be based on sound science, typically including clinical studies, and the role of these products in total diet

must be understood. The required scientific testing can be expensive enough to exclude smaller companies from the sector.

Food labelling is a central tool in the market success of functional foods, as the value added (the health benefit) is usually not readily apparent to the consumer at the point of purchase, at consumption, or even afterwards. Appropriate messages placed on packaging offer a direct channel to deliver the information of product properties to the buyer. Industry participants have indicated appropriate labelling regulations as a priority area in market development *(Hilliam, 1998; Functional Foods in Europe, 1998; Verschuren, 2002).*

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The flipside of the health claim legislation is the responsibility of governments to protect consumers from false or misleading advertising. There is also a business argument for strict regulations; even though labelling regulations are often stricter than industry would desire and may restrict marketing efforts, allowing misleading messages would erode consumer trust and could be equally damaging to market development. Finding the balance between protecting consumers from false advertising without overly restricting food companies' operations poses a challenge that governments worldwide are grappling with. The regulations are evolving even in mature markets. Despite the good intentions behind regulatory systems, the process is often slow to respond to this rapidly developing market.

At the global level, the regulatory situation is fragmented. A Food and Agriculture Organization survey found that 35 of the 74 countries covered had no regulations in place regarding health claims (including many countries in Latin America and Eastern Europe). Another thirty had regulations forbidding curative, therapeutic, or preventative claims or any reference to a disease. As of 2004, specified disease risk-reduction claims were permitted in Brazil, Canada, China, Indonesia, Philippines, Sweden and the United States. A framework for evaluating product-specific claims existed in Japan, the Netherlands and Sweden. *(Hawkes, 2004)* The process of obtaining approval for using claims varies. In international markets, the diverse and often ambiguous health claim regulations can pose a trade barrier for end consumer products. *(Hawkes, 2004)*

Consumer use and understanding of food labels differs significantly by geographic region. An internet-based survey indicated that 35 percent of Latin Americans always check nutrition information on food packaging. In Europe, the proportion of consumers reading labels was only half of this. *(Nielsen, 2005b)* The actual influence of health claims on food selection and commercial success of functional foods has been studied, but the findings have been mixed *(Hawkes, 2004).* Health claims are only one factor among many in determining food selection and socio-cultural factors and personal preferences may play an even stronger role.

Appendix 2. Market Environment Favorable for Functional Foods

Key determinants for the maturity of functional foods markets discussed in the preceding sections relate to consumer characteristics, general market properties, and general business environment including government policies.

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Success in domestic markets has certain prerequisite conditions, some of which are outside the direct influence of manufacturers and even marketers. These requirements for individual products include but are not limited to:

- Consumer need and awareness of health benefits;
- Consumer acceptance of a food solution and non-traditional taste;
- Acceptable price level;
- Optimal convenience, adequate retail or out-of-home availability;
- Proven safety and efficacy;
- A clear regulatory framework for making health claims;
- Assurance and support from different sources, including scientific opinion leaders.

(Weststrate et al., 2002)

Consumer interest in health maintenance and awareness of the role of functional foods in this are key factors generating demand. Public health statistics reveal that a need for functional foods exists in nearly any market but specific characteristics of consumer response to health problems and/or risks vary across cultures; in Asian cultures, for example, it is natural to use food for health purposes *(FAO, 2004)*. Also, acceptance of processed or "manipulated" foods varies. In general, northern Europeans tend to be more open to engineered foods than southern Europeans (Benkouider, 2004). Cultures with a strong belief that people can and ought to take control of their own health, view functional food innovations favourably *(Bech-Larssen & Gruneth, 2003)*.

In most markets, functional foods are mainly seen as food products and the factors influencing food selection are multiple; socio-cultural factors like local cuisine, ideology, religion and other beliefs, rituals, economic situation, group values, emotions, status, communications, and so forth. *(Fieldhouse, 1996)* Thus, acceptance of individual food solutions for health reasons is highly culturespecific.

Education of consumers is complicated. Foods that are functional from a nutrition science point of view are not all marketed using this competitive advantage. Some consumers may purchase them as conventional products, others in mature markets may base purchase decisions on prior knowledge and/or beliefs of certain ingredients or other properties and y may purchase products as functional, even in the absence of such marketing claims. Consumers may not see the difference between regulated health claims and other clever marketing information based on ingredients and non-health related statements: they may purchase products as functional foods even when scientifically the product does not meet the requirements. Consumers also require sufficient disposable income, as functional foods are typically priced significantly above comparable conventional products.

Innovation in the industry is driven by sophisticated demand and business atmosphere and benefits from a supportive regulatory environment. Government regulations must be compatible with the direction of the industry and the level

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of sophistication of demand. Public sector can play a role in innovation, but the resources and capacity are often limited and these limitations stress the role of private sector.

Priority areas in market development for industry participants include appropriate labelling regulations, consumer education, taste parity with regular products, and proof of efficacy. *(Fogliano, 2005)* Consumer education, national regulation on functional foods and harmonizing regulations with international standards, have been emphasized in many contexts as the key developments still needed to strengthen this sector, particularly in the currently less developed markets and countries *(Tee et al, 2002; Fogliano, 2005; Lajolo, 2002).*

Sector development thus requires collaboration in the fields of: nutrition, medicine, food chemistry and technology, education and government (Fogliano, 2005) and for an extensive discussion on stakeholder interactions related to functional foods, *see McConnon et al, 2002).* Consequently, there is a great need to facilitate multidisciplinary research and collaboration in market development efforts. Developing countries are at different stages of evolution with respect to the factors discussed above, as will be explored in *Annex 3.*

Table A1 Summary: Factors Affecting Market Success in Functional Foods

- Consumer awareness of health issues and the role of diet in human well-being
- Consumer acceptance of functional components and food solutions
- Sufficient disposable income level
- Clear regulatory environment
- Organized retail sector

Source: Authors.

Appendix 3. Functional and/or Health-Enhancing Foods in Developing Countries

This Annex examines functional foods in countries in Asia, Latin America and Eastern Europe: China, India, Brazil, Peru, and Russia. These countries were selected to represent different regions, different food and health related traditions, and different stages in the development of functional foods markets. Markets and the market environment have been assessed on the basis of general factors required for a successful functional foods market such as consumer awareness and acceptance, sufficient income levels, regulatory environment, organized retail sector, and so forth. Activities at in the supply chain including research, certification, marketing, and education are assessed based on existing literature, interviews and e-mail contacts with local or foreign experts. Challenges for both domestic and international market development are discussed. As this review was based on limited data, country level assessments should be considered preliminary. However, the brief country overviews illustrate the national differences and the issues involved in the functional foods sector.

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1 Asia

Japan, described earlier in this report, is a leading global producer of and market for functional foods. In other Asian countries, the markets and the regulatory situations are diverse and evolving. Generally Asian cultures see a close connection between food and medicine, which are believed to come from the same origin *(FAO, 2004)*.

There numerous functional food products include fresh and/or natural and processed products. A regional concern expressed by consumer groups is the lack of specific labelling regulations, especially the lack of scientific support for health claims and the lack of enforcement of safety standards. Proceedings from an FAO workshop indicate that some research is being conducted to validate health effects of some functional foods and/or ingredients and other research activity is mainly focused on product development *(FAO, 2004)*.

China and India are covered in more detail in the following section.

China

Population:	1.3 billion[a]
Number of metropolitan areas:	174[b]
Urban population:	40 percent[c]
Population under poverty level:	5 percent[c]
GDP/capita (PPP-adjusted):	US$6,300[a]

(a) CIA World Factbook

(b) GAIN files

(c) World Bank data

Background

Food processing has been one of the fastest growing segments in the Chinese economy in recent years. The industry is fragmented and estimates of the total number of food processing companies vary considerably. The underdeveloped agricultural and distribution system exacerbated by long distances, present problems. *(Bean, 2005; Taylor, 2006)*.

Chinese consumers spend nearly half their disposable income on food and beverages, although the proportion has decreased significantly over the past decade. Currently only 30 percent of Chinese food consumption is processed foods compared with 80 percent in developed countries *(Taylor, 2006; Bean, 2005)*. Trends visible in the food industry are consumer demands for convenience products and for healthier and fortified products as reflected in an increasing demand for high quality foreign food ingredients for the industry *(Taylor, 2006; Bean, 2006)*. With a population of over 1.3 billion, the minority high-income group is large, providing a market for value-added food items.

Food and beverages, increasingly purchased at supermarkets and hypermarkets, currently account for 46 percent of all food sales. In 2004, the number of supermarkets increased by 17 percent, although mainly in urban areas *(Taylor, 2006)*. Concurrently, the traditional outdoor markets are decreasing in number.

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Functional Foods

Concept

In Chinese philosophy food and medicine have the same origin. Traditional Chinese medicine has always used foods in health care, and to some extent, consumers still use foods based on the inherited knowledge of their properties, in addition to modern information on packaging. Traditionally, many conventional foods are believed to have therapeutic properties for example cold or cool or warm or hot, five tastes, and other properties. *(Dang, 2002; Weng & Chen, 1996).* Since 1995,with western-type functional foods entering the market, food regulations have recognized a special "health foods" category for foods with a proven physiological effect.

According to the regulations, functional foods are foods with a special health function, suitable for consumption by defined special groups of people. These foods exert effects on specific body functions and should not be confused with drugs, which are used for therapeutic purposes *(FAO, 2004; Xie, 2005).* Functional food (or "health food") products also include non-food forms such as extracts or tablets. The main differences compared to regular foods include a specific functional effect, a narrowly specified user group, and a recommended daily dosage *(Xie, 2005).*

Raw materials and functional ingredients for these "health foods" often come from traditional foods or traditional Chinese medicine. Products include whole fruits, teas and herbal extracts, ginseng, walnut, honey, and powder of spirulina *(Arai, 2002; FAO, 2004).* Despite the distinct category for functional foods, it is sometimes difficult to distinguish among conventional foods, functional foods,dietary supplements and even drugs. In regulations, 87 substances are classified for use both as food and medicine *(Xie, 2005).*

Market Description

China's "health food" industry experienced rapid growth from late 1980s to late 1990s, with the fastest increase among the urban higher income population. Continued expansion in the functional foods market is predicted as per capita spending on functional foods is expected to grow two-fold or more between 2004 and 2010. *(Benkouider, 2005; U.S. Commercial Service, 2006)* Currently, it still remains a fraction of that in the developed markets.

Factors driving the health food market include: economic growth, nutrition awareness, efforts to extend health food markets to rural areas, and traditional use in herbal medicine. *(U.S. Commercial Service, 2006a)* Increasing costs of modern health care may be an incentive for increasing the consumption of health foods.

Between 1995 and late 2005, the government had given approximately 7000 domestic and 500 imported products functional food approval *(Xie, 2005).* According to a locally conducted survey (not an original report), 89 percent of all health foods are functional foods, while 11 percent are in a supplement form. Imports account for 40 percent of health food (including supplements) sales, although imported products fall mainly in the dietary supplement category. Approved products primarily target enhancement of the immune system (34

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percent), combating fatigue (18 percent) and regulating cholesterol levels (16 percent) *(U.S. Commercial Service, 2006a)*

Short product life cycles in the market (3 to 5 years) are a notable characteristic. Advertising is conducted aggressively, although the recent regulatory changes have a stricter approach. *(U.S. Commercial Service, 2006a).* Functional foods are available through similar retail outlets as other foods *(Arai, 2002).*

Functional foods supply the necessary nutrients that are lacking in Chinese diets. Supplementary calcium is an example of a growing market opportunity as it is estimated that approximately one-third of the population has less than the required daily calcium intake. The number of calcium supplements and ingredients is substantial with the annual national market for calcium supplements estimated at more than a half billion U.S. dollars. The functional foods market has responded by producing high-calcium milks, noodles, biscuits, candy and flour (fortified with other vitamins and minerals). The increased variety of calcium fortified functional foods is expected to take market share from calcium supplements. Other supplements in high demand are iron, iodine (now obligatory in salt) and selenium *(Japan Development Institute, 2006).*

Regulation and Labelling of Functional Foods

New interim measures for functional food registration were enacted in 2005. The changes in the legislation aimed to standardize the approval process and the review of supporting scientific evidence *(U.S. Commercial Service, 2006a; Bugang 2005).* Product efficacy and safety must be demonstrated in clinical studies conducted in government-designated testing laboratories in order to gain product approval. This provision also applies to foreign products. The new regulations set out detailed guidelines on these safety and efficacy requirements and standards for manufacturing facilities. To gain market approval, testing is required for safety toxicology, physiological function (animal or human tests), effective ingredient or marker ingredient content, and hygiene *(Bugang, 2005).* Either animal testing, tests on humans, or both are required depending on the type of functional claim *(Xie, 2005).*

Stricter regulations on advertising were also established in 2005. Health food labels must clearly state product name, ingredients, effective and marker ingredient content, functions, suitable user group, instructions of use, standards, best used before date, storage methods and other important notes *(Bugang, 2005).* Misleading product description and labelling of health foods is prohibited and a prior approval system on the contents of health food advertisements is required. Health food production enterprises using illegal advertisements had been highly prominent problem prior to the new legislation *(U.S. Dept. of Commerce, 2006a).*

Opportunities and Challenges

Industry challenges include a limited variety of products in some domestic production, short product lifecycles for some approved brands, low level of R&D investment, old and inefficient equipment, and the unwillingness to source newer raw materials for ingredients. Problems also include poor quality control and

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management. *(U.S. Commercial Service, 2006a).* The Chinese research community is interested in processing herbal ingredients for the global functional foods industry *(Peverelli, 2003).* However, the stringent requirements for scientific evidence from costly clinical studies, which differ from the domestic approval process in major ways, is a barrier.

As illustrated by the recent changes in the regulatory system, quality problems and illegal advertising have plagued this sector. Problems have included untruthful or exaggerated marketing, use of banned chemicals in products, unapproved production and sale of functional foods, and failure to meet GMP requirements *(HKTDC 9/2002).*

Functional foods related research is actively conducted in several institutions. Adequate clinical and other investigations are crucial if Chinese health products (functional foods or otherwise) are to enter western markets. The knowledge of traditional Chinese medicine is based on ancient literature and tradition of use, but specific scientific evidence to substantiate the claims is lacking. Many products are combinations of potentially active ingredients, in which the active compounds and their physiological mechanisms are unknown *(Dai & Luo, 1996; Weng & Chen, 1996).*

Although some clinical studies on the effectiveness of traditional ingredients and products are being conducted in China and overseas, the ability for these studies meeting the required standards may be limited. In addition, requiring the identification of the active ingredients and explaining their effective mechanisms demands a complete change in scientific paradigm *(Kan, 1996).*

India

Population:	1.1 billion[a]
Number of metropolitan areas:	27
(population greater than1 million) [b]	
Urban population:	29 percent[c]
Population under poverty level:	29 percent[c]
GDP/capita (PPP-adjusted):	US$3,400[a]

(a) CIA World Factbook

(b) GAIN files

(c) World Bank data

Background

India is the world's second largest producer of fruits and vegetables but only a very small amount of perishable agricultural products are processed approximately 2 percent in comparison to 80 percent in the U.S. *(Rabo India Finance, 2005).* The food industry sector is small scale, and even in segments where processing is more common, this rarely represents adding value to products. Barriers to faster growth in the food sector include poor infrastructure and logistics, and tight food regulations (on especially on fake products). *(Govindan, 2005b; U.S. Commercial Service, 2006b).* Food imports are relatively limited except in the food additives sector.

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Small companies account for over 70 percent of food industry's output. Until now, foreign direct investment (FDI) into food processing industry has been limited, totalling only 4 percent since 1991 *(Govindan, 2005b)*. Multinational companies are now entering the market.

Most consumers still shop in traditional shops and markets, with supermarkets found only in major cities. Food retail development has been hindered until very recently by strict regulations (for example prohibiting FDI in this sector). The organized retail sector has less than a one percent market share and the presence of an unorganized and unbranded section is strong. Most traditional food retailers compete on price *(Govindan, 2005b; PWC, 2005/2006)*.

India's middle class is significant, estimated at 280 million *(U.S. Commercial Service, 2006b)*. Consumer spending has grown at an annual rate of more than ten percent in the past decade. Expenditures on food as a percentage of income are proportionately high, around 50 percent, as is typical for developing countries (PWC, 2005/2006). Although consumers generally prefer fresh products, demand for processed food is increasing *(Govindan, 2005b)*.

Functional Foods

Market Description

India has a long tradition in using foods for their health-promoting or functional properties, influenced, for example, by Ayurvedic medicine. These functional foods can include herbal extracts, spices, fruits, and nutritionally improved foods or foods products with added functional ingredients. Common ailments are often treated primarily with foods *(FAO, 2004)*. Increasing health-awareness of functional foods is further raising the demand for diet foods and fortified natural foods *(Govindan, 2005b; see-foodindustry.com 1/4/2005)*. Nine out of ten urban Indian consumers have been reported to generally choose foods based on health and wellness benefits *(Ciocca, 2003)*.

The government is active in the development of the functional foods industry. According to Ministry of Food Processing Industries representative, the Ministry is mandated to develop and promote throughout the country the foodprocessing sector including functional foods. It conducts seminars, workshops and training programs; and runs a financing scheme, providing grants-in-aid to the food processing companies that want their manufacturing/processing units certified to meet safety standards such as HACCP and ISO *(Japan Development Institute, 2006)*. In addition to the substantial government support, the functional foods industry is thriving in the private sector. According to the Frost and Sullivan marketing study, consumer goods giants in India understand their consumer targets well and are successfully positioned in both mass-market and higher value products *(Japan Development Institute. 2006)*. In India, as many suffer from deficiencies of iron, iodine and Vitamin A, fortified foods include wheat flour, iodized salt, calcium, vitamin-enriched jams and soft drinks. To deal with Vitamin A deficiency, prevalent in rural areas, food companies have introduced specific products with high vitamin A at affordable prices. For the high value market, companies have launched products such as low-sodium salt, catering to blood pressure patients *(Nutraingredients.com)*.

Robust industry growth is expected to continue in the functional foods industry with productivity expected to grow by 68 percent in the five years from 2005 to 2010. Based on this productivity growth, the size of the nutrition industry will nearly double to US$13.5 billion by 2010 (Ismail 2005). Additionally, India's population is large and predominantly young. With 516 million people between the ages of 20 and 55, this number is expected to increase to 800 million within the next 40 years. As the younger generation moves toward middle age and disposable income increases15, the need to maintain and/or establish a healthy diet will increase functional food consumption.

For processed foods in general, affordability limits domestic demand. Price difference between fresh and processed foods is great relative to the value added provided, and consumers are price sensitive *(Rabo India Finance, 2005).*

Regulation and Labelling of Functional Foods

In 2003, a Ministry of Health expert group report indicated a need, under food laws, to create new categories for regulating functional foods and dietary supplements. This category would include products intended to supplement the diet with nutrients, those with an established structure-function property and those marketed with health claims. It recommended that there should be mandatory safety testing for these products *(Ministry of Health, 2003).* The lack of a suitable regulatory category results in problems in misleading advertising and sales of these products.

In India, voluntary standards are developed by the Bureau of Indian Standards, the national standards body, which comprises representatives from various food sector stakeholder groups. In addition to developing national standards, the Bureau is involved in product certification, quality system certifications and testing, and consumer affairs. A network of testing organizations conducts conformity testing against relevant standards. Efforts are made to match Indian standards with international ones. *(U.S. Commercial Service, 2006b)*

According to key informants' interviews, several major bottlenecks are created by the current regulation *(Japan Development Institute, 2006)*:

- The Prevention of Food Adulteration (PFA) Act has specific definitions for every food preparation sold in the country and as such, it does not provide flexibility to the food manufacturers to produce new recipes without violating the law. To complicate matters, there are seven or eight different laws and resultant regulations governing genetically modified foods, drugs and pharmaceuticals respectively.
- It is difficult for manufacturers to quickly bring out new food preparations. In cases where scientific evidence requires amending the standards, the producers can appeal to have the PFA Rules amended. Under the PFA, the Central Committee for Food Standards, chaired by the Director General of Health Services, is responsible for the final decision regarding PFA rules.
- Since many of these recipes are classified as proprietary foods, manufacturers are reluctant to share data with the authorities, fearing this data might be shared with competitors.

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- The process of launching a new food product is difficult as the application process can by cumbersome.

Production of Functional Foods

Indian foods traditionally used for health-enhancement purposes have commercial potential if sufficient investments in R&D are made. However, R&D is mainly conducted in academic institutions and the transfer to the industry is not well developed *(Rabo India Finance, 2005)*. At farm level, most production for the food industry is not efficient as agriculture is fragmented, and suffers from low technology use, lack of information for appropriate decisions, and logistical issues *(Rabo India Finance, 2005)*.

According to a 2005 report, there were approximately 140 government-owned and 50 private laboratories for food testing. This network is considered clearly inadequate, especially as many of these laboratories lack facilities meeting international standards *(Rabo India Finance, 2005)*.

Although China is seen as the major competitor, Indian research technology in areas such as fermentation processes, plant extraction and even chemical synthesis are more developed than their Chinese counterparts. There is a growing conviction among researchers, government, and private sector that 4000-year-old Ayurvedic medicine and philosophy offers India several advantages. However, it is also recognized that for functional food products to be successfully exported, must be standardized, or at minimum, their potency must be measurable *(Japan Development Institute, 2006)*.

Recognizing the favourable government attitude and support, and the research friendly environment and available qualified human resources, several multinational firms have located in India including Herbalife, DuPont, GlaxoSmith Kline, Akzo Nobel Chemicals, Hindust Lever, Heinz, Novartis and Roche *(Japan Development Institute, 2006)*. A growing number of Indian companies are working internationally such as the Associated Capsules Group (the third most important company), Solae (an alliance between DuPont and Bunge), Avesthagen, RSA Vitamins, Zytex and MM Activ. These companies export a range of products including raw materials, formulated supplements, enzyme preparations, and immunological and diagnostic products *(Ismail, 2003)*.

Functional Food Constraints and Opportunities in the Indian Market

The market environment for functional foods in India can be considered as cooperative and relatively advanced. This is not to suggest that the market for functional foods in India is without constraints, however. Among the constraints, challenges and opportunities faced by the industry are the following: (see Japan Development Institute for more details)

1. Low income of vast majority of the population;
2. Existence of unscrupulous manufacturers;
3. Lack of testing infrastructure to validate manufacturers' claims;
4. Lack of physical infrastructure;
5. Lack of regulatory framework for functional foods; and
6. Some resistance to genetically modified foods.

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Latin America

Latin American cultures have a tradition of using foods, particularly many native plants, for specific functional foods purposes. The general consumer attitude towards health-promoting foods is positive. An internet-based study covering 38 nations worldwide found that consumers in Mexico, Brazil and Peru along with South Africa were the most convinced that food can offer health benefits as addition value to food products (Anonymous, Nutraceuticals International, 2005). In addition, 35 percent of Latin Americans say they always check nutrition information on food packaging, compared to only half of this percentage in Europe. Most often-checked label information includes calories, and fat and sugar content.16 *(Nielsen, 2005b)* High price is indicated as a barrier for using health-promoting foods much more often than in other regions *(Nielsen, 2005a)*.

Overall, the markets for processed functional foods are relatively undeveloped. More traditional health-enhancing plants or foods are sold through informal channels where the extent of this trade is not known (Lajolo, 2002). In the region, product health claims are generally not allowed and in many countries they are not regulated at all, allowing a range of products to be sold with functional or even curative claims (Hawkins, 2004; Lajolo, 2002). Currently, only the Brazilian legislation contains health and function claim regulations that are conform to international standards.

The Amazon region is estimated to host approximately 50,000 plant species, but there is very little data available on their nutrient and non-nutrient composition and many may contain components of interest in the health field. Some examples of these plants of interest are listed in Table A2. Many of them are already cultivated industrially *(Lajolo, 2002)*.

South American botanicals already established in the U.S. market include cat's claw, cayenne fruit, guarana, maca, mate leaf, pau d'arco bark, and stevia *(Brinckmann, 2003)*. Some of these are used to manufacture functional foods, although many are channelled into other product categories. In export related activities, Latin American companies have expressed their concern about trade barriers posed by the novel food regulations in place or proposed in the EU area *(BioTrade documents)*.

Table A2 Selected South-American Plants with Notable Nutrient/Non-Nutrient Composition

Source	Component/function of interest
Guava	lycopene, anthocyanins
Palm fruits like acai	lycopene, anthocyanins
Camu-camu fruit	ascorbic acid
Brazil nuts	Selenium
Maca, guarana, mate	energy giving properties
Various roots and tubers	oligosaccharides, polysaccharides, oils, sterols, saponins

Source: Lajolo 2002.

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There is limited laboratory capacity related to food analysis. Constraints to achieving a desired level of quality and laboratory accreditation indicated in a 2003 Inter-American Network of Food Analysis Laboratories (INFAL) workshop were in the areas of: human resources (lack of awareness, motivation, and commitment); financial issues (high costs of equipment, low salaries and training budgets); material resources; methodology; and cumbersome accreditation procedures *(INFAL, 2003)*.

The rest of this chapter provides a closer look into two countries, Brazil and Peru.

Brazil

Population:	188 million[a]
Number of metropolitan areas:	9[b]
Urban population:	83 percent (146 million)[c]
Population under poverty line:	rural 51percent, urban 15 percent[c]
GDP / capita (PPP-adjusted):	US$8,400[a]

(a) CIA World Factbook.

(b) GAIN files.

(c) World Bank data.

Background

Brazil has a sizable agricultural production sector supported by its large land area and favourable climate. As a result, the nation is largely self sufficient in food and is the world's fourth largest agricultural exporter. Agricultural production and processing together account for approximately one fourth of gross domestic product (GDP) *(EIU, 2005; Fonseca, 2005a)*.

Despite the large agricultural production, a relatively small amount of production is processed into higher value products. Unprocessed agricultural products, particularly soya and coffee, amount to 24 percent of exports, while processed agricultural products contribute 17 percent. Bulk agricultural products and low processed foods together account for over 60 percent of agro-food exports (Brooks & Lucatelli, 2004). The food industry still depends on foreign sources for special ingredients, such as food additives *(Hirata, 2004)*.

Food processing is the second-largest sector in the Brazilian economy representing 10 percent of national GDP in 2003. A large proportion of food industry production is consumed domestically; approximately 90 percent of sales revenue comes from the domestic market (Hirata, 2004). The sector consists of around 40,000 to 45,000 food processing companies. These include major multinational corporations like Unilever and Nestle, but a large majority of firms are local small and medium enterprises (SMEs) *(EIU, 2005; Hirata, 2004)*. Despite the large total number of companies, the food market is heavily consolidated. In 2003, the top ten food and beverage companies represented 45 percent of sales, of which five largest companies contributed 32 percent of sales *(EIU, 2005; Fonseca, 2005a)*.

Retailers are the major food and beverage distribution channel in Brazil. Supermarkets control 75 percent of the food market, which represents a

significantly higher proportion than in other large countries in the region. The top five supermarkets control close to half of food sales *(Fonseca, 2005a; Brooks & Lucatelli, 2004)*.

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The income gap in Brazil is large, but even with only 2.4 percent defined as affluent, this amounts to 1.16 million families, creating a sizable target market for value-added foods, including functional foods. The size of the middle class is estimated at a significant 61.9 million. More than half of wealthy families are concentrated in Sao Paulo state. These affluent consumers follow international trends and are demanding in their purchase decisions *(Fonseca, 2005a; Fonseca, 2005b)*.

Functional Foods

Market Description

As with other developing countries, factors driving future growth in functional foods include the demographic shift with aging population, rising disposable income levels, and an increasing awareness of the role of diet in preventing chronic diseases. Increasing media coverage of scientific research related to healthy eating and visible government health education campaigns assist in this *(Nutraceuticals World, 2005; Lima, 2006)*. Demand trends among the wealthier population segment tend to follow those in the rest of the world: recently the focus has been on food quality, environmental conservation, convenience and practicality of products. Factors influencing dietary behaviour also include social pressures; aesthetics and the desire to preserve youth *(Lima, 2006; interviews)*. Culturally, appearance is in an important consideration.

Regardless of the needs, health foods have a limited presence in the Brazilian market but the sector is relatively young, growing rapidly and has significant room for further growth. The small size of domestic target market has discouraged local companies from stronger market development efforts (Fonseca 2005). The Brazilian functional foods market is currently a small niche market, which, however, has been forecasted to reach value sales of US$1.9 billion by 2009. However, the growth of 29 percent in per capita spending on functional foods during this period is considerably lower than forecasts for some other emerging markets *(Benkouider 2005)*.

Dairy products present clearly the largest category of Brazilian functional foods sales. Functional dairy accounts for 73 percent of total functional foods sales, and 11 percent of all dairy sales in Brazil *(Nutraceuticals World, 2005)*. From a functional ingredient point of view, the currently available functional foods are most commonly products fortified with vitamins and minerals, dietary fibers or probiotics. Cholesterol-lowering spreads are also available; the first product with an approved health claim in the Brazilian market was in this category. Supermarkets are becoming the main distribution channel for functional food products *(Benkouider, 2005)*.

Regulation and Labelling of Functional Foods

Brazil has advanced regulations in place for the market entry and marketing of functional foods, and these are well harmonized with international standards. Before 1999, a whole array of products with unproved safety and undemonstrated

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health claims were found in the market. The regulations have been successful in weeding out many of those *(Lajolo, 2002)*.

Since 1999, all functional food products, both domestic and imported, must preregister with the Ministry of Health to gain permission to use structure-function or health claims in marketing. Mandatory registration also applies to similar food categories: foods with added essential nutrients, food for weight control, food with dietary restrictions of nutrients, foods for diets with controlled sweeteners, foods for special diets, new foods and or new food ingredients *(Silva, 2005)*.

Scientific support for the proposed health claims must be presented for review in order to gain approval. In using health claims, the role of healthy overall diet and lifestyle must be indicated. The regulations also apply to advertising and marketing in addition to food labels.

Since 1999, over 200 products with labelling claims have been approved with 14 different functional property claims (see Table A3). There are 25 types of substances or micro-organisms to which these functions have been attributed. To date, no products with a disease risk reduction claim has been approved *(ANVISA, 2005; Bellaglia, 2006; Cleber Ferreira dos Santos, 2006)*. As in all markets, the regulations are evolving. In 2005, a group of previously approved claims were revoked, because the products were not considered consistent with general dietary guidelines. In addition, as of early 2006, the use of nutrient-function claims has been temporarily put on hold, due to concerns regarding the total dietary intake of some nutrients. More research will be conducted before approvals continue *(Bellaglia, 2006)*.

Government Involvement

The government has taken an active role in improving the nutritional status of the population, which impacts the functional foods industry. Government regulations cover nutrition labelling and education, and the health claims. Such regulations offer consumers information to make wiser dietary choices. Consumer reception to the government's nutrition campaign has been positive – labelling is found useful and consumers demand more information about their foods *(Coitinho et al., 2002)*. In an international survey, over 50 percent of Brazilian respondents reported always checking nutrition information on food packaging (Nielsen, 2005b), although their full understanding of the information was not reported. This area currently presents a clear research gap. In addition to labelling regulations, the government nutrition awareness project has included other components increasing general understanding of foods and health through public media, schools, and by training teachers and health workers in the principles of healthy diets *(Coitinho et al., 2002)*.

Table A3 Food Components and Related Functions Approved for Health Claims in Brazil

- Omega 3 and the maintenance of healthy blood triglyceride levels
- Lutein and the protection against cellular damage from free radicals
- Lycopene and the protection against cellular damage from free radicals
- Dietary fiber and intestinal function

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- Lactulose and intestinal function
- Bifidobacter animallis and intestinal function
- Fructo-oligosaccharides and balanced intestinal flora
- Inulin and balanced intestinal flora
- Probiotics (9 species specified) and balanced intestinal flora
- Beta-glucan—helps reduce absorption of cholesterol
- Psyllium—reduces the absorption of fats
- Quitosan—reduces the absorption of fats and cholesterol
- Plant sterols—reduce the absorption of cholesterol
- Soy protein and reduction of cholesterol

Source: ANVISA 2005

Production of Functional Foods

Multinational companies are dominant in the sector in functional food production (Nutraceuticals World 2005). In the food ingredients sector in general, Brazilian manufacturers depend on foreign ingredients especially in special products such as colorings, flavorings, vitamins, *(Hirata, 2004)* and functional ingredients. According to a local source, an informal survey in 2004 suggested that approximately 80 percent of ingredients for functional foods are imported. The high prices of special ingredients drive up the prices of end products; health foods and/organic foods are sold at prices 40 to 300 percent over comparable conventional products *(Fonseca, 2005)*.

Opportunities and Challenges

Brazil's vast biodiversity holds remarkable potential for new functional ingredient discoveries. Various antioxidant compounds have been under much interest lately. Manufacturers in Japan and the U.S. obtain plant-based physiologically active ingredients from Brazil. Of these, acai-berry, guarana, and yacon have received global media attention. Investments in biodiversity related research have been described as inadequate.

The Brazilian Agricultural Research Corporation (EMPRABA) investigates numerous plants with potential uses in this sector, including tubers, tropical fruits and medicinal plants (EMBRAPA website). Overall, functional foods related research is primarily conducted in public institutions. Currently, most innovation in the food industry is occurring incrementally at the ingredient level. Processing equipment suppliers are not flexible enough to generate innovative solutions for the evolving food industry needs *(Lima, 2006)*.

From food industry point of view, the still low awareness of functional foods among Brazilian consumers limits the market. Research on consumer attitudes and behaviour with respect to functional foods presents a research gap *(Lima, 2006)*. High cost of obtaining functional ingredients and scientific substantiation also represent barriers for expanding markets.

Other market challenges to manufacturers are posed by regulations on the use of certain ingredients and strict health claim regulations. Because of the

regulations concerning labelling, products may be launched under alternative titles instead of as functional products *(Lima, 2006)*, or rely on consumers' previous knowledge of ingredients, which can be listed in packaging.

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Laboratory capacity is described as a barrier for development of functional foods markets in this region. A major task of food laboratories in recent years has been creating a food composition database to enable companies to comply with the mandatory nutritional label legislation.

Peru

Population:	28.3 million[a]
Number of metropolitan areas:	1[c]
Urban population:	74 percent (20.1 million)[c]
Population below poverty level:	Rural 65 percent, urban 40 percent[c]
GDP/capita (PPP-adjusted):	US$ 6,100[a]

(a) CIA World Factbook

(b) GAIN files

(c) World Bank data

Background

In Peru, the majority of locally consumed food is domestically processed. Even multinational companies tend to process through local subsidiaries, and imports contribute only 8 percent of food sales. Imports by the major food processor companies represented nearly half of all food imports in 2001 *(EIU, 2005; Gutierrez, 2003)*.

Food processors are concentrated in 86 companies, which make up 75 percent of total sales. Largest food companies are multinational corporations or have major foreign investment, while purely domestic enterprises tend to be smaller *(Gutierrez, 2003)*.

A notable characteristic in food retailing is the lack of consolidation. Three quarters or more of food sales continue to occur through small grocery stores and traditional markets, although the share of supermarkets and hypermarkets is increasing *(EIU, 2005)*. In 2004, of the total food retail market, 80 percent was concentrated in Lima, and major supermarket chains do not have outlets outside of Lima (Gutierrez, 2004).

Much of the population lives in poverty and 76 percent of the population are considered low income. High and middle-income populations only amount to approximately 1.6 million consumers *(Gutierrez, 2004)*, which limits the market for high value-added products. Overall, the proportion of disposable income spent on food, beverage and tobacco in Peru is around one third, which is typical of a low-income country *(EIU, 2005)*.

One third of the population of Peru and 60 percent of national income are concentrated in the capital, Lima *(Gutierrez, 2003)*. In urban wealthier areas a shift away from locally produced staples toward branded products and packaged processed foods is taking place *(EIU, 2005)*. However, there are cultural challenges for processed foods as the most Peruvians prefer fresh products and shopping for food at traditional markets *(Gutierrez, 2004)*.

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Functional Foods

Market Description

The market for healthy eating, in general, is still in early stages, but it has potential for growth. As in the entire region, demand for better-for-you type of low-fat and sugar-free products is increasing, but mainly among high-income consumers who are increasingly health conscious *(Gutierrez, 2004; EIU, 2005).*

Local demand for more specific functional food products seems to be directed at products made with local edible plants traditionally believed to have functional or even therapeutic properties, even though the effects have often not been substantiated by human studies. These fruits and vegetables and can be purchased and used raw, home cooked, or processed *(Source: interviews).*

Processed functional or health-enhancing foods are also sold by local branches of the largest multinational companies. Research on consumer attitudes regarding functional foods in Peru represents a research gap.

Regulation and Labelling of Functional Foods

Functional foods and their marketing and advertising in Peru are not clearly regulated and the existing fragmented regulations are not strongly enforced. Claims for health effects, usually without scientific backing, are prevalent in product packaging and advertising (Source: interviews).

Food and beverages in general are regulated for sanitation, where special diet food and additives have their own categories. Food label contents must comply with Peruvian standards for packaged products. The Peruvian food additives regulation is, in general aspects, based on the Codex or the U.S. regulations: additives not permitted by the Codex are prohibited and flavorings accepted by the U.S. FDA and the Peruvian Flavour and Extractive Manufacturing Association are allowed *(Gutierrez & Arellano, 2005).*

Production of Functional Foods

Peru hosts innumerable native plant species that, according to traditional knowledge in Peru and elsewhere, are believed to promote health or improve specific physiological functions. The growing conditions in the Andes are unique and produce unique varieties. However, at this stage, the suggested health effects of these local plants typically lack substantial scientific validation. Conservation and sustainability issues are included in the efforts to increase the cultivation and export of some of the non-traditional commodities *(BioTrade Peru, 2004).*

For local consumer markets, some of the native health-enhancing fruits and vegetables are sold fresh, but are also processed. Tubers maca and yacon are available in various forms (flours, extracts, syrups, chips, juices, and so forth), and also used as additives in many types of foods *(Hermann & Heller, 1997;* interviews). Statistics on how much of these consumer-ready products are exported or whether the export market is mainly at the ingredient level were not available. Dietary supplements, such as capsules containing these functional ingredients, are exported as end-products (IPPN materials; trade literature).

Functional food activities focus strongly on the possibilities of utilizing the country's exceptionally rich biodiversity. In these efforts, functional or

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healthenhancing foods are one sector among others including dietary supplements, cosmetics, and pharmaceuticals that use natural ingredients. A natural ingredients sector assessment from 2004 identified ten species for further analysis, on the basis of their potential in world markets. Of these, at least maca, camu camu, maize morado (purple corn), and yacon have functional foods applications. The value of exports of functional food plants especially purple corn and yacon have boomed, growing an average of 467 percent and 335 percent annually, respectively, in the years 1998 to 2002 *(BioTrade Peru, 2004).*

The website of Peruvian Institute of Natural Products (IPPN), lists 16 plants under investigation for commercial use, some of which, however, are at this stage more suitable for dietary supplements and natural medicines than functional foods. The main export destinations for maca and cat's claw, for which statistics are provided, are Japan and the United States, with 52 percent and 19 percent share of maca exports, respectively (2002 statistics). Dozens of companies are involved in exporting.

Biotrade-related activities often involve low level processing. Higher processing and the technology required for it are concentrated in Lima. The natural ingredients sector as a whole involves approximately 170 companies, out of which 80 companies export. Natural ingredients producers, mainly private, total around 20,000 *(BioTrade Peru, 2004).*

Basic agricultural and biological research on native Andean plants and their potential for use in functional foods is conducted in universities and other research centers including La Molina Agricultural University in Lima and at the CIP Potato Research Center. Research on the physiological effects of some crops has been conducted also in Japan and the United States.

Certification

As one segment of the natural ingredients industry aims heavily at export, the role of various standards and certifications is important. Organic certifications are widely used in Peruvian export-oriented agro-business and this is seen as a significant competitive advantage. Over 10,000 organic farmers have been certified in Peru since 1997. A national ecological certifying system was established in 1994 and is recognized in major foreign markets *(BioTrade Peru, 2004).*

Many export-oriented ingredient or food companies have obtained GMP and HACCP. (Source: company websites, IPPN materials). Voluntary certifications such as a biotrade certificate have been used by some companies to improve their position in international markets.

Another approach to improving export opportunities has been cooperation in lobbying for changes in regulations in foreign target markets. The EU novel food regulations have especially been identified as an unreasonable trade barrier for ingredients with a long tradition of use in the country of origin *(BioTrade.org website).*

Problems in trade of natural products include patent issues, novel food regulations in the EU, and requirement for GMPs for the United States supplement market *(BioTrade Peru, 2004).*

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Limited research restricts the value-added processing sector; there is a shortage of scientific and technological information, as well as information on clinical trials. Chemical analysis, research on functional and/or therapeutic value, and food-safety analysis are all areas where the needs are not being met. These types of studies are especially important for the export-oriented companies, as they are often demanded by overseas purchasers *(BioTrade Peru, 2004)*. Clinical trials to record efficacy of foods are mainly described as beyond the financial resources of the Peruvian companies.

Opportunities and Challenges

The opportunities in Peru are largely focused on local biodiversity. Involvement in functional foods sector can, in turn, strengthen the position of lesser-known native plants and help conserve biodiversity. Challenges for the functional foods sector and/or biotrade in a larger sense have been indicated in the following areas:

- The supply sources are dispersed; crops are mainly grown on small farms in remote areas.
  - o Storage and transportation problems
  - o Inability to cover demand in large quantities
- Poor linkages and mistrust in the value chain
  - o Understanding of the entire value chain and target market is missing
- Inadequate laboratory capacity
  - o Few specialized laboratories of chemical composition analysis
  - o Limited equipment and methods available for research
- Certification issues
  - o Most producers are not using GMP and HACCP
  - o Lack of training in quality control standards
  - o High cost of organic certification
  - o Inconsistent quality of raw materials
- Incomplete legislation
  - o Lack of enforcement of proper production and sales practices
- Capacity at farm level
  - o Production technology, storage, and handling require improvement
- Lack of information
  - o Difficult access to technical and scientific information, information of scientific studies relate to crop value as functional ingredient
  - o Limited knowledge on how to start exporting
  - o Inaccessible information about markets and consumers
- Small domestic market for value-added products
- Lack of integrated research and development strategies
- Lack of organization among farmers

Sources: BioTrade Peru, 2004; interviews.

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Eastern Europe

The functional foods market in Eastern Europe is relatively underdeveloped. Although health problems such as obesity are prevalent *(Benkouider, 2005)*, and death rates from heart disease in Central and Eastern Europe are significantly above the global average *(Anonymous CEE 2004)*, consumer awareness of nutrition and understanding of functional foods is still low *(Ciocca, 2003; Sofroniou, 2005)*.

The availability of health and wellness products in this region is limited; functional dairy products are present, but there is little development in other segments. The better-for-you reduced fat foods are expected to gain popularity with the growing obesity problem. *(Patton, 2005a)*.

Generally, no clear regulations for functional foods are in place in Eastern European countries, and incorrect and unregulated advertising may exacerbate consumer confusion. Overall, this sector is still in its infancy and little representative information is available in the literature on functional foods. The following section offers a more in-depth assessment of Russia.

Russia

Population:	143 million[a]
Number of metropolitan areas:	13 (population >1M)[b]
Urban population:	70 percent[b]
Population below poverty level:	17.8 percent[a]
GDP/capita (PPP-adjusted):	10,700 $[a]

(a) CIA World Factbook

(b) GAIN files

Background

Russia has experienced significant growth in GDP in the past years and consumer incomes have been growing rapidly. Disposable incomes grew by 19 percent in 2004 and consumer spending by 22 percent. *(Evdokimova, 2005; PWC, 2005/2006)*. In this geographically vast nation, however, regional differences are remarkable. Nearly 20 million consumers, 30 percent of retail trade and 40 percent of FDI is concentrated in the Moscow region. Per capita income in Moscow is three times the national average *(Taybakhtina, 2004)*.

The food processing sector is one of the leading industries. Factors driving rapid growth include the large population, rising incomes and consumer demand for new products. *(U.S. Commercial Service, 2006c)* Accordingly, the strongest growth in the food and beverage sector has been in companies, which focus on the higher-end products and emphasize quality *(PWC, 2005/2006)*. Growing categories in food domestic food processing include health foods and special diet foods *(EIU, 2005)*.

In 2003, approximately 22,000 companies were involved in food-processing, but the sector is gradually consolidating *(U.S. Commercial Service, 2006c)*. The presence of multinational corporations is strong and domestic companies are primarily SMEs *(PWC, 2005/2006)*. Moscow and St. Petersburg areas dominate

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the food industry with 35 to 40 percent of food products are manufactured in these two areas *(U.S. Commercial Service, 2006c)*. Approximately 40 percent of total food consumption is imported *(EIU, 2005)*.

The expanding food industry relies on imports of special ingredients. Multinationals and domestic food processors source food ingredients from foreign suppliers in order to provide competitive quality products. Local suppliers are not able to match foreign quality ingredients at this stage *(Evdokimova, 2005; EIU, 2005)*. Similarly, domestic food processing equipment does not meet modern criteria in terms of quality, but it is competitively priced *(U.S. Commercial Service, 2006c)*.

Food retail channels in Russia remain fragmented; close to half of food purchases in large cities and 70 percent or more in the outer regions are made in open markets or traditional stores *(Taybakhtina, 2004)*.

Diet-related issues have recently gained publicity as the most prominent public health problem is cardiovascular disease (CVD), which accounts for over 50 percent of deaths. Largely due to CVD22, life-expectancy in Russia is 12 years lower than in the U.S., and 5 years lower than in China. Inappropriate diet is a major factor in determining CVD risk. About 60 percent of Russian adults have blood cholesterol levels above the recommendation and 20 percent need medical attention. Overall, death rates from non-communicable diseases are three times higher in Russia compared with the EU average *(World Bank, 2005)*.

Functional Foods

Market Description

Although the Russian functional foods market is still undeveloped, numerous new products have been introduced in the past few years, and the demand for functional foods is high among the higher income population where a trend towards healthy lifestyle and healthier eating is evident *(Spiridovitsh, 2005; Taybakhtina, 2005b)*.

The value of Russian functional foods market was estimated at US$75 million in 2004, and annual growth of 20 percent is expected *(Patton 2005)*. However, the definition for functional foods for this figure was not indicated. Growth in certain sectors, such as enriched products has been extremely rapid *(Drujinina, 2005c)*.

Dairy industry has taken the lead in developing functional foods and largest growth is expected in this sector *(Spiridovitsh 2005)*. Probiotic products currently hold a noteworthy 35 percent market share in kefirs and 25 percent in drinking yogurts *(Drujinina 2005c)*. Functional properties are also becoming popular in the bakery and beverage sectors and functional foods differentiation strategies are used in oils, dietary fats and confectionery, and even in spirits. *(Drujinina, 2005a)*. The main reason for developments in the functional foods market is consumer demand: rising affluence and increasing health awareness, partly induced by public health education efforts and aggressive advertising of functional foods. In the dairy sector, 80 percent of advertising expenses in 2004 went into

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marketing functional products. *(Spiridovitsh, 2005)*. Consumer awareness has improved particularly about the role diet can play in reducing the extremely high prevalence of CVD in the country. The atmosphere is supportive towards companies investing in functional foods.

Russian consumers read product labels carefully and are ready to pay more for branded products *(Taybakhtina, 2005a)*. The concept of functional foods is best understood in the dairy sector, while some product segments, such as high fiber foods, suffer from low consumer awareness *(Taybakhtina, 2005a)*. In addition to still lagging consumer awareness, challenges for the sector are presented by the limited retail distribution, especially in rural areas. Expansion of functional foods market is likely to remain urban based for years (Benkouider, 2005).

Regulation and Labelling of Functional Foods

Russia has been harmonizing its food labelling regulations to better match those by the Codex and the EU. The new regulations, established at the end of 2004, include mandatory nutrient labelling for macro- and micronutrients, as well as specifically worded statements to use on organic products. Certain health claims are also permitted and scientific support for them is required *(Drujinina, 2004)*. Products have to be tested in the national testing center for clinical efficacy. (Details for this process were not available for this review.) In terms of quality standards, regulators have started to move away from detailed government standards toward producer responsibility *(Hager, 2005)*.

Production of Functional Foods

The leading functional foods company in Russia is the dairy and juice manufacturer Wimm-Bill-Dann (WBD). WBD together with Danone hold market leadership in functional dairy products, the most prominent sector in functional foods. Fifteen percent of Danone's products belong in the Activia functional product family *(Drujinina, 2005b)*. Local firms Ochakovo and Petmol have also launched probiotic product lines, although R&D costs as well as production and marketing investments are stated to be significantly higher than with traditional products, and this is a barrier to entry into this sector. *(Drujinina, 2005b)*. Still, most dairy processing companies have probiotic products in their product line *(Spiridovitsh, 2005)*.

Information was not found on the possible involvement of the agricultural sector in value-added production aiming at functional foods industry. This gap should be addressed for complete understanding of the possibilities of this industry in the near future.

Opportunities and Challenges

The growing domestic market concentrated in major urban centers presents a potential for new value-added products. Significant challenges to local food manufacturers result from the need for new machinery, technology, and functional ingredients, all of which must be imported as local supply is insufficient and of poor quality. Natural ingredients are particularly difficult to obtain from domestic markets.

Student Activity

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1. Discuss the concept of health enhancing food.

2. Explain the global scenario of health foods concisely.

3. Point out the situation of functional foods demand in United states.

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Summary

1. Functional food or medicinal food is any fresh or processed food claimed to have a health-promoting and/or disease-preventing property beyond the basic nutritional function of supplying nutrients.
2. Oat products are a widely studied dietary source of the cholesterol-lowering soluble fiber *b*-glucan.
3. Functional foods can be an opportunity for economic growth for many developing countries endowed with rich biodiversity and traditional knowledge of the health effects of certain indigenous plant species.
4. Functional foods represent a broad and heterogeneous food sector. The role of different supply chain players depends on the type of product and its physiologically functional characteristics.
5. Chinese consumers spend nearly half their disposable income on food and beverages, although the proportion has decreased significantly over the past decade. Currently only 30 percent of Chinese food consumption is processed foods compared with 80 percent in developed countries.
6. India has a long tradition in using foods for their health-promoting or functional properties, influenced, for example, by Ayurvedic medicine. These functional foods can include herbal extracts, spices, fruits, and nutritionally improved foods or foods products with added functional ingredients. Common ailments are often treated primarily with foods (FAO 2004).

Glossary

Functional food:— Any fresh or processed food claimed to have a health-promoting and/or disease-preventing property.

or

"Foods that have health benefits beyond the nutrients they contain."—American dietetic association

Bioactive compounds:— Naturally occurring chemical compounds contained in, or derived from, a plant, animal or marine source, that exert the desired health/wellness benefit.

Nutraceuticals:— A product isolated and purified from foods that is generally sold in medicinal forms are usually associated with food.

Medical foods:— Special dietary food intended for use solely under medical.

Dietary supplements:— A product that is intended to supplement the diet that bears or contains on or more of the dietary ingredients.

Traditional Processed Foods (TPF):— Conventional foods that have been manufactured by the traditional food processing industry.

Natural Health Products (NHP):— Includes homeopathic preparations, substances used in traditional medicines, minerals or trace elements; vitamins; amino acids; essential fatty acids; or other botanical, or animal or microoraganism derived substances.

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Review Questions

1. What are the basic concepts behind functional foods? Give the definition.
2. Discuss the historical background of functional foods.
3. Discuss the plant and animal sources of functional foods.
4. What are the basic economic opportunities from functional foods?
5. How do you see the future market prospects of functional foods?
6. What is the current scenario of functional foods industry in developing countries?
7. Discuss the condition of the Indian functional foods industry.
8. What are the significance of functional foods in the diets?

Further Readings

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UNIT—II

HYPER NUTRITIOUS AND FAT—FREE FOODS

Objectives

After going through this unit, students will be able to:

- state the concept of protein powder and its sources;
- discuss the method of extraction of proteins;
- point out the nutritional value of protein powder;
- explain the fundamentals of fat-free foods as well as its sources;
- state the importance of fat-free milk powder and low cholesterol oil.

STRUCTURE

2.1 Introduction

While most of us know that good nutrition is essential in helping us feel our best and reach our optimal health; finding time to eat a balanced diet on a daily basis seems a formidable task in this fast-paced, affluent society. Yet, though your life may be hectic, there are still many good tasting, healthy choices which can help you lose weight and improve your health.

Hyper nutritious foods are the kind of foods which contain extra nutrients. These foods leave fastest impact on the users since their nutritional values are very high. The quality of these foods varies dramatically and it is therefore

important to choose the right producer. Avoid foods that are chiefly made up. Foods that contain potentially harmful additives must naturally also be refrained from. Do not hesitate to ask more experienced nutritionist for advice regarding which brands they have had success with in the past.

Hyper nutritious foods may be used to improve sports performance and improve recovery from events and training. One important distinction exists in many weight training groups between hyper nutritious foods and anabolic steroids. There is a common misconception among non-hyper nutritious food users that use of hyper nutritious foods for muscle-building purposes is the same as steroid use or, at the very least, leads to steroid use. However, this charge is often challenged by users on the grounds that these foods do not mean to change natural hormone levels (primarily those of testosterone) beyond natural limits, while anabolic steroids do.

2.2 Protein Powders

Protein is a large molecule composed of one or more chains of amino acids in a specific order determined by the base sequence of nucleotides in the DNA coding for the protein.

Protein is something the body both is and cannot remain without. Proteins are required for the structure, function, and regulation of the body's cells, tissues, and organs.

Each protein has unique functions. Proteins are essential components of muscles, skin, bones and the body as a whole. Examples of proteins include whole classes of important molecules, among them enzymes, hormones, and antibodies.

Protein is one of the three types of nutrients used as energy sources by the body, the other two being carbohydrate and fat. Proteins and carbohydrates each provide 4 calories of energy per gram, while fats produce 9 calories per gram.

The word "protein" was introduced into science by the great Swedish physician and chemist Jöns Jacob Berzelius (1779—1848) who also determined the atomic and molecular weights of thousands of substances, discovered several elements including selenium, first isolated silicon and titanium, and created the present system of writing chemical symbols and reactions.

Protein is the main component of muscles, organs, and glands. Every living cell and all body fluids, except bile and urine, contain protein. The cells of muscles, tendons, and ligaments are maintained with protein. Children and adolescents require protein for growth and development.

Now, what does protein powder really mean? Protein powder is a dietary supplement. If taken everyday, it can boost your energy levels and at the same time help burn fat. It supplies adequate amounts of protein in the body. If you lack some protein in your body or if you are a bodybuilder wanting to get in shape fast, you can try it. In simplest definition, it is a protein supplement in powder form.

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Bodybuilders have long relied upon protein powder to make sure they get the high level of protein needed to beef up their bodies through lifting weights and exercise. However, protein powder is not just for bodybuilders or 98-pound weaklings hoping to bulk up. Research has shown that ingesting protein powder everyday can boost immune system health, facilitate the healing of wounds after surgery or injury, and promote healthy skin — in addition to fostering muscle strength and development. A human body needs daily protein because that is what muscles and tissues are built from, and there is no place where the body can store extra protein. The need for adequate protein in the human body is second only to the need for water.

Luckily, it has been found that most varied diets — including vegan get plenty of protein through daily intake of various food combinations. However, some people like to supplement their protein intake, or occasionally substitute a fast, easy protein shake for a meal.

Protein powders are made from four basic sources: whey (from milk), egg, soy and rice. Protein powders can also be a combination of one or more ingredients. These concentrated sources of protein are processed into the powdered form, to be reconstituted into liquid form as a protein shake, or mixed with fruit juice or milk. Additionally, protein powders can be sprinkled on cereal, stirred into soups or stews, and cooked into baked goods.

Protein powder is designed to be taken everyday as a dietary supplement. Even if you aren't a bodybuilder, starting your day with a protein powder shake can provide nutritional benefits. While many nutritionists advise consuming protein throughout the day, a healthy boost of protein first thing in the morning can stabilize your blood sugar levels throughout the rest of the day.

Some studies indicate a steady amount of excess protein may be unhealthy, especially for those with liver or kidney problems. The recommended daily dose is based on weight, age and activity levels. Athletes should consult a nutritionist specializing in sports medicine.

Uses and Benefits

It is used as a daily nutritional supplement. Like your favourite fruit juice or chocolate drink, it is normally mixed with water to make a very delicious shake. You may think that it is only designed for bodybuilders? Even if you're not, you are free to use and taste its goodness, as you'll be able to take in the nutrients your body needs as you drink.

Nutritionists say that a healthy intake of protein everyday, especially early in the morning, can help make blood sugar levels stable all throughout the day. It has also been investigated that daily consumption of protein powder can boost one's immune system as it assists in wound restoration, improves recovery, promotes lean muscle development as it fosters muscle strength. Furthermore, it was also proven to promote a healthy skin and enhance fat loss.

Most bodybuilders entrust their needed high levels of protein on powders, as it can boost up their energies while doing extreme exercises and lifting weights.

So if you have a dream to get bigger and stronger as well as lose fat easier, then make protein powders your regular pal. Make it a part of your diet.

Because protein is necessary for the healthy function, structure and regulation of body cells, tissues and organs, protein powders are formulated to inspire a maximum metabolic effect in the body. Protein powders are used aggressively by bodybuilders and athletes to improve performance and may be essential to supplement the diets of those who don't eat enough meat, chicken, fish, beef liver, soy, protein-containing vegetables, etc., foods known to be good sources of protein. Vegans often don't get enough protein through diet.

- Proteins are large molecules composed of long chain amino acids
- Protein powder is a dried derivative of animal or vegetable sources of protein, each of which is produced using various processes.
- Protein is needed to build muscle and maintain lean muscle in the body
- Protein is essential to the healthy functioning of every body system

Protein powders target in the body:

- Protein synthesis - for increased muscle mass and enhanced muscle recovery
- Energy production - to boost endurance and fight fatigue
- Fat utilization - reduce body fat and aid in weight management
- Cell health - for immune system strength and overall wellness

Flavours

As mentioned earlier, protein powders can be dissolved in water to form a delicious protein shake. It can also be dissolved and blended with milk. Moreover, for a good blend of flavour of your favorite meal, these powders can be added on cereal and mixed with soups.

Protein powders also come in different flavors that can surely suit your taste. These flavours may either be: vanilla, chocolate, raspberry, strawberry, rocky road.

Sources of Protein Powder

The hundreds, if not thousands, of protein powders and brands on the market all contain one of more of the following five sources of protein, and all are processed in ways formulated to mix with a beverage or make a protein shake or smoothie.

- Cow milk
- Eggs
- Soy
- Hemp
- Goat milk

Cow milk and goat milk proteins include whey and casein, which are separated from lactose and fat in a filtration process that leaves the proteins intact. Casein is the more prevalent protein in both cow and goat milk at roughly 80 percent. The remaining 20 percent of protein is whey.

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Soy protein typically comes from dried, defatted soy flakes which are subject to either a water or alcohol extraction process (to remove carbohydrates) and are then dried and ground.

Hemp protein is made from hemp oil which is cold-pressed from hemp seeds. The remaining hemp meal is cold-milled and the protein separated.

Egg proteins are derived in large part from egg whites and are isolated through some type of spray-drying or freeze-drying process.

There are four chief sources of protein powders. They can either be sourced from whey, egg, soy or rice. However, those obtained from whey or milk is the most popular and proven to be the most effective. These protein powders came from pure protein sources manufactured into powder. The processed powder is then dissolved in water to form a protein shake.

Milk

Whey protein is derived from milk and is the most commonly used protein supplement. It contains nonessential and essential amino acids, as well as branch chain amino acids (BCAA). Amino acids are the building blocks of protein. The body does not make essential amino acids, therefore they must be obtained through diet. Nonessential amino acids can be synthesized by the body. Whey is easily absorbed by your muscles and is extremely safe to use. Whey protein is not appropriate for those who have a milk allergy or who cannot tolerate lactose.

There are two categories of whey protein powders—concentrate and isolate. The concentrate form is more widely used, easier to find and less expensive. It contains approximately 30 to 85% protein. Whey isolate is a higher quality protein and is, therefore, more expensive. It contains more than 90% protein. Whey isolate is more easily abosorbed by the body and contains less fat and lactose.

Benefits of whey protein:

- Helps boost immunity
- Optimal source of amino acids
- Enhances muscle recovery after workouts and helps prevent muscle breakdown

Soy

Soy protein is derived from soy flour. Of all the various vegetable proteins, soy is the most complete protein. Similar to whey protein, soy protein has two types, the concentrate and the isolate, with the isolate being the purer, more expensive form. Soy protein is highly digestible and is comparable to milk and meat as a protein source. Soy protein is ideal for those who have dairy allergies, but should not be taken by those who have a soy allergies.

Benefits of soy protein:

- Helps to improve nutritional value of foods
- Lowers cholesterol
- Reduces the risk of heart disease
- Suitable for vegans

Egg

Egg protein is made from the egg white and is therefore fat-free and high in protein. It is considered the most perfect source of protein because it is complete in essential amino acids, branch chain amino acids and glutamic acid. It is completely and easily absorbed by the body. Because of its characteristics, egg protein is used as the standard against which all other proteins are measured. Egg protein should not be used by anyone who has an egg allergy.

Benefits of egg protein:

- Highest in the amino acids alanine, arginine, glycine and methine
- Fat-free

Rice

Rice protein is derived by carefully isolating the protein from brown rice. It is a complete protein containing all essential amino acids and nonessential amino acids. Rice protein is hypoallergenic, which makes it sutable for everyone.

Benefits of rice protein:

- Hypoallergenic
- Suitable for vegans
- Complete protein

Types of Protein Powder

Which powder is best? You might get confused with lots of brands of protein powders too choose from in the market world. Which one should I select? The first thing you must be sure of selecting the right one is the quality, also look at the brand of course. Is it top quality? Look at the nutritional information. Is it worth buying? The next thing that may enter your mind is: does it taste good? No matter how good a value your protein powder is, taste still matters.

Protein Powder. A simple name for one of the most debated food supplements amongst bodybuilding and weight training circles. A simple name also, for something that comes from such a wide variety of sources and is sold under so many different brands.

With so many types on the market, how do you know which one is the best for your needs? We hear a lot about Whey Protein Isolate, but what of the other protein powders available and how do they differ? Which is the best for gaining muscle and which is the best when you want to get lean?

Whey Protein

Whey Protein Isolate and Whey Protein Concentrate are the two main commercial forms of Whey Protein. Both are produced from whey (a by product of cheese making). WPI has higher, less damaged protein and lower fat, lactose and flavour levels than WPC. Both have extremely high protein quality and are highly digestibility. One great functional advantage of whey proteins is that they are highly soluble even in acid conditions. This means you can mix them into fruit juice without them going grainy and you can't even tell they are there.

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Whey protein is by and large the most popular and arguably the best type of protein and/or supplement on the market today. Often called the gold standard of protein, whey is a total protein meaning it contains all of the necessary amino acids due to its Branched-chain amino acids structure (BCAA's). BCAA's are naturally occurring molecules (leucine, isoleucine, and valine) that the body uses to build proteins. The term "branched chain" refers to the molecular structure of these particular amino acids. Muscles have a particularly high content of BCAA's; whey is the preferred choice for before and after workout protein shakes.

Pre-workout: Your pre-workout shake should be consumed approximately thirty minutes before your workout and have no more than 25—35 grams of protein. The decision on what to mix whey protein with lies solely with your personal preferences but most people will use either water or skim milk based on their tolerability to dairy products. Since milk is principally casein protein you may choose to mix with water for faster absorption unless the duration of your workout will surpass 80—90 minutes. Also, carbs (40—60 grams) should be taken with your shake to form an insulin spike so nutrients can be readily soaked up by cells. High GI carbs like dextrose are preferred for this situation, but fruits or oats would work just as well

Post-workout: Your post-workout shake should contain a slightly higher amount of whey protein and carbs. Target 30—50 grams of proteins and 60—100 grams of carbs. The insulin spike is essential for your post-workout as it will determine if the protein you are ingesting will be used to build muscle or replace depleted glycogen levels. Whey protein is the smart choice for your post-workout shake since it is absorbed the quickest by the body. There are 2 types of whey protein Concentrate and Isolate.

Strengths

- WPI contains about 10% immunoglobulin proteins which helps support the body's immune system.
- Contains the highest concentration (24—25%) of branched-chain amino acids (BCAA's) of any protein source.
- Enhances production of glutathione, one of the body's most powerful anti-oxidants.
- WPI contains a compound which has been shown to have pain killing properties which may decrease muscle soreness after intense weight training.
- WPI may have the ability to stimulate Insulin-like growth factor-1 (IGF-1) production.

Weaknesses

- WPI, particularly ion-exchange, is very expensive. If the WPI is not produced by ion-exchange it may not be have all the strengths mentioned above as these may be lost in other methods of processing.

- Levels of arginine, glutamine and the essential amino acid phenylalanine are low relative to the other types of protein powder.

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Casein

Milk protein is made up of about 80% casein and 20% whey protein. Casein has been around for a long time but it doesn't have the high profile among body-builders that whey protein does. The two main types of caseinate are sodium and calcium. Most of the people prefer to use calcium caseinate for it's lower sodium content and also because it absorbs a lot of moisture for a filling meal. It can also be mixed with neutral fruits and juices like pear and peach to make a high protein mouse-like dessert. Casein is not acid soluble so don't try to mix it with pineapple juice or other acidic juices or it will go grainy.

Casein protein is the slowest digesting protein in the market. Studies have demonstrated that casein protein can sustain the body with a regular supply of amino acids for at least seven hours, making casein the most anabolic protein, even more than whey. The reason behind this is really because casein forms a "gel" in acidic environments like the stomach, and so releases a steady supply of amino acids into the bloodstream, permitting your body to remain anabolic.

Since casein is kind of a slow digesting protein, consuming 30—50 grams before bed will stop catabolism while you're asleep. You may also consume casein protein across the day, just never after a workout. Post-workout protein should be soaked up fast into the bloodstream, making casein a particularly bad choice. Casein protein can be taken pre-workout as well, but this would not be the best use. A better pre-workout shake would be to mix together a blend of casein and whey protein, thus permitting you to drink it inside thirty minutes of your workout.

Milk contains over 80% casein protein, so mixing whey protein with milk will not only make your shake taste better but it will give you a make shift time-release formula, effective straight away and sustaining for hours to come. Also, mixing your casein with milk before bed will ensure you stay anti-catabolic across the night.

Strengths

- Slows the transit time of amino acids through the gut which helps increase their absorption.
- Contains very high (20%) glutamine content which can help spare muscle during training.
- High level of tyrosine, the 'pick me up' amino acid, compared to tryptophan, the 'sleep inducing' amino acid, so eating casein may give you a 'boost'.
- High levels of threonine, glutamine, and arginine, the 'glucogenic' amino acids which lend themselves to glucose production during exercise and may prevent muscle breakdown.

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Weaknesses

- Not as high in BCAA's as whey protein. Sodium caseinate contains high sodium levels.
- Has a bland, slightly chalky taste.

***Soy* protein Isolate**

Until recently soy protein was seen by bodybuilders and nutritionalists alike as a 'second class' protein, being incomplete in it's essential amino acid profile. The new Soy Protein Isolates on the market, in particular the Supro brand isolates have been shown to have the same quality as casein and whey proteins and have all the essential amino acids required to be used as the sole source of protein. Good new for vegetarians.

Soy protein is derived from soybeans and is the sole protein considered free of fat, cholesterol, and lactose. Soy is the only protein that does not come from animals, making it acceptable for vegetarians who need further protein supplementation in their diet. It's a complete protein and a good selection for folks who are lactose intolerant. Soy protein can be employed in pancake batters, breads, and other baked goods as well as other foods to increase there protein content. It is usually considered a medium digesting protein, somewhere in between the assimilation rate of whey and casein, making it a particularly flexible protein.

Notwithstanding all its flexibility and benefits, soy protein cannot compare to whey protein in most respects. However, soy proteins do contains saponins which have been proven to lower cholesterol levels by binding to cholesterol molecules in the little viscera, so decreasing the amount the body retains.

Strengths

- High level of BCAA's, glutamine and arginine, the 'critical cluster' amino acids which help spare muscle during a diet phase.
- May enhance production of thyroxin (thyroid stimulating hormone) and insulin. Increased thyroxin leads to a faster metabolism which is great news for anyone trying to lose body fat.
- Helps reduce nitrogen loss and enhances fat loss during low-calorie dieting.
- Soy protein contains isoflavones which may help to reduce the risk of heart disease, cancers and lower cholesterol levels.
- Relatively cheap compared to whey protein.

Weaknesses

- Not all soy protein powders are made from Supro brand soy protein isolate, so they may not have the necessary levels of essential amino acids and other strengths mentioned above. If in doubt, ring the company and ask which soy protein isolate they are using.
- Relatively low level of the essential amino acid methionine compared to other proteins.

- Contains up to 1% sodium which is not suitable for a bodybuilder close to contest.
- Has a distinct flavour and is slightly salty to taste which may be unpalatable to some people.

Egg White Protein

Spray dried egg whites are used in some 'egg and milk' protein powder mixes. Egg whites were once considered essential to a bodybuilding diet, but with the introduction of whey proteins they have lost popularity as a supplement.

Shockingly, egg protein powder contains no fat or cholesterol as it is formed from the whites of the eggs, and contains no egg yolks. For years, egg protein has been considered the ideal protein by weightlifters and sportsmen alike as it contains all eight necessary amino acids. The Biological value of a protein is ranked from one to a hundred, with a hundred meaning 100% of the protein ingested is kept in the body; egg protein has a BV of one hundred. Egg protein is also complete in Branched Chain Amino Acids and glutamic acid, making it simply and readily soaked up by the body.

Like soy protein, egg protein is a medium digesting protein and doesn't contain lactose, making it the ideal choice for folks who are lactose intolerant. Egg protein is considered superior to all other protein types as it has the highest content of amino acids alanine, arginine, glycine and methane.

Additionally, egg protein has the highest net nitrogen function rating, encouraging your body to use the most nitrogen (amino acids) to build muscle. The drawback of egg protein is that it is rather costly, so I would not consider it as your most important source of protein.

As you can see all Proteins are not created equal. Protein is an essential nutrient needed by everybody on a daily basis. Non-essential amino acids can be synthesized by the body from other amino acids, but essential amino acids like phenylalanine can't. Out of the 20 amino acids, eight are regarded as necessary and the simplest way to get these is through the foods and nutritional supplements we consume. Proteins are the basic building blocks of a muscle as they help repair and reconstruct muscles after a long workout which is how we become bigger and stronger. Weightlifters looking to gain muscle mass should consume more protein than the average person, somewhere in between 1—1.5 grams of protein per *lbs.* of bodyweight.

Strengths

- Excellent amino acid profile
- High quality 'whole food' protein source which has undergone minimal processing
- Add to water and use like fresh egg whites

Weaknesses

- Large amounts of egg white powder can cause stomach and bowel upsets
- Expensive and offer no other benefits other than amino acid profile

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- Hard to mix into water
- Relatively low levels of glutamine

How Protein Powders Work in the Body

Although protein powders may be derived from only one food source of protein, many combine the benefits of several sources, enhancing their overall benefit to the body system. Protein powder regimens and blends usually target specific metabolic purposes or pathways, such as energy production, fat utilization or digestion; or physical activity such as intense exercise, weightlifting or distance running. Certain protein powders are better than others at encouraging healing and trauma recovery, and all protein powders digest and absorb differently into the body. Protein unused by the body is excreted as waste.

Casein protein powder digests slowly which, before bedtime and between meals, can deliver a steady supply of amino acids needed to stop muscles from breaking down (catabolizing) during long periods of physical rest. Casein is insoluble in liquid, which is the reason why it digests slowly. Casein occurs as tiny micelles or globules after filtration. Goat milk casein may digest faster than cow milk casein.

Whey protein powder is more soluble in liquid, which makes it easier to mix with liquids and digest as a beverage - perfect for before and after workouts when it's crucial for amino acids to flow steadily to muscles for strength, recovery and to stave off catabolism.

Whey is said to have the highest Biological Value (BV) of all the proteins. The higher the Biological Value of the protein, the more nitrogen the body absorbs, uses and retains. As a result, proteins with the highest BV promote the most lean muscle gains.

Egg protein powder is among the most popular because it's typically devoid of fat and carbohydrates and is easy to digest and absorb. Egg protein powder typically contains high levels of sulfur-containing amino acids, which are said to be critical to hormone-producing pathways in the body. Egg protein powders are considered good for those who are allergic to cow milk proteins and for those who eat few eggs. Egg protein is said to have the highest BV next to whey protein

Soy protein powder tends to be rich in glutamine and arginine. It's absorbed quickly and easily into the body and delivers a multitude of health benefits, including soy isoflavones known to benefit the immune system. Reports differ as to whether soy is a complete protein source - most say it isn't.

Despite myths perpetuated by the bodybuilding community that soy protein imparts estrogen-like effects on the body and competes with the anabolic effects of testosterone, soy protein has been found to benefit muscle health in male bodybuilders.

Hemp protein powder is typically 50 percent protein. Hemp protein powders are typically high in fiber and contain beneficial fats omega 3, 6 and 9, GLA (gamma linolenic acid) and chlorophyll.

Protein Powder Benefits and Claims

Researchers at the Nutrition Institute in Knoxville, Tennessee say that protein powders are full of biologically active components that may play a role in optimizing the health of everyone - not just for bodybuilders and athletes. Among

the general health benefits of protein powder, say experts at the American College of Nutrition, are lower levels of body fat, enhanced weight loss capabilities, lean muscle preservation and improved immune function.

Research indicates that shakes or smoothies made from protein powder are said to be particularly beneficial when consumed before and after workouts. When compared with carbohydrate drinks or consuming nothing at all, beverages fortified with protein powder may lead to superior gains in muscle strength and mass.

- Soy protein powders are said to provide women with needed isoflavones that help balance hormones and strengthen bones.
- Whey protein powders work quickly to increase protein synthesis.
- Egg protein powders may help maintain and build new muscle and stimulate protein synthesis better than carbohydrates alone.
- Hemp protein powders are rich in essential fatty acids.

What to Look for in a Protein Powder

Most often used by athletes to enhance endurance and by bodybuilders to build muscle, protein powders may serve a variety of other lifestyles. To achieve optimum metabolic results from any protein powder, experts say consumers should look for the following ingredients as an indication of a quality and effectiveness:

Creatine - an amino acid that when taken as a supplement to whey protein may increase levels of insulin in the body, leading to heightened cell energy.

Glutamine - an amino acid that supports the immune system, enhances muscle recovery, aids digestion and promotes muscle growth.

Arginine - aids in the production of nitric oxide to increase blood flow and add volume to muscle cells by helping them retain water.

Carnosine - an amino acid dipeptide that helps muscles contract more intensely and for longer periods of time.

Omega-3 essential fatty acids EPA and DHA - eicosapentaenoic acid and docosahexaenoic acid may preserve muscle mass by helping the body burn fat stores.

CLA (Conjugated Linoleic Acid) - stimulates muscle growth and encourages fat loss.

GLA (Gamma Linolenic Acid) - a needed precursor for many prostaglandins responsible for promoting fat metabolism and muscle growth.

MCTs (Medium-Chain Triglycerides) - fuel for muscle during workouts.

Carnitine - a pseudo amino acid that burns fat for fuel during exercise. May enhance testosterone activity in muscle cells and aid in muscle recovery.

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Vitamins and minerals - experts advise to look for 50 percent or more of the RDI for essentials.

Fiber - five grams of fiber per dose is suggested.

Colostrum - contains insulin-1 growth factor to stimulate muscle growth.

Digestive enzymes - help the body digest and absorb protein quickly and deliver protein to muscles fast.

Side Effects of Protein Powder, Safety and Toxicity

There is literature which suggests that protein supplementation, without a balanced diet or sufficient exercise, may lead to dehydration, gout, liver and kidney damage, calcium loss and adverse gastrointestinal effects. Although little evidence suggests any toxicity or safety problems are associated with the general use of protein powder, it is neither inspected nor regulated by the FDA and, as such, its purity, safety and efficacy may be questionable from blend to blend and brand to brand. Consumer agencies warn users to be wary of protein powders manufactured outside the U.S.

Nutritionists and trainers suggest using protein powder with a purpose in mind and one focused on reasons for boosting protein intake such as enhanced endurance, a desire to build lean muscle, trauma recovery or muscle healing or a boost in immune system strength.

One documented setback to whey protein is its quick digestion and absorption into the bloodstream, resulting in many of its health-enhancing qualities being destroyed by the liver before benefiting muscle tissue. For this reason, protein powders made exclusively with whey protein may do nothing to stop catabolism, experts say. There are whey protein powders available, however, with delivery systems specifically designed to slow the absorption of whey protein and deliver more of its benefits to muscle.

Clinical Studies and Protein Powder Research

Incontrovertible scientific evidence suggests that protein is needed by all body systems to ensure good health. Clinical findings regarding protein powder, however, are relatively inconsistent, as are the criteria for control and experimental groups used in various published studies. Notwithstanding it's ranking by the FDA as a dietary supplement:

- Some studies indicate that soy protein powders may be superior to milk-based protein powders in helping to balance hormones in women and strengthen bones.
- Reports from Ohio State University researchers imply that a protein powder regimen may strengthen a man's prostate.
- University of Tokyo research indicates that long-term benefits of using protein powders result in quicker workout recovery and heightened levels of oxygen in the blood, possibly increasing overall athletic endurance.
- Research published in the Alternative Medicine Review reveal numerous benefits to engaging in a protein powder regimen:
- More lean tissue mass and muscle strength when used in conjunction with exercise

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- Peak power and work performance
- Balanced cholesterol, triglyceride and blood pressure levels
- Improved markers of health in cases of liver toxification
- Strengthen healthy cells and fight free radicals
- Helps boost levels of glutathione (a potent antioxidant) to enhance immune system strength
- Improve gastrointestinal immunity in infants when added to baby formula.

Protein Powder Efficacy and the FDA

Protein powders in the U.S. are sold without FDA approval of safety or effectiveness. One downside to efficacy is that some nutritionists insist that an increase in muscle mass resulting from the use of protein powder overtime may just be muscles retaining water - with a prolonged regimen sustaining these results. On the upside: protein powder supplementation may indeed build muscle mass, improve endurance and benefit a healthy immune system.

As a result of continued research, perspectives and opinions by nutritionists and dieticians regarding the effectiveness of protein powder supplementation have shifted in recent years. New findings suggest that, as a result of poor diet, escalating stress and new trends in bodybuilding and athletic performance, humans need more protein now than ever - and protein powder may be the most practical way to add pure protein to the diet without the fat and carbohydrates found in whole food protein sources.

Protein powders may do more good than harm, say experts, when used as directed and in conjunction with a balanced diet and sufficient exercise.

2.3 Method of Extraction of Proteins of Oil Seed and Legume Cakes

Depending on the source, the protein has to be brought into solution by breaking the tissue or cells containing it. There are several methods to achieve this: Repeated freezing and thawing, sonication, homogenization by high pressure, clarification via cellulose-based depth filters, or permeabilization by organic solvents. The method of choice depends on how fragile the protein is and how sturdy the cells are. After this extraction process soluble proteins will be in the solvent, and can be separated from cell membranes, DNA etc., by centrifugation. The extraction process also extracts proteases, which will start digesting the proteins in the solution. If the protein is sensitive to proteolysis, it is usually desirable to proceed quickly, and keep the extract cooled, to slow down proteolysis.

Five common methods are used to extract protein from oilseeds:

(a) *Water assisted:* Here the finely ground oilseed is either boiled in water and the oil that floats to the surface is skimmed off or ground kernels are mixed with water and squeezed and mixed by hand to release the protein and oil.

(b) *Manual pressing:* Here oilseeds, usually pre-ground, are pressed in manual screw presses. A typical press is shown in diagram 1.

(c) *Expelling:* An expeller consists of a motor driven screw turning in a perforated cage. The screw pushes the material against a small outlet, the "choke". Great pressure is exerted on the oilseed fed through the

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machine to extract the oil and protein. Expelling is a continuous method unlike the previous two batch systems.

(d) *Ghanis:* A ghani consists of a large pestle and mortar rotated either by animal power or by a motor. Seed is fed slowly into the mortar and the pressure exerted by the pestle breaks the cells and releases the oil along with protein. Ghani technology is mainly restricted to the Indian sub-continent.

(e) *Solvent extraction:* Oils from seeds or the cake remaining from expelling is extracted with solvents and the oil is recovered after distilling off the solvent under vacuum.

Most small enterprises will find that small expellers are the best technology choice. Methods such as water extraction and manual pressing only produce small amounts of oil per day, the extraction efficiencies are low and labour requirements high. Solvent extraction while highly efficient involves very substantial capital cost and is only economic at large scale. There are also health and safety risk from using inflammable solvents.

Equipment Required

The equipment needed to set up a small or medium scale oil extraction enterprise falls into three main categories:

- pre-extraction equipment; *e.g.,* dehullers, seed/kernel crackers, roasters, mills.
- extraction equipment; manual presses, ghanis, expellers
- equipment for basic refining of the oil; filters, settling tanks.

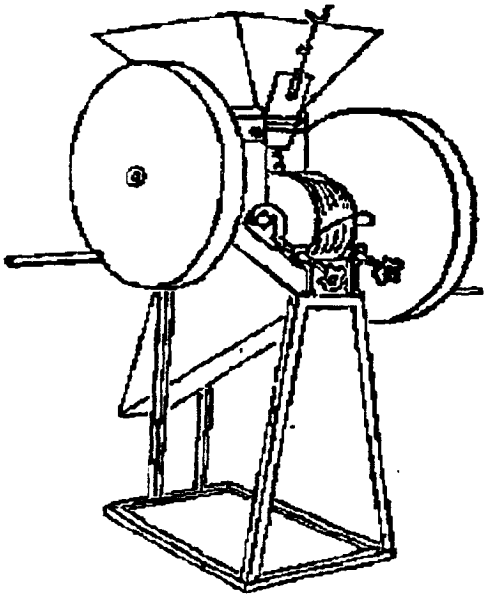

Fig. 1: Decorticating machine

The specific equipment required will depend on the particular crop being processed, the final protein and oil quality required and the scale of operation. In

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a small guide it is impossible to cover both the whole range of technical options and possible crops the following section concentrates on one example; the extraction of sunflower and groundnut oil by expeller.

Shelling or Dehulling

Most oil bearing seed need to be separated from outer husk or shell. This is referred to as shelling, hulling or decortication. Shelling increases the oil extraction efficiency and reduces wear in the expeller as the husks are abrasive. In general some 10% of husk is added back prior to expelling as the fiber allows the machine to grip or bite on the material.

A wide range of manual and mechanical decorticators are available and typical examples are shown in *Figure 1.*

After decortication the shell may have to be separated from the kernels by winnowing. At small scale this can be done by throwing the material into the air and allowing the air to blow away the husk. At larger scale mechanical winnowers and seed cleaners are available

Heating or Conditioning

Pre-heating the seeds prior to expelling speeds up the release of the oil. Pre-heating is generally carried out in a steam heated kettle mounted above the expeller.

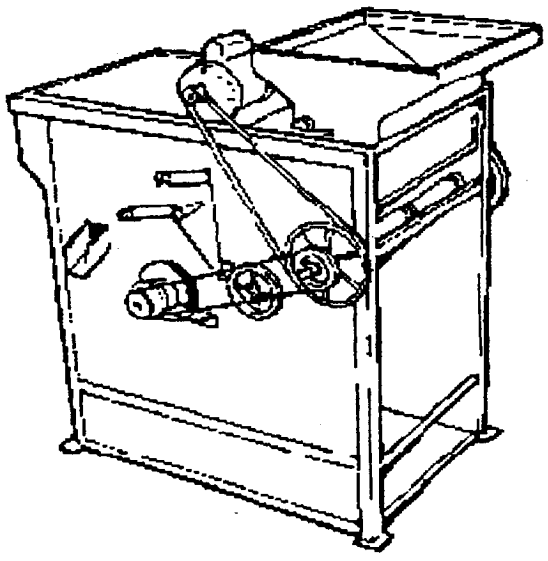

Fig. 2: Two screen Grain/seed cleaner cum grader

Expelling

A wide range of makes and sizes of expellers are available. In India in particular a number of efficient small or "baby" expellers are available. A typical example with a capacity of up to 100 kg/hr is shown in *figure 2.* This machine has a central cylinder or cage fitted with eight separate sections or "worms". This flexible system allows single or double-reverse use and spreads wear more evenly along the screw. When the screw becomes worn only individual sections require

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repair thus reducing maintenance costs. As the material passes through the expeller the oil is squeezed out, exits through the perforated cage and is collected in a trough under the machine. The solid residue, oil cake, exits from the end of the expeller shaft where it is bagged.

Filtration

The crude expelled oil contains solid particles. These can be removed by allowing the oil to stand and then filtering the clear oil by gravity through fine cloth. A better but more expensive method is pumping the crude oil through a filter press.

The typical system described above can be obtained for about $US 4500 (1992 price) and consists of:

- Decorticator with blower to remove shell, 150 kg/hr
- Boiler, 50 kg steam/hr at 30 psi
- Cooker
- Expeller 75—100 kg/hr
- Filter pump and press.

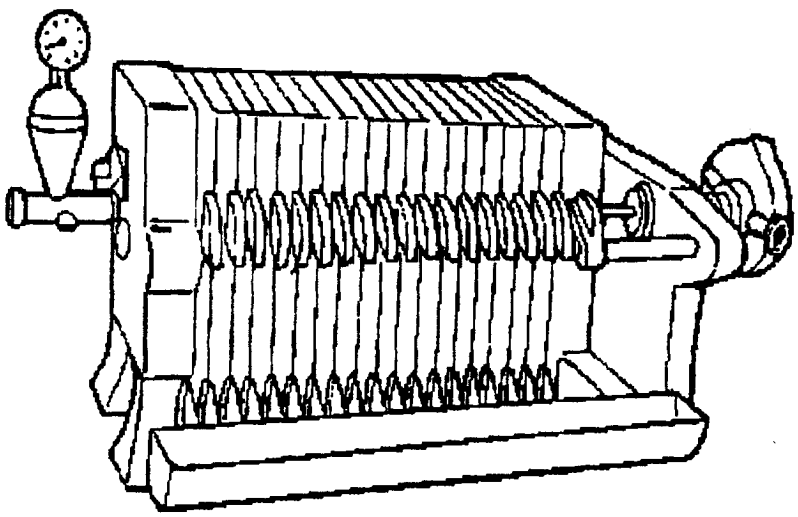

Fig. 3: A filer press

Protein Purification

Protein purification is a series of processes intended to isolate a single type of protein from a complex mixture. Protein purification is vital for the characterisation of the function, structure and interactions of the protein of interest. The starting material is usually a biological tissue or a microbial culture. The various steps in the purification process may free the protein from a matrix that confines it, separate the protein and non-protein parts of the mixture, and finally separate the desired protein from all other proteins. Separation of one protein from all others is typically the most laborious aspect of protein purification. Separation steps exploit differences in protein size, physico-chemical properties and binding affinity.

Purpose

Purification may be preparative or analytical. Preparative purifications aim to produce a relatively large quantity of purified proteins for subsequent use. Examples include the preparation of commercial products such as enzymes (*e.g.* lactase), nutritional proteins (*e.g.* soy protein isolate), and certain biopharmaceuticals (*e.g.* insulin). Analytical purification produces a relatively small amount of a protein for a variety of research or analytical purposes, including identification, quantification, and studies of the protein's structure, post-translational modifications and function. Among the first purified proteins were urease and Concanavalin A.

Strategies

Choice of a starting material is key to the design of a purification process. In a plant or animal, a particular protein usually isn't distributed homogeneously throughout the body; different organs or tissues have higher or lower concentrations of the protein. Use of only the tissues or organs with the highest concentration decreases the volumes needed to produce a given amount of purified protein. If the protein is present in low abundance, or if it has a high value, scientists may use recombinant DNA technology to develop cells that will produce large quantities of the desired protein (this is known as an expression system). Recombinant expression allows the protein to be tagged, *e.g.* by a His-tag, to facilitate purification, which means that the purification can be done in fewer steps. In addition, recombinant expression usually starts with a higher fraction of the desired protein than is present in a natural source.

An analytical purification generally utilizes three properties to separate proteins. First, proteins may be purified according to their isolectric points by running them through a pH graded gel or an ion exchange column. Second, proteins can be separated according to their size or molecular weight via size exclusion chromatography or by SDS-PAGE (sodium dodecyl sulfate-polyacrylamide gel electrophoresis) analysis. Proteins are often purified by using 2D-PAGE and are then analysed by peptide mass fingerprinting to establish the protein identity. This is very useful for scientific purposes and the detection limits for protein are nowadays very low and nanogram amounts of protein are sufficient for their analysis.

Evaluating Purification Yield

The most general method to monitor the purification process is by running a SDS-PAGE of the different steps. This method only gives a rough measure of the amounts of different proteins in the mixture, and it is not able to distinguish between proteins with similar molecular weight.

If the protein has a distinguishing spectroscopic feature or an enzymatic activity, this property can be used to detect and quantify the specific protein, and thus to select the fractions of the separation, that contains the protein. If antibodies against the protein are available then western blotting and ELISA can specifically detect and quantify the amount of desired protein. Some proteins function as receptors and can be detected during purification steps by a ligand binding assay, often using a radioactive ligand.

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In order to evaluate the process of multistep purification, the amount of the specific protein have to be compared to the amount of total protein. The latter can be determined by the Bradford total protein assay or by absorbance of light at 280 nm, however some reagents used during the purification process may interfere with the quantification. For example, imidazole (commonly used for purification of polyhistidine-tagged recombinant proteins) is an amino acid analogue and at low concentrations will interfere with the bicinchoninic acid (BCA) assay for total protein quantification. Impurities in low-grade imidazole will also absorb at 280 nm, resulting in an inaccurate reading of protein concentration from UV absorbance.

Another method to be considered is Surface Plasmon Resonance (SPR). SPR can detect binding of label free molecules on the surface of a chip. If the desired protein is an antibody, binding can be translated to directly to the activity of the protein. One can express the active concentration of the protein as the percent of the total protein. SPR can be an powerful method for quickly determining protein activity and overall yield. It is a powerful technology that requires an instrument to perform.

Precipitation and Differential Solubilization

In bulk protein purification, a common first step to isolate proteins is precipitation with ammonium sulfate $(NH_4)_2SO_4$. This is performed by adding increasing amounts of ammonium sulfate and collecting the different fractions of precipitate protein. One advantage of this method is that it can be performed inexpensively with very large volumes.

The first proteins to be purified are water-soluble proteins. Purification of integral membrane proteins requires disruption of the cell membrane in order to isolate anyone particular protein from others that are in the same membrane compartment. Sometimes a particular membrane fraction can be isolated first, such as isolating mitochondria from cells before purifying a protein located in a mitochondrial membrane. A detergent such as sodium dodecyl sulfate (SDS) can be used to dissolve cell membranes and keep membrane proteins in solution during purification; however, because SDS causes denaturation, milder detergents such as Triton X-100 or CHAPS can be used to retain the protein's native conformation during complete purification.

Ultracentrifugation

Centrifugation is a process that uses centrifugal force to separate mixtures of particles of varying masses or densities suspended in a liquid. When a vessel (typically a tube or bottle) containing a mixture of proteins or other particulate matter, such as bacterial cells, is rotated at high speeds, the angular momentum yields an outward force to each particle that is proportional to its mass. The tendency of a given particle to move through the liquid because of this force is offset by the resistance the liquid exerts on the particle. The net effect of "spinning" the sample in a centrifuge is that massive, small, and dense particles move outward faster than less massive particles or particles with more "drag" in the liquid. When suspensions of particles are "spun" in a centrifuge, a "pellet" may form at the

bottom of the vessel that is enriched for the most massive particles with low drag in the liquid. The remaining, non-compacted particles still remaining mostly in the liquid are called the "supernatant" and can be removed from the vessel to separate the supernatant from the pellet. The rate of centrifugation is specified by the angular acceleration applied to the sample; typically measured in comparison to the *g*. If samples are centrifuged long enough, the particles in the vessel will reach equilibrium wherein the particles accumulate specifically at a point in the vessel where their buoyant density is balanced with centrifugal force. Such an "equilibrium" centrifugation can allow extensive purification of a given particle.

Sucrose gradient centrifugation – a linear concentration gradient of sugar (typically sucrose, glycerol, or a silica based density gradient media, like Percoll) is generated in a tube such that the highest concentration is on the bottom and lowest on top. Percoll is a trademark owned by GE Healthcare companies. A protein sample is then layered on top of the gradient and spun at high speeds in an ultracentrifuge. This causes heavy macromolecules to migrate towards the bottom of the tube faster than lighter material. During centrifugation in the absence of sucrose, as particles move farther and farther from the center of rotation, they experience more and more centrifugal force (the further they move, the faster they move).

The problem with this is that the useful separation range of within the vessel is restricted to a small observable window. Spinning a sample twice as long doesn't mean the particle of interest will go twice as far, in fact, it will go significantly further. However, when the proteins are moving through a sucrose gradient, they encounter liquid of increasing density and viscosity. A properly designed sucrose gradient will counteract the increasing centrifugal force so the particles move in close proportion to the time they have been in the centrifugal field. Samples separated by these gradients are referred to as "rate zonal" centrifugations. After separating the protein/particles, the gradient is then fractionated and collected.

2.4 What is Fat?

Dietary fat is a vital nutrient our bodies need for health and daily functioning. As an energy source, it supplies essential fatty acids for growth, healthy skin, vitamin-absorption and regulation of bodily functions (Dietary Fats).

Fat is the most calorie-dense food energy source; it contains nine calories per gram while carbohydrates or protein each provide only four per gram.

Fat is also essential to keeping you feeling full (satiated) (Dietary Fats), but too much fat leads to weight gain. This is due to the fact that eating more fat leads to eating more calories (Dietary Fats).

Where Does Fat Go?

Fat is stored predominantly in the body as adipose tissue, but it is also contained in plasma and other cells. Energy is stored in fat deposits and they insulate the body, providing support and cushioning for the organs.

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Where Does it Come From?

According to the USDA, "Many foods in the milk group and in the meat and beans group (which includes eggs and nuts, as well as meat, poultry, and fish) are also high in fat, as are some processed foods in the grain group (Choose a Diet)."

The FDA and USDA recommend a diet that provides no more than 30 percent of total calories from fat (Choose a Diet). Examples are:

- 1,600 calories = 53 grams fat or less
- 2,200 calories = 73 grams of fat or less
- 2,800 calories = 93 grams of fat or less

Different Fats

Poly/Monounsaturated and Saturated Fat

There are different types of fat and you may often hear of saturated fats and trans fats, as both are unfavorable in large quantities.

The 2005 Dietary Guidelines recommend that only 10 percent or less of your daily calorie intake should be from saturated fats. Full-fat dairy foods, meat, certain oils are all sources of saturated fat (Choose a Diet), as are bakery products.

According to researchers at Harvard University, "...bad fats, meaning saturated and trans fats, increase the risk for certain diseases while good fats, meaning monounsaturated and polyunsaturated fats, lower the risk. The key is to substitute good fats for bad fats (Fats)."

The Guidelines recommend most of the fats we consume be polyunsaturated and monounsaturated fat. These can be found in fish, nuts and some oils, such as olive oil and peanut oil.

Cholesterol

Cholesterol is not actually a fat, but a fat-like substance that is also neccessary to the body, but in excess it can lead to heart problems. While some occurs naturally in the body, cholesterol can also be consumed in animal foods such as beef and shellfish. A high level of cholesterol in the blood is a major risk factor for coronary heart disease, which leads to heart attack, and also increases the risk of stroke. (American Heart Association)

The FDA suggests on food labels that we consume no more than 300 mg of cholesterol daily.

Trans Fat

Trans fat is found in foods such as crackers and baked goods. French fries, donuts and other commercially fried foods are major sources of trans fat as well.

Trans fats result from adding hydrogen to vegetable oils used in commercial baked goods and for cooking in most restaurants and fast-food chains. (American Heart Association) It's also found naturally occuring in some animal and dairy foods. The American Heart Association recommends trans fat intake should not exceed 1 percent of total calories each day (American Heart Association).

The cornerstone of any cholesterol lowering diet is fat-free foods. But just because a label states that it is fat free, that doesn't mean that it actually is.

2.5 Fat Free Foods

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According to the Food and Drug Administration, foods can be labelled as "fat free" only if they contain less than 0.5 g of fats (saturated fat or trans fats) per serving. Therefore, it is possible for the Nutritional Facts label to state that there are 0g of fat, even though there is a trace amount of fat present in the food.

If you decide to eat a lot of servings of the food, this could translate to many grams of fat and calories. Just because something is labelled as "fat free," it doesn't mean you can eat as much as you want to. Although it sounds like a small amount, numerous servings of fat-free products could add up pretty quickly in terms of fat and calories.

Many people think the real trick to losing weight is by eating fat free foods, but this is a false perception. Your body is a complex machine and the only way to lose weight is to understand properly how it works. Firstly you need to know that gaining weight is a process, just as losing weight is, and it did not happen overnight after all now did it? You gained weight in a natural way according to your lifestyle so surely losing it the same way is the best solution?

Losing weight with fat free foods, True or false?

The answer to 'do fat free foods help in losing weight' is plain and simple no. There is no relationship between fat calories that you absorb' and fat tissue on your body. You should know that your body can convert any type of calories into fat' and not just fat calories. For example you can take sugar which has zero fat calories in it yet you can gain weight from using eating sugar laden foods or just plain using too much sugar. If you see low fat cakes, cookies, desserts and foods, in your grocery store and buy them because you think they will lose weight, then think again. You can gain weight by eating low fat foods, and the same goes for eating normal fat foods, and the answer to the question 'can you lose weight by eating fat free foods comes again back to, No! Think on this, over the last few decades everyone has been crazy about moving to low fat products, yet everyone is still gaining weight. Low fat diets will not trick your complex body into losing those pounds, and you are wasting your time buying them, (unless you have to be on a special diet for medical reasons).

Non fat and Low fat Foods

If you want to lose weight, and your mission is non fat foods and low fat foods, then you need to start changing your mindset today. Non fat and low fat foods are also a tad more expensive than normal foods as well and not all of them taste so great either.

The real truth about weight loss, is that you do not need to worry about fat calories, and the same goes for carbs as well. What you do need to consider is the types of food combinations you eat and make sure that there is enough combination of all these different types of groups when you eat; Yes that includes fat. You need

a proper portion of fat calories, sugar, and carbohydrates, and if you know how and when to eat properly you will definitely start losing weight.

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Types of Fats

Saturated fat contributes the most to elevating blood cholesterol levels, especially LDL (the bad cholesterol). Typically saturated fat is found in animal fats and tropical oils. They tend to be more solid at room temperature.

Unsaturated fats (poly and mono) have less of an effect on elevating blood cholesterol levels. This, however, does not mean you can guzzle down the olive oil. Fat is still fat and you want a low total fat intake as well. Unsaturated fats are typically from plant sources and tend to be liquid at room temperature. Mono-unsaturated fats may help increase HDL (the good cholesterol).

Trans-fatty acids occur during the chemical process called hydrogenation. This is where a mostly unsaturated fat is "hydrogenated" to make it more saturated and thus more solid at room temperature. Margarine and shortening are examples. Trans-fats tend to have more of an effect on elevating blood cholesterol levels, especially LDL, compared to unsaturated fats, but they have less of an effect compared to saturated fat.

Bottom line: eat an overall low fat diet. When you do use fats try to use unsaturated fats, followed by transfats and lastly saturated fats.

Recommendation for heart healthy eating is to get 25-35% of your total Calories from fat: 7-10 % from saturated and trans-fats, 10 % from poly-unsaturated fats and 10-20% from mono-unsaturated fats.

Guide to Fat in Foods

Polyunsaturated	*Monounsaturated*	*Saturated*
Safflower Oil	Olive Oil	Coconut oil
Sunflower Oil	Olives	Coconut
Sunflower Seeds	Canola Oil	Palm Oil
Soybean Oil	Canola Seeds	Palm Kernel Oil
Soybeans	Avocado Oil	Cocoa Butter
Tofu	Avocados	Butter
Margarine	Peanut Oil	Cheese
Mayonnaise	Peanuts	Low-fat cheese
Low-fat mayonnaise	Peanut Butter	Chocolate
Salad dressings	Salad dressings	Lard
Pecans	Cashew nuts	Beef
Hazelnuts		Chicken
Fish		Turkey
Cottonseed Oil		Hydrogenated Fat

Corn Oil

Vegetable Shortening
Whole, 2 & 1% milkCream

Non-dairy substitutesBacon

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2.6 Dietary Polyunsaturated Fatty Acids (PUFA)

Dietary polyunsaturated fatty acids (PUFA) have effects on diverse physiological processes impacting normal health and chronic disease, such as the regulation of plasma lipid levels, cardiovascular and immune function, insulin action, and neuronal development and visual function.

Ingestion of PUFA will lead to their distribution to virtually every cell in the body with effects on membrane composition and function, eicosanoid synthesis, and signaling as well as the regulation of gene expression.

Cell specific lipid metabolism, as well as the expression of fatty acid-regulated transcription factors likely play an important role in determining how cells respond to changes in PUFA composition.

This review will focus on recent advances on the essentiality of these substances and on their interplay with cell physiology leading to new perspective in different therapeutically fields.

Chemistry

Chemically, PUFA belong to the class of simple lipids, as are fatty acids with two or more double bonds in cis position. The location of the first double bond, counted from the methyl end of the fatty acid, is designated by the omega- or n-number. In example: linoleic acid, in the n-6 family, is designated as C18:2 n-6 to indicate that it has 18 carbons and 2 double bonds, with the first double bond at the sixth carbon.

There are two main families of PUFA: n-3 and n-6. These fatty acids family are not convertible and have very different biochemical roles.

Linoleic acid (n-6) (LA) and alfa-linolenic acid (n-3) (LNA) are two of the main representative compounds, known as dietary Essential Fatty Acids (EFA) because they prevent deficiency symptoms and cannot be synthesized by humans.

Sources of PUFA

The predominant sources of n-3 fatty acids are vegetable oils and fish.

Vegetables oils are the major sources of LNA. In particular, LNA is found in the chloroplast of green leafy vegetables, such as purslane and spinach, and in seeds of flax, linseed, walnuts, etc. Purslane (Portulaca olearacea), a vegetable used in soups and salads along the Mediterranean basin and in Middle East, is the richest source of LNA of any green leafy vegetable examined to date.

Moreover, it is one of the few plants known to be a source of eicosapentaenoic acid (C20:5 n-3, EPA, also known as Timnodonic acid) (1). Canola oil (*Brassica napus)* is recognized by nutrition experts as having the best fatty acid ratio, having the lowest level of saturated fat (7%), relatively high monosturated fat (60% oleic acid) and a appreciable level of PUFA (22% LN and 11% LNA) *(Fig. 4)*.

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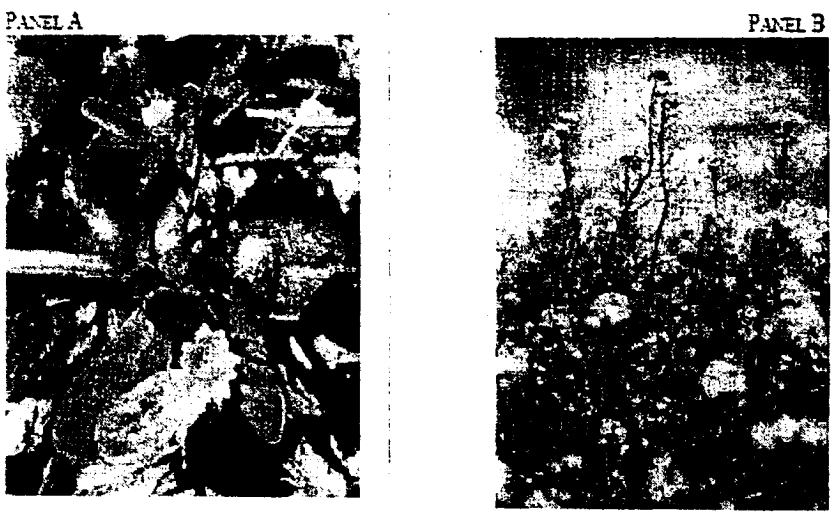

Fig. 4. Panel A: Purslane Flower (Portulaca Olearacea). Panel A: Purslane Flower (Portulaca Olearacea). Panel B: Canola Flower (Brassica Napus)

Other sources include nuts and seeds, vegetables and some fruits, and egg yolk, poultry, and meat, all of which collectively contribute minor quantities of n-3 fatty acids to the diet. Fish is the main source of EPA and of docosahexaenoic acid (C22:6 n-3, DHA, also known as Cervonic acid).

Vegetables are the main sources of n-6 fatty acids. The most important n-6 fatty acid, LA, is found in large amounts in western diets in corn oil, safflower oil, sunflower oil, and soybean oil. It is very plentiful in nature and found in practically all plant seeds with the exception of palm, and cocoa.

Evolutionary Aspects of Diet

Studies of hunter-gatherer societies indicates that man evolved on a diet that was low in saturated fat and the amounts of n-3 and n-6 fatty acids was quite equal.

Over the past 10000 years with the development of agriculture, changes began to take place in the food supply, especially during the last 100-150 years, that lead to increases in saturated fat from grain-fed cattle; increases in trans-fatty acids from the hydrogenation of vegetable oils; and enormous increase in n-6 fatty acids (about 30 g/day) due to the production of oils from vegetable seeds such as corn, safflower, and cotton.

Increases in meat consumption have lead to increased amounts of arachidonic acid (C20:4 n-6, AA), about 0.2-1.0 mg/day, whereas the amount of LNA is only 2.92 g/day and amounts of EPA, DHA are 48 and 72 mg/day, respectively. Thus a relative and absolute decrease in the amount of n-3 fatty acids has lead to an imbalance and increase in the ratio of n-6/n-3.

Intake of n-3 fatty acids is much lower today because of the decrease of fish consumption and the industrial production of animal feeds rich in grains containing n-6 fatty acids, leading to production of meat reach in n-6 and poor in n-3 fatty acids. The same is true for cultured fish and eggs. Even cultivated vegetables contain fewer n-3 fatty acids than do plants in the wild. In today's diet

this ratio is 20-30/1, whereas at the time when the human genetic code was established in response to diet, it was 1-4/1.

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Potency of Different Types of PUFA

Different types of PUFA are present on the market, with different content of n-3 PUFA and different bioavailability (Tab. 1).

Table 1. Concentration and Bioavailability of Different Types of PUFA

Type of oil	*% concentration of n-3 PUFA*	*% bioavailability*
Fish oil	25-30%	74-100 %
n-3 PUFA ethyl esters	up to 85%	21-57%
Free fatty acids	up to 65%	51%
Re-esterified triglycerides	min 70-75%	98%

An in vivo study on 24 healthy subjects comparing a single oral administration of n-3 PUFA ethyl esters versus re-esterified triglycerides of n-3 PUFA, demonstrated higher plasma levels of EPA, DHA and total n-3 PUFA in the group of subjects treated with extra-refined n-3 PUFA (data on file).

For these reasons, attention must be paid on the composition and chemical purity of available n-3 PUFA.

Metabolism of PUFA

Plants can insert additional double bonds into oleic acid, a monounsaturated fatty acid that has one double bond and form LA (with two double bonds) and LNA with three double bonds.

Vertebrate animals cannot insert double bonds more proximal to the methyl end than the seventh carbon atom. Furthermore, all metabolic conversion occurs without altering the methyl end of the molecule that contains the n-3 and n-6 double bonds. Therefore, once ingested, n-3 and n-6 fatty acids are not interconvertible.

Diet primarily contains EFA in the form of LA and LNA synthesized by plant. Within the human organism these 18-carbon precursor can be elongated and desaturated to more highly unsaturated members of their family, principally AA and DHA. The liver is the primary site for EFA metabolism, although it does take place in other tissue as well.

The first part of this pathway to AA and docosapentaenoic acid (C22:5 n-3, DPA) respectively, takes place in the endoplasmic reticulum and consists of sequential alternating elongation and desaturation steps catalyzed by fatty acid elongase, D6- and D5-desaturase. The D6-desaturase seems to be the rate-limiting step of the pathway. The mechanism of the final conversion to 22:5 n-6 and DHA is still not agreed upon by all lipid biochemist. Traditionally it has been thought to occur via a D4-desaturase, but no proof of the existence of this enzyme has ever been found. Currently most lipid biochemists are convinced that the last part occurs primarily via chain elongation and desaturation followed by a retro-conversion step of peroxisomal beta-oxidation, the so-called "Sprecher pathway".

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Biological and Functional Effects of PUFA

Essentiality

Both LNA and LA are now regarded as nutritionally EFA. However, all the classic symptoms of essential fatty acids deficiency (dermatitis, growth retardation, and infertility) can be completed cured by the n-6 fatty acids alone.

These symptoms relate to the biological function of n-6 fatty acids:

- LA is a structural component in the ceramides of the water barrier of the skin;
- AA is a precursor of eicosanoids, which are local hormones that participate in a number of physiological as well as pathophysiological conditions (*e.g.* parturition initiation, platelet aggregation, renal electrolyte regulation, blastocyte implantation, and activation of immune cells);
- n-6 fatty acids possibly also play a role as second messengers in the process of signal transduction across cell membranes;
- LA deficiency may develop as a secondary condition in other disorders, such as protein energy malnutrition and fat malabsorption, as a consequence of total parenteral nutrition with inadequate LA intakes.

The understanding of the essentiality of the n-3 fatty acids lags behind. The n-3 fatty acids can in part substitute for the n-6 fatty acids, maybe as a sparring effect, in ameliorating some of the EFAs deficiency symptoms (*e.g.* growth retardation), but are now considered also to have their own distinct role.

The biological functions of dietary n-3 fatty acids in the organism are:

- to provide energy and carbon atoms;
- EPA and DHA serve as a precursor for "n-3 eicosanoids" (see below). The "n-3 eicosanoids" in general, have a much lower potency than those derived from n-6 fatty acids and are only formed in considerable amounts in tissues at fairly high dietary intakes of EPA and DHA. For this reason the effects of n-3 fatty acids on the synthesis, bioactivity, and metabolic clearance of eicosanoid products accounts, at least in part, for their anti-inflammatory properties;
- Increasing evidence point to a specific role of DHA in membrane function, especially in retina and in neuronal tissues. Deficiencies of n-3 PUFA lead to a loss of DHA from brain and retina rod outer segment phospholipids with a compensatory replacement by 22:5 n-6. This minor change in membrane phospholipid structure is sufficient to lead to memory loss, learning disabilities, and impaired visual acuity.

Factors Affecting PUFA Status

Adequate supplies of EFAs are required throughout development and adult life in order to maintain normal functions (*e.g.* brain retinal function, reactivity of immune and inflammatory system, cardiovascular performance). As noted above, the truly essential fatty acids are LN and LNA, but it is clear that their long-chain PUFA derivatives (AA, EPA and DHA) are most important too. Unfortunately, various factors can interfere with the conversion of the parent EFAs to long-chain PUFA acting at the level of desaturases:

- **Training**

Regular exercise training per se influences the phospholipid fatty acid composition of muscle membranes. The effect exerted by regular exercise training on the muscle membrane phospholipid fatty acid composition in humans was examined by Helge. Subjects performed endurance training of the knee extensors of one leg for 4 wk. The other leg served as a control. Before, after 4 days, and after 4 wk, muscle biopsies were obtained from the vastus lateralis. After 4 wk, the phospholipid fatty acid contents of oleic acid 18:1(n-9) and DHA were significantly higher in the trained than in the untrained leg. The ratio between n—6 and n-3 fatty acids was significantly lower in the trained than in the untrained leg. Alterations in the activity of desaturase and elongase enzymes (estimated as product-to-precursor ratios of fatty acids in skeletal muscle phospholipids) could probably also influence fatty acid profile in skeletal muscle but it is not still exhaustively demonstrated. In this model, diet plays a minimal role, as the influence of dietary intake is similar on both legs.

- **Insulin Resistance**

Several data evidenced that insulin resistance is related to muscle phospholipid fatty acid composition. Insulin resistance is characterized by specific changes of the composition of fatty acids in the serum lipids and in the skeletal muscle membranes. Impaired insulin sensitivity is associated with high proportions of palmitic acid (16:0) and low levels of LA in serum. In addition, there are apparent changes of the fatty acid desaturase activities, suggesting an increased activity of the D-9 and D-6 desaturases and a decreased activity of the D-5 desaturase.

Experimental studies have indicated that insulin activates the D-9 and D-6 desaturases. In experimental diabetes and in spontaneously diabetic rats, there are reduced activities of D-9, D-6, and D-5 liver microsomal desaturases, which are restored after insulin treatment.

Insulin-deficient patients with type 1 diabetes have high levels of LA and low levels of the metabolites including AA in their serum lipids, with an increase of AA and a normalization of the PUFA after insulin treatment.

A high ratio between AA and DGLA, as a measure of D-5 desaturase activity, in the skeletal muscle phospholipids has been related to good insulin sensitivity.

Moreover, there is evidence that an increased unsaturation and a decreased ratio of n-6 to n-3 fatty acids in the muscle membrane are compatible with an increased membrane fluidity, findings that have been linked to the presence of an increased number of insulin receptors and an increased insulin binding.

Overall evaluation of the relationships between fatty acid composition of skeletal muscle phospholipids and muscle fiber type, and insulin sensitivity showed that:

- lower proportions of PUFA and higher proportions of saturated fatty acids, particularly palmitic acid (16:0), in skeletal muscle phospholipids are associated with insulin resistance in both animals and humans;

- insulin resistance is associated with lower proportions of oxidative slow-twitch type I fibers and higher proportions of glycolytic fast-twitch type IIb fibers;

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- a greater proportion of n-3 PUFA and a smaller proportion of palmitic acid (16:0) have been observed in membrane phospholipids of type I fibers compared with type IIb fibers;

- skeletal muscle characteristics are also influenced by environmental factors such as diet and physical activity;

- long-term endurance training has been shown to modify the muscle fiber distribution, with a shift away from the insulin-resistant type IIb fibers.

Relationships between fatty acid composition of skeletal muscle membrane and muscle fiber type, and insulin sensitivity in endurance trained and untrained young man, demonstrated that the proportion of type I fibers, as well as the insulin sensitivity was all higher in the trained group compared with the untrained group. The fatty acids founded in lower proportions (16:0 and 20:3n-6) in the trained group than in the untrained group were in general inversely correlated with the proportion of type I fibers and insulin sensitivity, whereas the fatty acids and ratios of fatty acids that it was found in higher proportions [18:0, 22:6(n-3), sum n-3, 20:4(n-6) to 20:3(n- 6), 18:0 to 16:0] in the trained than in the untrained group in general were positively correlated with those variables.

- **Vitamins Deficiency**

Vitamin B6 deficiency might be a crucial factor for D-6 desaturases activity, especially in aged people. In particular, using 20 month old rats fed a diet with a subnormal level of vitamin B6, a diminished D-6 desaturases activity for LA and also for LNA in vitamin B6-deficient animals, being approximately 63% and 81% respectively of the corresponding activity in control rats was observed. As a consequence, significant modifications in the relative molar content of microsomal fatty acids were observed. The content of AA and DHA decreased, LA content increased and a decrease in the unsaturation index was observed in liver microsomes of B6- deficient rats. This may be particularly important in aging, where D-6 desaturases activity is already impaired.

Vitamin E addition in brain microsomal membrane suspension induced an increase by more than two-fold in D-6 desaturases activity measured at substrate saturation using LA. In contrast, this activity was reduced by 25% in the liver. This raises the question of the multiple role of vitamin E in membranes, the control of membrane PUFA through synthesis, and their protection against peroxidation.

- **Excessive Alcohol Consumption**

PUFA play a major role in membrane structures that are modified during alcoholism as alcohol inhibits phospholipase activity. PUFA are also precursors of second *messengerseicosanoids*, involved in the regulation of blood pressure. Therefore excessive alcohol consumption has been related to hypertension and to alterations in liver PUFA metabolism. For these reasons the effects of ethanol on PUFA biogenesis in hepatocytes of Wistar Kyoto (WKY) rats and Spontaneously Hypertensive Rats (SHR), and the effects of a diet enriched with n-3 PUFA which is known to modulate hypertension, was investigated. Results showed that ethanol strongly inhibits the synthesis of PUFA in hepatocytes from SHR, which can explain the deficit of prostaglandin precursors observed in cardiovascular diseases

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linked to ethanol intoxication. n-3 PUFA supplemented diet reinforces the inhibition of AA synthesis, likely by a substrate competition toward D-5 desaturation.

In chronic alcoholics it was demonstrated that peripheral blood mononuclear cells produced less PGE2, and neutrophils produced less LTB4 than controls. Reduced PGE2 production by PBMC of alcoholics was corrected by the addition of exogenous AA.

PUFA in Chronic Diseases

Cardiovascular Diseases

Antiarrhythmic Effects

Epidemiological and interventional studies indicate that dietary n-3 PUFA reduces mortality due to coronary heart disease (CHD).

They act at a low dose, since one or two meals with fatty fish per week is sufficient to provide protection when compared with no fish intake.

Numerous experimental studies have indicated that low concentrations of exogenous n-3 PUFA reduce the severity of cardiac arrhythmia. This effect is probably responsible for the protective action of n-3 PUFA on CHD mortality. Such studies should take account of the fact that only a low dose of n-3 PUFA (20 mg/kg/day) is necessary to afford protection. Inhibition of myocardial thromboxane synthesis may play a role in this effect, as well as reduced cardiac responsiveness to a1-adrenergic stimulation.

Christensen et al indicate an antiarrhythmic effect of n-3 PUFA due to a favourable shift in vagal/sympathetic balance. This evidence is indirect but concordant with a large body of experimental and clinical evidence that a shift in vagal/sympathetic balance in favour of vagal modulation of the heart decreases susceptibility to cardiac arrhythmia and sudden death. In addition, several cardiovascular drugs that increase survival also increase vagal modulation of the heart.

The details of the antiarrhythmic action for n-3 PUFA remain to be elucidated (relative importance of cardiac ion channel, brain, or autonomic effects; but the overall body of evidence from epidemiological studies and clinical trials suggest that n-3 PUFA have an important antiarrhythmic effect in patients with CHD. Unfortunately, coronary heart disease is often announced by sudden cardiac death.

Moreover, it has been demonstrated that base-line blood levels of long-chain n-3 fatty acids were inversely related to the risk of sudden death. The epidemiological data suggest that the benefit of dietary fish is centered on a reduction in sudden cardiac death.

A case-control study in Seattle compared 334 victims of out-of-hospital primary cardiac arrest with 493 population-based controls. Compared with no dietary intake of EPA, > 5.5 g of n-3 PUFA per month was associated with a 50% decrease in the risk of primary cardiac arrest. This study found a strong inverse association between red-cell n-3 fatty-acid composition at the time of the arrest and the risk of primary cardiac arrest among subjects with no history of clinically recognized cardiac disease.

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The U.S. Physician's Health Study studied the effect of dietary fish on sudden cardiac death in 20551 U.S. male physicians who were free of cardiovascular disease at baseline and then followed for up to 11 years. During follow-up, 133 sudden deaths (death within 1 hour) occurred. A dietary intake of > 1 fishmeal per week was associated with a 52% reduction in sudden death. Eating fish more often than once a week did not confer additional benefit. Eating fish at least once a week was also associated with a 30% reduction in total mortality but not with a decrease in total myocardial infarction or non-sudden death.

The Lyon Diet Heart Study and the Indian Heart Study have both shown in clinical trials that diet can prevent fatal and nonfatal cardiovascular events in individuals with CHD. In both trials, saturated fats were replaced with monounsaturated fats and LNA present in canola oil. Vegetables and fruits were increased in the diets in these studies as well.

In addition, fish and fish oil have been shown to reduce all-cause mortality and cardiovascular death in patients who had myocardial infarction.

A recent randomized clinical trial, the GISSI-Prevenzione Trial, was reported. The trial included 11324 persons from the 172 participating Italian centers, randomized <3 months after myocardial infarction, to receive an approx. 900 mg capsule of n-3 PUFA (EPA:DHA of 1:2) or a 300 mg capsule of synthetic atocopherol (vitamin E), or placebo. Follow up averaged 3.5 years. There was a 20% decrease in all deaths, a 30% decrease in cardiovascular deaths, and a 45% decrease in sudden cardiac deaths. No significant benefit was found for vitamin E and/or placebo treatment. The investigators concluded that n-3 PUFA supplementation significantly reduced death, particularly sudden death, but not reinfarction or stroke. An antiarrhythmic action of n-3 PUFA was supported by these findings.

Given the safety and low cost of implementing a recommendation for a modest amount of fish in the diet, adequate dietary fish intake has a significant role to play in the primary and secondary prevention of out-of-hospital sudden cardiac death.

At high doses, dietary n-3 PUFA have several beneficial properties:

- act favourably on blood characteristics by reducing platelet aggregation and blood viscosity;
- are hypotriglyceridemic;
- exhibit anti thrombotic and fibrinolytic activities;
- exhibit anti inflammatory action;
- reduce ischemia/reperfusion-induced cellular damage. This effect is apparently due to the incorporation of eicosapentaenoic acid in membrane phospholipids.

Hypolipidemic Effects

The hypolipidemic effects of n-3 fatty acids are similar to those of n-6 fatty acids, provided that they replace saturated fats in the diet. n-3 PUFA have the added benefit of consistently lowering serum triacylglycerol concentrations, whereas the n-6 fatty acids do not and may even increase them.

Another important consideration is the finding that during chronic fish oil feeding postprandial triacylglycerol concentrations decrease. Furthermore, Nestel reported that consumption of high amounts of fish oil blunted the expected rise in plasma cholesterol concentrations in humans, due to the replacement of saturated fatty acids with PUFA. Studies in humans have shown that fish oils reduce the rate of hepatic secretion of very low-density lipoprotein and triacylglycerol and in normolipidemic subjects, n-3 fatty acids prevent and rapidly reverse carbohydrate-induced hypertriglyceridemia.

Antithrombotic Effects

The antithrombotic effects of fish oil are due to decreases in platelet aggregation, a decrease in TXA, increase in PGI2 and PGI3 production, decrease in whole blood viscosity and an increase in bleeding time.

Because of the increased amount of n-6 fatty acids in the Western diet, the eicosanoid metabolic products from AA, specifically prostaglandins, thromboxanes, leukotrienes, are formed in larger quantity than those formed from n-3 fatty acids, specifically EPA.

The eicosanoids formed from AA are biologically active in small quantities and if they are formed in large amounts, they contribute to the formation of thrombi and atheromas; the development of allergic and inflammatory disorders; and cell proliferation. Thus a diet rich in n-6 fatty acids shifts the physiologic state to one that is prothrombotic and proaggregatory, with increases in blood viscosity, vasospasm and vasoconstriction and decreases in bleeding time.

Bleeding time is shorter in groups of patients with hypercholesterolemia, hyperlipoproteinemia, myocardial infarction, other forms of atherosclerotic disease, type 2 diabetes, obesity, and hypertriglyceridemia. Atherosclerosis is a major complication in type 2 diabetes patients. Bleeding time is longer in women than in men and in younger than in older persons.

A recent randomized controlled trial showed the n-3 PUFA therapeutic effects on 188 stroke patients awaiting carotid endarterectomy. The patients, divided into three experimental groups were treated, over an average period of 42 days, respectively with fish-oil, sunflower-oil or a placebo, six times a day. Fish oil patients received 1.4 g of n-3 PUFA daily. Results demonstrated that n-3 PUFA helped to make scars harmless and stabilizes the health in stroke patients who are at high risk of the atherosclerotic plaques rupturing or forming clots. It was demonstrated that the proportions of EPA and DHA were higher in carotid plaque fractions in patients receiving fish oil compared with other groups. Fewer plaques from patients being treated with fish oil had thin fibrous caps and signs of inflammation and more plaques had thick fibrous caps and no signs of inflammation, compared with plaques in other groups.

The number of macrophages in plaques from patients receiving fish oil was lower than in the other two groups. This finding suggests that within a short time, a modest level of dietary n-3 PUFA supplementation has a role in establishment of plaque stability, thus reducing the risk of neurological events in patients with advanced carotid atherosclerosis.

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Prevention of Restenosis

Restenosis is a condition caused mainly by platelet aggregation, proliferation of smooth muscle cells, and coronary vasospasm.

The effect of n-3 supplementation on the incidence of restenosis after coronary angioplasty has been addressed in several clinical studies. Results suggest that patients undergoing coronary bypass surgery should be encouraged to consume high amounts of n-3 fatty acids.

Moreover, it appears that the longest the length of time that n-3 fatty acids were taken prior to surgery, the best the results obtained so far.

Hypotensive Effects

Evidence from laboratory investigations, observational studies, and clinical trials indicates that supplementation of diet with high doses of n-3 PUFA can reduce blood pressure. However, large quantities (*e.g.*, 3 g per day) are needed to see a minimal effect in nonhypertensive individuals and only very modest effects in hypertensive individuals. The most effective n-3 PUFA is DHA rather than EPA. It takes large amount of EFA to have hypotensive effect; eating more fish or flaxseed is unlikely to be beneficial, so the only way to get clinically significant doses is to take EFA in supplement form.

Diabetes

Type 2 diabetes is a multigenic, multifactorial disorder, characterized by hyperglycemia in the presence of insulin resistance, hypertriglyceridemia, and the development of vascular complications. Men and women with type 2 diabetes have 3-fold and 5-fold higher cardiovascular mortality, respectively, than the non-diabetic population, and this higher risk is also carried by nondiabetic first-degree relatives of type 2 diabetes subjects.

In 1993, *Borkman et al* showed that hyperinsulinemia and insulin resistance are inversely associated with the amount of 20- and 22-carbon fatty acids in muscle cell membrane phospholipids in patients with coronary heart disease and in normal volunteers. Such decreases in 20- and 22-carbon fatty acid concentrations could occur as a result of:

- low dietary intake of 20- and 22-carbon fatty acids;
- high dietary intake of trans fatty acids, which interfere with the desaturation and elongation of LA and LNA and thus lower AA, EPA, and DHA concentrations;
- genetic defects of D5 and D6 desaturase;
- genetic defects that interfere with the transport or binding of 20- and 22-carbon fatty acids, such as in intestinal fatty acid–binding protein;
- high dietary intake of LA, which leads to decreased production of AA and interferes with the desaturation and elongation of LNA to EPA and DHA;
- increased catabolism of AA, which reduces the number of available 20- and 22-carbon atoms;
- an increase in 20- and 22-carbon PUFA, (*i.e.*, AA, EPA, and DHA), leads to increases in membrane fluidity, the number of insulin receptors, and insulin action.

Moreover, maternal fasting insulin levels and triglyceride levels are significant predictors of the PUFA composition of the child's muscle membrane. The less unsaturated muscle membranes in children whose mothers have higher fasting insulin and triglyceride levels may reflect a genetic reluctance to incorporate PUFA into membranes, thus predisposing them to insulin resistance syndrome.

About 23 studies have been conducted on the effects of n-3 fatty acids in patients with type 2 diabetes. In most studies, fish oil consumption lowered serum triacylglycerol concentrations significantly, but in some studies, plasma glucose concentrations rose. In many of these studies, however, the number of subjects was small and the dose of n-3 fatty acids was >3g/d and controls were lacking.

The largest and longest reported placebo-controlled trial of the effect of n-3 fatty acids (6 g n-3 fatty acids (EPA and DHA)/d for 6 mo) on type 2 diabetes, showed convincingly that n-3 fatty acid intake, along with oral therapy for diabetes, can lower triacylglycerol concentrations with no adverse effects on glycemic control.

It is also known that the concentration of serum leptin (a hormone expressed and secreted in proportion to adipose mass) in patients with type 1 diabetes mellitus is influenced by the type of fat in the diet. In particular it has been found that n-3 fatty acids decreased leptin gene expression both in vivo and in vitro. The direct effects of PUFA on leptin promoter activity indicate a specific regulatory action of fatty acids on leptin expression.

Arthritis

Supplementation with n-3 fatty acids can modulate the expression and activity of degradative and inflammatory factors that cause cartilage destruction during arthritis.

Incorporation of n-3 fatty acids into articular cartilage chondrocyte membranes results in a dose-dependent reduction in:

- expression and activity of proteoglycan degrading enzymes (aggrecanases);
- expression of inflammation-inducible cytokines (IL-1alpha and TNF-alpha) and COX-2, but not the constitutively expressed COX-1.

These findings provide evidence that n-3 fatty acid supplementation can specifically affect regulatory mechanisms involved in chondrocyte gene transcription and thus further advocate a beneficial role for dietary fish oil supplementation in alleviation of several of the physiological parameters that cause and propagate arthritic disease.

Cancer

PUFA Effects on Cell Proliferation and Signal Transduction

Fat may regulate cellular functions by affecting the expression or activity of genes in the signal transduction pathway related to the control of cell growth and apoptosis.

High intake of n-6 PUFA induces various physiological and metabolic effects: increased ornithine decarboxylase activity in colon mucosa, resulting in enhanced epithelial polyamine levels and increased colon crypt cell proliferation;

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- enhanced activities of protein kinases (*i.e.*, protein kinase C) in rodent mammary gland and an increased number of oestrogen receptor binding sites;
- increased prostaglandin concentrations. Prostaglandins, thromboxanes, leukotrienes and hydroxy and hydroxyperoxy fatty acids are involved in tumor initiation and promotion, cell proliferation, tissue invasion and metastatic spread. Tumor cells produce larger amounts of eicosanoids than their normal cell counterparts and eicosanoids ultimately derived from linoleic acid have been linked to increased growth and metastasis. The finding that oleic acid and omega-3 PUFA, specifically EPA, block the desaturase reaction, the first step from linoleic acid to eicosanoids, may partially explain their inhibitory effects on tumorigenesis.

Omega-6 fatty acid

n-6 fatty acids (popularly referred to as omega-6 fatty acids or omega-6 fatty acids) are a family of unsaturated fatty acids which have in common a final carbon–carbon double bond in the n-6 position; that is, the sixth bond from the end of the fatty acid.

The biological effects of the n-6 fatty acids are largely mediated by their conversion to n-6 eicosanoids that bind to diverse receptors found in every tissue of the body. The conversion of tissue arachidonic acid (20:4n-6) to n-6 prostaglandin and n-6 leukotriene hormones provides many targets for pharmaceutical drug development and treatment to diminish excessive n-6 actions in atherosclerosis, asthma, arthritis, vascular disease, thrombosis, immune-inflammatory processes and tumor proliferation. Competitive interactions with the n-3 fatty acids affect the relative storage, mobilization, conversion and action of the n-3 and n-6 eicosanoid precursors.

Key n-6 fatty acids

Linoleic acid (18:2, n-6), the shortest-chained n-6 fatty acid, is an essential fatty acid. Arachidonic acid (20:4) is a physiologically significant n-6 fatty acid and is the precursor for prostaglandins and other physiologically active molecules.

Negative health effects

Some medical research suggests that excessive levels of n-6 fatty acids, relative to n-3 fatty acids, may increase the probability of a number of diseases and depression.

Modern Western diets typically have ratios of n-6 to n-3 in excess of 10 to 1, some as high as 30 to 1. The optimal ratio is thought to be 4 to 1 or lower.

Excess n-6 fats interfere with the health benefits of n-3 fats; in part because they compete for the same rate-limiting enzymes. A high proportion of n-6 to n−3 fat in the diet shifts the physiological state in the tissues toward the pathogenesis of many diseases: prothrombotic, proinflammatory and proconstrictive.

Chronic excessive production of n-6 eicosanoids is associated with heart attacks, thrombotic stroke, arrhythmia, arthritis, osteoporosis, inflammation,

mood disorders and cancer. Many of the medications used to treat and manage these conditions work by blocking the effects of the potent n-6 fat, arachidonic acid. Many steps in formation and action of n-6 hormones from n-6 arachidonic acid proceed more vigorously than the corresponding competitive steps in formation and action of n-3 hormones from n-3 eicosapentaenoic acid.

The COX-1 and COX-2 inhibitor medications, used to treat inflammation and pain, work by preventing the COX enzymes from turning arachidonic acid into inflammatory compounds. The LOX inhibitor medications often used to treat asthma, work by preventing the LOX enzyme from converting arachidonic acid into the leukotrienes. Many of the anti-mania medications used to treat bipolar disorder work by targeting the arachidonic acid cascade in the brain.

A high consumption of omega-6 polyunsaturated fatty acids (PUFAs), which are found in most types of vegetable oil, may increase the likelihood that postmenopausal women will develop breast cancer. Similar effect was observed on prostate cancer. Other analysis suggested an inverse association between total polyunsaturated fatty acids and breast cancer risk, but individual polyunsaturated fatty acids behaved differently from each other, a 20:2 derivative of linoleic acid was inversely associated with the risk of breast cancer.

Omega-3 Fatty Acid

n-3 fatty acids (popularly referred to as omega-3 fatty acids or omega-3 fatty acids) are a family of unsaturated fatty acids that have in common a final carbon–carbon double bond in the n-3 position; that is, the third bond from the methyl end of the fatty acid.

Important nutritionally-essential n-3 fatty acids are: α-linolenic acid (ALA), eicosapentaenoic acid (EPA), and docosahexaenoic acid (DHA), all of which are polyunsaturated. The human body cannot synthesize n-3 fatty acids de novo, but it can form 20- and 22-carbon unsaturated n-3 fatty acids from the eighteen-carbon n-3 fatty acid, α-linolenic acid. These conversions occur competitively with n-6 fatty acids, which are essential closely related chemical analogues that are derived from linoleic acid. Both the n-3 α-linolenic acid and n-6 linoleic acid are essential nutrients which must be obtained from food. Synthesis of the longer n-3 fatty acids from linolenic acid within the body is competitively slowed by the n-6 analogues. Thus accumulation of long-chain n-3 fatty acids in tissues is more effective when they are obtained directly from food or when competing amounts of n-6 analogs do not greatly exceed the amounts of n-3.

History

Although omega-3 fatty acids have been known as essential to normal growth and health since the 1930's, awareness of their health benefits has dramatically increased in the past few years.

The heart health benefits of the long chain omega-3 fatty acids: DHA and EPA omega-3 are the best known. These benefits were discovered in the 1970's by researchers studying the Greenland Eskimos. The Greenland Eskimos consumed large amounts of fat from seafood, but displayed virtually no cardiovascular disease. The high level of omega-3 fatty acids consumed by the Eskimos reduced triglycerides, heart rate, blood pressure and atherosclerosis.

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. On September 8, 2004, the U.S. Food and Drug Administration gave "qualified health claim" status to Eicosapentaenoic Acid (EPA) and docosahexaenoic acid (DHA) n-3 fatty acids, stating that "supportive but not conclusive research shows that consumption of EPA and DHA [n-3] fatty acids may reduce the risk of coronary heart disease." This updated and modified their health risk advice letter of 2001. Currently regulatory agencies do not accept that there is sufficient evidence for any of the other suggested benefits of DHA and EPA other than for cardiovascular health, and further claims should be treated with caution.

As the importance of omega-3 fatty acids to health has received increasing awareness, the number of food products enriched in omega-3 fatty acids has increased. Many companies add fish oil or flax oil into their final product to enrich it in omega-3 fatty acids. Some animal products, such as milk and eggs, can be naturally enriched for omega-3 fatty acids by feeding the animals a diet that is rich in omega-3 fatty acids.

Biological Significances

The biological effects of the n-3 are largely mediated by their interactions with the n-6 fatty acids; see Essential fatty acid interactions for detail.

A 1992 article by biochemist William E.M. Lands provides an overview of the research into n-3 fatty acids, and is the basis of this section.

The 'essential' fatty acids were given their name when researchers found that they were essential to normal growth in young children and animals. (Note that the modern definition of 'essential' is more strict.) A small amount of n-3 in the diet (~1% of total calories) enabled normal growth, and increasing the amount had little to no additional effect on growth.

Likewise, researchers found that n-6 fatty acids (such as alpha-linolenic acid and arachidonic acid) play a similar role in normal growth. However, they also found that n-6 was "better" at supporting dermal integrity, renal function, and parturition. These preliminary findings led researchers to concentrate their studies on n-6, and it was only in recent decades that n-3 has become of interest.

In 1963 it was discovered that the n-6 arachidonic acid was converted by the body into pro-inflammatory agents called prostaglandins. By 1979 more of what are now known as eicosanoids were discovered: thromboxanes, prostacyclins and the leukotrienes. The eicosanoids, which have important biological functions, typically have a short active lifetime in the body, starting with synthesis from fatty acids and ending with metabolism by enzymes. However, if the rate of synthesis exceeds the rate of metabolism, the excess eicosanoids may have deleterious effects. Researchers found that n-3 is also converted into eicosanoids, but at a much slower rate. Eicosanoids made from n-3 fats often have opposing functions to those made from n-6 fats (*i.e.*, anti-inflammatory rather than inflammatory). If both n-3 and n-6 are present, they will "compete" to be transformed, so the ratio of *n-3:n-6* directly affects the type of eicosanoids that are produced.

This competition was recognized as important when it was found that thromboxane is a factor in the clumping of platelets, which leads to thrombosis. The leukotrienes were similarly found to be important in immune/inflammatory-system response, and therefore relevant to arthritis, lupus, and asthma. These discoveries led to greater interest in finding ways to control the synthesis of n"6 eicosanoids. The simplest way would be by consuming more n"3 and fewer n"6 fatty acids.

Daily Values

As macronutrients, fats are not assigned recommended daily allowances. Macronutrients have AI (Acceptable Intake) and AMDR (Acceptable Macronutrient Distribution Range) instead of RDAs. The AI for n-3 is 1.6 grams/day for men and 1.1 grams/day for women while the AMDR is 0.6% to 1.2% of total energy.

"A growing body of literature suggests that higher intakes of alpha-linolenic acid (ALA), eicosapentaenoic acid (EPA), and docosahexaenoic acid (DHA) may afford some degree of protection against coronary heart disease. Because the physiological potency of EPA and DHA is much greater than that for alpha-linolenic acid, it is not possible to estimate one AMDR for all n-3 fatty acids. Approximately 10 percent of the AMDR can be consumed as EPA and/or DHA." There was insufficient evidence as of 2005 to set a UL (upper tolerable limit) for n-3 fatty acids.

A perceived risk of fish oil n-3 supplementation has been heavy metal poisoning by the body's accumulation of traces of heavy metals, in particular mercury, lead, nickel, arsenic and cadmium as well as other contaminants (PCBs, furans, dioxins), which potentially might be found especially in less-refined fish oil supplements. However, in reality, heavy metal toxicity from consuming fish oil supplements is highly unlikely. This is because heavy metals selectively bind with protein in the fish flesh rather than accumulate in the oil. An independent test in 2006 of 44 fish oils on the U.S. market found that all of the products passed safety standards for potential contaminants. The FDA recommends that total dietary intake of n-3 fatty acids from fish not exceed 3 grams per day, of which no more than 2 grams per day are from nutritional supplements.

Historically, the Council for Responsible Nutrition (CRN) and the World Health Organization (WHO) have published acceptable standards regarding contaminants in fish oil. The most stringent current standard is the International Fish Oils Standard (IFOS). Fish oils that typically make this highest grade are those that are molecularly distilled under vacuum, and have virtually no measurable level of contaminants (measured parts per billion and parts per trillion).

n-3 supplementation in food has been a significant recent trend in food fortification, with global food companies launching n-3 fortified bread, mayonnaise, pizza, yogurt, orange juice, children's pasta, milk, eggs, confections and infant formula.

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Sources

Fish

The most widely available source of EPA and DHA is cold water oily fish such as salmon, herring, mackerel, anchovies and sardines. Oils from these fish have a profile of around seven times as much n-3 as n-6. Other oily fish such as tuna also contain n-3 in somewhat lesser amounts. Consumers of oily fish should be aware of the potential presence of heavy metals and fat-soluble pollutants like PCBs and dioxins which may accumulate up the food chain.

Even some forms of fish oil may not be optimally digestible. Of four studies that compare bioavailability of the triglyceride form of fish oil vs. the ester form, two have concluded that the natural triglyceride form is better, and the other two studies did not find a significant difference. No studies have shown the ester form to be superior although it is cheaper to manufacture.

Although fish is a dietary source of n-3 fatty acids, fish do not synthesize them; they obtain them from the algae in their diet.

Eggs

Eggs produced by chickens fed a diet of greens and insects produce higher levels of n-3 fatty acids (mostly ALA) than chickens fed corn or soybeans. In addition to feeding chickens insects and greens, fish oils may be added to their diet to increase the amount of fatty acid concentrations in eggs. The addition of flax and canola seeds to the diet of chickens, both good sources of alpha-linolenic acid, increases the omega-3 content of the eggs.

Meat

The n-6 to n-3 ratio of grass-fed beef is about 2:1, making it a more useful source of n-3 than grain-fed beef, which usually has a ratio of 4:1.

In most countries, commercially available lamb is typically grass-fed, and thus higher in n-3 than other grain-fed or grain-finished meat sources. In the United States, lamb is often finished (*i.e.* fattened before slaughter) with grain, resulting in lower n-3.

The omega-3 content of chicken meat may be enhanced by increasing the animals' dietary intake of grains that are high in n-3, such as flax, chia, and canola.

Other Sources

Milk and cheese from grass-fed cows may also be good sources of n-3. One UK study showed that half a pint of milk provides 10% of the recommended daily intake (RDI) of ALA, while a piece of organic cheese the size of a matchbox may provide up to 88%".

The microalgae Crypthecodinium cohnii and Schizochytrium are rich sources of DHA (22:6 n-3) and can be produced commercially in bioreactors. This is the only source of DHA acceptable to vegans. Oil from brown algae (kelp) is a source of EPA. Walnuts are one of few nuts that contain appreciable n-3 fat, with approximately a 1:4 ratio of n-3 to n-6. Acai palm fruit also contains n-3 fatty acids.

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Omega-3 is also found in softgels in pharmacies and nowadays it is also found in combination with omega-6, omega-9 and shark liver oil.

Some vegetables, too, contain a noteworthy amount of n-3, including strawberries and broccoli.

The n-6 to n-3 Ratio

Clinical studies indicate that the ingested ratio of n-6 to n-3 (especially Linoleic vs Alpha Linolenic) fatty acids is important to maintaining cardiovascular health. However, two studies published in 2005 and 2007, found no such correlations in humans. Both n-3 and n-6 fatty acids are essential, *i.e.* humans must consume them in the diet. n-3 and n-6 compete for the same metabolic enzymes, thus the *n-6:n-3* ratio will significantly influence the ratio of the ensuing eicosanoids (hormones), (*e.g.* prostaglandins, leukotrienes, thromboxanes etc.), and will alter the body's metabolic function. Generally, grass-fed animals accumulate more n-3 than do grain-fed animals which accumulate relatively more n-6. Metabolites of n-6 are significantly more inflammatory (especially arachidonic acid) than those of n-3. This necessitates that n-3 and n-6 be consumed in a balanced proportion; healthy ratios of n-6:n-3 range from 1:1 to 4:1. Studies suggest that the evolutionary human diet, rich in game animals, seafood and other sources of n-3, may have provided such a ratio.

Typical Western diets provide ratios of between 10:1 and 30:1 - *i.e.*, dramatically skewed toward n-6. Here are the ratios of n-6 to n-3 fatty acids in some common oils: canola 2:1, soybean 7:1, olive 3–13:1, sunflower (no n-3), flax 1:3, cottonseed (almost no n-3), peanut (no n-3), grapeseed oil (almost no n-3) and corn oil 46 to 1 ratio of n-6 to n-3.

Powdered Milk

Powdered milk is a manufactured dairy product made by evaporating milk to dryness. One purpose of drying milk is to preserve it; milk powder has a far longer shelf life than liquid milk and does not need to be refrigerated, due to its low moisture content. Another purpose is to reduce its bulk for economy of transportation. Available as Dry Whole Milk (DWM), it is most commonly produced as Non-Fat Dry Milk (NFDM), also known as Dried Skim Milk (DSM).

History and Manufacture

While Marco Polo wrote of Mongolian Tatar troops in the time of Kublai Kahn carrying sun dried skimmed milk as "a kind of paste", the first usable commercial process to produce dried milk was invented by T.S. Grimwade and patented in 1855, though a William Newton had patented a vacuum drying process as early as 1837. Today, powdered milk is usually made by spray drying nonfat skim milk or whole milk. Pasteurized milk is first concentrated in an evaporator to about 50% milk solids. The resulting concentrated milk is sprayed into a heated chamber where the water almost instantly evaporates, leaving fine particles of powdered milk solids.

Alternatively, the milk can be dried by drum drying. Milk is applied as a thin film to the surface of a heated drum, and the dried milk solids are then

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scraped off. Powdered milk made this way tends to have a cooked flavour, due to caramelization caused by greater heat exposure.

Another process is freeze drying, which preserves many nutrients in milk, compared to drum drying.

The drying method and the heat treatment of the milk as it is processed alters the properties of the milk powder (for example, solubility in cold water, flavour, bulk density).

Uses

Powdered milk is frequently used in the manufacture of infant formula, confectionery such as chocolate and caramel candy, and in recipes for baked goods where adding liquid milk would render the product too thin. Powdered milk is also widely used in various sweets such as the famous Indian milk balls known as gulab jamun and popular Pakistani sweet delicacy (sprinkled with desiccated coconut) known as Chum chum (made with skim milk powder).

Powdered milk is also a common item in UN food aid supplies, fallout shelters, warehouses, and wherever fresh milk is not a viable option. It is widely used in many developing countries because of reduced transport and storage costs (reduced bulk and weight, no refrigerated vehicles). As with other dry foods, it is considered nonperishable, and is favoured by survivalists, hikers, and others requiring nonperishable, easy-to-prepare food.

Reconstituting one cup of milk from powdered milk requires one cup of potable water and one-third cup of powdered milk.

Powdered milk is also used in western blots as a blocking buffer to prevent nonspecific protein interactions, and is referred to as Blotto.

Food and Health

Nutritional Value

Milk powders contain all twenty standard amino acids (the building blocks of proteins) and are high in soluble vitamins and minerals. According to USAID the typical average amounts of major nutrients in the unreconstituted milk are (by weight) 36% protein, 52% carbohydrates (predominantly lactose), calcium 1.3%, potassium 1.8%. Their milk powder is fortified with Vitamin A and D, 3000IU and 600IU respectively per 100 g. Inappropriate storage conditions (high relative humidity and high ambient temperature) can significantly degrade the nutritive value of milk powder.

Oxysterols

Commercial milk powders are reported to contain oxysterols (oxidized cholesterol) in higher amounts than in fresh milk (up to 30 μg/g, versus trace amounts in fresh milk). The oxysterol free radicals have been suspected of being initiators of atherosclerotic plaques. For comparison, powdered eggs contain even more oxysterols, up to 200 μg/g.

In the 2008 Chinese milk scandal, melamine adulterant was found in Sanlu infant formula, added to fool tests into reporting higher protein content. Thousands became ill and some children died after consuming the product.

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2.7 Cholesterol

What is Cholesterol?

Cholesterol is a soft, waxy substance found in all of your body's cells. Your body needs it in order to work properly. This is because your body uses cholesterol to hold cells together. Your body also uses it to make hormones, vitamin D, and substances that help you digest foods.

However, if too much gets into your blood, it can cause problems. This is known as high cholesterol, hypercholesterolemia, or hyperlipidemia.

Where does it Come From?

Cholesterol comes from two places. Your body actually makes most of what it needs in the liver. The rest comes from the foods you eat.

Cholesterol is only made by animals, so you can only get it by eating animal products, such as:

- Meat
- Chicken
- Fish
- Eggs
- Butter
- Cheese
- Whole milk.

These foods can provide you with more than enough cholesterol. You will not find it in anything that comes from a plant. For example, cholesterol-free foods include fruits, vegetables, or whole grains.

How does the Body Transport It?

In order to get to all of your cells, cholesterol needs to travel through the bloodstream.

But because cholesterol is a fat, it separates from the blood, similar to the way that oil separates from water. To keep this from happening, proteins form a shell around it, making a "cholesterol complex." It is then released into the bloodstream and travels to where it needs to go.

A protein that is linked to cholesterol to form this complex is called a "lipoprotein." There are two main types of lipoproteins. One is good and the other can potentially be bad (but not always).

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LDL Cholesterol

The lipoprotein that can be bad is called "LDL," which stands for low-density lipoprotein. Remember, a lipoprotein forms a shell around cholesterol. Normally, LDLs transport it from your liver and deliver it to the necessary tissues. But if you have a lot of LDLs left over after all of your tissues have been taken care of, the LDLs will "let go" of the extra cholesterol while traveling through your blood. This can cause a buildup known as plaque and can lead to a condition called atherosclerosis, or narrowing and hardening of blood vessels.

HDL Cholesterol

The good lipoprotein is called "HDL," which stands for high-density lipoprotein. HDLs are "good," because they pick up the extra cholesterol that was dropped off by the LDLs and brings it to your liver. This way, your liver can repackage it to use it later, or simply get rid of it.

This is why it is good to have high levels of HDL in your system and low levels of LDL. Think of "H" for "high" to help you remember this about HDL. And "L" stands for low, which is a way to remember that you want low levels of LDL.

Cholesterol Testing

The only way to determine your cholesterol level is to have a blood test. According to recent guidelines, a person should get a fasting test every five years; however, a person with heart disease risk factors should have this test more frequently.

Several types of tests are available. Each test can look at different components of cholesterol and fats in the blood, including:

- Total cholesterol
- Low density lipoprotein (LDL) — the "bad" cholesterol
- High density lipoprotein (HDL) — the "good" cholesterol
- Triglycerides.

Some tests, like a lipid profile done at the doctor's office, will look at all four components. Other tests, like most home tests, only look at total cholesterol. Some tests also provide a ratio or VLDL (very low density lipoprotein) as part of their results.

The Numbers at a Glance

The following table outlines healthy cholesterol levels.

Cholesterol Category	*Healthy Level*
Total Cholesterol	Less than 200 mg/dL
LDL	Less than 100 mg/dL, but will depend on the number of risk factors
HDL	Greater than 40 mg/dL, but the higher the better

Triglycerides	Less than 150 mg/dL

(These levels are measured in milligrams [mg] of cholesterol per deciliter [dL] of blood.)

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High Cholesterol

High cholesterol is a condition that affects 40 million Americans and is one of the risk factors for developing heart disease. Each year, more than a million Americans have heart attacks and about a half-million die from heart disease.

Cholesterol Free Foods

In the grocery store, you will often see products labeled "no cholesterol." What does this mean? In some respects, it is a marketing gimmick. In fact, stores could put a sign above the entire produce section saying, "Cholesterol Free" because cholesterol is only found in products that originate from animals (see High Cholesterol Foods). Plant-based products have no cholesterol.

What are Cholesterol Free Foods?

Cholesterol free foods are plant-based foods. Types of cholesterol free foods include:

- Vegetables
- Fruits
- Whole grains and legumes.

You should be eating at least 3 to 5 servings of fruits and vegetables and 6 to 11 servings of whole grains and legumes each day as part of a cholesterol lowering diet. Fruits and vegetables are low in saturated fat and total fat, and have no cholesterol.

A diet high in fruit and vegetables may also help keep cholesterol levels low. Fruits and vegetables are great substitutes for foods high in saturated fat and cholesterol.

Breads, cereals, rice, pasta, and other grains, and dry beans and peas are generally high in starch and fiber and low in saturated fat and calories. They also have no dietary cholesterol, except for some bakery breads and sweet bread products made with high fat, high cholesterol milk, butter, and eggs.

Low Cholesterol, Low Saturated Fat Diet

Finding out that you have high cholesterol can shock you, but it's not the end of the world. There are ways to lower your cholesterol level, such as switching to a low cholesterol diet.

Here are some of the guidelines need to be followed for a low cholesterol diet:

1. Avoid food that's high in fat.

A low cholesterol diet minimizes intake of the following:

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(a) Animal fat, which is found in animal products such as cheese, milk, butter, and cream, and in fatty areas of meat, poultry, shellfish and fish. A low cholesterol diet limits the intake of food rich in animal fat.

(b) Vegetable fat, which is found in vegetable products such as coconut oil, palm oil, and cocoa butter (used in chocolate). It is often found in cupcakes, biscuits, chips, etc. A low cholesterol diet limits the intake of food rich in vegetable fat.

(c) Hydrogenated fat or trans-fatty acid, which is more commonly known as trans-fat. It is found in fries, doughnuts, and other processed food. A low cholesterol diet drastically reduces if not totally eliminates your intake of food rich in trans-fat.

2. Replace saturated fat with unsaturated fat.

There are two major types of fat- saturated and unsaturated (further classified into polyunsaturated and monounsaturated). A low cholesterol diet needs unsaturated fat as it lowers your cholesterol level.

A low cholesterol diet would use oil with unsaturated instead of saturated fat. Corn, sesame, sunflower, and soybean oil are high in polyunsaturated fat, while olive and canola oil are high in monounsaturated fat. If you need to use oil in your cooking, these are better options in a low cholesterol diet.

3. Avoid food that's high in cholesterol.

Cholesterol is a waxy, fat-like substance found in food that comes from animal products such as eggs, meat, poultry, shellfish, dairy products, and fish. Cholesterol is not fat, so you can find it in both high-fat and low-fat food. A low cholesterol diet limits the intake of high-cholesterol food.

On the other hand, food that comes from plants such as fruits, grains, vegetables, nuts and seeds contain no cholesterol at all, so choose these for a low cholesterol diet.

4. Choose food that's high in complex carbohydrates.

Simple carbohydrates include table sugar, white bread, soda, candy, and corn syrup. These should be avoided in a low cholesterol diet. Choose instead brown bread, pasta, fruits, rice, beans and oats, which are good sources of complex carbohydrates.

These are high-fiber food which makes you feel full longer after meals and improves your digestion too. However, try to eat them plain and forego the butter, milk, cream or rich sauces as these are high in calories, which must be avoided in a low cholesterol diet.

A low cholesterol diet doesn't mean you have to stop eating all your favorite food, just make sure you limit your intake of unhealthy food and switch to lighter varieties. To be truly effective, any diet (including the low cholesterol diet) must satisfy some of your cravings. For example, choose diet soda over regular soda; skim milk over whole milk; low fat butter over margarine.

Student Activity

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1. Point out the primary features of protein powder.

2. Explain the importance of fat free foods.

3. Write down the primary sources of cholesterol.

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Summary

1. Hyper nutritious foods are the kind of foods which contain extra nutrients. These foods leave fastest impact on the users since their nutritional values are very high.

2. Protein is a large molecule composed of one or more chains of amino acids in a specific order determined by the base sequence of nucleotides in the DNA coding for the protein.

3. Protein powders are made from four basic sources: whey (from milk), egg, soy and rice. Protein powders can also be a combination of one or more ingredients.

4. Most oil bearing seed need to be separated from outer husk or shell. This is referred to as shelling, hulling or decortication.

5. According to the Food and Drug Administration, foods can be labeled as "fat free" only if they contain less than 0.5 g of fats (saturated fat or trans fats) per serving.

6. The predominant sources of n-3 fatty acids are vegetable oils and fish.

7. n-6 fatty acids (popularly referred to as ω-6 fatty acids or omega-6 fatty acids) are a family of unsaturated fatty acids which have in common a final carbon–carbon double bond in the n-6 position; that is, the sixth bond from the end of the fatty acid.

8. Cholesterol is a soft, waxy substance found in all of your body's cells. Your body needs it in order to work properly. This is because your body uses cholesterol to hold cells together.

Glossary

Hyper nutritious foods:— Foods which contain extra nutrients.

Protein Powder:— A simple name for one of the most debated food supplements amongst bodybuilding and weight training circles.

Protein Purification:— a series of processes intended to isolate a single type of protein from a complex mixture.

Fat free food:— contain less than 0.5 g of fats (saturated fat or trans fats).

n-6 fatty acids:— a family of unsaturated fatty acids which have in common a final carbon–carbon double bond in the n-6 position.

n-3 fatty acids:— a family of unsaturated fatty acids that have in common a final carbon–carbon double bond in the n-3 position.

Saturated fat:— saturated fat is found in animal fats and tropical oils. They tend to be more solid at room temperature.

Unsaturated fats (poly and mono):— yielded typically from plant sources and tend to be liquid at room temperature.

Cholesterol:— it is only found in products that originate from animals.

Review Questions

1. What is hyper nutritious food? Give definition and examples.
2. What are the uses and benefits of protein powder?
3. Discuss the basic sources of protein powder.
4. What are the strengths of soy protein isolates?
5. How is protein purified?
6. What are the main features of fat free foods?
7. Write down a short notes on omega-6 and omega-3 fatty acids.
8. Discuss the fundamental qualities of cholesterol free foods.

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UNIT—III

NUTRACEUTICALS AND PHARMA FOODS

Objectives

After going through this unit, students will be able to:

- state the fundamentals of nutraceuticals;
- point out the importance of nutraceuticals;
- classify the sources of nutraceuticals;
- explain the role of nutraceuticals in human health and therapeutical applications;
- discuss the fundamentals of pharma foods and its nutritional implications.

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3.1 Introduction

Nutraceutical, a portmanteau of nutrition and pharmaceutical, refers to extracts of foods claimed to have a medicinal effect on human health. traditionally the nutraceutical was contained in a medicinal format such as a capsule, tablet or powder in a prescribed dose, although more modern Nutraceuticals such as Probiotic drinks and yogurt are now found in ordinary supermarkets alongside normally everyday versions of the product.

More rigorously, nutraceutical implies that the extract or food is demonstrated to have a physiological benefit or provide protection against a chronic disease. Functional foods are defined as being consumed as part of a usual diet but are demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions.

Examples of claims made for nutraceuticals are resveratrol from red grape products as an antioxidant, soluble dietary fiber products, such as psyllium seed husk for reducing hypercholesterolemia, broccoli (sulforaphane) as a cancer preventative, and soy or clover (isoflavonoids) to improve arterial health. Such claims are being researched and many sources are available to ascertain their foundation of basic research.

Other nutraceutical examples are flavonoids antioxidants, alpha-linolenic acid from flax seeds, beta-carotene from marigold petals, anthocyanins from berries, etc. With the US Dietary Supplement Health and Education Act (DSHEA), several other compounds were added to the list of supplements originally mentioned in FDA notification. Thus, many botanical and herbal extracts such as ginseng, garlic oil, etc., have been developed as nutraceuticals.

Nutraceuticals are often used in nutrient premixes or nutrient systems in the food and pharmaceutical industries.

As a result, the description nutraceutical is broadly used and can refer to anything from a vitamin supplement pill, to an energy enhancing drink, and more recently to foods which are claimed to have beneficial physiological effects. The following offers specific examples of the types of nutraceuticals available in the four major categories:

Dietary Supplements

- Vitamins
- Minerals

Herbs or Botanicals

- Ginsing
- Gingko Biloba
- Saint John's Wort
- Saw Palmetto

Functional Foods

- Oats, bran, psyllium and lignins for heart disease and colon cancer
- Prebiotics oligofructose for control of intestinal flora
- Omega-3 milk in prevention of heart disease
- Canola oil with lowered triglycerides for cholesterol reduction
- Stanols (Benecol) in reduction of cholesterol adsorption

Medicinal Foods

- Health bars with added medications
- Transgenic cows and lactoferrin for immune enhancement
- Transgenic plants for oral vaccination against infectious diseases

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Although by definition nutraceuticals are classified as food products, use of the term nutraceutical and the claims attributed to their properties often leads to some disagreement as to whether nutraceuticals should be classified as medicinal products. While this may change in the future, current regulations do not require the same government efficacy and testing standards mandated for pharmaceuticals and other medicinal products.

However, nutraceutical manufacturers are limited to "health claims" about their products and not "medicinal claims." If a manufacturer implies a claim about a nutraceutical's medicinal benefit, the product is required to comply with the same regulatory requirements for medicinal products with respect to safety, efficacy, testing, and marketing.

3.2 Importance of the Nutraceuticals

'Nutraceutical' is a term proposed to used a classify foods that 'provide medical or health benefits'. Nutraceutical is any food or food ingredient considered to provide medical or health benefits including the prevention and treatment of disease. Dr. Stephen DeFelice coined the term "Nutraceutical" from "Nutrition" and "Pharmaceutical" in 1989. The term nutraceutical is being commonly used in marketing but has no regulatory definition. Nutraceuticals and functional foods are assuming a middle ground between food and drugs due to growing body of evidence that supports their role in maintaining health and contributing to treatment of disease. "Traditional nutrient" refer to vitamins and minerals considered essential to the diet and/or to correct a classical nutritional deficiency disease, whereas "functional foods" may provide specific health benefits beyond basic nutrition when consumed a part of varied diet. Nutrient, herbals and dietary supplements are major constituents of nutraceuticals, which make them instrumental in maintaining health against various disease conditions and thus promote the quality of life. The focus of this article is to give a brief overview on Nutraceutical. Drug and food from natural origin play a significant role in the public health care system of any nation. The search for specific constituents of plant, animals, minerals and microbial origin which are beneficial to our mental and physical health has caused coining of terminologies such as Nutraceuticals, Cosmoceuticals, Dermaceuticals, Phytochemicals, Phytonutrient, Phytofoods, Functional foods.

Nutraceutical word–with "nutra" derived from nutrition and "ceutical" from pharmaceutical refers to substances that may be considered a food or part of a food and may provide medical and health benefits. 'A nutraceutical is any substance that is a food or a part of a food and provides medical or health benefits, including the prevention and treatment of disease. Such products may range from isolated nutrients, dietary supplements and specific diets to genetically engineered designer foods, herbal products, and processed foods such as cereals, soups and beverages.

It is important to note that this definition applies to all categories of food and parts of food, ranging from dietary supplements such as folic acid, used for the prevention of spina bifida, to chicken soup, taken to lessen the discomfort of the common cold. This definition also includes a bioengineered designer vegetable

food, rich in antioxidant ingredients, and a stimulant functional food or pharmafood.' Since the term was coined, its meaning has been modified. Health Canada defines nutraceutical as: 'a product isolated or purified from foods, and generally sold in medicinal forms not usually associated with food and demonstrated to have a physiological benefit or provide protection against chronic disease'.

Examples: beta-carotene, lycopene Nutraceuticals can be of different types Functional foods are foods that may provide health benefits beyond their basic nutritional value.

The benefits may come from naturally occurring parts of the foods themselves or from the manufacturing process. It is a food engineered or supplemented to give improved nutritional value. It exits at the interface between food and drugs. When functional food aids in the prevention and/or treatment of disease and/or disorders other than anemia, it is called a nutraceuticals. e.g. transgenic canola oil engineered for improved trans fatty acids content. A dietary supplement is a product that is indebted to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, and a herb that gives health benefits. The use of nutraceuticals, as an attempt to accomplish desirable therapeutic outcomes with other therapeutic agents has met with great monetary success. Nutraceutical have been found to be associated with the prevention and/or treatment of many chronic disease and aliments such as cancer, diabetes, heart disease, hypertension, arthritis, osteoporosis etc. Nutraceuticals and functional foods hold promise in clinical therapy as they have the potential to significantly reduce the risk of side effects associated with chemotherapy along with reducing the global healthcare cost. However, with all of the aforementioned positive points, nutraceuticals still need support of an extensive scientific study to prove "their effects with reduced side effects". Types of Nutraceuticals Nutraceutical are broadly categorized as follows. Substances with established nutritional function such as

- vitamins, minerals, amino acid and fatty acids nutrients.
- herbal and botanical products
- foods for viability, functional food,medical food
- health food, organic food
- sport and energy product
- natural medicinal products with specific health benefit

3.3 Types of Nutraceuticals

Using food products to promote health and cure disease is nothing new. Some common drugs used today are based on plants used in the distant past. Aspirin and other fever and pain relievers rely on chemicals similar to those found in willow bark. Opium, from poppies, is the basis of the potent pain reliever morphine. Many countries, such as India, China, and Tibet, have a long tradition of relying on herbs and other plant products (botanicals) for treating health problems.

In the United States, nutraceuticals are considered part of the field of complementary and alternative medicine—substances or treatments that can be

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used along with, or instead of, the usual medical approach. There are basically two types of nutraceuticals: dietary supplements and functional foods.

Dietary Supplements

Dietary supplements are defined by federal law as products taken by mouth that contain a "dietary ingredient" intended to add something to the foods you eat. Examples of dietary supplements are black cohosh for menopausal symptoms, *ginkgo biloba* for memory loss, and glucosamine/chondroitin for arthritis. If you take a daily multiple vitamin, you are taking a dietary supplement. Supplement ingredients may contain vitamins, minerals, herbs or other botanicals, amino acids, enzymes, organ tissues, gland extracts, or other dietary substances. They are sold in many forms, including tablets, capsules, liquids, powders, extracts, and concentrates.

Dietary supplements are easily available. Health food stores and online marketers sell them, as do many grocery stores and chain drugstores. The idea of dietary supplements appeals to many: In 2002, U.S. citizens spent about $18.7 billion on them; about $4.3 billion of that was spent on herbs and botanicals. If you use or are considering taking dietary supplements to prevent or treat medical conditions, you should be aware of the possible risks as well as the potential benefits.

Functional Foods

Functional foods are foods that may provide health benefits beyond their basic nutritional value. The benefits may come from naturally occurring parts of the foods themselves or from the manufacturing process. For instance, oat bran helps lower cholesterol, as do specially made types of margarine. In 1999, U.S. consumers spent about $16.2 billion on functional foods. Other than personal reactions and money spent on a food that doesn't deliver the intended benefit, functional foods rarely have serious unwanted effects.

Box 1

The Pros and Cons

Nutraceuticals may seem attractive because they do not require an appointment with a health care provider and are easily available without a prescription. Many people believe this approach is more natural than using prescription drugs. They feel dietary supplements will help them feel stronger and healthier, give them more energy, and prevent illness. Some people turn to these products when they feel standard treatments for their specific illnesses have failed.

There are also some drawbacks to using these products, however. For one thing, drugs—including prescription drugs and those sold over the counter—are regulated by the U.S. Food and Drug Administration. Drug manufacturers must submit scientific evidence that their products are safe and effective. Then they must manufacture the drugs in a strictly controlled manner that ensures they are pure and contain the exact amount of the specific ingredients they should. Dietary supplements, on the other hand, are regulated as foods, not as drugs. They may

contain more, less, or none of the actual effective ingredient, and they may be contaminated with other substances.

In addition, dietary supplement manufacturers are not required to submit scientific studies proving their products' safety and effectiveness. Just because dietary supplements seem natural does not mean they are safe, or that they will have the effects they promise. Supplements, just like drugs, can have unwanted side effects as well as desirable effects. Some supplements can interact with prescription drugs, causing harm.

3.4 Sources of Nutraceuticals

Nutraceuticals are whole foods, food ingredients or supplements that have specific health or medical benefits. For example, they may prevent or treat specific diseases, which means that they have properties extending beyond simple nutritional functions.

Nutraceuticals can come from plant, marine, animal, and microbial sources. Specifically, nutraceuticals include whole foods, food additives, herbs, phytonutrients (nutrients found in the skin of many vegetables and fruits, as well as in grains and seeds), probiotics *(see below)*, and vitamin, mineral and herbal supplements.

The following list covers only a few of the large number of nutraceuticals out there. Since most of these can be found in pill form, if it's too much of a hassle to incorporate all these foods in your diet, go to your local health food store and pick up some supplements.

Plant Based Nutraceuticals

They are phytochemicals – biologically active natural products such as glucosinolates in cruciferous vegetables (cole crops), limonoids in citrus fruits, lignans in flaxseed, lycopene in tomatoes, and catechins in tea. They all have specifc actions and can be used *e.g.* as antioxidants. They have a positive effect on health. Did you know that garlic contains diallyl sulfide, which lowers LDL cholesterol ?

Marine Based Nutraceuticals

Probably the best known marine nutraceuticals are the omega-3 fatty acids found in fish oils. Fish oils are lipids found in fish, particularly cold water fish, and other marine life such as phytoplankton. These oils are rich sources of long-chain polyunsaturated fatty acids (LCPUFA) of the n-3 (omega-3) type.

Microalgae are an important sources of products such as polyunsaturated fatty acids, astaxantin, lutein, beta carotene.

Animal or Microorganism Based

Food-grade microorganism or animal based nutraceuticals such as essential fatty acids and enzymes.

The enzymes includes carbohydrases, proteases, glutaminase,peptidase and lipase enzymes. They have applications as precursor systems for Maillard reactions, Hydrolyzed Vegetable Proteins (HVP), yeast extracts.

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3.5 Classification of Nutraceuticals

The food products used as nutraceutical contain the following- except probiotics; all the components are in fruits, vegetables and different type of herbal foods. 1. Antioxidant 2. Prebiotics 3. Probiotics 4. Omega 3. fatty acid 5. Dietary fibers.

Antioxidants

Antioxidants are substances, which retard or prevent deterioration, damage or destruction caused by oxidation. Fortunately, the body has an army of antioxidants for damage limitation. Antioxidant form an integral part of the nutraceutical market. During the last few years' research has confirmed that many have the common disease and ailments of 21st century (CVS, diabetes, cataracts, high blood pressure, infertilities, respiratory infection, and rheumatoid arthritis) are associated with tissue deficiency and/or low dietary levels of compounds called antioxidants. The oxygen is consumed in the body during metabolism by process called oxidation.

During oxidation free radicals are generated. These free radicals at a molecular level burn everything they touch. Antioxidants are power full electron donors and react with free radical damage the biomolecules. The formed antioxidant radical is stable and unreactive. Antioxidants are quite large in number and diverse in nature which oppose the process of oxidation largely by neutralizing free radicals at relatively small concentrations have the potential to inhibit to inhibit the oxidants chain reactions. Dietary antioxidants and some accessory molecules, such as zinc and certain vitamins are important in maintaining free radical scavenging systems, biosynthetic capacity, membranes, enzymes and DNA. Antioxidants are found in the vegetable oils. *e.g.* Soybean oil, canola oil, corn oil, oat oil, wheat germ oil, palm oil, evening prime rose oil.

Free Radicals

A free radical has defined as any species capable of independent existence that contain one more unpaired electron. Unpaired electron makes the molecule unstable and highly reactive. They are mainly derived from oxygen and nitrogen. Free radicals are short lived. Most of the free radicals are formed in the body from oxygen are super oxide, hydroxyl radical, nitric oxide, singlet oxygen, peroxyl radical, hydrogen peroxide and alkoxyl. The sources of free radicals are both endogenous and exogenous.

The free radicals disrupt the equilibrium of biological systems by damaging their major constituents' molecules (lipids, proteins, carbohydrates and DNA) that eventually lead to cell death.

Action of Antioxidants

Antioxidants are used to prevent the damage at the cellular level by using the following mechanisms:

- They may reduce the energy of the free radical
- Preventive (suppress radical formation)
- Repair (repair damage and reconstitute membranes)

Probiotics

Probiotics are live microbial food ingredients, which are beneficial to health. The prerequisite for probiotic action include survival in and adhesion to specific areas of the gastrointestinal tract and competitive exclusion of pathogens or harmful antigens. Probiotics are situated as health or functional foods whereby they are ingested for their purported positive advantages in the digested tract and/or systemic area like the liver, brain, vagina or blood stream. Colon is the most densely populated region of the gastrointestinal tract and harbors an estimated 500 different bacterial species.

Probiotic Bacterial Species

The various types of bacteria that are having the probiotics characteristics are—

- Lactobacilli
- Lactobacillus *rhamnosus*
- Lactobacillus *reuteri*
- Lactobacillus case
- Bifidobacterium
- Bifidobacterium *lactis*
- Bifidobacterium *longum*
- Bifidobacterium *breve*
- Bifidobacterium *infantis*
- Streptococcus
- Lactococcus
- Lactococcus *platinum*
- Lactococcus *reuteri*
- Lactococcus *agilis*
- Enterococcus
- Saccharomyces
- Bacillus
- Pediococcus

Characteristics of Probiotic Bacteria

Bacteria should have the following features:

1. GRAS (generally recognized as safe)
2. *In vitro* resistance to hydrochloric acid and pancreatic juice
3. Produce antimicrobial substances
4. Compete with bad bacteria to adhere on the gut wall.
5. Compete for the nutrients and stimulate immunity and
6. Alter the intestinal micro flora balance, inhibit growth of harmful bacteria, promote good digestion, boost immune function and increase resistance to infection.

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Prebiotics

Prebiotics are the substances, which reach to colon in intact form i.e. without getting depleted by the gastric pH and digestive acids. These prebiotics also selectively promote the growth of colonel probiotic bacteria; hence they act as fertilizers for these bacteria. These are collective term for non-digestive but a fermentable dietary carbohydrate that may selectively stimulates growth of certain bacterial groups' resident in the colon, such as Bifidobacteria, Lactobacilli considered to be beneficial for the human host. *e.g.* –inulin, which is soluble dietary fibres and resistant to digestive enzyme and thus reaches to large intestine or colon essentially intact, where it is fermented by resistant bacteria, Lactobacilli. A range of oligosaccharides have been tested using various in vitro methods, animal models and human clinical trials are:

1. Fructo oligosaccharides
2. Inulins
3. Lactilol
4. Lactulose
5. Galacto-oligosaccharides
6. Soybean oligosaccharides
7. Lactosucrose
8. Isomalto-oligosaccharides
9. Gluco-oligosaccharides
10. Xylo-oligosaccharides

The Food Components or Ingredients (Prebiotics)

A prebiotic nature has been attributed to many food components that the food or food components:

1. Resists host digestion, absorption and absorption processes.
2. Fermented by the microflora colonizing the gastrointestinal system.
3. Selectively stimulates the growth and/or the activity of one or a limited number of bacteria with the gastrointestinal system.

Polyunsaturated Fatty Acids

Essential fatty acids are needed for normal growth and development but cannot be synthesized by our body. Omega-3 fatty acids belong to this class. Long chain omega-3 fatty acids such as eicosapentaoic acid and docosagexanoic acids are built up in algae and plankton and the fish living on them. The natural vegetable oils and marine animal oils containing polyunsaturated fatty acid belong to Linoleic group (omega 6-type and omega 3-fatty acid) help to reduce cholesterol formation/deposition and prevent thromboxane formation. *e.g.* safflower oil, corn oil, soybean oil, mustard oil and marine fishes. Evening primrose oil, flax oil, hemp seed, borage seede. The following are diseases for which polyunsaturated fatty acids are preferred.

- Heart disease and stroke
- Rheumatoid arthritis

- Inflammatory arthritis
- Inflammatory bowel disease
- Asthma
- Cancer
- Chronic lung failure
- Kidney transplant

Dietary Fibers

Dietary fibers are used in health food products for normalization of intestinal transit time. They have dual effect on intestinal transit. First effect is on the bulk faeces, which are often increased, in substantial proportion (127% after ingestion of 20 g of wheat bran, this action with insoluble fibers. The other effect if dietary fibres are upon the duration of transit, which gets normalized around in 48 hrs. Long transit time gets shortened and short transit get longer. Dietary fibres are categorized into two groups:

Water Soluble Fibers

Soluble fibers dissolve in water and form a gel that binds the stool and inhibit the non-propulsive colon contractions, helps in bulking of stool and their quick passage through digestive tract. Oats, dried beans, legumes, chicory.

Water Insoluble Fibers

Insoluble fibers are present in brown rice, banana, vegetables and whole grains. Source of dietary fibers are:

- *Fresh fruit:* Apple, orange, apricot, plum, pineapple with fibers 18—30%
- *Vegetables:* Cabbage, carrot, lettuce, onion, tomato with fibers 9 to 12 %

3.6 Nutraceuticals— The Functional Foods of Future Diet

Nutraceuticals are soon to revolutionise the global food industry. The word combines 'nutrition' and 'pharmaceuticals' to mean that food extracts can be used as preventive drugs or food supplements. The entire concept is building on the research studies that link the importance of diet in combating diseases in man. What is new about this concept is the science's added knowledge about the disease preventing phytonutrients present in food stuffs.

Therefore, these functional foods cover everything from breakfast cereal that has been pumped full of vitamins to benecol, a margarinesque spread that actually lowers cholesterol.

The major phytonutrients identified to have nutraceuticals properties include terpenes, phytosterole, phenols and theols. The identification is based on their protective functions, the physical and chemical characteristics of their molecules.

Terpenes represent the largest class of phytonutrients. They are found in green foods, soya products and grains. Carotenoids and limonoids are the two major terpene subclasses. Carrots, tomatoes, parsley, orange and spinach are rich sources of carotenoids. They act as Vitamin A precursor and have preventive action against many eye diseases. It can also prevent the oxidation of Vitamin A

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and *E*. Limonoids act as antioxidants protecting lung tissues from free oxygen. Citrus peel can act as nutraceuticals supplying limonoids.

Phytosterols form another major class of phytonutrients, which are present in all plants. However, the rich sources having nutraceutical functions include yellow vegetables, seeds of pumpkins and yams. This phytochemical competes with dietary cholesterol for uptake in the intestine thereby blocking cholesterol absorption into the body. It also facilitates the excretion of cholesterol from the body. It can also prevent the development of tumor in breast and prostate glands.

Phenols comprise of a large group of phytonutrients with profound importance in preventive medicine. Berries, grapes and eggplants are rich in phenolic content. Phenoles have protective action against oxidative damage of tissues and inflammation. Flavonoides, anthocyanidines (flavonals) and isoflavones are the major subclasses coming under the phenolic group.

Flavonoides were once grouped, as Vit P but later deleted for want of specific deficiency disease symptoms. However, it has been proved that these phytochemicals can enhance the effectiveness of Vitamin *C*. They can also act against allergies, ulcers, tumors and platelet aggregation. It is effective in controlling high blood pressure and can reduce the risk of estrogen induced cancer.

Anthocyanidines or flavonals have significant role in collagen protein synthesis. They are important in sports medicine also. Athletes who exercise a lot produce free radicals that are tackled by anthocyanidins. Isoflavones can prevent tumor growth. Beans and other legumes are rich sources with nutraceutical properties. Important Isoflavones, genestein and daidzin found in soyabeans have nutraceutical properties against tumor growth.

People who consume traditional diets rich in soya food rarely experience breast, uterus and prostate cancer. The herb Pueraria lobata also contains Isoflavones that can be used in treatment against alcoholism. Isoflavones alter the speed at which the enzyme alcohol dehydrogenese converts alcohol into aldehydes. This cause lowered tolerance for alcohol and reduces the pleasure response to drinking. Theols are a major sulphur containing class of phytonutrients. The food sources having theolic nutraceutical properties include garlic, onions, mustard, and other cruciferous vegetables like cabbage and turnip. Important subclasses under theols are glucosinolates, allylic sulphides, indoles, isoprenoids and tocopherols. Cruciferous vegetables from rich sources of glucosinotates. They activate liver detoxification enzymes and can reduce tumour.

Allylic sulphides are potent antimutagenic and anticarcinogenic agents. It protects against tumours and gives cardio vascular protection. They can block the activity of toxins produced by bacteria and viruses thereby building immunity against diseases. Garlic and onions are the most potent members of this class. Allylic sulphides are also present in leeks, shallots and chives. The phytonutrient get released from these plants only when it is cut or smashed.

The subclass indoles are found in citrus and goose berry. They are found effective against the action of carcinogenic chemicals reaching the intestine.

They bind the carcinogens thereby protecting against cancer. Isoprenoids are active against free radicals in the body. Thus it reduces oxidative damage of tissues. Whereas Tocopherols found in grains and palm oil inhibits breast cancer.

The researches are soon to evolve vaccines that can be delivered to our bodies through foods like bananas and potatoes. The advantage is that it can eliminate the discomforts in administration and the need for refrigeration in storage.

Moreover, this makes the availability of vaccines easy and safe even in remote areas without refrigeration facilities. Vaccines currently being worked into bananas include those for hepatitis B and Norwalk Virus etc. Stage is not far where nutraceuticals will be our preferred prescriptions of tomorrow.

3.7 Processing of Nutraceutical Products

Nutraceutical's manufacturing process generally consists of the following operations:

- Sourcing ingredients for products
- Warehousing raw ingredients
- Measuring ingredients for inclusion in such products
- Blending the ingredients into a mixture with a homogeneous consistency
- Encapsulating, tableting or pouring the blended mixture into the appropriate dosage form using either automatic or semiautomatic equipment.

The next step, bottling and packaging, involves placing the product in packaging with appropriate tamper-evident features and sending the packaged product to a distribution point for delivery to retailers. Nutraceutical places special emphasis on quality control and conducts inspections throughout the manufacturing process, including raw material verification, homogeneity testing, weight deviation measurements and package quality sampling.

Nutraceuticals, which are often referred to as phytochemicals, or functional foods, are natural, bioactive chemical compounds that have health-promoting, disease-preventing, or medicinal properties. These products are isolated or purified from foods, and generally are sold in medicinal forms. They typically fall under the "supplement category" and often come in tablet, powder, or liquid form comprising herbs, vitamins, and other nutrients.

The Nutraceuticals industry is changing. Efficiency, Quality, and Environmental Consciousness are driving product success factors. Supercritical fluids extract selectively, and Phasex can tailor processes for specific extraction characteristics. This capability to fine tune the extraction characteristics of supercritical fluids provides a process and market advantage to produce concentrated fractions of active components.

Technology

Supercritical Fluids are now widely accepted for Extraction, Purification, Recrystallization, and Fractionation operations in many industries. The technology is used to process hundred of millions of pounds of Coffee, Tea, and Hops annually, and it is increasingly becoming of common use in the Pharmaceuticals industry for purification and nano-particle formation. Supercritical fluid processing is also gaining in the Botanicals, Vitamins, and Supplements industries, where they are becoming synonymous with the highest purity and quality.

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Supercritical fluid extraction is far more efficient than traditional solvent separation methods. Supercritical fluids are selective, thus providing the high purity and product concentrations. Additionally, there are no organic solvent residues in the extract or spent biomass. Extraction is efficient at modest operating temperatures, for example, at less than 50°C, thus ensuring maximum product stability and quality.

Quality

Supercritical Fluid extraction is the most efficient separation method for the Nutraceuticals market. It is capable of providing the highest purities and concentrations attainable. Typically, traditional organic solvent separation yields are high, but if heptane or methylene chloride solvents, for example, are used, there are almost assuredly trace solvents present in the extracts. Supercritical fluids provide organic solvent- free concentrated extracts: maximize your product yields, minimize your contamination, and ensure the highest purity and quality with supercritical fluids.

Production of Astaxanthin Concentrate

Organic solvents such as acetone and hexane have been used industrially for the extraction of astaxanthin from microalgae. The concentration of astaxanthin in these extracts, however, is limited because liquid solvents cannot differentiate between the lipids and the carotenoid.

Microalgae, such as Haematococcus pluviales, contains about 2% (w/w) astaxanthin and an average 30% total extract of lipids plus astaxanthin. Using organic solvents, the highest theoretical astaxanthin concentration achievable in the extract product is about 6.7%. Organic solvent extraction cannot produce a higher concentrate because the lipids and the astaxanthin are dissolved equally readily by acetone, for example. [The maximum astaxanthin concentration in the extract is calculated from the relation (% astaxanthin in algae) divided (by % extract/100).]

Much higher astaxanthin extract concentrations are achievable with supercritical fluids because of the ability to tailor their dissolving power (by tuning pressure). Lipids and carotenoids respond differently to supercritical CO_2 and can be selectively separated, resulting in an extract high in the carotenoid.

The table below gives some results from selected plant runs at Phasex using supercritical fluids compared to product typically obtained by acetone extraction.

Asta Content of Microalgae Feed	*Total Extract* (Lipids & Asta)*	*Asta Content of Supercritical Extract*	*Asta Content of Acetone Extract*
2.4%	28.4%	14.3%	8.5%
1.9%	26.6%	13.4%	7.1%
2.2%	27.6%	13.5%	8.0%

2.8%	26.3%	16.3%	10.6%
3.9%	33.7%	20.1%	11.6%

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Supercritical fluids are similarly applicable for the production of other concentrated carotenoid extract: Lycopene, lutein, zeaxanthin are typical of carotenoid compounds obtained from botanical substrates such as tomato, spinach, corn, and marigold.

Green Chemistry

Supercritical Fluid solvents are environmentally friendly and recyclable.

Supercritical CO_2 is certainly a Green Solvent; By far the most common supercritical fluid is gaseous Carbon Dioxide. By adjusting the processing pressure and temperature, the gas can act like a liquid solvent, but with selective dissolving powers. In the supercritical fluid phase, extraction concentration is carried out simply with changes in pressure, which results in a pure product fraction and a clean CO_2 gas stream, which is completely recycled to the process.

There are NO hazardous waste streams, NO harsh organic chemicals or residues, and the gaseous solvent is Recyclable.

Processing

Carbon dioxide is non-toxic, non-flammable, odorless, tasteless, inert, and inexpensive. The critical temperature of carbon dioxide is 88°F, just above room temperatures. In the past five years research and process development activity has focused on utilizing supercritical carbon dioxide technology in processing fine chemicals, pharmaceutical intermediates, and nutraceuticals. In addition to being a solvent for extraction and fractionation (purification) of organic compounds, carbon dioxide is increasingly being utilized as a medium for reactions, as a micronizing agent in Rapid Expansion in a Supercritical Solution process (RESS), as an anti-solvent for crystallization in Gas Anti-Solvent process (GAS), and as a carrier solvent for coating and depositing materials onto or into a solid matrix. Carbon dioxide technology is one of the fastest growing new process technologies being adopted by the food, pharmaceutical and nutraceutical industries.

Supercritical fluid technology will allow nutraceutical companies to develop products of standardized concentration of active ingredients, and will simultaneously produce nutraceutical products of much higher concentration (higher yields and purity) and quality (with less creation of artifacts), than possible by conventional chemical engineering unit operations, such as liquid/liquid extraction, distillation, mechanical micronization, liquid and/or gas phase reactions, etc.

Advantages of Carbon Dioxide as an Extraction Solvent for Nutraceuticals

Carbon dioxide as a solvent has many advantages. Probably the most important advantage is that it is a GRAS solvent that leaves no traces in the product. After extraction, the carbon dioxide is recycled and any trace carbon dioxide in

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the product dissipates to the atmosphere within a few hours. Also, unlike solvent extraction, the carbon dioxide is readily recycled by pressure and temperature adjustment, which is very mild and does not harm the product. Another advantage of supercritical fluid extraction is the capability of fractionating products to create coproducts. Solvent extraction requires a distillation step, (in which top notes are lost and distillation notes are created), that many times alters the taste, aroma and chemical composition of the product. Also, trace quantities of residual organic solvent are usually present in the product.

Botanicals can be fractionated to produce a natural colour fraction, an aroma fraction, an anti-oxidant fraction and/or a flavour fraction. This is important in producing nutraceuticals because unwanted strong flavours in certain botanicals such as garlic and rosemary can be separated from the nutraceutical components.

Finally, supercritical fluids can be adjusted to selectively extract certain compounds. For example, the supercritical fluid solvent can be adjusted to extract the pesticides from ginseng. The supercritical fluid process can be further adjusted to extract allergenic compounds from the gingko biloba. Supercritical carbon dioxide is finding broad acceptance in the nutraceutical industry because it does not harm products and produces higher concentration (quality) extracts.

Production Scale SFC

Production scale SFC has been successfully used for the separation of enantiomers and fatty acid esters. Large quantities of DHA and EPA ethyl esters from fish oils are routinely separated to >95% purity on a commercial production scale SFC unit.

Extraction of Fermentation Broths

Supercritical carbon dioxide countercurrent column extraction is currently being investigated as a new process for the extraction of bioactive compounds from fermentation broths. This process offers an inexpensive method to extract and simultaneously fractionate compounds of interest without leaving organic solvent residues in the product.

Partial List of Nutraceutical Products that can be Processed by Supercritical CO_2 –

- Extracts of chamomile flowers for anti-inflammatory and anti-spasmodic bioactive compounds (*e.g.* sesquiterpene, lactone, matricin, etc.)
- Extract of calamus root as an appetite stimulant—higher yield with SFE (8.3%) when compared to steam distillation (6.4%)
- Extracts of turmeric for bile preparations—no artifacts such as tolylmethylcarbinol created in steam distillation
- Valarian as a sedative preparation—valepotriates obtained undecompossed and at high yield (>90%)
- Wormwood extract as a carminative, cholagogue and stomachic—removal of *toxic 2-thujone* by fractional extraction from thermally unstable pharmacology active components

- Hydrogenation reactions in supercritical carbon dioxide that are a factor of 1,000 faster than conventional hydrogenation reactions with greater control over trans isomer formation
- Extraction of fermentation broths producing vitamins with bioactive compounds
- Enzymatic reactions in supercritical fluids such as conversion of lipids to methyl or ethyl esters
- Saw Palmetto—higher concentration of phytosterols (active ingredients)
- Ginseng—extraction of pesticides without extracting significant quantities of active ingredients
- Echinacea—more concentrated extract obtained by SFE than conventional technologies
- Feverfew—more concentrated extract obtained by SFE than conventional technologies
- Chitin (glucosamine)—able to separate astaxanthin co-product from chitosan using SFE, able to demineralize shells, and other processing steps
- St. John's Wort—more concentrated extract obtained by SFE than conventional technologies
- Kava-kava—more concentrated extract obtained by SFE than conventional technologies
- *Gingko biloba*—SFE reduces allergenic compounds in extract
- Garlic (allicin)—SFE extract more concentrated and deodorized plus higher yields when compared to conventional technologies
- Evening Primrose oil—more concentrated extract obtained by SFE than conventional technologies
- Rosemary extract—SFE extract more concentrated and deodorized plus higher yields when compared to conventional technologies
- Grape seed extract—more concentrated extract obtained by SFE than conventional technologies

3.8 Supercritical Fluid Extraction

Supercritical Fluid Extraction (SFE) is the process of separating one component (the extractant) from another (the matrix) using supercritical fluids as the extracting solvent. Extraction is usually from a solid matrix, but can also be from liquids. SFE can be used as a sample preparation step for analytical purposes, or on a larger scale to either strip unwanted material from a product (*e.g.* decaffeination) or collect a desired product (*e.g.* essential oils). Carbon dioxide (CO_2) is the most used supercritical fluid, sometimes modified by co-solvents such as ethanol or methanol. Extraction conditions for supercritical CO_2 are above the critical temperature of 31°C and critical pressure of 74 bar. Addition of modifiers may slightly alter this. The discussion below will mainly refer to extraction with CO_2, except where specified.

Advantages

Environmental Improvement and Reduced Product Contamination

SFE is an alternative to liquid extraction using solvents such as hexane or dichloromethane. There will always be some residual solvent left in the extract

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and matrix, and there is always some level of environmental contamination from their use. In contrast, carbon dioxide is easy to remove simply by reducing the pressure, leaving almost no trace, and it is also environmentally benign. The use of SFE with CO_2 is approved by the Soil Association for organic products. The CO_2 used is largely a by product of industrial processes or brewing, and its use in SFE does not cause any extra emissions.

Selectivity

The properties of a supercritical fluid can be altered by varying the pressure and temperature, allowing selective extraction. For example, volatile oils can be extracted from a plant with low pressures (100 bar), whereas liquid extraction would also remove lipids. Lipids can be removed using pure CO_2 at higher pressures, and then phospholipids can be removed by adding ethanol to the solvent.

Speed

Extraction is a diffusion-based process, with the solvent required to diffuse into the matrix, and the extracted material to diffuse out of the matrix into the solvent. Diffusivities are much faster in supercritical fluids than in liquids, and therefore extraction can occur faster. Also, there is no surface tension and viscosities are much lower than in liquids, so the solvent can penetrate into small pores within the matrix inaccessible to liquids.

Limitations

The requirement for high pressures increases the cost compared to conventional liquid extraction, so SFE will only be used where there are significant advantages. Carbon dioxide itself is non-polar, and has somewhat limited dissolving power, so cannot always be used as a solvent on its own, particularly for polar solutes.

The use of modifiers increases the range of materials which can be extracted. Food grade modifiers such as ethanol can often be used, and can also help in the collection of the extracted material, but reduces some of the benefits of using a solvent which is gaseous at room temperature.

Procedure

The system must contain a pump for the CO_2, a pressure cell to contain the sample, a means of maintaining pressure in the system and a collecting vessel. The liquid is pumped to a heating zone, where it is heated to supercritical conditions. It then passes into the extraction vessel, where it rapidly diffuses into the solid matrix and dissolves the material to be extracted. The dissolved material is swept from the extraction cell into a separator at lower pressure, and the extracted material settles out. The CO_2 can then be cooled, recompressed and recycled, or discharged to atmosphere.

Pumps

Carbon dioxide is usually pumped as a liquid, usually below 5°C and a pressure of about 50 bar. The solvent is pumped as a liquid as it is then almost incompressible. As a supercritical fluid, much of the pump stroke will be "used up" in compressing the fluid, rather than pumping it. For small scale extractions (up to a few grams/minute), reciprocating CO_2 pumps or syringe pumps are

often used. For larger scale extractions, diaphragm pumps are most common. The pump heads will usually require cooling, and the CO_2 will also be cooled before entering the pump.

Pressure Vessels

Pressure vessels can range from simple tubing to more sophisticated purpose built vessels with quick release fittings. The pressure requirement is at least 74 bar, and most extractions are conducted at under 350 bar. However, sometimes higher pressures will be needed, such as extraction of vegetable oils, where pressures of 800 bar are sometimes required for complete miscibility of the two phases.

The vessel must be equipped with a means of heating. It can be placed inside an oven for small vessels, or an oil or electrically heated jacket for larger vessels. Care must be taken if rubber seals are used on the vessel, as the CO_2 may dissolve in the rubber, causing swelling, and the rubber will rupture on depressurization.

Pressure Maintenance

The pressure in the system must be maintained from the pump right through the pressure vessel. In smaller systems (up to about 10 mL/min) a simple restrictor can be used. This can be either a capillary tube cut to length, or a needle valve which can be adjusted to maintain pressure at different flow rates. In larger systems a back pressure regulator will be used, which maintains pressure upstream of the regulator by means of a spring, compressed air, or electronically driven valve. Whichever is used, heating must be supplied, as the adiabatic expansion of the CO_2 results in significant cooling. This is problematic if water or other extracted material is present in the sample, as this may freeze in the restrictor or valve and cause blockages.

Collection

The supercritical solvent is passed into a vessel at lower pressure than the extraction vessel. The density, and hence dissolving power, of supercritical fluids varies sharply with pressure, and hence the solubility in the lower density CO_2 is much lower, and the material precipitates for collection. It is possible to fractionate the dissolved material using a series of vessels at reducing pressure. The CO_2 can be recycled or depressurized to atmospheric pressure and vented. For analytical SFE, the pressure is usually dropped to atmospheric, and the now gaseous carbon dioxide bubbled through a solvent to trap the precipitated components.

Heating and Cooling

This is an important aspect. The fluid is cooled before pumping to maintain liquid conditions, then heated after pressurization. As the fluid is expanded into the separator, heat must be provided to prevent excessive cooling. For small scale extractions, such as for analytical purposes, it is usually sufficient to pre-heat the fluid in a length of tubing inside the oven containing the extraction cell. The restrictor can be electrically heated, or even heated with a hairdryer. For larger systems, the energy required during each stage of the process can be calculated using the thermodynamic properties of the supercritical fluid.

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Simple Model of SFE

There are two essential steps to SFE, transport (by diffusion or otherwise) from with the solid particles to the surface, and dissolution in the supercritical fluid. Other factors, such as diffusion into the particle by the SF and reversible release such as desorption from an active site are sometimes significant, but not dealt with in detail here. Figure 1 shows the stages during extraction from a spherical particle where at the start of the extraction the level of extractant is equal across the whole sphere (Fig. 1a). As extraction commences, material is initially extracted from the edge of the sphere, and the concentration in the center is unchanged (Fig 1b). As the extraction progresses, the concentration in the center of the sphere drops as the extractant diffuses towards the edge of the sphere (Figure 1c).

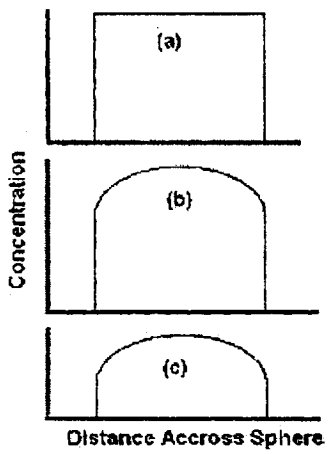

Fig. 1. Concentration profiles during a typical SFE extraction

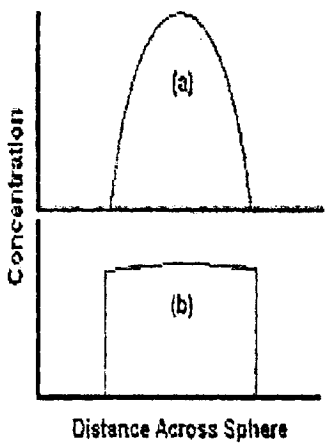

Fig. 2. Concentration profiles for (a) diffusion limited and (b) solubility limited extraction

The relative rates of diffusion and dissolution are illustrated by two extreme cases in *Fig.* 2. Figure 2a shows a case where dissolution is fast relative to diffusion.

The material is carried away from the edge faster than it can diffuse from the center, so the concentration at the edge drops to zero. The material is carried away as fast as it arrives at the surface, and the extraction is completely diffusion limited. Here the rate of extraction can be increased by increasing diffusion rate, for example raising the temperature, but not by increasing the flow rate of the solvent. Figure 2b shows a case where solubility is low relative to diffusion. The extractant is able to diffuse to the edge faster than it can be carried away by the solvent, and the concentration profile is flat. In this case, the extraction rate can be increased by increasing the rate of dissolution, for example by increasing flow rate of the solvent.

Optimisation

The optimum will depend on the purpose of the extraction. For an analytical extraction to determine, say, antioxidant content of a polymer, then the essential factors are complete extraction in the shortest time. However, for production of an essential oil extract from a plant, then quantity of CO_2 used will be a significant cost, and "complete" extraction not required, a yield of 70—80% perhaps being sufficient to provide economic returns.

In another case, the selectivity may be more important, and a reduced rate of extraction will be preferable if it provides greater discrimination. Therefore few comments can be made which are universally applicable. However, some general principles are outlined below.

Maximising Diffusion

This can be achieved by increasing the temperature, swelling the matrix, or reducing the particle size. Matrix swelling can sometimes be increased by increasing the pressure of the solvent, and by adding modifiers to the solvent. Some polymers and elastomers in particular are swelled dramatically by CO_2, with diffusion being increased by several orders of magnitude in some cases.

Maximizing Solubility

Generally, higher pressure will increase solubility. The effect of temperature is less certain, as close to the critical point, increasing the temperature causes decreases in density, and hence dissolving power. At pressures well above the critical pressure, solubility is likely to increase with temperature. Addition of low levels of modifiers (sometimes called entrainers), such as methanol and ethanol, can also significantly increase solubility, particularly of more polar compounds.

Optimising Flow Rate

The flow rate of CO_2 should be measured in terms of mass flow rather than by volume because the density of the CO_2 changes according to the temperature both before entering the pump heads and during compression. Coriolis flow meters are best used to achieve such flow confirmation. To maximize the rate of extraction, the flow rate should be high enough for the extraction to be completely diffusion limited (but this will be very wasteful of solvent). However, to minimize the amount of solvent used, the extraction should be completely solubility limited (which will take a very long time). Flow rate must therefore be determined depending on the competing factors of time and solvent costs, and also capital

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costs of pumps, heaters and heat exchangers. The optimum flow rate will probably be somewhere in the region where both solubility and diffusion are significant factors.

3.9 Therapeutic Applications of Nutraceutical

Drug and food from natural origin play a significant role in public health care system of any nation. The search for specific constituents of plant, animals, minerals and microbial origin which are beneficial to our mental and physical health has caused coining of terminology such as nutraceuticals, cosmaceuticals, dermaceuticals, phytochemicals, phytonutrients, phytonutrients, phytofoods, pharmafoods, designer foods or functional foods. The term nutraceuticals and functional foods are broad terms describing foods, food ingredients or dietary supplements that demonstrate specific health or medical benefits including the prevention and treatment of disease beyond basic nutritional functions.

The term nutraceutical was coined in 1989 by Stephen De Felico former chairman of the foundation for innovation in medicine an American organization. Nutraceuticals are food or part of food that provide medical of health benefits including the prevention and treatment of disease.

Interest in Nutraceuticals

Nutraceutical have the potential to play a role in healthy eating and to contribute to the prevention and treatment of diseases so that how functional components in foods could expand the role of disease prevention and treatment. The nutraceuticals are preferred due to:

1. Since new molecule is difficult to discover and more expensive and risky then ever before, many pharmaceutical companies are now trying to nutraceuticals so that there is undoubtedly a very huge and growing market.
2. The belief among consumers that these "food like substances" are either harmless or least toxic as compared to conventional pharmaceuticals.
3. Increased healthcare costs with conventional pharmaceuticals, recent legislation and scientific discoveries.
4. Inappropriate dietary habits are seen as contributing to the leading cause of deaths of due to coronary heart disease, certain type of cancers etc., the role of nutraceuticals in treating these conditions is thus speculated.
5. The emergence of diet-disease relations have lead to search of specific constituents of plants, animals and minerals having a beneficial role for our mental and physical health.
6. Nutraceuticals are gaining popularity as people are relying on them for safeguarding their health and avoiding side effects associated with drugs as well.
7. As public knowledge in this field has evolved, manufacturers have sought to fulfill their appetite for these products resulting in exploding market. Japan, USA, UK is the world leaders in the nutraceuticals market. These are around 5000 established nutraceutical products, worldwide.

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8. Long history of use and better patient tolerance as well as public acceptance.
9. Renewable source, Cultivation and processing environmental friendly and Local availability.
10. Plants constitute to be a major source of new lead generation.

Rising Health Consciousness: The Major Growth Driver

Consumer today are more aware when it come to health, which makes them go for nutritional supplements.

1. Aging baby boomers
   - o Energy and preventive care early senior
   - o Health maintenance care late seniors
   - o Rising heart and bone problems among aged population
2. Rising health consciousness
   - o Concern on health during second half of life
   - o Concern on maintaining the healthy/youthfulness
   - o Paradigm shift towards preventive health care
3. Dissatisfaction with modern medicine
   - o Increased side effects
   - o Rising healthcare cost in modern treatment
4. Increase acceptance of alternative treatments
   - o Economical
   - o Less side effects
   - o Use in diseases which are untreated by modern medicine
   - o Increased standardization of products

Nutraceuticals are natural bioactive, chemical compounds that have health promoting, disease preventing or medicinal properties. Nutraceuticals are found in a mosaic of products emerging from *(a)* the food industry, *(b)* the herbal and dietary supplement market, *(c)* pharmaceutical industry, and *(d)* the newly merged pharmaceutical/ agribusiness/ nutrition conglomerates. It may range from isolated nutrients, herbal products, dietary supplements and diets to genetically engineered "designer" foods and processed products such as cereals, soups and beverages. It is often difficult to distinguish

Nutraceuticals	*Reported activity/use*
Liquorice	Expectorant, treatment of peptic ulcer
Isoflavons in soybeans	Reduces cholesterol, prevention of osteoporosis
Phosphatidylcholine	Natural treatment of liver disease
Ginger	Carminative, antiemetic, treatment of dizziness

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Kambocha tea	Improve diet, relief from arthritis and menstrual cramps
Glucosamaine-sulphate, Chondroitin-sulphate, vit C, vit D, vit E, zinc, selenium, copper	Osteoarthritis
Lycopene, resveratrol, beta-1, 3-glucans, soy	Management of cardiovascular disease
Green tea	Treatment of cancer
Carotenoids, lycopene and lutein	Prostate cancer
Antipain, leupeptin	Urokinase inhibitor (prostrate cancer
Fenugreek *(Trigonella foenum-graceum)*	Anti-diabetic, anti-cancer
Noni *(Morinda citrifolia)*	Relief blood pressure, muscle pain
Thymus vulgaris, rhus coriaria	Antibacterial activity
Sorrel	Enhance immune system
Geranum sanuineum	Antiviral

Among nutrients, food additives and drugs independent of the matrix (food or pill) in which it is taken a dietary supplement can sometimes be food like and other times drug like. One way to differentiate between food and drugs could be examining how people are exposed to them. Drugs can be found sometimes in foods, and can participate in the metabolism. However, these substances are not normally exposed in humans at the dose at which they exert their beneficial effect. Some dietary supplements are drug like when ingested in amount that could never be achieved in the diet, even though they are essential nutrients when ingested in smaller quantities. *e.g.*, tryptophan is an essential amino acid required for metabolism and incorporation into proteins at low dose in humans. At high dose, it increases brain 5-hydroxytryptamine levels and thus acts as a drug to treat insomnia. Polyunsaturated fatty acid likes leptin and statins that increases bone formation. The nutraceutical containing phytosterols are effective in lowering LDL cholesterol. Proteins and non-protiens of bovine milk fat globule membrane are potent nutraceutical that effective as anticancer, anticholesterolemic, coronary heart disease. The nutraceuticals of plant origin may evolve to be considered a vital aspect of dietary disease-preventive food components. Many years ago, the National Institute of health does not support researches that are focused on dietary means to solve health problems. Noteworthy is the recent establishment of Centers for study of alternative medicine around the world. Careful studies are being done on the various phytonutrients for their role in the prevention of chronic degenerative diseases. The sources of nutraceuticals include ginseng, spirulina, *gingko biloba*, amino acids, glucosamine, chondroitin and Aegle marmelos that are to be formulated and consumed or administered internally

under the supervision of a qualified medical practioner and intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

3.10 Pharma Foods

A food product with a pharmacological additive meant to improve health is called pharma food, for example, to lower cholesterol.

Today, consumers are taking a more proactive approach to managing their health and the prevention of diet-related diseases, such as obesity, diabetes, cardiovascular and bone and joint diseases. Many of these diseases are at epidemic levels, and this combined with increasing patient power makes the prevention of these lifestyle diseases attractive markets for both the food and pharmaceutical industries. In this particular section of the chapter, we are going to discuss various kind of pharma foods. These foods are used as a measures to cure the deseases.

Diabetic Nuts

People with diabetes have an increased risk of developing heart disease later in life. This risk can be reduced by replacing unhealthy saturated fats in the diet with healthy polyunsaturated and monounsaturated fats, such as those found in nuts. Some people with diabetes also benefit from replacing some of the carbohydrate rich foods in their diet with foods rich in monounsaturated fats.

Nuts have also been shown to improve cholesterol and triglyceride levels of those with diabetes.

- Nuts high in monounsaturated fat include macadamias, cashews, almonds, pistachios, and pecans.
- Nuts high in polyunsaturated fat include walnuts, hazelnuts, pine nuts and Brazil nuts.

One type of polyunsaturated fat that is particularly beneficial for the heart is omega-3. Nuts high in omega-3 include walnuts and pecans.

Low Glycaemic Index

Cashews, chestnuts and pecans have a low Glycaemic Index (GI) which means the carbohydrate they contain is broken down slowly by the body. This results in a slow, steady rise in blood glucose levels which is beneficial for people with diabetes. While the GI of other nuts has not been tested, all nuts, with the exception of chestnuts, are low in carbohydrate and high in protein. This means they are likely to have a low GI but further research is required to confirm this.

Arginine

Arginine is an amino acid or building block of protein found in nuts. Arginine has been shown to help insulin work more effectively in people with diabetes.

It can also improve the overall health of blood vessels, assisting in the prevention of heart-related complications of diabetes.

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Fibre

Nuts are a source of fibre. A diet high in fibre, particularly soluble fibre, improves blood glucose levels, helps insulin work more effectively, and lowers "bad" LDL cholesterol and triglyceride levels in people with diabetes.

Antioxidants

Antioxidants in nuts include phenolic compounds, tocotrienols, luteolin and flavonoid compounds. All of these help prevent clogged arteries, and improve the functioning of blood vessel walls.

Vitamin E

A diet low in vitamin E has been associated with the development of type 2 diabetes. Vitamin E has also been shown help insulin work more effectively in people with diabetes. An average serve (30 g) of nuts provides ~ 20% of the recommended dietary intake for vitamin E.

Why Should Nuts be Part of a Healthy Diet?

Healthy Fats

Just because nuts are high in fat doesn't mean they are unhealthy. Nuts are a great source of the good fats – monounsaturated and polyunsaturated fats – which are essential for regulating blood cholesterol.

- Nuts high in monounsaturated fats include macadamias, cashews, almonds, pistachios, and pecans.
- Nuts high in polyunsaturated fats include walnuts, hazelnuts, pine nuts and Brazil nuts.

Fibre

All nuts contribute fibre to the diet and eating foods rich in fibre, especially soluble fibre, helps to satisfy hunger for longer. Dietary fibre helps to lower blood cholesterol and is essential for healthy bowel function.

Vitamin E

Vitamin E is an antioxidant that helps protect tissues in the body from damage. An average serve (30 g) of mixed nuts provides ~20% of the recommended daily requirements.

Folate

Folate is a B vitamin associated with heart health, cancer protection and a lower risk of birth defects in newborn babies. Hazelnuts, chestnuts, cashews, pine nuts, pistachios and walnuts provide some folate.

Magnesium

Magnesium is a mineral essential for good nerve and muscle function and for strong bones. An average serve (30 g) of Brazil nuts, almonds and cashews provides more than 75% of the recommended dietary intake for magnesium.

Zinc

Zinc is needed for many processes in the body and is necessary for a strong immune system, and healing and protecting the skin. A third of a cup of cashews, almonds or pecans provides more than 15% of your recommended daily intake.

or gelatin such as Lokum/Turkish Delight, jelly beans, gumdrops, jujubes, cola bottles gummies, etc.

- **Marshmallow:** "Peeps" (a trade name), circus peanuts, fluffy puff, etc.
- **Marzipan:** An almond-based confection, doughy in consistency, served in several different ways. It is often formed into shapes mimicking (for example) fruits or animals. Alternatively, marzipan may be flavoured, normally withspirits such as Kirsch or Rum, and divided into small bite-sized pieces; these flavoured marzipans are generally served coated in chocolate to prevent the alcohol from evaporating, and are very common in northern Europe. Marzipan is also used in cake decoration. Its lower-priced version is called Persipan.
- **Divinity:** A nougat-like confectionery based on egg whites with chopped nuts.

Not all confections equate to "candy" in the American English sense. Non-candy confections include:

- **Pastry:** A baked confection whose dough is rich in butter, which was dispersed through the pastry prior to baking, resulting in a light, flaky texture; see also pie and tart.
- **Chewing Gum:** Uniquely made to be chewed, not swallowed. However, some people believe that at least some types of chewing gum, such as certain bubble gums, are indeed candy.
- **Ice Cream:** Frozen flavoured cream, often containing small chocolates and fruits.
- **Halvah:** Confectionery based on tahini, a paste made from ground sesame seeds.
- **Alfajor:** a traditional South American cookie typically consisting of two round sweet biscuits joined together with a sweet jam, generally dulce de leche (milk jam).
- **Dragée** - Coated almonds and other types of coated candy.

Risks

Excessive consumption of confectionery has been associated with increased incidences of type 2 diabetes, obesity, and tooth decay.

3.11 Sodium Free

The most common sodium salt, sodium chloride, is used for seasoning and warm-climate food preservation, such as pickling and making jerky (the high osmotic content of salt inhibits bacterial and fungal growth). The human requirement for sodium in the diet is about 500 mg per day, which is typically less than a tenth as much as many diets "seasoned to taste." Most people consume far more sodium than is physiologically needed.

For certain people with salt-sensitive blood pressure, this extra intake may cause a negative effect on health. However, low sodium intake may lead to sodium deficiency. To avoid the overdose of sodium, sodium free foods are recommended.

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A low-salt diet is beneficial for certain people with cardiovascular disease. Preliminary evidence has linked salt consumption with increased cardiovascular disease incidence and death among overweight people. Low-salt diets seem to be especially important for people with hypertension (high blood pressure). Salt intake has been definitively linked to hypertension in Western societies, and eliminating salt from the diet lowers blood pressure in most people.

Many people have difficulty finding ingredients in their local areas which are sodium free. So it seems worthwhile to discuss some of the more common ingredients in this section.

Low Sodium/Salt

A claim that a food is low in sodium, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.12 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. In the case of foods naturally low in sodium, the term "naturally" may be used as a prefix to this claim.

Very Low Sodium/Salt

A claim that a food is very low in sodium, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.04 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml. In the case of foods naturally very low in sodium, the term "naturally" may be used as a prefix to this claim.

Sodium-Free or Salt-Free

A claim that a food is sodium-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.005 g of sodium, or the equivalent value for salt, per 100 g. In the case of foods naturally sodium-free, the term "naturally" may be used as a prefix to this claim.

What are the Health Benefits of a Low Sodium Diet?

A low sodium diet is often recommended for those trying to prevent or reduce high blood pressure, diabetics or those with chronic kidney disease. Research also shows that populations with high sodium diets experience higher blood pressure as they age. Low sodium diets also tend to have fewer processed foods and more fruits and vegetables, which carry their own health benefits.

How Much Sodium Should One Eat?

The recommended maximum sodium intake is 2300 mg per day. However, many of us eat up to three times. A single fast food combo can contain more than 1500 mg of sodium.

What are Common Sources of Sodium?

Baking soda, baking powder, monosodium glutamate (MSG) are sources of sodium that are often overlooked. However, most of our sodium intake comes from eating processed foods. Many processed foods are very high in sodium, even though they may not taste salty; examples include baked goods, frozen

dinners, packaged side dishes, and soups. Most restaurant meals are also very high in sodium.

Are all high sodium foods bad for you?

Not always. Sodium's bad rap is linked to the fact that we now eat foods that are far more concentrated in sodium than is available naturally; these foods also tend to be highly processed and poor in nutrients. However, some foods are naturally higher in sodium.

Sea salt in its least processed form has a grayish tinge due to its mineral content, including iron, magnesium and potassium. Sea vegetables are also naturally higher in sodium as well as other vital micronutrients such calcium, iron, and vitamins A, C, E and B_{12}. If you are on a low sodium diet and enjoy sea vegetables, you may have to wait until your blood pressure is back to optimum levels before you reintroduce them to your diet. If you are on a no added salt diet, you may be able to enjoy sea veggies in moderation. Talk to your healthcare practioner for advice.

What can one eat on a low sodium diet?

It depends on the sodium level your healthcare practioner has recommended. Whole foods such as fresh fruits, vegetables, unsalted nuts and seeds and dried beans are naturally lower in sodium and should make up the bulk of your diet for better overall health. A no added salt diet (NAS) means simply putting the shaker away, and avoiding obviously salty foods like chips or canned soups.

A more restrictive diet, such as 2.3 grams sodium per day, means choosing whole foods and low sodium options of processed foods. At Choices markets, we maintain a listing of low sodium products available in store and label low sodium choices with an orange shelf tag. However, because ingredients are subject to change, please check the nutrition facts panels before you buy.

Is a food sodium free if it is labelled "no added salt"

Not necessarily. Some foods are naturally higher in sodium, and will contain sodium even if there is no salt added during processing. For example, Bragg's Liquid Seasoning has no added salt, but contains 140 mg of sodium per half teaspoon. Always check the Nutrition Facts label first, unless the package says "no sodium" or "sodium free". These are regulated terms that ensure a food has less than 5 mg of sodium per serving.

What about Potassium salt substitutes?

Some sodium free salt substitutes simply use potassium instead of sodium. Potassium occurs naturally in fruits, vegetables and whole grains. While extra potassium in your diet can help balance sodium levels, freely using potassium salt substitutes can aggravate kidney conditions. In addition, if you are currently on potassium sparing medication, such as certain diuretics, excess potassium can build and harm your heart. It may be best to stick to tried-and-true no salt added herb mixtures such as Mrs. Dash.

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Tips for Reducing Salt Intake

1. Avoid hidden sources of salt.

75% of our sodium intake comes from hidden sources, including packaged,prepared and restaurant foods.

2. Shop the perimeter of the supermarket.

Fresh foods like fruits, vegetables, lean meats and dairy are naturally lower in sodium. A diet that focuses on these foods has been clinically proven to lower high blood pressure more than just sodium restriction alone.

3. At restaurants, choose simpler foods without a lot of sauces.

Lean meats with vegetable sides and salads (ask for oil and vinegar at the table instead of dressing) are both good choices.

4. Spice up your life!

Many people use salt because they are uncertain of using the spice cabinet.

5. Have fun with food.

Buy a new exotic cookbook for inspiration, enlist some help and spend an evening cooking up some fun....Thai, Indian, and North African cuisine have wonderful flavours so that you can happily omit the salt.

6. Drop that muffin!

Be aware that baked goods are often remarkably high in sodium – baking soda is a salt!

7. Choose salt free versions of food.

Convenience foods like beans, canned tomatoes and other vegetables often come in salt free versions. Remember: frozen veggies are the more nutritious and naturally salt free!

8. Read labels!

Salt lurks where you least expect it. Reading labels helps you to avoid hidden sources. Just be sure to watch serving size – some seasonings will even use grams instead of milligrams to describe the sodium content to make it look lower than it is.

9. Switch sides.

Certain condiments, such as soy sauce, ketchup and BBQ sauces are very high in sodium. Try making your own mayo for a picnic potato salad. It is quite easy and quick if you do it while the eggs are cooking. Add a little dry mustard or garlic for extra zip! Salsa is another condiment that can be made easily from garden fresh ingredients and can be made ahead.

10. Be careful with salt substitutes.

Many are made with potassium instead of sodium and can aggravate kidney problems. If you are taking a potassium sparing diuretic, an excess of potassium can build and harm the heart. Stick to tried and true, salt free flavouring blends.

3.12 Lactose Free

Lactose is the simple sugar found in milk and milk products. It can also be found in a variety of other foods and even as a filler in some pills and capsules. The enzyme lactase, present in the lining of the small intestine, splits lactose into two simple sugars. These simple sugars can then be absorbed by the body and used as nourishment.

In infants, milk is the main part of the diet, so it is natural and normal for lactase production to gradually decrease as the diet becomes more varied. This tends to occur in childhood and adolescence in African Americans, Native American Indians, Hispanics, Arabs, Jews, and Asians. Northern European white races seem to keep lactase production the longest.

When lactase is absent, lactose passes through the intestine to the colon (large bowel), carrying extra fluid with it. In the colon, bacteria breakdown lactose into lactic acid and certain gases. Lactic acid is an irritant and laxative. It can cause symptoms such as bloating, diarrhea, abdominal cramps, and gas or flatus.

Lactase activity is reduced in people with certain intestinal conditions such as Crohn's disease and celiac disease (gluten enteropathy). Patients taking certain drugs and alcoholic patients may also be lactose intolerant. Finally, patients with surgical removal of part of the stomach or a large portion of the small intestine may need to reduce lactose in the diet.

It is important to remember that while lactose intolerance can cause quite uncomfortable symptoms, it does not cause damage to the intestine. The purpose of this diet is to eliminate lactose or reduce it to tolerable levels.

Nutrition Facts

Dairy products are important sources of calcium, riboflavin, and vitamin D. Some lactose-intolerant people are able to tolerate certain dairy products in small amounts, and their diets may provide enough of these nutrients. However, the physician or registered dietitian may recommend certain vitamin supplements and/or a calcium supplement for some patients.

Millions of people all over the world are changing to a lactose free food diet. With over 70 percent of the world's population diagnosed as having a milk allergy lactose free diets are becoming quite popular.

Many people are forced into changing to a lactose free food diet when they begin to notice digestion problems. Many times babies are diagnosed with a milk allergy early in life.

Lactose is a type of sugar that naturally exists in milk. People who have a milk allergy do not have high levels of the enzymes that breakdown lactose, which leads to digestive problems. Problems experienced by people who are lactose intolerant include:

- Diarrhoea
- Gas
- Stomach cramps
- Bloating

Many people are changing to a lactose free food diet because of other reasons. Milk has been known to cause problems for diabetics and contribute to cancer and high blood pressure in some people.

The first step to changing to a lactose free food diet such as Fertiggerichte is to become educated on what lactose is and products contain lactose. Milk and dairy products are pretty obvious but other products also contain lactose. Some drink mixes, such as hot chocolate mixes or breakfast powders also contain lactose.

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Look at labels before you buy foods. Many pasta sauces are made with cream or cheese. Dressings, sauces, baked goods, cereals, and many other everyday foods have a lactose component.

The nutrition labels on packaged items should give you the information you need to determine if a food contains lactose.

Also be careful when ordering in restaurants. There are many vegetarian restaurants in most cities that prepare lactose free food. These restaurants offer healthy food that tastes great and are the perfect choice for a person with milk allergies. In a regular restaurant stick to fresh items and don't be afraid to ask your server to check with the chef if you are unsure of an item.

The second in changing to a lactose free food diet is to keep positive about your situation. It is easy to become depressed if you are no longer able to have your favourite foods.

Fortunately, many companies are now making lactose free foods including Fertiggerichte that are as good as your old favorites. Many grocery stores have a lactose free section.

Another way to keep positive is to think of all the yummy fresh foods you can have and how healthy you will be on your new diet. You can experiment with new recipes and food items.

Special Considerations

Tolerance of lactose is variable. Some people can eat small amounts of lactose without having symp- toms while others need to avoid it completely.

- **Low-Lactose Diet:** generally eliminates only milk and milk products. However, some can tolerate milk in small amounts (2 oz) throughout the day or as part of a meal. Some can tolerate small amounts of yogurt. These patients can experiment to find a level of lactose they can tolerate. Some people can build up their level of tolerance by gradually introducing the lactose-containing foods.
- **Lactose-Free Diet:** all lactose products must be eliminated, including foods that are prepared with milk, both at home and in commercially packaged foods. These people may be able to use 100% lactose free milk or soy milk. Labels should always be read carefully.
- **Lactase Digestive Aids and Products:** Many people can drink milk in which the lactase has been partially or completely broken down. The following products may be available at a pharmacy or grocery store.

Lactaid and Dairy Ease Enzyme Products— check with a pharmacist, registered dietitian, or a physician for individual guidance on the use of these products.

- **Drops:** These are added to milk. Five, 10, or 15 drops per quart of milk will generally reduces lactose content by 70%, 90%, or 99% respectively over a 24-hour period
- **Caplets/Capsules:** A person chews or swallows 1 to 6 of these when starting to eat foods containing lactose

Lactaid Milk

- Non-fat or 1% low-fat is 70% lactose reduced
- Non-fat calcium-fortified is 70% lactose reduced and 500 mg of calcium per cup has been added
- Non-fat Lactaid 100 is completely lactose free

Dairy Ease Milk

- Available in non-fat, 1%, or 2% low-fat - all are 70% lactose reduced

Soy Milk

- Calcium-fortified soy milk has no lactose, is low in fat and is a good source of Vitamin D.

Food Groups

Group	Lactose-Free	Lactose-Containing
Milk & milk products	100% lactose-free milk, soy milk	milk: whole, skim, 1%. 2%; buttermilk; sweet acidophilus milk; lactose-reduced milk; evaporated milk; acidophilus milk; sweetened condensed milk; instant hot chocolate and cocoa mixes; cheese
Vegetables	fresh, frozen, and canned vegetables without added milk or milk products; tomato paste and purée; tomato and spaghetti sauces without cheese	creamed or breaded vegetables, packaged dried potato mixes, tomato and spaghetti sauce with cheese
Fruits	fresh, frozen, canned, and dried fruits	none
Breads & grains	water-based breads (Italian, French, Jewish rye), rice and popcorn cakes, graham crackers, rusks, Pareve-Jewish bakery products, cooked and dry cereals without added milk solids, pasta, rice, oats, barley, cornmeal,	the following made with milk or milk products, breads, rolls, biscuits, muffins, pancakes, sweet rolls, waffles, crackers, instant and dry cereals with added milk products, some packaged grain mixes, packaged macaroni mixes

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	bulgar, and other plain grains	
Meat or meat substitutes	plain beef; lamb; veal; pork; wild game; poultry; fish; shellfish; eggs; kosher prepared meat products; peanut butter; peas, beans, or lentils (dried, canned or frozen); all nuts and seeds; tofu	eggs, fish, meat, or poultry (breaded or creamed); luncheon meats; sausage; frankfurters; some brands of egg substitutes and powdered eggs
Fats & oils	bacon, butter, margarine without milk derivatives (whey), salad dressing without cheese or milk, vegetable oils, olives, most non-dairy creamers, mayonnaise, gravy made without milk or milk products	cream, half & half, sour cream, cream cheese, chip dips, some types of margarine, salad dressing with cheese or milk, whipped toppings
Sweets & desserts	angel food cake, gelatin, fruit ice, fruit popsicles, fruit roll ups, hard candy, gum drops, jelly beans, licorice, fruit pie fillings	ice cream, ice milk, some brands of sherbet, soufflé, mousse, pudding, custard, packaged dessert mixes, milk chocolate, toffee, caramel, butterscotch
Beverages	Postum, lactose-free nutritional supplements (Sustacal, Ensure, Nutren), vegetable juice, fruit juices and drinks, tea, carbonated beverages, beer, wine, distilled spirits (gin, rum, etc.), cocoa powder, most coffee	instant iced tea, instant coffee, Ovaltine, chocolate drink mixes, cordials, liqueurs, milk-based nutritional supplements (Carnation Instant Breakfast)

Soups	bouillon, broth, meat, or vegetable stock soups; bisques and chowders made with water, soy milk, or 100% lactose-free milk	cream soup, canned and dehydrated soup mixes containing milk products
Miscellaneous	popcorn, plain pretzels, plain potato and corn tortilla chips, salsa, mustard, ketchup, pickles, uncreamed horseradish, relish, sauces made without milk or milk products, sugar, honey, jams and jellies, maple and corn syrup, molasses, herbs, spices, salt, pepper	cream or cheese sauces, ranch-style or cheese-flavored snack pretzels or chips, cheese curls, sugar substitutes with lactose added, medications and vitamin/mineral supplements with lactose added

3.13 Phenylalanine Free Foods

Phenylalanine (abbreviated as Phe or F) is an amino acid with the formula $HO_2CCH(NH_2)CH_2C_6H_5$, which is found naturally in the breast milk of mammals and manufactured for food and drink products and are also sold as nutritional supplements for their reputed analgesic and antidepressant effects. Phenylalanine is structurally closely related to dopamine, epinephrine (adrenaline) and tyrosine. It is a direct precursor to the neuromodulator phenylethylamine a commonly used dietary supplement.

This essential amino acid is classified as nonpolar because of the hydrophobic nature of the benzyl side chain. The codons for L-phenylalanine are UUU and UUC. It is a white, powdery solid. L-Phenylalanine (LPA) is an electrically-neutral amino acid, one of the twenty common amino acids used to biochemically form proteins, coded for by DNA.

Phenylketonuria

Phenylketonuria (PKU) is a rare, inherited, metabolic disorder that can result in mental retardation and other neurological problems. People with this disease have difficulty breaking down and using (metabolizing) the amino acid phenylalanine. PKU is sometimes called Folling's disease in honor of Dr. Asbjorn Folling who first described it in 1934.

Phenylalanine is an essential amino acid. These substances are called "essential" because the body must get them from food to build the proteins that makeup its tissues and keep them working. Therefore, phenylalanine is required for normal development. Phenylalanine is a common amino acid and is found in

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all natural foods. However, natural foods contain more phenylalanine than required for normal development. This level is too high for patients with PKU, making a special low-phenylalanine diet a requirement.

The incidence of PKU is approximately one in every 15,000 births (1/15,000).There are areas in the world where the incidence is much higher, particularlyIreland and western Scotland. In Ireland the incidence of PKU is 1/4,500 births. This is the highest incidence in the world and supports a theory that the genetic defect is very old and of Celtic origin. Countries with very littleimmigration from Ireland or western Scotland tend to have low rates of PKU.In Finland, the incidence is less than 1/100,000 births. Caucasians in the United States have a PKU incidence of 1/8,000, whereas Blacks have an incidence of 1/50,000.

There are a number of specific types of PKU. Maternal phenylketonuria is a condition in which a high level of phenylalanine in a mother's blood causes mental retardation in her child when in the uterus. A woman who has PKU and is not using a special low-phenylalanine diet will have high levels of phenylalanine in her blood. Her high phenylalanine levels will cross the placenta and affect the development of her child. The majority of children born from thesepregnancies are mentally retarded and have physical problems, including smallhead size (microcephaly) and congenital heart disease. Most of these children do not have PKU. There is no treatment for maternal phenylketonuria. Control of maternal phenylalanine levels is thought to limit the effects of maternal phenylketonuria.

Hyperphenylalaninemia is a condition in which patients have high levels of phenylalanine in their blood, but not as high as seen in patients with classical PKU. There are two forms of hyperphenylalaninemia: mild and severe.

Tyrosinemia is characterized by a high levels of two amino acids in the blood, phenylalanine and tyrosine. Patients with this disease have many of the same symptoms as seen in classical PKU, including mental retardation. Treatmentconsists of a special diet similar to the diet for PKU. The main difference between the two diets is that patients with tyrosinemia must eat a diet that is low in both phenylalanine and tyrosine.

The underlying cause of PKU is mutation in the gene that tells the body to make the enzyme phenylalanine hydroxylase. This enzyme allows the body to breakdown phenylalanine and ultimately use it to build proteins. Normally, the first step in phenylalanine metabolism is conversion to tyrosine, another amino acid. The genetic mutations result in no enzyme or poor quality enzyme beingmade. As a consequence, phenylalanine is not converted and builds up in the body. The high levels of phenylalanine can be detected in the blood and urine.

PKU is a genetic disease. A child must inherit defective genes from both parents to develop PKU. A person with one defective gene and one good gene will develop normally because the good gene will make sufficient phenylalanine hydroxylase. People with one good gene are called carriers because they do not have the disease, but are capable of passing the defective gene on to their children.

If both parents are carriers of defective phenylalanine hydroxylase genes, then the chances of their child having PKU is one in four or 25%. The chances

that their child will be a carrier is two in four, or 50%. These percentages hold for each pregnancy.

Children with PKU appear normal at birth, but develop irreversible mental retardation unless treated early. Treatment consists of a special diet that contains very little phenylalanine.

This diet must be used throughout the patient's life. Untreated newborns develop disease symptoms at age three to five months. At first they appear to be less attentive and may have problems eating. By one year of age, they are mentally retarded.

Patients with PKU tend to have lighter coloured skin, hair, and eyes than other family members. They are also likely to have eczema and seizures. PKU patients have a variety of neurologic symptoms. Approximately 75—90% of PKU patients have abnormal electrocardiograms (ECGs), which measure the activity of their heart. Their sweat and urine may have a "mousy" smell that is caused by phenylacetic acid, a byproduct of phenylalanine metabolism. Untreated PKU children tend to be hyperactive and demonstrate loss of contact with reality (psychosis).

PKU must be detected shortly after birth. Although children with PKU appear normal at birth, they already have high phenylalanine levels. Screening is theonly way to detect PKU before symptoms start to develop. In many areas of the world, screening newborns for PKU is performed routinely. The test is typically performed between one and seven days after birth. Blood is obtained by pricking the heel of the newborn and analyzing it for phenylalanine concentration.

The only treatment for persons with PKU is to limit the amount of phenylalanine in their diet. PKU patients should eat a special diet that is low in phenylalanine. The diet has small amounts of phenylalanine because it is essentialfor normal growth and development. The diet should be started before the fourth week of life to prevent mental retardation. If started early enough, thediet is 75% effective in preventing severe mental retardation. Many natural foods, including breast milk, must be avoided because they contain more phenylalanine than PKU patients can tolerate. However, low protein, natural foods,including fruits, vegetables, and some cereals, are acceptable on the diet. Monitoring of blood phenylalanine levels must be done to ensure that normal levels are maintained.

Patients who make a small amount of phenylalanine hydroxylase can eat a limited amount of regular food if their phenylalanine levels remain within an acceptable range. Low-phenylalanine and phenylalanine-free foods are available commercially. The special diet must be used throughout the patient's life.

What is Included in a Low Phenylalanine Food Pattern?

The diet for PKU consists of a phenylalanine-free medical formula and carefully measured amounts of fruits, vegetables, bread, pasta, and cereals. Many people who follow a low phenylalanine (phe) food pattern eat special low protein breads and pastas. They are nearly free of phe, allow greater freedom in food choices, and provide energy and variety in the food pattern.

What is Not Included in a Low Phenylalanine Food Pattern?

Foods that contain large amounts of phe must be eliminated from a low phe diet. These foods are high protein foods, such as milk, dairy products, meat,

fish, chicken, eggs, beans, and nuts. These foods cause high blood phe levels for people with PKU.

3.14 Fiber Rich Foods

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A fiber deficiency increases risk of constipation, hemorrhoids, high cholesterol, high blood sugar, obesity, colon cancer and heart disease. In other words, high fiber foods are essential if someone wants to look and feel best.

And if that's not enough, eating more foods from this list of high fiber foods will give him/her the strength and inclination to get up and "go" – on a "regular" basis.

Most Americans get only about 10 grams of fiber daily. That's not nearly enough. One need an intake of 30 to 40 grams of fiber a day for optimum health.

Fiber is an indigestible part of all plant foods. It is found in fruits, vegetables, grains and beans. The digestive system cannot stomach fiber, so it is excreted undigested. Well, you may think you don't need fiber, because it's excreted undigested, but that's not true.

Let's imagine the following condition:

You overeat at least once or twice a week, more often at weekends, and your regular menu doesn't include much fiber. Well, this might be your life style; however you should consider that it may cause you lots of health problems like:

- indigestion
- discomfort stomach aches
- gases in the digestive tract
- constipation
- hemorrhoids
- you got tired faster
- can't concentrate on what you're doing

It means you become less productive at work and more irritable at home. Besides all this, you gain weight and that's the moment when you realize you have a problem.

In order to solve a problem, you should first find the reason for it. In this case it's the lowered intake of fiber-rich foods and respectively - the higher intake of foods containing no fiber (like meat). The average amount of fiber intake is about 25—30 grams per day. Unfortunately most people regular diets include less than 10—15 grams daily.

A person should start consuming more fiber-rich foods:

- all bran cereal
- beans
- peas
- spinach
- sweet corn
- wholemeal brown bread

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- red cabbage
- carrots
- baked potato with skin
- apples, bananas, oranges and all fruits

There are two types of fiber - soluble and insoluble. If someone starts eating more food rich in fiber, he/she be amazed of its beneficial effects over his/her body, health and way of life.

Soluble fiber forms glue like gel in the intestinal tract. The gel softens stools (no more constipation) and improves the digestion (no more indigestion).

Fiber slows down stomach emptying and the person feels fuller longer. This effect helps him/her eat less, his/her body burns additional calories to digest fiber and he/she can lose weight.

Insoluble fiber is an excellent natural laxative, because of its abilities to hold onto water and to push waste faster along the intestines - this way fiber decreases the risk of colon cancer.

Eating more dietary fiber can have numerous health benefits, and fortunately there are a lot of fiber rich foods which can easily be added to the diet. These foods are readily available at grocery markets, and they can be prepared in a variety of ways; eating a high fiber diet does not have to mean eating woody, bland foods. Small adjustments in life style and diet can make a big difference, and one of the easiest adjustments to make is eating more fiber.

Whole grains are especially fiber rich foods. They can also be integrated into one's diet relatively easily, by switching to whole grains instead of hulled grains. Brown rice instead of white rice, whole wheat bread instead of white bread, and bran cereals instead of cereals made with refined grains are all options for adding more whole grains into the diet. Whole grains have a somewhat more intense, nutty flavour, but many people find this flavour enjoyable once they become accustomed to it.

Vegetables like corn, carrots, and whole potatoes are also fiber rich foods, along with dark leafy greens such as kale and broccoli. In addition to being high in fiber, these foods also have lots of vitamins and minerals, making them a great addition to the diet. Vegetables can be eaten raw or cooked, and prepared in an assortment of ways from salads to casseroles so that they don't get boring. Beans and legumes such as lentils are some additional fiber rich foods.

Some fruits are also high in fiber. Berries in particular have lots of fiber, as do apples and guavas. Fresh whole fruit is an easy snack, and fruit can make a great alternative to snacks made from processed foods, which may be lower in fiber and less beneficial in terms of their nutritional content. Fruit can also be eaten in smoothies, for people who are not fond of eating plain whole fruit.

Many weight loss plans include a recommendation to add more dietary fiber, and fiber rich foods can also be generally beneficial for human health, in the case of people who are not interested in weight loss. Eating more fiber tends to smooth digestion, and it can alleviate some intestinal problems. High fiber diets have also been linked to a decrease in the incidence of colon cancer, and since many fiber rich foods are also rich in vitamins and minerals, they provide general nutritional support which can be highly beneficial.

Student Activity

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1. Discuss the features of nutraceuticals.

2. Explain the therapeutical applications of nutraceuticals.

3. Discuss the basic features of phenylalanin free foods.

Summary

1. Nutraceutical, a portmanteau of nutrition and pharmaceutical, refers to extracts of foods claimed to have a medicinal effect on human health. traditionally the nutraceutical was contained in a medicinal format such as a capsule, tablet or powder in a prescribed dose.

2. Nutraceutical word–with "nutra" derived from nutrition and "ceutical" from pharmaceutical refers to substances that may be considered a food or part of a food and may provide medical and health benefits.

3. Dietary supplements are defined by federal law as products taken by mouth that contain a "dietary ingredient" intended to add something to the foods you eat. Examples of dietary supplements are black cohosh for menopausal symptoms, ginkgo biloba for memory loss, and glucosamine/chondroitin for arthritis.

4. A free radical has defined as any species capable of independent existence that contain one more unpaired electron. Unpaired electron makes the molecule unstable and highly reactive.

5. Dietary fibres are used in health food products for normalization of intestinal transit time. They have dual effect on intestinal transit. First effect is on the bulk faeces, which are often increased, in substantial proportion (127% after ingestion of 20 g of wheat bran, this action with insoluble fibres. The other effect if dietary fibres are upon the duration of transit, which gets normalized around in 48 hrs.

6. A food product with a pharmacological additive meant to improve health is called pharma food, for example, to lower cholesterol.

7. Lactose is the simple sugar found in milk and milk products. It can also be found in a variety of other foods and even as a filler in some pills and capsules. The enzyme lactase, present in the lining of the small intestine, splits lactose into two simple sugars.

Glossary

Nutraceutical: foods claimed to have a medicinal effect on human health.

Dietary supplement: product that contain a "dietary ingredient".

Free Radicals: species capable of independent existence that contain one more unpaired electron.

Probiotics: living microbial food ingredients.

Supercritical Fluid Extraction (SFE): A process of separating one component (the extractant) from another (the matrix) using supercritical fluids as the extracting solvent.

Pharma Food: A food product with a pharmacological additive meant to improve health.

Arginine: an amino acid or building block of protein found in nuts.

Confectionery: the set of food items that are rich in sugar.

Lactose: the simple sugar found in milk and milk products.

Phenylketonuria (PKU): a rare, inherited, metabolic disorder that can result in mental retardation and other neurological problems.

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Review Questions

1. Give the definition and examples of nutraceuticals.
2. What are the significance of nutraceuticals?
3. What the basic sources of nutraceuticals?
4. Classify the nutraceuticals and discuss each one of them.
5. Why is nutraceutical considered as the functional food of future diet?
6. Give the defition and examples of pharma foods.
7. Why is diabetic nuts important in the diets?
8. What is the significance of confectionaries?
9. Discuss about the lactose free and fiber rich foods.

Further Readings

Functional Foods: Designer Foods, Pharmafoods, Nutraceuticals (Hardcover) by Israel Goldberg (Editor); Publisher: Chapman & Hall (December 1994)

Methods of Analysis for Functional Foods and Nutraceuticals by W. Jefferey Hurst (editor); Publisher -CRC Press USA; year - 2002

Functional Foods Biochemical and Processing Aspects, Vol. I; Author - G. Mazza (editor); Publisher -CRC Press USA; year - 1998

Functional Foods Biochemical and Processing Aspects, Vol II; Author - John Shi; G. Mazza; Marc Le Maguer (editors); Publisher - CRC Press, USA; year - 2002

Functional Foods Designer Food, Pharmafoods, Nutraceuticals by Author - Goldberg, I. (editor); Publisher - Chapman and Hall, New York; year - 1994

Handbook of Fermented Functional Foods by Author - Edward R Farnworth; Publisher - CRC Press, USA; year - 2003

UNIT—IV

DIETARY SUPPLEMENTS AND NON NUTRITIVE SWEETENERS

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Objectives

After going through this unit, students will be able to:

- understand fortification of nutrients in the processed foods;
- state the concept of food processing;
- expain the role of dietary supplements in health;
- point out the need, importance and types of non-nutritive sweeteners;
- discuss the therapeutical applications of sweeteners.

STRUCTURE

4.1 Introduction

A dietary supplement, also known as food supplement or nutritional supplement, is a preparation intended to provide nutrients, such as vitamins, minerals, fiber, fatty acids or amino acids, that are missing or are not consumed in sufficient quantity in a person's diet. Some countries define dietary supplements as foods, while in others they are defined as drugs.

Supplements containing vitamins or dietary minerals are included in the Codex Alimentarius Commission, a guidebook on food safety sponsored by the United Nations.

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4.2 Regulation

European Union

The Food Supplements Directive requires that supplements be demonstrated to be safe, both in quantity and quality. Some vitamins are essential in small quantities but dangerous in large quantities, notably Vitamin A. Consequently, only those supplements that have been proven to be safe may be sold without prescription. A survey conducted in Ireland in 2001, of adults aged 18—64 years, suggested that with the possible exception of niacin (flushing) and vitamin B6 (neuropathy), there appears to be little risk of the occurrence of adverse effects due to excessive consumption of vitamins in this population, based on current dietary practices.

As a category of food, food supplements cannot be labeled with drug claims in the bloc but can bear health claims and nutrition claims.

Legal Challenge

The dietary supplements industry in the UK, one of the 27 countries in the European Union, strongly opposed the Directive. In addition, a large number of consumers throughout Europe, including over one million in the UK, and many doctors and scientists, have signed petitions against what are viewed by the petitioners as unjustified restrictions of consumer choice. In 2004, along with two British trade associations, the Alliance for Natural Health had a legal challenge to the European Union's Food Supplements Directive referred to the European Court of Justice by the High Court in London. Although the European Court of Justice's Advocate General subsequently said that the EU's plan to tighten rules on the sale of vitamins and food supplements should be scrapped, he was eventually overruled by the European Court, which decided that the measures in question were necessary and appropriate for the purpose of protecting public health. ANH, however, interpreted the ban as applying only to synthetically produced supplements - and not to vitamins and minerals normally found in or consumed as part of the diet. Nevertheless, the European judges did acknowledge the Advocate General's concerns, stating that there must be clear procedures to allow substances to be added to the permitted list based on scientific evidence. They also said that any refusal to add a product to the list must be open to challenge in the courts.

Russia

Russian legislation, Ministry of Health's order number 117 dated as of 15 April 1997, under the title "Concerning the procedure for the examination and

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health certification of Biologically Active Dietary Supplements", provides the usage of the following terminology:

> As a rule, BADSs are foodstuffs with clinically proven effectiveness. BADSs are recommended not only for prophylactics, but can be included into a complex therapy for the prevention of pharmaceutical therapy's side effects and for the achievement of complete remission.

The development of BADSs and their applications has been very fast moving. They were originally considered as dietary supplements for people who had heightened requirements for some normal dietary components (for example, sportsmen). Later, they were employed as preventive medicines against chronic diseases.

United States

In the United States, a dietary supplement is defined under the Dietary Supplement Health and Education Act of 1994 (DSHEA) as a product that is intended to supplement the diet and contains any of the following dietary ingredients:

- a vitamin
- a mineral
- an herb or other botanical (excluding tobacco)
- an amino acid
- a dietary substance for use by people to supplement the diet by increasing the total dietary intake, or
- a concentrate, metabolite, constituent, extract, or combination of any of the above

Furthermore, it must also conform to the following criteria:

- intended for ingestion in pill, capsule, tablet, powder or liquid form
- not represented for use as a conventional food or as the sole item of a meal or diet
- labelled as a "dietary supplement"

4.3 Fortification of Nutrients in the Processed Foods

Food fortification is the public health policy of adding micronutrients (essential trace elements and vitamins) to foodstuffs to ensure that minimum dietary requirements are met.

Simple diets based on staple foods with little variation are often deficient in certain nutrients, either because they are not present in sufficient amounts in the soil of a region, or because of the inherent inadequacy of the diet. Addition of micronutrients to staples and condiments can prevent large-scale deficiency diseases in these cases.

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Rationale

Several ranges of food supplements are recognised:

- additives which repair a deficit to "normal" levels
- additives which appear to enhance a food
- supplements taken in addition to the normal diet

Many physicians today disagree with the premise that foodstuffs need supplementation, but accept that - for example added calcium may provide benefit, or that adding folic acid may correct a nutritional deficiency especially in pregnant women.

On a more controversial level, but well founded in scientific basis, is the science of using foods and food supplements to achieve a defined health goal. A common example of this use of food supplements is the extent to which body builders will use amino acid mixtures, vitamins and phytochemicals to enhance natural hormone production, increase muscle and reduce fat.

Moving on from this reasonably accepted usage, there is increasing evidence for the use of food supplements in established medical conditions. This nutritional supplementation using foods as medicine (nutraceuticals) has been effectively used in treating disorders affecting the immune system up to and including cancers. This goes beyond the definition of "food supplement", but should be included for the sake of completeness.

Food Supplements

There are several main groups of food supplements which can be considered:

- Vitamins and co-vitamins
- Essential minerals
- Essential fatty acids
- Essential amino acids
- Glyconutrients
- Phytonutrients

Examples of Fortified Foods

Iodised salt has been used in the United States since before World War II.

Folic acid is added to flour in many industrialized countries, and has prevented a significant number of neural tube defects in infants. It is, however, not uniform in its application, with more intake of folic acid through fortified flour among those who were already receiving high amounts through their diet.

Niacin has been added to bread in the USA since 1938 (when voluntary addition started), a programme which substantially reduced the incidence of pellagra.

Vitamin D is added to a few foods (especially margarine).

Fluoride salts are added to water and toothpastes to prevent tooth decay. Water fluoridation is a controversial topic in some segments of the general public, although less so amongst established scientific bodies.

Calcium is frequently added to fruit juices, carbonated beverages and rice.

"Golden rice" is a variety of rice which has been genetically modified to produce beta carotene.

A wide range of iron compounds, including ferrous sulfate, ferrous fumarate and even elemental iron powder are added to food (usually cereal flours, but also table salt, milk and condiments) in a number of countries to prevent iron deficiency anemia. Although iron intake is often sufficient in developing countries, the bioavailability of the dietary iron is low, due to such factors as polyphenols and phytic acid binding the iron and preventing its absorption. Major challenges in iron fortification are to avoid undesirable changes in the appearance and taste of the food, and to target the population segment that needs the fortification the most.

4.4 Food Processing

Food processing is the set of methods and techniques used to transform raw ingredients into food or to transform food into other forms for consumption by humans or animals either in the home or by the food processing industry. Food processing typically takes clean, harvested crops or slaughtered and butchered animal products and uses these to produce attractive, marketable and often long-life food products. Similar process are used to produce animal feed.

Extreme examples of food processing include the delicate preparation of deadly fugu fish or preparing space food for consumption under zero gravity.

Food Processing Methods

Common food processing techniques include:

- Removal of unwanted outer layers, such as potato peeling or the skinning of peaches.
- Chopping or slicing *e.g.* diced carrots.
- Mincing and macerating
- Liquefaction, such as to produce fruit juice
- Fermentation *e.g.* in beer breweries
- Emulsification
- Cooking, such as boiling, broiling, frying, steaming or grilling
- Deep frying
- Baking

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- Mixing
- Addition of gas such as air entrainment for bread or gasification of soft drinks
- Proofing
- Spray drying
- Pasteurization
- Packaging

History

Food processing dates back to the prehistoric ages when crude processing incorporated slaughtering, fermenting, sun drying, preserving with salt, and various types of cooking (such as roasting, smoking, steaming, and oven baking). Salt-preservation was especially common for foods that constituted warrior and sailors' diets, up until the introduction of canning methods. Evidence for the existence of these methods exists in the writings of the ancient Greek , Chaldean, Egyptian and Roman civilizations as well as archaeological evidence from Europe, North and South America and Asia. These tried and tested processing techniques remained essentially the same until the advent of the industrial revolution. Examples of ready-meals also exist from pre industrial revolution times such as the Cornish pasty and the Haggis

Modern food processing technology in the 19th and 20th century was largely developed to serve military needs. In 1809 Nicolas Appert invented a vacuum bottling technique that would supply food for French troops, and this contributed to the development of tinning and then canning by Peter Durand in 1810. Although initially expensive and somewhat hazardous due to the lead used in cans, canned goods would later become a staple around the world. Pasteurization, discovered by Louis Pasteur in 1862, was a significant advance in ensuring the microbiological safety of food.

In the 20th century, World War II, the space race and the rising consumer society in developed countries (including the United States) contributed to the growth of food processing with such advances as spray drying, juice concentrates, freeze drying and the introduction of artificial sweeteners, colouring agents, and preservatives such as sodium benzoate. In the late 20th century products such as dried instant soups, reconstituted fruits and juices, and self cooking meals such as MRE food ration were developed.

In western Europe and North America, the second half of the 20th century witnessed a rise in the pursuit of convenience, food processors especially marketed their products to middle-class working wives and mothers. Frozen foods (often credited to Clarence Birdseye) found their success in sales of juice concentrates and "TV dinners". Processors utilised the perceived value of time to appeal to the

postwar population, and this same appeal contributes to the success of convenience foods today.

Benefits

Mass production of food is much cheaper overall than individual production of meals from raw ingredients. Therefore, a large profit potential exists for the manufacturers and suppliers of precessed food products. Individuals may see a benefit in convenience, but rarely see any direct financial cost benefit in using processed food as compared to home preparation. Poor quality ingredients and sometimes questionable processing and preservation methods detract greatly from the overall benefit gained by individual consumers.

More and more people live in the cities far away from where food is grown and produced. In many families the adults are working away from home and therefore there is little time for the preparation of food based on fresh ingredients. The food industry offers products that fulfil many different needs: From peeled potatoes that only have to be boiled at home to fully prepared ready meals that can be heated up in the microwave oven within a few minutes.

Benefits of food processing include toxin removal, preservation, easing marketing and distribution tasks, and increasing food consistency. In addition, it increases seasonal availability of many foods, enables transportation of delicate perishable foods across long distances, and makes many kinds of foods safe to eat by de-activating spoilage and pathogenic microorganisms. Modern supermarkets would not be feasible without modern food processing techniques, long voyages would not be possible, and military campaigns would be significantly more difficult and costly to execute.

Modern food processing also improves the quality of life for allergists, diabetics, and other people who cannot consume some common food elements. Food processing can also add extra nutrients such as vitamins. Processed foods are often less susceptible to early spoilage than fresh foods, and are better suited for long distance transportation from the source to the consumer. Fresh materials, such as fresh produce and raw meats, are more likely to harbour pathogenic microorganisms *(e.g. Salmonella)* capable of causing serious illnesses.

Drawbacks

In general, fresh food that has not been processed other than by washing and simple kitchen preparation, may be expected to contain a higher proportion of naturally-occurring vitamins, fiber and minerals than an equivalent product processed by the food industry. Vitamin C, for example, is destroyed by heat and therefore canned fruits have a lower content of vitamin C than fresh ones.

Food processing can lower the nutritional value of foods, and introduce hazards not encountered with naturally-occurring products. Processed foods often

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include food additives, such as flavourings and texture-enhancing agents, which may have little or no nutritive value, or be unhealthy. Preservatives added or created during processing to extend the 'shelf-life' of commercially-available products, such as nitrites or sulphites, may cause adverse health effects. Use of low-cost ingredients that mimic the properties of natural ingredients (*e.g.* cheap chemically-hardened vegetable oils in place of more-expensive natural saturated fats or cold-pressed oils) have been shown to cause severe health problems, but are still in widespread use because of cost concerns and lack of consumer knowledge about the effects of substitute ingredients.

Processed foods often have a higher ratio of calories to other essential nutrients than unprocessed foods, a phenomenon referred to as "empty calories". So-called junk food, produced to satisfy consumer demand for convenience and low cost, are most often mass-produced processed food products. Because processed food ingredients are often produced in high quantities and distributed widely amongst added-value food manufacturers, failures in hygiene standards in 'low-level' manufacturing facilities that produce a widely-distributed basic ingredient can have serious consequences for many final products. Consequently, adequate government regulation of ingredient manufacturers is an essentially important factor in securing the production of generally-safe processed foods. Blame for failures in the process of food safety regulation therefore often fall on the governmental department entrusted with this task.

Performance Parameters for Food Processing

When designing processes for the food industry the following performance parameters may be taken into account:—

- Hygiene, e.g. measured by number of microorganisms per *ml* of finished product
- Energy consumption, measured *e.g.* by "ton of steam per ton of sugar produced"
- Minimization of waste, measured *e.g.* by "percentage of peeling loss during the peeling of potatoes'
- Labour used, measured *e.g.* by "number of working hours per ton of finished product"
- Minimization of cleaning stops measured *e.g.* by "number of hours between cleaning stops"

Trends in Modern Food Processing

Cost Reduction

- Profit Incentive drives most of the factors behind any industry; the food industry not least of all. Health concerns are generally subservient to profit

potential, leading the food processing industry to often ignore major health concerns raised by the use of industrially-produced ingredients (partially-hydrogenated vegetable oils, for example, a well-known and well-researched cause of heart disease, that is still commonly used in processed food to increase profit margin.) Consumer pressure has led to a reduction in the use of industrially-produced ingredients in processed food, but the (often slight) potential for increased profits has barred widespread accceptance by the industry of recognized health problems caused by over-consumptiom of processed foods.

Health

- Reduction of fat content in final product *e.g.* by using baking instead of deep-frying in the production of potato chips, another processed food
- Maintaining the natural taste of the product *e.g.* by using less artificial sweetener than they used before...

Hygiene

The rigorous application of industry and government endorsed standards to minimise possible risk and hazards. In the USA the standard adopted is HACCP.

Efficiency

- Rising energy costs lead to increasing usage of energy-saving technologies, *e.g.* frequency converters on electrical drives, heat insulation of factory buildings and heated vessels, energy recovery systems, keeping a single fish frozen all the way from China to Switzerland
- Factory automation systems (often Distributed control systems) reduce personnel costs and may lead to more stable production results

Industries

Food processing industries and practices include the following:

- Cannery
- Industrial rendering
- Meat packing plant
- Slaughterhouse
- Sugar industry
- Vegetable packing plant

Markets and Demographics

To get an understanding of how nutrients are now being used in foods, comprehension of the marketplace is essential. As Liz Sloan claims in Food

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Technology's Demographic Directions: Mixing Up the Market, Boomers at an age when they are most likely to experience a chronic illness for the first time, along with another 49 million older Americans, the timing for condition-specific and risk-reducing foods and beverages is now. Four out of ten (40%) Boomer food shoppers report they already have high blood pressure, 37% high cholesterol, and 20% diabetes.

Approaching these market needs requires the careful application of science and technology in the development of new food products. In this case, the development of foods carrying vitamins and minerals to address or serve specific health requirements. Food is evolving from the traditional "three meals a day" to individual meal solutions, such as single-serve bars and beverages. Innovations in packaging, marketing, and positioning matter are being matched to innovation in science and ingredients.

Applications

Processors may add nutrients to foods by adding liquids or dry premixes containing pre-measured levels of desired vitamins, minerals, and other nutrients.

Most vitamins cannot be synthesized by the body and must be supplied by the diet. Because of their importance, processed foods are often enriched with vitamins and minerals. Important nutritionally, the vitamins also serve as functional additives in food products. Ascorbic acid and the tocopherols are used to prevent oxidation. The carotenoids are used as colorants in dairy products, baked goods, and beverages. It is important for food technologists to consider the following factors when formulating a food product with added nutrients:

Overall Product Composition. The physical and chemical properties of a food such as pH, water activity, oil, or water content influence nutrient stability. Macro-ingredients such as protein and fiber may affect stability and bio-availability of nutrients. Fortification can cause profound changes in a product's sensory characteristics. Essential minerals such as iron can cause adverse reactions in the colour and flavour of foods. Which form of nutrient to use should be carefully considered. Ascorbic acid can lower pH and impart tartness. This can be corrected by using the sodium salt of vitamin C and taking advantage of the acid/base buffering effect. Other vitamins, such as beta-carotene can also change the colour of a food.

Ingredients Interactions. Interaction among the nutrients and with other food components is a key factor in viable added nutrients will be in food products. Vitamin C may improve the absorption of iron. Iron will accelerate vitamin degradation in foods. This degradation may lead to sensory problems.

Processing Considerations. Most vitamins are unstable at high temperatures; while most nutrients are not adversely affected by heat. For vitamins the best

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method of heat processing is to raise the temperature, but reduce the exposure time. Freezing is generally beneficial for nutrients; however, blanching and washing can cause loss of water-soluble vitamins.

Shelf-life and Packaging. Package selection is affected by intended use and shelf-life considerations. These factors must be balanced with inherent sensitivities of the product and added nutrients. Vitamin C and beta-carotene must be protected from oxygen. Shelf-life loss can be overcome by adding appropriate nutrient overages.

Nutrigenomics. Nutrigenomics is how nutrients affect genes and enables foods to be developed that can be used to prevent and treat diseases. The application of nutrigenomics may allow food product developers to better target condition-specific foods.

4.5 Role of Dietary Supplements in Health

There are some select groups that are more likely to use and benefit from using dietary supplements. If you fall into one of the following groups of individuals you may want to consider taking a supplement: (create an anchor for each of the following)

- athletes
- weight loss
- older adult
- pregnancy
- vegetarians

Why Might Athletes Take Dietary Supplements?

Athletes with less than optimal nutritional status compromise their physical performance. Athletes face several barriers to good nutrition—lack of nutrition knowledge, dietary extremism, poor practical skills in choosing or preparing meals, a busy lifestyle, and frequent travel. Nutrition plays a very important part in athletic performance, yet many active people fail to consume a diet that helps them perform at their optimum level. The first and most important modification an athlete must make to his or her diet to ensure optimal performance is to increase the energy intake in proportion to the energy used. Athletes also require more water, protein, vitamins and minerals (especially iron and calcium).

To fulfill the extra nutritional requirements, athletes may turn to dietary supplements such as vitamin, mineral, protein and carbohydrate supplements. Before you stock up on these expensive dietary aids however, remember that it is cheaper and easier to just eat more food.

Ergogenic Aids

A substance used by an athlete to improve performance is called an ergogenic aid. Athletes have used ergogenic aids since ancient times. Ancient Greek

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Olympians ate mushrooms to increase their chances to win the laurel wreath and Aztec athletes ate human hearts. Nowadays the ergogenic aid industry is massive, and almost all sporting magazines contain advertisements for new "revolutionary" ergogenic aids. The world of sports is a competitive business. Athletes fear that others are taking something that will give them an advantage. This means that many athletes will try out new substances on the off chance that it will give them the edge over other competitors. Forgotten in the push to excel are the unknown dangers of unproven substances and the temptations for misuse and abuse. Supplements can be harmful as well as useful.

Supplements that may used by athletes as an ergogenic include:—

Ergogenic Aid	*Proposed Action*	*What Research Says*	*Side Effects*
Androstenedione	steroid hormone that increases testosterone levels	no documented benefits	major
Caffeine	increases fat metabolism, thus sparing glucose and glycogen stores; stimulates the central nervous system	supports	mild
Carbohydrates	an important energy source for muscles	supports	mild at high doses
Creatine	delays fatigue and improves performance during high, intense bursts of exercise; builds muscle mass	supports, however there is limited data on long-term use	mild
DHEA	increases amount of steroids produced in the body	no benefit in health athletes	may be dangerous
HMB	prevents muscle breakdown, speeds up muscle repair, and increase lean body mass	limited; some strength benefits	none
Protein	helps build muscle and improves muscle repair	supports; high force outputs from their	none

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		muscles, such as sprinters and weight lifters, need extra protein to ensure muscle maintenance	
Pycnogenol	boosts antioxidant levels, enhances recovery	Supports, dietary sources offer same benefit	none
Tryptophan	increases athletic endurance; decreases pain perception	no definite results; no benefit in trained athletes	potentially dangerous
Vitamin B_6 (Pyridoxine)	increases growth of muscle and decreases anxiety	no benefit unless individual has deficiency	mild at high doses
Vitamin B_{12} (Cobalamin)	increases growth of muscle	no benefit unless individual has deficiency	none
Vitamin C	acts as an antioxidant; increases energy production and aerobic reactions	no benefit unless individual has deficiency	mild at high doses
Vitamin E	acts as an antioxidant; increases aerobic capacity	no definite results	mild
Zinc	increases muscle mass and aerobic capacity	few studies; mostly negative	mild

Source: Ahrendt DM. Ergogenic aids: Counseling the athlete. American Family Physician. 2001;63:913-22.

Supplements for those Wishing to Lose Weight

The thought of taking a pill to lose weight will never fail to attract interest. Many supplement manufacturing companies sell products that claim to be able to do this by "stimulating metabolism" or "blocking fat digestion." A review of

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the scientific studies turns up no solid evidence for the long term effectiveness of these products. Two over-the-counter dietary supplements that are promoted to accelerate metabolism with subsequent weight loss have been labelled dangerous by the FDA. These two products are Ephedra (also known as Ma Huang, Ephedra sinica or Chinese ephedra), and Phenylpropanolamine.

In addition, other commonly used weight loss supplements like Cola acuminata, dwarf elder, Yohimbine, and Garcinia camborgia are either lacking controlled clinical trials, or in the case of the last two supplements, were shown in clinical trials to be ineffective (Garcinia was successful in trials as part of a mixture with other substances. It is unclear, however, if Garcinia itself was effective). The FDA also states that the safety of these weight loss supplements is currently unknown. With the increased marketing and use of these products, FDA has received an increasing number of reports of adverse reactions associated with their use including:

- Nervousness
- Dizziness
- Tremors
- Alterations in blood pressure or heart rate
- Headache
- Gastrointestinal distress
- Chest pain
- Myocardial infarction (heart attack)
- Hepatitis
- Stroke
- Seizures
- Psychosis
- Death

These adverse reactions have been reported both in young, healthy individuals and persons with confounding or complicating conditions such as high blood pressure. In addition, a stimulant "overdose" syndrome has been reported in children and teenagers who have used these products.

Older Adults (65+)

Older adults (65+) are at an increased risk for poor nutrition.

- With age, there is a reduction in lean body mass which reduces the body's energy requirements.
- Older adults eat less total food.
- Appetite may be decreased due to reduced taste and smell sensitivity.
- Drug side effects can reduce appetite and reduce absorption and metabolism of vitamins and minerals.

- Some nutrient requirements increase with age, especially calcium, vitamin E, vitamin D, riboflavins, folate, vitamin B_{12} and protein.

Undernutrition in older adults can lead to loss of muscle protein and deficiencies of vitamins B-6, B-12, D and E as well as calcium, folate and magnesium. These nutritional inadequacies can lead to the following:

- Lethargy and weakness
- Reduced bone density leading to weak, brittle bones and painful disabling fractures
- Nervous system dysfunction
- Delayed wound healing
- Inability to carry out normal activities of daily living

Recommendations for the Older Adult

An adequate and balanced diet is without a doubt the best way to ensure adequate nutrition. However, much scientific evidence suggests that complementing the diet with a daily multivitamin-and-mineral supplement is a sensible precaution to help avoid nutrient deficiencies that are common in older adults.

Choose a supplement with very little or no iron. Iron needs of older adults are low, and excess iron increases the risk of developing cancer and heart disease.

In addition, look for a supplement that has no more than 100% of the RDA or DRI for vitamin A. With age, vitamin A is absorbed and retained more efficiently. The potential for vitamin A toxicity is therefore greater than at a younger age. Vitamin A toxicity is a serious matter, leading to such health problems as headache, vomiting, bone abnormalities, and liver damage.

Choose a dietary supplement that does not contain:

- More than 100% RDA for iron
- More than 100% RDA for vitamin A

Many vitamin and mineral supplements are aimed at the older adult. Read the labels and decide with the above warnings in mind.

If you are thinking about taking single nutrient supplements, only calcium and vitamin D have been specifically recommended for older adults. If you have any doubt whatsoever, visit your physician and get an individualized dietary assessment before taking supplements.

If you are currently taking any medication, be sure to discuss with your physician what supplements you can take. Many drugs interact with dietary supplements. Some supplements can prevent drugs from working. Other supplements can intensify drug effects to dangerous levels. Your physician and pharmacist will be able to provide more information.

Pregnant or Planning on Getting Pregnant

Pregnant women must consider both their own requirements and the requirements of the baby. Vitamins and minerals are needed during pregnancy

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for the maintenance of the mother's health, to support the developing infant's growth, and to help prevent developmental defects.

Supplements to Consider:

- **Folic Acid:** Scientific studies show that the risk of recurrent neural-tube defects is decreased in women who take folic acid before conception and during the first 6 weeks of pregnancy. A standard vitamin and mineral supplement will provide adequate folate to reduce the risk of this birth defect.
- **Iron:** During pregnancy, iron stores become low due to increased iron need for the fetus. The need is particularly great during the last trimester.
- **Zinc:** Zinc supplementation significantly reduces the incidence of low birth-weight babies. In addition, most measurements of labour and fetal health were better in women who took modest zinc supplements.
- **Calcium:** Calcium and phosphorus are vital to the structure of bones and teeth. In the last trimester of pregnancy, skeletal growth is highest and the fetus draws calcium directly from the mother's stores. In addition, clinical trials have shown that adequate calcium during pregnancy lowers blood pressure and may reduce the incidence of premature births.
- A simple multivitamin/mineral supplement is recommended for pregnant women who do not ordinarily consume an adequate diet and for women in high-risk categories, such as multifetal gestation, cigarette smokers, and alcohol and drug abusers.

Recommendations for Pregnancy

During pregnancy, some women can especially benefit from certain nutrients. In general, these would all be contained in a prenatal multivitamin/mineral supplement. Those requiring vitamin and mineral supplementation in addition to a prenatal supplement include:

- Vegetarians may need supplemental vitamin B_{12} and zinc.
- Women carrying twins, taking seizure medication, or who have sickle cell anemia could benefit from additional folate.
- Women who do not use dairy products and/or do not get enough sunlight would benefit from additional vitamin D.
- Adolescents and smokers may benefit from a multivitamin/mineral supplement.

Supplementing additional nutrients other than iron and a prenatal multivitamin/mineral tablet is not only unnecessary, but can be dangerous. For example, taking mega doses of vitamin A may cause birth defects. Daily vitamin

A intake in the range of 10,000 IU or more can result in defects of the fetal skeletal, urinary tract, and central nervous systems. Before taking any supplements, seek advice from your physician or a registered dietitian.

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Vegetarians

Any restriction in the foods one would eat holds the potential for dietary inadequacies. It is through eating a wide variety of foods that we are assured of getting the wide range of nutrients humans need for good health. Dietary studies have often found that vegetarians, especially vegans, consume some vitamins and minerals at less than recommended amounts. A well-chosen vegetarian diet, on the other hand, can be entirely adequate, obviating the need for dietary supplements.

Although lacto-ovo-vegetarians have no obvious need for dietary supplements, vegans are a different story. At least one study has concluded that vegans need to increase their intake of vitamin B_{12}, riboflavin and possibly even iodine, iron and zinc.

— **Lacto-ovo-vegetarian**

Avoids all animal flesh (fish, chicken and red meats) yet consumes dairy products and eggs.

— **Lacto-vegetarian**

Avoids all animal flesh and eggs yet consumes dairy products.

— **Ovo-vegetarian**

Avoids all animal flesh and dairy products yet consumes eggs.

— **Vegan**

Not only avoids all meats but also abstains from all animal products such as eggs and dairy products.

4.6 Non-Nutritive Sweeteners

Non-nutritive, or high-intensity, sweeteners satisfy America's sweet tooth without adding calories. Presently, manufacturers are using three such sweeteners to replace sugar in a variety of food and nonfood items such as mouthwashes and pill coatings.

One of these is saccharin, 300 times sweeter than table sugar and with zero calories. It is sold in liquid, tablets, packets, and in bulk. Saccharin has had a stormy past, with studies in the United States and Canada implicating it in the development of certain cancers. In the late 1970s, FDA contracted with the National Academy of Sciences (NAS) to study cancer-causing agents and toxic substances in foods, including saccharin. NAS reports showed that saccharin is a potential cancer-causing agent in humans. A congressional moratorium protecting

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saccharin's continued use has been renewed periodically by Congress. The required label warning on saccharin states, "Use of this product may be hazardous to your health. This product contains saccharin which has been determined to cause cancer in laboratory animals."

Aspartame - about 200 times sweeter than table sugar and with the same number of calories per teaspoonful has been shown to be safe. However, some people have reported that they are sensitive to it, although such a sensitivity has not been confirmed by scientific studies. Certain individuals suffering from a rare genetic disease called phenylketonuria cannot tolerate the amino acid phenylalanine, one of the building blocks of aspartame as well as naturally occurring proteins. Therefore, products containing aspartame must bear on the label a statement that they contain phenylalanine. Aspartame is available in packets and is used in numerous foods, including cereals, beverage bases, and ready-to-drink iced tea, but because it is not generally heat stable, it is not used for cooking. Food technologists have been working on ways to overcome this instability.

Acesulfame K (K is the chemical symbol for potassium)-130 times sweeter than table sugar which was approved by FDA in July 1988 as a sugar substitute in packets or tablets and as an ingredient in such products as chewing gum, dry drink mixes, and gelatins. The body does not metabolize acesulfame K so it contributes no calories. Soluble in water, it is stable at normal temperatures and does not breakdown during cooking.

FDA banned the use of the sweetener cyclamate in 1970 because of concerns over its safety, but cyclamate is again under consideration for use in specific products, such as tabletop sweeteners and nonalcoholic beverages.

Under Development

Scientists continue to develop new sugar substitutes. For example, among the nutritive sweeteners, petitions for the use of the sugar alcohols isomalt (in gelatins, hard and soft candies, and baked goods), maltitol (in candy and cough drops), lactitol (in candy, chewing gum, baked goods, and frozen dairy desserts), and hydrogenated starch hydrolisates (in candy, chewing gum, and confections) are under current FDA review, says Art Lipman, Ph.D., a supervisory consumer safety officer with FDA's direct additives branch.

People may have an inherent preference for sweetness, and that may have helped our ancestors survive, since bitter-tasting plants are generally not fit to eat. But beyond survival, people seem to have discovered that sweet flavours really help make eating pleasurable.

A sweetener is a food additive which adds the basic taste of sweetness to a food; artificial sweeteners and natural sweeteners that aren't purely sugar are sugar substitutes.

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Nutritive Sweeteners

- Sugar alcohols
- Honey
- Fruits
- Syrups, including
  - o Maple syrup
  - o Birch syrup
  - o Pine syrup
  - o Hickory syrup
  - o Poplar syrup
  - o Palm syrup
  - o Sugar beet syrup
  - o Sorghum syrup
  - o Corn syrup
  - o Cane syrup
  - o Golden syrup
  - o Barley malt syrup
  - o Molasses (treacle)
  - o Brown rice syrup
  - o Agave syrup
  - o Yacon syrup

Non-Nutritive Sweeteners

- Acesulfame potassium, also known as Sunett
- Alitame, also known as Aclame
- Aspartame, also known as Equal or Nutrasweet
- Anethole
- Cyclamate
- Glycyrrhizin
- Lo han guo
- Neotame
- Perillartine
- Saccharin, also known as Sweet 'n' Low
- Stevioside
- Sucralose, also known as SucraPlus and Splenda
- Sugar of lead, also known as Lead(II) acetate (obsolete due to excessive toxicity)
- Inulin

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A sugar substitute is a food additive that duplicates the effect of sugar in taste, but usually has less food energy. Some sugar substitutes are natural and some are synthetic. Those that are not natural are, in general, referred to as artificial sweeteners.

An important class of sugar substitutes are known as high-intensity sweeteners. These are compounds with sweetness that is many times that of sucrose, common table sugar. As a result, much less sweetener is required, and energy contribution often negligible. The sensation of sweetness caused by these compounds (the "sweetness profile") is sometimes notably different from sucrose, so they are often used in complex mixtures that achieve the most natural sweet sensation.

If the sucrose (or other sugar) replaced has contributed to the texture of the product, then a bulking agent is often also needed. This may be seen in soft drinks labelled as "diet" or "light," which contain artificial sweeteners and often have notably different mouthfeel, or in table sugar replacements that mix maltodextrins with an intense sweetener to achieve satisfactory texture sensation.

In the United States, five intensely-sweet sugar substitutes have been approved for use. They are saccharin, aspartame, sucralose, neotame, and acesulfame potassium. There is some ongoing controversy over whether artificial sweetener usage poses health risks. The U.S. Food and Drug Administration regulates artificial sweeteners as food additives. Food Additives must be approved by the FDA, which publishes a Generally Recognized as Safe (GRAS) list of additives. To date, the FDA has not been presented with scientific information that would support a change in conclusions about the safety of the five approved artificial sweeteners. The safe conclusions are based on a detailed review of a large body of information, including hundreds of toxicological and clinical studies.

There is also an herbal supplement, stevia, used as a sweetener. Controversy surrounds lack of research on stevia's safety and there is a battle over its approval as a sugar substitute. The majority of sugar substitutes approved for food use are artificially-synthesized compounds. However, some bulk natural sugar substitutes are known, including sorbitol and xylitol, which are found in berries, fruit, vegetables, and mushrooms. It is not commercially viable to extract these products from fruits and vegetables, so they are produced by catalytic hydrogenation of the appropriate reducing sugar. For example, xylose is converted to xylitol, lactose to lactitol, and glucose to sorbitol. Still other natural substitutes are known, but are yet to gain official approval for food use.

Some non-sugar sweeteners are polyols, also known as "sugar alcohols." These are, in general, less sweet than sucrose, but have similar bulk properties and can be used in a wide range of food products. Sometimes the sweetness profile is 'fine-tuned' by mixing high-intensity sweeteners. As with all food

products, the development of a formulation to replace sucrose is a complex proprietary process.

4.7 Artificial Sweeteners Used by Food Industry

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The food and beverage industry is increasingly replacing sugar or corn syrup with artificial sweeteners in a range of products traditionally containing sugar.

Artificial sweeteners cost the food industry only a fraction of the cost of natural sweeteners in spite of the extremely high profit margins for manufacturers of artificial sweeteners. So it is not surprising that the food industry is promoting its "diet" or "light" products heavily, thus moving the customers over to its even more profitable artificially-sweetened products.

According to market analysts Mintel, a total of 3,920 products containing artificial sweeteners were launched in the U.S. between 2000 and 2005. In 2004 alone, 1,649 artificially-sweetened products were launched. According to market analysts Freedonia, the United States artificial sweetener market is set to grow at around 8.3% per year to $189 million in 2008.

Aspartame is currently the most popular sweetener in the U.S. food industry, as the price has dropped significantly since the Monsanto Company patent expired in 1992. However, sucralose may soon replace it, as alternative processes to Tate & Lyle's patent seem to be emerging. According to Morgan Stanley, this can mean that the price of sucralose will drop by 30%.

Reasons for Use

Sugar substitutes are used for a number of reasons including:

- To assist in weight loss; some people choose to limit their food energy intake by replacing high-energy sugar or corn syrup with other sweeteners having little or no food energy. This allows them to eat the same foods they normally would, while allowing them to lose weight and avoid other problems associated with excessive caloric intake.
- Dental care — sugar substitutes are toothfriendly, as they are not fermented by the microflora of the dental plaque.
- Diabetes mellitus — people with diabetes have difficulty regulating their blood sugar levels. By limiting their sugar intake with artificial sweeteners, they can enjoy a varied diet while closely controlling their sugar intake. Also, some sugar substitutes do release energy, but are metabolized more slowly, allowing blood sugar levels to remain more stable over time.
- Reactive hypoglycemia — individuals with reactive hypoglycemia will produce an excess of insulin after quickly absorbing glucose into the bloodstream. This causes their blood glucose levels to fall below the amount

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needed for proper body and brain function. As a result, like diabetics, they must avoid intake of high-glycemic foods like white bread, and often choose artificial sweeteners as an alternative.

- Avoiding processed foods — individuals may opt to substitute refined white sugar with less-processed sugars such as fruit juice or maple syrup.
- Cost — many sugar substitutes are cheaper than sugar.

Sugar Substitute Health Issues

A 2005 study by the University of Texas Health Science Center at San Antonio showed that increased weight gain and obesity was associated with increased use of diet soda in a population based study. The study did not establish if increased weight leads to increased consumption of diet drinks or if consumption of diet drinks could have an effect on weight gain.

Animal studies have indicated that artificial sweeteners can cause body weight gain. A sweet taste induces an insulin response, which causes blood sugar to be stored in tissues (including fat), but because blood sugar does not increase with artificial sugars, there is hypoglycemia and increased food intake the next time there is a meal. After a while, rats given sweeteners have steadily increased caloric intake, increased body weight, and increased adiposity (fatness). Furthermore, the natural responses to eating sugary foods (eating less at the next meal and using some of the extra calories to warm the body after the sugary meal) are gradually lost.

Cyclamate

In the United States, the U.S. Food and Drug Administration (FDA) banned the sale of cyclamate in 1970 after lab tests in rats involving a 10:1 mixture of cyclamate and saccharin indicated that large amounts of cyclamates causes bladder cancer, a disease to which rats are particularly susceptible. However, a dosage of salt (which is consumed in far higher quantities than cyclamate) equivalent to the quantity given to the rats daily, was shown to kill them instantly. The findings of these studies have been challenged and some companies are petitioning to have cyclamates reapproved. Cyclamates are still used as sweeteners in many parts of the world, and are used with official approval in over 55 countries.

Saccharin

Aside from Sugar of lead, Saccharin was the first artificial sweetener and was originally synthesized in 1879 by Remsen and Fahlberg. Its sweet taste was discovered by accident. It had been created in an experiment with toluene derivatives. A process for the creation of saccharin from phthalic anhydride was developed in 1950, and, currently, saccharin is created by this process as well as the original process by which it was discovered. It is 300 to 500 times as sweet as

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sugar (sucrose) and is often used to improve the taste of toothpastes, dietary foods, and dietary beverages. The bitter aftertaste of saccharin is often minimized by blending it with other sweeteners.

Fear about saccharin increased when a 1960 study showed that high levels of saccharin may cause bladder cancer in laboratory rats. In 1977, Canada banned saccharin due to the animal research. In the United States, the FDA considered banning saccharin in 1977, but Congress stepped in and placed a moratorium on such a ban. The moratorium required a warning label and also mandated further study of saccharin safety.

Subsequently, it was discovered that saccharin causes cancer in male rats by a mechanism not found in humans. At high doses, saccharin causes a precipitate to form in rat urine. This precipitate damages the cells lining the bladder ("urinary bladder urothelial cytotoxicity") and a tumor forms when the cells regenerate ("regenerative hyperplasia"). According to the International Agency for Research on Cancer, part of the World Health Organization, "Saccharin and its salts was downgraded from Group 2B, possibly carcinogenic to humans, to Group 3, not classifiable as to carcinogenicity to humans, despite sufficient evidence of carcinogenicity to animals, because it is carcinogenic by a non-DNA-reactive mechanism that is not relevant to humans because of critical interspecies differences in urine composition."

In 2001, the United States repealed the warning label requirement, while the threat of an FDA ban had already been lifted in 1991. Most other countries also permit saccharin but restrict the levels of use, while other countries have outright banned it.

Aspartame

Aspartame was discovered in 1965 by James M. Schlatter at the G.D. Searle company (later purchased by Monsanto). He was working on an anti-ulcer drug and spilled some aspartame on his hand by accident. When he licked his finger, he noticed that it had a sweet taste. It is an odorless, white crystalline powder that is derived from the two amino acids aspartic acid and phenylalanine. It is about 200 times as sweet as sugar and can be used as a tabletop sweetener or in frozen desserts, gelatins, beverages, and chewing gum. Its chemical name is L-alpha-aspartyl-L-phenylalanine methyl ester and its chemical formula is $C_{14}H_{18}N_2O_5$. Though it has no bitter aftertaste as does saccharin, its drawback is that it might not taste exactly like sugar because it reacts with other food flavours. When eaten, aspartame is metabolized into its original amino acids and has a relatively low food energy.

Initial safety testing suggested that aspartame caused brain tumors in rats; as a result, the additive was held up in the United States for many years in the

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FDA's approval process. In 1980, the FDA convened a Public Board of Inquiry (PBOI) consisting of independent advisors charged with examining the purported relationship between aspartame and brain cancer. The PBOI's conclusions were unclear as to whether aspartame causes brain damage, and recommended against approving aspartame at that time, citing unanswered questions about cancer in laboratory rats. In 1981, FDA Commissioner Arthur Hull Hayes, newly appointed by President Ronald Reagan, approved aspartame as a food additive. He was closely associated with the artificial sweetener industry, having several close friends, most notably Donald Rumsfeld, former United States Secretary of Defense, and then the CEO of G.D. Searle. Hayes cited data from a single Japanese study that had not been available to the members of the PBOI, as his reason for approval.

Since the FDA approved aspartame for consumption, some researchers have suggested that a rise in brain tumor rates in the United States may be at least partially related to the increasing availability and consumption of aspartame. Some research, often supported by companies producing artificial sweeteners, has failed to find any link between aspartame and cancer or other health problems. A recent research showed a clear link between this substance and cancer; a link that may be sufficient evidence for the FDA to pull aspartame from the market. This research has led the Center for Science in the Public Interest to classify aspartame as a substance to be avoided in its Chemical Cuisine Directory. However, the EFSA's press release about the study, published on 5 May 2006, concluded that the increased incidence of lymphomas/leukaemias reported in treated rats was unrelated to aspartame, the kidney tumors found at high doses of aspartame were not relevant to humans, and that based on all available scientific evidence to date, there was no reason to revise the previously established Acceptable Daily Intake levels for aspartame.

Several European Union countries approved aspartame in the 1980s, with EU-wide approval in 1994. The European Commission Scientific Committee on Food reviewed subsequent safety studies and reaffirmed the approval in 2002. The European Food Safety Authority reported in 2006 that the previously established Adequate Daily Intake was appropriate, after reviewing yet another set of studies. It has also been investigated and approved by the Joint Expert Committee on Food Additives of the United Nations Food and Agricultural Organization and World Health Organization.

4.8 Preparation and Uses of Non-nutritive and Artificial Sweeteners

Non-nutritive sweeteners can be used in place of table sugar to sweeten hot and cold beverages. In addition, saccharin, sucralose, and acesulfame K are heat-stable and are suitable for baking. Keep in mind that non-nutritive sweeteners carry more intense sweetness than sugar. When substituting these products for

sugar, only small amounts are needed to achieve the same level of sweetness. As a result, quantity modifications of several ingredients in a recipe may be necessary to accommodate the use of saccharin, sucralose, or acesulfame K.

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Buying and Storing Tips

Saccharin, aspartame, sucralose, and acesulfame K have very long shelf lives. Store in original packaging in a dry location at room temperature.

Varieties

Acesulfame K

Acesulfame K (Sunette), or acesulfame potassium, was discovered in 1967 in Germany. It was approved in 1988 by the FDA as a tabletop sweetener and for use in baked goods, frozen desserts, beverages, and candies. Consisting of carbon, nitrogen, oxygen, hydrogen, sulfur, and potassium atoms, acesulfame K is 200 times sweeter than table sugar. Acesulfame K is not digested, so it contributes no calories to the diet. Some animal studies suggest a possible cancer-promoting effect.

Aspartame

Aspartame (NutraSweet) was discovered in 1969, and in 1981 was approved by the FDA for use in foods. Aspartame is produced from two amino acids—aspartic acid and phenylalanine—and is 180 times sweeter than sucrose. Although the FDA points to more than 100 scientific experiments that purportedly document the safety of aspartame, many consumers and scientists are not convinced that long-term daily intake of aspartame is completely safe, and are concerned about the growing number of foods that contain this ingredient. Aspartame intake is known to be dangerous for persons with phenylketonuria, a metabolic disorder that results in dangerously high blood levels of phenylalanine. In addition, aspartame is not recommended for use by pregnant or lactating women.

Saccharin

Saccharin was discovered in 1879, and is currently produced from a purified compound found in coal tar. Saccharin is 300 times sweeter than sugar, but has a slightly bitter or metallic aftertaste. It is not metabolized in the digestive tract and is excreted rapidly in the urine. As a result, saccharin does not contribute calories to the diet. Three scientific experiments in the early 1970s suggested that saccharin might be a carcinogen (cancer-causing substance) when given to rats in large doses. In response, the FDA proposed a ban on saccharin for all uses except as an over-the-counter drug. Significant public opposition to the FDA ban on saccharin ensued, prompting the FDA to pass the Saccharin Study and Labelling Act in 1977, which placed a two-year moratorium on any ban of the sweetener until further research was available. The law also required that any foods containing

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saccharin must carry a label that reads, "Use of this product may be hazardous to your health. This product contains saccharin which has been determined to cause cancer in laboratory animals." Most long-term animal studies have found no cancer-causing effects from saccharin consumption. On December 15, 2000, Congress passed legislation to remove the warning label that had been required on saccharin-sweetened foods and beverages since 1977. The National Toxicology Program has removed saccharin from its list of cancer-causing substances.

Sucralose

Sucralose is derived from table sugar (sucrose). It closely resembles table sugar in taste, is highly water-soluble, and is exceptionally stable at high temperatures. In 1998, the FDA approved it as a tabletop sweetener and for use in baked goods, beverages, gelatin, and frozen dairy desserts. In 1999, FDA expanded the approved uses for sucralose, allowing it as a general-purpose sweetener for all foods. Sucralose is not absorbed from the digestive tract, so it adds no calories to consumed food. In addition, sucralose does not increase blood sugar levels. As there is very little research on sucralose use by humans, it may be advisable for people to use it in limited amounts until more is known about its long-term effects.

Equal

Equal is an artificial sweetener containing aspartame, dextrose, and maltodextrin.

Alitame

Like aspartame, Alitame is made from amino acids. Alitame is 2,000 times sweeter than sugar. Pfizer, a pharmaceutical company and manufacturer of this sweetener, petitioned the FDA in 1986 for approval. As of 1992, the approval is still pending.

Cyclamate

Cyclamate was synthesized in 1937 at the University of Illinois by a student who accidentally discovered its sweet taste. The patent for cyclamate was first purchased by DuPont and then later sold to Abbott Laboratories. In those days, Abbott's reported interest was to use the product to mask the bitter taste of an antibiotic and a pentobarbital elixir. Cyclamate was initially marketed as tablets that were recommended for use as a tabletop sweetener for people with diabetes and others who had to restrict their intake of sugar. Although it is approved for use in many countries, cyclamate is banned in the United States due to concerns over potential carcinogenicity.

Nutrition Highlights

Acesulfame K, 1g

Calories: 0.0

Protein: 0.0g

Carbohydrate: 0.0g

Total Fat: 0.0g

Fiber: 0.0g

Aspartame, 1 packet (1g)

Calories: 0.0

Protein: 0.0g

Carbohydrate: less than 1.0g

Total Fat: 0.0g

Fiber: 0.0g

Sucralose, 1 packet (1g)

Calories: 0.0

Protein: 0.0g

Carbohydrate: 0.0g

Total Fat: 0.0g

Fiber: 0.0g

New Ingredients Driving Sugar-free Development

The use of ingredients to improve the nutritional status of food products by replacing sugar is one of the major driving forces for new product development, according to Roquette.

And the French group is confident that this trend is likely to continue.

Sales of food and beverage categories considered by consumers as being unhealthy are, in general, falling. Combined with growing regulatory pressure on the industry to provide healthier food, this provides a strong incentive for food makers to invest in new ingredients.

"By taking advantage of the many nutritional and technical properties offered by two different ingredients polyols and soluble fibre confectionery products are possible that are not only sugar-free but also safe for teeth, low in calories, rich in fibre and suitable for diabetics and produce a low glycaemic response," said Yves Le Bot, Roquette global confectionery development manager.

In order to further tap this growing market, the company has recently developed a recipe for high-chew sugar-free chewy sweets. The extra 'chew' is provided by a combination of mannitol, Lycasin 80/55 maltitol syrup and Nutriose 06 soluble fibre.

The firm said that other food products could also benefit from such combinations. "Sugar-free pound cakes, muffins and sponge cake can be high in fibre, deliver long-lasting energy and still remain delicious," said the company in a statement.

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In addition, Roquette has recently developed no-sugar-added and source-of-fibre hamburger buns that are sweet and are claimed to have the same colour and texture as original buns. A combination of Nutriose FB 06 and Maltisorb P 200 maltitol powder was used to achieve this result.

And in the field of beverages, Roquette recently reported success in formulating a good-tasting sugar-free syrup. Routin, the second largest French syrup producer after Teisseire, launched a sugar-free fruit syrup using Roquette's Nutriose FB06 product earlier this year.

The company claimed that the soluble fibre ingredient compensates for the lack of body and mouthfeel traditionally associated with sugar-free drinks, and also beings some added health benefits.

The light drinks sector represents around 20 per cent of the soft drinks market in volume in France, according to Roquette.

Can we Use an Artificial Sweetener?

An artificial sweetener is a low calorie substance used as sweetener to replace sugars. Carbohydrates, including sugars, are our body's main source of energy. We eat sugars occurring in fruits (fructose) and dairy products (lactose) and added sugars (sucrose).

We may want to replace sugars by an artificial sweetener such as aspartame when we want to loose weight. Also, diabetics need to limit their consumption of sugars; they can replace them by an artificial sweetener.

4.9 Current Market Trends

The global confectionery market is one of the most mature sectors of the food and drink industry, worth an estimated $97.5bn in value terms during 2003. This represents an increase of more than 14 percent compared with the $85.61bn recorded in 1999. During the same period, the market rose by 9 per cent in volume terms, and now stands at over 15 million tonnes.

Chocolate represents the largest sector in value terms, with sales worth around $53.66bn in 2003. This equates to just over 55 percent of total market value. By volume, sugar confectionery (such as mints, boiled sweets and toffees) is the largest sector, with sales of over 7.6 million tonnes in 2003. The reason for this apparent discrepancy is the fact that chocolate is usually sold at a higher price, whereas many forms of sugar confectionery are low-value items, particularly within the developing regions of the world.

Branching Out

Many confectionery markets in the more developed parts of the world have entered a period of maturity, with growth levels having slowed significantly in recent years. This has been particularly apparent in sectors such as chocolate

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and sugar confectionery, in regions such as Western Europe and North America. Reasons for the slowdown in market growth have included growing competition from other forms of snack (such as crisps, biscuits and cereal bars), demographic changes (such as a declining numbers of children and teenagers) and the increasingly negative health perceptions surrounding confectionery.

To counteract the slowdown in market growth, the world's leading confectionery suppliers have been pursuing opportunities in less developed regions. Some of the more notable areas are Eastern European countries and Russia, where the sheer size of the population creates an attractive potential market. Other areas of future growth include China, India and some of the Latin American markets. In more developed regions, manufacturers are focusing on product innovation, which has been identified as crucial in maintaining consumer interest and thereby growing the market in future.

Many of the recent innovations in the global confectionery market can be grouped into categories. The more significant include health/functional foods, flavours and packaging.

Health/Functional Foods

Healthier confectionery now appears in many forms. In previous years, this category was generally limited to low-fat or low-sugar lines, but it has since grown to incorporate products such as organic, sugar-free and low-carbohydrate confectionery, as well as confectionery items marketed as providing specific functional health benefits. According to the latest estimates, the world market for functional confectionery is worth over $7bn and is growing.

One of the largest categories in the market is sugar-free confectionery. This market has experienced a period of fairly rapid growth, due to the increasing use of alternative sweeteners such as xylitol. Sugar-free items now account for the vast majority of chewing gum sales in many countries, over 95 percent in markets such as Finland, Sweden and the Czech Republic. One of the world's largest brands is Wrigley's Extra, which has a leading position in many regions. In contrast, the share of the global market taken by regular sugared gum has declined.

Many chewing gums are now marketed as offering extra health benefits, as well as being sugar free. Some of the more common benefits include breath-freshening and tooth whitening, while gums containing stimulants (such as caffeine and guarana) are also in evidence. Some gums now claim to help remineralise the teeth, while Airwaves from Wrigley now occupies a leading slot as a medicated confectionery brand. Elsewhere, Daygum Microtech from Perfetti Van Melle contains micro particles for the removal of plaque during the day.

Many of these trends are also apparent in the sugar confectionery market. The rising popularity of breath-freshening products has contributed towards a growth in demand for mints. This trend has also resulted in the emergence of the breath-freshening strips category, as evidenced by products such as Eclipse Strips (or Extra Thin Ice) from Wrigley and Listerine Actives from Pfizer. Meanwhile,

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some varieties of boiled sweets are now fortified with extra vitamins, typically the ACE trio, which gives them added health appeal. The Japanese sugar confectionery market contains a large number of examples of what is termed 'etiquette candy', which helps to prevent halitosis.

The growing popularity of low-carb diets such as Atkins and South Beach has created a demand for confectionery geared towards this particular group of dieters. As might be expected, most low-carb confectionery products have appeared in the USA, such as 1g Sugar Carb bars from Hershey Foods and various products from Russell Stover. During 2004, this trend spread to Europe with the launch of low-carb varieties of both KitKat and Rolo from Nestlé. This category also includes organic chocolate and sweets, as well as low-fat products, sales of which are generally highest in the European markets.

Flavour Factors

A wide variety of taste preferences exist within the confectionery market, creating opportunities for manufacturers across the globe. The type and flavour of products favoured across the world varies according to region, and local tastes can therefore form the basis of new product development.

It is worth noting that many of these have been limited editions, brought onto the market for the purpose of growing a brand's sales in the short term. One recent example of a local market variation is the growth of sales in white chocolate in some European markets, at the expense of more traditional varieties such as milk and plain. This indicates a trend towards sweeter varieties of chocolate. In the sugar confectionery market, however, one of the most noteworthy trends in recent years has been the growth in sales of sour-flavoured sweets, especially in the children's sector. Consumers are also demanding confectionery with a stronger, more intense flavour.

White chocolate varieties of many popular brands have emerged in recent years. In addition, Cadbury launched Dream in 2003, a white chocolate brand which has been particularly successful in the UK and New Zealand. Leading brands to have been extended with white chocolate varieties include Maltesers (from Masterfoods), KitKat and Smarties (from Nestlé) and various lines from smaller suppliers such as Lindt and Sprüngli.

Other flavours have also been introduced into the chocolate market. One of the more popular is cappuccino, which has featured in brands such as Galak and Marabou. The chocolate confectionery market has also witnessed the emergence of bars with flavours such as cola, and varieties based on fruit.

In the sugar confectionery market, sour flavours based around lemon, apple and pineapple have been very much in vogue of late. In the UK, the Chewits range from Leaf was extended in 2003 with Xtremely Sour varieties, providing an even more intense taste. Other major sugar confectionery brands to have been extended with sour varieties include Maynards Wine Gums (from Cadbury), Starburst (from Masterfoods) and a number of Haribo lines. The growth in the market for medicated confectionery has also increased demand for flavours based around honey and menthol.

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Outside Europe, there is a wide diversity of sugar confectionery flavours. In Japan, for example, green tea is a frequent ingredient for sweets, while Chupa Chups developed a lychee-flavoured lollipop specifically for the Chinese market a few years ago. Sugar confectionery markets in the Americas have featured the emergence of hotter sweets based around flavours such as chilli, mainly to cater for the increasing Hispanic population.

Hotter flavours are also apparent in the market for chewing gum. Although minty varieties dominate in most parts of the world, cinnamon remains a popular choice in the USA, as evidenced by the success of Wrigley's Big Red flavour. Some of the more unusual chewing gum flavours to emerge in recent years include varieties based around fruit, as well as more exotic flavours. A chewing gum combining liquorice and black pepper was launched in Denmark during 2002, while plant extract flavours frequently appear in the Japanese market.

Packaging Patterns

Confectionery suppliers have also used packaging as a way of bringing innovation to the market. During 2003, Nestlé launched KitKat Kubes in the UK market, bite-sized pieces of KitKat ideal for sharing or eating on the move. Bite-sized chocolate lines are very much in vogue across much of Europe, due to increasing consumer concern over portion sizes, and the fact that these can easily be shared with family and friends. The success of brands such as Celebrations and Miniature Heroes can largely be attributed to the growing popularity of sharing products. Convenience is one of the market's main drivers, resulting in the emergence of flip-top packets, which are easy to open and carry around. Among the major brands to have appeared in this format are Skittles Gum from Masterfoods and Wrigley's Extra.

Children's Confectionery

Some of the market's other innovations include combining confectionery with toys, very often based on popular characters from films or TV programmes. This form of innovation is most prevalent in the children's sector, since character tieins give the products added appeal and novelty value.

The children's confectionery sector remains a main area for product innovation. Some of the more notable examples in recent years have included Flashin Lix Candy, lollipops that light up when licked. Sugar confectionery sold via Pez dispensers is also popular in many parts of the world.

Large and Small Innovators

The global confectionery market is contested by a number of multinational suppliers. Among the largest are Nestlé, Masterfoods, Cadbury, Wrigley and Hershey Foods, most of which operate in most regions of the world. Many of these leading suppliers are responsible for much of the innovation occurring in the industry, since all possess substantial budgets for R&D purposes. However, the industry also contains a number of smaller firms, some of which operate in very specific market niches and therefore place a strong emphasis on product innovation.

Student Activity

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1. Explain the importance of food fortification.

2. Point out the significance of dietary supplemets in human health.

3. Discuss the features of artificial sweetners.

Summary

1. A dietary supplement, also known as food supplement or nutritional supplement, is a preparation intended to provide nutrients, such as vitamins, minerals, fiber, fatty acids or amino acids.
2. Food fortification is the public health policy of adding micronutrients (essential trace elements and vitamins) to foodstuffs to ensure that minimum dietary requirements are met.
3. Non-nutritive sweeteners can be used in place of table sugar to sweeten hot and cold beverages. In addition, saccharin, sucralose, and acesulfame K are heat-stable and are suitable for baking.
4. A sugar substitute is a food additive that duplicates the effect of sugar in taste, but usually has less food energy. Some sugar substitutes are natural and some are synthetic.
5. An artificial sweetener is a low calorie substance used as sweetener to replace sugars.

Glossary

Dietary supplement: a preparation intended to provide nutrients, such as vitamins, minerals, fiber, fatty acids or amino acids.

Food fortification: the public health policy of adding micronutrients (essential trace elements and vitamins) to foodstuffs.

Food processing: the set of methods and techniques used to transform raw ingredients into food or to transform food into other forms for consumption.

Sugar substitute: a food additive that duplicates the effect of sugar in taste, but usually has less food energy.

Review Questions

1. What is dietary supplement?
2. How is dietary supplement regulated in European countries?
3. What is food fortification? Give some examples of food fortification.
4. Discuss the role of dietary supplements in health.
5. What is non nutritive sweetners? Give examples.
6. What are the basic uses of artificial sweetners?

Further Readings

Phytochemicals in Nutrition and Health by M.S. Meskin, W.R. Biidlack, A.J. Davies, S.T. Omaye; Publisher - CRC Press USA; year - 2002

Food Allergy and Intolerance by Author - Victoria Jack (editor); Publisher - Leatherhead Food Research Association; year - 3 times per year

Parker, K.G. and Green T.H.; Developments in sweetners— Applied sciences publishers

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UNIT—V

BIOTECHNOLOGY

Objectives

After going through this unit, students will be able to:

- state the definition, need, importance of biotechnology and food biotechnology;
- explain the Improvement in the method of food processing using biotechnology;
- understand the importance of food biotechnology;
- discuss the concepts pertaining to the genetically modified foods.

STRUCTURE

5.1 Introduction

Biotechnology is technology based on biology, especially when used in agriculture, food science, and medicine. United Nations Convention on Biological Diversity defines biotechnology as:

"Any technological application that uses biological systems, dead organisms, or derivatives thereof, to make or modify products or processes for specific use."

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Biotechnology is often used to refer to genetic engineering technology of the 21st century, however the term encompasses a wider range and history of procedures for modifying biological organisms according to the needs of humanity, going back to the initial modifications of native plants into improved food crops through artificial selection and hybridization. Bioengineering is the science upon which all biotechnological applications are based. With the development of new approaches and modern techniques, traditional biotechnology industries are also acquiring new horizons enabling them to improve the quality of their products and increase the productivity of their systems.

Before 1971, the term, biotechnology, was primarily used in the agriculture and agriculture industries. Since the 1970s, it began to be used by the Western scientific establishment to refer to laboratory-based techniques being developed in biological research, such as recombinant DNA or tissue culture-based processes; or horizontal gene transfer in living plants, using vectors such as the Agrobacterium bacteria to transfer DNA into a host organism. In fact, the term should be used in a much broader sense to describe the whole range of methods, both ancient and modern, used to manipulate organic materials to reach the demands of food production. So the term could be defined as, "The application of indigenous and/or scientific knowledge to the management of (parts of) microorganisms, or of cells and tissues of higher organisms, so that these supply goods and services of use to the food industry and its consumers.

Biotechnology combines disciplines like genetics, Microbiology, molecular biology, biochemistry, embryology, and cell biology, which are in turn linked to practical disciplines like chemical engineering, information technology, and biorobotics. Patho-biotechnology describes the exploitation of pathogens or pathogen derived compounds for beneficial effect.

5.2 History

Although not normally thought of as biotechnology, agriculture clearly fits the broad definition of "using a biological system to make products" such that the cultivation of plants may be viewed as the earliest biotechnological enterprise. Agriculture has been theorized to have become the dominant way of producing food since the Neolithic Revolution. The processes and methods of agriculture have been refined by other mechanical and biological sciences since its inception. Through early biotechnology, farmers were able to select the best suited and highest-yield crops to produce enough food to support a growing population. Other uses of biotechnology were required as crops and fields became increasingly large and difficult to maintain. Specific organisms and organism byproducts were used to fertilize, restore nitrogen, and control pests. Throughout the use of agriculture, farmers have inadvertently altered the genetics of their crops through introducing them to new environments and breeding them with other plants—one of the first forms of biotechnology. Cultures such as those in Mesopotamia, Egypt, and India developed the process of brewing beer. It is still done by the

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same basic method of using malted grains (containing enzymes) to convert starch from grains into sugar and then adding specific yeasts to produce beer. In this process the carbohydrates in the grains were broken down into alcohols such as ethanol. Ancient Indians also used the juices of the plant Ephedra vulgaris and used to call it Soma. Later other cultures produced the process of Lactic acid fermentation which allowed the fermentation and preservation of other forms of food. Fermentation was also used in this time period to produce leavened bread. Although the process of fermentation was not fully understood until Louis Pasteur's work in 1857, it is still the first use of biotechnology to convert a food source into another form.

Combinations of plants and other organisms were used as medications in many early civilizations. Since as early as 200 BC, people began to use disabled or minute amounts of infectious agents to immunize themselves against infections. These and similar processes have been refined in modern medicine and have led to many developments such as antibiotics, vaccines, and other methods of fighting sickness.

In the early twentieth century scientists gained a greater understanding of microbiology and explored ways of manufacturing specific products. In 1917, Chaim Weizmann first used a pure microbiological culture in an industrial process, that of manufacturing corn starch using Clostridium acetobutylicum, to produce acetone, which the United Kingdom desperately needed to manufacture explosives during World War I.

The field of modern biotechnology is thought to have largely begun on June 16, 1980, when the United States Supreme Court ruled that a genetically-modified microorganism could be patented in the case of Diamond v. Chakrabarty. Indian-born Ananda Chakrabarty, working for General Electric, had developed a bacterium (derived from the Pseudomonas genus) capable of breaking down crude oil, which he proposed to use in treating oil spills.

Revenue in the industry is expected to grow by 12.9% in 2008. Another factor influencing the biotechnology sector's success is improved intellectual property rights legislation—and enforcement—worldwide, as well as strengthened demand for medical and pharmaceutical products to cope with an ageing, and ailing, U.S. population.

Rising demand for biofuels is expected to be good news for the biotechnology sector, with the Department of Energy estimating ethanol usage could reduce U.S. petroleum-derived fuel consumption by up to 30% by 2030. The biotechnology sector has allowed the U.S. farming industry to rapidly increase its supply of corn and soybeans—the main inputs into biofuels—by developing genetically-modified seeds which are resistant to pests and drought. By boosting farm productivity, biotechnology plays a crucial role in ensuring that biofuel production targets are met.

5.3 Applications

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Biotechnology has applications in four major industrial areas, including health care (medical), crop production and agriculture, non food (industrial) uses of crops and other products (*e.g.* biodegradable plastics, vegetable oil, biofuels), and environmental uses.

For example, one application of biotechnology is the directed use of organisms for the manufacture of organic products (examples include beer and milk products). Another example is using naturally present bacteria by the mining industry in bioleaching. Biotechnology is also used to recycle, treat waste, clean up sites contaminated by industrial activities (bioremediation), and also to produce biological weapons.

A series of derived terms have been coined to identify several branches of biotechnology, for example:-bioinformatics

- Bioinformatics is an interdisciplinary field which addresses biological problems using computational techniques, and makes the rapid organization and analysis of biological data possible. The field may also be referred to as computational biology, and can be defined as, "conceptualizing biology in terms of molecules and then applying informatics techniques to understand and organize the information associated with these molecules, on a large scale." Bioinformatics plays a key role in various areas, such as functional genomics, structural genomics, and proteomics, and forms a key component in the biotechnology and pharmaceutical sector.
- Blue biotechnology is a term that has been used to describe the marine and aquatic applications of biotechnology, but its use is relatively rare.
- Green biotechnology is biotechnology applied to agricultural processes. An example would be the selection and domestication of plants via micropropagation. Another example is the designing of transgenic plants to grow under specific environmental conditions or in the presence (or absence) of certain agricultural chemicals. One hope is that green biotechnology might produce more environmentally friendly solutions than traditional industrial agriculture. An example of this is the engineering of a plant to express a pesticide, thereby eliminating the need for external application of pesticides. An example of this would be Bt corn. Whether or not green biotechnology products such as this are ultimately more environmentally friendly is a topic of considerable debate.
- Red biotechnology is applied to medical processes. Some examples are the designing of organisms to produce antibiotics, and the engineering of genetic cures through genomic manipulation.
- White biotechnology, also known as industrial biotechnology, is biotechnology applied to industrial processes. An example is the designing

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of an organism to produce a useful chemical. Another example is the using of enzymes as industrial catalysts to either produce valuable chemicals or destroy hazardous/polluting chemicals. White biotechnology tends to consume less in resources than traditional processes used to produce industrial goods.

- The investments and economic output of all of these types of applied biotechnologies form what has been described as the bioeconomy.

5.4 Biotechnology and Medicine

In medicine, modern biotechnology finds promising applications in such areas as

- drug production;
- pharmacogenomics;
- gene therapy; and
- genetic testing;

Pharmacogenomics

Pharmacogenomics is the study of how the genetic inheritance of an individual affects his/her body's response to drugs. It is a coined word derived from the words "pharmacology" and "genomics". It is hence the study of the relationship between pharmaceuticals and genetics. The vision of pharmacogenomics is to be able to design and produce drugs that are adapted to each person's genetic makeup.

Pharmacogenomics results in the following benefits:

1. ***Development of tailor-made medicines.*** Using pharmacogenomics, pharmaceutical companies can create drugs based on the proteins, enzymes and RNA molecules that are associated with specific genes and diseases. These tailor-made drugs promise not only to maximize therapeutic effects but also to decrease damage to nearby healthy cells.
2. ***More accurate methods of determining appropriate drug dosages.*** Knowing a patient's genetics will enable doctors to determine how well his/her body can process and metabolize a medicine. This will maximize the value of the medicine and decrease the likelihood of overdose.
3. ***Improvements in the drug discovery and approval process.*** The discovery of potential therapies will be made easier using genome targets. Genes have been associated with numerous diseases and disorders. With modern biotechnology, these genes can be used as targets for the development of effective new therapies, which could significantly shorten the drug discovery process.
4. ***Better vaccines.*** Safer vaccines can be designed and produced by organisms transformed by means of genetic engineering. These vaccines will elicit the immune response without the attendant risks of infection. They will be inexpensive, stable, easy to store, and capable of being engineered to carry several strains of pathogen at once.

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Pharmaceutical Products

Most traditional pharmaceutical drugs are relatively simple molecules that have been found primarily through trial and error to treat the symptoms of a disease or illness. Biopharmaceuticals are large biological molecules known as proteins and these usually target the underlying mechanisms and pathways of a malady (but not always, as is the case with using insulin to treat type 1 diabetes mellitus, as that treatment merely addresses the symptoms of the disease, not the underlying cause which is autoimmunity); it is a relatively young industry. They can deal with targets in humans that may not be accessible with traditional medicines. A patient typically is dosed with a small molecule via a tablet while a large molecule is typically injected.

Small molecules are manufactured by chemistry but larger molecules are created by living cells such as those found in the human body: for example, bacteria cells, yeast cells, animal or plant cells.

Modern biotechnology is often associated with the use of genetically altered microorganisms such as *E. coli* or yeast for the production of substances like synthetic insulin or antibiotics. It can also refer to transgenic animals or transgenic plants, such as Bt corn. Genetically altered mammalian cells, such as Chinese Hamster Ovary (CHO) cells, are also used to manufacture certain pharmaceuticals. Another promising new biotechnology application is the development of plant-made pharmaceuticals.

Biotechnology is also commonly associated with landmark breakthroughs in new medical therapies to treat hepatitis B, hepatitis C, cancers, arthritis, haemophilia, bone fractures, multiple sclerosis, and cardiovascular disorders. The biotechnology industry has also been instrumental in developing molecular diagnostic devices that can be used to define the target patient population for a given biopharmaceutical. Herceptin, for example, was the first drug approved for use with a matching diagnostic test and is used to treat breast cancer in women whose cancer cells express the protein HER2.

Modern biotechnology can be used to manufacture existing medicines relatively easily and cheaply. The first genetically engineered products were medicines designed to treat human diseases. To cite one example, in 1978 Genentech developed synthetic humanized insulin by joining its gene with a plasmid vector inserted into the bacterium Escherichia coli. Insulin, widely used for the treatment of diabetes, was previously extracted from the pancreas of abattoir animals (cattle and/or pigs). The resulting genetically engineered bacterium enabled the production of vast quantities of synthetic human insulin at relatively low cost.

According to a 2003 study undertaken by the International Diabetes Federation (IDF) on the access to and availability of insulin in its member countries, synthetic 'human' insulin is considerably more expensive in most countries where both synthetic 'human' and animal insulin are commercially available: *e.g.* within European countries the average price of synthetic 'human' insulin was twice as high as the price of pork insulin. Yet in its position statement, the IDF writes that "there is no overwhelming evidence to prefer one species of insulin over another"

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and "[modern, highly-purified] animal insulins remain a perfectly acceptable alternative.

Modern biotechnology has evolved, making it possible to produce more easily and relatively cheaply human growth hormone, clotting factors for hemophiliacs, fertility drugs, erythropoietin and other drugs. Most drugs today are based on about 500 molecular targets. Genomic knowledge of the genes involved in diseases, disease pathways, and drug-response sites are expected to lead to the discovery of thousands more new targets.

Genetic Testing

Genetic testing involves the direct examination of the DNA molecule itself. A scientist scans a patient's DNA sample for mutated sequences.

There are two major types of gene tests. In the first type, a researcher may design short pieces of DNA ("probes") whose sequences are complementary to the mutated sequences. These probes will seek their complement among the base pairs of an individual's genome. If the mutated sequence is present in the patient's genome, the probe will bind to it and flag the mutation. In the second type, a researcher may conduct the gene test by comparing the sequence of DNA bases in a patient's gene to disease in healthy individuals or their progeny.

Genetic testing is now used for:

- Carrier screening, or the identification of unaffected individuals who carry one copy of a gene for a disease that requires two copies for the disease to manifest;
- Confirmational diagnosis of symptomatic individuals;
- Determining sex;
- Forensic/identity testing;
- Newborn screening;
- Prenatal diagnostic screening;
- Presymptomatic testing for estimating the risk of developing adult-onset cancers;
- Presymptomatic testing for predicting adult-onset disorders.

Some genetic tests are already available, although most of them are used in developed countries. The tests currently available can detect mutations associated with rare genetic disorders like cystic fibrosis, sickle cell anemia, and Huntington's disease. Recently, tests have been developed to detect mutation for a handful of more complex conditions such as breast, ovarian, and colon cancers. However, gene tests may not detect every mutation associated with a particular condition because many are as yet undiscovered, and the ones they do detect may present different risks to different people and populations.

Gene Therapy

Gene therapy may be used for treating, or even curing, genetic and acquired diseases like cancer and AIDS by using normal genes to supplement or replace defective genes or to bolster a normal function such as immunity. It can be used

to target somatic (*i.e.*, body) or gametes (*i.e.*, egg and sperm) cells. In somatic gene therapy, the genome of the recipient is changed, but this change is not passed along to the next generation. In contrast, in germline gene therapy, the egg and sperm cells of the parents are changed for the purpose of passing on the changes to their offspring.

There are basically two ways of implementing a gene therapy treatment:

1. Ex vivo, which means "outside the body" – Cells from the patient's blood or bone marrow are removed and grown in the laboratory. They are then exposed to a virus carrying the desired gene. The virus enters the cells, and the desired gene becomes part of the DNA of the cells. The cells are allowed to grow in the laboratory before being returned to the patient by injection into a vein.
2. In vivo, which means "inside the body" – No cells are removed from the patient's body. Instead, vectors are used to deliver the desired gene to cells in the patient's body.

Currently, the use of gene therapy is limited. Somatic gene therapy is primarily at the experimental stage. Germline therapy is the subject of much discussion but it is not being actively investigated in larger animals and human beings.

As of June 2001, more than 500 clinical gene-therapy trials involving about 3,500 patients have been identified worldwide. Around 78% of these are in the United States, with Europe having 18%. These trials focus on various types of cancer, although other multigenic diseases are being studied as well. Recently, two children born with severe combined immunodeficiency disorder ("SCID") were reported to have been cured after being given genetically engineered cells.

Gene therapy faces many obstacles before it can become a practical approach for treating disease. At least four of these obstacles are as follows:

1. ***Gene delivery tools.*** Genes are inserted into the body using gene carriers called vectors. The most common vectors now are viruses, which have evolved a way of encapsulating and delivering their genes to human cells in a pathogenic manner. Scientists manipulate the genome of the virus by removing the disease-causing genes and inserting the therapeutic genes. However, while viruses are effective, they can introduce problems like toxicity, immune and inflammatory responses, and gene control and targeting issues. In addition, in order for gene therapy to provide permanent therapeutic effects, the introduced gene needs to be integrated within the host cell's genome. Some viral vectors effect this in a random fashion, which can introduce other problems such as disruption of an endogenous host gene.
2. ***High costs.*** Since gene therapy is relatively new and at an experimental stage, it is an expensive treatment to undertake. This explains why current studies are focused on illnesses commonly found in developed countries, where more people can afford to pay for treatment. It may take decades before developing countries can take advantage of this technology.

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3. ***Limited knowledge of the functions of genes.*** Scientists currently know the functions of only a few genes. Hence, gene therapy can address only some genes that cause a particular disease. Worse, it is not known exactly whether genes have more than one function, which creates uncertainty as to whether replacing such genes is indeed desirable.
4. ***Multigene disorders and effect of environment.*** Most genetic disorders involve more than one gene. Moreover, most diseases involve the interaction of several genes and the environment. For example, many people with cancer not only inherit the disease gene for the disorder, but may have also failed to inherit specific tumor suppressor genes. Diet, exercise, smoking and other environmental factors may have also contributed to their disease.

5.5 Biotechnology and Agriculture

"Responsible biotechnology is not the enemy; starvation is. Without adequate food supplies at affordable prices, we cannot expect world health or peace."
—Jimmy Carter, Former President of the United States, 11 Jul. 1997,

Crop Yield

Using the techniques of modern biotechnology, one or two genes may be transferred to a highly developed crop variety to impart a new character that would increase its yield. However, while increases in crop yield are the most obvious applications of modern biotechnology in agriculture, it is also the most difficult one. Current genetic engineering techniques work best for effects that are controlled by a single gene. Many of the genetic characteristics associated with yield (*e.g.*, enhanced growth) are controlled by a large number of genes, each of which has a minimal effect on the overall yield. There is, therefore, much scientific work to be done in this area.

Reduced Vulnerability of Crops to Environmental Stresses

Crops containing genes that will enable them to withstand biotic and abiotic stresses may be developed. For example, drought and excessively salty soil are two important limiting factors in crop productivity. Biotechnologists are studying plants that can cope with these extreme conditions in the hope of finding the genes that enable them to do so and eventually transferring these genes to the more desirable crops. One of the latest developments is the identification of a plant gene, At-DBF2, from thale cress, a tiny weed that is often used for plant research because it is very easy to grow and its genetic code is well mapped out.

When this gene was inserted into tomato and tobacco cells, the cells were able to withstand environmental stresses like salt, drought, cold and heat, far more than ordinary cells. If these preliminary results prove successful in larger trials, then At-DBF2 genes can help in engineering crops that can better withstand harsh environments. Researchers have also created transgenic rice plants that are resistant to rice yellow mottle virus (RYMV). In Africa, this virus destroys majority of the rice crops and makes the surviving plants more susceptible to fungal infections.

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Increased Nutritional Qualities and Quantity of Food Crops

Proteins in foods may be modified to increase their nutritional qualities. Proteins in legumes and cereals may be transformed to provide the amino acids needed by human beings for a balanced diet. A good example is the work of Professors Ingo Potrykus and Peter Beyer on the so-called Golden rice (discussed below).

Improved Taste, Texture or Appearance of Food

Modern biotechnology can be used to slow down the process of spoilage so that fruit can ripen longer on the plant and then be transported to the consumer with a still reasonable shelf life. This alters the taste, texture and appearance of the fruit. More importantly, it could expand the market for farmers in developing countries due to the reduction in spoilage. However, there is sometimes a lack of understanding by researchers in developed countries about the actual needs of prospective beneficiaries in developing countries. For example, engineering soybeans to resist spoilage makes them less suitable for producing tempeh which is a significant source of protein that depends on fermentation. The use of modified soybeans results in a lumpy texture that is less palatable and less convenient when cooking.

The first genetically modified food product was a tomato which was transformed to delay its ripening. Researchers in Indonesia, Malaysia, Thailand, Philippines and Vietnam are currently working on delayed-ripening papaya in collaboration with the University of Nottingham and Zeneca.

Biotechnology in cheese production: enzymes produced by microorganisms provide an alternative to animal rennet – a cheese coagulant - and an alternative supply for cheese makers. This also eliminates possible public concerns with animal-derived material, although there are currently no plans to develop synthetic milk, thus making this argument less compelling. Enzymes offer an animal-friendly alternative to animal rennet. While providing comparable quality, they are theoretically also less expensive.

About 85 million tons of wheat flour is used every year to bake bread. By adding an enzyme called maltogenic amylase to the flour, bread stays fresher longer. Assuming that 10—15% of bread is thrown away as stale, if it could be made to stay fresh another 5—7 days then perhaps 2 million tons of flour per year would be saved. Other enzymes can cause bread to expand to make a lighter loaf, or alter the loaf in a range of ways.

Reduced Dependence on Fertilizers, Pesticides and Other Agrochemicals

Most of the current commercial applications of modern biotechnology in agriculture are on reducing the dependence of farmers on agrochemicals. For example, Bacillus thuringiensis (Bt) is a soil bacterium that produces a protein with insecticidal qualities. Traditionally, a fermentation process has been used to produce an insecticidal spray from these bacteria. In this form, the Bt toxin occurs as an inactive protoxin, which requires digestion by an insect to be effective. There are several Bt toxins and each one is specific to certain target insects. Crop plants have now been engineered to contain and express the genes for Bt toxin,

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which they produce in its active form. When a susceptible insect ingests the transgenic crop cultivar expressing the Bt protein, it stops feeding and soon thereafter dies as a result of the Bt toxin binding to its gut wall. Bt corn is now commercially available in a number of countries to control corn borer (a lepidopteran insect), which is otherwise controlled by spraying (a more difficult process).

Crops have also been genetically engineered to acquire tolerance to broad-spectrum herbicide. The lack of cost-effective herbicides with broad-spectrum activity and no crop injury was a consistent limitation in crop weed management. Multiple applications of numerous herbicides were routinely used to control a wide range of weed species detrimental to agronomic crops. Weed management tended to rely on preemergence — that is, herbicide applications were sprayed in response to expected weed infestations rather than in response to actual weeds present. Mechanical cultivation and hand weeding were often necessary to control weeds not controlled by herbicide applications. The introduction of herbicide-tolerant crops has the potential of reducing the number of herbicide active ingredients used for weed management, reducing the number of herbicide applications made during a season, and increasing yield due to improved weed management and less crop injury. Transgenic crops that express tolerance to glyphosate, glufosinate and bromoxynil have been developed. These herbicides can now be sprayed on transgenic crops without inflicting damage on the crops while killing nearby weeds.

From 1996 to 2001, herbicide tolerance was the most dominant trait introduced to commercially available transgenic crops, followed by insect resistance. In 2001, herbicide tolerance deployed in soybean, corn and cotton accounted for 77% of the 626,000 square kilometres planted to transgenic crops; Bt crops accounted for 15%; and "stacked genes" for herbicide tolerance and insect resistance used in both cotton and corn accounted for 8%.

Production of Novel Substances in Crop Plants

Biotechnology is being applied for novel uses other than food. For example, oilseed can be modified to produce fatty acids for detergents, substitute fuels and petrochemicals. Potatoes, tomatoes, ricererere tobacco, lettuce, safflowers, and other plants have been genetically-engineered to produce insulin and certain vaccines. If future clinical trials prove successful, the advantages of edible vaccines would be enormous, especially for developing countries. The transgenic plants may be grown locally and cheaply. Homegrown vaccines would also avoid logistical and economic problems posed by having to transport traditional preparations over long distances and keeping them cold while in transit. And since they are edible, they will not need syringes, which are not only an additional expense in the traditional vaccine preparations but also a source of infections if contaminated. In the case of insulin grown in transgenic plants, it is well-established that the gastrointestinal system breaks the protein down therefore this could not currently be administered as an edible protein. However, it might be produced at significantly lower cost than insulin produced in costly, bioreactors. For example,

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Calgary, Canada-based SemBioSys Genetics, Inc. reports that its safflower-produced insulin will reduce unit costs by over 25% or more and approximates a reduction in the capital costs associated with building a commercial-scale insulin manufacturing facility of over $100 million, compared to traditional biomanufacturing facilities.

Criticism

There is another side to the agricultural biotechnology issue. It includes increased herbicide usage and resultant herbicide resistance, "super weeds," residues on and in food crops, genetic contamination of non-GM crops which hurt organic and conventional farmers, damage to wildlife from glyphosate, etc.

5.6 Biological Engineering

Biotechnological engineering or biological engineering is a branch of engineering that focuses on biotechnologies and biological science. It includes different disciplines such as biochemical engineering, biomedical engineering, bio-process engineering, biosystem engineering and so on. Because of the novelty of the field, the definition of a bioengineer is still undefined. However, in general it is an integrated approach of fundamental biological sciences and traditional engineering principles.

Bioengineers are often employed to scale up bio-processes from the laboratory scale to the manufacturing scale. Moreover, as with most engineers, they often deal with management, economic and legal issues. Since patents and regulation (*e.g.*, U.S. Food and Drug Administration regulation in the U.S.) are very important issues for biotech enterprises, bioengineers are often required to have knowledge related to these issues.

The increasing number of biotech enterprises is likely to create a need for bioengineers in the years to come. Many universities throughout the world are now providing programs in bioengineering and biotechnology (as independent programs or specialty programs within more established engineering fields).

Bioremediation and Biodegradation

Biotechnology is being used to engineer and adapt organisms especially microorganisms in an effort to find sustainable ways to clean up contaminated environments. The elimination of a wide range of pollutants and wastes from the environment is an absolute requirement to promote a sustainable development of our society with low environmental impact. Biological processes play a major role in the removal of contaminants and biotechnology is taking advantage of the astonishing catabolic versatility of microorganisms to degrade/convert such compounds.

New methodological breakthroughs in sequencing, genomics, proteomics, bioinformatics and imaging are producing vast amounts of information. In the field of Environmental Microbiology, genome-based global studies open a new era providing unprecedented in silico views of metabolic and regulatory networks, as well as clues to the evolution of degradation pathways and to the molecular adaptation strategies to changing environmental conditions. Functional genomic

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and metagenomic approaches are increasing our understanding of the relative importance of different pathways and regulatory networks to carbon flux in particular environments and for particular compounds and they will certainly accelerate the development of bioremediation technologies and biotransformation processes.

Marine environments are especially vulnerable since oil spills of coastal regions and the open sea are poorly containable and mitigation is difficult. In addition to pollution through human activities, millions of tons of petroleum enter the marine environment every year from natural seepages. Despite its toxicity, a considerable fraction of petroleum oil entering marine systems is eliminated by the hydrocarbon-degrading activities of microbial communities, in particular by a remarkable recently discovered group of specialists, the so-called hydrocarbonoclastic bacteria (HCCB).

5.7 Food Biotechnology

Modern biotechnology refers to various scientific techniques used to produce specific desired traits in plants, animals or microorganisms through the use of genetic knowledge. Since its introduction to agriculture and food production in the early-1990's, biotechnology has been utilized to develop new tools for improving productivity. In 2005, twenty-one countries planted biotech crops covering a total of 222 million acres. These crops include soybeans, corn, cotton, canola, papaya, and squash that are improved versions of the traditional varieties. In addition, rapid-rise yeast and an enzyme used to make cheese are both commonly produced through biotechnology.

Biotechnology is a broad term that applies to the use of living organisms and covers techniques that range from simple to sophisticated. For centuries people have crossbred related plants or animal species to develop useful new varieties or hybrids with advantageous traits, such as better taste or increased productivity. Traditional crossbreeding produces changes in the genetic makeup of a plant or animal. The process can be very time consuming as it is necessary to breed several generations in order to not only obtain the desired trait, but also remove numerous unwanted traits.

In contrast, modern agricultural biotechnology techniques, such as genetic engineering, allow for more precise development of crop and livestock varieties.

The genes that directly express desired traits, such as agronomic performance, are identified more readily. Therefore, the genetic makeup of food-producing crops and livestock can be improved more efficiently. Gene technology not only provides the potential to select the exact characteristics desired, but it also enables us to transfer genes for desired traits more precisely.

Crop Biotechnology

There are three main categories of biotechnology-enhanced crops in use or development.

- Enhanced input traits, such as herbicide tolerance, insect and virus protection, and tolerance to environmental stressors such as drought.

- Value-added output traits, such as corn with higher amounts of lysine for animal feed, or vegetable oils with increased levels of omega-3 fatty acids.
- Crops that produce pharmaceuticals or improve the processing of bio-based fuels.

Today, crops in production are primarily those with enhanced input traits.

Animal Biotechnology

The use of genetic information to improve livestock selection and breeding, referred to as animal genomics, is an important tool in agriculture today. Genomics information can also help in determining optimum nutritional needs for animals. This aids in consistent production of high-quality meat, eggs, or milk.

Cloning is another modern technology that facilitates breeding of the healthiest and most productive livestock. The genetic makeup of the animal is not changed in any way. In fact, this form of assisted reproduction allows livestock breeders to produce an identical twin of the best available animals, which is itself used to breed future generations. As of 2005, foods produced from cloned animals or their offspring were not yet commercially available.

Genetic engineering is another potential tool being explored in breeding programs for food-producing animals. Potential benefits of such advances may include animals that mature more quickly or have enhanced nutritional characteristics, such as pigs that produce pork higher in omega-3 fatty acids. The product that would most likely be ready for commercialization in the near future is a variety of salmon, currently under regulatory review, that grows to maturity more quickly than its non-biotech counterpart.

Growth and Acceptance

According to a 2005 report by the International Society for the Acquisition of Agri-Biotech Applications (ISAAA), crops enhanced through biotechnology were planted extensively in the U.S., Canada, Brazil, Argentina, Uruguay, Paraguay, and Australia. These seven countries planted 208.7 million acres of biotech crops, or about 94 percent of the worldwide biotech crop acreage.

The second leading biotech crop producers were small-scale farms in countries that need to increase production to improve incomes in rural areas and supply growing urban populations. These countries included China, India, South Africa, Mexico, Philippines, Columbia, Honduras, and Iran, with acreage of 13.2 million. Small farms in Spain, Germany, Portugal, France, Czech Republic, and Romania accounted for an additional 350,000 acres of biotech crops in 2005.

Farmers have embraced biotechnology because it provides agronomic (agricultural) benefits. The precise agronomic performance of a given variety depends on the growing location, weather, and other factors. Fortunately, the positive impact of biotechnology on crop performance translates into benefits for the environment.

The National Center for Food and Agricultural Policy (NCFAP) found that in 2004, compared to 2003, the combined impact of the 11 biotech crops used in

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the U.S. resulted in 62 million fewer pounds of pesticides used. According to a recent, peer-reviewed study by PG Economics, biotech crops have created significant economic and environmental benefits since they were introduced in 1996.

Moreover, biotech crops have reduced pesticide applications by 379 million pounds – an amount that could fill a 15-mile train of railcars. NCFAP also found that planting herbicide-tolerant crops allowed farmers to conserve soil by avoiding tilling (plowing) the soil frequently. The study by PG Economics also found that biotech crops allowed farmers to reduce tractor usage for tilling the soil, due to more effective weed control. This change in procedure saved 464 million gallons of diesel fuel and decreased greenhouse gas emissions (carbon dioxide) by 22 billion pounds. The reduction of greenhouse gas emissions is equivalent to taking five million cars off the road for a full year.

Moreover, crop performance and pest management, benefits of biotechnology, translate into economic benefits for farmers, as well as environmental benefits.

According to PG Economics, net income for farmers growing biotech crops increased by more than $27 billion globally over the period 1996—2004. U.S. farmers have planted more acres of biotech crops than any other country and consequently have received the largest additional income benefits, amounting to nearly $11 billion.

Consumer Acceptance

According to IFIC's quantitative survey of U.S. consumers (2006), overall, awareness of food biotechnology seems to incline consumers to be more, not less, favourably disposed to the technology. Specifically, these consumers are more likely to know these foods are in stores today, state likelihood to purchase the foods, and expect benefits from the technology.

Consumer opinion is split in regard to animal biotechnology. However consumers are more favorable once they understand "why" the technology is being utilized. For example, sixty percent of consumers confirm that the potential benefit of animal biotechnology improving "the quality and safety of food" would positively impact their impression of the technology. Furthermore, favourability may increase slightly with FDA assurances of safety of food produced using animal biotechnology.

An important aspect of the survey is that food safety and labelling concerns are solicited from consumers on an open ended basis, thereby allowing consumers to volunteer unprompted, top-of-mind concerns. On an open-ended basis, only one percent name biotechnology as a labeling issue. A majority of consumers state that there is no information that they would like to see added to food labels. Furthermore, more than half of consumers said they support the FDA's current labeling policy for foods produced through biotechnology. Food biotechnology meets with greater concern in some other world regions. Improved access to science-based, consumer-focused information about biotechnology is important in order to ensure that the global community realizes the benefits.

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5.8 Importance of Food Biotechnology

We have used biotechnology to manufacture food products for more than 8,000 years. Bread, alcoholic beverages, vinegar, cheese and yogurt, and many other foods owe their existence to enzymes found in various microorganisms. Today's biotechnology will continue to affect the food industry by providing new products, lowering costs and improving the microbial processes on which food producers have long relied.

Many of these impacts will improve the quality, nutritional value and safety of the crop plants and animal products that are the basis of the food industry. In addition, biotechnology offers many ways to improve the processing of those raw materials into final products: natural flavours and colours; new production aids, such as enzymes and emulsifiers; improved starter cultures; more waste treatment options; "greener" manufacturing processes; more options for assessing food safety during the process; and even biodegradable plastic wrap that kills bacteria.

Improving the Raw Materials

The first generation of transgenic crops primarily benefited farmers. Although there are consumer benefits in growing these crops, the benefits are largely invisible to consumers. For example, studies have shown that because insect-resistant corn (Bt corn) sustains relatively little insect damage, fungi and molds cannot infect those plants as easily as non-insect-resistant crops. Therefore, the level of toxins, such as aflatoxin, produced by these pathogens, some of which are fatal to livestock, is much lower in Bt corn than non-Bt corn.

The benefits of the next wave of biotechnology crops will be more obvious to consumers. Some of those benefits will involve improvements in food quality and safety, while others will provide consumers with foods designed specifically to be healthier and more nutritious.

Health and Nutritional Benefits

A variety of healthier cooking oils derived from biotechnology are already on the market. Using biotechnology, plant scientists have decreased the total amount of saturated fatty acids in certain vegetable oils. They have also increased the conversion of linoleic acid to the fatty acid found mainly in fish that is associated with lowering cholesterol levels.

Another nutritional concern related to edible oils is the negative health effects produced when vegetable oils are hydrogenated to increase their heat stability for cooking or to solidify oils used in making margarine. The hydrogenation process results in the formation of trans-fatty acids.

Biotechnology companies have given soybean oil these same properties, not through hydrogenation, but by using biotechnology to increase the amount of the naturally occurring fatty acid, stearic acid. Animal scientists are also using biotechnology to create healthier meat products, such as beef with lower fat content and pigs with a higher meat-to-fat ratio.

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Other health and nutritional benefits of crops improved through biotechnology include increased nutritional value of crops, especially those that are food staples in developing countries. Scientists at Nehru University in New Delhi used a gene found in the South American plant amaranth to increase the protein content of potatoes by 30 percent. These transgenic potatoes also contain large amounts of essential amino acids not found in unmodified potatoes. Other examples include golden rice and canola oil, both of which are high in vitamin A. The golden rice developers further improved rice with two other genes that increase the amount and digestibility of iron.

Biotechnology also promises to improve the health benefits of functional foods. Functional foods are foods containing significant levels of biologically active components that impart health benefits beyond our basic needs for sufficient calories, essential amino acids, vitamins and minerals. Familiar examples of functional foods include compounds in garlic and onions that lower cholesterol and improve the immune response; antioxidants found in green tea; and the glucosinolates in broccoli and cabbage that stimulate anticancer enzymes.

We are using biotechnology to increase the production of these compounds in functional foods. For example, researchers at Purdue University and the U.S. Department of Agriculture, created a tomato variety that contains three times as much of the antioxidant lycopene as the unmodified variety. Lycopene consumption is associated with a lower risk of prostate and breast cancer and decreased blood levels of "bad cholesterol." Other USDA researchers are using biotechnology to increase the amount of ellagic acid, a cancer protective agent, in strawberries.

Product Quality

We are also using biotechnology to change the characteristics of the raw material inputs so that they are more attractive to consumers and more amenable to processing. Biotechnology researchers are increasing the shelf life of fresh fruits and vegetables; improving the crispness of carrots, peppers and celery; creating seedless varieties of grapes and melons; extending the seasonal geographic availability of tomatoes, strawberries and raspberries; improving the flavour of tomatoes, lettuce, peppers, peas and potatoes; and creating caffeine-free coffee and tea.

Japanese scientists have now identified the enzyme that produces the chemical that makes us cry when we slice an onion. Knowing the identity of the enzyme is the first step in finding a way to block the gene to create "tearless" onions.

Much of the work on improving how well crops endure food processing involves changing the ratio of water to starch. Potatoes with higher starch content are healthier because they absorb less oil when they are fried, for example. Another important benefit is that starchier potatoes require less energy to process and therefore cost less to handle. Many tomato processors now use tomatoes derived from a biotechnology technique, somaclonal variant selection. The new tomatoes, used in soup, ketchup and tomato paste, contain 30 percent less water and are

processed with greater efficiency. A *1 or 2 percent* increase in the solid content is worth $35 million to the U.S. processed-tomato industry.

Another food processing sector that will benefit economically from better quality raw materials is the dairy products industry. Scientists in New Zealand have now used biotechnology to increase the amount of the protein casein, which is essential to cheese making, in milk by 13 percent.

Biotechnology also allows the economically viable production of valuable, naturally occurring compounds that cannot be manufactured by other means. For example, commercial-scale production of the natural and highly marketable sweetener known as fructans has long eluded food-processing engineers. Fructans, which are short chains of the sugar molecule fructose, taste like sugar but have no calories. Scientists found a gene that converts 90 percent of the sugar found in beets to fructans. Because 40 percent of the transgenic beet dry weight is fructans, this crop can serve as a manufacturing facility for fructans.

Safety of the Raw Materials

The most significant food-safety issue food producers face is microbial contamination, which can occur at any point from farm to table. Any biotechnology product that decreases microbes found on animal products and crop plants will significantly improve the safety of raw materials entering the food supply. Improved food safety through decreased microbial contamination begins on the farm.

Transgenic disease-resistant and insect-resistant crops have less microbial contamination. New biotechnology diagnostics, similar to those described in the chapter on medical applications of biotechnology, detect microbial diseases earlier and more accurately, so farmers can identify and remove diseased plants and animals before others become contaminated.

Biotechnology is improving the safety of raw materials by helping food scientists discover the exact identity of the allergenic protein in foods such as peanuts, soybeans and milk, so they can then remove them. Although 95 percent of food allergies can be traced to a group of eight foods, in most cases we do not know which of the thousands of proteins in a food triggered the reaction. With biotechnology techniques, we are making great progress in identifying these allergens. More importantly, scientists have succeeded in using biotechnology to block or remove allergenicity genes in peanuts, soybeans and shrimp.

Finally, biotechnology is helping us improve the safety of raw agricultural products by decreasing the amount of natural plant toxins found in foods such as potato and cassava.

Food Processing

Microorganisms have been essential to the food processing industry for decades. They play a role in the production of the fermented foods listed in *Table1*. They also serve as a rich source of food additives, enzymes and other substances used in food processing.

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Improving Food Fermentors

Because of the importance of fermented foods to so many cultures, scientists are conducting a lot of work to improve the microorganisms that carry out food fermentations. The bacterium responsible for many of our fermented dairy products, such as cheese and yogurt, is susceptible to infection by a virus that causes substantial economic losses to the food industry. Through recombinant technology, researchers have made some strains of this bacterium and other important fermentors resistant to viral infection.

We have known for years that some bacteria used in food fermentation produce compounds that kill other, contaminating bacteria that cause food poisoning and food spoilage. Using biotechnology we are equipping many of our microbial fermentors with this self-defense mechanism to decrease microbial contamination of fermented foods.

Food Additives and Processing Aids

Microorganisms have been essential to the food industry not only for their importance as fermentors, but also because they are the source of many of the additives and processing aids used in food processing. Biotechnology advances will enhance their value to the food industry even further.

Food additives are substances used to increase nutritional value, retard spoilage, change consistency and enhance flavour. The compounds food processors use as food additives are substances nature has provided and are usually of plant or microbial origin, such as xanthan gum and guar gum, which are produced by microbes. Many of the amino acid supplements, flavors, flavour enhancers and vitamins added to breakfast cereals are produced by microbial fermentation. Through biotechnology, food processors will be able to produce many compounds that could serve as food additives but that now are in scant supply or that are found in microorganisms or plants difficult to maintain in fermentation systems.

Food processors use plant starch as a thickener and fat substitute in low-fat products. Currently, the starch is extracted from plants and modified using chemicals or energy-consuming mechanical processes. Scientists are using biotechnology to change the starch in crop plants so that it no longer requires special handling before it can be used.

Table 1. Microbial Fermentation is Essential to the Production of these Fermented Foods

beer	distilled	tamari
bologna	liquors	tea
bread/baked	kefir	tempeh
goods	miso	tofu
buttermilk	olives	vinegar
cheeses	pickles	wine
cider	salami	yogurt
cocoa	sauerkraut	
coffee	sour cream	
cottage cheese	soy sauce	

Enzymes produced by microbial fermentation play essential roles as processing aids in the food industry. The first commercial food product produced by biotechnology was an enzyme used in cheese making. Prior to biotech techniques, this enzyme had to be extracted from the stomach of calves, lambs and baby goats, but it is now produced by microorganisms that were given the gene for this enzyme.

The production of high-fructose corn syrup from cornstarch requires three enzymes, and those same enzymes are important in making baked goods and beer. Other enzymes are essential to the production of fruit juices, candies with soft centers, and cheeses. The food industry uses more than 55 different enzyme products in food processing. This number will increase as we discover how to capitalize on the extraordinary diversity of the microbial world and obtain new enzymes that will prove important in food processing.

Food Safety Testing

In addition to the many ways biotechnology is helping us enhance the safety of the food supply, biotechnology is providing us with many tools to detect microorganisms and the toxins they produce. Monoclonal antibody tests, biosensors, polymerase chain reaction (PCR) methods and DNA probes are being developed that will be used to determine the presence of harmful bacteria that cause food poisoning and food spoilage, such as Listeria and Clostridium botulinum.

We can now distinguish E. coli 0157:H7, the strain of E. coli responsible for several deaths in recent years, from the many other harmless E. coli strains. These tests are portable, quicker and more sensitive to low levels of microbial contamination than previous tests because of the increased specificity of molecular technique. For example, the new diagnostic tests for Salmonella yield results in 36 hours, compared with the three or four days the older detection methods required.

Biotechnology-based diagnostics have also been developed that allow us to detect toxins, such as aflatoxin, produced by fungi and molds that grow on crops, and to determine whether food products have inadvertently been contaminated with peanuts, a potent allergen.

5.9 Genetically Modified Foods

Genetically Modified (GM) foods are foods derived from genetically modified organisms. The DNA of genetically modified organisms has been modified through genetic engineering, unlike similar food organisms developed through the conventional genetic modification of selective breeding (plant breeding and animal breeding) or mutation breeding. GM foods were first put on the market in the early 1990s. Typically, genetically modified foods are transgenic plant products: soybean, corn, canola, and cotton seed oil, but animal products have been developed. For example, in 2006 a pig engineered to produce omega-3 fatty acids through the expression of a roundworm gene was controversially produced. Researchers have also developed a genetically-modified breed of pigs that are able to absorb plant phosphorus more efficiently, and as a

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consequence the phosphorus content of their manure is reduced by as much as 60%. Critics have objected to GM foods on several grounds, including perceived safety issues, ecological concerns, and economic concerns raised by the fact that these organisms are subject to intellectual property law.

What are Genetically-Modified Foods?

The term GM foods or GMOs (genetically-modified organisms) is most commonly used to refer to crop plants created for human or animal consumption using the latest molecular biology techniques. These plants have been modified in the laboratory to enhance desired traits such as increased resistance to herbicides or improved nutritional content. The enhancement of desired traits has traditionally been undertaken through breeding, but conventional plant breeding methods can be very time consuming and are often not very accurate. Genetic engineering, on the other hand, can create plants with the exact desired trait very rapidly and with great accuracy. For example, plant geneticists can isolate a gene responsible for drought tolerance and insert that gene into a different plant. The new genetically-modified plant will gain drought tolerance as well. Not only can genes be transferred from one plant to another, but genes from non-plant organisms also can be used. The best known example of this is the use of Bt genes in corn and other crops. Bt, or Bacillus thuringiensis, is a naturally occurring bacterium that produces crystal proteins that are lethal to insect larvae. Bt crystal protein genes have been transferred into corn, enabling the corn to produce its own pesticides against insects such as the European corn borer. For two informative overviews of some of the techniques involved in creating GM foods, visit Biotech Basics (sponsored by Monsanto) or Techniques of Plant Biotechnology from the National Center for Biotechnology Education.

What are Some of the Advantages of GM foods?

The world population has topped 6 billion people and is predicted to double in the next 50 years. Ensuring an adequate food supply for this booming population is going to be a major challenge in the years to come. GM foods promise to meet this need in a number of ways:

- *Pest resistance.* Crop losses from insect pests can be staggering, resulting in devastating financial loss for farmers and starvation in developing countries. Farmers typically use many tons of chemical pesticides annually. Consumers do not wish to eat food that has been treated with pesticides because of potential health hazards, and run-off of agricultural wastes from excessive use of pesticides and fertilizers can poison the water supply and cause harm to the environment. Growing GM foods such as B.t. corn can help eliminate the application of chemical pesticides and reduce the cost of bringing a crop to market.
- *Herbicide tolerance.* For some crops, it is not cost-effective to remove weeds by physical means such as tilling, so farmers will often spray large quantities of different herbicides (weed-killer) to destroy weeds, a time-consuming and expensive process, that requires care so that the herbicide doesn't harm the crop plant or the environment. Crop plants genetically-

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engineered to be resistant to one very powerful herbicide could help prevent environmental damage by reducing the amount of herbicides needed. For example, Monsanto has created a strain of soybeans genetically modified to be not affected by their herbicide product Roundup. A farmer grows these soybeans which then only require one application of weed-killer instead of multiple applications, reducing production cost and limiting the dangers of agricultural waste run-off.

- *Disease resistance.* There are many viruses, fungi and bacteria that cause plant diseases. Plant biologists are working to create plants with genetically-engineered resistance to these diseases.
- *Cold tolerance.* Unexpected frost can destroy sensitive seedlings. An antifreeze gene from cold water fish has been introduced into plants such as tobacco and potato. With this antifreeze gene, these plants are able to tolerate cold temperatures that normally would kill unmodified seedlings. (Note: I have not been able to find any journal articles or patents that involve fish antifreeze proteins in strawberries, although I have seen such reports in newspapers. I can only conclude that nothing on this application has yet been published or patented.)
- *Drought tolerance/salinity tolerance.* As the world population grows and more land is utilized for housing instead of food production, farmers will need to grow crops in locations previously unsuited for plant cultivation. Creating plants that can withstand long periods of drought or high salt content in soil and groundwater will help people to grow crops in formerly inhospitable places.
- Nutrition Malnutrition is common in third world countries where impoverished peoples rely on a single crop such as rice for the main staple of their diet. However, rice does not contain adequate amounts of all necessary nutrients to prevent malnutrition. If rice could be genetically engineered to contain additional vitamins and minerals, nutrient deficiencies could be alleviated. For example, blindness due to vitamin A deficiency is a common problem in third world countries. Researchers at the Swiss Federal Institute of Technology Institute for Plant Sciences have created a strain of "golden" rice containing an unusually high content of beta-carotene (vitamin A). Since this rice was funded by the Rockefeller Foundation, a non-profit organization, the Institute hopes to offer the golden rice seed free to any third world country that requests it. Plans were underway to develop a golden rice that also has increased iron content. However, the grant that funded the creation of these two rice strains was not renewed, perhaps because of the vigorous anti-GM food protesting in Europe, and so this nutritionally-enhanced rice may not come to market at all.
- Pharmaceuticals Medicines and vaccines often are costly to produce and sometimes require special storage conditions not readily available in third world countries. Researchers are working to develop edible vaccines in tomatoes and potatoes. These vaccines will be much easier to ship, store and administer than traditional injectable vaccines.

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- *Phytoremediation.* Not all GM plants are grown as crops. Soil and groundwater pollution continues to be a problem in all parts of the world. Plants such as poplar trees have been genetically engineered to clean up heavy metal pollution from contaminated soil.

Method

Genetic engineering begins with the identification and isolation of a gene which expresses a desirable trait, with the aid of restriction enzymes. Then a recipient plant or animal is selected, and the gene is inserted and incorporated into its genome through a vector such as agrobacterium, through a gene gun shooting an elemental particle covered in plasmid DNA, electroporation, or a virus. Once part of the recipient, the newly inserted gene becomes part of the genome of the recipient and is regulated in the same way as its other genes.

The advantage of genetic engineering, as illustrated in the next section, is that genes can be introduced that do not occur in the germplasm of the target species and its closely related wild relatives.

Development

The first commercially grown genetically modified whole food crop was a tomato (called FlavrSavr), which was modified to ripen more slowly by Californian company Calgene. Calgene took the initiative to obtain FDA approval for its release in 1994 without any special labelling, although legally no such approval was required. It was welcomed by consumers who purchased the fruit at a substantial premium over the price of regular tomatoes. However, production problems and competition from a conventionally bred, longer shelf-life variety prevented the product from becoming profitable. A variant of the Flavr Savr was used by Zeneca to produce tomato paste which was sold in Europe during the summer of 1996. The labelling and pricing were designed as a marketing experiment, which proved, at the time, that European consumers would accept genetically engineered foods.

Currently, there are a number of food species in which a genetically modified version exists.

Food	Properties of the genetically modified variety	Modification
Soybeans	Resistant to glyphosate or glufosinate herbicides	Herbicide resistant gene taken from bacteria inserted into soybean
	Resistant to glyphosate or glufosinate herbicides, Insect resistance - using Bt proteins some previously used as pesticides in organic crop production.	
Corn, field	Vitamin-enriched corn	New genes added/transferred into plant genome.

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	derived from South African white corn variety M37W has bright orange kernels, with 169x increase in beta carotene, 6x the vitamin C and 2x folate.	
Cotton (cottonseed oil)	Pest-resistant cotton	B.t. crystal protein gene added/transferred into plant genome
Hawaiian Papaya	Variety is resistant to the Papaya ringspot virus.	New gene added/transferred into plant genome
Tomatoes	Variety in which the production of the enzyme polygalacturonase (PG) is suppressed, retarding fruit softening after harvesting.	A reverse copy (an antisense gene) of the gene responsible for the production of PG enzyme added into plant genome
Potatoes	Amflora variety produces starch composed almost exclusively of the amylopectin component of starch.	The gene for granule bound starch synthase (GBSS) (the key enzyme for the synthesis of amylose) was switched off by inserting antisense copy of the GBSS gene.
Rapeseed (Canola)	Resistance to herbicides (glyphosate or glufosinate), High laurate canola	New genes added/transferred into plant genome
Sugar cane	Resistance to certain pesticides, High-sucrose cane.	New genes added/transferred into plant genome
Sugar beet	Resistance to glyphosate, glufosinate herbicides	New genes added/transferred into plant genome
Sweet corn	Produces its own bioinsecticide (B.t. toxin)	Gene from the bacteria Bacillus thuringiensis added to the plant.
Rice	Genetically modified to contain high amounts of Vitamin A (beta-carotene)	"Golden rice" Three new genes implanted: two from daffodils and the third from a bacterium

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In addition, various genetically engineered microorganisms are routinely used as sources of enzymes for the manufacture of a wide variety of processed foods. These include alpha-amylase from bacteria, which converts starch to simple sugars, chymosin from bacteria or fungi that clots milk protein for cheese making, and pectinesterase from fungi which improves fruit juice clarity.

5.10 Growing GM Crops

Between 1997 and 2005, the total surface area of land cultivated with GMOs had increased by a factor of 50, from 17,000 km^2 (4.2 million acres) to 900,000 km^2 (222 million acres).

Although most GM crops are grown in North America, in recent years there has been rapid growth in the area sown in developing countries. For instance in 2005 the largest increase in crop area planted to GM crops (soybeans) was in Brazil (94,000 km^2 in 2005 versus 50,000 km^2 in 2004.) There has also been rapid and continuing expansion of GM cotton varieties in India since 2002. (Cotton is a major source of vegetable cooking oil and animal feed.) It is predicted that in 2008/9 32,000 km^2 of GM cotton will be harvested in India (up more than 100 percent from the previous season). Indian national average cotton yields of GM cotton were seven times lower in 2002, because the parental cotton plant used in the genetic engineered variant was not well suited to the climate of India and failed. The publicity given to transgenic trait Bt insect resistance has encouraged the adoption of better performing hybrid cotton varieties, and the Bt trait has substantially reduced losses to insect predation. Though controversial and often disputed, economic and environmental benefits of GM cotton in India to the individual farmer have been documented.

In 2003, countries that grew 99% of the global transgenic crops were the United States (63%), Argentina (21%), Canada (6%), Brazil (4%), China (4%), and South Africa (1%). The Grocery Manufacturers of America estimate that 75% of all processed foods in the U.S. contain a GM ingredient. In particular, Bt corn, which produces the pesticide within the plant itself, is widely grown, as are soybeans genetically designed to tolerate glyphosate herbicides. These constitute "input-traits" are aimed to financially benefit the producers, have indirect environmental benefits and marginal cost benefits to consumers.

In the U.S., by 2006 89% of the planted area of soybeans, 83% of cotton, and 61% maize were genetically modified varieties. Genetically modified soybeans carried herbicide-tolerant traits only, but maize and cotton carried both herbicide tolerance and insect protection traits (the latter largely the Bacillus thuringiensis Bt insecticidal protein). In the period 2002 to 2006, there were significant increases in the area planted to Bt protected cotton and maize, and herbicide tolerant maize also increased in sown area.

Crop Yields

Several studies supported by organic growers have claimed that genetically modified varieties of plants do not produce higher crop yields than normal plants.

One study by Charles Benbrook, Chief Scientist of the Organic Center, found that genetically engineered Roundup Ready soybeans do not increase yields

(Bendrook, 1999). The report reviewed over 8,200 university trials in 1998 and found that Roundup Ready soybeans yielded 7—10% less than similar natural varieties. In addition, the same study found that farmers used 5—10 times more herbicide (Roundup) on Roundup Ready soybeans than on conventional ones.

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Coexistence and Traceability

The United States and Canada do not require labelling of genetically modifed foods. However, in certain other regions, such as the European Union, Japan, Malaysia and Australia, governments have required labelling so consumers can exercise choice between foods that have genetically modified, conventional or organic origins. This requires a labelling system as well as the reliable separation of GM and non-GM organisms at production level and throughout the whole processing chain. Research suggests that this may prove impossible.

For traceability, the OECD has introduced a "unique identifier" which is given to any GMO when it is approved. This unique identifier must be forwarded at every stage of processing. Many countries have established labelling regulations and guidelines on coexistence and traceability. Research projects such as Co-Extra, SIGMEA and Transcontainer are aimed at investigating improved methods for ensuring coexistence and providing stakeholders the tools required for the implementation of coexistence and traceability.

Detection

Testing on GMOs in food and feed is routinely done using molecular techniques like DNA microarrays or qPCR. These tests can be based on screening genetic elements (like p35S, tNos, pat, or bar) or event-specific markers for the official GMOs (like Mon810, Bt11, or GT73). The array-based method combines multiplex PCR and array technology to screen samples for different potential GMOs, combining different approaches (screening elements, plant-specific markers, and event-specific markers).

The qPCR is used to detect specific GMO events by usage of specific primers for screening elements or event-specific markers. Controls are necessary to avoid false positive or false negative results. For example, a test for CaMV is used to avoid a false positive in the event of a virus-contaminated sample.

Economic and Political Effects

- Many proponents of genetic engineered crops claim they lower pesticide usage and have brought higher yields and profitability to many farmers, including those in developing nations. This view is supported by the widespread adoption of genetically-engineered crops by farmers in regions where they are available. A few genetic engineering licenses allow farmers in less economically developed countries to save seeds for next year's planting.
- In August 2003, Zambia cutoff the flow of Genetically Modified Food (mostly maize) from UN's World Food Programme. This left a famine-stricken population without food aid.
- In December 2005 the Zambian government changed its mind in the face of further famine and allowed the importation of GM maize. However,

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the Zambian Minister for Agriculture Mundia Sikatana has insisted that the ban on genetically modified maize remains, saying "We do not want GM (genetically modified) foods and our hope is that all of us can continue to produce non-GM foods."

- In April 2004 Hugo Chávez announced a total ban on genetically modified seeds in Venezuela.
- In January 2005, the Hungarian government announced a ban on importing and planting of genetic modified maize seeds, which was subsequently authorized by the EU.
- On August 18, 2006, American exports of rice to Europe were interrupted when much of the U.S. crop was confirmed to be contaminated with unapproved engineered genes, possibly due to accidental cross-pollination with conventional crops.

Intellectual Property

Traditionally, farmers in all nations saved their own seed from year to year. Allowing farmers to follow this practice with genetically modified seed would result in seed developers losing the ability to profit from their breeding work. Therefore, genetically-modified seed are subject to licensing by their developers in contracts that are written to prevent farmers from following this traditional practice. Many objections to genetically modified food crops are based on this change.

Enforcement of patents on genetically modified plants is often contentious, especially because of gene flow. In 1998, 95—98 percent of about 10 km^2 planted with canola by Canadian farmer Percy Schmeiser were found to contain Monsanto Company's patented Roundup Ready gene although Schmeiser had never purchased seed from Monsanto. The initial source of the plants was undetermined, and could have been through either gene flow or intentional theft. However, the overwhelming predominance of the trait implied that Schmeiser must have intentionally selected for it. The court determined that Schmeiser had saved seed from areas on and adjacent to his property where Roundup had been sprayed, such as ditches and near power poles.

Although unable to prove direct theft, Monsanto sued Schmeiser for piracy since he knowingly grew Roundup Ready plants without paying royalties(Ibid). The case made it to the Canadian Supreme Court, which in 2004 ruled 5 to 4 in Monsanto's favour. The dissenting judges focused primarily on the fact that Monsanto's patents covered only the gene itself and glyphosate resistant cells, and failed to cover transgenic plants in their entirety. All of the judges agreed that Schmeiser would not have to pay any damages since he had not benefited from his use of the genetically modified seed.

In response to criticism, Monsanto Canada's Director of Public Affairs stated that "It is not, nor has it ever been Monsanto Canada's policy to enforce its patent on Roundup Ready crops when they are present on a farmer's field by accident...Only when there has been a knowing and deliberate violation of its patent rights will Monsanto act."

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Future Developments

Future envisaged applications of GMOs are diverse and include drugs in food, bananas that produce human vaccines against infectious diseases such as Hepatitis B, metabolically engineered fish that mature more quickly, fruit and nut trees that yield years earlier, foods no longer containing properties associated with common intolerances, and plants that produce new plastics with unique properties. While their practicality or efficacy in commercial production has yet to be fully tested, the next decade may see exponential increases in GM product development as researchers gain increasing access to genomic resources that are applicable to organisms beyond the scope of individual projects. Safety testing of these products will also, at the same time, be necessary to ensure that the perceived benefits will indeed outweigh the perceived and hidden costs of development. Plant scientists, backed by results of modern comprehensive profiling of crop composition, point out that crops modified using GM techniques are less likely to have unintended changes than are conventionally bred crops.

What are Some of the Criticisms Against GM Foods?

Environmental activists, religious organizations, public interest groups, professional associations and other scientists and government officials have all raised concerns about GM foods, and criticized agribusiness for pursuing profit without concern for potential hazards, and the government for failing to exercise adequate regulatory oversight. It seems that everyone has a strong opinion about GM foods. Even the Vatican and the Prince of Wales have expressed their opinions. Most concerns about GM foods fall into three categories: environmental hazards, human health risks, and economic concerns.

Environmental Hazards

- Unintended harm to other organisms Last year a laboratory study was published in Nature showing that pollen from B.t. corn caused high mortality rates in monarch butterfly caterpillars. Monarch caterpillars consume milkweed plants, not corn, but the fear is that if pollen from Bt corn is blown by the wind onto milkweed plants in neighboring fields, the caterpillars could eat the pollen and perish. Although the Nature study was not conducted under natural field conditions, the results seemed to support this viewpoint. Unfortunately, B.t. toxins kill many species of insect larvae indiscriminately; it is not possible to design a B.t. toxin that would only kill crop-damaging pests and remain harmless to all other insects. This study is being reexamined by the USDA, the U.S. Environmental Protection Agency (EPA) and other non-government research groups, and preliminary data from new studies suggests that the original study may have been flawed. This topic is the subject of acrimonious debate, and both sides of the argument are defending their data vigorously. Currently, there is no agreement about the results of these studies, and the potential risk of harm to non-target organisms will need to be evaluated further.
- Reduced effectiveness of pesticides Just as some populations of mosquitoes developed resistance to the now-banned pesticide DDT, many people are

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concerned that insects will become resistant to B.t. or other crops that have been genetically-modified to produce their own pesticides.

- Gene transfer to non-target species Another concern is that crop plants engineered for herbicide tolerance and weeds will cross-breed, resulting in the transfer of the herbicide resistance genes from the crops into the weeds. These "superweeds" would then be herbicide tolerant as well. Other introduced genes may cross over into non-modified crops planted next to GM crops. The possibility of interbreeding is shown by the defense of farmers against lawsuits filed by Monsanto. The company has filed patent infringement lawsuits against farmers who may have harvested GM crops. Monsanto claims that the farmers obtained Monsanto-licensed GM seeds from an unknown source and did not pay royalties to Monsanto. The farmers claim that their unmodified crops were cross-pollinated from someone else's GM crops planted a field or two away. More investigation is needed to resolve this issue.

There are several possible solutions to the three problems mentioned above. Genes are exchanged between plants via pollen. Two ways to ensure that non-target species will not receive introduced genes from GM plants are to create GM plants that are male sterile (do not produce pollen) or to modify the GM plant so that the pollen does not contain the introduced gene. Cross-pollination would not occur, and if harmless insects such as monarch caterpillars were to eat pollen from GM plants, the caterpillars would survive.

Another possible solution is to create buffer zones around fields of GM crops. For example, non-GM corn would be planted to surround a field of B.t. GM corn, and the non-GM corn would not be harvested. Beneficial or harmless insects would have a refuge in the non-GM corn, and insect pests could be allowed to destroy the non-GM corn and would not develop resistance to B.t. pesticides. Gene transfer to weeds and other crops would not occur because the wind-blown pollen would not travel beyond the buffer zone. Estimates of the necessary width of buffer zones range from 6 meters to 30 meters or more. This planting method may not be feasible if too much acreage is required for the buffer zones.

Human Health Risks

- Allergenicity Many children in the U.S. and Europe have developed life-threatening allergies to peanuts and other foods. There is a possibility that introducing a gene into a plant may create a new allergen or cause an allergic reaction in susceptible individuals. A proposal to incorporate a gene from Brazil nuts into soybeans was abandoned because of the fear of causing unexpected allergic reactions. Extensive testing of GM foods may be required to avoid the possibility of harm to consumers with food allergies. Labelling of GM foods and food products will acquire new importance, which I shall discuss later.
- *Unknown effects on human health.* There is a growing concern that introducing foreign genes into food plants may have an unexpected and

negative impact on human health. A recent article published in Lancet examined the effects of GM potatoes on the digestive tract in rats. This study claimed that there were appreciable differences in the intestines of rats fed GM potatoes and rats fed unmodified potatoes. Yet critics say that this paper, like the monarch butterfly data, is flawed and does not hold up to scientific scrutiny. Moreover, the gene introduced into the potatoes was a snowdrop flower lectin, a substance known to be toxic to mammals. The scientists who created this variety of potato chose to use the lectin gene simply to test the methodology, and these potatoes were never intended for human or animal consumption.

On the whole, with the exception of possible allergenicity, scientists believe that GM foods do not present a risk to human health.

Economic Concerns

Bringing a GM food to market is a lengthy and costly process, and of course agri-biotech companies wish to ensure a profitable return on their investment. Many new plant genetic engineering technologies and GM plants have been patented, and patent infringement is a big concern of agribusiness. Yet consumer advocates are worried that patenting these new plant varieties will raise the price of seeds so high that small farmers and third world countries will not be able to afford seeds for GM crops, thus widening the gap between the wealthy and the poor. It is hoped that in a humanitarian gesture, more companies and non-profits will follow the lead of the Rockefeller Foundation and offer their products at reduced cost to impoverished nations.

Patent enforcement may also be difficult, as the contention of the farmers that they involuntarily grew Monsanto-engineered strains when their crops were cross-pollinated shows. One way to combat possible patent infringement is to introduce a "suicide gene" into GM plants. These plants would be viable for only one growing season and would produce sterile seeds that do not germinate. Farmers would need to buy a fresh supply of seeds each year. However, this would be financially disastrous for farmers in third world countries who cannot afford to buy seed each year and traditionally set aside a portion of their harvest to plant in the next growing season. In an open letter to the public, Monsanto has pledged to abandon all research using this suicide gene technology.

5.11 How are GM Foods Regulated and What is the Government's Role in This Process?

Governments around the world are hard at work to establish a regulatory process to monitor the effects of and approve new varieties of GM plants. Yet depending on the political, social and economic climate within a region or country, different governments are responding in different ways.

In Japan, the Ministry of Health and Welfare has announced that health testing of GM foods will be mandatory as of April 2001. Currently, testing of GM foods is voluntary. Japanese supermarkets are offering both GM foods and unmodified foods, and customers are beginning to show a strong preference for unmodified fruits and vegetables.

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India's government has not yet announced a policy on GM foods because no GM crops are grown in India and no products are commercially available in supermarkets yet India is, however, very supportive of transgenic plant research. It is highly likely that India will decide that the benefits of GM foods outweigh the risks because Indian agriculture will need to adopt drastic new measures to counteract the country's endemic poverty and feed its exploding population.

Some states in Brazil have banned GM crops entirely, and the Brazilian Institute for the Defense of Consumers, in collaboration with Greenpeace, has filed suit to prevent the importation of GM crops. Brazilian farmers, however, have resorted to smuggling GM soybean seeds into the country because they fear economic harm if they are unable to compete in the global marketplace with other grain-exporting countries.

In Europe, anti-GM food protestors have been especially active. In the last few years Europe has experienced two major foods scares: bovine spongiform encephalopathy (mad cow disease) in Great Britain and dioxin-tainted foods originating from Belgium. These food scares have undermined consumer confidence about the European food supply, and citizens are disinclined to trust government information about GM foods. In response to the public outcry, Europe now requires mandatory food labeling of GM foods in stores, and the European Commission (EC) has established a 1% threshold for contamination of unmodified foods with GM food products.

In the United States, the regulatory process is confused because there are three different government agencies that have jurisdiction over GM foods. To put it very simply, the EPA evaluates GM plants for environmental safety, the USDA evaluates whether the plant is safe to grow, and the FDA evaluates whether the plant is safe to eat. The EPA is responsible for regulating substances such as pesticides or toxins that may cause harm to the environment. GM crops such as B.t. pesticide-laced corn or herbicide-tolerant crops but not foods modified for their nutritional value fall under the purview of the EPA. The USDA is responsible for GM crops that do not fall under the umbrella of the EPA such as drought-tolerant or disease-tolerant crops, crops grown for animal feeds, or whole fruits, vegetables and grains for human consumption. The FDA historically has been concerned with pharmaceuticals, cosmetics and food products and additives, not whole foods. Under current guidelines, a genetically-modified ear of corn sold at a produce stand is not regulated by the FDA because it is a whole food, but a box of cornflakes is regulated because it is a food product. The FDA's stance is that GM foods are substantially equivalent to unmodified, "natural" foods, and therefore not subject to FDA regulation.

The EPA conducts risk assessment studies on pesticides that could potentially cause harm to human health and the environment, and establishes tolerance and

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residue levels for pesticides. There are strict limits on the amount of pesticides that may be applied to crops during growth and production, as well as the amount that remains in the food after processing. Growers using pesticides must have a license for each pesticide and must follow the directions on the label to accord with the EPA's safety standards. Government inspectors may periodically visit farms and conduct investigations to ensure compliance. Violation of government regulations may result in steep fines, loss of license and even jail sentences.

As an example the EPA regulatory approach, consider B.t. corn. The EPA has not established limits on residue levels in B.t corn because the B.t. in the corn is not sprayed as a chemical pesticide but is a gene that is integrated into the genetic material of the corn itself. Growers must have a license from the EPA for B.t corn, and the EPA has issued a letter for the 2000 growing season requiring farmers to plant 20% unmodified corn, and up to 50% unmodified corn in regions where cotton is also cultivated. This planting strategy may help prevent insects from developing resistance to the B.t. pesticides as well as provide a refuge for non-target insects such as Monarch butterflies.

The USDA has many internal divisions that share responsibility for assessing GM foods. Among these divisions are APHIS, the Animal Health and Plant Inspection Service, which conducts field tests and issues permits to grow GM crops, the Agricultural Research Service which performs in-house GM food research, and the Cooperative State Research, Education and Extension Service which oversees the USDA risk assessment program. The USDA is concerned with potential hazards of the plant itself. Does it harbor insect pests? Is it a noxious weed? Will it cause harm to indigenous species if it escapes from farmer's fields? The USDA has the power to impose quarantines on problem regions to prevent movement of suspected plants, restrict import or export of suspected plants, and can even destroy plants cultivated in violation of USDA regulations. Many GM plants do not require USDA permits from APHIS. A GM plant does not require a permit if it meets these 6 criteria: (1) the plant is not a noxious weed; (2) the genetic material introduced into the GM plant is stably integrated into the plant's own genome; (3) the function of the introduced gene is known and does not cause plant disease; (4) the GM plant is not toxic to non-target organisms; (5) the introduced gene will not cause the creation of new plant viruses; and (6) the GM plant cannot contain genetic material from animal or human pathogens.

The current FDA policy was developed in 1992 (Federal Register Docket No. 92N–0139) and states that agri-biotech companies may voluntarily ask the FDA for a consultation. Companies working to create new GM foods are not required to consult the FDA, nor are they required to follow the FDA's recommendations after the consultation. Consumer interest groups wish this process to be mandatory, so that all GM food products, whole foods or otherwise,

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must be approved by the FDA before being released for commercialization. The FDA counters that the agency currently does not have the time, money, or resources to carry out exhaustive health and safety studies of every proposed GM food product. Moreover, the FDA policy as it exists today does not allow for this type of intervention.

How are GM Foods Labelled?

Labelling of GM foods and food products is also a contentious issue. On the whole, agribusiness industries believe that labelling should be voluntary and influenced by the demands of the free market. If consumers show preference for labeled foods over non-labeled foods, then industry will have the incentive to regulate itself or risk alienating the customer. Consumer interest groups, on the other hand, are demanding mandatory labelling. People have the right to know what they are eating, argue the interest groups, and historically industry has proven itself to be unreliable at self-compliance with existing safety regulations. The FDA's current position on food labelling is governed by the Food, Drug and Cosmetic Act which is only concerned with food additives, not whole foods or food products that are considered "GRAS" - generally recognized as safe. The FDA contends that GM foods are substantially equivalent to non-GM foods, and therefore not subject to more stringent labelling. If all GM foods and food products are to be labelled, Congress must enact sweeping changes in the existing food labelling policy.

There are many questions that must be answered if labeling of GM foods becomes mandatory. First, are consumers willing to absorb the cost of such an initiative? If the food production industry is required to label GM foods, factories will need to construct two separate processing streams and monitor the production lines accordingly. Farmers must be able to keep GM crops and non-GM crops from mixing during planting, harvesting and shipping. It is almost assured that industry will pass along these additional costs to consumers in the form of higher prices. Secondly, what are the acceptable limits of GM contamination in non-GM products? The EC has determined that 1% is an acceptable limit of cross-contamination, yet many consumer interest groups argue that only 0% is acceptable. Some companies such as Gerber baby foods and Frito-Lay have pledged to avoid use of GM foods in any of their products. But who is going to monitor these companies for compliance and what is the penalty if they fail? Once again, the FDA does not have the resources to carry out testing to ensure compliance.

What is the level of detectability of GM food cross-contamination? Scientists agree that current technology is unable to detect minute quantities of contamination, so ensuring 0% contamination using existing methodologies is not guaranteed. Yet researchers disagree on what level of contamination really is

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detectable, especially in highly processed food products such as vegetable oils or breakfast cereals where the vegetables used to make these products have been pooled from many different sources. A 1% threshold may already be below current levels of detectability.

Finally, who is to be responsible for educating the public about GM food labels and how costly will that education be? Food labels must be designed to clearly convey accurate information about the product in simple language that everyone can understand. This may be the greatest challenge faced be a new food labeling policy: how to educate and inform the public without damaging the public trust and causing alarm or fear of GM food products.

In January 2000, an international trade agreement for labelling GM foods was established. More than 130 countries, including the U.S., the world's largest producer of GM foods, signed the agreement. The policy states that exporters must be required to label all GM foods and that importing countries have the right to judge for themselves the potential risks and reject GM foods, if they so choose. This new agreement may spur the U.S. government to resolve the domestic food labelling dilemma more rapidly.

Conclusion

Genetically-modified foods have the potential to solve many of the world's hunger and malnutrition problems, and to help protect and preserve the environment by increasing yield and reducing reliance upon chemical pesticides and herbicides. Yet there are many challenges ahead for governments, especially in the areas of safety testing, regulation, international policy and food labeling. Many people feel that genetic engineering is the inevitable wave of the future and that we cannot afford to ignore a technology that has such enormous potential benefits. However, we must proceed with caution to avoid causing unintended harm to human health and the environment as a result of our enthusiasm for this powerful technology.

Student Activity

1. Discuss the important applications of biotechnology.

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2. Explain the significance of biotechnology in the agriculture.

3. Point out the importance of food biotechnology.

Summary

1. Biotechnology is technology based on biology, especially when used in agriculture, food science, and medicine.

2. Biotechnology has applications in four major industrial areas, including health care (medical), crop production and agriculture, nonfood (industrial) uses of crops and other products (*e.g.* biodegradable plastics, vegetable oil, biofuels), and environmental uses.

3. Proteins in foods may be modified to increase their nutritional qualities. Proteins in legumes and cereals may be transformed to provide the amino acids needed by human beings for a balanced diet.

4. Modern biotechnology refers to various scientific techniques used to produce specific desired traits in plants, animals or microorganisms through the use of genetic knowledge.
5. Genetically Modified (GM) foods are foods derived from genetically modified organisms.

Glossary

Biotechnology: technology based on biology, especially when used in agriculture, food science, and medicine.

Blue biotechnology: a term that has been used to describe the marine and aquatic applications of biotechnology.

Green biotechnology: biotechnology applied to agricultural processes.

Red biotechnology: the biotechnology which id applied to medical processes.

White biotechnology: the biotechnology applied to industrial processes.

Biotechnological engineering: it is a branch of engineering that focuses on biotechnologies and biological science.

Review Questions

1. Give the definition of biotechnology and discuss its historical background.
2. Which are the fields biotechnology applied in effectively? Discuss.
3. What is the importance of biotechnology in food industry?
4. What are the health and nutritional benefits of biotechnology?
5. Write a short note on genetically modified food.
6. What are the advantages of GM foods?
7. Discuss the political and economic effect of GM crops.

Further Readings

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Agricultural Biotechnology - Challenges and Prospects Edited by Mahesh K. Bhalgat, William P. Ridley, and Allan S. Felsot; Publishers: OUP 2004

Agricultural Biotechnology and Intellectual Property Protection: Seeds of Change Edited by J Kesan; Publishers: CABI June 2007

Bioinformatics - Applied Mycology and Biotechnology, Volume 6 Edited by Dilip K Arora, Randy Berka and Gautam B. Singh; publishers: Elsevier science September 2006

Functional Foods and Biotechnology Edited by Kalidas Shetty, Gopinadhan Paliyath, Anthony Pometto, Robert E. Levin

Bioprocesses and Biotechnology for Functional Foods and Nutraceuticals

(కత్తిరించి పంపవలెను)

అధ్యాపకుల, విద్యార్థుల సలహాలు, సూచనలు :

అధ్యాపకులు, విద్యార్థులు ఈ స్టడీ మెటీరియల్‌కు సంబంధించిన సలహాలు, సూచనలు, ముద్రణ దోషాలు తెలియపరచినచో, పునర్ముద్రణలో తగు చర్యలు తీసుకొనగలము. తెలియపరచవలసిన చిరునామా : **డిప్యూటీ డైరెక్టర్, దూరవిద్యా కేంద్రం, ఆచార్య నాగార్జున విశ్వవిద్యాలయం, నాగార్జున నగర్ - 522 510.**

Course	Year	Paper No. &Title

(కత్తిరించి పంపవలెను)

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