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<b>(21) International Application Number:</b> PCT/EP00/03725 <b>(22) International Filing Date:</b> 25 April 2000 (25.04.00) <b>(30) Priority Data:</b> 09/299,778 26 April 1999 (26.04.99) US <b>(71) Applicant (for all designated States except AG AU BB CA CY GB GD GH IE IL IN KE LK LS MN MW NZ SD SG SZ TT TZ UG ZA ZW):</b> UNILEVER N.V. [NL/NL]; Weena 455, NL-3013 AL Rotterdam (NL). <b>(71) Applicant (for AG AU BB CA CY GB GD GH IE IL KE LK LS MN MW NZ SD SG SZ TT TZ UG ZA ZW only):</b> UNILEVER PLC [GB/GB]; Unilever House, Blackfriars, London, Greater London EC4P 4BQ (GB). <b>(71) Applicant (for IN only):</b> HINDUSTAN LEVER LTD. [IN/IN]; Hindustan Lever House, 165-166 Backbay Reclamation, Mumbai 400 020 (IN).		<b>(72) Inventors:</b> CHEN, Mandy, Kim; Lipton, Research & Development, 3701 Southwestern Boulevard, Baltimore, MD 21229 (US). PATRICK, Matthew; Lipton, Research & Development, 3701 Southwestern Boulevard, Baltimore, MD 21229 (US). REDDY, Podutoori, R.; Lipton, Research & Development, 3701 Southwestern Boulevard, Baltimore, MD 21229 (US). <b>(74) Agent:</b> BOERMA, Caroline; Unilever N.V., Patent Department, P.O Box 137, NL-3130 AC Vlaardingen (NL). <b>(81) Designated States:</b> AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>Without international search report and to be republished upon receipt of that report.</i>
<b>(54) Title:</b> ENRICHED SPREADS		
<b>(57) Abstract</b>  A water-in-oil spread including phytoestrogens, preferably isoflavones. It can be expected that the reported beneficial health effects of phytoestrogens may be enjoyed by the consumer by consuming the spread. The spreads of the invention have good taste, notwithstanding the presence of the often-bitter tasting isoflavones. The spread may be an emulsion comprising added phytoestrogens and at least 0.25 wt. % of calcium (e.g., calcium moiety of a calcium salt), especially at least 0.5 wt. % of calcium. The spread may be an emulsion comprising phytoestrogens and one or more, preferably at least two, of the following vitamins: D, E, B6 and B12. Preferably the spread also includes elevated levels of calcium and/or magnesium. The spread may also be provided with a level and type of triglycerides such that at least 5 wt. % polyunsaturated fatty acid moieties are present (based on the total weight of the spread) to provide consumers with access to both of these substances in a beneficial food form.		

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ENRICHED SPREADS

## 5 BACKGROUND OF THE INVENTION

Phytoestrogens are compounds found in plants which have certain estrogen-like effects. These include  
10 isoflavones, lignans, flavones and coumestans. They have been touted in the press for beneficial health effects without certain disadvantages which have been attributed to estrogen, such as increased risk of cancer. Health conditions for which phytoestrogens have been mentioned  
15 include cancer of the breast, cancer of the prostate, cancer of the uterus, cancer of the bowel, hypercholesterolemia, atherosclerosis, colon cancer, antioxidation, benign breast disease, premenstrual syndrome, and symptoms associated with menopause.

20

Phytoestrogens are weakly estrogenic and competitively inhibit the response of tissue to estrogens. They have been found in vitro to stimulate production of sex hormones-binding globulin (SHBG) from human cells. Phytoestrogens  
25 are described in Price et al. "Naturally occurring oestrogens in foods--A review," Food Additives and Contaminants," 1985, Vol. 2, NO. 2, 73-106, the disclosure of which is incorporated by reference herein.

30 Numerous references exist in the patent and scientific literature to phytoestrogens and related compounds.

Crank et al. US 5,858,449 is directed to isoflavone-enriched soy protein products and methods for their  
35 manufacture. One of the key factors said to limit the use

of soy protein isolates especially in nutritional beverages, milk replacers, and dairy products is the soy taste. Soy concentrates are said not to be used in such products because of the strong soy taste and the presence  
5 of the soy fiber as an insoluble component with undesirable mouthfeel.

Crank's finished product is said to display desirable flavor and functional properties. The isoflavone content is  
10 said to be substantially increased compared to traditional soy protein isolates. The product may be an ingredient in dairy or meat-based food products such as infant formula, nutritional beverage, milk replacer, bologna, imitation processed cheese spread, water-injected ham, yogurt and  
15 frozen dessert. The Crank et al. soy product has a protein content greater than 60% dry matter, dietary fiber less than 4% dry matter, sucrose greater than 10% dry matter, sulfur containing amino acid greater than 2.2% of total amino acid content, stachyose content less than 1.5% dry  
20 matter, and total isoflavone content greater than 2500 mcg/g.

It is said that the soy should be present as an ingredient in cheese spread at from 10-50% of the protein  
25 used in the formula. A yogurt includes whey, vegetable oil, sugar, emulsifiers, salts, vitamins and minerals. The soybean products include daidzein, genistein, and glycitein.

30 WO 98/08503 discloses administration of an isoflavone-type compound used for various conditions. It can be used with vitamin E. Use as additives in foods and drinks such

as health bars or desserts is mentioned. Among the many forms of formulation suitable for oral administration mentioned are oil-in-water and water-in-oil emulsions. The term "food stuffs" is said to be used in as wide as  
5 possible sense. The compounds are said to act synergistically with vitamin E to protect biological molecules from oxidation.

Gorbach et al, U.S. Patent No. 5,498,631 is directed  
10 to a method for treating symptoms of menopause, premenstrual syndrome or a condition resulting from reduced levels of indigenous estrogen by administering to the women an effective amount of an isoflavoid. The dietary products preferably include a soy extract containing enriched  
15 isoflavonoids provided in a palatable food carrier, (e.g. a confectionery bar, biscuit, cereal or beverage).

Gorbach US 5,733,926 is directed to a method for treating Alzheimer's disease or age-related loss of  
20 cognitive function comprising administering an isolated isoflavonoid selected from genistein, daidzein, biochanin A, formononetin, O-desmethylangolensin, glycitin and equol. It may be provided in a food carrier such as a confectionery bar, biscuit, cereal or beverage.

25

Barnes et al., U.S. Patent No. 5,506,211 discloses that the isoflavone genistein inhibits the acid secretion of osteoclasts and reduces bone resorption. The claims mention use of a genistein/glucoside conjugate. Foodstuffs  
30 such as soy which contain genistein or concentrated forms thereof may be ingested to provide an animal with an effective amount of genistein. Conjugated forms of

genistein are absorbed in the large bowel and thus are said to have advantageous biodistribution properties. Various soy products such as soy protein may be used.

5        In human treatments, suitable methods include administering from two to 50 milligrams to 20 to 50 milligrams of genistein in the form of a food product. This may be achieved by ingesting between by about two to 50 milligrams or about 20 to 50 milligrams of soy isolated  
10 soy protein per day per person.

Feuer et al., U.S. Patent No. 4,163,746 discloses 5-methylalkoxy isoflavones useful as weight gain promoters. In the form of pharmaceutical compositions, the  
15 compositions may be in solid or liquid form. The liquid may be, for example, an emulsion. The composition contains conventional diluents or carriers such as talc, magnesium stearate, calcium carbonate, starch and water. Optionally other agents such as emulsifying agents may be used.  
20 Further biologically active components such as vitamins may be used. In the example at the top of column 5, 26% calcium phosphate, 1% of a vitamin premix and 0.05% of a mineral premix are used. Further additives mentioned include vitamins, amino acids, choline chlorides, salts of  
25 mineral acids, trace elements and other known subjects of biological importance.

Stadler Nee Szoke et al., U.S. Patent No. 4,826,963 is directed to inclusion complexes of 7-isopropoxyisoflavon  
30 formed with cyclodextrin. A commercial product iprisoflavon includes 7-isopropoxyisoflavon, talcum, and magnesium.

Jackson et al., U.S. Patent No. 5,654,011 is directed to dietary supplement for supplementing the nutritional needs of pre-perimenopausal women comprising of about 200 5 to about 500 milligrams calcium, about 100 to about 200 milligrams magnesium, about 0.5 to about 1.5 milligrams boron, from about 0.5 to about 1.5 milligrams copper, about 2 to about 2.6 milligrams manganese, about 10 to 13 milligrams zinc, about 200 to about 300 IU Vitamin D, about 10 12 to 18 milligrams iron, about 400 to about 440 mug folic acid, about 2 to about 10 mug Vitamin B<sub>12</sub>, about 50 to about 100 milligrams Vitamin B<sub>6</sub>, about 50 to about 100 microgram chromium, about 100 to about 200 IU Vitamin E, about 100 to about 1,000 mg Vitamin C and about 8 to less 15 than 50 mg. phytoestrogen, in a mixture with a biologically acceptable carrier. The invention is directed to dietary supplements formulated to supplement a woman's specific micronutrient and phytochemical needs. Dietary supplements of the invention may be formulated as a tablet, capsule, 20 powder, gel or liquid or dietary bar. Jackson et al. US 5,807,586 also discloses vitamins, plus minerals plus phytoestrogens.

Levy et al., U.S. Patent No. 5,780,060 (Centre National 25 Bela Recherche Scintifique) is directed to microcapsules based on crosslinked plant polyphenols, particularly flavonoids. These may be incorporated in a composition such as a cosmetic, pharmaceutical, dietetic or food composition. The anti-free radical and/or anti-oxidizing 30 agent of the plant polyphenols is cited. The microcapsules may be formed by interfacial crosslinking of an emulsion. Active substances can include iron oxide, titanium oxide,

zinc oxide, talc or kaolin, a vegetable oil such as cereal germ oil, a deodorized fish liver oil or an oily solution of a lipo soluble substance such as vitamin A, vitamin D2, vitamin E or tocopherol, an essential fatty acid such as  
5 linoleic acid, linolenic acid or arachidonic acid.

Kuznicki et al., U.S. Patent No. 5,464,619 is directed to a composition preferably in the form of a beverage which includes green tea solids, flavanols, sodium ions,  
10 potassium ions, and carbohydrate. Minor ingredients which may include flavoring agents, colorings, preservatives, acidulants, gums, emulsifiers, oils and vitamins may be included. Preferably the vitamins include vitamins A, C and E, although D and B may be included. Additional  
15 minerals may be included, such as calcium, chromium, copper, fluorine, iodine, iron, magnesium, maganese, phosphorus, selenium, silicone, molybdenum and zinc.

WO 98/50026 (Novogen) discloses treatment or  
20 prevention of menopausal symptoms or osteoporosis by administration of isoflavones, formononetin or daidzein with one or more adjuvants, carriers and/or excipients.

Zilliken, U.S. Patent No. 4,157,984 is directed to  
25 antioxidant compositions useful as stabilizers for food compositions including edible fats and oils. The compositions are prepared from a natural source, tempeh, a fermented soybean product. An ergostadienriol which possesses antioxidative properties and which in combination  
30 with mixtures of isoflavones provides compositions having exceptional antioxidative properties is disclosed. This

can be used alone or in mixtures with isoflavones or other compounds.

Shlyankevich, U.S. Patent No. 5,424,331 (Biovirus  
5 Research) is directed to a composition for treatment or  
prevention of osteoporosis which includes one or more  
phytoestrogen compounds, calcium contained in a  
biologically acceptable calcium salt, magnesium contained  
in a biologically acceptable magnesium salt, zinc contained  
10 in a biologically acceptable zinc salt, beta carotene,  
vitamin D and vitamin E. The compositions may be  
administered either as a dietary supplement or as a  
pharmaceutical.

15 Potter et al., U.S. Patent No. 5,855,892 is directed  
to a method of altering the concentration of cholesterol  
constituents in human blood. The method includes  
administering a daidzein material as a pharmaceutical  
composition or in a dietary supplement including soy  
20 protein based dietary supplements. Inert pharmaceutically  
acceptable carriers useful for the invention are said to  
include calcium sulfate, dicalcium phosphate, magnesium  
stearate, and disintegrating agents include calcium  
carbonate. The foods to which daidzein may be added are  
25 said to include all foods. Specifically mentioned are  
beverages such as nutritional beverages, cheeses such as  
hard and soft cheeses, frozen desserts such as ice cream,  
salad dressings, and dips and spreads such as mayonnaise  
and chip dips. In Example 1 the isolated soy proteins  
30 containing isoflavones are fortified with calcium.

Shlyankevich, U.S. Patent No. 5,569,459 is directed to a composition for controlling the stimulation of estrogen production which includes phytoestrogen compounds, a sedative which is a valerian root dry extract, passion  
5 flower dry extract, or ginseng root powder, optionally dried licorice root, optionally beta carotene, optionally pyridoxidine hydrochloride, optionally vitamin E, optionally calcium salt, optionally magnesium, optionally zinc, optionally coumestan and optionally pantothenic acid.  
10

WO 9610341 (Schouten Industries) discloses substantially pure hypocotyls of Glycine max which may be used in food and other products. They may be used as raw materials for isolation of isoflavones such as daidzin,  
15 genistin and glycitin. They may be incorporated in drinks, dairy products, bakery products, health teas and other products. In Example 2, a tomato juice cocktail is disclosed including tomato concentrate, green tea natural beta carotene, natural vitamin E and Glycine max hypocotyl.  
20 The product contained 10 mg genisteine/daidzeine as glucosides per can of 163 ml.

WO 9821947 (Internutria) discloses a composition for alleviating persistent reproductive transition nighttime  
25 symptoms comprising phytoestrogen and melatonin. The composition can be sprinkled on foods or blended with a food or drink. The food or drink may be solid, semi-solid or liquid. Examples are cereal products, baked goods, puddings, food bars, frozen products such as ice cream,  
30 cake mixes or spreads. Some other specific carriers mentioned include sorbet, sherbet, tea, and milk. A dry powder for beverages is found in 6.5.A.

Zilliken US 4,390,559 is directed to isoflavones useful as antioxidants and useful in antioxidant compositions including edible fats and oils. The compounds  
5 can be recovered from tempeh, fermented soybean product. Effective amounts of the antioxidant compositions for improving the stability of oils or fats such as lard, corn oil, olive oil, bean oil, safflower oil, vegetable oil, cottonseed oil, polyunsaturated oils, animal fats and oils  
10 and the like are said to be in amounts of about 0.01 to 1.0 weight percent, more or less.

Schouten Industries, USA sells a soybean isolate product called SoyLife® comprising 40.5% protein, 11.2%  
15 fatty acid, 3.0% isoflavones, and 4.1% saponins. They suggest incorporating 1% to 5% of the SoyLife® product in any foods, including dietary drinks.

One difficulty which has been encountered in promoting  
20 ingestion of phytoestrogens, is the off-taste from which phytoestrogen-containing preparations often suffer.

#### **SUMMARY OF THE INVENTION**

25

In accordance with a first aspect of the invention, it has now been found that a beneficial form for ingestion of phytoestrogens is in the form of a water-in-oil spread. For instance, it has been discovered that phytoestrogens can  
30 advantageously be consumed, particularly in elevated amounts, when included in the form of a bread spread. It can be expected that the reported beneficial health effects

of phytoestrogens may be enjoyed by the consumer by consuming the spread without the need for pharmaceutical type pills, capsules, etc. Accordingly, in one embodiment, the present invention concerns an edible plastic spread, comprising added phytoestrogen, said phytoestrogen being present at a level of at least 0.01 wt.%, and said phytoestrogen comprising at isoflavone. The spreads of the invention have good taste, notwithstanding the presence of the often-bitter tasting isoflavones. It is further preferred that this spread is a water in oil spread. In another embodiment, the spread contains an isoflavone at a level of at least 0.05 wt.%,

In another preferred embodiment, the spread is an emulsion comprising added phytoestrogens and at least 0.25 wt. % of a calcium salt, especially at least 0.5 wt. % of a calcium salt. The spread is preferably a water-in-oil emulsion. The spread is an excellent vehicle to provide women with the phytoestrogens and calcium both of which have enjoyed favorable reports concerning health effects.

In another preferred embodiment of the invention, the spread is an emulsion comprising phytoestrogens and one or more, preferably at least two, of the following vitamins: D, E, B6 and B12. Preferably the spread also includes elevated levels of calcium and/or magnesium. Preferably this spread is also a water-in-oil emulsion.

In another preferred feature of the invention, a spread is provided with phytoestrogens and a level and type of triglycerides such that at least 5 wt. % polyunsaturated fatty acid moieties are present (based on the total weight

of the spread) to provide consumers with access to both of these substances in a beneficial food form. Health benefits for both phytoestrogens and polyunsaturated fatty acids have been widely reported. More preferably, the level and type of triglycerides is selected so that the spreads include at least 7 wt.%, especially up to a level of 20 wt. % polyunsaturated fatty acid moieties.

The spreads of the invention also may provide soy proteins in advantageous levels so as not to unduly impair the quality of the product, preferably between 0.4 wt.% and 2 or 3 wt.%.

Isoflavones which may be used include genistein and daidzein. It is preferred that the phytoestrogen is an isoflavone, preferably being genistein.

Advantageously, the spreads of the invention are readily manufactured.

20

#### DETAILED DESCRIPTION OF THE INVENTION

Preferred sources of phytoestrogen isoflavones include soy, clover, including red clover and subterranean clover, grams, chickpeas, ground nuts, lentils and beans, at levels of between 40 and 300 mg/100g dry weight. Isoflavones are found in plants primarily bound to sugars such as glucose, as glycosides. Smaller amounts are found in plants in the aglucone form. Soy may be used in the form of soybean flour; or the hull and/or hypocotyl may be used.

Preferred sources of Lignan phytoestrogens are found in common human foods such as oilseeds, eg, flax, cereals, legumes and vegetables. An example is metairesinol. Lignan levels in oilseeds may range from 20-60 mg/100g dry weight, while other plant sources may range from, e.g., 0.1- 0.6 mg/100g. Coumestans are found in, eg., sprouts of soy and alfalfa at levels ranging between 0.12mg and 7mg per 100 g dry weight. Phytoestrogen estrogens are closely related to animal estrogens and have been found in plants  
10 such as apple, licorice, and date palm.

Processes for isolating phytoestrogens and phytoestrogen moiety-containing compounds and complexes from plants are well known. These include the process of  
15 Fluery et al. US Patent No. 5,141,746, the disclosure of which is incorporated by reference, Gugger et al. US Patent No. 5,702,752 and Shen et al. US Patent No. 5,637,562. Phytoestrogens are also available in the form of soy isoflavone concentrate obtained from soy flour and sold  
20 under the SoyLife® trade name by Schouten USA, Inc. of Minneapolis, Minnesota. Also, ADM of Decatur, Illinois offers Novasoy® dietary supplement ingredient which is said to be rich in genistin and daidzin. The product is said to have 40% total isoflavones.

25

Preferred levels of the phytoestrogens are at least 0.01 wt. % on the total weight of the spread, preferably at least 0.05 wt. %.

30 Other ingredients reported to have health benefits which may be included in the spreads are the sterols and sterol esters or stanols and stanol esters such as

sitosterol, sitostanol, their fatty acid esters, and the like at up to about 20%, especially up to about 10% of the spread based on the sterol moiety.

5        Examples include alpha sitosterol, beta sitosterol, stigmasterol, ergosterol and campesterol, alpha spinosterol and brassiciasterol. Although the foregoing are some of the more important phytosterols, at least 44 phyosterols have been identified and it will be apparent to one of  
10 ordinary skill that many of these will be appropriate for the present invention. Phytosterols are identified in bean (1993) phytosterols in "*Advance in Lipid Research*", pages 193-218, Paoletti, and Kiritchevsky, (Eds) Academic press, NY, the disclosure of which is incorporated herein by  
15 reference. The disclosure of "*Effect of Plant Sterols on Lipids and Atherosclerosis*", Pollack, O.J., *Pharmac, Ther.*, 31, 177-208 (1985) mentioned above is also incorporated by reference herein.

20        Among the more important sources are rice bran, corn bran, corn germ, wheat germ oil, corn oil, safflower oil, oat oil, olive oil, cotton seed oil, soybean oil, peanut oil, black tea, orange juice, valencia, green tea, Colocasia, kale, broccoli, sesame seeds, shea oils,  
25 grapeseed oil, rapeseed oil, linseed oil, canola oil, tall oil from wood pulp and other resinous oil from wood pulp.

The spread is advantageously prepared by combining a fat phase with an aqueous phase, after which the mixture is  
30 processed into an emulsion and the phytoestrogens and other additives are added.

Spreads according to the invention generally contain from less than 80% by weight of edible triglyceride materials. Suitable edible triglyceride materials are for example disclosed in Bailey's Industrial Oil and Fat Products (1979). In higher fat spreads, the level of triglyceride material will generally be more than 60% and less than 80%, preferably from 70 to 79% by weight. In spreads of reduced fat content the level of triglycerides will generally be from 30-60%, more generally from 35 to 45% by weight. In very low fat spreads the level of triglycerides will generally be from 0 to 40%, for example, 30%, 25%, 20% or even 10% or about 0%, all percentages being by weight on total weight of the spread.

Optional ingredients in the fat-continuous phase which is combined with the aqueous composition include emulsifiers, salt (particularly sodium chloride), preservatives, flavors, protein, vitamins, especially fat soluble vitamins such as vitamin A, antioxidants, antimicrobials, and preservatives, including citric and other acids. The emulsifiers can include mono- and diglycerides, partial polyglycerol esters, lecithin and polyoxyethylene sorbitan monoesters such as TWEEN 60 and TWEEN 80. One advantageous emulsifier is a polyglycerol polyricinoleate sold under the name Admul Wol available from Quest International, Naarden, the Netherlands.

Emulsifiers may be included at from 0.05 to 2% by weight, typically not more than 1% by weight.

30

It is preferred that the fat used is triglyceride fat derived from vegetable sources including soybean, canola,

corn, sunflower, palm, Palm kernal, rapeseed, coconut, safflower, cottonseed, peanut and olive oils. Other digestible fat sources which may be used are fish oil, milk fat, skim milk fat, butterfat, lard and tallow. The oil will be hardened by hydrogenation if that is necessary to achieve the desired melting characteristics. Also, fractionation and interesterification may be used to obtain fats of the desire melting range. Especially preferred are fats having relatively large proportions of polyunsaturated fatty acid moieties, such as canola and soybean oils. The fat compositions mentioned in Netherlands patent documents No. NL 143115, NL 178559, NL 155436, NL 149687, NL 155177, and European patent documents EP 41303, EP 209176, EP 249282, and EP 470658, the disclosures of which are incorporated by reference, are highly suitable. If a fat blend is used it is most preferred that it comprises at least 30%, more preferably at least 45% of polyunsaturated fatty acid moieties, based on the total weight amount of the fat in the fat based food product to promote cholesterol lowering.

The fat can be a single fat or a blend. The use of a fat composition comprising a considerable amount of PUFA (polyunsaturated fatty acid) rich triglycerides is in particular considered highly beneficial.

Non-digestible fats may also be used as the fat source. Among the non-digestible fats are included polyol polyesters of C<sub>8</sub> to C<sub>22</sub> fatty acids such as sucrose polyester, sucrose polyethers, silicone oils/siloxanes, polycarboxylic acid esters, branched chain fatty acid triglycerides, neopentyl alcohol esters, dicarboxylic acid

esters, jojoba oil and triglycerol ethers. Non-digestible fats may be used as from 0 to 100% of the fat, especially from 10 to 90%, and most especially from 25 to 75%.

5 Non-lipid fat replacers may also be used, to provide body to the product. These include protein-based fat replacers such as those described in Singer et al., U.S. Patent No. 4,961,953 and cellulosic bulking agents such as microcrystalline cellulose and carboxymethyl cellulose.  
10

Coloring agents, such as beta carotene, paprika, turmeric, annatto and yellow #5 and 6 and combinations thereof may be employed. The yellow color may desirably be used in combination with an opacifier like  $TiO_2$ . It has  
15 been found that providing an appropriate color may be important since phytoestrogen sources such as soy flour impart a brownish color.

Soy protein may be present in the compositions of the  
20 invention, particularly where it is present with the phytoestrogens which are added to the spread, as in soy flour. Other proteins can conveniently be in the form of milk protein from whole, skim or other low fat milk and may comprise whey proteins (with or without lactose), acid  
25 casein and caseinates. In addition or instead of soy, other vegetable protein, such as peanut protein, cottonseed protein and the like may also be used.

In addition to sodium chloride, flavor enhancers which  
30 may be employed include lactones, lipolyzed butter oils and started distillates, diacetyl, 2-octanone, butyric acid, hexanoic acid, and other fatty acids, esters of butyric

acid, hexanoic acid, and other fatty acids, esters of butyric acid, delta-hydroxy acids and their glycerol esters and mixtures thereof.

5       Preservatives, such as benzoic acid, sorbic acid, phosphoric acid, lactic acid, acetic acid, hydrochloric acid and the soluble salts thereof may be used. Likewise, the emulsion may include antimicrobials such as potassium sorbate, sodium sorbate, potassium benzoate, sodium  
10 benzoate and phosphoric acid.

Antioxidants may include normal propyl gallate, the tocopherols, including Vitamin E, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), nordihydroguaiaretic  
15 acid (NDGA), tertiary-butylhydroquinon (TBQH) and citric acid.

It will be appreciated that normally more hydrophobic additives will be added to the fat phase whereas more  
20 hydrophilic additives will normally be added to the aqueous phase.

The aqueous phase comprises water and, optionally other ingredients. A preferred ingredient is one or more  
25 gelling agents such as gelatin. Where the spread is a low fat spread, it is advantageous that the aqueous composition is gelled, which in some respects compensates for the lower amounts of fat in the product. It may be advantageous for the aqueous composition to be pre-gelled, i.e., gelled  
30 prior to combining the aqueous composition with the fat-continuous emulsion. Other suitable gelling agents include waxy maize starch such as Ultra-Tex 2, available from the

National Starch and Chemical co., Bridgewater, NJ or a rice starch such as Remyrise AC. A particularly effective combination of gelling agents has proved to be gelatin and waxy maize or rice starch. Other gelling agents include  
5 carrageenan, and a gelling hydrolyzed starch derivatives such as gelling maltodextrin, for example, Paselli maltodextrin SA2®.

The amount of gelling agent may lie between 0 and 30%,  
10 mostly between 0.1 and 25% based on the weight of the aqueous phase of the spread. If hydrolyzed starches are present, their level may be from 2-20%; other gelling agents may be used at levels of up to 10%, mostly 1-7%, most preferred 2-5%, all of these percentages being based  
15 on the weight of the aqueous phase.

Hydrocolloids which are thickening rather than gelling agents may also be used. Hydrocolloids are described in Zeitschrift fur Lebensmitteltechnologie und Verfahrenstechnik  
20 32 (1981) 6, pp. 253-256. Hydrocolloids in addition to those mentioned above include polysaccharides such as native and modified starches, cellulose derivatives, pectins, galleon, xanthan gum, agar, Danish agar, furcelleran, gum arabic, guar gum, locust bean gum, algin,  
25 and alginates. Hydrocolloids will generally be used at levels of from 0.2 to 6%, based on total products. It will be appreciated that the gelling and thickening agents may be used in various combinations.

30 Additional ingredients which may be present in the aqueous phase include salt (particularly sodium chloride), preservatives, such as potassium sorbate, lactic and other

acid, proteins, coloring agents, flavors, antimicrobials, antioxidants and vitamins, particularly water-soluble vitamins such as the B vitamins.

5 Proteins, water-soluble coloring agents, flavors, preservatives and antimicrobials and antioxidants useful in the aqueous composition are the same as those discussed above in connection with the fat phase, it being appreciated that generally the more hydrophilic additives  
10 are best placed in the aqueous phase.

Although melatonin may be added, compositions in which melatonin is essentially not present, especially compositions in which melatonin is completely absent, are  
15 preferred.

Sources of phytoestrogens include Indian liquorice (*Abrus precatorius*); various species of *Acacia spp.* including, *A. aneura*, *A. cibaria*, *A. longifolia*, and *A.*  
20 *oswaldii*; ground nut (*Apios tuberosa*); ground bean (*Arachis hypogea*); milk vetch (*Astragalus edulis*); marama bean (*Bauhinia esculenta*); sword bean (*Cajanus cajan indicus*); jack bean (*Canavalia ensiformis*); sword bean (*Canavalia gladiata*); seaside sword bean (*Canavalia rosea*); various  
25 *Cassia spp.* including *C. floribunda*, *C. laevigata*, and *C. occidentalis*; carobbean (*Ceratonia siliqua*); chick pea (*Cicer arietinum*); yebnut (*Cordeauxia edulis*); various *Crotalaria spp.* including *C. laburnifolia*, and *C. pallida*; cluster bean (*Cyamopsis psoralioides*); tallow tree  
30 (*Detarium senegalense*); sword bean (*Entada scandens*); balu (*Erythrina edulis*); soyabean (*Glycine max*); inga

(*Ingaedulis*); Polynesian chestnut (*Inocarpus fagifer*);  
hyacinth bean (*Lablab purpureus*); grass pea or Indian vetch  
(*Lathyrus sativus*); cyprus vetch (*Lathyrus ochrus*); lentil  
(*Lens culinaris*); jumping bean (*Leucaneal eucocephala*);  
5 various *Lupinus* spp. including *L. albus*, *L. luteus*, *L.*  
*angustifolium*, *L. mutabilis*, and *L. cosentinii*; ground bean  
(*Macotylma geocarpa*); hose gram (*Macrotyloma uniflorum*);  
alfalfa (*Medicago sativa*); velvet bean (*Mucuna pruriens*);  
yam beans (*Pachyrhizuz erosus*, *P. tuberosus*); African  
10 locust bean (*Parkia clappertoniana*); *Parkia speciosa*; poil  
bean tree (*Pentaclethra macrophylla*); various *Phaseolus*  
spp. including *P. acutifolium*, *P. vulgaris*, *P. luntus*, *P.*  
*coccineus*, *P. adenathus*, *P. angulris*, *P. aureus*. *P.*  
*calcaratus*, *P. mungo*, and *P. polystachyus*; garden bean  
15 (*Pisum sativum*P); djenko bean (*Pithecolobium lobatun*);  
mesquite (various *Prosopis* spp.); goa bean (*Psophocarpus*  
*scandens*, *P. tetragonolobus*); various *Psoralea* spp.;  
*Sesbania bispinosa*; yam bean (*Sphenostylis stenocarpa*);  
tamarind (*Tamarindus indica*P); fenugreek (*Trigonella*  
20 *foenumgracum*); vetches (various *Vvia* spp. including *V.*  
*sativa*, *VC. Atropurpurea*, *V. ervilia*, and *V. monantha*);  
broad bean (*Vivia faba*); black gram (*Vigna mungo*); various  
*Vigna* spp including *V. radiata*, *V. aconitifolia*, *V.*  
*adanatha*, *V. angularus*, *V. tribolata*, *V. unbelata*, and *V.*  
25 *unguiculata*; and earth pea (*Voandzeia subterranea*).

The balance of the spread is largely water, which may  
be incorporated at levels of up to 99.9% by weight, more  
generally from 10 to 98%, preferably from 20 to 97% by  
30 weight. Spreads according to the invention may be fat- or  
water-continuous.

**EXAMPLE**

<b>Ingredients</b>	<b>%</b>
<b>Oil Phase</b>	<b>40.00</b>
Canola Oil	28.08
Bean Oil	2.77
Partially hydrogenated bean oil, melting point 42°C	8.70
Lecithin	0.22
Saturated distilled monoglyceride (iodine value <5)	0.22
Flavor	Trace
Vitamin A	0.01
<b>Aqueous phase</b>	<b>60.00</b>
Water	51.13
Salt	1.50
Lactic Acid	0.09
Potassium Sorbate	0.11
Calcium disodium EDTA	0.01
Pork Gelatin	2.00
Soylife micro (soy germ flour)	2.86
Beta tricalcium phosphate	1.88
Xanthan gum	0.10
Artificial color Yellow 5	0.04
Titanium dioxide	0.28
Vitamin mix B6, B12 & E	0.07
<b>Total</b>	<b>100.00</b>

5 The spread is prepared by the following procedure

The oil phase was prepared by heating the liquid oil and partially hydrogenated bean oil in a tank to 65°C. The emulsifiers, lecithin and monoglycerides were mixed and the

mixture was held for 30 minutes to completely melt the fat crystals.

Vitamin A, flavor were added to the heated oil phase.

5

The aqueous phase was prepared by adding xanthan gum to the water at 40°C in a tank. After hydrating the gum for 15 minutes, tricalcium phosphate was dispersed. All the other dry ingredients were added and mixed with a high  
10 shear mixer to obtain a homogeneous aqueous phase. The contents in the tank were batch pasteurized by heating to 80°C and holding for 5 minutes and cooled to 55°C.

The fat and aqueous phases are mixed together at  
15 approximately 55°C in a heated tank in a ratio of approximately 40 parts fat phase to 60 parts aqueous phase.

This emulsion is water continuous. The emulsion is then passed through a cooled, scraped-surface heat exchanger (A-unit) where the emulsion is cooled to a temperature where  
20 the fat will begin to crystallize (few degrees C below the alpha point 4°C) and the aqueous phase will begin to gel, if the aqueous phase has the gelling agents, and/or there is increase in viscosity if only thickening agents are present in the aqueous phase. The cooled emulsion is then  
25 passed into a slowly agitated, variable speed crystallizer (C\*-unit) where the product is inverted from a water-continuous emulsion to a fat-continuous emulsion by quickly increasing the shaft speed. The inversion was aided by injecting 100% fat into the system. The C\* unit is  
30 referred to as the inverter unit. The inverter speed was 1000 rpm. The shaft speed in the inverter unit depends on its dimensions but normally varies from 200-2000 rpm. The

fat continuous emulsion is passed into an additional C unit running at shaft speed of 300 rpm to provide gentle mixing while the fat continues to crystallize from the alpha to beta prime form.

5

Extra cooling capacity can be added to the process by including additional A-units. Extra residence time can be added to the process by including additional C-units.

- 10 Unless stated otherwise or required by context, the terms "fat" and "oil" are used interchangeably herein. Where a phase is said to constitute essentially the entire product, it is meant that such phase constitutes at least 98 wt. %, especially more than 99 wt. % of such product.
- 15 Unless otherwise stated or required by context, percentages are by weight.

**Claims**

1. An edible, plastic water-in-oil spread comprising added phytoestrogen wherein (i) said phytoestrogen is present at a level of at least 0.01 wt% of said spread of said spread and comprises isoflavone or (ii) said spread further includes at least 0.25 wt. % calcium salt, or (iii) said spread further includes at least one of vitamins D, E, B6 or B12.
2. The spread according to claim 1 wherein said phytoestrogens are selected from the group consisting of genistein, genistin, daidzein, glycitein, formonenetin, biochanin A and saponins.
3. The spread according to any one of claims 1 or 2, characterized in that said phytoestrogen is an isoflavone.
4. The spread according to claim 1 wherein said phytoestrogens are obtained from soy.
5. The spread according to claim 4 wherein said phytoestrogens are added in the form of soy flour.
6. The spread according to any one of claims 1 to 5, characterized in that the spread comprises added calcium salt.
7. An edible, plastic spread comprising phytoestrogens at a level of at least 0.01 wt. % and at least one of (i) 0.25 wt. % calcium salt, or (ii) at least two of

vitamins D, E, B6 and B12.

8. An edible, plastic spread according to claim 7, wherein at least two of vitamins D, E, B6 and B12 are present at a level of 0.01 wt.%, preferably 0.05 wt.%, for vitamin E, at least 0.001 wt.%, preferably 0.002 wt%, for vitamin B<sub>6</sub> and 0.001 wt%, preferably 0.002 wt.% for vitamin B<sub>12</sub>.
9. An edible, plastic spread comprising one or more isoflavones at a level of at least 0.01 wt.%, at least 0.4 wt.% soy protein, and at least 0.25 wt.% calcium salt.
10. An edible, plastic spread comprising one or more isoflavones at a level of at least 0.05 wt%.
11. An edible, plastic spread comprising according to claim 9, characterized in that the spread contains less than 2 wt.% protein.
12. The spread according to claim 10 wherein said protein is present at a level of less than 1.5 wt.%.
13. The spread according to claim 11 further comprising saponins at a level of at least about 0.05 wt.% and tocopherols at a level of at least 0.001 wt.%.
14. The spread according to claim 12 further comprising triglycerides such that at least 5 wt.%, preferably at least 10 wt%, polyunsaturated fatty acid moieties are present.

15. The spread according to claim 13 wherein said polyunsaturated fatty acid moieties are present at a level of up to 20 wt %.
16. The spread according to any one of claims 1-3, 6-14, wherein the phytoestrogen is an isoflavone, the isoflavone being genistein.