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(54) **METHODS FOR HYPERTHYROIDISM IN A CAT AND COMPOSITION COMPRISING LIMITED IODINE**

VERFAHREN FÜR DIE SCHILDDRÜSENÜBERFUNKTION BEI DER KATZE SOWIE
ZUSAMMENSETZUNGEN MIT EINGESCHRÄNKTEM JODGEHALT

PROCEDES DE PREVENTION DE L'HYPERTHYROIDIE CHEZ LE CHAT ET COMPOSITION A
TENEUR EN IODE LIMITEE

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Description**FIELD**

5 **[0001]** This invention relates generally to the management of the adult feline with hyperthyroidism disease and, more particularly, to uses for restoring normal thyroid function in a feline having hyperthyroidism.

BACKGROUND

10 **[0002]** The treatment options currently available to treat cats with hyperthyroidism are chronic administration of anti-thyroid drugs, surgical removal of one or both of the thyroid glands, and use of radioactive iodine to destroy the glandular tissue. However, each of these intervention has limitations and side effects. Accordingly, an unfilled need exists for methods for managing a feline with hyperthyroidism that improve the quality and quantity of life of the animal.

SUMMARY

[0003] Accordingly, the inventors herein have succeeded in discovering that restricting iodine intake in felines having hyperthyroidism improves thyroid function thereby restoring thyroid function to a more nearly normal state.

20 **[0004]** Thus, in various embodiments, the present invention can involve a use of iodine in the manufacture of a feline diet for restoring thyroid function to a more nearly normal state in a feline having hyperthyroidism wherein the amount of iodine in the feline diet is less than 1 mg/kg of diet on a dry matter basis. The use can comprise restricting the amount of iodine intake in the feline. The iodine restriction in the diet can be to a maximum amount less than 1 mg/kg of diet, a maximum amount equal to about or less than 0.6 mg/kg of diet, a maximum amount equal to about or less than 0.4 mg/kg of diet or a maximum amount equal to about or less than 0.35 mg/kg of diet on a dry matter basis. Minimum amount of iodine can be an amount to maintain health in the feline and, in particular, an amount greater than 0.005 mg/kg or an amount equal to about or greater than 0.01 mg/kg.

25 **[0005]** In various embodiments, the uses according to the invention result in diet compositions which can contain from 10% to 50% protein, from 15% to 45% protein, from 20% to 40% protein or from 25% to 35% protein on a dry matter basis. The protein can comprise iodine at a concentration of not more than 0.6 mg/kg crude proteins, not more than 0.4 mg/kg crude protein or not more than 0.2 mg/kg crude protein. The protein can comprise a vegetable protein such as potato concentrate, soy concentrate, soy protein isolate, soybean meal, corn gluten meal or combinations thereof. Alternatively or additional, the protein comprises an animal protein such as meat protein isolate, pork lungs, chicken, pork liver, poultry meal, egg or combinations thereof.

30 **[0006]** The uses result in compositions which can, in various embodiments, further comprise from 10 to 20% fat and from 5% to 55% carbohydrate.

DETAILED DESCRIPTION

40 **[0007]** The present invention, thus, results in diets containing a restricted amount of iodine for felines having hyperthyroidism to restore thyroid function to a more nearly normal state.

[0008] Hyperthyroidism in cats can be diagnosed and assessed as to severity according methods and disease characteristics well known in the art. (see, for example, Peterson et al., in *The cat: diseases and clinical management*, R. G. Sherding, Ed., New York, Churchill Livingstone, 2nd Edition, pp. 1416-1452, 1994; Gerber et al. *Vet Clin North Am Small Anim Pract* 24:541-65, 1994).

45 **[0009]** The term "iodine", as used herein, refers to the iodine atom without reference to its molecular form. Thus, the term iodine includes without restriction the atom iodine, which may be present in one or more chemical forms, such as iodide, iodate, periodate, and erythrosine.

[0010] The abbreviation "T4", as used herein, refers to the iodine-containing amino acid thyroxine, 3,5,3',5'-tetraiodothyronine. The term "free T4" refers to T4 that is not bound to a carrier protein such as thyroid-binding globulin, albumin, and prealbumin.

50 **[0011]** The abbreviation "T3" as used herein, refers to the iodine-containing amino acid 3,5,3'-triiodothyronine. The term "free T3" refers to T3 that is not bound to a carrier protein such as thyroid-binding globulin, albumin, and prealbumin.

[0012] The abbreviation "GSH", as used herein, refers to the tripeptide glutathione.

[0013] The abbreviation "GPX", as used herein, refers to the selenium-dependent enzyme glutathione peroxidase.

55 **[0014]** Concentration of iodine or other mineral elements in foods and feedstuffs can be expressed alternatively on a molar basis (micromoles per kilogram) or on a weight basis (milligrams per kilogram, identical to parts per million, "PPM"). Iodine has a molecular weight of 126.9. Thus a molar concentration of 2.76 micromoles of iodine per kilogram is equal to a weight concentration of 0.35 PPM. Selenium has a molecular weight of 78.96. Thus a molar concentration of 1.25

micromole of selenium per kilogram is equal to a weight concentration of 0.1 mg/kg.

[0015] In various embodiments of the present invention, iodine can be present in the diet compositions at a maximum concentration less than 1 mg/kg of diet, a maximum concentration equal to about or less than 0.8 mg/kg of diet, a maximum concentration equal to about or less than 0.6 mg/kg of diet, a maximum concentration equal to about or less than 0.4 mg/kg of diet, a maximum concentration equal to about or less than 0.35 mg/kg of diet on a dry matter basis, a maximum concentration equal to about or less than about 0.3 mg/kg of diet a maximum concentration equal to about or less than 0.25 mg/kg of diet, or a maximum concentration of equal to about or less than 0.2 mg/kg diet on a dry matter basis. The minimum concentration of iodine can be an amount sufficient to maintain health in the feline and, in particular, an amount greater than 0.005 mg/kg or an amount equal to about or greater than 0.01 mg/kg on a dry matter basis.

[0016] Intake in an animal of a nutrient from a food, feedstuff, beverage, or supplement can be expressed as the product of the concentration of the nutrient element in the food, feedstuff, beverage, or supplement and the amount of said food, feedstuff, beverage, or supplement ingested by said animal.

[0017] Nutrients can be provided to a feline in the form of cat food. A variety of commonly known cat food products are available to cat owners. The selection of cat and dog food includes, as an example, wet cat foods, semi-moist cat foods, dry cat foods and cat treats. Wet cat food generally has a moisture content greater than 65%. Semi-moist: cat food typically has a moisture content between 20% and 65% and may include humectants, potassium sorbate, and other ingredients to prevent microbial growth (bacteria and mold). Dry cat food (kibble) generally has a moisture content below 10% and its processing typically includes extruding, drying and/or baking in heat. Cat treats typically may be semi-moist, chewable treats; dry treats in any number of forms; chewable bones or baked, extruded or stamped treats; confection treats; or other kinds of treats as is known to one skilled in the art.

[0018] Nutrients also may be provided to a feline in a form other than prepared cat food. Thus, for example, Kyle et al. added a vitamin-mineral mixture to a canned cat food (Kyle et al., New Zealand Veterinary Journal 42:101-103, 1994). Drinking water or other fluid similarly may be used to provide nutrients to a feline.

[0019] Commercial canned cat food products contain varying amounts of iodine and selenium as shown in Tables 1 and 2.

TABLE 1. CANNED CAT FOOD.

LABEL DESCRIPTION (n=28)	SELENIUM (mg/kg DM)	IODINE (mg/kg DM)
SHEBA Gourmet salmon dinner	0.812	1.55
WHISKAS Ground Mealtime	0.837	1.96
WHISKAS Homestyle Chicken & Salmon	0.863	1.18
WHISKAS Ocean Whitefish & Tuna	1.01	2.98
NUTRO Max Cat Chicken & Lamb	1.28	47.87
NUTRO Kitten Chicken & Ocean Fish	1.34	3.24
NUTRO Cat Chicken & Liver Formula	1.16	30.91
FRISKIES Prime Entrée	1.36	4.57
FRISKIES Senior Ocean Whitefish & Rice	1.78	10.59
FANCY FEAST Sliced Beef Feast	1.50	1.30
FANCY FEAST Sardines, Shrimp & Crab	4.23	1.35
FANCY FEAST Ocean Whitefish & Tuna	2.45	5.45
FANCY FEAST Tender Liver & Chicken	1.84	3.08
FANCY FEAST Seafood	2.09	3.27
FANCY FEAST Fish & Shrimp	3.17	1.33
FANCY FEAST Trout	1.29	1.09
FANCY FEAST Tuna & Mackerel	2.24	2.02
HEINZ 9 LIVES Super Supper	2.38	2.47
HEINZ 9 LIVES Ocean Whitefish & Tuna	1.90	5.06

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(continued)

LABEL DESCRIPTION (n=28)	SELENIUM (mg/kg DM)	IODINE (mg/kg DM)
HEINZ 9 LIVES Poached Salmon	1.60	52.27
IAMS Adult Beef Formula	1.95	4.5
IAMS Adult Chicken Formula	1.32	3.18
IAMS Adult Ocean Fish Formula	2.56	5.14
IAMS Adult Salmon Formula	1.70	4.88
BEST CHOICE Ocean Whitefish & Tuna	1.63	2.11
BEST CHOICE Salmon Dinner	1.66	4.38
BEST CHOICE Fisherman's Catch	2.27	4.48
KOZY KITTEN Fish Dinner	1.32	7.07
AVERAGE	1.77	7.83

TABLE 2. DRY CAT FOOD.

LABEL DESCRIPTION (n =14)	SELENIUM (mg/kg DM)	IODINE (mg/kg DM)
WHISKAS Original	0.551	1.34
IAMS Kitten Formula	0.599	2.96
IAMS Weight Control Formula	0.544	3.16
IAMS Original Cat Formula	0.602	2.80
EUKANUBA Adult Chicken & Rice	0.797	2.12
PURINA Kitten Chow	0.973	3.05
PURINA Meow Mix Chicken-Turkey-Salmon	0.636	2.39
PURINA Cat Chow Original	0.729	5.94
PURINA O.N.E. Regular	0.813	2.45
NUTRO Max Cat Lite	0.479	3.38
NUTRO Max Cat Chicken-Rice-Lamb	0.430	3.32
FRISKIES Ocean Fish	0.717	1.97
FRISKIES Chef's Blend	0.720	2.17
HEINZ 9 LIVES Tuna & Eggs	1.01	1.79
AVERAGE	0.69	2.77

[0020] Commercial cat foods generally include ingredients from the following classes: protein from animal and/or plant sources; individual amino acids; fats; carbohydrate sources, vitamins; minerals; and additional functional ingredients such as preservatives, emulsifiers, and the like.

[0021] Protein sources for use in cat foods can comprise from 45% to 100% crude protein on a dry matter basis. Twenty-one protein ingredients commonly used in commercial production of cat foods were analyzed for their contents of selenium and iodine. The results were expressed as mg/kg dry matter (DM) and also as mg/kg crude protein (CP) as shown in Table 3 below.

TABLE 3.

Protein Ingredient	Crude Protein (% DM)	Selenium		Iodine	
		mg/kg DM	mg/kg CP	mg/kg DM	mg/kg CP
potato concentrate	75	0.08	0.11	0.084	0.11
soy concentrate	72	0.15	0.21	0.098	0.14
soy protein isolate	91.5	0.27	0.30	0.144	0.16
soybean meal	48.5	0.45	0.93	0.01	0.02
corn gluten meal	64	1.25	1.95	0.02	0.03
chicken backs	75	0.41	0.55	0.02	0.03
rice protein isolate	60	0.75	1.25	0.041	0.07
pea protein concentrate	50	1.79	3.58	0.049	0.10
wheat protein conc.	75	1.84	2.45	0.091	0.12
wheat protein isolate	90	2.13	2.37	0.141	0.16
pork liver	72	3.11	4.32	0.15	0.21
beef spleen	66	1.22	1.85	0.24	0.36
beef tongue	63	0.77	1.22	0.28	0.44
pork lung lobes	75	1.71	2.28	0.29	0.39
beef lung	56	0.93	1.66	0.38	0.68
meat protein isolate	98	0.77	0.79	0.575	0.59
deboned turkey	44.5	0.31	0.70	0.69	1.55
Mackerel	67	4.15	6.19	1.03	1.54
Oceanfish	58	1.76	3.03	1.44	2.48
poultry by-product meal	67	0.97	1.45	2.05	3.06
Eggs	50	1.28	2.56	3.1	6.20

[0022] As shown in the table, potato concentrate and soy isolate contain low selenium and low iodine concentrations.

[0023] Protein content in the feline diet manufactured according to the use of the present invention can be in an amount of from 10%, from 15%, from 20%, from 25%, from 30%, from 35% up to 40%, up to 45%, up to 50%, up to 55%, up to 60%, up to 70%, up to 80%, up to 90% or greater on a dry matter basis.

[0024] Iodine can be present in the protein component at a concentration less than 1.0 mg/kg crude protein, a concentration equal to about or less 0.8 mg/kg crude protein, a concentration equal to about or less than 0.6 mg/kg crude protein, a concentration equal to about or less than 0.4 mg/kg crude protein, a concentration equal to about or less than 0.2 mg/kg crude protein, a concentration equal to about or less than 0.1 mg/kg crude protein, a concentration equal to about or less than 0.05 mg/kg crude protein or a concentration equal to about or less than 0.02 mg/kg.

[0025] The protein can be present from animal sources such as meat or meat byproducts or from plant sources such as from vegetable protein sources. Animal protein sources can include meat protein isolate, pork lungs, chicken, pork liver, poultry meal, egg and combinations thereof. Vegetable protein sources can include potato concentrate, soy concentrate, soy protein isolate, soybean meal, corn gluten meal and combinations thereof.

[0026] Carbohydrate can be supplied from grain ingredients. Such grain ingredients can comprise vegetable materials, typically farinaceous material, which can supply primarily, dietary digestible carbohydrate and indigestible carbohydrate (fiber) and less than 15% protein on a dry matter basis. Examples include without limitation brewers rice, yellow corn, corn flour, soybean mill run, rice bran, cellulose, gums, and the like. Typically, carbohydrate can be present in the compositions of the present invention in amounts of from 5%, from 10%, from 15%, from 20%, from 25%, from 30%, up to 35%, up to 40%, up to 45%, up to 50%, up to 55%, up to 60%, up to 70%, up to 80%, up to 90% or greater, on a dry matter basis.

[0027] Fats used in cat food include without limitation animal fats and oils, such as choice white grease, chicken fat, and the like; vegetable fats and oils; and fish oils. Fats can be present in the cat food compositions of the present

invention in concentrations of from 5%, from 10%, from 15%, up to 20% up to 25%, up to 30% up to 35%, up to 40% or greater on a dry matter basis.

[0028] The percentage of ingredients for use in a cat food composition to achieve particular percentages of protein, carbohydrate and fat can be determined by methods well known in the art. For example, one can employ known computer programs using linear programming techniques to design pet food diets with specific characteristics. An example of such a program is the VLCFX ("Visual Least Cost Formulation-extended") Product Formulation and Management System provided by Agri-Data Systems, Inc., Phoenix, AZ.

[0029] Individual amino acids can also be included as ingredients in cat food when required to supplement the protein ingredients. Such amino acids that can be added to cat food are known in the art.

[0030] Vitamins and minerals may can be included into the cat food compositions of the present invention. Sources of vitamins can include complex natural sources such as brewers yeast, and engivita yeast, and synthetic and purified sources such as choline chloride. Minerals in the cat food compositions of the present invention can include dicalcium phosphate, calcium carbonate, calcium sulfate, potassium chloride, potassium citrate, iodized and non-iodized salt as required to achieve a desired iodine content, and other conventional forms of the mineral nutrients known in the art (see, for example, National Research Council, Nutrient Requirement of Cats, Washington, DC, National Academy of Sciences, page 27, Table 5 footnotes, 1978).

[0031] The following examples are further illustrative of the present invention, but it is understood that the invention is not limited thereto.

EXAMPLE 1

[0032] This example illustrates the effect of feeding hyperthyroid cats a low iodine and low selenium diet.

[0033] A low iodine, low selenium dry cat food, designated diet 30643, was prepared with the following composition and characteristics: crude protein, 30-34%; fat, 10-20%; carbohydrate, 35-55%; selenium, 0.2 mg/kg on a dry matter basis; iodine, 0.2 mg/kg on a dry matter basis, with grain ingredients comprising 50-55%; vegetable protein (soy concentrate) comprising 30-35%; animal fat comprising 8-10%; and other ingredients comprising 5-6%.

[0034] Ten geriatric cats with an average age of 13.5 years and hyperthyroid disease were allotted into two groups based on age and serum total T4 level. One group was fed a control dry cat food containing, per kg of dry matter, 2.5 mg of iodine and 0.6 mg of selenium. The other group was fed diet 30643, containing, per kg of dry matter, 0.2 mg of iodine and 0.2 mg of selenium. The diets were fed for eight weeks. Food intake was measured daily and body weight was measured weekly.

[0035] Blood was drawn aseptically every two weeks after overnight removal of food. Blood for complete blood counts and serum for thyroid hormone analyses were analyzed immediately. Blood for other measurements was centrifuged at 5000g and the serum harvested and frozen and stored at -70°C until analyzed for serum chemistries and iodine and selenium concentrations.

[0036] Serum total T3 and T4 concentrations were measured by radioimmunoassay for use in cats. Serum free T4 concentrations were determined by use of equilibrium dialysis to separate the bound forms from the free forms. Radioimmunoassay was used to measure the concentrations of the free forms in the dialysate.

[0037] The assay for estimating free T3 in feline serum used an ¹²⁵I-triiodothyronine (T3) derivative that does not bind significantly to the natural binding proteins in serum. In addition, a high affinity antibody was used which binds both the derivative and T3. These two T3 compounds allow for a classical equilibrium radioimmunoassay to be performed without interference from binding proteins and bound T3. The assay antibody was bound to the wall of 12 x 75 mm polypropylene tubes for simple solid phase separation of bound assay fractions from free fractions. The remainder of the assay was standard radioimmunoassay technology.

[0038] Serum and dietary iodine were measured by epithermal instrumental neutron activation analysis (Spate et al., J Radioanalytical Nuclear Chem 195: 21-30, 1995).

[0039] The results of this feeding trial were as shown in Table 4.

TABLE 4.

Analyte	Diet	Week 0	Week 8	Change	Statistical significance	Normal range
Serum total T4, nmol/L	control	72.8	75.3	+10	n.s.	10 - 55
	diet 30643	74.6	47.6	- 27	P < 0.05	
Serum free T4, pmol/L	Control	24.4	22.0	+1	n.s.	10 - 17
	diet 30643	29.6	17.6	-12	P < 0.05	

(continued)

Analyte	Diet	Week 0	Week 8	Change	Statistical significance	Normal range
Serum total T3, nmol/L	Control	1.58	1.58	+0.10	n.s.	0.6 - 1.4
	diet 30643	1.64	0.90	-0.74	P< 0.05	
Serum free T3, pmol/L	Control	10.52	8.18	-1.60	n.s.	1.5 - 6.0
	diet 30643	9.96	5.32	-4.64	P< 0.05	
Serum iodine, mg/L	Control	0.178	0.201	+0.016	n.s.	--
	diet 30643	0.148	0.045	-0.103	P< 0.05	--
	Control	1.12	0.485	-0.67	P<0.05	--
Urine iodine, µg/mg creatinine	Control	1.12	0.485	-0.67	P< 0.05	--
	diet 30643	1.09	0.034	-1.06	P< 0.05	--
Serum selenium, mg/L	Control	0.53	0.51	0	n.s.	--
	diet 30643	0.50	0.38	-0.12	P< 0.05	--
Serum GPX, U/mL	Control	5.01	6.11	1.31	P< 0.05	--
	diet 30643	4.52	4.90	0.37	n.s.	--

[0040] Cats fed diet 30643 showed significant reductions in serum total T3 and T4, to normal levels, whereas the concentrations of these thyroid hormones in cats fed the control diet were unchanged. Free T3 and T4 showed similar statistically significant reductions in the cats fed the diet 30643. Serum selenium and iodine levels decreased in the cats fed the low diet 30643 but were unchanged in the cats fed the control diet. Serum glutathione peroxidase (GPX), an index of selenium nutritional status, was unchanged in the cats fed diet 30643 but increased in the cats fed the control diet. GPX, a selenium-containing enzyme, has important antioxidant functions, so decreased activity of GPX is undesirable. The dietary selenium requirements for growing cats has been shown to be 0.15 mg/kg dry matter (Wedekind et al., J Anim Physiol Anim Nutr (Berl) 87: 315-23, 2003). Thus, diet 30643 apparently provided sufficient selenium to maintain GPX activity. Urinary iodine concentrations decreased significantly for cats consuming both diets.

[0041] Other observations were significant decreases in serum alanine amino transferase (39%), serum alkaline phosphatase (33%), and serum phosphorus (13%) all of which are consistent with normalization of thyroid function in the cats receiving diet 30643.

EXAMPLE 2

[0042] This example illustrates a factorial study of the effects of feeding hyperthyroid cats a diet low in selenium (Low Se) or a diet low in iodine (Low I), compared to a control diet (High Se & I) with amounts of iodine and selenium approximating the average analytical values for commercial dry cat food described above.

[0043] Fifteen geriatric cats with hyperthyroid disease were allotted into three groups and for nine weeks were fed one of three diets comprising dry cat foods of identical compositions except for the contents of iodine and selenium as shown in Table 5.

TABLE 5.

Diet description	Coding	Se (mg/kg DM)	I (mg/kg DM)
Low Selenium, typical iodine	Low Se	0.30	2.49
Low Iodine, typical selenium	Low I	0.66	0.27
Typical Iodine and Selenium 1	High Se & I	0.73	2.52
Average value of dry cat foods, <i>vide supra</i>		0.69	2.77

[0044] The diets comprised a mixture of soy protein isolate concentrate and contained 158 mg/kg dry matter basis of isoflavones. Food intake was measured daily and body weight was measured weekly.

[0045] Blood was drawn aseptically after overnight removal of food. Blood for complete blood counts and serum for

thyroid hormone analyses were analyzed immediately. Blood for other measurements was centrifuged at 5000g and the serum harvested and frozen and stored at -70°C until analyzed for serum chemistries and iodine and selenium concentrations.

[0046] Serum and dietary iodine were measured by epithermal instrumental neutron activation analysis (EINAA) at the University of Missouri reactor facility using a boron nitride irradiation capsule as described by Spate et al. Spate VL, Morris JS, Chickos S, Baskett CK, Mason MM, Cheng TP, Reams CL, West C, Furnee C, Willett W, Horn-Ross P. Determination of iodine in human nails via epithermal neutron activation analysis. J Radioanalytical Nuclear Chem 1995; 195: 21-30.

[0047] The results of this feeding trial were as shown in Table 6.

TABLE 6.

Analyte	Diet	Week 0	Week 9	Change	Statistical significance	Normal range
Serum total T4, nmol/L	Low Se	70.8	90.0	+19.2	n.s.	10-55
	Low I	79.8	46.2	-33.6	P< 0.05	
	High Se & I	73.2	85.0	+11.8	n.s.	
Serum total T3, nmol/L	Low Se	1.42	1.70	+0.28	n.s.	0.6-1.4
	Low I	2.04	1.06	-0.98	P< 0.05	
	High Se & I	1.54	1.76	+0.22	n.s.	
Serum iodine, mg/L	Low Se	0.158	0.155	-0.003	n.s.	--
	Low I	0.148	0.049	-0.099	P< 0.05	
	High Se & I	0.191	0.152	-0.039	P< 0.05	
Urinary iodine, mcg/mg of creatinine	Low Se	0.236	0.215	-0.021	n.s.	--
	Low I	0.245	0.047	-0.198	P< 0.05	
	High Se & I	0.349	0.249	-0.100	n.s.	

[0048] Feeding cats with hyperthyroidism a low-iodine diet for nine weeks normalized circulating thyroid hormone levels. Feeding a low-selenium diet with a typical iodine content and feeding a high-selenium diet with a typical iodine content had no beneficial effect on circulating thyroid hormone levels in hyperthyroid cats. These results indicate that the selenium content of the diet had little or no effect on the normalization of thyroid function in hyperthyroidism observed in Examples 3 and 4, whereas restricting the iodine intake had a significant normalizing effect on thyroid hormone status.

EXAMPLE 3

[0049] This example illustrates a field trial of the effect of feeding iodine-restricted foods in cats with hyperthyroid disease.

[0050] Two feline test diets were formulated to provide iodine at a concentration of 0.35 mg/kg dry matter. One test diet, diet 46836, was manufactured in the form of a dry cat food. The other test diet, diet 50742, was manufactured in the form of a canned cat food. Both the dry cat food and the canned cat food comprised soybean meal. Ten replicates of each manufactured cat food were analyzed for iodine. The iodine content of the dry cat food ranged from 0.27 to 0.60 mg/kg dry matter basis (mean = 0.38 mg/kg). The iodine content of the canned cat food ranged from 0.14 to 0.27 mg/kg dry matter basis (mean = 0.21 mg/kg).

[0051] A multi-center prospective study was conducted to evaluate the effect of these feline test diets in cats with hyperthyroid disease. Measures included thyroid hormone profiles and serum chemistries measured at 0, 2, 4, and 6 weeks. Enrollment criteria were based on elevated total T4 and/or free T4. In the majority of cases, cats also exhibited one or more clinical signs associated with hyperthyroid disease: weight loss, heart murmur/tachycardia, unkempt hair coat, thyroid gland enlargement, increased appetite, vomiting, increased activity, diarrhea, polyuria/polydipsia, aggressiveness, and panting.

[0052] Hyperthyroid cats were fed a 50:50 mixture of the canned cat food and dry cat food. In 6 weeks this test diet significantly reduced serum total T4 levels almost to the normal range. Results are shown in Table 7.

TABLE 7.

Metabolite	Week 0	Week 6	Change	Significance of change	Normal range
Serum total T4, nmol/L	103.0	60.1	-31.5	P< 0.05	10-55

[0053] The average serum total T4 level decreased substantially in this trial despite the fact that the iodine content of the diet fed to these cats was higher and more variable than that of the diets fed in the earlier trials described in Examples 1 and 2 (Tables 4 and 6). The iodine content of the dry cat food ranged from 0.27 to 0.60 mg/kg dry matter basis (mean = 0.38 mg/kg). The iodine content of the canned cat food ranged from 0.14 to 0.27 mg/kg dry matter basis (mean = 0.21 mg/kg). The 50:50 mixture of the two cat foods which comprised the diet of these cats was not analyzed directly. However, based on the ranges of iodine content of the individual component cat foods, the iodine content of the diet as fed most likely ranged from about 0.25 mg/kg dry matter basis to about 0.4 mg/kg dry matter basis.

EXAMPLE 4

[0054] This example illustrates the composition of a dry cat food useful in the method of the invention.

[0055] The usual method of making pet foods, particularly for dogs and cats, is generally well-known. For dry diets, diet components can be combined in a preconditioner and then fed into an extruder where they are mixed, heated (cooked) and expanded. The extrudate can then be emitted from the extruder and cut using standard knife blades into proper sized particles. Kibbles can then be moved through a dryer to achieve the desired moisture. Kibbles can then be cooled and flavor and other nutrients can be added. Typical diet components include protein ingredients, grain ingredients, various adjuvants such as vitamins, minerals, amino acids and the like, as well as moisture and the like. Other diet components maybe applied to the extruded particles.

[0056] Wet diets can be prepared in a different manner. Meat, grains and other ingredients, can be mixed in a cooker and then deposited in a can. The cans can then be sealed and sent through a retort for sterilization.

[0057] In various embodiments of the present invention, the dry cat food comprises one or more protein ingredients of vegetable or animal origin, chosen based on selenium and iodine content. Useful vegetable protein ingredients comprise potato concentrate, soy concentrate, soy protein isolate, soybean meal, and corn gluten meal. Useful protein ingredients, of animal origin comprise meat proteins isolate, pork lungs, chicken, pork liver, poultry meal, and egg. The protein ingredients, preferably present in amount of 20% to 50% of the total mixture, will provide the bulk of the desired protein content in the final product.

[0058] The grain ingredients will include primary farinaceous ingredients, which may be any of the more common grains, such as corn and rice, and their derivatives, including, for example, corn meal and corn flour, as well as sources of dietary fiber, including soybean mill run, cellulose, and the like. Commonly the grain ingredients will be present in amount of 30-65% of the total mass.

[0059] The protein ingredients, grain ingredients, vitamins, minerals and amino acids are combined and mixed together. This mixture is processed by heating it above 100°C (212°F) and subjecting it to super-atmospheric pressure in an extruder, and extruding it through an extrusion die into the atmosphere. As the material issues from the die it expands into a porous, expanded product due to the pressure drop across the die and the flashing off of the water as steam. The extrudate is then cut into bite-size kibbles, dried to a moisture content of less than about 10% by weight, optionally coated with fat, optionally dusted with one or more palatability enhancing agents and other functional ingredients known to those skilled in the art, and packaged.

[0060] The resulting dry cat food may have the following composition by analysis: moisture, 6.5-7.0%; crude protein, 33.6-35.4%, dry matter basis; iodine, 0.15-0.34 mg/kg, dry matter basis.

[0061] Any discussion of references cited herein is intended merely to summarize the assertions made by their authors and no admission is made that any reference or portion thereof constitutes relevant prior art. Applicants reserve the right to challenge the accuracy and pertinence of the cited references.

Claims

1. Use of iodine in the manufacture of a feline diet for restoring thyroid function to a more nearly normal state in a feline having hyperthyroidism, wherein the amounts of iodine in the feline diet is less than 1 mg/kg of diet on a dry matter basis.
2. The use of claim 1, wherein the amount of iodine is less than 0.35 mg/kg of diet on a dry matter basis.

3. The use of claim 1 or claim 2, wherein the amount of iodine intake is greater than 0.005 mg/kg of diet on a dry matter basis.
- 5 4. The use of any one of the preceding claims, wherein the diet comprises protein at a concentration of from 10% to 50% on a dry matter basis, preferably from 20% to 40% on a dry matter basis.
5. The use of claim 4, wherein the protein comprises iodine at a concentration of not more than 0.6 mg/kg crude protein, preferably of not more than 0.2 mg/kg crude proteins.
- 10 6. The use of claim 4 or 5, wherein the protein comprises a vegetable protein, preferably a vegetable protein selected from the group consisting of potato concentrate, soy concentrate, soy protein isolate, soybean meal, corn gluten meal and combinations thereof.
- 15 7. The use of claim 4 or 5 wherein the protein comprises an animal protein, preferably an animal protein selected from the group consisting of meat protein isolate, pork lungs, chicken, pork liver, and combinations thereof.
8. The use of any one of the preceding claims, wherein the diet further comprises fat at a concentration of from 10 to 20% and carbohydrate at a concentration of from 10% to 55%.

Patentansprüche

- 25 1. Verwendung von Jod zur Herstellung einer Katzennahrung zur Wiederherstellung der Schilddrüsenfunktion auf einen fast normalen Zustand bei einer Katze mit Schilddrüsenüberfunktion, wobei die Menge Jod in der Katzennahrung kleiner als 1 mg/kg der Nahrung auf Basis der Trockenmasse ist.
2. Verwendung nach Anspruch 1, wobei die Menge an Jod kleiner als 0,35 mg/kg der Nahrung auf Basis der Trockenmasse ist.
- 30 3. Verwendung nach Anspruch 1 oder Anspruch 2, wobei die Menge an Jod größer als 0,005 mg/kg der Nahrung auf Basis der Trockenmasse ist.
4. Verwendung nach einem der vorhergehenden Ansprüche, wobei die Nahrung Protein in einer Konzentration von 10% bis 50% auf Basis der Trockenmasse umfasst, vorzugsweise 20% bis 40% auf Basis der Trockenmasse.
- 35 5. Verwendung nach Anspruch 4, wobei das Protein Jod in einer Konzentration von nicht mehr als 0,6 mg/kg Rohprotein umfasst, vorzugsweise nicht mehr als 0,2 mg/kg Rohprotein.
- 40 6. Verwendung nach Anspruch 4 oder 5, wobei das Protein pflanzliches Protein umfasst, vorzugsweise ein pflanzliches Protein ausgewählt aus der Gruppe bestehend aus Kartoffelkonzentrat, Sojakonzentrat, Sojaproteinisolat, Sojamehl, Maisglutenmehl und Kombinationen davon.
- 45 7. Verwendung nach Anspruch 4 oder 5, wobei das Protein tierisches Protein umfasst, vorzugsweise ein tierisches Protein ausgewählt aus der Gruppe bestehend aus Fleischproteinisolat, Schweinelunge, Geflügel, Schweineleber und Kombinationen davon.
8. Verwendung nach einem der vorhergehenden Ansprüche, wobei die Nahrung ferner Fett in einer Konzentration von 10 bis 20% und Kohlenhydrat in einer Konzentration von 10% bis 55% umfasst.

Revendications

- 55 1. Utilisation d'iode dans la fabrication d'un aliment pour chat destiné à ramener la fonction thyroïdienne à un état plus près de la normale chez un chat souffrant d'hyperthyroïdie, dans laquelle la quantité d'iode dans l'aliment pour chat est inférieure à 1 mg/kg d'aliment en matière sèche.
2. Utilisation selon la revendication 1, dans laquelle la quantité d'iode est inférieure à 0,35 mg/kg d'aliment en matière sèche.

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3. Utilisation selon la revendication 1 ou la revendication 2, dans laquelle la quantité d'iode est supérieure à 0,005 mg/kg d'aliment en matière sèche.
- 5 4. Utilisation selon l'une quelconque des revendications précédentes, dans laquelle l'aliment comprend des protéines à une concentration de 10 % à 50 % en matière sèche, de préférence de 20 % à 40 % en matière sèche.
5. Utilisation selon la revendication 4, dans laquelle les protéines comprennent de l'iode à une concentration non supérieure à 0,6 mg/kg de protéines brutes, de préférence non supérieure à 0,2 mg/kg de protéines brutes.
- 10 6. Utilisation selon les revendications 4 ou 5, dans laquelle les protéines comprennent des protéines végétales, de préférence des protéines végétales choisies dans le groupe constitué par du concentré de tomate, du concentré de soja, de l'isolat de protéines de soja, de la farine de soja, du fin gluten de maïs et leurs combinaisons.
- 15 7. Utilisation selon les revendications 4 ou 5, dans laquelle les protéines comprennent des protéines animales, de préférence des protéines animales choisies dans le groupe constitué de l'isolat de protéines carnées, des poumons de porc, du poulet, du foie de porc et leurs combinaisons.
- 20 8. Utilisation selon l'une quelconque des revendications précédentes, dans laquelle l'aliment comprend en outre une matière grasse à une concentration de 10 à 20 % et des hydrates de carbone à une concentration de 10 à 55 %.

REFERENCES CITED IN THE DESCRIPTION

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