



Australian Pesticides and Veterinary Medicines Authority

<p>GUIDELINES FOR THERAPEUTIC PET FOODS THAT REQUIRE REGISTRATION BY THE APVMA AS VETERINARY CHEMICAL PRODUCTS</p>

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Guidelines for therapeutic pet foods that require registration by the APVMA as Veterinary Chemical Products

Under the Agvet Codes of the participating states and territories, veterinary chemical products must be registered by the APVMA. “Veterinary chemical product” is broadly defined in these Codes (see AgVet Codes 5 Definition of a veterinary chemical product in Appendix 1). Certain products are excluded from that definition and are declared not to be veterinary chemical products (see AgVet Code Regulations 8 Definition of a veterinary chemical product in Appendix 1). Products that fit the exemption provisions of the AgVet Code Regulations do not need to be registered by the APVMA.

The AgVet Codes do not recognise pet foods as a separate type of veterinary chemical product and so the claims made on the label of the pet food product are an important factor in determining whether or not the product needs to be registered. In addition pet foods may fall into the definition of a veterinary chemical product by virtue of what they contain or are used for (ie when they are specifically formulated and used as therapeutic pet foods).

This guideline is the result of extensive consultation within the Pet Food Industry Association of Australia (PFIAA) and the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Definition of Terms

The following terms are defined for the purposes of this guideline. The relevant Agricultural and Veterinary Chemicals (AgVet) Code definitions are included in Appendix 1 of this document.

Nutrient claim means a claim that specifies the level of nutrients in a product, eg. milk is a good source of calcium.

Nutrition message means a message that sets out, in general terms, the nutritional consequences for good health of the intake of a nutrient, eg. milk is a good source of calcium: calcium is essential for healthy teeth and bones.

Health claim means a claim that relates the nutrient or nutrients in a product to risk reduction of a disease condition, eg. milk is a good source of calcium; and a calcium-rich diet can reduce the risk of developing osteoporosis.

Pet food means a food or food mixture that contains one or more nutritional ingredients and is intended to be fed to animals for the maintenance of life, normal growth, production, work, reproduction or performance. Pet foods can take a number of forms for example wet, dry, semi moist, drinks, snacks, treats etc.

Therapeutic claim relates the nutrient or nutrients in a product to the prevention, treatment, alleviation or cure of a disease or condition, eg. a calcium-rich diet prevents the progression, or reverses the progression, of osteoporosis.

Therapeutic pet food is a pet food that:

- is to be used or intended to be used, under veterinary supervision; and/or
- has been formulated, or is represented to provide a beneficial component in the prevention, treatment, alleviation, cure or recovery of a specific condition ie it meets the definition of a veterinary chemical product.

Veterinary chemical product (as defined in the AgVet Codes) is a substance or mixture of substances that is represented as being suitable for, or is manufactured, supplied or used for, administration or application to an animal by any means, or consumption by an animal, as a way of directly or indirectly:

- (a) preventing, diagnosing, curing or alleviating a disease or condition in the animal or an infestation of the animal by a pest; or
- (b) curing or alleviating an injury suffered by the animal; or
- (c) modifying the physiology of the animal:
 - (i) so as to alter its natural development, productivity, quality or reproductive capacity; or
 - (ii) so as to make it more manageable; or
- (d) modifying the effect of another veterinary chemical product.

As an example a pet food label making the claim “.... a calcium-rich diet prevents, treats, alleviates or cures the progression, of osteoporosis....” would require registration with the APVMA as it is a product that is represented as preventing, treating, alleviating or curing the disease osteoporosis.

Guideline on which pet foods must be registered by the APVMA

The following guidelines are based upon the relevant provisions in the Agvet Codes. They provide guidance as to what pet foods require registration and the effect that certain claims have on the need to register a product with the APVMA.

Guideline 1:

A pet food which:

- contains one or more nutritional ingredients;
- is intended to be fed to animals for the maintenance of life, normal growth, production, work, reproduction or performance; and
- makes no therapeutic claim

— does not need to be registered by the APVMA. Therefore a product label which contains a nutrient claim, a nutrient message or a health claim but no therapeutic claim will not require registration.

Note:

- nutritional ingredients can be active constituents if they meet the definition of an active constituent (as relevant to a veterinary chemical product). For example vitamins and minerals are nutritional ingredients at normal nutritional levels but are defined as veterinary chemical products if they are used for a purpose mentioned in paragraph (2) (a), (b), (c) or (d) of the definition of a veterinary chemical product (see Appendix 1); and
- once a nutritional ingredient is added to, or specifically identified in, a pet food to perform a therapeutic role in a specific disease or condition that pet food falls into the definition of a therapeutic pet food.

Guideline 2:

A pet food which:

- is specifically formulated and used as a therapeutic pet food ;
- has a label that makes a therapeutic claim; and/or
- includes the words “prescription”, “therapeutic” or “medicated” on the label — must be registered by the APVMA.

Therapeutic and other claims on pet foods

Any product making a therapeutic claim must substantiate the claim in the APVMA registration process.

In general, claims for ‘maintenance of health’ or ‘reduction of risk of a condition or disease’ do not require registration. Pet foods making ‘maintenance of health’ or ‘reduction of risk of a condition or disease’ claims can be described as containing specific nutrients or nutrient ratios. The nutrient or nutrient ratios can be claimed to contribute to healthy, skin, eyes, intestine etc as appropriate or can be related to risk reduction of a disease or condition.

The following non-exhaustive list is a guide as to which claims are considered therapeutic claims and hence require registration, and other claims which do not require registration.

Obesity

- weight control or obesity diets do NOT require registration unless a specific claim for the treatment, cure or prevention of obesity is made.

Aging

Requires Registration:

- "...prevents, cures or treats the progression of renal disease, diabetes, heart disease etc" or words to that effect.

Does not require registration:

- any product which contains adjusted mineral levels, modified protein content, modified texture, modified caloric density or similar, and not claiming disease intervention.
- "...for those leading a less active life style" or words to that effect.
- "...helps maintain a healthy..." or words to that effect.

Teeth

Requires Registration

- claims in the prevention, treatment or cure of gum disease, gingivitis, periodontal disease.

Does not require registration

- cleaning agents.
- any product which aids in the reduction/control of plaque, tartar, bad breath, malodour, stain.
- any reference to strong teeth.
- maintains healthy gums or words to that effect.

Gut

Requires Registration

- claims referring to prevention, treatment or cure of diarrhoea, constipation, colitis, inflammatory bowel disease, or other specific gastrointestinal diseases.
- claims for prebiotic ingredients in hypocholesterol action, immunomodulation, increased absorption of vitamins and minerals or any other implied therapeutic action.

Does not require registration

- claims referring to flatulence, odour of stool, digestibility, well formed stools, consistency of stools, maintaining or promoting gut health.
- claims referring to prebiotic ingredients as 'non-digestible food ingredients that promote a healthy gut microflora'.

Behavioral Disorders

Requires Registration

- any product with claims involving prevention, treatment or cure of primary behavioral disorders and/or aggression.

Immune System

Requires Registration

- claims referring to prevents, treats, cures immune system dysfunction.
- claims referring to prevents, treats, cures neoplasia / cancer / tumour.

Does not require registration

- "...helps maintain a healthy immune system..." or words to that effect.
- "...supports natural defences..." or words to that effect.

Allergy

Requires Registration

- any product with a claim for preventing, treating or curing allergy or intolerance.

Does not require registration

- "This product does not contain... (soy, beef, artificial preservatives etc.)" or words to that effect.
- "If your dog/cat requires a beef free diet, feed this product" or words to that effect.

Musculo-skeletal

Requires Registration

- prevents, treats or cures any musculo-skeletal disease/condition

Does not require registration

- promotes normal/ optimal growth and development of musculo-skeletal system.
- "This diet, when used as directed will help reduce the risk of nutritional developmental bone disorders in susceptible breeds" or words to that effect.
- "An unbalanced diet can lead to..." or words to that effect.

Skin and Coat

Requires Registration

- any reference to prevention, treatment or cure of pruritus, itchiness, allergic conditions, food allergies, fungal diseases, bacterial diseases, etc.

Does not require registration

- "helps maintain a healthy..." or words to that effect.
- any references to a normal dog ie. shiny glossy coat, scurf, bright eyes, skin.

FUS/FLUTD

Requires Registration

- “...treats, cures or prevents FUS, FLUTD, struvite uroliths, etc...” or words to that effect.

Does not require registration

- reduces the risk of (feline) urinary tract struvite stone formation.
- “...helps maintain urinary tract health...” or words to that effect.

Renal

Requires Registration

- prevents, treats or cures any renal condition.

Cardiac

Requires Registration

- prevents, treats or cures any cardiac condition

APPLYING FOR REGISTRATION

The therapeutic Pet Food Guidelines for those pet foods that require registration currently cover data requirements and assessment process for dry and canned complete rations. Other formulation types eg snacks, treats, chews or other non complete rations will need to be considered on a case by case basis – most likely using a modular system – the type of assessment depending on the ingredients and the purpose of the product.

Application requirements

An application to register a new therapeutic pet food will consist of:

1. A completed Category 10 veterinary chemical product application form can be downloaded from Vet [MORAG](#). The formulation declared as guaranteed average typical analysis along with the ingredient must be list in the form. If an applicant believes that information requested in the application form is not appropriate or relevant, a statement to this effect should be included in the form and an explanation given.
2. In most cases, the fee for selected modules under Category 10 will apply. For a primary application, Module 1 (\$460 screening fee) plus Module 8.2 (\$680 efficacy and safety review fee), as wells a finalization Module 11.2 (\$1,070) will be charged, for a total of \$ 2,210.

Depending on the nature of the application, other modules may apply:

- **Example 1:** Module 2.3 (\$935 chemistry and manufacturing fee) may be included if the application requires consideration of shelf life, packaging, pack sizes, manufacturing processes and specifications of product and ingredients.

- **Example 2:** Module 10.3 may be added if assessment of a manufacturing site, such as for GMP, is required.

As mentioned above, a finalisation module will also apply. This module will be 11.1 (\$2,025) if three or more modules are required for evaluation, or 11.2 (\$1,070) if less than three modules are required.

For a secondary application that depends totally on data assessed in the primary application, only the screening and finalisation modules apply. An application to register a new petfood that contains a new 'active' will be considered under Category 2.

3. Text formatted and version controlled label including leaflet, if applicable
4. Documentation to substantiate the therapeutic claim(s) proposed for the product. Documentation may include but is not limited to papers or reports in peer-reviewed journals or reputable publications or other appropriate studies. The "specific dietary input" of the therapeutic diet may include, but is not limited to the following: ingredients, nutrient content, nutrient digestibility, nutrient form, or source of nutrient.
5. Where the shelf life is nominated as 12 months for a dry product or 24 months for a canned product supporting stability data is not required. Where a longer shelf life has been proposed, then supporting stability data must be provided.

Registration and approval of a therapeutic pet food will relate to the specific formulation. Therefore for every proposed formulation, a separate product must be registered. Any variations to a registered therapeutic pet food product will be dealt with as any other application received for a veterinary chemical product:

eg. minor changes to the formulation or additional package sizes to those originally approved. Registrants should refer to MORAG for further information on what is required for applications for variations to registered conditions.

Labelling

The following minimum information must appear on the label:

- The statement "For use as directed by your veterinarian" or similar wording
- Product name – the name should be distinctive, clearly distinguish the product from all other products and inform users of the product's essential nature
- Product claim
- Nutrient composition relating to claim/ingredient list
- Product weight
- Storage directions
- Expiry date
- APVMA approval number
- Company address and contact phone number.

The position and format of the statements are not prescribed. The statement ‘For use as directed by your veterinarian’ or similar wording should however be prominent (eg bold or bold capital letters) and should appear on the main panel. Where the proposed product labelling is to incorporate a language or languages other than English, a declaration must be included in the application for registration stating that all information in non-English conveys only the meaning of that expressed in the English language.

Expert review panel

The PFIAA Therapeutic Pet Food Sub-Committee will nominate to the APVMA a pool of nutritional experts willing to be members of an Expert Review Panel. The Panel will comprise of persons generally regarded and accepted by the PFIAA Sub-Committee as having canine and/or feline nutritional expertise. Panel members will be drawn from a wide cross-section of the Australasian academic community in order to provide expertise on the many facets of therapeutic nutrition. The membership of the Panel will be reviewed annually by the Sub-Committee and proposed changes submitted to the APVMA through the Industry Technical Committee. Prospective members of the Panel will be required to supply the APVMA with an up-to-date copy of their *curriculum vitae*.

In determining applications for registration, including considering any documentation or data to substantiate a proposed “prevent” or “cure” claim for a product, the APVMA may seek the opinion of a member(s) of the Panel. That member will not be related to or have any interest in the application. The APVMA’s purpose in doing so would be to obtain an independent expert opinion in relation to a matter that must ultimately be determined by the APVMA.

Other relevant information

Further guidance for companies to determine how they may best provide information about communicating the health benefits of pet foods can be found in the PFIAA Code of Conduct for the Provision of Information on Pet Food Products, Appendix 1 Code of Practice for the Communication of Health Benefits of Pet Food Products.

Contact details for PFIAA are:

Pet Food Industry Association of Australia tel (03) 9698 4339

Agvet Codes of the participating States and Territories

“3 active constituent, in relation to a proposed or existing agricultural or veterinary chemical product, means the substance that is, or one of the substances that together are, primarily responsible for the biological or other effect identifying the product as an agricultural chemical product or a veterinary chemical product, as the case may be

“3 claim includes any statement

“5 Definition of veterinary chemical product

- (1) This section defines what is meant by an veterinary chemical product for the purposes of this Code.
- (2) Subject to subsections (3) and (4), a veterinary chemical product is a substance or mixture of substances that is represented as being suitable for, or is manufactured, supplied or used for, administration or application to an animal by any means, or consumption by an animal, as a way of directly or indirectly:
 - (a) preventing, diagnosing, curing or alleviating a disease or condition in the animal or an infestation of the animal by a pest; or
 - (b) curing or alleviating an injury suffered by the animal; or
 - (c) modifying the physiology of the animal:
 - (i) so as to alter its natural development, productivity, quality or reproductive capacity; or
 - (ii) so as to make it more manageable; or
 - (d) modifying the effect of another veterinary chemical product.
- (3) A veterinary chemical product includes:
 - (a) a vitamin, a mineral substance, or an additive, if, and only if, the vitamin, substance or additive is used for a purpose mentioned in paragraph (2) (a), (b), (c) or (d); and
 - (b) a substance or mixture of substances declared by the regulations to be a veterinary chemical product.
- (4) A veterinary chemical product does not include:
 - (a) a substance or mixture of substances that is:
 - (i) prepared by a pharmacist in accordance with the instructions of a veterinary surgeon; or
 - (ii) prepared by a veterinary surgeon;
in the course of the practice, by the person preparing the substance or mixture of substances, of his or her profession as permitted by or under a law of this jurisdiction; or
 - (b) a substance or mixture of substances declared by the regulations not to be a veterinary chemical product.”

Agricultural and Veterinary Chemicals Code Regulations

“Interpretation

3. (1) In these Regulations, unless the contrary intention appears:.....

“nutritional ingredient” includes, but is not limited to, the following:

- (a) protein meals (as a protein source);
- (b) fermentation products from human foods, (including brewer’s grains, yeasts and yeast extracts);
- (c) hay, including lucerne hay and peanut hay;
- (d) chaff;
- (e) straw;
- (f) grains, other similar seeds and the products of those grains or seeds;
- (g) vitamins, minerals and amino acids at normal nutritional levels;
- (h) salt, limestone and inorganic phosphorus sources;
- (i) fats and oils;
- (j) milk by-products;
- (k) non-protein nitrogen sources;
- (l) molasses;.....

“stockfood” means a basic food or food mixture that:

- (a) contains one or more nutritional ingredients; and
- (b) is intended to be fed to animals for the maintenance of life, normal growth, production, work, reproduction or performance;.....

Definition of “veterinary chemical product”—section 5 of the Code

8. (1) For the purposes of paragraph 5 (3) (b) of the Code, a substance or mixture of substances included in any of the following classes of substances or mixtures of substances is declared to be a veterinary chemical product:

- (a) allergenic substances supplied or used for administration to an animal by any means, or for consumption by an animal;
- (b) medicated blocks or licks;
- (c) enzymes supplied or used for administration to an animal by any means, or for consumption by an animal;
- (d) stockfood non-active constituents except stockfood non-active constituents excluded from this class by an order under section 7 of the Act;
- (e) direct-fed microbial products;
- (f) sheep branding substances.

(2) Section 7 of the Act (which deals with the power to make orders) applies to the prescription of stockfood non-active constituents excluded from the class described in paragraph (1) (d).

(3) For the purposes of paragraph 5 (4) (b) of the Code, a substance or mixture of substances included in any of the following classes of substances or mixtures of substances is declared not to be a veterinary chemical product:

- (a) stockfoods;
- (b) medicated stockfoods to which subregulation (4) applies;
- (c) medicated premixes to which subregulation (4) applies;

- (d) blocks and licks (other than medicated blocks or licks) to which subregulation (5) applies;
 - (e) premixes to which subregulation (5) applies;
 - (f) stockfood supplements to which subregulation (5) applies;
 - (g) colour intensifiers for aviary birds.
- (4) This subregulation applies to a medicated stockfood or medicated premix if:
- (a) any veterinary chemical product that is incorporated in the medicated stockfood or medicated premix:
 - (i) is a registered chemical product; and
 - (ii) is incorporated at a rate of use in accordance with the approved label for containers for that registered chemical product; and
 - (b) the container for the medicated stockfood or medicated premix is labelled in accordance with the directions on the approved label for that registered chemical product.
- (5) This subregulation applies to a block, lick, premix or stockfood supplement:
- (a) for which the only claim on the label consists of the words “to supplement diets where levels may be low”, or words to that effect; and
 - (b) that incorporates, in respect of any vitamin, mineral or amino acid listed on the label, not less than 25% of the daily requirement of that vitamin, mineral or amino acid for the species for which the premix or stockfood supplement is intended.
- (6) For the purposes of paragraph (5) (b), the daily requirement of a vitamin, mineral or amino acid is the amount of the vitamin, mineral or amino acid specified as the daily requirement by:
- (a) if the species is a dog, cat or horse—the US National Research Council of the US National Academy of Sciences; or
 - (b) if the species is a ruminant, a pig or poultry—the relevant feeding standard.
- (7) In paragraph (6) (b), “**the relevant feeding standard**” means:
- (a) in the case of a ruminant—the standard “Feeding Standards for Australian Livestock: Ruminants Standing Committee on Agriculture, Ruminants Subcommittee East Melbourne 1990”, published by CSIRO; or
 - (b) in the case of a pig—the standard “Feeding Standards for Australian Livestock: Pigs Standing Committee on Agriculture, Pig Subcommittee East Melbourne c1987”, published by CSIRO; or
 - (c) in the case of poultry—the standard “Feeding Standards for Australian Livestock: Poultry Standing Committee on Agriculture, Poultry Subcommittee East Melbourne c1987”, published by CSIRO.