



Animal Nutrition Association of Canada

The Case for Modernization of the Canadian Feeds Regulations

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EXECUTIVE SUMMARY

Feed industry regulation in context

Few sectors have received as much attention in recent years as food production. Both in Canada and internationally, heightened concerns over food contamination have resulted in increased pressure on the entire agri-food sector, as consumers understandably seek assurances that their food supply is safe.

Canada's feed industry accepts the fact that, as an integral part of the agri-food value chain, it should be subject to regulation. However, the prevailing view within the industry is that the current regulatory framework – largely unchanged for over a quarter-century – is outdated and misdirected. It must therefore be refocused and modernized to reflect the realities of today's feed industry, and to allow government to redirect scarce enforcement resources where they are most needed.

The primary emphasis of the regulatory system should be on the identification and control of risk, both in the ingredients used to produce feeds and in the manufacturing environment itself. Therefore, the regulations should focus clearly on safety, rather than attempt to control the nutrient content of feeds, as is now the case.

The current process of registering feed and feed ingredients is slow, cumbersome and unpredictable. It discourages companies (both international and Canadian) from expending the time and effort needed to register new ingredients for sale in Canada. The Animal Nutrition Association of Canada (ANAC) proposes a complete refocusing of the registration system to enhance control over feed and facility safety, in a manner consistent with that used by several of Canada's trading partners.

The role of ANAC's FeedAssure program as a risk-control measure

ANAC's FeedAssure program is a Hazard Analysis Critical Control Point (HACCP)-based¹ feed safety management system under which almost 170 facilities are certified, accounting for more than 70 percent of Canada's commercial feed production. FeedAssure is a voluntary program that applies the highest risk control standards to feed production. To maintain their status, certified facilities undergo annual independent audits. FeedAssure has recently been deemed equivalent to the Canadian Food Inspection Agency's own Food Safety Enhancement Program (FSEP).²

If recognized appropriately by CFIA, FeedAssure would allow the agency to focus its scarce enforcement resources where they are needed most – on the hundreds of production facilities with no hazard identification and control systems in place. However, FeedAssure-certified facilities currently receive little credit in the facility inspection process.

We therefore propose enhanced recognition of FeedAssure as a risk-control measure, coupled with an appropriate level of government oversight to ensure that the program and its third-party audit component continue to adhere to established HACCP standards.

Guiding principles for regulatory modernization

To lay the groundwork for ANAC's efforts to bring about regulatory reform, the association's board of directors in 2009 endorsed a set of guiding principles for a new regulation. These principles – which are entirely consistent with CFIA's strategic outcomes – are intended to provide the context for more detailed regulatory proposals that the association hopes will be developed cooperatively with CFIA in the coming months.

ANAC proposes that a modernized regulation should first and foremost focus on three core objectives:

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

Proposals for a modernized regulatory framework

1. Establish a collaborative process between government and industry

The first step is to institute a formal dialogue between ANAC and CFIA aimed at reaching agreement on a modernized regulatory framework. We would propose that a senior-level working group of our two organizations be created, to open discussions early in 2011 with a view to finalizing an agreement in principle before

the end of the year. As appropriate, affected stakeholders from government, the agri-food sector and the scientific community should be given the opportunity to provide their perspectives and participate in the dialogue.

*“Canada has not kept up with the regulatory advances of its major trading partners and competitors. The Canadian regulatory framework reflects the concerns of 50 years ago and its fears of locally produced, poor quality feed. Since then, the feed industry has become national, scientific and capital-intensive and capable of meeting the content requirements once devised by the National Research Council of Canada.”
(O. Lippert)*

2. Provide enhanced recognition of FeedAssure as a risk-control measure

A key component of a modernized, risk-based regulatory system already exists in Canada, with the majority of commercial feed production taking place at feed mills which are HACCP-certified through ANAC’s FeedAssure program.

ANAC recommends enhanced recognition of FeedAssure as a risk-control measure, coupled with government oversight to the extent needed to ensure adherence to HACCP standards and a code of good manufacturing practice (GMP). Applying this approach would allow CFIA to deploy scarce enforcement resources more effectively, by reducing the frequency of site inspections of FeedAssure-certified facilities, by focusing on oversight and program compliance for these facilities, and by stepping up inspections of establishments with no accredited risk control measures in place.

3. Refocus registration system to include facilities

ANAC proposes that the feed regulatory system undergo a shift in focus, whereby the regulations would require the registration of feed mills based on their risk profile. This would replace the current process of attempting to control nutrient content through registration of feeds and feed ingredients. In addition, the current Table 4 of the *Feeds Regulations* would be eliminated and replaced with a science-based screening process to evaluate ingredient risk.

Registration conditions for production facilities would be stratified on the basis of the safety risk associated with their operating procedures and ingredients used. These conditions would also take into account the presence or absence of hazard identification and control systems such as the FeedAssure program.

Once a mill is registered, there would be no further need to register feeds, as long as they are composed of GRAS-type or pre-authorized ingredients, and medications used according to approved dosages and combinations.

ANAC proposes the creation of a permanent industry-government-scientific committee to evaluate applications for ingredient authorization. This body would be charged with the responsibility for recommending to the regulators which feed ingredients should fall into a GRAS-type category, and which would need to be pre-authorized on the basis of risk associated with their intended use.

INTRODUCTION

1. ANAC and the Canadian feed industry

The Animal Nutrition Association of Canada (ANAC) is the national trade association for Canada's animal feed industry. ANAC's 170 member companies manufacture livestock, poultry and fish feed and supply grains, oilseed meals, micro-ingredients and other commodities and services to the industry. ANAC member companies account for approximately 90 percent of commercial feed production in Canada.

ANAC advocates on behalf of the feed industry with government regulators and policy makers, to foster a favourable business environment for its members while maintaining the highest standards of feed and food safety. Close to 170 feed mills and related facilities are certified under ANAC's HACCP-based feed-safety program, FeedAssure, representing about 70 percent of Canadian commercial feed production.

The feed industry is an important part of Canada's agri-food economy and a key partner in the country's food safety system. Feed represents the largest input cost for livestock and poultry producers – up to 75 percent of the total cost, depending on species. The estimated total commercial production of feed in Canada is 20 million tonnes. In addition, an estimated 10 million tonnes is produced on-farm. Swine, dairy and poultry feeds account for approximately 85 percent of the complete feeds manufactured and sold by commercial manufacturers in Canada. Annual sales for all species (excluding companion animals) total over C\$4 billion.

2. Evolution of the feed industry and regulatory framework: 1970–2010

The current *Feeds Act and Regulations* came into force in 1983 at a time of rapid change in the animal feed and primary food animal industries. Before this time, animal feed was produced in modest amounts primarily at small locations across Canada, and these feeds were sold locally to thousands of farmers. Most feed mills produced many different feeds, and each mill produced feed for the complete range of farm animals. Not all

feed mills had trained nutritionists, and they relied on National Research Council (NRC) estimates of nutrient requirements as a starting point for diet formulation. Rudimentary computing hardware and software, combined with a limited supply of alternative ingredients, limited reformulation.

Pressure to involve the feed industry in the regulation of the Canadian food supply led to the passage of various federal statutes. Requiring the registration of all feeds was deemed unmanageable because of the volume of multi-species feeds produced at small facilities across Canada. The *Feeds Regulations* exempted feeds from registration under two conditions: (i) if single ingredient feeds were considered safe and listed in Schedule IV of the regulations and (ii) if the nutrient inclusion rates were within minimum and maximum limits specified in a list that became known as Table 4.³ This approach to registration drastically reduced the cost and administrative burden and generally met the needs of the feed industry at that time.

The next 20 years saw a rapid growth in scientific knowledge of livestock nutritional needs. This knowledge growth was supported by rapid developments in the capacity of formulation systems and their integration with feed manufacture, processing, quality control, labelling and data storage. At the same time, livestock industries began to specialize and consolidate. Fewer farms raised more than one species, and animal numbers became more concentrated on farms that were often clustered across Canada.

This specialization in pigs, poultry, dairy and beef cattle, fish or other minor species was associated with greater knowledge of animal health and welfare, environmental control and the realization that animal production could affect certain aspects of meat, milk and egg quality and composition. These refinements led to demand for more specialized feeds and greater flexibility in formulation to respond to fluctuating ingredient prices and availability.

“The impact of Table 4 within the 1983 Feeds Regulations has evolved from one of mutual benefit to both feed manufacturers and regulatory agencies to the current situation of imposing restrictions on best practices of feed manufacture.”
(S. Leeson)

For example, sophisticated animal industries increasingly demanded feeds formulated to supply digestible or metabolizable nutrients rather than simply the total level of nutrients, which was previously deemed acceptable. Such demand for increased knowledge and sophistication of feed formulation and the role of individual feeds within lifecycle feed programs was fueled by rapid growth in animal nutrition research.

As a result, knowledge of the nutrient requirements of farm animals was transferred directly to corporate animal nutritionists, making NRC standards redundant, even within the usual five-to-eight-year period between standard NRC reviews. For certain species, such as poultry, the NRC abandoned the costly attempt at providing timely information, with the latest (and likely the last) information update in 1994.

The demand for more exact specification of animal feeds has led to rapid advancements in mill quality control, with greater knowledge of the nutrient content of incoming ingredients and guarantees of the nutrient profile of commercial feeds. This development, coupled with new technology in electronic control over most steps in feed manufacture, has resulted in unprecedented quality control in the manufacturing process. Mills can now match an animal's nutrient requirements with greater precision and deliver feeds with consistent nutrient composition.

PROBLEMS ARISING FROM THE FEED REGULATORY SYSTEM

1. Overview of the main issues

Canada's feed industry accepts the fact that, as an integral part of the agri-food value chain, it should be subject to regulation. However, the prevailing view within the industry is that the current regulatory framework – largely unchanged for more than a quarter-century – is outdated and misdirected. The industry's position is that the regulations need to be modernized so that they focus clearly on safety, and not on the nutritional efficacy of feed, as is currently the case.

The emphasis of the regulatory system must be on the identification and control of risk, both in the ingredients used to produce feeds and in the manufacturing environment itself. In addition, a modern regulatory approach can contribute to consumer protection, through prohibitions against false or misleading product claims and labelling. However, there is no place for regulations in controlling the nutrient content of feeds: today's competitive marketplace will ensure that in order for feed manufacturers to succeed, they must supply a quality product that performs as it is represented.

If the Canadian animal agriculture sector is to succeed in the global marketplace, it must have access to the full range of feeds available to its international competitors. However, the system of regulatory approvals in this country creates such a burden on both domestic and international suppliers that many feed ingredients available internationally do not find their way onto the Canadian market.

“No other feeds legislation or similar regulatory process world-wide appears to dictate (or even mention) dietary nutrients or their concentrations...”
(S. Leeson)

It is also important to note that many of the problems the terrestrial animal feed industry faces as a result of the current regulatory system are also encountered by Canada's aquafeed sector. A recent report prepared for the Canadian Aquafeed Working Group, which is co-chaired by a representative of Fisheries and Oceans Canada, describes difficulties with the

Feeds Regulations that are in every way similar to those faced by the mainstream feed sector, and recommends solutions that are fully consistent with the proposals made in this paper.⁴

An evaluation of the Feed Program conducted by CFIA in 2007 came to many of the same conclusions.⁵ Notably, it found that the *Feeds Regulations* were outdated, were affecting the success of the agency's Feed Program and needed to be reviewed.

Three main problems are created by the current regulatory system:

- a. The *Feeds Regulations* focus too little on safety and too much on the nutrient content of feed and feed ingredients, which are matters best controlled by market competition.
- b. The feed-registration system is slow, cumbersome and unpredictable; it creates unwarranted costs and barriers to the introduction of new feeds and feed ingredients.
- c. CFIA gives too little recognition to the risk control capabilities of ANAC's HACCP-based FeedAssure program, and thus devotes excessive resources to repeated inspections of certified facilities, rather than concentrating on sites that have no recognized feed safety systems in place.

2. Regulations focus too much on nutrient content rather than safety

Canadian feed manufacturers face a number of challenges in complying with the *Feeds Regulations* as they affect modern feed formulation and feeding practices. Table 4 of the regulations poses particular difficulties.

The *Feeds Regulations* were amended in 1983 to exempt feeds from registration if they met the criteria for quality by providing a basic supply of selected nutrients. Prior to that time, all feeds needed to be registered. As an alternative, Table 4 of Schedule I was created to specify the range of nutrients within which feeds could be formulated. A feed containing all the identified nutrients within specified ranges is exempt from registration.

At the time it was introduced more than a quarter-century ago, this arrangement was acceptable to both the feed industry and regulatory agencies. However, developments since that time have made Table 4 obsolete. It does not accommodate modern concepts of nutrition or feed formulation, nor does it support feed companies in their efforts to focus on food safety and environmental sustainability. Canada is unique in the world in

that no other national regulatory agency has taken this approach, and no other agency dictates nutrient levels in legislation governing animal feeds.

Among the challenges⁶ the industry faces in complying with Table 4 are the following:

- **Required nutrients** – Developments in feed formulations and animal nutrition over the last 30 years have eliminated the need for some of the nutrients listed in Table 4. For example, cobalt and magnesium are normally not added to diets for monogastric animals. Despite such modern developments, feeds that do not meet Table 4 requirements must be registered. The costs and time associated with registration often remove any incentive to develop more efficient formulas and thereby often force manufacturers to use less-than-optimal nutrient levels.
- **Minimum nutrient levels** – Advances in animal nutrition have shown that mandating minimum nutrient levels is inappropriate; however Table 4 has not been modernized to reflect these advances. This is particularly significant with phosphorus and trace minerals, where newer products (such as phytase and organic trace minerals) can be used more efficiently.⁷ Moreover, in certain regions, most notably in western Canada, saline levels in the water supply sometimes makes it essential to reduce the dietary supply of sodium below the minimum specified in Table 4, particularly in the case of poultry.
- **Maximum nutrient levels** – At the other end of the scale, the maximum levels of nutrients dictated by Table 4 are generally set so high that they are rarely exceeded during feed formulation and manufacture. However, some exceptions would need to be taken into account, where exceeding current Table 4 maximum levels could pose safety or environmental risks. Later in this paper, ANAC advances a number of proposals for regulatory change; among these is a process for identifying and dealing with feed ingredients that have the potential to create a risk, and would therefore need to be pre-authorized before use.
- **Nutrient balance** – Feeds may meet the regulatory guidelines but still be neither safe nor efficacious. Table 4 makes no attempt to create or control the balance between nutrients listed, or to accommodate the concept of nutrient density. For example, the energy level of diets is the major factor influencing feed intake and ultimately the nutrient density of the diet required, yet Table 4 does not specify or guarantee diet energy levels. There are many instances where animal health could be compromised if the only criteria were that feeds contain the nutrient levels required by Table 4.
- **New ingredients** – Table 4 does not accommodate the use of new ingredients that can help livestock absorb nutrients that would otherwise be excreted into the environment. For example, Table 4 does not allow decreased levels of phosphorus below the specified minimum in hog diets even when phytase is added. Adding phytase to hog feeds to reduce phosphorus, a common practice in other countries, reduces the amount of phosphorus excreted, while providing appropriate nutrition. Table 4 perpetuates the overuse of phosphorus in hog diets, and thereby exacerbates the environmental impact.
- **Outdated nutrient requirements** – By today's standards, the nutrients required by Table 4 are of little significance to animals or those who feed them. Animal feed would certainly not be purchased based on the minor trace elements specified in Table 4. More commonly, feed is purchased from manufacturers based on prior experience of animal productivity, cost, financing arrangements and considerations of supplier reliability. Quality assurance in today's feed industry is more concerned with food safety, food composition, animal welfare and environmental stewardship. The nutrient composition of diets is certainly not a focus of international HACCP and feed-mill registration systems.

With the exception of certain nutrients where exceeding the specified maximum level might pose a risk (and for which ANAC proposes an alternate solution later in this paper) the rationale underlying the existence of Table 4 is obsolete. The assumption seems to be that, without Table 4, feed manufacturers would attempt to supply diets with inferior or inappropriate nutrient levels. In today's industry, vigorous competition among feed manufacturers combined with more sophisticated modern farming methods, will ensure that the nutrient composition of feed is continually evaluated in the marketplace. Sophisticated record keeping and the ability to generate real-time data, now make diet composition and quality easier to monitor. These factors reinforce the need to question the current system of feed registration and the need to regulate nutrient content.

3. Feed registration creates unwarranted costs and hinders innovation

Closely associated with Table 4's impact on feed manufacturers are the complex application process, long timelines and related costs associated with the feed registration system. All new feeds and feed ingredients that do not fit within the Table 4 ranges, or are absent from Schedule IV of the regulations, must be approved and registered.

“It should be noted that the feed industry recognizes the importance of high standards in the regulatory process. However, if the system is outdated and does not recognize new science and is slow and untimely in its administration, then the high standards are offset by the lack of innovative products that can be brought to the market.”
(George Morris Centre)

The barriers created by the current process of registering feed ingredients discourage companies (both international and Canadian) from expending the time and effort needed to register new ingredients for sale in Canada, which is a small market by global standards. As a result, Canadian feed manufacturers are too often denied the opportunity to produce competitive feeds for domestic and international distribution.

The feed registration process is complicated by the degree of regulatory oversight imposed. Of the three submission categories listed here, the second and third both require a pre-market evaluation of their safety and nutritional efficacy:

- **Category 1: Standard Feed or Ingredient** – Feeds including approved ingredients listed in Schedule IV or V of the Regulations, although the nutrient levels do not match the Table 4 requirements. This category requires no safety or efficacy data review.
- **Category 2: New Feed or Ingredient** – Feeds and ingredients already approved and listed in Schedule IV or V of the Regulations but being proposed for a new use. This category requires a safety or efficacy data review.
- **Category 3: Novel Feed or Ingredient** – New feeds and ingredients with no history of use as a feed or ingredient. This category requires a safety and efficacy data review.

The highly regulated approach underlying the current registration system leads to numerous problems for companies attempting to introduce new feeds or feed ingredients. Among the most frequently cited difficulties are the following:

- **Misdirected focus on efficacy** – The determination of efficacy is perhaps the most difficult aspect of the registration process for the feed industry to accept. The ultimate decision as to whether a feed or ingredient is efficacious for its intended purpose is based entirely on questions of nutrient value. As discussed earlier, the prevailing view among Canadian industry participants, as well as governments in

other parts of the world, is that the regulatory system should focus on the safety of feed and its ingredients; no useful purpose is served by attempts to regulate feed efficacy.

- **Long approval timelines** – Long delays in receiving a final decision from CFIA on an application for registration are a continuing source of frustration for the industry. Case studies compiled for ANAC by the George Morris Centre⁸ attest to a registration process that can go on for many months or even years and still end in rejection. The average length of time for CFIA to complete a review and reach a decision on a novel feed application was 435 days in the 2009–10 fiscal year. Applications for registration renewal – required every three years – averaged 203 days during the same period. However, the target service standard set by the agency for all application types is 90 days.
- **Delays in amending regulations** – When a new feed ingredient has been approved by CFIA, a regulatory amendment is required to add it to Schedule IV or V of the regulations. These amendments are processed only once per year – not every time an ingredient is approved. Although companies receiving approval for their feed ingredients may begin using them before the amendments are enacted, the delay between the ingredient’s approval and its publication in Schedule V or IV may lead to different companies trying to register similar ingredients.
- **Restrictions on use of registered ingredients** – Schedules IV and V are prescriptive and list feed ingredients by type, for example, energy feeds, protein feeds and vitamin products. If a company wants to use a feed ingredient for another purpose, the ingredient must be approved and registered for that purpose. In addition, complete feeds must be registered and approved prior to marketing, even if the single ingredients making up these feeds have already been approved and listed in Schedule 4.

4. Inspection system gives too little credit to FeedAssure risk controls

First developed by ANAC in 1999, the HACCP-based FeedAssure program now certifies almost 170 facilities across the country, accounting for more than 70 percent of Canada’s commercial feed production. FeedAssure is a voluntary feed-safety management and certification program that applies the highest risk-control standards to feed production. To maintain their certification, FeedAssure facilities undergo annual audits by an independent, internationally recognized testing and verification firm.

If recognized appropriately by CFIA, FeedAssure would allow the agency to focus its scarce enforcement resources where they are needed most – on the hundreds of primarily smaller production facilities with no hazard identification and control systems in place. However, FeedAssure-certified facilities are still subject to repeated site inspections, and under the current enforcement system, are eligible for just one less partial inspection per year.

“The federal government has yet to fully engage the feed industry in creating the necessary regulatory support for comprehensive, risk-based and transparent ‘farm to fork’ initiatives such as those in Europe and Australia/New Zealand and now being designed by the U.S. The counterpart to the European and Australia/New Zealand programs in Canada is FeedAssure™, a feed industry-customized HACCP (Hazard Analysis Critical Control Point) program of processes and controls that bring the highest safety standards to the production of feed.”
(O. Lippert)

In ANAC’s view, this is an inadequate recognition of the merits of the program, especially considering that CFIA has recently deemed FeedAssure to be equivalent to the agency’s own Food Safety Enhancement Program (FSEP).⁹ We therefore propose enhanced recognition of FeedAssure as a risk-control measure, coupled with an appropriate level of government oversight to ensure that the program and its third-party audit component continue to adhere to established HACCP standards.

Progress toward securing CFIA recognition of FeedAssure has been slow. From 2007 to 2008, CFIA and ANAC collaborated on an inspection-harmonization pilot project in preparation for the agency’s new Compliance Verification System (CVS), which was implemented in 2009. At that time, CFIA acknowledged that, in the context of the CVS inspection approach, FeedAssure certification “merits recognition as a useful risk-mitigation measure.”

In August 2010 – after more than three years of effort to bring the program to the point where it could be officially recognized by CFIA – the agency advised ANAC that:

“...the FeedAssure/ProQualité program meets all Food Safety Enhancement Program (FSEP) standards. The CFIA considers the Animal Nutrition Association of Canada (ANAC) voluntary Hazard Analysis Critical Control Point (HACCP) program FeedAssure, an industry success story and a very proactive step for the Canadian feed industry in support of food safety.”

The acknowledgement by CFIA that FeedAssure is equivalent to the FSEP program is particularly significant. The agency describes FSEP as “its approach to the development, implementation and maintenance of HACCP systems in all federally registered establishments; it is an effective food safety management system; it enhances the establishment’s ability to achieve and maintain compliance with the relevant regulatory requirements; and it is consistent with the CFIA’s Quality Management Program (QMP)¹⁰ for fish and seafood products and with HACCP initiatives being developed by provincial governments.”

The CFIA Quality Management Program for fish processing represents a modern approach, reducing the frequency of facility inspections and placing greater emphasis on program compliance. Applying a similar approach to facilities where the FeedAssure program is in place would constitute appropriate recognition of the risk identification and control systems implemented at certified facilities.

TOWARD A SOLUTION

1. Cabinet directive gives priority to regulatory renewal

The 2007 *Cabinet Directive on Streamlining Regulation* requires that regulatory frameworks that appear out of step with current realities be examined by federal government departments and agencies with a focus on:

- the effectiveness of the current regulation in meeting the policy objective(s);
- the current instrument selection, level of intervention, and degree of prescriptiveness;
- clarity and accessibility of the regulation to users; and
- the overall impact on competitiveness, including trade, investment and innovation.

The goal of the Directive is to promote a life-cycle management approach to regulations to ensure that they remain relevant and that negative impacts and unintended consequences are assessed and remedied as needed.

The Directive states, “when regulating, the federal government will... advance the efficiency and effectiveness of regulation by ascertaining that the benefits of regulation justify the costs, by focusing human and financial resources where they can do the most good, and by demonstrating tangible results for Canadians.”

As the Canadian Food Inspection Agency’s 2007 evaluation report pointed out, the *Feeds Regulations* are outdated and overdue for review. ANAC believes that the *Cabinet Directive* supports the association’s argument for modernization of the *Feeds Regulations*.

2. Guiding principles for regulatory modernization

ANAC’s position is that a modernized regulatory approach should first and foremost focus on risk mitigation to enhance feed safety. At the same time, a new regulation should recognize that the feed industry represents the best source of expertise to meet the nutritional performance needs of its customers in animal production. Further, the regulations should not act as a hurdle to market access, nor contribute to an unlevel competitive playing field.

In 2009, the ANAC board of directors endorsed a set of guiding principles for a new regulation. It was the association’s intent that these should provide the context for more detailed regulatory proposals to be the subject of dialogue with CFIA going forward.

It is ANAC’s view that a modernized regulation should:

- focus on three core objectives:
 - safety – maintenance of animal health and welfare, protection of the human food supply and mitigation of environmental risks
 - market access and competitiveness – regulations must not create barriers to innovation and market entry, nor put the Canadian feed industry at a competitive disadvantage with its international counterparts
 - consumer protection – control over false or misleading claims, and assurance that labelling reflects the intended use of the product
- be outcome-based to target demonstrable safety risks
- be founded on science to minimize subjective application and accommodate alternative compliance approaches
- be consistent with or incorporate international best practices

These guiding principles are consistent with CFIA’s strategic outcomes:

- Minimization of public health risks from the food supply
- A safe and sustainable plant and animal resource base
- Consumer protection and market access

3. International best practices

The guiding principles proposed by ANAC for a modernized feeds regulation include the suggestion that Canada take into account the best practices of its trading partners and international competitors. Most countries have legislative and regulatory systems governing the manufacture and sale of animal feeds. While regulatory approaches vary, the common element is a focus on feed safety and the control of risk as it relates to ingredient use and manufacturing practices.

The concern for better control over hazards in food production has in recent years led to the development of risk management systems that monitor and control production processes throughout the system – from receipt of raw ingredients to delivery of

finished products. This has prompted governments and food industries in Canada¹¹ and around the world to accept HACCP systems as an effective way to identify and control hazards.

“To succeed in the international feed market, Canada needs a contemporary regulatory regime attuned to the high standards set in the European Union and the United States. Without a critical appraisal and modernization, Canada’s current feed regulations may cause the domestic industry to stagnate.”
(O. Lippert)

Governments in several countries have embarked on, or are engaged in, a process of modernizing their regulatory systems. In the European Union (EU), companies manufacturing feed must be certified under a HACCP system to be deemed safe, subject to periodic compliance inspections. The United States is expected to mandate risk-based process controls and good manufacturing practices for feed industry operations. While not a full HACCP-based approach like the EU’s, the new US Animal Feed Safety System will likely adopt similar requirements for hazard identification and remediation. The Stock Feed Manufacturer’s Council of Australia operates FeedSafe®. Developed in cooperation with state and federal authorities, this voluntary program serves as the Quality Assurance Accreditation Program for the Australian feed industry.

In many countries, feed mills are registered with the appropriate government agency. Once registered, the feed manufacturer faces no further restrictions in formulating animal feeds, provided ingredients are pre-approved or recognized to be safe for their intended use. Labelling requirements for complete feeds are sometimes more detailed than in Canada, and this is part of a general move towards accountability, traceability and transparency within the feed and animal agriculture industries.

Canada has yet to engage the animal feed industry in providing the necessary regulatory support to the kind of comprehensive, risk-based and transparent “farm to fork” initiatives seen in Europe, Australia and New Zealand, and now being developed in the United States.

The EU animal feed regulations are perhaps the clearest and most rigorous, and were developed following a long consultative process and with the active participation of the feed industry.

New regulations dealing with the feed industry came into force in November 2010, more than 15 years after Europe was struck with dioxin and BSE scares. The regulations¹² focus entirely on animal and public health. Other than detailed requirements for labelling, no attempt is made to set mandatory or maximum levels of any nutrients in animal feeds.

A defining feature of the European reforms lies in the active participation of the continent’s feed industry. The European Feed Manufacturers’ Federation (FEFAC) developed the voluntary European Feed Manufacturers’ Guide (EFMC) in 1998.¹³ The EFMC was designed to provide principles and standards for every stage in the feed manufacturing process, allowing full transparency and traceability of all ingredients used, including pre-mixtures and additives.

Canada has not kept up with the regulatory advances of its major trading partners and competitors. The Canadian regulations reflect the concerns of 50 years ago, and fears over locally produced, poor-quality animal feed. Since that time, feed manufacturing has become a transnational, scientific and capital-intensive industry capable of meeting and exceeding appropriately directed regulatory requirements and public expectations for food safety.

4. Consideration of human health impacts

Feed industry regulation should concern itself with safety as it affects animal welfare and the integrity of the human food supply. In this context, feed manufacturers are addressing public and government concern over antimicrobial resistance. This is an issue that can potentially have a detrimental effect on our ability to treat disease in humans. However, antibiotic use in animal agriculture is also important to prevent and treat disease and to be able to deliver a safe product to consumers. Therefore, antibiotics need to be used judiciously in all stages of animal production.

Closely linked to the question of antimicrobial resistance and the potential use of alternatives to antibiotics in livestock production, is the need for the industry to pursue innovative approaches through the introduction of new feed additives into the Canadian market. This will require a regulatory system that encourages innovation by removing hurdles currently present in the ingredient approval process.

As animal science explores alternatives to antibiotics in the years to come, the resulting technologies will have a much smaller magnitude of effect than antibiotics. These alternatives will be analogous to dietary changes that are used to reduce the risk of certain diseases in humans. If we are to move to this next generation of solutions, a new regulatory approach will be needed to redefine the boundary between functional nutrients and drugs. The screening and approval processes for the two categories are quite different, and they are also the responsibility of two different regulatory bodies – CFIA and the Veterinary Drugs Directorate (VDD) of Health Canada. However, at present, no triage process is in place to provide appropriate guidance on which applications are the responsibility of which agency.

Over the past three years, the Canadian Animal Health Products Regulatory Advisory Committee (CAHPRAC) has brought together representatives of government, industry associations and veterinary pharmaceutical manufacturers, to address deficiencies in the current animal health product review system. Co-chaired by VDD and the Canadian Animal Health Institute, CAHPRAC has functioned as a forum to assist in clearing the backlog of submissions for approval of veterinary products, and in accelerating VDD'S internal review process. This would suggest that CAHPRAC might be the best organization to advise CFIA and VDD on a triage initiative, whereby it would be determined whether a product submitted for approval should be treated as a drug or feed product, and therefore which of the two agencies should be responsible for the review.

PROPOSALS FOR A MODERNIZED REGULATORY FRAMEWORK

1. Establish a collaborative process between government and industry

The first step is to institute a formal dialogue between ANAC and CFIA aimed at reaching agreement on a modernized regulatory framework. We would propose that a senior-level working group of our two organizations be created, to open discussions early in 2011 with a view to finalizing an agreement in principle before the end of the year. As appropriate, affected stakeholders from government, the agri-food sector and the scientific community should be given the opportunity to provide their perspectives and participate in the dialogue.

A feeds regulation for the 21st century should be founded on safety, provide the right level of consumer protection, remove barriers to innovation and market access, and ensure a level competitive playing field. We suggest that such a dialogue is in line with the *Cabinet Directive on Streamlining Regulation*, which directs all departments and agencies charged with administering federal regulation to “ensure that regulatory activities result in the greatest overall benefit to current and future generations of Canadians.” This paper is intended to form the basis for a cooperative effort with CFIA officials to find solutions acceptable to both the industry and the regulator.

2. Provide enhanced recognition to FeedAssure as a risk-control measure

A key component of a modernized, risk-based regulatory system already exists in Canada, with the majority of commercial feed production taking place at feed mills that are HACCP-certified through ANAC’s FeedAssure program. HACCP certification requires implementation of recognized standards for risk identification and control, coupled with independent verification of compliance.

As discussed earlier, CFIA has now officially acknowledged that FeedAssure “meets all Food Safety Enhancement Program (FSEP) standards.” In ANAC’s view, this should form the basis for a new inspection approach by CFIA, which would allow the agency to redirect its scarce enforcement resources to where they are most needed.

ANAC recommends enhanced recognition of FeedAssure as a risk-control measure, coupled with government oversight to the extent needed to ensure adherence to HACCP standards and a code of good manufacturing practice (GMP). The CFIA Quality Management Program for fish processing represents an appropriate regulatory model, as it places increased emphasis on compliance with established safety standards.

Applying this approach to the feed industry would allow CFIA to deploy scarce enforcement resources more effectively, by reducing the frequency of site inspections of FeedAssure-certified facilities, by focusing on oversight and program compliance for these facilities, and by stepping up inspections of establishments with no accredited risk control measures in place.

3. Refocus registration system to include facilities

ANAC proposes that the feed regulatory system undergo a shift in focus, whereby the regulations would require the registration of feed mills based on their risk profile. This would replace the current process of attempting to control nutrient content through registration of feeds and feed ingredients. In addition, the current Table 4 of the *Feeds Regulations* would be eliminated and replaced with a science-based screening process to evaluate ingredient risk.

a. Facility registration

Registration conditions for production facilities would be stratified on the basis of safety risk associated with their operating procedures and ingredients used. For example, as part of its Compliance Verification System, CFIA has established a four-level risk ranking system for facilities, based on the deemed level of animal health risk, combined with the degree of medication risk in the feeds produced. This type of approach might form the basis for a facility risk-ranking model. Registration conditions would also take into account the presence or absence of hazard identification and control systems such as the FeedAssure program.

A facility registration system of the type proposed by ANAC is directionally similar to the approach used in several other countries, particularly the European Union. The key factor is an emphasis on safety controls to identify and control both ingredient and production facility risks. This would then be coupled with the appropriate level of government oversight to ensure ongoing compliance with recognized HACCP program standards.

b. Ingredient authorization

Once a mill is registered, there would be no further need to register feeds, as long as they are composed of GRAS-type or pre-authorized ingredients, and medications used according to approved dosages and combinations. Such an approach would reduce the burden on the current registration system, and should enable fast-track authorization of feed ingredients by regulators in cases where evaluation of potential risk is necessary.

The most important component of this process would be the establishment of a mechanism acceptable to both government and industry, under which feed ingredients would be reviewed and classified according to their potential safety risk. This would need to be conducted in an unbiased and scientifically sound manner.

ANAC therefore proposes the creation of a permanent industry-scientific committee to evaluate applications for ingredient authorization. This body would be charged with the responsibility for recommending to the regulators which feed ingredients should fall into a GRAS-type category, and which would need to be pre-authorized on the basis of risk associated with their intended use.

CONCLUSION

As has been discussed throughout this paper, Canada's feed regulatory system is outdated and unable to meet the needs of the feed industry in the 21st century. The current emphasis on control over nutrient content rather than feed safety and risk management means that the regulations are dictating to the industry how feed should be formulated to achieve a notional level of animal performance. At the same time, recognized and independently verified measures to identify and control feed safety risks receive little credit in the regulatory system.

“One way in which the government can help to further develop a prosperous feeds industry is to create a progressive business environment that fosters innovation. In this context, this includes a current and efficient feeds regulatory system...”
(George Morris Centre)

The government and the feed industry, with the support of affected stakeholders, should work cooperatively to reach agreement on a set of regulatory measures suited to today's needs for safety throughout the agri-food value chain. A new regulatory framework should build on those guiding principles where there is already agreement between the Canadian Food Inspection Agency and the feed industry: maintenance of animal health, protection of the human food supply, mitigation of environmental risks, market access and consumer protection.

In the Animal Nutrition Association of Canada's view, the regulators and the industry, given the recognition that this is the right time to begin modernizing the regulatory framework, are well positioned to bring about substantive change. We can enhance safety in the industry, remove regulatory barriers and encourage innovation, if we are prepared to move away from established views and practices that no longer serve the best interests of the government, the feed industry or the Canadian public.

REFERENCES

Bureau, D. P., 2010. *The Challenges Imposed by the Current Canadian Feed Regulatory System on the Aquaculture Sector in Canada*. University of Guelph, prepared for the Canadian Aquafeed Working Group, Fisheries and Oceans Canada.

Leeson, S., 2010. *Deficiencies in the Canadian Feed Regulatory System and the Need for Performance-Based Regulation*. University of Guelph, prepared for the Animal Nutrition Association of Canada.

Lippert, O., 2010. *Overview of International Animal Feed Regulations*. Interchange Public Affairs, prepared for the Animal Nutrition Association of Canada.

Scott, T. A., 2010. *What are the Consequences of Defining the Minimum Levels of Phosphorus in Animal Diets?* University of Saskatchewan, prepared for the Animal Nutrition Association of Canada.

Smedley, K. O., 2010. *Comparison of Approval Process and Risk-Assessment Procedures for Feed Ingredients*. Center for Regulatory Services Inc., prepared for the International Feed Industry Federation, Feed Additive Comparison Project Task Force.

Stiefelmeyer, K. and Schmidt, C., 2010. *Making the Case for Feed Regulatory Reform: A Case Study Approach*. George Morris Centre, prepared for the Animal Nutrition Association of Canada.

Treasury Board Secretariat, 2007. *Cabinet Directive on Streamlining Regulation*.

NOTE:

The above-referenced research reports prepared for the Animal Nutrition Association of Canada may be viewed in their entirety on the ANAC website at www.anacan.org.

ENDNOTES

¹ The concern for better control of hazards in the food and related industries has resulted in the development of preventive systems to monitor and control processing steps prior to the delivery of finished products. This has prompted many governments and food processing companies to regard a Hazard Analysis Critical Control Point (HACCP) system as an effective way to identify and control hazards. The HACCP approach is risk-based and makes industry, rather than government inspectors, primarily responsible for identifying steps in food production where food safety hazards are most likely to occur, and for establishing controls that prevent or reduce these hazards.

² The Food Safety Enhancement Program (FSEP) is the Canadian Food Inspection Agency's approach to encourage and support the development, implementation and maintenance of HACCP systems in all federally registered establishments.

³ Table 4 of Schedule I was first incorporated in the *Feeds Regulations* in 1983 (SOR/83-593). The original Table 4 established nutrient ranges for chickens, turkeys, swine, beef and dairy cattle and sheep. In 1990, Table 4 was slightly modified (SOR/90-73) and then expanded to include diets also for horses, goats, ducks and geese (SOR/90-92) and then finally modified to include rabbits, mink and salmonid fish (SOR/90-730).

⁴ Bureau, *The Challenges Imposed by the Current Feed Regulatory System on the Aquaculture Sector in Canada*.

⁵ Canadian Food Inspection Agency, 2007. *An Evaluation of the Feed Program*. Prepared for Audit, Evaluation and Risk Oversight, available at www.inspection.gc.ca.

⁶ Much of the discussion on Table 4 is based on Leeson, *Deficiencies in the Canadian Feed Regulatory System and the Need for Performance-Based Regulation*.

⁷ There are estimates that 80 percent of the finite inorganic phosphorus (90 percent of which is used in food production) is wasted and contributes to eutrophication of our water sources. Research has demonstrated that by both reducing the amount of phosphorus in animal diets and increasing its bioavailability, phosphorus excretion by farm animals can be decreased by over 50 percent. (Scott, *What are the Consequences of Defining the Minimum Levels of Phosphorus in Animal Diets?*)

⁸ Stiefelmeyer and Schmidt, *Making the Case for Feed Regulatory Reform: A Case Study Approach*.

⁹ The Food Safety Enhancement Program (FSEP) is the Canadian Food Inspection Agency's approach to encourage and support the development, implementation and maintenance of HACCP systems in all federally registered establishments.

¹⁰ The Quality Management Program (QMP) is a regulatory-based system that requires all federally registered fish processing plants in Canada to develop and implement an in-plant quality control program.

¹¹ *Growing Forward*, Canada's agriculture policy framework, also recommends the adoption of HACCP-based risk-management systems.

¹² European Parliament, Brussels, 2009. *Regulation of the European Parliament and of the Council on the Placing on the Market and Use of Feed*. PE-CONS 3611/5/09, AGRILEG 28, CODEC 209

¹³ See numerous searchable articles in *Feed International* magazine at www.fi-digital.com.