



## **Modernizing the Feeds Regulations**

### **A Proposal by the Animal Nutrition Association of Canada for a Risk-Based Framework for Feed Ingredients**

*January 2013*

## **Background and Objectives**

The process now underway to modernize the Canadian Feeds Regulations offers a unique opportunity to redesign the regulatory framework and align it more closely with our global trading partners. This would allow the new Canadian regulation to incorporate a science-based system that recognizes benefits and risks proportionately, and uses innovative approaches to develop a best-in-class regulatory process. The Animal Nutrition Association of Canada (ANAC) offers the following proposals for consideration by CFIA and agri-food stakeholders in the regulatory modernization process relating to the classification and authorization of feed ingredients.

As a first step, it is important to take into consideration the foundational underpinnings of a new feed regulatory program. We believe these include:

1. Recognizing and further developing feed industry best practices to ensure the safe and effective use of feed ingredients.
2. Developing new risk-based CFIA regulatory procedures that focus on ensuring the integrity and quality of feed ingredients and their safety in the target species, humans, and as required, the environment.
3. Enabling market access and competitiveness such that regulations do not create barriers to innovation, nor put the Canadian feed or livestock industry at a competitive disadvantage with its international counterparts.
4. Safeguard consumer protection to ensure that purchasers of feeds are not subjected to false or misleading information.

Figure 4 depicts ANAC's proposed ingredient authorization approach, which focuses on the key criteria of risk classification and claim evaluation.

## **Defining the Terms: Feed Ingredients, Nutrients and Nutritional Disorders**

Prior to determining how feed ingredients are regulated we must first define what a feed is and what will be controlled by the *Feeds Regulations*. The Feeds Act defines "feed" as follows:

*"feed" means any substance or mixture of substances containing amino acids, anti-oxidants, carbohydrates, condiments, enzymes, fats, minerals, non-protein nitrogen products, proteins or vitamins, or pelletizing, coloring, foaming or flavouring agents and any other substance manufactured, sold or represented for use:*

- (a) for consumption by livestock,*
- (b) for providing the nutritional requirements of livestock, or*
- (c) for the purpose of preventing or correcting nutritional disorders of livestock,*

*or any substance for use in any such substance or mixture of substances.*

***Recommendation 1- Maintain the definition of “feed” as contained in the Feeds Act.***

Although we propose that the definition of a feed be kept as found in the Act, it is appropriate to define and provide interpretations as to what is a nutrient, a feed ingredient, and a drug. Current definitions of a nutrient, feed and drug frequently overlap due to their impact on:

- (a) normal physiology, and,
- (b) optimizing physiology which is expressed as improved growth/productivity, improved production efficiency, enhanced protein yield and quality (e.g. effects on milk, carcass composition, eggs), and reproductive efficiencies.

This overlap of definitions and modes of action creates confusion. Specifically, in the Food and Drugs Act 1985, a drug may aid in the “mitigation or prevention of a disease, disorder, abnormal physical state” while in the Feeds Act, a feed may be used “for the purpose of preventing or correcting nutritional disorders of livestock”. These acts in effect overlap in terms of their application in regards to optimizing animal performance, and, in the mitigation of metabolic and sub-clinical disease thereby resulting in a lack of clarity as to how products are classified and regulated, and what claims are allowed.

This in combination with the absence of a defined mechanism to review and approve products that do not have safety concerns has led to a cumbersome regulatory environment and one that deters international companies from bringing products to the Canadian marketplace. For example, an ingredient that is classified as a feed in Europe and the US will sometimes be classified as a drug in Canada. When these products are classified in such a way in this country, the manufacturers may simply decide not to make them available in the Canadian marketplace. This is the case because, a) it is much harder and much more costly to get a product approved as a drug versus a feed and, b) the cost of obtaining Canadian regulatory approval cannot be justified given the relatively small size of the Canadian market.

Currently, regulation of feed ingredients in Canada is lacking:

1. an effective mechanism to recognize ingredients which enhance nutrient availability in animals with increased needs related to high production performance;
2. consensus between industry and government over the levels at which nutrients cease to perform normally and instead have pharmacologic (i.e. drug) effects (e.g. copper and zinc in pig starters, vitamin E and selenium in ruminants);
3. regulatory flexibility so sources of nutrients that have greater biological availability (e.g. some chelated trace minerals) and new technologies that enhance nutrient availability (e.g. phytase) can be utilized to their full potential;

4. the option to designate a feed as a nutrient source, or a feed additive as modifying the availability of a nutrient, without forcing applicants to provide and support a specific performance or health claim, or intended purpose. The issue here is not always that the applicant does not want to make a claim. Rather, such claims are often interpreted incorrectly as drug effects, rather than nutrient effects; the product must then be submitted for approval as a drug and not a feed ingredient.
5. a scientifically-based, objective process of determining whether a claim constitutes a drug or feed claim. Claims where there is no established distinction must now first be evaluated on a case by case basis by the Veterinary Drugs Directorate (VDD), with industry having little comprehension of the rationale for the drug vs. feed decision. While traditional drug claims are the responsibility of VDD, the proposals in this paper present an alternative approach in what we suggest are “non-drug” related productivity and health claims.

These situations have resulted in a lack of harmony between the Canadian regulatory environment and that applied to animal feed regulation in the United States of America (USA) and European Union (EU). Consequently, Canadian livestock producers do not have access to a number of new technologies (some of which were developed in Canada) to which their international competitors have access.

Providing clear definitions and associated interpretations for a nutrient, feed ingredient and drug will act as a starting point in building the modernized Feeds Regulations to ensure that ingredients being approved as a feed elsewhere in the world are being similarly categorized in Canada. In this regard, a summary of the regulatory definitions used for feed and feed ingredients and drugs within the EU, Canada and the USA is found in Appendix 1. Using these as “best practice” starting points, ANAC offers the following series of recommendations:

***Recommendation 2-*** *Using the current feed definition as cited in recommendation 1, it is recommended that additional emphasis and a revised interpretation be applied as follows:*

*1- For part “b” of the feed definition, which indicates “providing the nutritional requirements of livestock”, it is recommended that this definition allow for the use of feed ingredients for the optimization of growth and production efficiency of animals.*

*2- In the case of part “c” which states “for the purpose of preventing or correcting nutritional disorders of livestock”, within this definition the role of feeds in correcting and mitigating various metabolic and subclinical nutritional disorders e.g. sub-acute ruminal acidosis, ketosis, and subclinical necrotic enteritis should be permitted given the nutritional etiologies of these syndromes.*

**Recommendation 3:** For the purposes of the modernized regulations, and the Canadian definition of a nutrient, it is recommended that the USDA (Animal Diets and Feed Management, Nutrient Management Technical Note No. 8, January 2012) definition for nutrient be adopted and refined to state:

A nutrient is “Any ingredient or compound in the diet that supports reproduction, growth, lactation, or maintenance of life processes”.

**Recommendation 4:** In terms of a definition for nutritional disease, it is proposed that the following definition be adopted:

A nutritional disorder is “Any disorder in animals that is directly or indirectly caused by a lack of an essential nutrient or conditionally essential nutrient (those that must be supplied only under special conditions, such as stress, illness, etc.) in the diet, or a nutritional imbalance.”

### **Defining Claims**

To complete this discussion, it is necessary to establish what constitutes a “claim”. It should be noted that claims are infrequently defined in regulatory documents in the EU, Canada and the USA. That said, the term “claim” usually refers to labelling that draws attention to the presence or absence of a particular substance and an attributable characteristic (usually a benefit). As there is currently no definition in the Canadian Feeds Regulations for what constitutes a claim, this is often left to interpretation. Therefore, it is felt that there is a need to define the term “claim” in a new regulation governing ingredient authorization.

**Recommendation 5:** Adopt a simplified overarching feed claim definition. Combining and modifying a number of Codex definitions, the following is recommended:

*Claim:* “Any representation which states, suggests or implies that a feed has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality that impacts an animal’s productivity and health.”

### **Learning from an Established Model for Ingredient Authorizations**

While not currently adapted to food animals, Health Canada has designed and enabled a regulatory process for low risk products to be used in companion animals, the outcome of which could be directly applied to low-risk food animal feed ingredients. Details of this program may be found within Appendix 3.

**Recommendation 6:** The modernization of the Feeds Regulations should adopt an approach similar to the Health Canada Veterinary Drugs Directorate (VDD) Low-Risk Veterinary Health Products (LRVHP) Program, which focuses on identifying and mitigating risk and establishes a regulatory framework, including the creation of an approved ingredient list for use in livestock and poultry feed..

The approach outlined in recommendation 6 would build on existing frameworks and would allow for a more efficient, effective, and proportionate system that first and foremost ensures safety, while also fostering innovation. With this, a two-phase regulatory approach for feed ingredient authorization is proposed. With the primary focus on risk and safety, an initial assessment will be made based upon the attributes of the ingredients as presented in *Figure 1: The Risk Continuum*.

***Recommendation 7:*** *It is recommended that CFIA, in collaboration with Health Canada's VDD and industry, create a positive list of recognized safe feed ingredients using current approvals in Canada, as well as those from foreign jurisdictions whose systems are recognized by Canada. The focus should be on the assessment of animal, human and environmental safety only. Once an ingredient is on this positive list, it may be used in any mixed feed without further evaluation by CFIA. Should a product not be deemed low risk, or should it be new and therefore have no history of use, a CFIA risk assessment will be required.*

In the second phase, product efficacy will be addressed (See *Figure 2: The Efficacy Continuum*). Given that feed ingredients and drugs can both have an impact on animal physiology, the regulations should recognize that physiological effects are not the exclusive domain of drugs. Therefore, claims dealing with animal physiology should therefore be permitted for feed ingredients where appropriate. In addition, note that while efficacy can be demonstrated for all feed ingredients, the need to regulate efficacy in those ingredients that have been widely used by the feed industry is not required.

***Recommendation 8:*** *It is recommended that a positive list of permissible claims be developed and pre-approved for use with feed ingredients. If an ingredient carries an approved claim, then that claim may also be used in mixed containing that ingredient without further efficacy assessment. Examples of such claims are provided in Figure 3: Permissible Claims.*

Recommendation 8 would allow regulatory focus to be placed on those ingredients that have not been in widespread use or those for which the proposed claim has not been included in the permissible claim list. Therefore, the following recommendation is made:

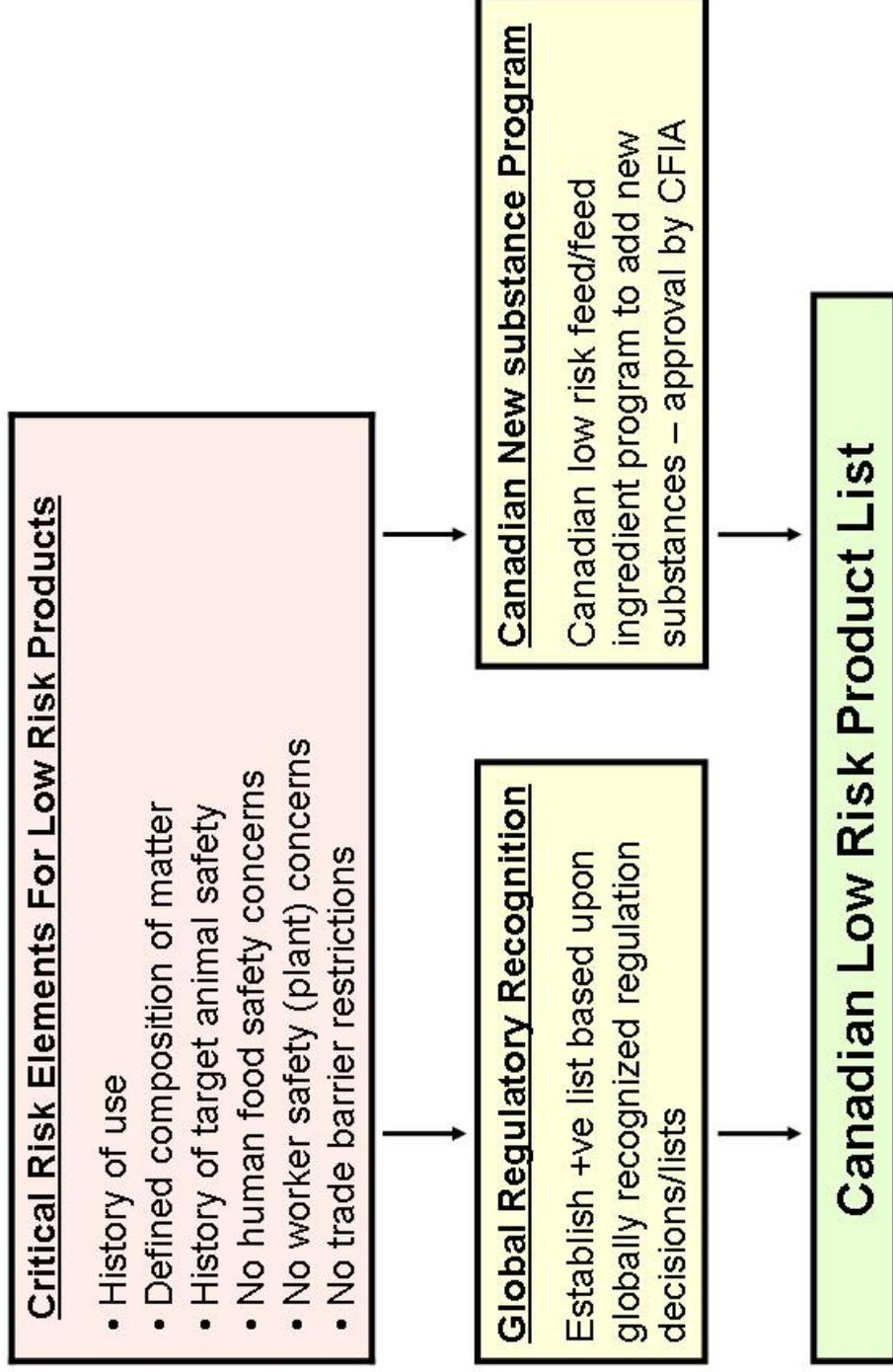
***Recommendation 9:*** *It is recommended that pre-market efficacy approval by CFIA not be required for low-risk ingredients either without claims, or with claims included on the permissible claim list.*

## **Conclusions**

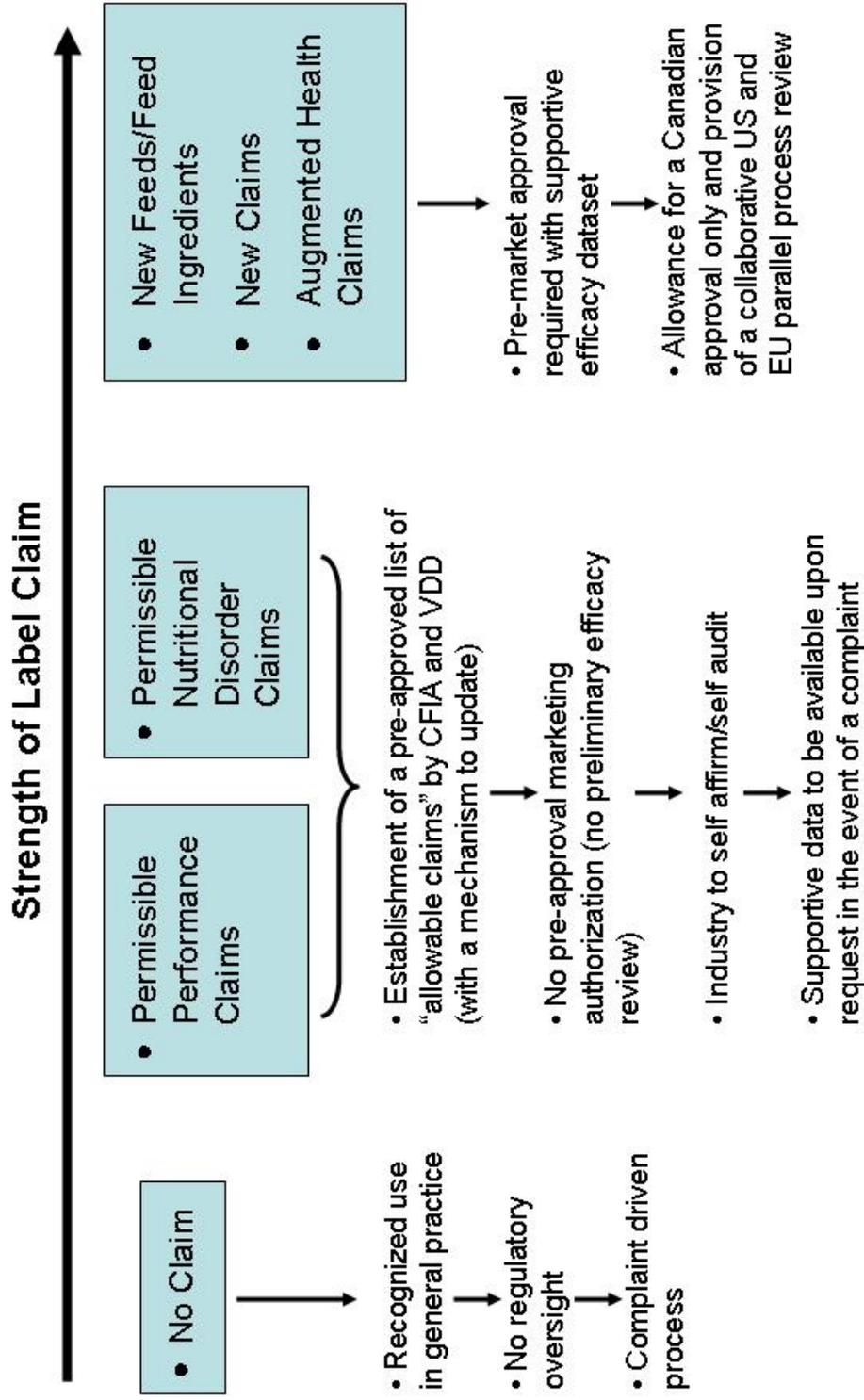
With a modernized regulatory approach to feed ingredients as recommended in this paper, a number of benefits become apparent:

1. Protection of animal and human health and the environment,
2. Assurance of a secure, safe and abundant animal protein component of the food chain,
3. Promotion of competitiveness, innovation and a level playing field,
4. Cost-effective regulations based on risk associated with ingredients,
5. Promotion of the development of new substances/innovations by putting in place an outcome-based review mechanism which allows for timely approvals, and permits appropriate claims to be used for feed ingredients,
6. Greater convergence with regulatory systems used by global trading partners, through the creation of a positive product list that recognizes these global approvals, and, with agreed upon balanced claims and,
7. Use of industry best practices which enable more streamlined, cost-effective control processes.

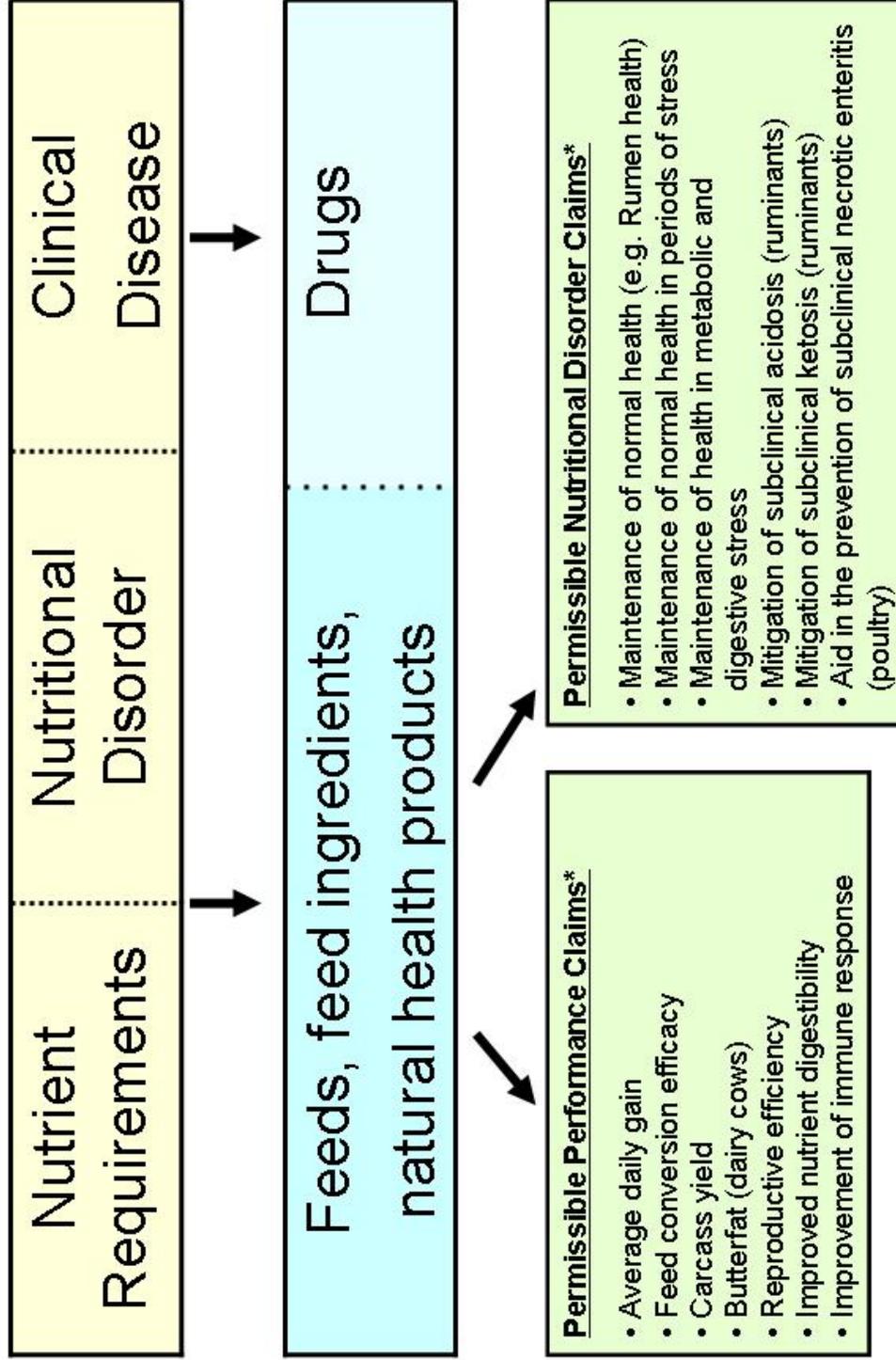
# Figure 1: The Risk Continuum



# Figure 2: The Efficacy Continuum

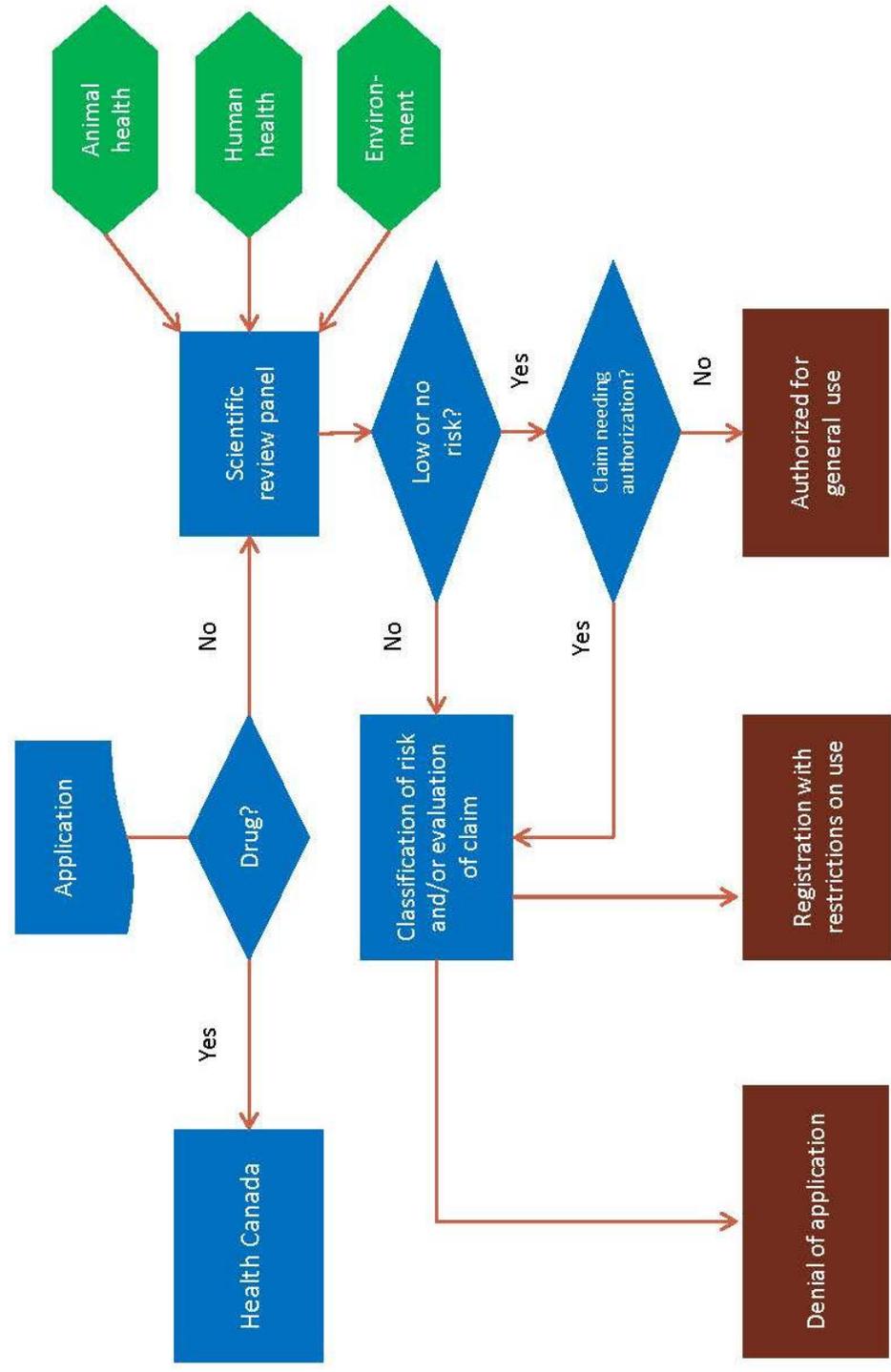


# Figure 3: Permissible Feed Claims



\* Represents examples (not an exhaustive list).

**Figure 4: Proposed ingredient authorization model**



## APPENDIX 1 - Defining Feeds/Feed Ingredients/ Nutrients/ Drugs

### European Union

**Feed (feeding stuff):** Any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals. (EU REGULATION (EC) No 178/2002, article 2)

Following on from this broad definition of feed, recital 3 of Regulation (EC) No 767/2009 states that 'feed may take the form of feed materials, compound feed, feed additives, pre-mixtures or medicated feeding stuffs.'

**Feed additives:** Substances, micro-organisms or preparations, other than feed material and pre-mixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3).

(a) *favourably affect the characteristics of feed;*

(b) *favourably affect the characteristics of animal products;*

(c) *favourably affect the colour of ornamental fish and birds;*

(d) *satisfy the nutritional needs of animals;*

(e) *favourably affect the environmental consequences of animal production;*

(f) *favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs; or*

(g) *have a coccidiostatic or histomonostatic effect.* (EC) No 1831/2003)

**Feed intended for particular nutritional purposes:** *feed which can satisfy a particular nutritional purpose by virtue of its particular composition or method of manufacture, which clearly distinguishes it from ordinary feed. Feed intended for particular nutritional purposes does not include medicated feedingstuffs within the meaning of Directive 90/167/EEC; (EU Council Directive 93/74/EEC, article 2)*

**Feed materials:** Products of vegetable or animal origin, whose principal purpose is to meet animals' nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of pre-mixtures. (EC) No 767/2009, Article 2

**Food (foodstuff):** Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. (EU REGULATION (EC) No 178/2002, article 2)

### **Veterinary Medicinal Product**

(a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or

(b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis; ((EU REGULATION (EC) 2001/82/EC (article 1))

## Canada

**Drug:** includes any substance or mixture of substances manufactured, sold or represented for use in:

- a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in man or animal;
- b) restoring, correcting or modifying organic functions in man or animal; or
- c) disinfection in premises in which food is manufactured, prepared or kept."

Vitamins, minerals, and other nutrients in injectable and bolus dosage forms for use in animals are also considered to be drugs. (Food and Drugs Act (1985))

**Feed:** Any substance or mixture of substances containing amino acids, anti-oxidants, carbohydrates, condiments, enzymes, fats, minerals, non-protein nitrogen products, proteins or vitamins, or pelletizing, coloring, foaming or flavoring agents and any other substance manufactured, sold or represented for use:

- (a) for consumption by livestock,
- (b) for providing the nutritional requirements of livestock, or
- (c) for the purpose of preventing or correcting nutritional disorders of livestock; or any substance for use in any such substance or mixture of substances (Feeds Act 1985)

**Novel feed:** A feed, comprising an organism or organisms, or parts or products thereof, that

- (a) is not set out in Schedule IV or V, or
- (b) has a novel trait. (Feeds Regulations 1983)

**Novel trait:** A characteristic of the feed that:

- (a) has been intentionally selected, created or introduced into the feed through a specific genetic change, and
- (b) based on valid scientific rationale, is not substantially equivalent, in terms of its specific use and safety both for the environment and for human and animal health, to any characteristic of a similar feed that is set out in Schedule IV or V. (Feeds Regulations 1983)

**Single ingredient feed:** means any substance or mixture of substances that is assessed or evaluated as being acceptable for use in feeds and that is described in an item of Schedule IV or V; (Feeds Regulations 1983)

## United States of America

**Animal feed:** An article intended for use for food for animals other than man and that is intended for use as a substantial source of nutrients in the diet of the animal and is not limited to a mixture intended to be the sole ration of the animal. (FFDCA, 201 (w))

**Drug:** means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). (FFDCA 201(g)(1))

"Other than food" articles have been interpreted by the courts as an article that provides taste, aroma, and/or nutritive value. Claims on animal feed labels are limited to those that can be attributed to the taste, aroma, or nutritive value of the food. Claims that indicate that a product can be used to diagnose, cure, mitigate, treat or prevent disease, or alter the structure or

function of the body, in a manner or extent that exceeds its nutritive value, are not permitted on animal feed labels. For animals, the Food and Drug Administration Center for Veterinary Medicine (CVM) regulates two classes of products: food or drugs. Depending on the intended use, an animal food supplement product is considered either a food or drug. There is no separate category for "supplements" for animals. Depending on the stated intended use, a product is either a food or drug.

**Feed:** Edible material(s) which are consumed by animals and contribute energy and/or nutrients to the animal's diet. (Usually refers to animals rather than man.) AAFCO Feed Inspector's Manual 2000

**Food:** (1) Articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. (FFDCA, 201(f))

**Food additive:** Any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include:

- (1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or
- (2) a pesticide chemical; or
- (3) a colour additive; or
- (4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act [enacted Sept. 6, 1958], the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following);
- (5) a new animal drug; or
- (6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement. (FFDCA, 201(s))

**Nutrient:** A feed constituent in a form and at a level that will help support the life of an animal. The chief classes of feed nutrients are proteins, fats, carbohydrates, minerals and vitamins. (AAFCO Feed Inspector's Manual 2000)

## APPENDIX 2 - Defining Efficacy and Claims

**EU Feed Claims:** The labelling and the presentation of feed materials and compound feed may draw particular attention to the presence or the absence of a substance in the feed, to a specific nutritional characteristic or process or to a specific function related to any of these, provided that the following conditions are met: (a) the claim is objective, verifiable by the competent authorities and understandable by the user of the feed, and (b) the person responsible for the labelling provides on request of the authority responsible for carrying out official controls a scientific substantiation by generally accepted scientific evidence of the truthfulness of the claim, either via publicly available scientific evidence or through documented company research. The scientific substantiation shall be available at the time the feed is placed on the market. In the case where the authority responsible for carrying out official controls has doubts in respect of existence of sufficient scientific substantiation of the claim concerned, it may submit the issue to the Commission. The Commission may adopt a decision, where appropriate after obtaining an opinion from the Authority, according to the procedure laid down in Article 29(2) (REGULATION (EC) No 767/2009)

**USA Claim:** A claim says something about the advertised drug or what it does. Claims usually relate to benefits. (“Drug Advertising: A Glossary of Terms” FDA)

**Codex Claim:** is any representation which states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality. (Codex Alimentarius Commission, 1997 - CAC/GL 1-1979)

**Codex Food health claim:** is any representation on labelling or advertising that states, suggests or implies that a relationship exists between consumption of a food or an ingredient and a person's health (Codex Alimentarius Commission, 1997). *Also cited by Health Canada*

**Codex Nutrition claim:** means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. (Codex Alimentarius Commission, 1997 - CAC/GL 1-1979)

**Efficacy:** The capacity to produce a desired effect. (The American Heritage Dictionary of the English Language, 4th edition, 2006)

**Efficacy:** The extent to which a specific intervention, procedure, regimen, or service produces a beneficial result under ideal conditions. (Stedman's Medical Dictionary 2006)

### **APPENDIX 3 – The Health Canada Veterinary Drugs Directorate Low Risk Veterinary Health Products (LRVHP) Program**

The LRVHP is a program that allows the option for low risk veterinary products for non-food animals to obtain a temporary (1 year) notification number rather than obtain a Notice of Compliance and Drug Identification number (DIN) through the usual regulatory process. While initially intended for companion animal products, the LRVHP provides a framework that may be considered for food animal products and clearly establishes a Canadian precedent to regulate low risk products in a proportionate risk based manner.

The notification process is administered by the North American Compendiums (NAC), which operates independently of Health Canada. The NAC is responsible for processing notification applications, ensuring products meet the conditions specified by Health Canada, and issuing the product a Notification Number (NN). All products with an NN are added to the Notified Product List, which is made available to the public. Once this process occurs, Health Canada may take action if the product is not compliant with the requirements of the INP, is found to be unsafe, or, has a misleading label.

LRVHPs are only permitted to contain admissible substances that are found on the List of Substances. These include (but are not limited to) homeopathic medicines, botanicals, vitamins, minerals, fungi and bacteria. This list was developed by Health Canada and is updated periodically. 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. These conditions may include route of administration, target species, or, contraindications.

A list of non-admissible substances that that present an unacceptable health risk, and/or, require a higher level of oversight during administration is also provided and must be complied with. In order for a product to receive an NN, the following eligibility requirements must be met, in addition to the requirements described above:

1. Sufficient evidence demonstrating safety of the product
2. Sufficient evidence to support product efficacy when used as intended
3. Product label is consistent with the information provided in the Notification Form with respect to health claims and conditions of admissible substances
4. No specified risk materials (SRM) can be used during the manufacturing or processing of the product
5. Claims are limited to general health claims. Specific therapeutic claims (claims to diagnose, prevent, cure or treat a disease or abnormal physiological condition) are not allowed.

Once an NN is received, a post-market surveillance program must be established and adverse events recorded and reported to the NAC. The adverse event report must be submitted to the NAC when the notification is being renewed (on a yearly basis). GMP requirements for manufacturing practices and quality control systems are similar to those for human natural health products (NHPs).

## **APPENDIX 4 – Recap of Recommendations**

**Recommendation 1-** *Maintain the definition of “feed” as contained in the Feeds Act.*

**Recommendation 2-** *Using the current feed definition as cited in recommendation 1, it is recommended that additional emphasis and a revised interpretation be applied as follows:*

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