



Health Santé
Canada Canada



Canadian Food Inspection Agency
Agence canadienne
d'inspection des aliments

Guidance document on classification of veterinary drugs and livestock feeds

Published by authority of the Minister of Health and the Minister of Agriculture and Agri-Food

**Veterinary Drugs Directorate
Health Products and Food Branch
Health Canada
&
Animal Feed Division
Animal Health Directorate
Canadian Food Inspection Agency**

<p>Our mission is to help the people of Canada maintain and improve their health.</p> <p style="text-align: right;"><i>Health Canada</i></p>	<p>Our mission is to be dedicated to safeguarding food, animals and plants, which enhances the health and well-being of Canada's people, environment and economy.</p> <p style="text-align: right;"><i>Canadian Food Inspection Agency</i></p>
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Foreword

Guidance documents are meant to provide assistance on *how* to comply with the policies and governing statutes and regulations. They also serve to provide review and compliance guidance to government employees, thereby assuring that mandates are implemented in a fair, consistent and effective manner.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document *may be* acceptable provided they are supported by adequate scientific justification. Alternate approaches should be discussed in advance with the relevant program area to ensure that applicable statutory or regulatory requirements have been met.

As a corollary to the above, it is equally important to note that Health Canada and the Canadian Food Inspection Agency (CFIA) reserve the right to request information or material, or define conditions not specifically described in this guidance, in order to allow for the adequate assessment of the safety, efficacy or quality of a product. Both Health Canada and the CFIA are committed to making sure that such requests are justifiable and that decisions are clearly documented.

This Guidance document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidelines and applicable regulations.

This Guidance document is dynamic in nature, and is offered without prejudice to future measures, which Health Canada and the CFIA might take in this area. Persons using the information in this document do so at their own risk and responsibility and are liable for their use of and any reliance on the information contained in it and any loss or damage resulting there from.

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1. Introduction

1.1 Background

In Canada, products consumed by livestock species are largely regulated as either veterinary drugs or livestock feeds.

Veterinary drugs (henceforth referred to as drugs) are regulated under the *Food and Drugs Act* and *Regulations* by Health Canada. Within Health Canada, the Veterinary Drugs Directorate (VDD) has the mandate to evaluate and monitor the safety, quality and effectiveness, to set standards and to promote the prudent use of veterinary drugs, including veterinary natural health products, administered to food-producing and companion animals. The VDD's classification of a product is guided by the requirements of the *Food and Drugs Act* and *Regulations*.

Livestock feeds (henceforth referred to as feeds) are regulated under the *Feeds Act* and *Regulations*, which are administered by the Canadian Food Inspection Agency (CFIA). The CFIA verifies that livestock feeds manufactured and sold in Canada or imported are safe, effective and are labelled appropriately. Effective feeds contribute to the production and maintenance of healthy livestock.

1.2 Definitions

Pursuant to the *Food and Drugs Act*, a “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 physiological state, or its symptoms in human beings or animals,
- (b) restoring, correcting or modifying organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept.

Pursuant to the *Feeds Act*, a “feed” is defined as any substance or mixture of substances containing amino acids, antioxidants, carbohydrates, condiments, enzymes, fats, minerals, non-protein nitrogen products, proteins or vitamins, or pelletizing, colouring, foaming or flavouring agents and any other substance manufactured, sold or represented for use:

- (i) for consumption by livestock;
- (ii) for providing the nutritional requirements of livestock, or;
- (iii) for the purpose of preventing or correcting nutritional disorders* of livestock,

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

*A definition and interpretation of a nutritional disorder can be found in Appendix A.

1.3 Context

The overlap of the definitions for these two types of products creates a challenge whereby nutritional and non-nutritional products may be classified as either a drug and a feed, or both. In the past, difficulties associated with the interpretation of the drug and feed definitions have resulted in significant confusion, which led to inefficiencies regarding product evaluation and approval, as well as compliance and enforcement activities. Therefore, there is a need for a clear and transparent classification process for some products intended for use in livestock species.

1.4 Purpose & objectives

The purpose of this guidance document is to present guidelines and criteria for classification in order to clarify the differences between drugs and feeds, and to assist in determining the appropriate regulatory oversight for a product destined for use in livestock species. The pursued objectives are:

- a) to improve the transparency of the classification process, to increase the consistency in decisions by regulators, and make these more predictable to stakeholders;
- b) to resolve industry confusion and to provide better guidance to manufacturers of such products regarding the appropriate regulatory department, submissions and processes for a product approval.

2. Scope & application

2.1 Scope

The classification approach presented in this document applies to a broad range of products, intended for oral consumption **only** and for livestock species (dairy and beef cattle, sheep, fish, goats, chickens, turkeys, ducks, geese, rabbits, horses and swine) **only**, and in most types of animal production (for ex., dairy cattle *vs.* beef cattle, broilers chickens *vs.* laying hens). In some situations, products may neither fit a drug nor a feed classification. Such products may be classified (and therefore regulated) as veterinary biologics, veterinary medical devices, disinfectants, pest control products or consumer products. Please note that these types of products are beyond the scope of this guidance and will not be further discussed in this document. Medicated feeds have a clear regulatory definition and are also excluded from the scope of the classification guidance.

2.2 Application

This guidance document is applicable to products (drugs and feeds) that are subject to the pre-market evaluation process (new) and to the existing products currently sold on the Canadian market (authorized for sale). The present document is intended to be used in conjunction with other regulatory tools from Health Canada and CFIA, such as feed schedules, policies, guidelines, regulations, etc.

3. Guiding principles

For a product classification to be consistent with both regulatory mandates, the following general principles will be applied:

1. The primary consideration will be the respect of the definitions of a drug in the *Food and Drugs Act* and of a feed in the *Feeds Act*. Guidance will be consistent with the objectives of Health Canada and CFIA and their respective regulatory frameworks, including public health and safety.
2. Classification decisions from other international veterinary regulatory authorities will be considered during the classification process.
3. The potential risk to health from an ingredient or a product is generally not a factor for classification – it is taken into consideration during assessment of the product’s safety (AFTER the product has been classified). The regulatory frameworks under the drug and feed legislations provide a tier of controls to mitigate the risks posed by a product. If these risks are considered unacceptable, it will result in the product not being permitted for sale, regardless of its classification.
4. **The determination of a drug or feed classification can result from the consideration of only one of the most pertinent classification criterion listed below, but generally requires the consideration of multiple criteria taken together as a whole.**
5. Depending on the product, some criteria may not be given equal weight in support of a classification decision.
6. Some products may be considered both nutritional and therapeutic, based on differences in ingredients concentrations, dosage recommendations/inclusion rates or other factors.

Based on a complete assessment of each of the criteria identified below, the differences between drugs and feeds can be identified to facilitate a regulatory classification. Please see the document *Drug/Feed classification flowchart* (shown in appendix B) for a step-by-step approach to the

classification process.

4. Classification criteria

4.1 Route of administration

The fact that a substance or a product is administered in feed or in water does **not** have a significant impact on the regulatory classification of a product.

4.2 Mode of administration

4.2.1 Final product form

The product form refers to the final form in which a substance or product is available and ready for use/administration, without requiring any further manufacturing. Common product forms for therapeutic products (or “dosage” forms) include tablets, capsules, boluses, aerosols or inhalers, creams, lotions, solutions or suspensions and implants.

The form of a product is usually dependent on the route of administration of the substance in question. Most products in dosage form are considered drugs, with some exceptions, depending on other criteria (for ex., purpose, label). Products in forms that can be consumed in a voluntary manner, such as mash, liquid, pellets, flakes, free choice blocks, etc., are typically (but not exclusively) classified as feeds.

4.2.2 Forceable administration

Generally, products for forceable administration (administered orally but via gavages or drenches) are considered drugs. However, some pastes, pumps and non-injectable syringes that are:

- (1) labelled for inclusion into feeds, and
- (2) for which no drug claim is made,

are regulated as feeds under the *Feeds Act* and *Regulations*. All products must indicate physical form in their product name (for ex., paste) in order to be considered feeds.

All other products for forceable administration will continue to be regulated as drugs.

4.3 Known medicinal ingredients

Some ingredients are inherently medicinal or therapeutic in nature, either due to their characteristics, their function (activity) and effect(s) on the organism or their purpose in the formulation. For example, some substances like penicillin, neomycin, or plant extracts like digitalin or digoxin have an intrinsic therapeutic function or activity. This knowledge is usually derived from scientific literature or reference textbooks. In the case of a multiple-ingredient product, if one or more ingredients in its composition have a therapeutic nature or effect, the product would be considered a drug. Also, some herbal ingredients have a generally recognized therapeutic use and no recorded nutritional use. These types of herbal ingredients are considered medicinal ingredients and classified as drugs.

To help identify ingredients currently considered as medicinal (therapeutic), please refer to Appendix C for a definition and an alphabetical listing of known medicinal ingredients.

4.4 Representation/Intended purpose

Key considerations for the classification of a product are its representation (1) and intended purpose (2):

1. The representation associated with a product include indications for use (they may be explicit or implied), health claims presented as a word, sentence, a picture, a symbol, a paragraph or an implication on product labels, package inserts or advertisements (including information available on the Internet), as well as its intended purpose and history of use.
2. The intended purpose of a product is the **desired effect** to be achieved by the administration of this product to a particular animal species during a particular situation, or under specific conditions (for ex., health or disease states, nutritional needs). The activity or properties of the ingredient(s) present in a product are also considered to provide information on the product's intended (desired) effect.

Together, these product characteristics are used to create a clear picture of what the product is and does. While the “representation for use” criterion would not be considered the only basis for a classification decision, it may be taken into account and influence the final decision because of its impact on the purpose of the product. Therefore, an indication/claim present on a product label or in the advertising material is an important **but not determining** factor to be considered for product classification.

However, indications (or claims) present on a product, whether they are supportable or not, will be determinants for the submission of an application to the appropriate regulatory body. For the classification of products in the “grey zone” between drugs and feeds, applications should be submitted to VDD as a single-window contact for classification.

Notes on advertising:

In classifying products, VDD and CFIA's Animal Feed Division (AFD) may also look to how the product is advertised or promoted. Although web sites alone are not extensions of the label of a product, claims made in the media, including those made on web sites of various stakeholders or social media, may be considered evidence of the intended purpose of the product for classification purposes.

4.4.1 Therapeutic indications (claims)/purposes

Therapeutic claims, indications or purposes refer to the treatment of a disease, disorder or abnormal physical state; or treatment, mitigation of its symptoms; or the modification of an organic function (such as digestion). Therapeutic claims can only be made for products which have a therapeutic purpose or intent of use (drugs), and are therefore not suitable for feeds. Examples of therapeutic (or drug) claims are:

- Treatment claims (treatment of a disease (acetonemia), a condition (intoxication) or abnormal state (wounds, oedema) or its symptoms (diarrhea));
- Control claims (control intestinal parasites, control breeding);
- Prevention claims (prevent mastitis, prevent acetonemia, prevent bloat, prevent coccidiosis), **excluding prevention of nutritional deficiency claims**;
- Mitigation claims (reduce severity of pneumonia, relief pain associated with colic, relief of inflammation, decrease incidence of laminitis, reduction of early mortality);
- Animal Performance claims (production claims) **not** supported by a nutritional purpose or mode of action (stimulate egg production, increase litter size).

***Note:** This list of acceptable indications for drugs is not exhaustive and others indications or claims not acceptable for feeds would require further assessment for classification.*

4.4.2 Nutritional indications (claims)/purposes

Feeds are not intended to have any therapeutic purpose or activity. Products with such purposes are not considered feeds but are considered drugs. Feed products are typically fed for a reasonable amount of time as part of a balanced feeding program with the intent of meeting the nutritional requirements necessary for maintenance, growth and production of livestock. They can also include non-nutritive products such as flavours, pellet binders, preservatives, anti-caking agents and other products that facilitate the manufacture, storage or palatability of feeds. Feeds are also known to be vehicles (carriers) for delivery of therapeutic products such as medicated feeds.

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 supporting growth, maintenance and production in livestock species. An intended purpose that

states suggests or implies that the consumption of a specific nutrient or nutritive substance significantly reduces the incidence or prevents the development of a nutritional disease; disorder or deficiency in a healthy animal may also be acceptable in this category of claims. Examples of nutritional claims that would be acceptable for feeds include:

- Nutritional disorder* prevention claims excluding disease prevention (prevention of “white muscle disease” in cattle due to selenium deficiency; prevention of anemia due to iron deficiency in neonatal piglets, prevention of scoliosis due to vitamin C deficiency in salmonid fish); *More information on nutritional disorders can be found in Appendix A.
- Animal performance (Production) claims within a nutritional context (increased milk production from feeding a by-pass; amino acid (compared to unprotected source of the same nutrient));
- Increased nutrient bioavailability (organic complex minerals claiming increased bioavailability compared to a certain inorganic source; enzymes such as phytases to increase available phosphorus).

Feeds can also be non-nutritive for the following purposes or claims:

- Nutrient preservation (for ex., forage additives, mould inhibitors, feed antioxidants) not supported by a therapeutic purpose or mode of action (please see section 4.7 on Mode of Action);
- Facilitating agents intended to aid or improve the manufacturing or handling properties of a feed (for ex., pelleting aid, anti-caking agents, carriers, etc.) not supported by a therapeutic purpose or mode of action;
- Colouring agents to colour the feed or tissues/eggs of livestock;
- Flavouring agents to flavour feeds.

Note: Products making nutritional claims on their label will require registration with CFIA prior to import, manufacture and sale in Canada. These types of claims would be permitted for feeds provided that they are supported by adequate scientific evidence that has been assessed and approved by the CFIA’s Animal Feed Division (AFD).

4.5 Composition

Although the composition of a product alone does not necessarily determine its classification, the presence of an ingredient, or its level, may aid in determining the correct regulatory classification of that product.

4.5.1 Type of ingredients

The components of a product or its ingredients are assessed to determine the activity or purpose of

that product. The nature of each ingredient, its intrinsic characteristics, its physical and chemical properties, the degree of modification (for ex., compound, extract, isolate) and its associated function(s) and role(s) in the product are investigated in detail to provide evidence to support the intended use of a product.

4.5.2 Concentration (or level) of ingredients

The concentration, strength or level of ingredients may be useful in determining its particular role in the formulation and the intent (or purpose) of the ingredient in the product as a whole. An ingredient may have a particular function until it reaches a certain threshold or concentration, at which point it has a pharmacological or therapeutic effect (for ex., propylene glycol 1% or less = inactive ingredient vs. propylene glycol 50% or 100% = active ingredient).

Also, a nutritional ingredient such as a vitamin or a mineral can have a therapeutic effect at a higher amount, based on the concentration in the product and dosage recommendations (for ex., calcium, iron, copper, zinc, vitamin A, vitamin C, some plants and plant oils, etc.).

4.6 Directions for use

4.6.1 Dosage recommendations/Feeding rates

The recommended dosage or rate of administration of a product may assist in identifying the therapeutic or nutritional purpose of that product. For example, a very specific dosage regimen may suggest a therapeutic purpose or intended effect for a product.

The inclusion rates or dosage recommendations can sometimes be considered for classification of products as drugs, particularly for vitamin, mineral or electrolyte products. For feed products, the feeding rate is used to determine if the final amount of an ingredient or nutrient received by a particular species is within or higher than regulatory standards (for ex., supplementation levels recommended by NRC, Table 4 maximums, maximum limits prescribed in Schedule IV and V of the *Feeds Regulations*, etc.).

4.6.2 Duration of treatment/feeding & timing of administration

The duration of treatment and timing of administration criteria do not automatically lead to a drug or feed classification.

These specifics of directions for use are usually not a useful or relevant consideration for the classification of a product as a drug. They are quite varied for drug products since they are closely associated with the animal species and the disease (or condition) for which the drugs are indicated.

In general, products considered as feeds are part of a balanced feeding program and have to be fed for a reasonable period of time, on a continuous basis. The duration of mineral or vitamin supplementation may vary according to specific physiological periods in the production life of animals. For example, a nutritional product to be fed to dairy cattle in lactation or during gestation, or a mineral product fed during the first days of life for piglets, would be consistent with a feed supplementation regime.

4.7 Mode of action

In biological terms, a mode of action (MoA) refers to the mechanism or the manner in which an action, effect or result is obtained in an organism. The MoA and its effect are often related to the chemical structure of an ingredient or substance. A substance usually exhibits its action through an interaction between that substance and a cellular constituent, usually referred as a receptor, which results in a direct response, or which blocks the response to another agent. There are many specific receptor site(s) or enzyme(s) in a body that can trigger a biological response to a substance.

4.7.1 Therapeutic modes of action

A therapeutic mode of action is the specific biochemical interaction through which an ingredient (or combination of ingredients) produces a pharmacological effect. For example, acetyl salicylic acid (chemical substance) produces an irreversible inhibition of the enzyme cyclooxygenase (MoA), which suppresses the production of prostaglandins and thromboxanes (physiological effect), thereby reducing pain and inflammation (therapeutic effect).

Similarly to a pharmacological action, immunological and metabolic actions are also considered to be biochemical interactions leading to a particular biological response. An immunological action is an action in or on the body by stimulation and/ or mobilisation of cells and/or products from the immune system. A metabolic action is an action that involves an alteration, including stopping, starting or changing the speed of the normal chemical processes participating in, and available for, normal body functions (for ex., a partitioning agent for growth promotion).

When an ingredient or a product has an action that restores, changes or affects the physiological function(s) of an animal beyond the generally recognized physiological effects of nutrition, this action falls within the definition of a drug as per the *Food and Drugs Act* and is considered to be therapeutic.

Modes of action consistent with drugs:

- Indirect mechanism to stimulate appetite (stimulation of the CNS);
- Mode of action in **both** feed and animals (antifungal substance added at a high concentration in feeds, for prevention of moulds in the feed and mycotoxicosis in cattle);
- Any mode of action inside the animal, not related to the digestive process;
- Specific internal mechanism of action, such as:
 - i) modification of cells or cellular functions;
(for ex., insulin stimulate cells to absorb blood glucose)
 - ii) modification of a protein, enzyme, amino-acid, or its activity;
 - iii) modification of an organ or its activity;
(for ex., decrease size of thyroid or decrease its activity)
 - iv) modification, elimination or blocking of a metabolic pathway;
- Bio-regulation mechanisms (bio-feedback) which controls expression and/or modification of some biological components;
- Artificial stimulation of the non-specific (innate) immune system:
 - 1) Recognition phase:
 - i) production of an increase number of immunological cells or proteins;
 - ii) activation of the complement reactions;
 - 2) Elimination phase:
 - i) increased phagocytic activity of immunological cells;
 - ii) increased cytotoxic activity of immunological cells;
 - ii) increase in cellular migration and in the inflammatory reaction;

Excluding the mechanisms resulting in the development of an adaptative or acquired immunity (an immunological response or the modulation of an immune response to an infectious agent) in animals, which are associated with the **veterinary biologics** (for ex., vaccines and antibody products, including adjuvants).

- Action on the intestinal flora (substance/product not absorbed by the body and acting directly within the intestinal lumen) that may have some prophylactic/therapeutic effect.

Note: This list of acceptable modes of action for drugs is not exhaustive. Other modes of actions would require a description and further assessment for classification.

4.7.2 Nutritional modes of action

A nutritional mode of action could be defined as a process where recognized nutrients** (when supplied at required levels), are digested/absorbed by the animal to maintain physiological functions, resulting in minor differences in biological activity and without a significant and lasting change or

modification on the cellular, tissue, organic and metabolic reactions of the body. This process usually results in established and recognized physiological rates of growth, maintenance and/or production characteristics for healthy livestock species.

** In the context of feeds, a **nutrient** can be defined as any substance that can be metabolized by an animal to give energy and build or maintain tissue to meet scientifically supported nutrient requirements. There are six types of nutrients: minerals, vitamins, fats, protein, carbohydrates and water.

Modes of action consistent with feeds:

- Action directly in the feed itself, before consumption, to improve or conserve the nutrient content of the feed, to aid or improve in the manufacturing or handling of the feed and to change the colour or smell of feeds (for ex., pellet binders, flow agents, colouring agents, flavouring agents, mould inhibitors, mycotoxin binders);
- Action limited to the normal digestive process of feeds (for ex., absorption of mineral and vitamins through the intestinal mucosa, improve digestibility and bioavailability of nutrients).

Note: This list of acceptable mechanisms of action for feeds is not exhaustive.

The MoA criterion may not always be a definitive one and should be evaluated in conjunction with other criteria such as the physiological particulars of the intended species (for ex., ruminants vs. non-ruminants), intent of use and concentrations of ingredients, before a final classification decision can be reached.

5. Classification decision process

The Veterinary Drug Directorate (VDD) and the Animal Feed Division (AFD) of CFIA encourage sponsors to initiate the classification process of their products by using the present guidance document, flowchart and other appendices. After self-assessing that a product would be classified as a drug, they can contact the VDD for information on submission requirements. The Veterinary Drugs section [www.hc-sc.gc.ca/dhp-mps/vet/index-eng.php] of Health Canada's website can also be consulted for additional information.

Once a product is determined to be a feed, they can proceed to submit a registration application to the AFD. Information on the registration process is available in the Regulatory Guidance [<http://www.inspection.gc.ca/animals/feeds/regulatory-guidance/rg-1/eng/1329109265932/1329109385432>] section of CFIA's website.

If classification questions remain or issues arise after the review of this guidance, sponsors should

contact VDD, as a single-window access for classification. VDD will collaborate with the AFD for information sharing and discussion to reach a joint classification decision. The applicant will be informed in writing of the final decision concerning the regulatory classification of a product. Drug decisions will be communicated by VDD; feed decisions will be communicated by AFD.

A classification template has been developed to facilitate the organization and presentation by the industry of the necessary information for an accurate product classification. This template is shown in Appendix D. To obtain an electronic version of the template, please contact VDD.

Classification requests from industry should include a cover letter, the completed template and the related supporting documentation. All classification requests should be submitted in writing (mail, e-mail or fax) to VDD at the coordinates below:

Veterinary Drugs Directorate
Health Canada
11 Holland Avenue, Suite 14
Ottawa, ON K1A 0K9
Address Locator: 3000A
Fax: 613-957-3861
Tel: 613-954-5687
e-mail: classification-vet@hc-sc.gc.ca

Any classification reconsideration request should be submitted in writing to VDD at the above address and be accompanied with a valid scientific rationale, as well as the appropriate supportive documentation. VDD will consult with AFD as needed.

6. Implementation

This guidance document will come into effect as of the online publication date. The publication, coordination and implementation of this guidance document of understanding will be the joint responsibility of Health Canada's VDD and the CFIA's AFD. For questions or additional information on the content of this document, please contact VDD.

Appendix A

Nutritional disorders

1. Definitions:

- **Disease:** An impairment of the normal state of the living animal or plant body or one of its parts that interrupts or modifies the performance of the vital functions, which is typically manifested by distinguishing signs and symptoms, and is a response to environmental factors (as malnutrition, industrial hazards, or climate), to specific infective agents (as worms, bacteria, toxins, or viruses), to inherent defects of the organism (as genetic anomalies), or to combinations of these factors.

(Reference: Merriam –Webster Medical Dictionary)

In short, a disease refers to damage to an **organ, part, structure, or system** of the body such that it does not function properly or a state of health leading to such dysfunction.

Examples: heart disease, diabetes, bile duct obstruction.

- **Nutrient:** As defined under section 4.7.2 “*Nutritional modes of action*” (second paragraph), a nutrient can be defined as any substance that can be metabolized by an animal to give energy and build or maintain tissue to meet scientifically recognized nutrient requirements. There are six types of nutrients: minerals, vitamins, fats, protein, carbohydrates and water.
- **Nutritional disorder:** Any disorder in animals that is directly or indirectly caused by a lack of nutrients or a nutritional imbalance in the diet.

Metabolic disorders and multifactorial disorders in which nutrition plays an important role are **not** considered to be nutritional disorders. Examples of such conditions are: post-parturient hypocalcemia (milk fever); acetonemia (ketosis) or pregnancy toxemia; metabolic acidosis; laminitis; abomasal displacement; enterotoxemia; urolithiasis (urinary calculi).

- **Tonic (or conditioner):** As defined under Subsection 2. (1) Interpretation of the *Feeds Regulations 1983*, a tonic or conditioner means a mineral feed formulated and represented for the correction of a specified nutrient deficiency or to aid recovery from a specified nutrient deficiency and is for use only while the condition persists (for ex., single-ingredient product of magnesium, or zinc).

2. Criteria:

- **Criteria for a nutritional disorder:**
 1. Presence of deficiency, excess or imbalance of a specific nutrient in the diet;
 2. Cause/effect relationship between clinical signs of disorder and absence of nutrient in the diet;
 3. Diet supplementation prevents and/or resolves the condition

All criteria need to be met for a condition to be considered a nutritional disorder.

- **Criteria Feed vs. Drug:**

Feed	Drug
Diet deficiency	Abnormal requirement from animal (deficiency due to disease state)
Interference between nutrients in diet	Lack of absorption from the body (due to disease state)
Physiological (normal) increase in animal requirements (for ex., parturition, lactation, sweating, etc.)	Abnormal requirement from animal (secondary to disease) (for ex., dehydration following diarrhea, bicarbonate in the presence of metabolic acidosis)
Relevant species (species with recognized nutritional need)	Species with no recognized deficiency or dietary requirement
Ingredients from approved and recognized feed source of vitamin/mineral	New source may have other properties or purposes
Scientific data supporting a nutritional purpose for a specific nutrient	Scientific data supporting a therapeutic (drug) purpose for a specific nutrient

If one of the above drug criteria is met, the ingredient or product would be excluded from a feed classification and considered a drug.

Any treatment claim or therapeutic indication associated with these nutritional conditions (diseases) would result in the product being classified as a drug. Prevention/correction claims would be acceptable for feeds under the following situations:

- a) Prevention:
 - i) when it is intended to meet nutritional requirements, and
 - ii) when it is intended to prevent a nutritional disorder caused by a deficiency in one specific nutrient, by a modification of the diet.

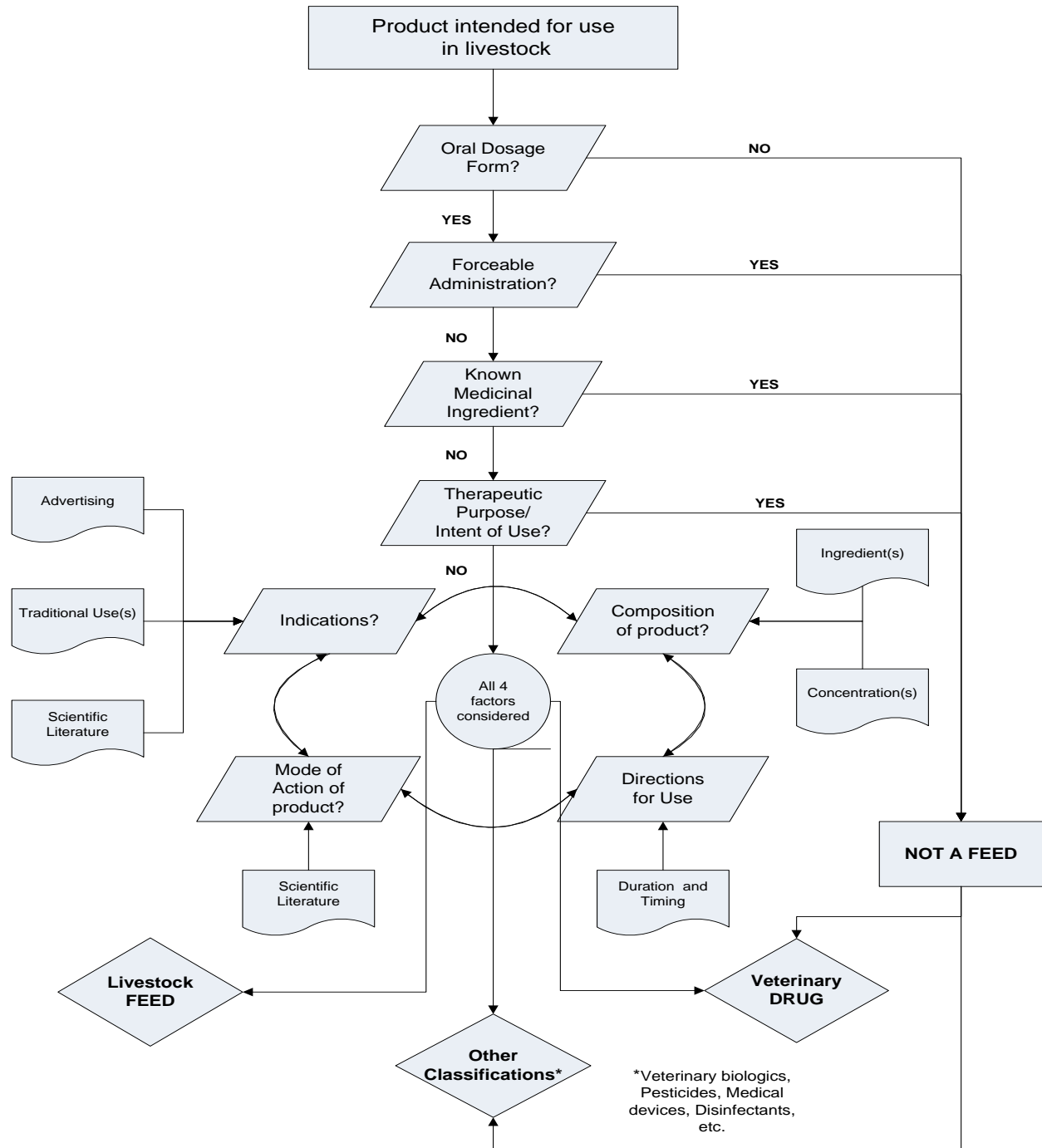
- b) Correction: when referring to the correction of a specific nutritional disorder caused by a deficiency in one specific nutrient, by modification of the diet.

- c) Approved nutritional sources are used for nutrient supplementation (for ex., Schedule IV of the *Feeds Regulations*)

Note: Products making such claims on their label will require registration with CFIA prior to import, manufacture and sale in Canada.

Appendix B

Drug/Feed classification flowchart



Appendix C

Known medicinal ingredients

1. Introduction

A known medicinal ingredient is a substance, part of a substance or a combination of substances associated with a therapeutic (medicinal) property or pharmacological effect. Based on a large number of classification requests, VDD and AFD have established a list of substances which have been classified as medicinal ingredients. These classifications were made based on the scientific knowledge current at the time of the request and related to the indications proposed by the sponsor. However, some medicinal ingredients may also have a non-medicinal purpose, depending of the concentration (level) or other factors. For your information, the list contains these “exceptions”, which are ingredients listed on the Feeds Schedules IV and V in the *Feed Regulations* and used in feeds for non-medicinal purposes.

Important notes:

- 1) The following list has been developed only for the purpose of this document, in order to facilitate product classification. It should not be considered as an exhaustive and complete list. However, it is our commitment to update/revise it on a regular basis.*
- 2) Classifications associated with proprietary information have not been included in this list.*
- 3) If a substance is not present in the list below, and you wish to ascertain the classification of this substance, the template shown in Appendix D can be submitted to VDD for classification purposes. For any questions, comments or additional guidance, please contact VDD.*

2. List of substances currently classified as medicinal ingredients

(in alphabetical order)

Name of medicinal ingredient	Synonym(s)	Exception(s) (as approved feed ingredients)
A		
<i>Achillea millefolium</i> (whole plant)	Yarrow, Wound wort	
Activated charcoal		
Adenosine-5-monophosphate	5-adenylic acid	
<i>Aloe vera</i> (whole plant)		
Alpha-galactosidase		
Arabinogalactan		
<i>Arctium lappa</i> (whole plant, leaf, except fruit extract (antioxidant))	Burdock	

Name of medicinal ingredient	Synonym(s)	Exception(s) (as approved feed ingredients)
Attapulgate ^{a,b} (a: treatment of non-infectious diarrhea in calves) (b: 25,8 mg/kg BW and more)		<i>Schedule IV, part I, item 8.118</i> Anticaking agent: max 0.25% finished feed Emulsifier: max 2.5% of a liquid feed supplement
Arsenical		
B		
Belladone (homeopathic substance)	<i>Atropa belladonna,</i> <i>deadly nightshade</i>	
Bentonite ^{a, b} (a: prevention or treatment of diarrhea) (b: approx 400 mg/ml and more)	Montmorillonite	<i>Schedule IV, part I, items 8.5, 8.6, and 8.89</i> Anticaking agent or pelleting aid: max. 2% total diet
Bituminosulphonates		
<i>Borage oil</i>	<i>Borago officinalis</i> seed oil	
<i>Boswellia serrata</i>	Boswellia	
Bromelain		
C		
Calcium glucoheptonate		
Calcium levulinate		
Calcium pidolate		
Calcium salts, when sold for the treatment of hyperphosphatemia		
<i>Calendula officinalis</i> (whole plant)	Pot marigold	
Carnitine, salts and derivatives	L-carnitine, Levocarnitine	L-carnitine: <i>Schedule IV, part I, item 5.6.16</i> Swine feeds: as an amino acid, max. 0.1% total ration
<i>Carya basilike</i>	Black walnut hull powder, <i>Juglans nigra</i> powder	
<i>Centella asiatica,</i> (whole plant, extract and active principles thereof)		
Cetyl myristoleate	Myristoleic acid (cetyl ester of)	

Name of medicinal ingredient	Synonym(s)	Exception(s) (as approved feed ingredients)
Chamazulene	Chamomille extract	
Chondroitin sulfate		
Chromium ^a (for regulation of glycemia)		Chromium yeast dehydrated: <i>Schedule IV, part II, item 6.38</i> Approved as a source of chromium for first lactation dairy cows at a level not to exceed 0.4 mg/kg chromium in the complete feed. Chromium proprionate: <i>Schedule IV, part II, item 6.47</i> Approved for growing swine at level not to exceed 0.2 mg/kg of chromium in the complete feed.
Coenzyme Q10		
Copper calcium edetate		
Copper glycinate		
Copper sulfate ^{a, c} (for the treatment of aspergillosis and hexamitiasis in poultry)		<i>Schedule IV, part I, items 6.27 & 6.28</i> Table IV: Maximum allowed in complete swine feeds is 125 ppm of copper.
Cranberry extract ^a , (dry) (prevent urinary tract infections)		
D		
N, N-dimethylglycine.	Dimethylglycine hydrochloride	
E		
<i>Echinacea angustifolia</i>	<i>Echinacea purpurea</i> , American cone flower, Purple cone flower	
<i>Eleutherococcus senticosus</i>	Siberian ginseng, Eleuthero	
Ephedrine hydrochloride		
Epidermal growth factor	EGF	
<i>Equisetum arvense</i>	Horsetail,	
<i>Eucalyptus globulus</i> (whole plant, essential oil)		

Name of medicinal ingredient	Synonym(s)	Exception(s) (as approved feed ingredients)
<i>Eucalyptus polybractea</i>	<i>Blue-leaf mallee</i>	
<i>Eupatorium perfoliatum</i> (whole plant)	Boneset, Feverwort, Thoroughwort	
Ergot alkaloids and their salts	<i>Claviceps purpurea</i>	
<i>Eurycoma longifolia</i>	Malaysian ginseng	
F		
Fenugreek cotyledon		
<i>Filipendula ulmaria</i>	Meadowsweet	
Folic acid ^{a, b} (a: prevention of birth defects in pregnant animals; treatment of pancreatic insufficiency, femoral thrombo-embolism; for use with drugs interfering with folate absorption; for prevention or treatment of enteritis) (b: 50 mcg/g and higher)	Vitamin B9	<i>Schedule IV, part I, item 7.1.10</i> Vitamin
G		
Gamma oryzanol ^a (to stimulate release of testosterone and growth hormone, antioxidant, antacid, stimulate immune system)	Rice bran oil, Rice bran extract, <i>Oryza sativa</i> L.	<i>Schedule IV, Part I, item 4.5.22</i> Rice bran oil Energy feed.
<i>Gingko biloba</i>	Gingko, Maidenhair tree	
Glucosamine hydrochloride		
Glucosamine sulfate		
L-Glutamine ^a (to preserve intestinal mucosa, to help cellular repair)		
Green-lipped mussel	GLM, <i>Perna canaliculus</i>	
H		
<i>Hamamelis virginiana</i> (whole plant, extract)	Hammelis, Witch hazel	
<i>Harpagophytum procumbens</i>	Devil's claw root	

Name of medicinal ingredient	Synonym(s)	Exception(s) (as approved feed ingredients)
Hemp ^a (stalks, seed, oil, which contain below 0.3% THC) (to stimulate immune system, reduce inflammation, etc.) (over 0.3 % THC = controlled substance)	<i>Cannabis sativa</i>	
Hesperidin	Bioflavonoid, Bioflavonoid complex, Bioflavonoid extract, Citrus bioflavonoid	<i>Schedule V, part I, item 14.7.</i> Neohesperidin dihydrochalcone (a derivative of hesperidin) is approved as a flavor ingredient. Not to exceed 100 ppm in the feed.
Humic acids and their sodium salts ^a (immunostimulant, antiviral, antioxidant)	Humate	
Hyaluronic acid		
Hydrogen peroxide		
Hydroxocobalamin (crystalline form)	Vitamin B12a	
I		
Inosine		
J		
<i>Juglans nigra</i> (whole plant)	Black walnut	
K		
Kaolin ^b (more than 2.5 % in product)		<i>Schedule IV, part I, item 8.87</i> Anticaking agent: max. 2.5% of finished feed
L		
Larch arabinogalactan		
<i>Lobelia inflata</i>	Lobelia, Indian tobacco	
M		
Melatonin		
Methylsulfonylmethane	MSM	
Milk Thistle	<i>Silybum marianum</i>	

Name of medicinal ingredient	Synonym(s)	Exception(s) (as approved feed ingredients)
Mineral oil ^b (concentration of 100%)	Heavy mineral oil	<i>Schedule IV, part I, item 8.33</i> Dust control/lubricant: Max. 0.6% in complete diet Max. 3% in mineral premixes and mineral feeds
<i>Morinda citrifolia</i> (whole plant, leaves, root, fruit extract)	Noni plant	
<i>Morus nigra</i>	Black mulberry	
N		
O		
Oregano oil ^b (50 ppm and more in complete feed)		<i>Schedule V, part II, item 15.1</i> Flavouring ingredient: Less than 50 ppm in complete feed
Oxygen (solubilized in oral in oral dosage forms)		
P		
Pancreatic enzymes	Amylase, lipase, protease	
<i>Papaver rhoeas</i>	Red poppy seeds, Corn poppy	
Pau-d' arco	<i>Handroanthus impetiginosus</i> , Red lapacho, Taheebo, Trumpet bush.	
Peppermint oil ^a (to stimulate immune system and control intestinal bacterial overgrowth)	<i>Mentha x piperita</i>	<i>Schedule V, part I, item 16.20</i> Flavouring ingredient: Max. 100 ppm in the complete diet/feed
<i>Peumus boldus</i>	<i>Boldea fragrans</i>	
Potassium bromide		
Propylene glycol ^b (100-130 grams/cow/day around calving)		<i>Schedule IV, part I, item 8.43</i> Emulsifying agent Typical use rates: 0.01-0.02%
Psyllium (whole plant, seed, husk)	<i>Plantago ovata</i>	<i>Schedule IV, part II, item 8.55</i> Psyllium seed husk approved as a dietary source of fibre, not to exceed 2.0% of the total diet.

Name of medicinal ingredient	Synonym(s)	Exception(s) (as approved feed ingredients)
Q		
Quercertin	<i>Elytrigia repens</i> , Quack grass	
Quinine hydrochloride		
Quinine sulfate		
R		
Raspberry Leaves (dry, powder)	Leaves of <i>Rubus idaeus</i>	
<i>Rehmannia glutinosa</i>	Chinese floxglove	
<i>Rumex crispus</i>	Yellow dock	
S		
S-Adenosylmethionine	<i>SAMe</i>	
Saw palmetto (whole plant, liposterolic extract, fruit extract)	<i>Serenoa repens</i>	
Sea buckthorn (whole plant, plant juice, fruit oil)	<i>Hippophae rhamnoides</i>	
Shark cartilage	<i>Squalus acanthias</i>	
Sodium bicarbonate ^a (prevention and treatment of dehydration, metabolic acidosis and other electrolytes imbalances).		<i>Schedule IV, part I, item 6.71</i> Mineral feed: approved source of sodium for livestock feeds; also used as an ingredient in buffer feeds for dairy cows and beef cattle on high grain diets.
Sodium diacetate ^a (to control salmonella in animals)		<i>Schedule IV, part I, item 8.55</i> Used in mould inhibitor products
Sodium hyaluronate		
Sodium salicylate		
Sodium selenite ^a (treatment of muscular dystrophy)		<i>Schedule IV, part I, item 6.77</i> Mineral feed: approved source of selenium. The regulatory maximum is 0.3 mg/kg in the total diet for most livestock; 0.1 mg/kg for fish and rabbits
<i>Solidago virgaurea</i>	Golden Rod	
<i>Spirulina maxima</i> , <i>Spirulina platensis</i> (whole plant)	<i>Arthrospira platensis</i> , Blue- Green algae, Aphanizomenon flos-aquae (AFA)	

Name of medicinal ingredient	Synonym(s)	Exception(s) (as approved feed ingredients)
Streptococcus thermophilus extract		
<i>Symphytum officinale</i>	Comfrey	
T		
Tannic acid		
Taxifolin		
Thymus nucleic acid		
Thyroactive casein	Thyroprotein	
Trimethylglycine	TMG, betaine	
<i>Tussilago farfara</i>	Coltsfoot	
U		
<i>Ulmus rubra</i>	Slippery elm	
<i>Urtica dioica</i> (whole plant, extracted juice)	<i>Common nettle,</i> <i>Stinging nettle,</i>	
<i>Uva ursi</i> (dry leaves, leaf powder, liquid extract)	<i>Arctostaphylos</i> <i>uva-ursi,</i> Bear's grape, Bearberry	
V		
<i>Valeriana officinalis</i> (whole plant)	Valerian root	
<i>Verbena officinalis</i> (whole plant)	Vervain	
Vitamin C ^{b,c} (b: 5.5 mg/g and higher) (c: in poultry)	L-ascorbic acid or L-ascorbate	<i>Schedule IV, part I, item 7.1.2</i> Vitamin Acceptable levels are those in accordance to NRC requirements
Vitamin K1	Phytonadione	
<i>Vitex agnus-castus</i> (whole plant)	Monk's pepper, Chasteberry, Chastetree	
W		
White willow (whole plant, stem bark)	<i>Salix alba</i>	
Y		

Name of medicinal ingredient	Synonym(s)	Exception(s) (as approved feed ingredients)
<i>Yucca shidigera</i> extract ^a (for osteoarthritis, for gastric disorders)		<i>Schedule IV, part II, item 8.61</i> Odour control agent Typical usage rates: 20-40 g/tonne of complete feed
Z		
Zeolites	Aluminosilicate minerals	<i>Schedule IV, part II, item 8.59</i> As an approved flow/anticaking agent: not to exceed 2% of the complete feed. Calcium sodium aluminosilicate and Sodium aluminosilicate are listed in part I of Schedule IV at a level not to exceed 2% of the complete feed.
Zinc ^{a,b} (a: for the treatment of diarrhea) (b: 2 mg/g (2,000 mg/kg) and higher)		<i>Schedule IV, part I, item 6.85</i> Zinc oxide, as single feed ingredient (source of zinc) Table 4 maximum: 500 mg/kg of zinc in complete feeds

Footnotes:

- a: When associated with therapeutic claims (examples of such claims given in brackets)
- b: When associated with a therapeutic concentration/level (determined level identified in brackets)
- c: When intended for use in a species with no nutritional requirement (particular species indicated in brackets)

Appendix D

Information template for classification requests of veterinary drugs and livestock feeds

Instructions:

- 1) Please note that the information requested in this template is for **classification purposes only** and should not be confused with an official submission for product approval.
- 2) When a required field or section is not applicable, please indicate “N/A” and provide a justification/rationale.
- 3) Once completed, this template will be treated as confidential and protected at security level B.
- 4) After assessing the information in this template, the Veterinary Drugs Directorate (VDD) or the Animal Feed Division (AFD) will provide the applicant with an official regulatory classification and the related regulatory requirements for its product(s). For questions or clarifications, please contact VDD (the single-window access for product classification) by phone at 613-954-5687 or via e-mail at classification-vet@hc-sc.gc.ca

A. Product information:

(to be completed by manufacturer, sponsor or consultant)

1. Brand name

2. Purpose/ Intent of use * **(required)**

3. Indications (Claims), including intended species * **(required)**

4. a) Dosage form * **(required)**

(Please check one or all boxes applicable)

- Tablets
- Capsules
- Chewables
- Granules
- Powder
- Soluble Powder
- Solution
- Suspension
- Concentrate
- Cream
- Ointment
- Shampoo
- Other (please specify): _____

4. b) Mode of administration * **(required)**

(Please check one or all boxes applicable)

- Added to pet food/livestock feed
- Added to drinking water
- Direct (forced) oral administration
- Parenteral
- Other (please specify): _____

5. Composition (or complete formulation) of the product * **(required)**

(Please add more lines if more than 2 ingredients)

i) Ingredient	ii) Purpose	iii) Quantity
1- _____	_____	_____
2- _____	_____	_____

5. a) For each ingredient that is a chemical:

(Please add more lines if this applies to more than 2 ingredients)

i) Chemical Abstracts Service (CAS) Number:

1- _____

2- _____

5. b) For each ingredient that is a feed ingredient:

(Please add more lines if this applies to more than 2 ingredients)

i) International Feed Number (IFN):

1- _____

2- _____

ii) Category:

1- _____

2- _____

5. c) For each ingredient that is a plant, plant material or micro-organism:

(Please add more lines if this applies to more than 2 ingredients)

i) Common name: 1- _____

2- _____

ii) Latin binomial name: 1- _____

2- _____

iii) For plants, part(s) used: 1- _____

2- _____

iv) or bacteria, strain used: 1- _____

2- _____

5. d) i. If extract:

(Please add more lines if this applies to more than 2 ingredients)

- extraction ratio: 1- _____
2- _____

- crude equivalent: 1- _____
2- _____

- short description of manufacturing process:
1- _____

2- _____

ii. If essential oil:

- complete formulation (% of pure essential oil, % any other oil, etc.)
1- _____

2- _____

6. Mode of action * **(required)**
(as documented or postulated)

7. Complete directions for use and/or Dosage recommendations * **(required)**

8. Status of this product in international regulatory jurisdiction(s)
(such as EMA, EFSA, APVMA, FDA, AAFCO, etc.)

9. Any other product information considered to be relevant

B. Additional information:

(Please enclose with this document)

- Copy of the proposed label * (required)**
- Copy of any advertising material (with source of the publication) * (required)**
- Supporting documentation and references for some sections (*e.g.*, intent of use, mode of action)
- Available research documentation (including source) pertaining to each active ingredient
- List of comparable (similar) products (with labels), if available
- Available information about the regulatory status of similar products,
- Available supporting documentation from a regulatory authority, if available

C. Applicant information:

1. Name * (required)

2. Company Name

3. Telephone number * (required)

4. E-mail address * (required)

Appendix E

Stress-Related Indications (or Claims)

1. Introduction

Historically, almost all indications or claims containing the term “stress” were associated with a therapeutic purpose, hence a drug classification. The purposes of this appendix are to clarify in more detail for stakeholders:

- 1) the acceptability of the use of the word “stress” in product indications; and
- 2) which type of stress-related indications are considered therapeutic (drug-related), as well as which ones are considered non-therapeutic and acceptable for livestock feeds.

2. Definition

For the purpose of this document “stress” is defined as “the sum of the biological reactions to any adverse stimulus physical, mental, or emotional, internal or external, that tends to disturb the homeostasis of an organism. Should these reactions be inappropriate, they may lead to disease states. The term is also used to refer to the stimuli that elicit the reactions, e.g., heat, nutritional, lactational, confinement, transportation.”

(according to Baillière’s Comprehensive Veterinary Dictionary)

3. a) Criteria for acceptability of stress-related indications

- **Clarity:**

The term “stress” is too general in describing the condition of an animal. It is recommended that product labelling and advertising avoid the vague, imprecise and confusing use of the term “stress”.

- **Specificity:**

In cases where the word stress is used, it must be accompanied with concrete and measurable qualifiers. To specify the context, the cause(s) of stress, the impact (consequences), the purpose/intent of use of the product, or the timing of administration, needs to be added in the indication.

Examples of unacceptable indications (claims) are given in table E-1 at the end of this document.

3. b) Criteria for classification of stress-related indications

- Stress-related indications (claims) will be classified as therapeutic or non-therapeutic independently of the timing of the stress event/change or of the product administration.

- An indication (claim) related to stress is considered to be **therapeutic** if it refers to:

1) a product preventing or treating major/severe consequences (including clinical signs and diseases) of a stressful event or change; and/or

2) a product directly affecting the physiological function or structure of organs in animals in a stressful situation.

In other words, claims which refer to the reduction of clinical signs or altered organ structure or function, when triggered by a stressful event, are only appropriate for veterinary drugs.

- An indication (claim) related to stress is considered **non-therapeutic** if it refers to:

1) a product providing nutrients or supporting a nutritional intent; and/or

2) a product supporting animal performance (i.e., production claims) in presence of stressful events or procedures associated with normal animal husbandry practices (e.g., vaccination, castration, dehorning, tail clipping, etc.).

Examples of therapeutic and non-therapeutic indications are also given in the table E-1 below. Please note that this table is for illustrative purposes only and should not be considered as an exhaustive & complete list.

Table E-1: Examples of stress-related indications

Acceptable stress-related indications (therapeutic)	Acceptable stress-related indications (non-therapeutic)	Unacceptable stress-related indications
<ul style="list-style-type: none"> ◦ <i>“Reduces the incidence of gastro-intestinal problems (diarrhea or other) in calves following the stress of transportation.”</i> ◦ <i>“Prevents anxiety and nervous behaviours in horses during transportation.”</i> ◦ <i>“Prevents aggressive (e.g., tail biting) behaviours in swine.”</i> 	<ul style="list-style-type: none"> ◦ <i>“Reduces the impact of vaccination and other routine farm practices on the average daily gain (ADG) of growing veal calves.”</i> ◦ <i>“Supplement to be used during periods of stress caused by routine vaccinations”</i> ◦ <i>“Calcium supplement for use during the period around calving.”</i> ◦ <i>“Maintain performance during stressful periods of production.”</i> 	<ul style="list-style-type: none"> ◦ <i>“Reduces the impact of stress in calves.”</i> ◦ <i>“Reduce stress-related illnesses in poultry.”</i> <i>“Alleviates/prevents stress in cattle.”</i> ◦ <i>“Helps recovery after a stress period in horses.”</i>

4. Other Considerations:

Please note that, as with all classifications, the criteria and process described in the Drug/Feed Classification flowchart (especially those indicated in the circle) will be followed for the classification of a product intended for use in periods of stress.

Appendix F-1

Mycotoxin Detoxification Agents (MDAs)

1. Background

Mycotoxins are toxic compounds produced by different types of fungus (mainly *Aspergillus*, *Penicillium* and *Fusarium* genera). Under favourable environmental conditions, particularly those linked to temperature and moisture, these fungi may proliferate in livestock feeds such as cereal grains, and produce mycotoxins. Attempts to reduce mycotoxin contamination have prompted the utilization of various techniques and products including heat-treatment, physical separation, soaking, de-hulling, or cleaning of seeds. The use of Mycotoxin Detoxification Agents (MDAs) is one technique that is discussed in this annex. The general purpose of MDAs is to ensure feed safety, to prevent harmful residues from entering the food chain, and to prevent animal disease. Due to product classification issues arising from the uses of MDAs, the classification criteria previously used are now being reconsidered and clarified as follows.

2. Definition:

Mycotoxin Detoxifying Agents (MDAs): MDAs are substances or mixtures of substances incorporated into a feed matrix to mitigate the toxicity of known mycotoxins by reducing the animal's exposure to mycotoxins. This may be done by reducing their reactivity through direct binding, decreasing their bioavailability, reducing their intestinal absorption, or promoting their excretion.

3. Relevant classification criteria

3. a) Mode of action

MDAs may be regulated as a veterinary drug or a livestock feed depending on the mode of action as demonstrated or claimed by the product proponent.

- If the mode of action involves physiological functions in the animal system (such as binding to the gastrointestinal (GI) mucosa, stimulating the immune response, eliciting an endogenous enzymatic response, absorption into the systemic circulation, metabolic transformation), then the MDA may be classified as a veterinary drug.

As an example, digestives enzymes can inactivate some mycotoxins. Another example would be a combination product including a binding substance and an ingredient that helps hepatic detoxification processes.

- If the mode of action occurs in the feed matrix prior to the ingestion of the treated feed by the animal (e.g., binding to the mycotoxin or inactivation), then the product may be classified as a livestock feed. Also, if the detoxification of the mycotoxin (from binding, inactivation, enzymatic degradation or biotransformation) occurs after solubilisation in the GI tract of the animal without dissociating or modifying biological functions within the animal, then the product may be classified as a livestock feed.
- As an example, aluminosilicates bind some mycotoxins, thus preventing their absorption across the digestive tract. Another example is the enzymatic degradation or biotransformation of mycotoxins by exogenous enzymes to reduce potential toxicity.

Products with a dual mode of action, or having other modes of action should be submitted to VDD for further assessment for classification.

3. b) Mycotoxin-related indications:

- Indications related to the prevention of disease in animals or indications related to the treatment of clinical signs of mycotoxicosis (or associated diseases) would be considered therapeutic in nature. Products presenting such indications would be classified as veterinary drugs. Examples of acceptable indications for veterinary drugs are given in the table below:

Therapeutic (or drug) indications
Prevent aflatoxicosis in growing chickens
Prevent mortality associated with <i>Aspergillus</i> toxins in poultry
Reduce abortions or still births in sows associated with the ingestion of zearalenone
Prevent vomiting, diarrhea and other ill effects of <i>Fusarium</i> toxins in swine
Prevent fescue foot in horses

- Indications related to reducing the contamination of feeds by acceptable modes of action in feed may be considered as non-therapeutic indications. Products presenting such indications may be acceptable for classification as livestock feeds. Examples of acceptable indications for livestock feeds are given in the table below:

Non-Therapeutic (including Nutritional) Indications
Reduce (or minimize or prevent) exposure to Ochratoxin A in livestock feeds.
Inactivate Vomitoxin (Deoxynivalenol) in livestock feeds
Decrease the bioavailability of Aflatoxin B1 by binding it in livestock feeds
Degrade Fumonisin B1 and Zearalenone in livestock feeds.

4. Other Considerations:

- Please note that MDAs will not be permitted for use in feeds that do not comply with Canadian standards for mycotoxins.
- As with all classifications, the criteria and process described in the Drug/Feed Classification flowchart will be followed.