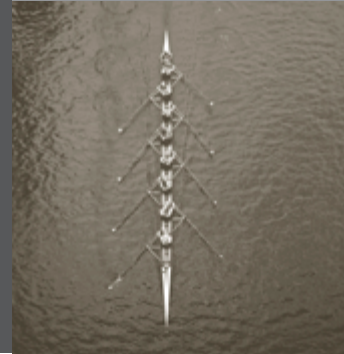


case 10

Raisio Group and the Benecol Launch*



Case [A]: The Situation in January 1997

During 1996, Raisio Group, a 57-year-old grain-milling company based in Raisio in the south-west of Finland, emerged from obscurity to become the second most valuable public company in Finland (after Nokia) and the focus of worldwide attention. The launch of Benecol, its cholesterol-lowering margarine, at the end of 1995 had attracted the interest of food processors and supermarket groups throughout the world and fueled a surge of investor interest. Demand for the product had outstripped Raisio's capability to produce the active ingredient in Benecol, stanol ester. On the Helsinki stock market, foreign demand pushed Raisio's share price from FIM61 at the beginning of the year to FIM288 at the end (after touching FIM322 during the summer).¹ CEO Matti Salminen commented:

1996 will go down in the Raisio Group's history as the "Benecol year" – such was the role of this new cholesterol-reducing margarine in increasing the Group's visibility and raising its profile in all our sectors of operations. Although we have not been able to meet even the domestic demand for Benecol margarine so far, the product is already known worldwide and great expectations are attached to it. The Benecol phenomenon quintupled the value of our shares, increasing the Group's capitalization by billions of Finnish marks.²

It was the international prospects for Benecol margarine (and potentially other food products incorporating stanol ester) that had drawn a bevy of stock analysts

* This case draws upon an earlier case by Michael H. Moffett and Stacey Wolff Howard, *Benecol: Raisio's Global Nutraceutical*, Thunderbird, The American Graduate School of International Management. Case No. A06-99-0004, 1999. I am grateful to Ayan Bhattacharya for assistance in preparing this case.

and portfolio managers to Raisio's headquarters. Not only was the potential market for Benecol considered huge – the US alone was seen as having a multi-billion market potential – but the profit opportunities also appeared excellent. In Finland, Benecol was selling at about six times the price of regular margarine. In addition to being first to market, Raisio had the ability to sustain its market leadership through its patents relating to the production and use of the active ingredient, stanol ester, and recognition of its Benecol brand name.

However, within Raisio, a vigorous debate had broken out as to the best strategy for exploiting the vast commercial potential that Benecol offered. Raisio was a significant margarine manufacturer in Finland and the domestic launch of Benecol was the result of its own independent efforts. Outside of Finland, Raisio had few facilities and limited experience. A number of multinational food companies and leading food retailers had approached Raisio expressing interest in licensing agreements, joint ventures, and supply agreements – for Benecol margarine, for the active ingredient stanol ester, or for both.

History

The Raisio Group began life in 1939 as Vehnä Oy, a grain-milling company located in the town of Raisio. In 1950, a vegetable oil factory called Oy Kasviöljy-Växtölje Ab was founded next to the milling plant. The two companies cooperated in introducing rapeseed cultivation to Finland. They eventually merged in 1987 to form Raisio Tehtaat Oy Ab.³ From cereals and vegetable oil, the company expanded into animal feeds, malt production, potato starch, and margarine. In the 1960s, production of starch provided the basis for the supply of a number of chemical products, mainly to the paper industry.

During this period Raisio developed a substantial export business. This began with malt exports to Sweden, followed by exports of margarine, pasta, and other food products to the Soviet Union and subsequently to Poland. In the St. Petersburg area of Russia and in Estonia, Raisio's Melia-branded products were market leaders in flour, pasta, and muesli. Finland's accession to the European Union in 1995 allowed Raisio to expand its sales in other Europe countries. By 1996, 39% of Raisio's sales were outside of Finland. Raisio's increased international presence included margarine plants in Sweden and Poland, and joint-venture plants supplying starch and other products for the paper industry in Sweden, the US, France, Germany, and Indonesia.

From its earliest days, Raisio had shown considerable entrepreneurial initiative and technical ingenuity. Its first oil-milling plant was constructed by its own employees using spare parts, scrap metal, and innovative improvisation. Raisio's first margarine plant was built partly to stimulate demand for its own production of rapeseed oil, which was not widely used in margarine production at that time. Raisio also maintained an active program of R&D. Benecol was the result of Raisio's research into plant sterols. Raisio's annual report tells the story:

The cholesterol-reducing effects of plant sterols were known as early as the 1950s and ever since that time, scientists all over the world have been studying plant sterols and their properties.

In 1972, a project led by Professor Pekka Puska was launched in North Karelia. The purpose of the project, which enjoyed international prestige, was to reduce the high cardiovascular rates in the region.

In 1988, the Department of Pharmacy at the University of Helsinki started cooperation with the Helsinki and Turku Central Hospitals and the Raisio Group aimed at studying the effect of rapeseed oil on blood cholesterol levels. Professor Tatu Miettinen, who had already done extensive research on fat metabolism, suggested research on plant sterols to the Raisio Group.

The following year, R&D Manager Ingmar Wester (of Raisio's Margarine Sub-division) and his research team found a way of turning plant sterol into fat-soluble stanol ester suitable for food production. A patent application was filed in 1991. This started a period of intense research aimed at producing indisputable evidence of the cholesterol-reducing effect of stanol ester. In 1993, the North Karelia project launched a long-range stanol ester study as part of its other clinical research.

The digestive tract receives cholesterol from two sources, i.e. food and the human body itself. Normally, some 50% of the cholesterol that enters the digestive tract is disposed of and the rest is absorbed by the body. Fat-soluble plant stanol was shown as efficiently preventing the absorption of cholesterol. In a diet containing stanol ester, 80% of the cholesterol entering the digestive tract is disposed of and only 20% is absorbed by the body. The plant stanol itself is not absorbed, but disposed of naturally.

The findings of the North Karelia study were published in the New England Journal of Medicine in November 1995. (The article reported that, after a 14-month trial, a daily intake of 25 grams reduces total cholesterol in the bloodstream by 10% and the level of more harmful LDL cholesterol by 14%.) At the same time the first patents were issued for the production and use of stanol ester.

The first stanol ester product, Benecol margarine, was introduced on the Finnish market. The interest it aroused soon exceeded all expectations both in Finland and internationally. The registered name, Benecol, has since been confirmed as the common name for all products containing stanol ester.

Production of stanol ester began with experimental equipment, which limited the supply. The availability of plant sterol, the raw material, was another limiting factor. All plants contain small amounts of plant sterol, but it can be recovered economically only from plants processed in very large quantities. Since there had been no demand for plant sterols, no investments had been made in separation facilities.⁴

Exhibit 10.1 describes the cholesterol reducing properties of sterols and stanols. Appendix 10.1 gives information on Raisio's main patents relating to stanol ester.

Raisio in 1997

At the beginning of 1997, the Raisio Group had annual sales of \$866 million and 2,594 employees. The Group comprised three divisions:

- Foodstuffs (47% of total sales), including the subdivisions: margarine (39% of sales), Melia Ltd. (flour, pasta, breakfast cereal, muesli), oil milling, potato processing (mainly frozen French fries), malting, and Foodie Oy (rye products, pea soup, frozen pastry dough, salad dressings).
- Chemicals (34% of sales).
- Animal feeds (19% of sales).

EXHIBIT 10.1**Sterols and Stanols**

Sterols play a critical role in maintaining cell membranes in both plants and animals. Plant sterols (phytosterols) can reduce the low-density lipoprotein (LDL) in human blood, therefore reducing the risk of coronary heart disease. In plants, more than 40 sterols have been identified, of which sitosterol, stigmasterol, and campesterol are the most abundant.

Plants stanols (phytostanols) are similar to sterols and are also found naturally in plants – though in much smaller quantities than sterols.

The effect of plant sterols in lowering human cholesterol levels has been known since the 1950s. Sitosterol has been used as a supplement and as a drug (Cytellin, marketed by Eli Lilly) to lower serum cholesterol levels. However, the use of plant sterols was limited by problems of poor solubility.

A important breakthrough was made by Finnish chemist, Ingvar Wester, who hydrogenated plant sterols (derived from tall oil, a by-product of pine wood pulp) to produce stanol, then esterified the stanol to produce stanol ester which is fat-soluble. Unlike sterol ester, stanol

ester is not absorbed by the body. Clinical trials in Finland showed stanol ester reduced total blood serum cholesterol in humans by up to 15%.

Plant sterols can also be produced as a byproduct of vegetable oil processing. One of the final stages of processing of vegetable oil is deodorization – high-temperature distillation that removes free fatty acids. From the resulting distillate sterols can be recovered.

Plant sterols themselves have a waxy consistency and a high melting point, creating solubility issues for the food processor. While they are oil-dispersible to some extent in their raw form, the amount required to produce an efficacious effect in a finished product can cause granulation. The answer to this problem is esterification: to make stanols and sterols fat-soluble. During 1996, Unilever was working on the esterification of plant sterols. Meanwhile, Archer Daniels Midland was believed to be developing processes that would allow the introduction of sterols into nonfat systems, thus creating entirely new product lines (e.g. adding sterols to beverages).

Outside of Finland, Raisio had subsidiaries in Sweden, Estonia, Latvia, UK, France, Spain, Germany, Belgium, Poland, Canada, USA, and Indonesia. Raisio also had joint ventures in Mexico (49% ownership) and Chile (50%). Figure 10.1 shows Raisio's share price. Table 10.1 shows Raisio's financial performance.

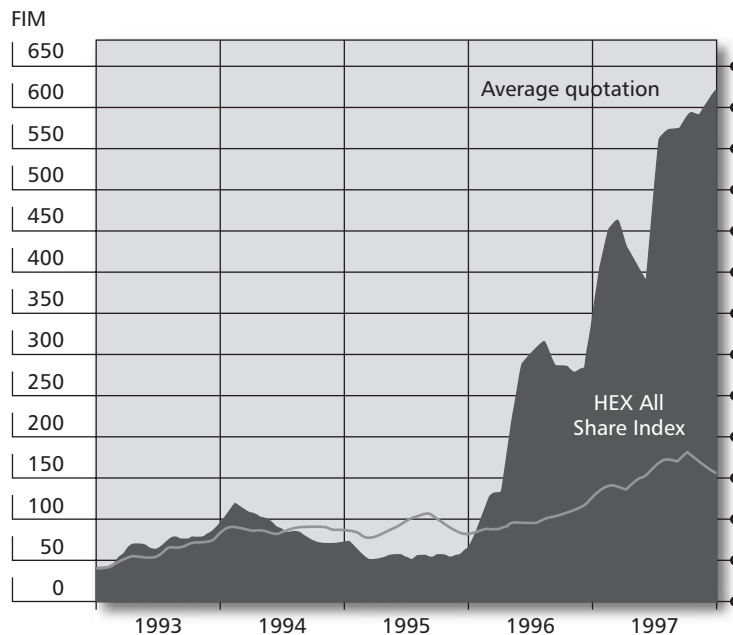
The Benecol Launch

Raisio launched Benecol margarine with a retail price of around FIM25 (\$4.50) for a 250 gram tub – this compared with FIM4 for regular margarine. Despite the high price, the product flew off the shelves as quickly as it appeared and Raisio was forced to institute a system of rationing supplies to distributors. During 1996, Raisio estimated that it was only able to satisfy about two-thirds of domestic demand.

TABLE 10.1 Raisio's financial performance, 1987–1996

	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996
Sales (FIM m)	2,011	2,184	2,487	2,557	2,315	3,070	3,549	3,518	3,224	3,928
change, %	+9	+9	+14	+3	-9	+33	+16	-1	-8	+22
Exports from Finland (FIM m)	126	106	110	136	172	241	389	358	519	735
International sales (FIM m)	288	16	189	217	279	405	561	568	886	1,541
Operating margin (FIM m)	214	247	232	213	316	431	492	428	383	420
% of turnover	10.6	11.3	9.3	8.3	13.6	14.0	13.9	12.2	11.9	10.7
Profit after depreciation (FIM m)	147	167	120	90	185	252	294	230	183	196
% of turnover	7.3	7.6	4.8	3.5	8.0	8.2	8.3	6.5	5.7	5.0
Pre-tax profit ^a (FIM m)	97	98	91	64	63	114	185	35	140	162
% of turnover	4.8	4.5	3.7	2.5	2.7	3.7	5.2	1.0	4.3	4.1
Return on equity (%)	15.5	15.3	5.4	0.1	6.9	10.3	10.3	9.4	6.8	5.8
Return on investment (%)	12.6	13.1	9.0	5.8	10.7	13.7	12.4	10.3	8.5	8.5
Shareholders' equity (FIM m)	670	994	1,123	1,224	1,246	1,426	1,517	1,564	1,648	1,973
Balance sheet total (FIM m)	1,831	2,257	2,493	2,872	2,702	3,268	3,302	3,071	3,175	3,678
Equity ratio (%)	36	44.3	46.0	43.7	47.3	44.3	46.5	51.4	52.1	54.0
Quick ratio	0.8	1.0	0.8	0.8	0.9	0.8	1.0	1.1	0.9	1.1
Current ratio	1.6	1.7	1.6	1.5	1.6	1.5	1.6	1.6	1.6	1.8
Gross investments (FIM m)	101	329	269	462	197	293	174	188	380	387
% of turnover	5.0	15.1	10.8	18.1	8.5	9.5	4.9	5.3	11.8	9.9
R&D expenditure (FIM m)	16	28	31	52	31	35	40	54	54	87
% of turnover	0.8	1.3	1.2	2.0	1.3	1.1	1.1	1.5	1.7	2.2
Direct taxes (FIM m)	5	10	27	25	20	20	47	21	32	64
No. of employees	1,538	1,581	1,877	1,987	803	1,985	2,106	1,958	2,054	2,365

^a Before appropriations, taxes, and minority interest.

FIGURE 10.1 Raisio's share price (unrestricted shares, Helsinki Stock Exchange)

To facilitate the speedy development of the Benecol business, in March 1996 Benecol margarine was transferred from the Margarine Subdivision to a separate Benecol Unit. The unit was headed by Jukka Kaitaranta, who reported to deputy chief executive and head of the Food Division, Jukka Maki. It was intended that, during 1997, Benecol would become a separate division within Raisio. The Benecol Unit was responsible for developing all aspects of the business. It was responsible for acquiring plant sterol, producing stanol ester, managing international publicity of the project, and conducting research.

The key problem was limited supplies of the active ingredient, stanol ester. While plant sterols – the raw material from which stanol ester is produced – are a common by-product of industries that mass-process vegetable matter, almost no one had the systems in place to collect them. Raisio's primary source of supply of plant stanols was UPM-Kymmene, Europe's biggest pulp and paper company. During 1996, it negotiated increased supplies from UPM-Kymmene and also sought access to sterols from vegetable oil processors. Also in 1996, the Group built its first stanol ester plant, which was located in Raisio, and announced plans for a second plant to bring total stanol ester capacity up to 2,000 tonnes a year by January 1998. Mr. Kari Jokinen, chief executive of Raisio's Margarine Division, estimated that this production of stanol ester would allow the production of 25 million kilos of margarine, which could supply a total market of 60 million people.⁵ The Benecol Unit also began work on a new 1,500 square meter R&D laboratory at Raisio's main industrial site.

During 1996, Raisio began planning for the international launch of Benecol. Its first overseas market was to be Sweden. The Swedish launch would be facilitated by Raisio's acquisition of a 77.5% stake in Carlshamm Mejeri AB, one of Sweden's main

margarine producers, for \$44.4 million. However, Raisio's horizons were not limited to Scandinavia – nor even to Europe. Benecol margarine was seen as having a huge international potential. Sales to the US market could be massive, given that Americans spent some \$33 billion a year on health foods and slimming products. Some estimates suggested that sales of Benecol margarine could reach \$3 billion.

By January 1997, Raisio was being bombarded with requests and proposals from all over the world. Sainsbury, at the time Britain's leading supermarket chain, requested an own-label version of Benecol margarine.⁶ Other food processing companies were interested in purchasing licenses either for Benecol margarine or for Raisio's stanol ester technology, or for both.

Raisio's senior executives recognized that product formulation, marketing strategy, and distribution policies would need to be adapted to the requirements of different national markets. Moreover, there were complex national regulations relating to the marketing of food products – especially those that included additives claiming to have health benefits. The Raisio executives were especially interested in an approach from McNeil Consumer Products, a division of the US-based pharmaceutical and consumer products company Johnson & Johnson. McNeil was the world's biggest supplier of over-the-counter medicines, and was known by its leading brand-name products such as Tylenol, Imodium, and Motrin. McNeil was headquartered in Fort Washington, Pennsylvania and was able to field a range of relevant resources – not least Johnson & Johnson's worldwide marketing and distribution system.

Competition

In formulating a strategy for the global exploitation of Benecol, Raisio faced a number of uncertainties. One issue that especially concerned Raisio executives was the potential for Benecol to encounter competition. In 1991, Raisio had filed its first patent relating to its process for the production of stanol ester from plant sterols and for its use in reducing cholesterol as an additive to human foods. In 1996, its first US patent relating to stanol ester was issued. In the same year, Raisio filed a broader patent relating to the processing and use of stanol ester (see appendix 10.1). However, a number of competing products were available for reducing cholesterol. In particular, the cholesterol-reducing properties of naturally available plant sterols were well known. While Raisio believed it owned the only effective means for converting plant sterols into a fat-soluble form, it thought it likely that other processes might offer alternative approaches to the use of plant sterols as a food additive. Tor Bergman, head of chemicals (and soon to be appointed head of the Benecol Division as well) reckoned that Raisio had an 18 to 24 month lead over competitors.

Apart from plant sterols and stanols, a growing array of cholesterol-reducing drugs was available on the market. The major category was statins, which included Lovastatin (brand name Mevacor), Simvastatin (brand name Zocor), Pravastatin (brand name Pravachol), Fluvastatin (brand name Lescol), and Atorvastatin (brand name Lipitor). Statins worked through slowing down the production of cholesterol by the body and by increasing the liver's ability to remove the LDL-cholesterol already in the blood.

In addition there are a number of natural food products that have the effect of reducing cholesterol within the blood. These include fish oil, garlic, flax seed, dietary fiber, policosanol (fatty alcohols derived from waxes of sugar cane), and guggulipid (an ancient herb from India).

Regulation

Benecol margarine falls into a wide category of products generally referred to as “nutraceuticals” or “functional foods.” These are food products or supplements that may have a functional or physiological effect that is beneficial. Nutraceuticals have traditionally included food supplements such as vitamin pills, herbal products, and more recently food products with additives that offer particular nutritional benefits – energy enhancing drinks, vitamin-enriched cereals, and the like. Nutraceuticals occupy a middle ground between food and medicines. The regulations relating to them also fall between food regulations and drug regulations. They also vary greatly between countries. Thus, Japan was one of the few countries that recognized functional foods as a distinct category and, since 1991, has had a well-developed administrative system for vetting and approving health claims relating to food. Canada, on the other hand, made no distinction between functional foods and drugs in relation to health claims – inevitably, this resulted in a highly restrictive regulatory climate for functional foods. Typically, regulations required that claims regarding the beneficial effects of food products could only be *health* claims (i.e. improved health) and not *medicinal* claims (i.e. claims relating to the prevention or cure of a disease). The most important markets for Benecol would be the US and European Union. Here the regulations were far from clear-cut (see exhibit 10.2).

EXHIBIT 10.2

Country Regulations Relating to “Functional Foods”

USA

Under the 1990 *Nutrition Labeling and Education Act* (NLEA), the US Food and Drug Administration allowed health claims in the case of certain well-documented relationships, e.g. between calcium and osteoporosis and sodium and hypertension.

The 1997 *Food and Drug Administration Modernization Act* (FDAMA) allowed for two types of health claim:

- 1 Authoritative statement health claims (e.g. relating to whole grain foods and risk of heart disease and certain cancers, and potassium and risk of high blood pressure and stroke).
- 2 Qualified claims restricted to dietary supplements – typically in the form of pills, capsules, tablets or liquids, labeled as

dietary supplements and not represented or marketed for consumption as a conventional food or sole item of a meal. Such claims could be based on a preponderance of scientific evidence.

In practice this meant three possible paths for gaining approval of a food product offering stated health benefits:

- 1 As a dietary supplement. This was the simplest path. The applicant had to file notification to the FDA 60 days prior to commercial rollout together with supporting evidence.
- 2 As a food additive. This was a more time-consuming process involving much stronger evidence and a determination by an independent panel of experts assembled by the applicant and reporting to the FDA.

- 3 As a pharmaceutical. Finally, a new food product could be approved as a drug. This process typically required several years.

CANADA

The Canadian Food and Drug Act stipulated that all products represented for the cure, treatment, mitigation, prevention, risk reduction, and correction or modification of body structure and function are regulated as a “drug” regardless of the available scientific evidence.

EUROPEAN UNION

During the 1990s, the EU was in the process of harmonizing legislation among its individual member countries regarding health claims for food products. Regulation No. 258/97 concerning novel foods and novel food ingredients applied to new foods or ingredients that were primary molecular structures, micro-organisms, or were isolated from plants or isolated from animals (but was not applicable to food additives). Such novel foods were to be assessed by the government of a member state, which would make an initial assessment to determine whether the product met EU standards of safety and accurate labeling and whether an additional assessment was needed. “If neither the Commission nor the Member States raise an objection, and if no additional assessment is required, the Member State informs the applicant that he may place the product on the market . . . Any decision or provision concerning a novel food or food ingredient which is likely to have an effect on public health must be referred to the Scientific Committee for Food.”

Fast-track approval was possible for products that were essentially similar to products already on the market, but entirely new products required a full assessment by the Scientific Committee for Food. It would appear that Benecol was a new food product (given its first-time use

of stanol ester). However, the fact that it had already been marketed in Finland before the EU’s regulation had taken effect might provide it with a loophole to avoid full-assessment approval.

JAPAN

In 1991, Japan became the first global jurisdiction to implement a regulatory system for functional foods. Under the Japanese system, Foods for Specific Health Use (FOSHU) had a specific regulatory approval process separate from foods fortified with vitamins and minerals, and dietary supplements not carrying FOSHU claims. FOSHU are defined as “foods in the case of which specified effects contributing to maintain health can be expected based on the available data concerning the relationship between the foods’/ food’s contents and health, as well as foods with permitted labeling which indicates the consumer can expect certain health effects upon intake of these particular foods.” Approved FOSHU foods bear a seal of approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) identifying their role in disease prevention and health promotion. To achieve FOSHU status and an approved health claim, companies submit a scientific dossier to MHLW, which includes scientific documentation demonstrating the medical and nutritional basis for the health claim, including the recommended dose of the functional ingredient. MHLW has established a detailed approval process, which typically takes about one year to complete. Japan was estimated to have the world’s second largest functional food market behind the US.

Sources: Michael H. Moffett and Stacey Wolff Howard, *Benecol: Raisio’s Global Nutraceutical*, Thunderbird, The American Graduate School of International Management, 1999. Sean A. MacDonald, “A Comparative Analysis of the Regulatory Framework Affecting Functional Food and Functional Food Ingredient Development and Commercialization in Canada, the United States (US), the European Union (EU), Japan and Australia/New Zealand,” *Agriculture and Agri-Food Canada*, August, 2004.

The Emerging Strategy

Until the beginning of 1997, Raisio had pursued a largely self-sufficient strategy for the exploitation of its stanol ester technology. It had fabricated stanol ester itself in its own plant using its own technology. Rather than selling the stanol ester to other food manufacturers for incorporation into their own products, it had followed a strategy of vertical integration. Its stanol ester was used only in its own branded margarine, Benecol, which was produced in its own factories and marketed and distributed through its own sales and distribution system.

If it was to exploit the full potential of its innovation, Raisio would need to draw upon the resources of other companies. Clearly the market for cholesterol-reducing foods was worldwide. Also, the potential for using stanol ester in foods was not restricted to margarine. Raisio envisaged its use in a variety of health food products, including salad dressings, dairy products, and snack bars. If Raisio's stanol ester technology was to be exploited effectively throughout the EU, in North America, the Far East, and Australasia, then this would require food processing facilities, market knowledge, regulatory know-how, and distribution facilities that were quite beyond Raisio's ability to provide. A critical issue was time. Raisio patents related to its own process of producing stanol ester and incorporating it within food products. While Raisio's technology and the patent protection it had received bought it a few years' lead-time, it was unlikely that other companies would not find alternative approaches to use plant sterols as a cholesterol-reducing food additive.

In Johnson & Johnson, Raisio had a potential partner that had the capabilities needed to introduce Benecol margarine – and other Benecol products – to the world market. Not only did J&J possess global manufacturing, marketing, and distribution capabilities, it also possessed extensive experience in the food and drug approval procedures of the US, Europe, and most other countries. J&J was widely considered to be one of the most effective health product marketing companies in the world, with an outstanding reputation for quality and social responsibility, a global sales and distribution reach, and vast experience in guiding products through government regulations relating to foods and drugs. It viewed nutraceuticals as an important strand of its growth strategy: Its first nutraceutical was Lactaid for people unable to digest lactose. Lactaid was sold in caplets and as lactose-reduced milk and lactose-free foods. It also supplied sucralose, a low-calorie sweetener that had been approved by the US Food and Drug Administration and was sold in nearly 30 countries.

At the same time, there were voices within Raisio that saw risks in an exclusive relationship with Johnson & Johnson. If stanol ester was a potential additive to a wide range of products, did it make sense for Raisio to become identified with a single product – margarine – and was it desirable for Raisio to link its fortunes with a single partner? An alternative approach for Raisio would be to focus on the supply of its key ingredient, stanol ester. At one meeting of Raisio's executive committee, the case of Monsanto and NutraSweet was discussed. It was noted that following the development of NutraSweet (the branded name for aspartame), Monsanto did not forward integrate into the production of diet foods and beverages, but became a supplier of NutraSweet to a wide range of different beverage suppliers and food processors.

In relation to the production and supply of stanol ester, Raisio also faced some critical strategic choices. The crucial problem in 1996 appeared to be limited capacity for producing stanol ester. Even with a new plant planned for 1997, Raisio would

still be unable to supply the potential market for Benecol margarine in Finland and nearby markets. If, as anticipated, the demand for Benecol products was to be worldwide, it would need to produce stanol ester in all regions where Benecol products were manufactured and marketed. Thus, even if Raisio agreed a licensing agreement with Johnson & Johnson to produce and market Benecol products, Raisio would need to specify the terms under which stanol ester would be supplied. All Raisio's sterol requirements were supplied by the pulp and paper group, UPM-Kymmene. Raisio had cooperated closely with UPM-Kymmene in developing the technology for separating plant sterols during wood pulp processing. To ensure access to adequate supplies of plant sterols for its stanol ester production, Raisio would need to collaborate closely with the processors of forest and agricultural products. Raisio was considering forming a joint venture with UPM-Kymmene specifically for the extraction and supply of plant sterols. Irrespective of whether the global licensing deal with J&J for the production and distribution of Benecol products went ahead, Raisio faced critical decisions with regard to the production of stanol ester and the supply of plant sterols. Should it keep its production of stanol ester in-house, or should it license this technology also?

Case [B]: Developments 1997–2000

The Agreement With Johnson & Johnson

During 1997, negotiations between Raisio Group and Johnson & Johnson's McNeil subsidiary progressed to the point where an agreement was signed between the two companies. Raisio's 1997 annual report outlined the deal:

In July 1997, the Raisio Group signed a cooperation agreement with the American McNeil Consumer Products Company, which is part of the Johnson & Johnson Group. The contract gives McNeil the sole right to use the Benecol trademark and patents on the US, Canadian, and Mexican markets. The Raisio Group retains the right to supply the stanol ester required for the products. McNeil aims to introduce the first products during 1998. Raisio received a lump payment for assignment of these license rights and will receive remunerations related to operative development and royalties for the sales of Benecol products and for deliveries of stanol ester.

Johnson & Johnson is the world's biggest and most versatile producer of health-related products. Its turnover totaled USD21.6 billion in 1996 and it has 170 operative companies in 50 countries.

In November a new letter of intent was signed, which will extend cooperation with Johnson & Johnson to global dimensions. Europe and Japan will take their places by the side of the United States as the chief Benecol markets. The agreement also includes a plan to strengthen the position of the Benecol brand by cooperating with other companies producing strong brands that fit in with the Benecol product family. The letter of intent leads to a final agreement on March 2, 1998.

These agreements confirm the principle that the Raisio Group will keep the entire production of stanol ester in its own hands and will develop Benecol production and marketing in Finland and neighboring areas. Global marketing will be carried out with a strong and skilled cooperation partner.⁷

Expectations for Benecol were high. Raisio's consultants estimated total worldwide sales of nutraceuticals at \$35 billion a year, excluding supplements (such as vitamins and minerals). Of these, functional foods comprised about one-third (\$10–12 billion) with an annual growth of 25–35%. If consumer reaction to Benecol in other industrialized nations was anything like that in Finland, Benecol promised to be a blockbuster. By the beginning of 1998, Raisio's share price exceeded EUR12 – up 1,200% over three years.

The agreement would involve close cooperation between Raisio and Johnson & Johnson. Not only would Raisio be supplying J&J with stanol ester, the agreement also provided for the two companies to coordinate medical and clinical research and marketing, and cooperate in product development on a project-by-project basis.

Putting together the partnership with J&J was the dominant priority of Raisio's top management during the first half of 1997. As a result, several other initiatives were put on hold. Raisio's 1997 annual report noted that: "The introduction of Benecol products was delayed on the Finnish market because of the extensive license negotiations at group level and the need to adopt a common approach on all markets."⁸

Stanol Ester Production

Given the optimism for worldwide sales of Benecol and Raisio's current inability to meet home demand because of a shortage of stanol ester, the worldwide launch of Benecol margarine depended critically on expanding the production of stanol ester.

The first priority was increasing Raisio's purchases of plant sterol. Raisio's 1997 Annual Report described the quest:

The plant sterol needed to produce stanol ester has from the very beginning been supplied by Kaukus Oy, part of the UPM-Kymmene Group. Kaukas separates the sterol during the pulp cooking process and is a pioneer in sterol separation techniques.

In April 1997, Raisio and UPM-Kymmene set up a joint venture called Sterol Technologies Ltd. Raisio's holding is 65%. The company develops sterol separation methods and markets them to the forest industry. In October 1997, Sterol Technologies began to build an experimental sterol recovery unit at the Kaukas mill, which is scheduled for completion in March 1998.

An agreement has been made with the French company Les Derives Raisiniques et Terpeniques to achieve a major increase in its sterol production. The new plant covered by the agreement should go on stream in 1999. The entire additional capacity has been reserved for Raisio Benecol.

In August, a letter of intent was signed with the American Westvaco Corporation on cooperation in studying ways of producing plant sterol in America. The aim is to build a sterol production plant in South Carolina to go on stream in 2000.

In November, an agreement was signed with the Chilean company Harting S.A. on establishing a joint venture called Detsa S.A. in Chile. Raisio's holding is 49%. Detsa will build a sterol plant and Sterol Technologies will be responsible for the technology.

When the Detsa plant is completed in 1999, Raisio Benecol will have close to 400 tonnes of raw sterol a year at its disposal. Refined into stanol ester, this amount will satisfy the daily needs of 4 million people. If the percentage of

population accounted for by users of Benecol settles as the same level as in Finland, this amount will be sufficient to supply markets comprising close on 200 million consumers.⁹

Raisio had been operating a prototype stanol ester plant at its headquarters since 1996. It had planned to build an adjoining unit to expand stanol ester production. However, following the J&J deal Raisio decided that the priority was to begin stanol ester production in America. Hence, in June 1997, Raisio began construction of a stanol ester plant at Charleston, South Carolina.

The International Launch

United States During 1998, J&J planned for the launch of Benecol margarine both in the US and Europe. After considerable analysis and discussion, J&J decided that, for the purposes of meeting the FDA regulations, it would introduce Benecol spreads to the US market as a dietary supplement. As Exhibit 10.2 of the [A] case explains, this would involve the least delay and would allow J&J to promote Benecol's cholesterol-reducing benefits.

However, in October 1998, a letter from the FDA torpedoed the US launch:

The purpose of this letter is to inform you that marketing the product with the prototype label . . . would be illegal under the Federal Food, Drug and Cosmetic Act . . . The label for the Benecol spread, through the statement that the product replaces butter or margarine, vignettes picturing the product in common butter or margarine uses, statements promoting the texture and flavor of the product, and statements such as “. . . helps you manage your cholesterol naturally through the food you eat,” represents this product for use as a conventional food. Therefore, the product is not a dietary supplement.

As a food with an additive that had not been approved as safe, Benecol margarine was subject to FDA regulation and J&J would have to embark on the protracted process of submitting evidence of stanol ester's safety and efficacy.

J&J halted the US launch of Benecol and decided that it would introduce the product as a food product without any explicit health claims. By early 1999 Benecol received “Generally Recognized As Safe” (GRAS) status from a panel of independent experts that allowed Benecol to be launched in May 1999.

Europe In Europe, J&J avoided the regulatory tussles that had delayed the US launch of Benecol, principally because the 1995 introduction into Finland had predated the new EU regulations. Nevertheless, the European launch still needed to take account of different national regulations and Benecol's formulation also needed to be adapted to different national preferences. In March 1999, Benecol was launched in the UK and in Belgium, Netherlands, and Luxemburg in September. The European launch comprised four products: regular and low-fat Benecol spread (margarine) and a natural and a herb cheese spread. In the fall of 2000, Benecol products were launched in Sweden and Denmark.

Competition

Unilever The delays to Benecol's international launch eliminated Raisio's first-mover advantage in cholesterol-reducing margarine. Almost simultaneous with

Benecol's US debut, Unilever launched its rival product, Take Control, which contained sterol esters derived from vegetable oil. Because Take Control's sterol esters were simpler and less expensive to prepare than Raisio's stanol ester (it did not require a complex hydrogenation process), the Unilever product could be sold at a lower price. Initially, Raisio and J&J were not overly concerned at the price differential, in the belief that stanol ester was more effective than sterol ester in cholesterol reduction. However, some new research evidence suggested that the differential was probably very small.

In September 2000, Raisio and J&J received some rare good news from the FDA. After a careful review of the evidence, the FDA had determined that J&J could issue explicit health claims for the effects of stanol ester within Benecol margarine in reducing coronary heart disease. The only downside was that the ruling gave equal rights to Unilever for its sterol ester ingredient.

Despite overcoming the regulatory hurdles, the market reaction to Benecol was disappointing. J&J spent \$49 million on advertising Benecol within the US, but US retail sales for Benecol between May and December 1999 reached just \$17 million. Another estimate put US sales between May 1999 and August 2000 at \$42 million.

Unilever's initial launch met similar results. During 1999 it was estimated that Take Control was supported by \$15 million in advertising only to generate \$13 million in sales. By January 2000, Take Control had gained 1.6% of the US margarine market, with Benecol holding 1.2%. In response to this poor consumer response, J&J shifted the emphasis of its marketing strategy from consumer advertising to providing information to US doctors on the health benefits of Benecol.

In Europe, J&J was able to enter the market for cholesterol-reducing margarine before Unilever in most countries. Unilever launched its sterol ester margarine as "Pro-activ" – an extension to its existing Flora and Becel ranges of low saturated fat margarines. In the UK, Unilever's Flora Pro-activ was launched early in 2000 – nine months after Benecol. Yet, Unilever's superior sales and distribution for grocery products and its lower price (Benecol retailed at £2.49 per 250 g pack compared with Flora Pro-activ at £1.99) meant that Unilever soon had twice the market share of Benecol.¹⁰ Market observers also noted that Unilever's marketing was more effective than J&J's:

The brand is backed by the Flora Project, a nutrition marketing effort that educates people about heart disease prevention including diet, smoking cessation, lifestyle habits and exercise. Flora sponsors the London marathon, as well as other sporting events. Before Pro-active came onto the market, tubs of regular Flora already bore the words, 'as part of a healthy diet helps lower cholesterol,' a statement scientifically backed by Unilever. Moreover, the Flora name had a massive 'share of mind' – from the 1980s until the mid-1990s, the Flora brand accounted for 60 per cent of media spending in the spreads category. Because Flora was associated in consumers' minds for 30 years with heart health – and with good taste – it was logical to leverage the Flora brand assets.

The London Flora marathon seamlessly became the London Flora Pro-active marathon. There is little company communication about the ingredient – the words 'plant sterols' are mentioned only on about page six of the information leaflet. But that is as it should be – Unilever is selling the benefits of Flora, a known and trusted food brand; it is not selling plant sterols, specifically.

In contrast, rival Johnson & Johnson's McNeil Consumer Products group had no pre-existing supermarket brand to extend when it launched the

cholesterol-lowering spread, Benecol, in Finland in late 1995 (then owned by Raisio). Benecol, therefore, started out with zero brand equity in the UK. By the time Pro-active joined it on the market, Benecol had garnered \$30 million in sales – no small achievement for an entirely new brand – and it held a 0.5 per cent volume share and 2.5 per cent value share.

As the brand creator, Benecol had to set the price point, which it did at seven times the price of regular spreads. In response, Unilever added to Pro-active's competitive advantage by bringing it to market 25 per cent cheaper than Benecol.

Add to these factors the massive brand equity of the Flora name, and it is no surprise that Flora Pro-active is now outselling Benecol in the UK by a factor of almost three-to-one.¹¹

Other competitors Unilever was not the only company interested in the market for stanol and sterol esters. By 2000, some of Raisio's worst fears were being realized. Several companies had either entered the market for cholesterol-reducing nutraceuticals, or had announced their intention to enter:

- *Forbes Medi-Tech and Novartis.* In April 1999, the Swiss pharmaceutical company Novartis signed a five-year agreement with Canadian biotechnology company Forbes Medi-Tech to license Phytrol – a plant sterol-based ingredient with similar cholesterol-reducing properties to stanol ester. Novartis would become responsible for clinical trials, regulatory submissions, and commercialization of end products. Phytrol (marketed also as Reducol) received FDA “Generally Recognized As Safe” approval in May 2000.¹² In 2000, Novartis announced a joint venture with Quaker Oats to form Altus Foods, which would manufacture healthy foods containing Phytrol. Novartis launched a number of products including breakfast cereals and cereal bars under the Aviva brand name. However, market response was, at best, tepid. In the UK, the Aviva range was withdrawn six months after the launch.
- *Paulig.* In July 1999, Finland's Paulig (a company known for its coffee and spice operations) announced its own plant sterol ingredient, Teriaka, derived from maize, soy, and pine trees. Because its manufacture utilizes normal processing technology and does not require chemical synthesis or high temperatures/pressures, it was believed that it could gain quick approval under the EU's Novel Foods Regulations.
- *Procter & Gamble* introduced a line of cooking oils containing sterol esters under the brand name, CookSmart.
- *Archer Daniels Midland* developed a patent-pending sterol ingredient that is dispersible in liquids, allowing sterols to be added to beverages, milk products, and other water-based and non-fat products.
- *Monsanto* in 2000 received a patent on a “phytosterol protein complex” composed of sterols, proteins, and edible oil. The product claimed to enhance the cholesterol-reducing effects of sterols.

Mounting Crisis

During 2000, Raisio was incurring rapidly increasing losses from its Benecol Division. During the first half of 2000, it reported losses of EUR44.0 million, mostly resulting from a non-recurring charge of EUR38.0 million. This compared with a

TABLE 10.2 Raisio Group financial indicators, 1996–2000

	1996	1997	1998	1999	2000
<i>Sales and operations</i>					
Turnover (€m)	661	858	833	763	800
change, %	+22	+30	–3	–8	+5
Exports from Finland (€m)	124	135	178	145	131
Total international turnover (€m)	259	423	421	374	399
% of turnover	39.2	49.3	50.5	49.0	49.9
Gross investments (€m)	65	73	75	61	49
R&D expenditure (€m)	15	17	18	16	18
% of turnover	2.2	1.9	2.1	2.1	2.3
Average personnel	2,365	2,817	2,904	2,897	2,775
<i>Profitability</i>					
Operating result (€m)	33	41	52	16	–32
% of turnover	5.0	4.8	6.3	2.1	–4.0
Result before extraordinary items (€m)	28	35	42	6	–47
Result before taxes and minority interest (€m)	27	20	39	–2	–47
% of turnover	4.1	2.3	4.7	–0.3	–5.8
Return on equity (ROE), %	4.5	7.8	9.2	0.4	–14.9
Return on investment (ROI), %	9.2	10.1	11.1	4.0	–4.2
<i>Financial and economical position</i>					
Shareholders' equity (€m)	291	298	317	304	260
Net interest-bearing liabilities (€m)	119	143	174	233	251
Balance sheet total (€m)	619	643	690	744	750
Equity ratio, %	47.3	46.6	46.0	41.0	34.7
Quick ratio	1.1	0.8	0.7	0.6	0.7
Current ratio	1.8	1.5	1.2	1.2	1.2
Cash flow from business operations	43	60	47	6	16

SOURCE: RAISIO GROUP 2000 ANNUAL REPORT

profit that totaled EUR11.2 million during the corresponding period in 1999 (although this resulted entirely from a one-time payment under the agreement with J&J). Revenues for the first six months of Raisio's Benecol Division were down from EUR47 million to EUR16 million between 1999 and 2000, reflecting the end of payments from J&J and sharply reduced sales of stanol ester to J&J. Tables 10.2 and 10.3 show Raisio's financial performance between 1996 and 2000.

The company's report for the first half of 2000 analyzed the problems:

The development of the Group's Benecol business derives from a vision dating back to 1996–97 which predicted a rapid and impressive rise in Benecol products containing stanol ester into global functional foods. This vision was based on Raisio and McNeil's joint assessment and on market and need analyses by leading international consultants.

Raisio then made safeguarding long-term availability of the main raw material in Benecol products – sterol – its strategic goal. Action aimed at large-scale

TABLE 10.3 Raisio Group divisional performance, 1996–2000 (millions of euros)

		1997	1998	1999	2000
Benecol	Turnover	16	48	52	23
	Operating profit	n.a.	n.a.	7.5	–45.6
Margarine	Turnover	282	235	200	204
	Operating profit	n.a.	n.a.	79.5	78.0
Grain	Turnover	287	274	235	244
	Operating profit	n.a.	n.a.	0.8	0.7
Chemicals	Turnover	278	277	299	347
	Operating profit	n.a.	n.a.	20.3	11.9

n.a. = not available.

SOURCE: RAISIO GROUP ANNUAL REPORTS 1998–2000.

procurement of sterol was therefore taken immediately on both the plant and the wood sterol markets. Plant sterols were acquired under long-term purchasing agreements, as world supply was limited and indeed inadequate for the targets then set for Benecol operations.

The limited nature of plant sterol production thus faced Raisio with a strategic challenge, in view of which several projects were launched aimed at developing more wood sterol separation. The biggest are a tall oil and sterol separation project in Chile (Detsa) and the Weststerol project planned for North America. Supplies of wood sterol were also ensured through various contracting and financing arrangements.

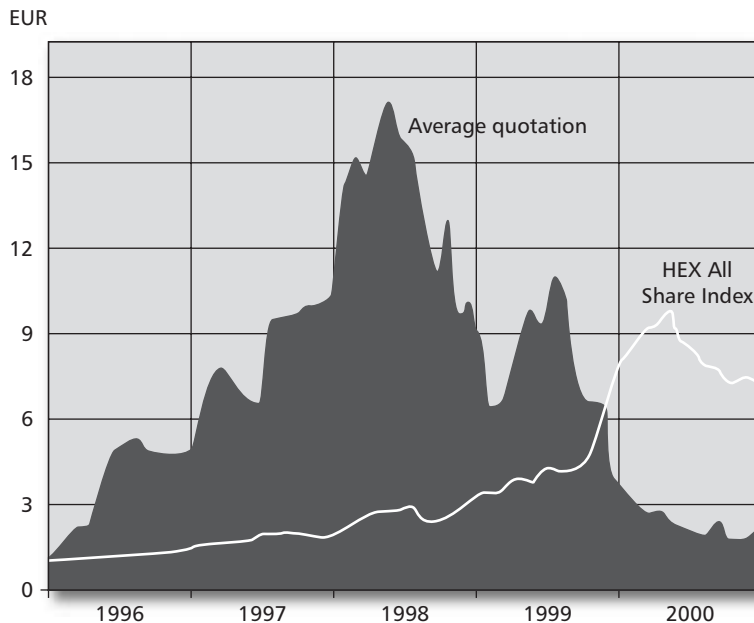
Since the launch in Finland in 1995, however, Benecol products have actually reached the market only in the USA, UK, Ireland and the Benelux countries, and mainly only in the second half of 1999, and in Sweden and Denmark this autumn. Market penetration has thus been slower than expected, partly due to regulatory obstacles. Current experience suggests that the expectations concerning cholesterol-reducing foods on which Raisio's plans were based were overly optimistic. So far, less than 20 per cent of the targets have been achieved.

As a result of its high expectations and targets, Raisio has tied up substantial resources in both wood sterol projects and sterol and stanol stocks. In today's market situation, however, the company has had to review and re-assess its sterol strategy and the preconditions for completing ongoing projects, as well as the value of the sterols and stanols already procured.

To stem the losses, Raisio renegotiated several of its long-term sterol purchase agreements, withdrew from its sterol separation joint venture in Chile, and suspended its Solixin plant sterol project in New Zealand. Other sterol separation projects were to be reviewed on a case-by-case basis. Inventories of sterol and stanol were re-valued at current market prices and several of the fixed assets involved written down.

The central problem, it believed, lay with the agreement with J&J. J&J's worldwide license meant that Raisio was completely dependent on J&J's commitment to Benecol and the success of J&J's marketing strategy. Observing Unilever's ability to push Benecol into second place in the US and Europe, many at Raisio believed that the company had backed the wrong horse. Despite J&J's expertise with FDA regulations

FIGURE 10.2 Raisio Group plc, price of unrestricted shares (Helsinki stock exchange)



Note: Figures 10.1 and 10.2 are not directly comparable because of a 10:1 share split in June 1998. Figure 10.2 shows Raisio's share price adjusted for the share split.

and healthcare, and its massive R&D budget, in terms of marketing food products and selling to supermarkets, J&J like other big pharmaceutical companies had neither the expertise nor the access of the huge packaged consumer goods companies.

During 2000, Raisio's share price was in free-fall. By the fall of 2000, Raisio's shares had lost 85% of their value compared with the peak in mid-1998 (see figure 10.2). CEO Tor Bergman, who, as head of Raisio's Chemical Division and head of the Benecol Division, had been the primary architect of the Benecol strategy, was the main casualty of the collapse. He left Raisio in August 2000 and was replaced as CEO by Lasse Kurkilahti. The new CEO's review of 2000 was in sharp contrast to the optimistic tone of previous communications to shareholders. After acknowledging 2000 to be "the worst in the past ten years," he went on to outline the challenge of Raisio competing internationally:

Earlier, Raisio competed with Finnish and Nordic companies; now, its competitors are European or global players . . . The diversified enterprises that formed during the '80s in a closed economy will not survive in today's open economy, where a business's only hope lies in being competitive. The Raisio Group has to focus its resources on the fewer fields.¹³

Benecol would occupy a prominent position among these "fewer fields." However, to succeed, the Division needed a new strategy. The starting point was a new relationship with J&J. By December 2000, a new agreement was reached:

... This gives the Benecol Division the opportunity to implement a global strategy concentrating on functional food ingredients – that is, stanol and sterol ester – in certain clinical areas. The new agreement covers two main aspects of the Benecol stanol ester business. The companies agreed that McNeil would concentrate on markets in North America, the EU (excluding Finland, Sweden and Denmark), Japan and China. Raisio's market area, in turn, comprises Scandinavia, the Baltic region, the former East European countries, the Near East, Latin America, the Far East and Oceania. The two companies also agreed on a new market-driven delivery agreement for Benecol ingredients. Further, Raisio acquired global rights to sell and market sterol ester. Both companies may agree independently to involve third parties in their market areas in order to expand the product range. Since the agreement was signed, a number of promising openings have been made with prospective new partners . . .

During 2001 the Benecol Division will put its new global ingredient strategy into operation . . . The objective is to create a global network of business partners through which it can market stanol and sterol ester to consumers in various types of food. New cooperation agreements with Mastellone Hnos in Argentine (December, 2000), and Valio (December, 2000) and Atria (January, 2001) in Finland are the first examples of implementation of Raisio's new strategy. These agreements provide an excellent basis for further progress in 2001.

Appendix 10.1

Raisio's Principal Patents Relating to Stanol Ester

US Patent No. 5,502,045 "Use of a stanol fatty acid ester for reducing serum cholesterol level"

Inventors: Tatu Miettinen, Hannu Vanhanen, Ingmar Wester.

Assignee: Raisio Tehtaat Oy AB

Filed: November 22, 1993

Awarded: March 26, 1996

Abstract

The invention relates to a substance which lowers cholesterol levels in serum and which is a .beta.-sitostanol fatty acid ester or fatty acid ester mixture, and to a method for preparing the same. The substance can be used as such or added to a food.

Claims

We claim:

- 1 The method of reducing the absorption of cholesterol into the bloodstream comprising orally introducing into the body an effective amount of a substance containing a .beta.-sitostanol fatty acid ester prepared by the interesterification of .beta.-sitostanol with a fatty acid ester containing between 2 and 22 carbon atoms in the presence of an interesterification catalyst.
- 2 The method according to claim 1, wherein the interesterification of .beta.-sitostanol is carried out in a solvent free food grade process.
- 3 The method according to claim 2, wherein the interesterification occurs at a temperature of approximately 90 degree–120 degree C and a vacuum of approximately 5–15 mmHg.
- 4 The method according to claim 3, wherein the catalyst is sodium ethylate.
- 5 The method of claim 1, wherein the fatty acid ester comprises a mixture of fatty acid esters.

- 6 The method according to claim 1, wherein the .beta.-sitostanol is prepared by hydrogenation of a commercial .beta.-sitosterol mixture.
- 7 The method according to claim 1, wherein the interesterification is carried out in the presence of a stoichiometric excess of the fatty acid ester.
- 8 The method according to claim 1, wherein an effective amount of the substance is between about 0.2 and about 20 grams per day.

Extract from "Description" Section

. . . The present invention relates to the use of a sterol of an entirely different type for lowering the cholesterol level in serum. What is involved is fatty acid esters of alpha-saturated sterols, especially sitostanol fatty acid esters (sitostanol = 24-ethyl-5.alpha.-cholestane-3.beta.-ol), which have been observed to lower cholesterol levels in serum with particular efficacy. The said esters can be prepared or used as such, or they can be added to foods, especially to the fatty part of a food. The sitostanol fatty acid ester mixture is prepared by hardening a commercial .beta.-sitosterol mixture (sitosterol = 24-ethyl-5-cholestene-3.beta.-ol). .beta.-sitostanol can be prepared by a prior-known cholesterol hardening technique by hardening .beta.-sitosterol by means of a Pd/C catalyst in an organic solvent (43). This mixture has the approval of the FDA (Cytellin, Eli Lilly). A hardening degree of over 99% is achieved in the reaction. The catalyst used in the hardening is removed by means of a membrane filter, and the obtained sitostanol is crystallized, washed and dried. In accordance with the invention, the .beta.-sitostanol mixture, which contains campestanol approx. 6%, is esterified with different fatty acid ester mixtures by a commonly known chemical interesterification technique (44, 45, 46). A methyl ester mixture of the fatty acids of any vegetable oil can be used in the reaction. One example is a mixture of rapeseed oil and methyl ester, but any fatty acids which contain approx. 2 to 22 carbon atoms are usable. The method according to the invention for the preparation of stanol fatty acid esters deviates advantageously from the previously patented methods in that no substances other than free stanol, a fatty acid ester or a fatty acid ester mixture, and a catalyst are used in the esterification reaction. The catalyst used may be any known interesterification catalyst, such as Na-ethylate.

United States Patent No. 5,958,913 "Substance for lowering high cholesterol level in serum and methods for preparing and using the same"

Inventors: Tatu Miettinen, Hannu Vanhanen, Ingmar Wester.

Assignee: Raisio Benecol Ltd.

Filed: November 5, 1996

Awarded: September 28, 1999

Abstract

The invention relates to a substance which lowers LDL cholesterol levels in serum and which is fat soluble .beta.-sitostanol fatty acid ester, and to a method for preparing and using the same. The substance can be taken orally as a food additive, food substitute or supplement. A daily consumption of the .beta.-sitostanol ester in an amount between about 0.2 and about 20 grams per day has been shown to reduce the absorption of biliary and endogenic cholesterol.

Claims

What is claimed is:

- 1 A food composition suitable for reducing blood serum cholesterol levels or reducing absorption of cholesterol from the intestines into the bloodstream, the food composition comprising a nutritional substance and a blood serum cholesterol level reducing or cholesterol absorption reducing effective amount of a sterol component comprising at least one 5.alpha.-saturated sterol fatty acid ester.

- 2 The food composition as claimed in claim 1, wherein the sterol component comprises .beta.-sitostanol fatty acid ester.
- 3 The food composition as claimed in claim 1, wherein the fatty acid contains about 2 to 22 carbon atoms.
- 4 The food composition as claimed in claim 2, wherein the fatty acid contains about 2 to 22 carbon atoms.
- 5 The food composition as claimed in claim 1, wherein the 5.alpha.-saturated sterol fatty acid ester is produced by esterifying the alpha-saturated sterol and a fatty acid ester in a solvent-free food grade process.
- 6 The food composition as claimed in claim 2, wherein the .beta.-sitostanol fatty acid ester is produced by esterifying .beta.-sitostanol and a fatty acid ester in a solvent-free food grade process.
- 7 The food composition as claimed in claim 5, wherein the esterifying step is conducted in the presence of an esterification catalyst.
- 8 The food composition as claimed in claim 6, wherein the esterifying step is conducted in the presence of an esterification catalyst.
- 9 The food composition as claimed in claim 7, wherein the esterification catalyst comprises sodium ethylate.
- 10 The food composition as claimed in claim 8, wherein the esterification catalyst comprises sodium ethylate.
- 11 The food composition as claimed in claim 5, wherein the esterifying step is conducted at a temperature of about 90–120 degree C under a vacuum of about 5–15 mmHg.
- 12 The food composition as claimed in claim 6, wherein the esterifying step is conducted at a temperature of about 90–120 degree C under a vacuum of about 5–15 mmHg.
- 13 The food composition as claimed in claim 5, wherein the esterifying step is conducted without the presence of additional interesterifiable lipids.
- 14 The food composition as claimed in claim 6, wherein the esterifying step is conducted without the presence of additional interesterifiable lipids.
- 15 The food composition as claimed in claim 1, wherein the nutritional substance comprises a member selected from the group consisting of cooking oil, margarine, butter, mayonnaise, salad dressing and shortening.
- 16 The food composition as claimed in claim 2, wherein the nutritional substance comprises a member selected from the group consisting of cooking oil, margarine, butter, mayonnaise, salad dressing and shortening.
- 17 A method for reducing the cholesterol level in blood serum of a subject in need thereof, comprising orally administering to the subject the food composition as claimed in claim 1, wherein the sterol component is present in a blood serum cholesterol level reducing effective amount.
- 18 A method for reducing the cholesterol level in blood serum of a subject in need thereof, comprising orally administering to the subject the food composition as claimed in claim 2, wherein the sterol component is present in a blood serum cholesterol level reducing effective amount.
- 19 The method as claimed in claim 17, wherein about 0.2 to 20 grams per day of the sterol component are orally administered.
- 20 The method as claimed in claim 18, wherein about 0.2 to 20 grams per day of the sterol component are orally administered.
- 21 A method for reducing the absorption of cholesterol from the intestines into the bloodstream of a subject in need thereof, comprising orally administering to the subject the food composition as claimed in claim 1, wherein the sterol component is present in a cholesterol absorption reducing effective amount.

- 22 A method for reducing the absorption of cholesterol from the intestines into the bloodstream of a subject in need thereof, comprising orally administering to the subject the food composition as claimed in claim 2, wherein the sterol component is present in a cholesterol absorption reducing effective amount.
- 23 The method as claimed in claim 21, wherein about 0.2 to 20 grams per day of the sterol component are orally administered.
- 24 The method as claimed in claim 22, wherein about 0.2 to 20 grams per day of the sterol component are orally administered.

Brief Description of the Invention

The present invention relates to a sterol of an entirely different type for lowering the cholesterol levels in blood serum. The substance comprises a fatty acid ester of alpha saturated sterols, especially sitostanol fatty acid esters, which have been observed to lower cholesterol levels in serum with particular efficacy.

The present invention includes a method of reducing the absorption of cholesterol into the bloodstream from the digestive tract by orally introducing into the body an effective amount of a fatty acid ester of a beta-sitostanol. More preferably, the invention further includes orally introducing between about 0.2 and about 20 grams per day of beta-sitostanol fatty acid ester into the body. The ester is introduced either as a food additive, a food substitute or a food supplement. When used as a food additive, the fatty acid ester of the beta-sitostanol may be added to food products such as cooking oils, margarines, butter, mayonnaise, salad dressings, shortenings, and other foods having an essential fat component.

Notes

- 1 FIM = Finnish marks. The average exchange rate during 1996 was US\$1 = FIM4.54.
- 2 "Chief Executive's Review," Raisio Group Annual Report, 1996, p. 3.
- 3 The company was renamed Raisio Group plc in September 1997. Throughout this case we shall refer to the company as "Raisio Group."
- 4 Raisio Group 1997 Annual Report, p. 38.
- 5 "Market split over 'miracle' margarine," *Financial Times*, October 25, 1996, p. 26.
- 6 "Wonder spread from Finland," *The Grocer*, May 18, 1996, p. 9.
- 7 Raisio Group 1997 Annual Report, p. 39.
- 8 *Ibid.*, p. 39.
- 9 *Ibid.*, p. 40.
- 10 www.nutraingredients.com/news/ng.asp?id=36575-the-benecol-story
- 11 Julian Mellentin, "Trusted Brands Sell Healthy Hearts," *Functional Foods and Nutraceuticals*, June 2002 (www.ffmpeg.com/NH/ASP/strArticleID/105/strSite/FFN Site/articleDisplay.asp).
- 12 *Chemical Business Newbase*, October 20, 2000.
- 13 Raisio Group 2000 Annual Report, p. 5.