

ESU 009– Recent development in area of nutraceuticals and functional foods

Lecture 42





Nutraceuticals

- ❖ Dr Stephen De Felice, coined the term '**Nutraceutical**' and defined it as a '*food, or parts of a food, that provide medical or health benefits, including the prevention and treatment of disease*'.
- ❖ Another definition from the USA is '**diet supplement that delivers a concentrated form of a presumed bioactive agent from a food, presented in a non-food matrix, and used to enhance health in dosages that exceed those that could be obtained from normal food**'.

Relationship between Nutraceuticals and other health products

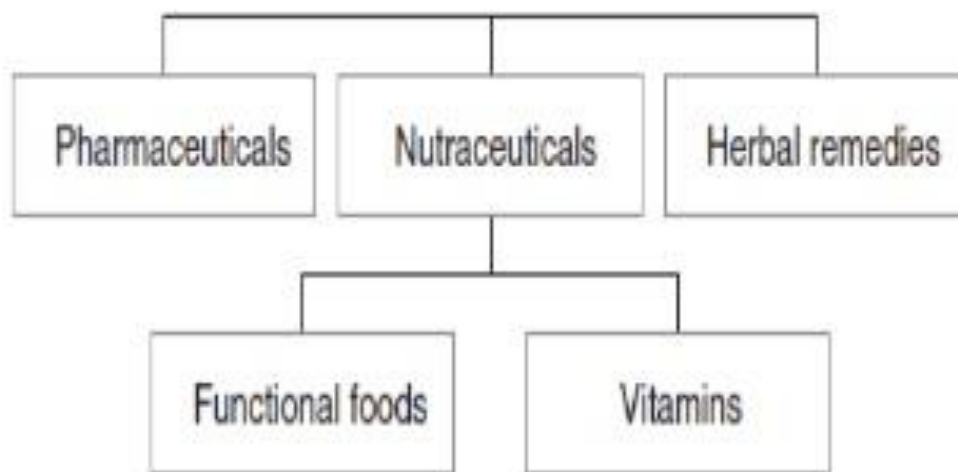


Figure 1.1 The relationship between nutraceuticals and other health products.

- **Pharmaceuticals** are usually classed as medicines by law, but some are freely available without legal constraints and some are legally classed as medicines. For example, in certain countries melatonin is classed as a medicine and is not freely available.
- **Herbal remedies** may be classed as medicines because of their perceived risks with self-medication.
- **Functional foods** are closely related to nutraceuticals as they often contain nutraceuticals in a food-based formulation, such as carotenoids, but others are novel biotechnological entities derived from foods, for instance, pre- and probiotics. A new term for these has recently been coined – ‘**Phoods**’ – which presumably aims to blur the distinction between pharmaceuticals and foods in the minds of consumers.
- **Vitamins** can also be classed as medicines, but may be freely available. The distinction between certain vitamins and nutraceuticals is blurred (e.g. β -carotene, which is a vitamin A

Why consumers choose alternative over conventional remedies?



- Many patients are not satisfied with the treatment they are given by their doctors due to adverse effects or because it has been ineffective.
- Another reason for choosing alternative over conventional remedies is that patients may feel that conventional medicine is impersonal or technologically orientated.
- Some patients prefer to have personal control over their healthcare and therefore are happier to self-select than be told what to take by their doctor.



NUTRACEUTICAL FORMULATIONS AVAILABLE

- Manufacturers are increasingly marketing novel formulations.
- Tablets, capsules and softgels are still the most widely available formulations, but new formulations such as soft chews, and fast dissolving tablets and strips are becoming available.
- As with pharmaceuticals, nutraceutical manufacturers are extolling the virtues of controlled release formulations for release of precise levels of active entities over a particular time period, in order to achieve maximum therapeutic effects. An example of the use of this technology is the Novasoy soya isoflavone range.

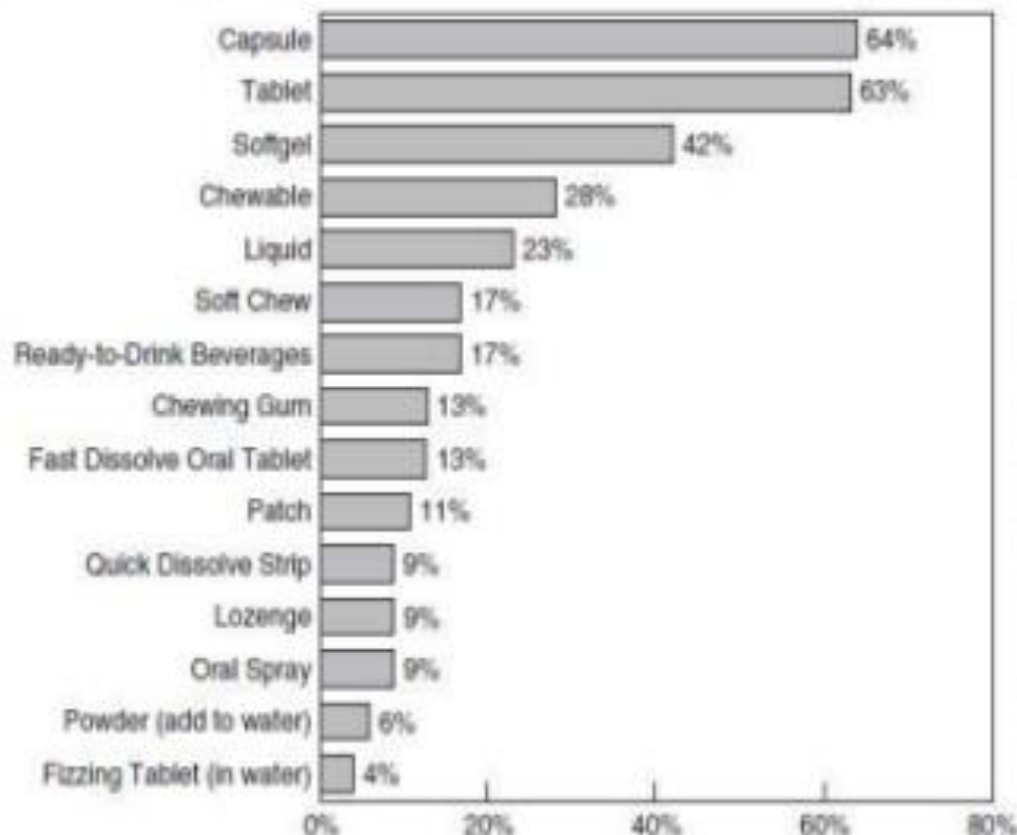


Figure 1.3 Consumer preference for various nutraceutical formulations (USA survey, 2004). Permission to reproduce from Nutraceuticals World, Ramsey, NJ, USA is gratefully acknowledged.

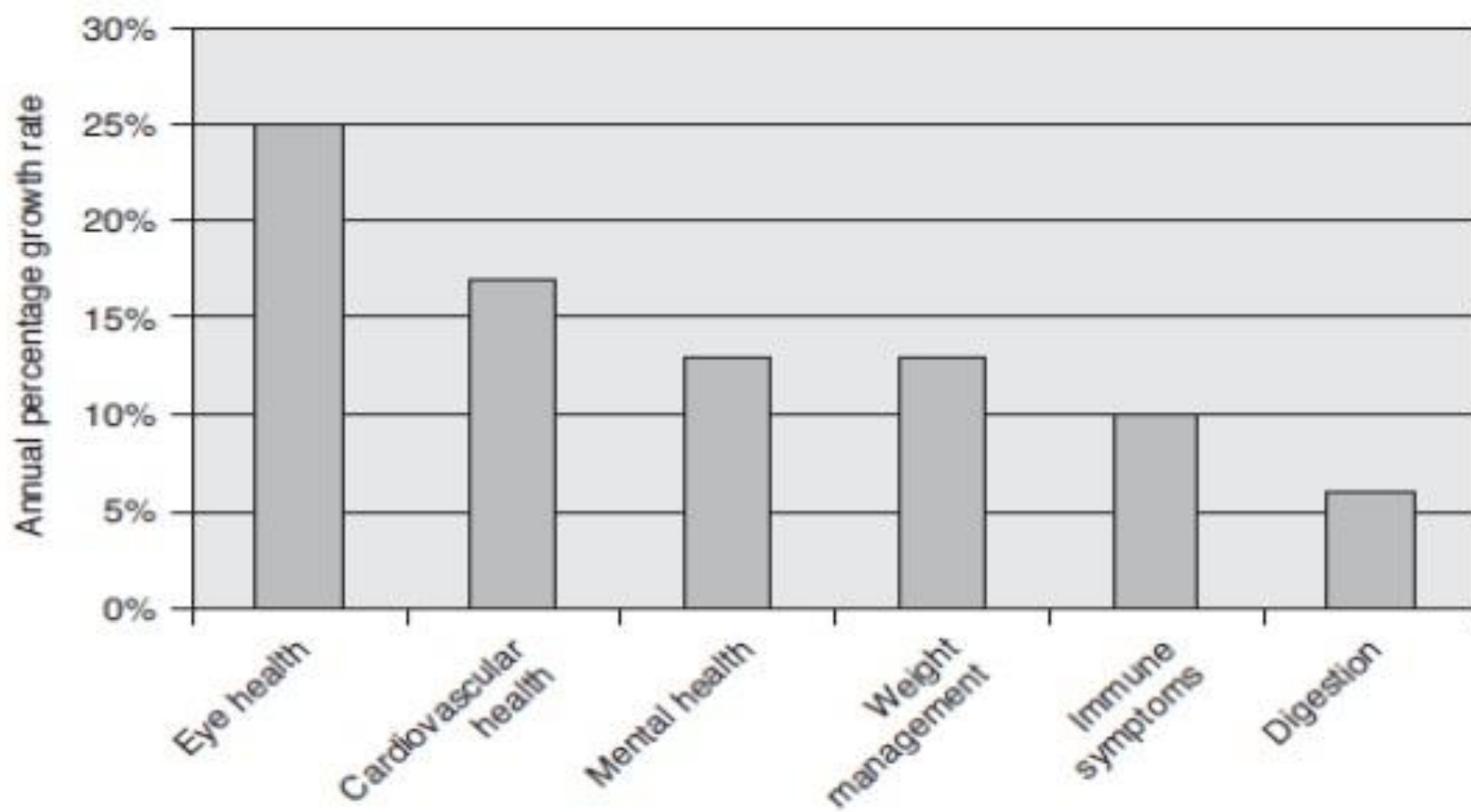
MAJOR NUTRACEUTICALS

S.N	NUTRACEUTICAL	SOURCE	Therapeutic area	Formulation Available
1	Glucosamine	Bovine trachea, shellfish	Joint, skin and animal health	Tablet, capsule, patch, gel, effervescent tablet, sustained release tablet.
2	Chondroitin	Bovine trachea/cartilage	Joint and veterinary health	Tablet, nasal drops
3	Methylsulfonyl-methane	Meat, milk, capers, etc.	Joint and veterinary health	Tablet, capsule, cream, powder
4	Coenzyme Q10	Common foods	Cardiovascular health, cancer prevention, respiratory, skin and animal health (antioxidant)	Tablet, capsule, chewtab, drops, gel, gum, softgel
5	Melatonin	Bovine pineal glands	Cardiovascular health, cancer prevention, sport enhancement, sleep improvement & bone health (antioxidant)	Tablet, patch, liquid
6	Carnitine	Heart, skeletal muscle	Sport enhancement, cardiovascular and bone health, weight optimisation, veterinary health	Tablet
7	Acetyl-L-carnitine	Brain, liver, kidney	Mental health, sport enhancement, weight management	Capsule
8	Octacosanol/ policosanol	Sugarcane waste, wheatgerm, rice bran	Cardiovascular health, sport enhancement	Tablet, capsule

S.N	NUTRACEUTICAL	SOURCE	Therapeutic area	Formulation Available
9	S-Adenosyl methionine	Meat, yeast, vegetable ²⁶	Joint and mental health	Tablet
10	Docosahexaenoic acid/eicosapentaenoic acid (DHA/EPA)	Fish, algae, plankton, ²⁹ seal blubber ³⁰	Joint, cardiovascular, eye and mental health, cancer prevention, bone, respiratory, skin and veterinary health	Oil, soft capsule
11	γ -Linolenic acid	Oenothera biennis, Borago officinalis	Skin health, joint health	Oil, soft capsule
12	α -Linolenic acid	Linum usitatissimum	Cancer prevention, respiratory health (antioxidant)	Soft capsule
13	Conjugated linoleic acid	Beef, dairy products ³⁷	Weight management, sport enhancement	Soft capsule
14	Flax lignans	Linum usitatissimum	Cardiovascular health, cancer prevention, women's health (antioxidant and weakly oestrogenic)	Soft capsule
15	Pycnogenol	Pinus pinaster	Cardiovascular, eye, respiratory, and oral health (antioxidant)	Capsule
16	Resveratrol Red wine,	Polygonum capsidatum root, Veratrum sp., Vaccinium macrocarpon	Cardiovascular health, cancer prevention, women's health (antioxidant & weakly oestrogenic)	Tablet, capsule

S.N	NUTRACEUTICAL	SOURCE	Therapeutic area	Formulation Available
17.	Grape seed proanthocyanidin extract (GSPE)	Vitis vinifera	Cardiovascular and skin health (antioxidant)	Tablet, capsule, patch, gel, effervescent tablet, sustained release tablet
18	Lycopene	Foods, including tomato, green algae	Cardiovascular and respiratory health, cancer prevention (antioxidant)	Tablet, capsule, oral gel
19	Lutein	Tomato, butternut squash	Cardiovascular, eye and skin health (antioxidant)	Capsule
20	Zeaxanthin	Butternut squash	Eye health (antioxidant)	Capsule
21	Astaxanthin	Fish, shellfish	Eye and veterinary health (antioxidant)	Tablet, capsule, liquid
22	Lipoic acid	Meat, liver	Cardiovascular and mental health, veterinary health	Tablet
23	Dehydroepiandrosterone	Wild yams	Cardiovascular and mental health, veterinary health	Tablet
24	Soy isoflavones	Soy and fermented soy products	Cardiovascular, mental, bone, women's and skin health, cancer prevention (antioxidant and oestrogenic)	Tablet, powder
25	Green tea extracts	Camelia sinensis	Cardiovascular, bone, skin and oral health, cancer prevention and weight management (antioxidant)	Tablet, capsule, powder, tea
26	Creatine	Skeletal muscle	Mental health, sport enhancement	Tablet, capsule, effervescent tablet, liquid

Predicted growth rate of nutraceutical usage



Permission to use this data from Dr C Gaertner, Cognis, is gratefully acknowledged.

USE OF NUTRACEUTICALS FOR TREATING SPECIFIC DISEASES

s.no.	Medical condition	Incidence of use (%)	Nutraceuticals used
1	Prostate cancer	5.3	Lycopene, dehydroepiandrosterone
2	Enlarged prostate	16.9	Lycopene
3	Osteoarthritis	29.7	Glucosamine, chondroitin, methylsulfonylmethane
4	Neck, back, or joint pain	25.3	Glucosamine, chondroitin, methylsulfonylmethane
5	Degenerative eye conditions	9.9	Lutein
6	Memory loss	8.9	Fish oil, coenzyme Q10
7	Insomnia	20.0	Melatonin
8	Perimenopause	4.6	Soy products

Data extracted from Gunther S, Patterson R E, Kristal A R, Stratton K L, White E. Demographic and health-related correlates of herbal and specialty supplement use, *Journal of the American Dietetic Association* 2004; 104: 27–34, with permission from the American Dietetic Association.

Manufacture and Analysis of major Nutraceuticals



- Most nutraceuticals are natural products, being derived roughly equally from plants & animals. Some are endogenous human metabolites, while others are common dietary constituents that appear in human metabolism, for example lycopene. A number of entities exist in higher plants, and are commercially extracted from them, although some are present in insufficient levels for commercial exploitation, such as methylsulfonylmethane (MSM) and dehydroepiandrosterone (DHEA), and consequently are produced commercially by chemical synthesis.
- Similarly, those of animal origin may be produced by chemical synthesis, (e.g. carnitine, creatine and the carotenoids,) but may also be produced by fermentation, e.g. coenzyme Q₁₀ (Co Q₁₀) and S-adenosyl methionine (S-AMe).
- The n-3 fatty acids such as DHA)/EPA and ALA are usually available as complex mixtures, containing supradietary levels of the active constituents, and often partial purification from the other fatty acids is not carried out..



- In certain cases nutraceuticals exist in a number of isomeric forms, which may have varied activities or even be toxic; e.g carnitine, in which the D-form is toxic and thus chiral synthesis of the L-form is carried out.
- A number of nutraceuticals have **GRAS (Generally Recognized As Safe)** status as defined by the US Food and Drug Administration (FDA), and increasingly manufacturers are gaining GRAS certification for products not normally ingested (in realistic levels) by consumption of foodstuffs, such as MSM and octacosanol/policosanols.
- As with pharmaceuticals, the analytical procedures used for identification and quantification of nutraceuticals are becoming increasingly sophisticated, reflecting the analytical advances, and the desire by manufacturers to produce detailed information about levels of active constituents in the natural materials, formulated products & also in biological fluids in an attempt to determine the fate of ingested entities.

Use of Nutraceutical supplements: demographic trends

- 57% of 979 adults agreed that they would like to use supplements more often, but were unsure of what to buy. This indicated a need for more information to be available. (Mintel Market Research in November 1998)
- prime target users of supplements - middle-aged females with an above average income & above average education. There were also occasional users who used supplements at a time of illness or stress, rather like a medicine. These users were more varied in age and income and were less likely to take supplements on a long-term basis.(Mintel Market Research in March 1999)
- Consumers use nutraceutical supplements for many varied reasons e.g.,
 - supplementation of a poor diet,
 - to improve overall health,
 - to delay the onset of age-related diseases,
 - after illness,
 - for stress,
 - recommended by a health professional,
 - in pregnancy and slimming,
 - to improve sports performance and to treat symptoms (colds, coughs, arthritis, etc.).



Functional Foods

- ⌘ In most countries there is no legislative definition of the term and drawing a border line between conventional and functional foods is challenging even for nutrition and food experts.
- ⌘ A 'functional food' is a natural or formulated food that has enhanced physiological performance or prevents or treats a particular disease. This term was first used in Japan, and by 1998 it was the only country to legally define 'Foods for specified health use' (FOSHU).
- ⌘ Functional food is a **'food that has a component incorporated into it to give it a specific medical or physiological benefit, other than purely nutritional benefit'**.

[Department for Environment, Food and Rural Affairs (Defra), UK]



Functional food development

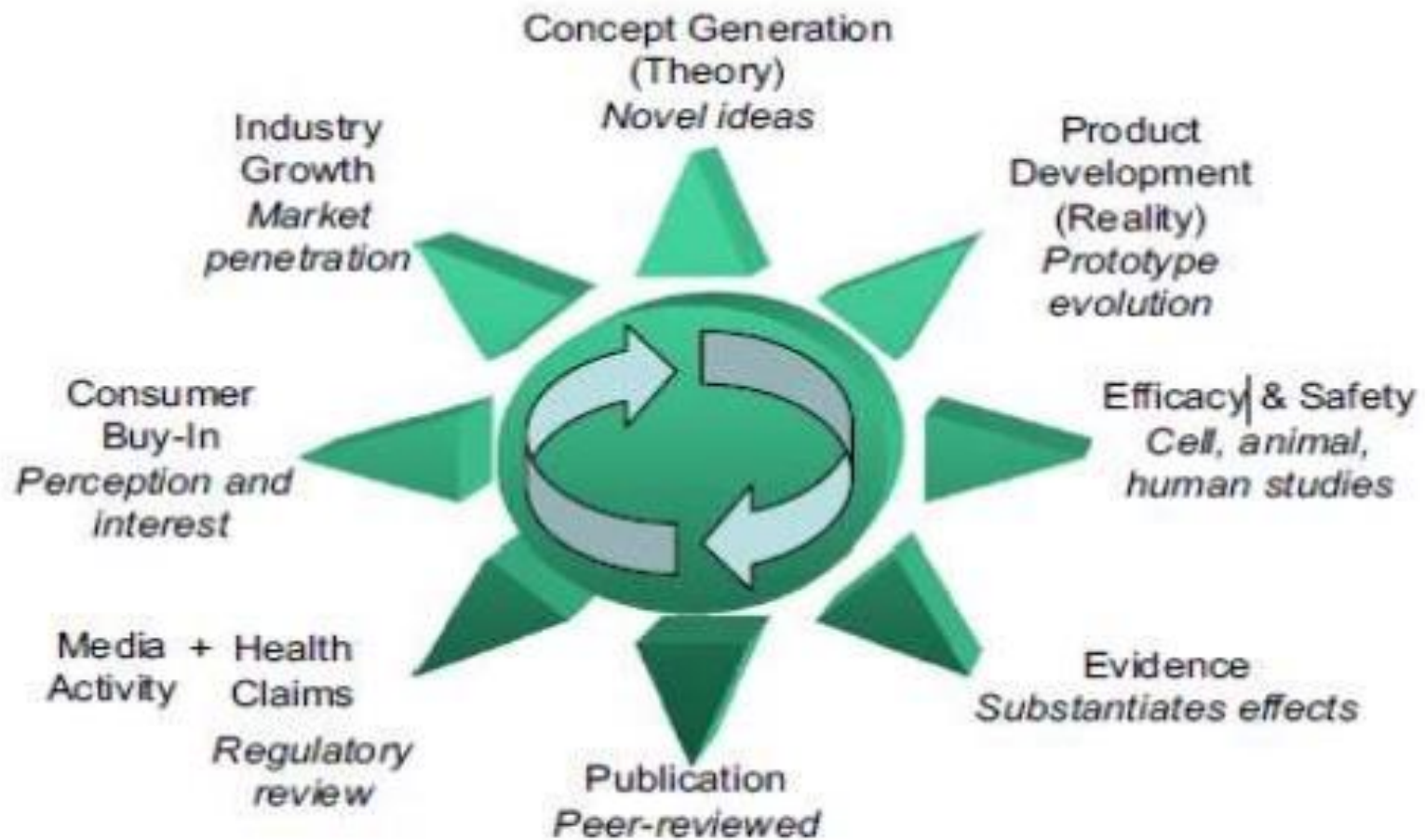


Fig. 1. Functional foods and health promotion: cycle of success.

- 1. Concept testing:** The process through which innovation in nutritional science occurs develops through intersecting alliances of various stakeholders as depicted in Fig. 1. Involved are research, industry, regulatory and consumer sector interests.
- 2. Product development:** develop a real-world test product that embraces that concept. For instance, production of a probiotic enriched yogurt, a cheese enriched with omega 3 fats.
- 3. Efficacy/safety and evidence:** Expression of a nutrition health concept through development of a product needs to be followed by verification that the product will mirror the original concept through the testing of biological efficacy. **Efficacy assessment** is an essential element of establishing the credibility of functional food entities , performed using in vitro or in vivo systems. Evidence also needs to be provided by parallel studies conducted across several jurisdictions and conducted in both academic and private sector institutional laboratories.
- 4. Publication:** for dissemination of biological efficacy data is through publications in peer-reviewed journals. It is equally important that negative, as well as positive, efficacy and safety results be disseminated through peer-reviewed publication in order to provide a balanced evaluation of the true merits of that ingredient.

5. Health claims and regulatory review: involves communication of the health messages generated through active research and regulatory review of a specific food product to the general public. Regulatory review is required in order to translate peer-reviewed published data supporting the efficacy and safety of a given bioactive product within a novel food matrix or capsule into policy changes consistent with approving products for sale of functional food products.

- In the UK, the Joint Health Claims Initiative (JHCI) provides guidance on claims that are allowed for functional foods, such as fortified breakfast cereals and 'bio'-yoghurts. In some cases although *medical* claims such as 'helps prevent heart disease' are not allowed, *health promoting* claims, such as 'helps lower cholesterol' can be made, if scientific evidence exists.
- Companies marketing nutraceuticals cannot advertise specific medical claims for their products without a medicine licence. When launching a new product they have the option of either not doing any research at all or researching it thoroughly and possibly obtaining a patent

- Unfortunately many companies tend towards the former route because of the expense, To bring a medicine to market can take about ten years and cost US\$0.8–1.7 billion,⁹ but to market an unlicensed nutraceutical can take a fraction of this time and money.

6.Industry growth Securing specific messages on foods attesting to their health benefits represents a vital part of the cycle of moving a functional food from concept to a marketing success story. Given that consumers are both interested and informed about foods that confer health benefits beyond simply providing nutrients (Heller, 2006) the presence of an informative, authoritative claim on a food will stimulate the market share penetration of that product within its sector.

Thank you

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