ANIMAL NUTRITION ASSOCIATION OF CANADA

Supplement to the January 2013 Paper

on Feed Ingredient Regulatory Modernization

To build on the January 2013 ANAC proposal on feed ingredient modernization, the following additional details are offered to add clarity. No new concepts are introduced in this document.

1. Feed Ingredient Definition

Clear definitions will be required in the modernized regulations. To complement the definitions proposed in our January 2013 report (Recommendations 3, 4, and, 5) ANAC proposes the follow feed ingredient definition:

> "any substance or mixture of substances for use in water or feed other than drugs, micro-premixes, macro-premixes, mineral feeds, supplements and complete feeds"

2. Developing the Positive List

As indicated in the January 2013 report, Recommendation 7, the development of a positive list of approved ingredients is proposed. Key components to develop and implement the use of this list are as follows:

A. Required information

For each ingredient on the positive list, the following information will be included:

- Ingredient category (6 categories as defined below)
- Ingredient name
- Ingredient definition
- Species (all unless specified)
- Use restrictions (if applicable for safety reasons)
- Caution statements (if required)
- Required label information (if any)
- Maximum contaminant levels (if applicable)

The 6 ingredient categories proposed are:

- Energy
- Protein
- Technological additives (act within the feed)
- Sensory additives
- Nutritional additives
- Zootechnical additives (act within the animal)

B. Construct the Positive List Using a Phased Approach

I. Building on the Current CFIA Schedules IV and V

Schedules IV and V of the current Feeds Regulations will serve as an ideal starting point to which other ingredients can be added.

II. Ingredients New to Canada but Used in International Markets

Ingredients approved by foreign jurisdictions whose review and authorization methods are acceptable to Canada will be considered for addition to the Canadian list on a case by case basis in a scientific fashion and based on safety. The applicant need only submit the evidence of foreign approval and reference to the list where the approved feed ingredient is shown.

III. Authorization of Ingredients New to the Global Market

One of the underlying principles of regulatory modernization is to encourage innovation and foster a competitive environment. Therefore, efforts should be made for Canada to become a leader in the development and regulatory approval of totally new feed ingredients.

Applications for these new ingredients would focus on safety and, where applicable, would include:

- Ingredient category (as defined above)
- Ingredient description and composition
- Target animal safety and toxicological data
- Manufacturing process with specifications and quality control considerations
- Directions for use (feeding instructions)
- MSDS
- Shelf life / stability
- Guaranteed activity (specifically for technological, nutritional and zootechnical additives)
- Validated lab method (e.g. AOAC or validated by 3rd party). Revalidation by CFIA not necessary.

To recognize and protect feed ingredient innovations, encourage new ingredient development, and allow sponsors to recoup their research and development costs, a proprietary data exclusivity mechanism is proposed. New ingredient sponsors conducting the required development activities should be eligible for five years of data exclusivity from the time the ingredient is approved for use in Canada. To qualify, ingredient sponsors will make a formal request to CFIA for exclusivity in advance. If another company wishes to market the same ingredient (assuming no patent protection) they should be allowed to do so as long as they generate their own data set. At the end of the five-year data exclusivity period, the ingredient will be added to the positive list and will thereby be made generally available.

IV. Amendments to Ingredients on the Positive List

With the development of the positive list, amendments to ingredients may occur from time to time. Such amendments will require a submission to CFIA, with contents dependent upon the proposed change. These may include:

- Amendment to the name or definition of an ingredient: explanation of change
- For additional species: safety data
- Amendments to feeding instruction: safety data at the new feeding rate
- For a change in product composition as a result of manufacturing: submit the new process

V. International Memoranda of Understanding
In the longer term, it is suggested that CFIA conduct a formal assessment of the regulatory processes used by foreign authorities, such as the US, EU, Asia and Latin America. This would enable a determination of whether those jurisdictions' processes meet Canadian safety standards. This should ultimately lead to memoranda of understanding (or mutual recognition agreements) between Canada and the foreign regulatory bodies.

3. Claims

To expand on Recommendation 3 (nutrient definition), Recommendation 4 (nutritional disorder definition), Recommendation 5 (claim definition) and Recommendations 8 and 9 (the development and use of claims) made in ANAC's January 2013 paper, the following additional information is offered.

A. Performance or Nutritional Disorder Claims
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"*. It is recognized that nutrition allows producers to manage animals to optimize their physiology and wellness status. It is also recognized that nutritional disorders span a definition larger than a deficiency of a particular nutrient in feed. Feed ingredient claims for both animal performance and nutritional disorders should be permissible. However there will be occasions when the sponsor does not wish to make a claim and the regulations should enable this.

Companies wishing to make performance or nutritional disorder claims must have data suitable to modern regulatory approaches available, to substantiate the claim(s) at the time the product is placed on the market.

ANAC proposes that regulatory language reflect the general parameters for claims, however the regulations do not need to be prescriptive in defining their format. For example, guidance documents could provide the necessary information to allow sponsors to make appropriate claims.

B. Post-Market Treatment of Claims
Given the provisions and safeguards described above, there should be no CFIA pre-market assessment of claims. Instead, the use of a post-market monitoring and complaint-driven process will address non-substantiated or inappropriate claims. This approach should incorporate measures to provide appropriate sanctions for complaints upheld, while enabling protection against frivolous complaints.