

The Need to Modernize the Regulatory Treatment of Animal Feed Additives

A Proposal for Classifying Zootechnical Additives as Feed
Ingredients

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A. EXECUTIVE SUMMARY

1. Objectives of this proposal

The development of a comprehensive regulatory framework for modernization of the Canadian *Feeds Regulations* is well underway and has provided an opportunity to review best practices related to feed ingredient classification and authorization. The passage of the *Agricultural Growth Act* and the corresponding amendments to the *Feeds Act* allowing for the consideration of foreign government assessments has also facilitated a potential convergence of international methodologies and approaches related to feed and ingredient authorizations. Furthermore, with increasing worldwide emphasis on antimicrobial resistance and recent government commitments on the decreased and judicious use of antimicrobial drugs in Canada and the United States, it is an opportune time to overhaul the regulatory framework in Canada for the class of ingredients known as zootechnical additives¹. More specifically, mechanisms for classifying and authorizing zootechnical additives as feed ingredients are discussed.

It has long been ANAC's position that regulatory oversight should be based on the following foundations:

- Safety – maintenance of animal health, protection of the human food supply, and mitigation of environmental risks
- Market access and competitiveness – regulations must not create barriers to innovation and market entry, nor put the Canadian feed industry or producers at a competitive disadvantage with its international counterparts
- Consumer protection – control over false or misleading claims, and assurance that labelling reflects the intended use of the product

2. Challenges with current drug/feed classification

Nutritional strategies and feed additives (e.g. probiotics, prebiotics, enzymes, organic acids, and trace minerals) are increasingly being used to favourably affect animal performance and health. In other jurisdictions, notably the European Union,

¹ *In the European Union, a zootechnical additive is any additive used to affect favourably the performance of animals in good health or used to affect favourably the environment. The category „zootechnical additives“ is further divided into four functional groups (Annex I of Regulation (EC) No 1831/2003):*
(a) digestibility enhancers: substances which, when fed to animals, increase the digestibility of the diet, through action on target feed materials;
(b) gut flora stabilisers: microorganisms or other chemically defined substances, which, when fed to animals, have a positive effect on the gut flora;
(c) substances which favourably affect the environment;
(d) other zootechnical additives.

zootechnical ingredients are classified as feed additives and act as important nutritional alternatives to traditional therapeutic drugs and antimicrobials. Their benefits in managing common animal production disorders and improving animal health and welfare are recognized in a simplified regulatory authorization process.

In Canada, however, the definitions of feeds and drugs overlap with regard to their intended use; and approved claims around mitigation of nutritional disorders are limited. For instance, claims that indicate modes of action affecting physiological functions beyond the generally recognized physiological effects of nutrition are classified as drugs instead of feeds. Enzymes and probiotics would thus be treated as drugs in Canada whereas they would be considered zootechnical additives in Europe.

The more rigid and demanding drug approval process (versus the feed ingredient process) has deterred international companies from bringing zootechnical additives into the Canadian marketplace. The majority of these products are not manufactured in the same way as drugs and therefore would not meet the same level of good manufacturing practice (GMP) requirements for approval in Canada. The result is a competitive disadvantage for livestock and poultry producers whose global counterparts regularly use these additives as part of their nutritional toolkit. Furthermore, the consideration of these products as feed ingredients would not be contrary to the *Feeds Act*; rather, the determination of their regulatory requirements is described in Health Canada/the Canadian Food Inspection Agency's "Guidance Document on Classification of Veterinary Drugs and Livestock Feeds".

Reviewing and redefining the nature of "drug vs. feed" claims and the associated classification and authorization would address some of the problems related to:

- *Prudent and judicious use of antimicrobials in animals.* The current regulatory approach conflicts with stewardship efforts that recommend increasing access to antimicrobial alternatives and encouraging innovation, as outlined in the 2014 federal framework document on "Antimicrobial Resistance and Use in Canada" as well as the Spring 2015 "Report of the Auditor General of Canada on Antimicrobial Resistance".
- *Competitive disadvantage due to differences in classification with other jurisdictions.* Canadian livestock and poultry producers do not have access to a number of new technologies (some of which were developed in Canada with both public and private funding) to which their international competitors have access.

3. Recommendations:

The following recommendations would provide the needed flexibility for the authorization of zootechnical additives, and would result in more consistent ingredient classifications as is the case in other jurisdictions. It is important to note that these recommendations are fully consistent with the *Feeds Act*, as according to the Act, a feed may be used “for the purpose of preventing or correcting nutritional disorders of livestock”.

1. Allow claims for general health and wellness for feed ingredients that pose no safety concerns. For example, nutritional indications as described in Health Canada/the Canadian Food Inspection Agency’s “Guidance Document on Classification of Veterinary Drugs and Livestock Feeds” could be expanded to state:

Nutritional indications or purposes refer to the presence of one or more nutrient(s) or nutritive substance(s) which are scientifically recognized for providing the nutritional requirements essential for general health and wellness, supporting normal growth and production in livestock species.

2. Allow claims in feed ingredients for the prevention and/or mitigation of sub-clinical and metabolic disorders by removing criterion “2” for the classification of nutritional disorders contained within Health Canada/the Canadian Food Inspection Agency’s “Guidance Document on Classification of Veterinary Drugs and Livestock Feeds”. (E.g. Nutritional disorders that can be mitigated with nutritional strategies, as is the case for sub-acute ruminal acidosis, ketosis, and subclinical necrotic enteritis, should be permitted.)
3. Discontinue the current practice of classifying zootechnical additives as drugs when they have a mode of action “that restores, changes or affects the physiological function(s) of an animal beyond the generally recognized physiological effects of nutrition”.
4. Allow zootechnical additives to be approved through the feed ingredient regulatory pathway. This will ensure that both animal and human safety are evaluated. As well, any claims associated with these products will be assessed and approved via the premarket registration process.

The discussion points in this paper are offered to expand on ANAC’s recommendations.

B. THE NEED TO FACILITATE ALTERNATIVE NUTRITIONAL STRATEGIES

Historically, livestock and poultry have been selected for optimal performance, rapid growth, and high feed conversion. These traits have placed food animals at greater risk of nutritional disorders and poor gastro-intestinal health, both clinical and sub-clinical. The resulting animal health issues, reduced animal welfare, and financial losses make the prevention of these nutritionally-related production diseases of paramount importance.

For decades, the addition of antimicrobials to feed has been used to counter these vulnerabilities. The mounting public and regulatory pressure to minimize antimicrobial use has compounded the need for alternative nutrition and farm management strategies to enhance animal performance while maintaining animal health and the ability to withstand disease. Zootechnical additives are commonly used in other countries as alternative nutritional approaches to aid in disease mitigation, and have been authorized in the European Union for more than 20 years. Canada, in contrast to other jurisdictions, has lower use of zootechnical additives and has lagged behind in the use of these innovative technologies due to their regulatory requirements.

The Spring 2015 “Report of the Auditor General of Canada on Antimicrobial Resistance” and the Public Health Agency of Canada’s 2014 framework document on “Antimicrobial Resistance and Use in Canada” both underline the importance of innovation and facilitation of alternatives as effective strategies in managing antimicrobial resistance.

1. Auditor General’s Report on Antimicrobial Resistance

The World Health Organization considers resistance to antibiotics to be the most urgent concern; and in 2011, the Public Health Agency of Canada (PHAC) identified it as “one of the highest public health risks facing Canadians”. According to the 2015 “Report of the Auditor General of Canada on Antimicrobial Resistance”, PHAC and Health Canada “have not fulfilled key responsibilities to mitigate the public health risks posed by the emergence and spread of antimicrobial resistance in Canada”. The report found that while steps have been taken to promote prudent antimicrobial use in humans, “Health Canada has not taken some important steps needed to promote prudent antimicrobial use in food animals”. The World Health Organization has identified measures needed to combat the spread of antimicrobial resistance, including implementation of a comprehensive national strategy that incorporates stimulation of research and innovation. In April 2012, PHAC endorsed the development of a pan-Canadian strategy to reduce, limit, and control the emergence and spread of antimicrobial resistance by

focusing on “increasing knowledge and developing tools to better address the issue”, among other strategies.

Although broad stakeholder consultation is in progress to address a number of deficiencies identified in the report, additional emphasis on facilitating the widespread use of innovative antimicrobial alternatives in the marketplace is still required.

2. Federal Framework on Antimicrobial Resistance and Use in Canada

Further consideration for allowing new nutritional approaches and specific feed ingredients to mitigate nutritional diseases and help improve animal health, as outlined in this proposal, is supported by two of the three pillars in the Public Health Agency of Canada’s 2014 federal framework document on “Antimicrobial Resistance and Use in Canada”.

- *Stewardship and promotion of prudent antimicrobial use:* “Through opportunity to modernize its legislative and regulatory authorities, the Government of Canada will engage with those who must comply with the regulations to identify innovative approaches to facilitate access to alternatives.”
- *Innovation:* “Creating new solutions to counteract loss in antimicrobial effectiveness through research and development.”
“Under the Growing Forward 2 policy framework, money is available to support industry-led and/or internal research aiming to identify alternatives to antibiotics or their prudent use in livestock production.”

In the case of zootechnical additives, government, academia and industry have been developing novel therapies and alternatives to reduce antimicrobial usage through funding and research. The onerous process to have the alternatives approved for use (mechanism for approval as drugs vs. feed ingredients) and the inability to communicate on the benefits of the alternatives (claims), however, impede their registration and usage in Canada, thus contradicting the framework priorities. (See Appendix 1 for examples of research with private and public funding that would be considered as zootechnical additives). Consequently, some of the zootechnical alternatives funded and developed in Canada are only authorized for use in other countries.

3. Challenges with the current regulatory framework

Most new feed ingredients in Canada are subject to premarket authorization with submission requirements varying according to the composition, intended use, species, and method of manufacture. The most significant determinant for the regulation of the ingredient as a feed or drug is the intended use.

The regulatory definitions of a nutrient, feed, and drug frequently overlap, often resulting in a more complex, sometimes prohibitive, authorization process compared with other jurisdictions. In the *Food and Drugs Act*, a drug may aid in the “mitigation or prevention of a disease, disorder or abnormal physical state” while in the *Feeds Act*, a feed may be used “for the purpose of preventing or correcting nutritional disorders of livestock”. Therefore, classifying products intended for optimization of animal performance or the mitigation of metabolic and sub-clinical disorders as a drug or feed would not contravene either of the Acts. The proposals in this paper focus on changes to *regulatory guidance and interpretation* to facilitate the use of zootechnical additives in feed.

Canada permits certain feed ingredients to have animal-production claims (to within normal production parameters), but all products intended for the prevention, treatment, or, mitigation of disorders and diseases are regulated as animal drugs. Drug claims are evaluated on a case by case basis by the Veterinary Drugs Directorate. As per Health Canada/the Canadian Food Inspection Agency’s “Guidance Document on Classification of Veterinary Drugs and Livestock Feeds”, an ingredient having a mode of action that “restores, changes or affects the physiological function(s) of an animal beyond the generally recognized physiological effects of nutrition” is considered a drug. This includes actions on the intestinal flora that may have a therapeutic effect. Probiotics, for example, which modulate gastro-intestinal microflora and provide a barrier against pathogen colonization by producing metabolic substrates that are utilized to stimulate the immune system, would thus be classified as drugs and must undergo the more rigorous drug approval process compared to being treated as a feed ingredient. In contrast, probiotics are considered zootechnical feed additives in Europe and have been widely used in humans and companion animals in Canada without being classified as drugs.

4. Examples of nutritional diseases mitigated using nutrition/feed ingredients

In addition to playing a role in maintaining health, optimizing growth, and ensuring a strong immune system, zootechnical additives can also help mitigate nutritional disorders. Critical periods of stress such as the transition period in dairy cows and post-weaning period of piglets, leave animals vulnerable to periods of decreased growth, poor feed intake, and sub-clinical or clinical disorders.

The following examples demonstrate the role of feed and feed ingredients in mitigating metabolic, sub-clinical, and, early onset disorders using nutritional approaches. In Europe and the United States, the nutritional products used would be classified as feed ingredients while in Canada; they would require authorization as drugs.

- *Sub-Acute Ruminant Acidosis (SARA) in Ruminants*

Sub-acute ruminal acidosis (SARA), clinically expressed as intermittent anorexia/diarrhea, poor body condition, liver abscesses, and decreased milk production for example (Dirksen, 1985; Enemark, 2008; Aschenbach et al., 2011; Penner et al., 2011), may result when the elevated energy needs of ruminants are met by feeding highly fermentable diets (common nutritional strategy for increasing energy). The inadequate adaptations of the rumen to the diet and consequent decreases in ruminal pH lead to SARA. **Specific yeast strains or probiotics (also known as direct-fed microbials)** have been utilized to optimize and increase lactic acid and nutrient digestibility in the rumen of cows thus counteracting the effects of the high levels of dietary carbohydrates necessary to maintain the animals' energy requirements (Nisbet and Martin, 1991; Callaway and Martin, 1997; Nocek et al., 2006).

- *Sub-clinical Ketosis in Ruminants*

Sub-clinical ketosis, which can cause significant economic loss and may lead to decreased milk yield and impaired fertility for example, is a common condition among dairy cows during prolonged periods of negative energy balance (e.g. the last three weeks of gestation). Sub-clinical ketosis is prevented by nutritional management, specifically the maintenance and promotion of feed intake, especially during late gestation. Feed additives such as **vitamins** (e.g. niacin) (Aschemann et al., 2012; Doreau et al., 1996), **ruminal buffers** (e.g. sodium bicarbonate) (Bigner, 1997), and **viable yeast products** (Nocek and Kautz, 2006) have proven to be beneficial in preventing sub-clinical ketosis by improving nutrient intake and digestibility.

- *Sub-clinical Necrotic Enteritis in Broiler Chickens*

Sub-clinical necrotic enteritis is a gastrointestinal disorder that can lead to poor digestion and absorption, reduced weight gain, and a poor feed-conversion ratio (Elwinger et al., 1992; Kaldhusdal et al., 2001). While clinical outbreaks of necrotic enteritis may cause high levels of mortality, sub-clinical forms may evade diagnosis due to a lack of overt clinical signs among the flock, thereby resulting in greater economic losses via reduced performance and condemnation of carcasses at slaughter (Kaldhusdal and Hofshagen, 1992; Dahiya et al., 2006). Dietary variables have been identified as one of the major predisposing factors for the precipitation of sub-clinical necrotic enteritis. Feed ingredients such as **direct-fed microbials** (including competitive exclusion products and probiotics) (Boyd, West et al., 2011; McReynolds, Waneck et al., 2009; Shivaramaiah, Pumford et al., 2011), **organic acids** (Skånseng et al., 2010), and **feed enzymes** (Liu, Guo et al., 2010) may also be useful in mitigating necrotic enteritis and provide an alternative to antimicrobials.

- *Post-weaning Diarrhea in Pigs*

Weaning of pigs commonly results in significant stress, characterized by low feed intake, body weight loss, decreased feed efficiency, and high incidences of intestinal disturbances including diarrhea. To prevent post-weaning performance decreases, antibiotics or some mineral compounds such as zinc oxide have traditionally been included in diets for weanling pigs. Dietary supplementation with **organic acids** have also been demonstrated to mitigate the incidence and severity of the digestive problems frequently encountered (Partanen et al., 2009; Tsiloyiannis et al., 2001).

Zootechnical additives offer many potential benefits to the animal food industry due to their direct physiological effect(s) on animals and potential reduction in the need to administer pharmaceuticals. It is evident from the examples above that nutrition and feed ingredients have the potential to both maintain normal animal physiology and mitigate or intervene in a number of physiological disorders that may progress to metabolic and sub-clinical disease. The modernization of feed ingredient claims provides an opportunity to recognize, regulate and facilitate the use of these products for the mitigation of various nutrition/ feed-based disorders.

C. WORKING TOWARDS A SOLUTION

1. Model approaches for feed ingredient claims

The European Food Safety Authority (EFSA), the Health Canada Human Natural Health Product Directorate, and the Veterinary Drugs Directorate (VDD)—via their Low Risk Veterinary Health Products (LRVHP) Program for companion animals—allow for extended product claims and can be used as frameworks in a modernized Canadian approach to feed ingredient claims. The three programs allow for a science-based review mechanism whereby applicable products can be approved with claims proportionate to their intended use, effectiveness and risk.

i. The European Union – Feed Additives

The provisions for feed additive claims in Europe concerning the optimization of nutrition and protection from physiological conditions (including sub-clinical nutritional disorders) serve as a useful reference for claims around zootechnical additives in Canada.

Before a feed additive can be marketed in Europe, the applicant must submit applications to EFSA, the European Commission, and, the Community Reference Laboratory (CRL) to obtain authorization for their product. The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) is responsible for providing independent scientific advice on the safety and efficacy of additives, products and substances used in animal feed to support the authorization process for feed additives. Feed additives are products used to improve the quality of animal feed by enhancing flavour, digestibility, food quality, or, performance and health of the animals (EC No 1831/2003). In the European context, allowed feed additives include zootechnical additives such as digestibility enhancers and gut flora stabilizers.

Claims concerning optimization of nutrition and support or protection of physiological conditions are permitted, unless they contain a claim stating “it will prevent, treat or cure a disease” (with the exception of coccidiostats and histomonostats, which are not being considered in this proposal). Claims concerning nutritional imbalances are permitted provided they are not associated with pathological symptoms (see Appendix 2).

A class of compound feeds, called dietetic feeds, are defined and intended for animals whose process of assimilation absorption or metabolism is impaired. They are

designated as feedingstuffs intended for particular nutritional purposes (PNP) (e.g. use of feed containing high levels of zeolite, such as from synthetic sodium aluminium silicate, two weeks prior to calving in dairy cows for the reduction of the risk of milk fever). Dietetic feeds may only be marketed for PNPs if the intended use is included in a list set out in Directive 2008/38/EC and they meet the essential nutritional characteristics for the respective particular nutritional purpose specified in the list. (Most PNPs relate to dogs, cats, and equines. See Appendix 3 for PNPs associated with livestock feed). Depending on the nature of the PNP, there may be specific requirements with regards to the composition and labelling of the feed.

ii. Canada – Human Natural Health Products

Recently, Health Canada adopted a new risk-based approach to the approval of human natural health products (NHPs) with a focus on maintaining safety whilst reducing the administrative burden for products where there is a deep history of use. Products are categorized into three levels of risk (Class 1, 2, 3), proportionate to the standard of evidence necessary to support safety, efficacy, and claims associated with the product.

For Class 3 products, there is a low level of certainty in terms of their safety and efficacy, and, as such, these products require the highest level of pre-market review to include clinical trial evidence and a full pre-market assessment. Class 3 products would include a new product claiming to cure cancer or Multiple sclerosis, for example.

For Class 2 products, there is a medium level of certainty and these products require a medium level of pre-market review to include evidence such as published literature, in addition to pre-cleared information. Class 2 products include existing authorized products with a proposed new claim.

For Class 1 products, there is a high level of certainty for the safety and efficacy and these products require the lowest level of pre-market review. Claims permitted for Class 1 products include:

- treatment, cure, risk reduction or prevention of minor diseases or conditions (including symptoms or risk factors of those conditions), which naturally resolve in a timely manner,
- treatment of minor symptoms or risk factors of major conditions or the risk reduction of these conditions, and

- general health maintenance, support, or promotion that refers to modification of a biochemical or physiological function of a nutritional nature or imply benefit to a minor disease or health condition.

For example, applicants can apply for the claim "for the maintenance of good health" providing the product contains an essential nutrient such as a source of calcium. These essential ingredients may be isolated ingredients or constituents of ingredients.

Structure-function health claims imply the modification of an organic function related to a specific body structure. These general health claims are prefixed by either "supports", "maintains", or "promotes" versus "treats", "prevents", or "cures". For example:

- "Supports the immune system"
- "Supports liver function by aiding in carbohydrate metabolism"
- "Helps support digestion by adding to the body's natural micro flora" (Pathway for Licensing Natural Health Products Making Modern Health Claims - Health Canada Guidance Document 2012)

See Appendix 4 for additional information on permissible health claims for human natural health products.

iii. Canada - Low Risk Veterinary Health Products (LRVHP)

Health Canada recently implemented a regulatory process, applicable to companion animals and horses not intended for slaughter, which allows for general health claims for low-risk products. The list of LRVHPs was developed by Health Canada and includes, but is not limited to, homeopathic medicines, botanicals, vitamins, minerals, fungi and bacteria. Substances on the list are believed to present no significant risk to the target animal and may include specific conditions that must be met for the substance to be considered low-risk. Conditions may include route of administration, target species, or contraindications. In order for a product to be approved, there must be sufficient evidence to demonstrate safety and efficacy, and claims must be limited to general health claims, such as "promotes a healthy gut microflora" or "helps maintain healthy immune function". (See Appendix 5 for further examples.) Specific therapeutic claims (claims to diagnose, prevent, cure or treat a disease or abnormal physiological condition) are not allowed.

2. Proposals within a Canadian regulatory context

It is clearly recognized that nutrition enables animal nutritionists, producers, and veterinarians the ability to optimize animals' physiology and wellness. While traditional drug claims (e.g. *disease* treatment) should remain the responsibility of the VDD, a mechanism for the regulation and approval of zootechnical products should be considered. A refined regulatory model is proposed that includes the expansion of allowable nutritional disorder claims, the addition of general wellness claims for feed ingredients, and the recognition that ingredients with the mode of action "that restores, changes or affects the physiological function(s) of an animal beyond the generally recognized physiological effects of nutrition" may be feed ingredients and not drugs.

i. Expand the definition of a nutritional disorder

Under the *Feeds Act*, the definition of a feed includes "(b) providing the nutritional requirements of livestock", and, "(c) for the purpose of preventing or correcting nutritional disorders of livestock". Health Canada/the Canadian Food Inspection Agency's "Guidance Document on Classification of Veterinary Drugs and Livestock Feeds" defines a nutritional disorder as:

"Condition caused by a deficiency of a particular nutrient in the feed. It includes micro- and macronutrients of minerals and vitamins, carbohydrates, fats and proteins. Also known as nutritional deficiency disease. Nutritional disorders can be caused by an insufficient intake of feed or of certain nutrients, by an inability of the body to absorb and use nutrients, or by overconsumption of certain feeds. Examples include anaemia caused by an insufficient intake of iron, and impaired sight because of inadequate intake of vitamin A."

Three additional criteria must be met for a nutritional disorder:

1. Presence of deficiency in diet of a specific nutrient;
2. Cause/effect relationship between clinical signs of disease and absence of nutrient in the diet;
3. Diet supplementation prevents and/or resolves the condition "

There are a number of nutrition-related problems that fall outside the above definition for a nutritional disorder, including:

- Increased nutrient demand due to stressors such as lactation and weaning in high performance animals. Conventional feeding programs may meet nutritional

demands under moderate production parameters, but deficiencies may arise at elevated production, or when feed intake is decreased (for example dairy cattle during transition period).

- Increased susceptibility to disease due to certain feeds having a pre-disposing effect on gut health, immunity and overall general health (e.g. wheat-induced sub-clinical necrotic enteritis).

Recognizing that “nutritional disorders” spans a definition larger than a deficiency of a particular nutrient in feed, the definition of a nutritional disorder should be modified to encompass sub-clinical conditions that do not manifest with distinguishing signs or symptoms (unlike a clinical disease). Currently, this line of thinking conflicts with criterion “2” above which states that there must be a “relationship between clinical signs of disease and absence of nutrient”.

In addition, feed ingredients can be utilized to: (a) provide essential nutrients, (b) provide conditionally essential nutrients (required during periods of stress), (c) optimize the gastro-intestinal environment (for example, pH, viscosity, and microbiota), and (d) impart beneficial effects on overall immunity. As such, defined outcomes for particular feed ingredients (such as improved growth or feed conversion) and the prevention of metabolic and sub-clinical nutritional disorders (supported by appropriate scientific evidence) should be permitted under the modernized approach.

ii. Allow for general health claims

It is proposed that nutritional indications, as described in Health Canada/the Canadian Food Inspection Agency’s “Guidance Document on Classification of Veterinary Drugs and Livestock Feeds”, should be expanded to include claims for general health and wellness. For example, the new definition could be modified to state:

*“Nutritional indications (claims) or purposes refer to: the presence of one or more nutrient(s) or nutritive substance(s) which are scientifically recognized for providing the nutritional requirements **essential for general health and wellness**, supporting normal growth and production in livestock species.*

General health claims may include for example:

- *Contains x (e.g. probiotics) to support the immune system*
- *Contains a source of x to support digestion*
- *Contains mineral x for the maintenance of health”*

D) RECOMMENDATIONS

The following recommendations would provide the needed flexibility for the authorization of zootechnical additives, and would result in more consistent ingredient classifications as is the case in other jurisdictions. It is important to note that these recommendations are fully consistent with the *Feeds Act*, as according to the Act, a feed may be used “for the purpose of preventing or correcting nutritional disorders of livestock”.

1. Allow claims for general health and wellness for feed ingredients that pose no safety concerns. For example, nutritional indications as described in Health Canada/the Canadian Food Inspection Agency’s “Guidance Document on Classification of Veterinary Drugs and Livestock Feeds” could be expanded to state:

Nutritional indications or purposes refer to the presence of one or more nutrient(s) or nutritive substance(s) which are scientifically recognized for providing the nutritional requirements essential for general health and wellness, supporting normal growth and production in livestock species.

2. Allow claims in feed ingredients for the prevention and/or mitigation of sub-clinical and metabolic disorders by removing criterion “2” for the classification of nutritional disorders contained within Health Canada/the Canadian Food Inspection Agency’s “Guidance Document on Classification of Veterinary Drugs and Livestock Feeds”. (E.g. Nutritional disorders that can be mitigated with nutritional strategies, as is the case for sub-acute ruminal acidosis, ketosis, and subclinical necrotic enteritis, should be permitted.) (See Appendix 6 for example claims.)
3. Discontinue the current practice of classifying zootechnical additives as drugs when they have a mode of action “that restores, changes or affects the physiological function(s) of an animal beyond the generally recognized physiological effects of nutrition”.
4. Allow zootechnical additives to be approved through the feed ingredient regulatory pathway. This will ensure that both animal and human safety are evaluated. As well, any claims associated with these products will be assessed and approved via the premarket registration process.

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Appendix A1: Examples of zootechnical research projects funded by industry and government (NSERC/AAFC)

Effect of two prebiotics on gut microflora in healthy and Salmonella challenged broilers
Xin Zhao, McGill University

Development of probiotic formulations with immune enhancing activities for chickens
Shayan Sharif, University of Guelph

Formulation and delivery of immunostimulatory oligodeoxynucleotides containing CpG motifs (CpG-ODN) with carbon nanotubes (CNTs) against poultry diseases
Susantha Gomis, University of Saskatchewan

Delivery of immunostimulatory oligodeoxynucleotides containing CpG motifs to broiler chickens as an alternative to antibiotics [Currently applying for NSERC funding]
Susantha Gomis, University of Saskatchewan

Use of encapsulated essential oils for controlling enteric bacterial pathogens in chickens
Joshua Gong, Agriculture and Agri-Food Canada

Evaluation of butyrate glycerides for developing an alternative to dietary antibiotics in poultry
Joshua Gong, Agriculture and Agri-Food Canada

Alternative antimicrobials from chicken blood
Max Hincke, University of Ottawa

Development of an enzyme/yeast-based prebiotic for poultry
Bogdan Slominski, University of Manitoba

Appendix A2 - Annex I A: Guidance on the implementation of Article 13 of Regulation (EC) No 767/2009 on claims (FEFAC/ COPA-COGECA 2011)

This annex of the Code provides guidance to the person responsible for the labelling on the development of and the presentation of claims.

In this introduction of this annex it is meaningful to provide a delineation of claims in order to provide guidance and assistance to the operators, the purchaser and the authorities. The following sections of this annex will provide further detailed guidance of the relevant aspect of development and presentation of claims:

1. Basic conditions for use of a claim

Claims are permitted providing that the following conditions are met:

- The claim is objective;
- The claim is verifiable by the competent authorities;
- The claim is understandable by the user of the compound feed;
- The claim can be substantiated (further details in Annex I B);
- The claim is not misleading;
- The claim is not prohibited (further details in this Annex I A, section 3).

2. Basic description of a claim

Claims on compound feed may be made in relation to specific characteristics of the compound feed itself including the following properties of the compound feed:

- Appearance / processing of the compound feed;
- Composition of the compound feed (feed additive(s) or feed material(s) or combination thereof, including where relevant specific process undergone by the feed additive(s) or feed material(s);
- Nutritional and/or analytical characteristics of the compound feed;
- The function of the compound feed.

As such, a claim can include reference to the nutritional nature and/or functional effect of the compound feed as well as its effect on animal performance, quality of animal products and livestock management aspect provided that the claim can be substantiated according to the criteria as specified in Annex I B and does not conflict with the following limitation:

The labelling of the compound feed cannot include a claim that contains reference to the compound feed will prevent, treat or cure diseases, except for coccidiostats and histomonostats as authorised under Regulation (EC) No 1831/2003; this point shall not,

however, apply to claims concerning nutritional imbalances provided that there are no pathological symptom associated therewith.

Claims in relation to functions listed in Regulation (EC) No 1831/2003 on feed additives may be made for compound feed when this function is exerted in the compound feed, whether this function is linked to the presence of an authorised feed additive for this function or to a feed material or to the compound feed itself.

Claims on a substance not authorised as feed additive but naturally present in the compound feed can also be made for compound feed.

Claims concerning optimization of the nutrition and support or protection of the physiological conditions are permitted, with the exception of those listed in Article 13(3) of the Regulation.

Whenever the name(s) of one or more feed additive(s) and/or feed material(s) is mentioned in a claim other than referring to its absence, the name(s) and total amount(s) of the substance(s)/product(s) shall be indicated on the label under the appropriate heading.

For claims related to the presence of a feed additive, the claim linked to the functional group indicated in the regulation authorising the additive is preferred. Claims related to functions of a feed additive not specified in the regulation authorising the feed additive may be made if properly substantiated. However, claims linked to a function that would normally require a brand specific approval are not allowed, unless the feed additive is authorised for that purpose.

Claims concerning nutritional imbalances are permitted provided there is no pathological symptom associated therewith.

3. Basic approach on substantiation of a claim

Annex I B will in further detail provide guidance on the substantiation of a claim. In the basic nature, the substantiation can consist of one or more of the following:

- Formulation evidence
- Scientific literature (peer reviewed articles)
- Scientific opinions and publications from worldwide authorities (e.g. EFSA, FDA, national feed/food authorities)
- Research & Development trials
 - External
 - In-house
- Long standing and well recognised use

The claim can include reference to conclusions from the above, provided that the claim meets the criteria as described above in the description of a claim. This means that the claim can include the following wordings provided that such claims can be verified and substantiated through the above-mentioned means of substantiations of the claim:

- “stimulates appetite”,
- “increases daily weight gain”,
- “improves feed conversion ratio”
- “fosters increased pigmentation of egg yolk colours”
- “reinforces peristalsis through enhanced motility in the digestive tract”

4. Typology of claims

Below is a typology of claims based on their nature. In practice, claims may be a combination of several of the claims listed below, one (primary claim) being directly connected to the other (secondary claim).

One example is rumen protected methionine which will increase milk yield and influence composition of milk (in particular increase protein content of milk) through improved function of the liver in dairy cows, as methionine plays an important role in the mobilization of fat depots and further methionine stimulates the liver more effectively to eliminate waste metabolites.

Another example is particle size profile of compound feed as coarse particle size:

- will influence the profile of the microflora in the digestive tract in pigs, as coarse particles will support growth of lactobacillus in the digestive tract of pigs;
- will reactivate the function of the gizzard in poultry and influence the pH of the content in the gizzard and the digestive tract;
- will make the content of the stomach more firm and thereby create an improved pH gradient through the stomach leading to reduced likelihood of gastric contents with low pH coming in contact with the white part of the gastric mucosa in pigs.

4.1 Nutritional and compositional claims

The purpose of this type of claim is to justify the coverage of quantitative and qualitative requirements in essential nutrients (energy, proteins, vitamins, minerals, etc.) or constituent exerting a function in the compound feed, whether this function is claimed or not. Nutritional and compositional claims can be based on any of the following origins or combination thereof:

- on the presence/absence of a substance (feed material, feed additive, analytical constituent). Examples:

- “Contains / brings / source of / provides / concentrated in / rich in [substance]” (e.g. bicarbonate, acid salts, lipotropic factors, vitamins, trace elements)
- “Contains [name of substance] adapted to nutritional needs of [species]”
- “Naturally rich in [substance]” (e.g. beta-carotene)
- “Enriched with [substance]” (e.g. bicarbonate, acid salts, lipotropic factors, vitamins)
- “High in [substance]” (e.g. b energy, omega 3, polyunsaturated fatty acids)
- “Low in [substance]” (e.g. fibre, proteins)
- a feed additive/feed material present in the compound feed under a special form, process or origin (often associated with a functional or livestock management claim).
Examples:
 - “Contains digestible / available / chelated / coated / rumen-protected / micronized [substance]” (e.g. vitamins, mineral, feed material)
 - “Contains [specified feature] [name of substance]” (e.g. controlled, vegetable, natural)
- a specific production process which improves the quality of the compound feed (often associated with a functional or livestock management claim). Examples:
 - Heat treated
 - Expanded
 - Coarse grinded
 - Pelleted

4.2 Functional claims

These claims are related to a specific effect on certain physiological functions of the animal (growth, development, etc.). They may be connected to a specific feed material, feed additive or constituent, whether its presence is claimed or not, or to the appearance of the compound feed, e.g. its physical form (meal, crumbles, particle size etc.) or a specific process undergone by the compound feed (heat treatment, pelleting).

- Support, or reinforce physiological functions of the animal or enable return to normal physiological status. These are claims other than those related to specific authorised nutritional purposes. Examples:
 - Provides elements necessary at a given rearing phase (lactation, starter, weaning, egg laying, flushing)
 - Contributes to good liver function
 - Contributes to bone solidity

- Contributes to the preservation of udder integrity
- Contributes to a regular digestive transit/motility
- Contributes to/has positive impact on animals immunity
- Supports a specific function (starting growth, ossification, feathering)
- Facilitates organ fat mobilisation
- Fosters feed, drinking water intake
- Fosters digestion, appetite, production
- Fosters epithelial renewal (digestive, cutaneous)
- Facilitates farrowing, parturition, egg laying, hatching
- Fosters assimilation, digestibility, digestion (of feed ration, fat)
- Facilitates organ fat mobilisation and/or use
- Maintains bowel flora balance (buccal cavity, rumen, small intestine, duodenum)
- Optimises, orientates (rumen fermentations)
- Covers the needs of ... (microflora)
- Increases blood content in ...by...
- Contains added amino acid(s) allowing a reduction of total protein concentration in this feed.
- Contributes to bone strength.
- Fosters adaptation to or reduces consequences of ... (to be specified: e.g. heat, cold)
- Fosters, contributes to, helps a good transition in case of change (in feed, in silo, in environment, in housing, in climate, stress by partial depopulation)
- Fosters obtaining compensatory growth or laying
- Fosters restart of reproduction cycles
- Stimulates or maintains rumen activity, contributes to rumen balance
- Fosters rest and udder involution
- Contributes to a regular libido expression, sexual activity
- Reduces aggressiveness, dominance, cannibalism
- Contributes to, participates in a good quality colostrum
- Enhancing animal performance. Examples:
 - Stimulates, fosters, improves growth
 - Contains [substance] which improves growth of the animals
 - Fosters the development of muscles
 - Increases milk production, milk secretion (e.g. sows)
 - Increases egg-laying rate
 - Increases the success rate of artificial insemination, serving

- Improves viability of a group of animals
- Enhancing the efficiency of the compound feed. Examples
 - Contributes to reducing the feed conversion ratio, reduces the feed conversion ratio in the framework of
 - Improves feed efficiency (feed conversion ratio, nitrogen retention)
 - Contains phytase, which increases the digestibility of phytic phosphorus, hence improving phosphorus absorption”
 - Contains [substance] improving the digestibility of non-starch polysaccharides, hence improving the energy value of the feed
 - Contains [substance] improving the degradability of e.g. fibres contained in the diet.
 - Contains [substance] which reduces viscosity of the faeces
 - ...

4.3 Livestock management claims

These claims are related to the role of compound feed with specific effects on managing environmental, sanitary risks or improving the quality of food (pigmentation, selenium). They may be connected to a specific feed material, feed additive or constituent, whether its presence is claimed or not, or to the appearance of the compound feed, e.g. its physical form (meal, crumbles, particle size etc.) or a specific process undergone by the compound feed (heat treatment, pelletisation).

- Reduction of an environment risk. Examples:
 - Contributes to improving the litter, favourable to a dry litter
 - Reduces ammonia, methane, emissions
 - Reduces phosphorous, nitrogen, emissions
 - Reduces odour emission
 - Contributes to a better animal welfare, competition, establishment of dominance, locomotion
 - Contains ‘phytase’, which increases the digestibility of phytic phosphorus thus having a favourable impact on the environment
 - Contains ‘phytase’ which reduces the load of phosphorus in the environment.
 - ...
- Reduction of a sanitary risk factor. Examples:
 - Participates in integrated management, in integrated pest management
 - Helps the risk management of, fosters, improves (in a given adverse sanitary situation)

- Contributes to the integrated management of the risk of respiratory problems
- Contains [substance] which contributes to control the impact of mycotoxins
- Enhancing the quality (nutritional, organoleptic, microbiological, etc. value) of animal products (meat, egg, milk, etc.) Examples
- Contains [substance], which improves the quality of animal produce.
- Contains [substance], which enhances/accentuates the colour of the egg/flesh
- Contains [substance], which ensures an improved consistency of the colour in the food products.
- Limits meat oxidation
- Taste-enhancing, improves tenderness
- Improves egg shell solidity
- Increases egg weight
- Contributes to milk somatic cell count concentration
- Only for coccidiostats and histomonostats: Aids in the prevention of coccidiosis caused by ...

5. Prohibited claims

- The following claims are prohibited:
 - Claims concerning optimization of the nutrition and support or protection of the physiological conditions which explicitly use the following words “preventing, treating or curing a disease”.
 - Claims suggesting that, whatever the process, a compound feed holds specific or own characteristics whereas the features in question are common to all similar compound feed.
- The labelling or the presentation of the compound feed shall not claim that:
 - It will prevent, treat or cure disease, except for coccidiostats and histomonostats as authorised under Regulation (EC) No 1831/2003; this point shall not, however, apply to claims concerning nutritional imbalances provided that there is no pathological symptom associated therewith.
 - It has particular nutritional purposes as referred to in the list of authorised intended uses referred to in Directive 2008/38/EC unless its specific provisions are complied with.

The following expression should not be used: dose, dosage, cures, treat, treatment, remedy, prevent, relieves, heals, etc.

**Appendix A3: Examples of Feed Ingredients for Specific Nutritional Purposes as set out
in Part B: List of Intended Uses (Directive 2008/38/EC)**

Nutritional Purpose	Essential Nutritional Characteristics	Species	Labelling declarations	Length of time	Other Provisions
Reduction of the risk of ketosis	Ingredients providing glucogenic energy sources	Dairy cows and ewes	<ul style="list-style-type: none"> — Ingredients providing glucogenic energy sources — Propan-1,2-diol (if added as a glucose precursor) — Glycerol (if added as a glucose precursor) 	<p>3 to 6 weeks after calving</p> <p>last 6 weeks before and the first 3 weeks after lambing</p>	
Reduction of the risk of tetany (hypomagnesaemia)	High level of magnesium, easily available carbohydrates, moderate level of protein and low level of potassium	Ruminants	<ul style="list-style-type: none"> — Starch — Total sugars — Magnesium — Sodium — Potassium 	3 to 10 weeks during periods of fast grass growth	<p>In the instructions for use, guidance shall be provided on the balance of the daily ration, with regard to the inclusion of fibre and easily available energy sources. In the case of feedingstuffs for ovines indicate on the package, container or label:</p> <p>‘Especially for lactating ewes.’</p>
Reduction of the risk of acidosis	Low level of easily fermentable carbohydrates and high buffering capacity	Ruminants	<ul style="list-style-type: none"> — Starch — Total sugars 	Maximum 2 months	<p>In the instructions for use, guidance shall be provided on the balance of the daily ration, with regard to the inclusion of fibre and easily fermentable carbohydrate sources. In the case of feedingstuffs for dairy cows indicate on the package, container or label:</p> <p>‘Especially for high yielding cows.’</p> <p>In the case of feedingstuffs for ruminants for fattening, indicate on the package, container or label:</p> <p>‘Especially for intensively fed.’</p>

Stabilisation of physiological digestion	<ul style="list-style-type: none"> — Low buffering capacity, and highly digestible ingredients 	Piglets	<ul style="list-style-type: none"> — Highly digestible ingredients including their treatment if appropriate — Buffering capacity — Source(s) of astringent substances (if added) — Source(s) of mucilaginous substances (if added) 	2 to 4 weeks	Indicate on the package, container or label: 'In case of risk of, during periods of, or recovery from, digestive disturbance.'
Reduction of the risk of milk fever	<ul style="list-style-type: none"> — Low level of calcium and/or 	Dairy cows	<ul style="list-style-type: none"> — Calcium — Phosphorus — Magnesium 	1 to 4 weeks before calving	Indicate in the instructions for use: 'Stop feeding after calving'
	<ul style="list-style-type: none"> — Low cations/anions ratio 		<ul style="list-style-type: none"> — Calcium — Phosphorus — Sodium — Potassium — Chlorides — Sulphur 	1 to 4 weeks before calving	Indicate in the instructions for use: 'Stop feeding after calving'
	<ul style="list-style-type: none"> or — High level of zeolite (synthetic sodium aluminium silicate) 		Content of synthetic sodium aluminium silicate	The 2 weeks before calving	Indicate in the instructions for use: — 'The amount of feed shall be restricted to ensure that a daily intake of 500 g sodium aluminium-silicate per animal is not exceeded.' — 'Stop feeding after calving'
<ul style="list-style-type: none"> or — High level of calcium in the form of highly available calcium salts 	Total calcium content, sources and respective quantity of calcium	Start at first signs of parturition to two days subsequent to parturition	Indicate on the package, container or label: — The instruction of use i.e. the number of applications and the time before and after calving. — The text 'It is recommended that a nutritional expert's opinion be sought before use'.		

Appendix A4 - Pathway for Licensing Natural Health Products Making Modern Health Claims (Health Canada Guidance Document 2012)

General Health Claims

Products with general health claims include those that have low therapeutic impact and are therefore subject to the appropriate evidence requirements. The following categories are those general health claims that may be authorized if all required conditions/considerations are met.

"Source of/Provides/Contains" Claims

Examples

- Source of fibre
- Provides antioxidants

Evidence requirements

Applicants wishing to apply for a "source of" claim are required to test for the presence of the constituent or ingredient (i.e., identification testing) and may be asked to provide evidence for quantification such as an assay at the finished product or raw material stage; however, this will not be a requirement upon submission. Applicants should have the results of the aforementioned tests maintained such that they could be provided to Health Canada in a timely manner upon request.

Claims Based on Constituents

Many medicinal ingredients of NHPs have constituents that on their own can support a specific health claim. Products that are standardized as a source of such a constituent at a relevant quantity can have a more specific claim based on that constituent.

Examples

- Helps maintain eyesight, skin membranes and immune function
 - Cod liver oil is known to contain vit A (palmitate), vit D3 (cholecalciferol), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)

Evidence requirements

Applicants applying for these types of claims must provide evidence in the form of identification testing (for the constituent) as well as assays to determine the quantity of the constituent. To support the more specific claim, applicants can attest to a Natural Health Product Monograph such as the Multi-Vitamin-Mineral Supplement Monograph.

The applicant can also provide clinical evidence as well as supporting evidence from animals or *in vitro* evidence to support the more specific claim. Applicants should include the name of the constituent in the claim or list it as a constituent of the medicinal ingredient so that consumers know the claim is not false or misleading and can make informed choices.

Claims for the Maintenance of Good Health

Applicants can apply for the claim "for the maintenance of good health" providing the product contains an essential nutrient. These essential ingredients may be isolated ingredients or constituents of ingredients.

Examples

- A source of vitamin x for the maintenance of good health
- A source of mineral x for the maintenance of good health

Evidence requirements

To apply for one of these claims the ingredient must be present in the product and will be identified and assayed for in the product. If the essential nutrient is a constituent of an ingredient, the applicant will be asked to identify through constituent testing (identification testing and assay) which ingredient contains the specific nutrient at the finished product stage; however this will not be a requirement upon submission. An applicant can also apply, for the product as a whole, to use the claim "for the maintenance of good health" without identifying the essential nutrient in the claim if it is listed as a constituent of the medicinal ingredient so that it is clear to the consumer that the product contains that nutrient.

General Claims to Help/Support/Maintain/Promote Health

Structure-function health claims imply the modification of an organic function related to a specific body structure. These general health claims are prefixed by either "supports," "maintains" or "promotes" versus "treats," "prevents" or "cures." "Supports" and "maintains" are claims usually referring to the maintenance of a steady state whereas "promotes" usually implies an improvement to the state or condition. The low therapeutic impact claim qualifier "helps" is used to indicate that the product addresses or treats only one/some components of the disease or intended health benefit. These claims must not be to treat or cure Schedule A diseases but may support mechanisms of action associated with reduction of the risk of a Schedule A disease. These claims differ from general health maintenance claims in that there is an implied relationship between

the claim and the product, and the claim and health outcome, whereas the general health maintenance claim does not contain such a relationship. It should be noted that a general health maintenance claim does not necessarily equate to poor evidence; on the contrary, most general health maintenance claims are supported by higher levels of evidence including clinical trials and text book evidence.

Examples

- Supports the immune system
- Promotes liver function

Evidence requirements

These claims are often supported by clinical trials and observational or epidemiological studies in humans, but other forms of evidence could be considered acceptable. The minimum evidence required to support these types of claims includes at least some human evidence (clinical and/or epidemiological), clinical text books that describe how constituents work in the body, and supporting evidence such as animal and *in vitro* studies that provide more information surrounding the mechanism of action.

Where supported by the evidence, it is beneficial to the consumer to provide more detail on the mechanisms of action by relating that to a body system or function.

Examples

- Support liver function by aiding in carbohydrate metabolism
- Helps support digestion by adding to the body's natural micro flora

Generalized claims based on mechanism of action

When clinical endpoints/markers discussed in the evidence are not clearly recognizable, are not well known, or could not be easily understood by the public, claims must be generalized for the average consumer to understand. In the case of biomarkers, evidence should be provided for the validation of the biomarker.

Examples

- Helps to reduce blood C reactive protein levels, a clinical marker of inflammation.

When evidence to support a claim describes a biochemical pathway the claim may be generalized to discuss organ function or health. It should be noted that a generalized claim based on a mechanism of action does not necessarily equate to poor evidence.

Appendix A5 – Examples of Acceptable and Non-Acceptable Health Claims for Notifiable Low Risk Veterinary Health Products (Interim Notification Program: Low Risk Veterinary Health Products Claims Guidance, 2012)

General Health Claim (Acceptable for Notification)	Therapeutic Claim (Non-acceptable for Notification)
<i>"Supports natural defences"</i>	<i>"Prevents infections"</i>
<i>"Helps to maintain physical performance" "For the maintenance of energy and general vitality"</i>	<i>"Increases physical performance"</i>
<i>"Helps maintain a healthy immune function"</i>	<i>"Preventing, treating, curing immune system dysfunction"</i>
<i>"Helps maintain a healthy skin/coat"</i>	<i>"To relieve hot spots", "For wound healing"</i>
<i>"Has a role in maintaining the integrity of skin, hair and hooves"</i>	<i>"For the prevention of laminitis"</i>
<i>Claims referring to flatulence, odour of stool, digestibility, well-formed stools, consistency of stools, maintaining or promoting regularity.</i>	<i>"Prevents, treats or cures gum disease, gingivitis, periodontal disease" "Prevents, treats or cures diarrhea, constipation, colitis, inflammatory bowel disease, or other specific gastrointestinal diseases" "Relieves symptoms of gastric or duodenal ulcer" "For the relief of colic" "Treats indigestion" "A natural approach to bowel disease" "Discourages vomiting" "Acts as a laxative" "For the treatment of parasites"</i>
<i>"Promotes a healthy gut microflora" "Promotes a healthy gut flora" "For good intestinal health" "Maintains balance of healthy microflora" Provides friendly bacteria that play an important role in basic digestion, proper metabolism and overall well-being"</i>	<i>"Helps combat digestive problems" "Decreases intestinal disorders" "Prevents/controls diarrhea", "Helps avoid diarrhea associated with antibiotic use" "Helps to reduce biomarkers of allergy"</i>
<i>"Helps maintain/promote urinary tract health"</i>	<i>"Treats, cures or prevents FUS, FLUTD, struvite uroliths, etc." "Soothes bladder infections" "For urinary incontinence" "Supports the process of dissolving crystals"</i>

<p><i>"For the normal functioning of the heart"</i></p> <p><i>"Helps promote heart health"</i></p> <p><i>"Support for healthy heart and arteries"</i></p> <p><i>"Contributes to vascular health"</i></p>	<p><i>"Reduces the risk of heart disease"</i></p> <p><i>"Prevents, treats or cures any cardiac condition"</i></p>
<p><i>"For the health of respiratory organs"</i></p>	<p><i>"For the treatment of bronchitis"</i></p> <p><i>"Prevents the recurrence of secondary infections"</i></p>
<p><i>"Supports the health of the respiratory tract, helps maintain moisture balance in nose, throat and lungs"</i></p>	<p><i>"Relieves coughing, shortness of breath"</i></p> <p><i>"Clears sinus infections"</i></p>
<p><i>"Promotes normal/optimal growth and development of the musculo-skeletal system"</i></p> <p><i>"Supports bone health"</i></p> <p><i>"May help maintain joint and bone health"</i></p> <p><i>"Promotes joint health"</i></p> <p><i>"May help in the improvement of joint health and function"</i></p> <p><i>"helps support the function of the joints"</i></p>	<p><i>"For inflammation due to osteoarthritis"</i></p> <p><i>"To reduce swelling and lameness"</i></p> <p><i>"Prevents the progression, or reverses the progression, of osteoporosis"</i></p> <p><i>"For the treatment of degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses"</i></p>
<p>Nutritional claims starting with <i>"has a role in..."</i>, <i>"is involved in..."</i>, <i>"required for..."</i>, or <i>"needed for..."</i> normal metabolic or physiological functions. (e.g. <i>Vitamin C has a role in maintaining healthy cartilage, tendons and bone</i>", <i>"Selenium has a role in preventing cellular oxidation"</i>)</p>	<p><i>"Prevents, cures or treats the progression of renal disease, diabetes, heart disease etc."</i></p>
<p>Claims for combination vitamins and mineral supplements <i>"Factor in the maintenance of good health"</i></p>	<p><i>"Prevents, treats or cures pruritus, itchiness, allergic conditions, food allergies, fungal diseases, bacterial diseases"</i></p>
<p><i>"For the maintenance of water and electrolyte balance"</i></p>	<p><i>"To correct electrolyte imbalances"</i></p> <p><i>"To treat hypokalemia"</i></p>
<p><i>"Can help maintain healthy blood glucose levels"</i></p>	<p><i>"Regulates blood sugar levels"</i></p>
<p>No disease claims permissible</p>	<p><i>"Prevents, treats, or cures neoplasia/cancer/tumour".</i></p> <p><i>"Prevents, treats, or cures allergy or intolerance"</i></p> <p><i>"Reduces injury from head trauma"</i></p> <p><i>"Provides relief from the effects of epilepsy"</i></p> <p><i>"Improves insulin availability and production for diabetic pets"</i></p>

Appendix A6 – Nutritional Disorder Claims

Examples of potential indications (claims) for the prevention and/or mitigation of sub-clinical and metabolic disease.

<i>Nutritional disorders</i>	<i>Species</i>	<i>Acceptable indications for feeds</i>
Sub-clinical Ketosis	Cattle	“As an aid in the prevention of sub-clinical ketosis”
Sub-Acute Ruminant Acidosis	Cattle	“As an aid in the prevention of sub-acute ruminant acidosis”
Pregnancy toxemia	Sheep, cattle	“As an aid in the prevention of pregnancy toxemia”
Hepatic lipidosis	Cattle	“As an aid in the prevention of hepatic lipidosis”
Hypocalcemia	Cattle, horses, sheep, goats	“As an aid in the prevention of hypocalcemia”
Necrotic enteritis	Poultry	“As an aid in the prevention of sub-clinical necrotic enteritis”