



Animal Nutrition Association of Canada

Making the Case for Feed Regulatory Reform:  
A Case Study Approach

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## **Making the Case for Feed Regulatory Reform: A Case Study Approach**

### **Final Report**

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## 1. Introduction and Background

Regulations are necessary for the organization of society. A good regulatory framework protects the health and environment of its citizens, contributes to economic growth, and promotes investments that, in turn, improve a nation's productivity and improve its standard of living. A dysfunctional regulatory system, however, hinders productivity and innovation and reduces competitiveness and job opportunity (RIAS Inc, 2000). We would add to the RIAS Inc notions that protecting health and environment are not necessarily trade-offs for competitiveness and innovation. A regulatory system that is slow and burdensome can actually do more harm to animal and human health and the environment by stifling the very innovation that could improve them.

A competitive and innovative agri-products sector can provide Canadians with fresh, healthy and safe foods or new foods with added health benefits, it can be a steward of the land, it can be a part of the development of new energies or energy efficiency, and it can be a sector utilizing new technologies to make its highly skilled workforce more productive. Indeed, many political leaders like to talk about these potentials for Canada's agri-food sector. Unfortunately, however, this talk does not translate into opportunities because the sector's ability to realize its potential is hindered by the current regulatory system, one that impedes Canada's competitiveness and innovation. The perceived result is a loss in growth and competitiveness across many sectors, including biotechnology, agri-food and agri-products, and financial services.

Many studies show that the issues plaguing Canada's regulatory system span all of its components and a wide swath of the sector, including pesticide regulatory approvals, animal health products, seed registration and new food approvals and health claims<sup>1</sup>.

Canada's feed industry is facing similar issues with respect to feed regulations and is struggling to work within this regulatory environment as it calls for reform. Research and anecdotal evidence regarding these regulatory issues has resulted in increased understanding of the problem. However, a case study analysis providing empirical data to back statements that regulatory delays and compliance burdens have impacted the economy would offer a more complete understanding of the magnitude of the issue.

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<sup>1</sup> **Brethour, C. et al. 2004.** The Competiveness Impacts of Canada's Agricultural Product Review Regulations. Research conducted by the George Morris Centre. Prepared for the Canadian Animal Health Institute. **Brethour, C. et al. 2005.** Possible Incremental Measures to Address Horticulture Sector Concerns With Pesticide Regulation in Canada. Research conducted by the George Morris Centre. For Agriculture and Agri-Food Canada.; **CANTOX. 2007.** International Comparison on the Management of Health Claims and Novel Foods. CANTOX Health Science International.; **Stiefelmeyer et al. 2008.** Food Regulatory Systems: Canada's Performance in the Global Marketplace: A Case Study Approach. Research conducted by the George Morris Centre. Prepared for Food and Consumer Products of Canada.

## ***1.1 Purpose and Objectives***

The purpose of this study, using a case study approach, is to identify the impact of Canada's current feed regulatory system on companies registering new feed ingredients and working to comply with feed regulations in Canada. As well, the report includes estimates, where possible, of the magnitude of the opportunity costs to agri-food sector participants imposed by this system.

Specifically, the study:

- Describes the Canadian feed regulatory system and where the hurdles occur within it.
- Estimates the direct cost to feed companies resulting from the compliance burden of the *Feeds Act* and *Feeds Regulations, 1983*.
- Estimates the lost market opportunities to feed companies resulting from the inefficiencies of the feed and feed ingredient registration system.
- Qualitatively estimates the potential lost market opportunities for Canadian primary agriculture and aquaculture as a result of the inefficient regulatory framework.

To convey the need for feed regulation modernization and reform, this study provides five examples of Canadian feed ingredient suppliers' experiences with the regulatory approval process. These cases provide actual examples of regulatory delays and denials that have impacted the feed industry's ability to provide the Canadian livestock segment with innovative and competitive products.

## **2. Canada's Feed Regulatory System**

### **2.1 Introduction to Canada's Feed Regulatory System**

The term “regulatory system” is used to describe a designed framework governing human interactions. The framework is comprised of prescribed formal rules, which are the objects of social goals, such as safety or economic growth, and delegated procedures and authority to ensure compliance to these rules. The components of the system include legislation, regulations, administration and enforcement.

#### **Legislation and Regulations**

Relevant Canadian legislation and regulations pertaining to livestock feeds are the *Feeds Act and Regulations, 1983*. The stated purpose of legislation is what guides overall decision-making and formation of policy. The purpose of the Canadian *Feeds Act* is to “ensure that feeds manufactured or imported to Canada are safe, effective and labeled correctly. The *Act* is supplemented by the *Feeds Regulations*, designed to ensure the safety and efficacy of livestock feeds.

#### **Administration and Enforcement**

The Animal Feed Division of the Canadian Food Inspection Agency (CFIA) is the federal agency responsible for the safety and regulation of livestock feed in Canada. CFIA is responsible for ensuring that both “livestock feeds manufactured and sold in Canada and feeds imported into Canada are safe, effective and labeled appropriately” (CFIA, 2010).

“The CFIA was created in 1997 and delivers federal inspection services for food safety as well as plant protection and animal health. The CFIA is responsible for the administration and enforcement of the following acts: Agriculture and Agri-Food Administrative Monetary Penalties Act, Canada Agricultural Products Act, Canadian Food Inspection Agency Act, Feeds Act, Fertilizers Act, Fish Inspection Act, Health of Animals Act, Meat Inspection Act, Plant Breeders' Rights Act, Plant Protection Act, and Seeds Act. The Agency is also responsible for enforcement of the Consumer Packaging and Labeling Act and the Food and Drugs Act as they relate to food, and the administration of the provisions of the Food and Drugs Act as they relate to food, except those provisions that relate to public health, safety or nutrition which remain under the responsibility of the Minister of Health” (FAO, 2010).

CFIA's responsibility with respect to livestock feed is to administer the *Feeds Act and Regulations*, as well as enforce the legislation. As listed on CFIA's Livestock Feeds webpage, CFIA's activities include:

- evaluating and approving ingredients for use in livestock feeds;
- establishing standards and policies for the exemption of feeds from registration;
- evaluating and registering specialty products of specific safety or efficacy concern;
- monitoring feeds for the presence of residues of chemicals, pesticides, contamination by heavy metals, mycotoxins and salmonella and - verifying drug guarantees in feeds;

- investigating detections of feed related contamination of meat, milk or eggs and producer complaints;
- reviewing labels of medicated feeds for compliance so that all applicable cautions and warnings are provided for safe use;
- inspecting commercial feed mills and farms involved in the production of medicated feeds.

## **2.2 *Impediments within the Canadian Feeds Regulatory System***

This section describes a number of the impediments of the current Canadian feeds regulatory system and their effects on getting new and innovative feeds to market, or reapproving previously approved feed ingredients. The impediments are described as either legislative and regulatory or administrative<sup>2</sup>.

### ***Legislation and Regulation***

#### **Table 4**

In 1983, the Feeds Regulations were amended to “exempt feeds if they met criteria for ‘quality’ in terms of providing a basic supply of selected nutrients” (Leeson, 2010). Table 4 within Schedule 1 of the Feeds Regulations imposes a range of nutrients within which nutritionists can formulate feeds. Therefore, if all levels of nutrients within a feed/diet fall within the minimum and maximum levels specified, then a feed is exempt from registration. Table 4 has remained largely unchanged since its implementation in 1983.

Leeson (2010) notes that in 1983, the intent was to lessen the registration burden and cost of feed registration, and that Table 4 accomplished this. However, since that time development and innovations in the industry have been significant and have resulted in Table 4 becoming restrictive and unaccommodating to modern feed formulation – including utilizing feed as more than delivering simple nutrient profiles but also targeting specific issues such as animal performance. Challenges that the industry faces in trying to comply with Table 4 are listed below:

#### ***Nutrients within Table 4***

A number of the nutrients listed in Table 4 are no longer utilized or needed in many livestock feeds due to new feed developments and processes over the last 30 years. Despite these new developments, in order to by-pass formal registration, feeds must still meet Table 4 requirements, making more efficient formulas redundant and requiring nutrients that are no longer optimal<sup>3</sup>.

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<sup>2</sup> The information in this section is largely taken from work already completed. Particularly, Leeson, 2010 and ANAC, 2009.

<sup>3</sup> Leeson (2010) provides a number of examples.

### *Nutrient Minimums and Maximums*

Again, due to a number of developments within the feed industry it has been found that the use of minimum nutrient levels in feeds is inappropriate, in particular with phosphorous and trace minerals, when newer products such as phytase enzymes and organic trace minerals can be used more efficiently. However, Table 4 has not been updated to accommodate for this.

The range that the nutrients must fall into frustrates the ability of many feeds to get to customers in a timely fashion. Feeds that don't fit within the ranges must be registered, thereby preventing timely feeding to herds. For example, a nutritionist will review a herd, prepare a feed ration and need to get it to the herd but the feed must be reviewed and registered by CFIA.

### *Nutrient Balance*

Leeson (2010) also states that "Table 4 makes no attempt to create or control the balance between nutrients listed in the specifications or to accommodate the concept of nutrient density". Leeson (2010) notes that there are many instances where animals could be compromised if the only criteria were that feeds contained a mix of nutrients at the levels listed in Table 4. Therefore not all feeds that fit within the regulatory guidelines may be safe and efficacious (Leeson, 2010).

### *Supplements*

Feed supplements are concentrated feed ingredients that target specific issues such as livestock health, feed efficiency and animal and reproductive performance, and are to be mixed with grains and/or forages. By design, they do not provide all of the nutrients listed in Table 4 since Table 4 only accommodates complete feeds. Therefore, supplements are also assessed based on Table 4 requirements without consideration of what the supplement will be mixed with and its nutritive properties. In most cases, supplements must be registered because most do not meet Table 4 requirements.

### *Environment and the Phytase example*

Thirty years ago the industry and society were less concerned about industry's environmental footprint than today and Table 4 reflects that. Table 4 does not accommodate the use of new ingredients and additives that can help to improve retention of many nutrients preventing shedding of these nutrients into the environment by livestock (Leeson, 2010).

One popular example is the use of phytase enzymes in place of inorganic phosphates. Leeson (2010) explains it below:

"Phytase is now used world-wide as a replacement for inorganic phosphates. This novel enzyme releases phosphorus in phytic acid found in plant material, replacing anywhere from 15% to almost 30% of the mineral conventionally supplied by inorganic phosphorus sources such as calcium phosphates. This direct replacement of enzyme for phosphate mineral reduces manure accumulation of phosphorus by a corresponding amount. Table 4 has not evolved to accommodate the practice of using phytase enzyme, and perpetuates the very dated concept of



the need for too high a level of total phosphorus in the diet. Phytase usage is now the norm rather than the exception in feed formulation world-wide, and so regardless of the outcome of deliberations about Table 4, the concern about the minimum requirements of phosphorus being too high must be addressed for environmental protection reasons”.

The industry could one day decide that it wanted to reduce its environmental footprint by using low phosphate feeds but with the restrictions in Table 4 this is something that cannot be provided.

#### *Table 4 Summary*

The above discussion shows that Table 4 is outdated and inhibiting feed nutritionists from providing new, efficient and timely feeds to the livestock industry. The requirements of Table 4 do not apply to current science and do not do much for food safety.

No other country in the world has taken the approach that Canada has to dictate and enforce nutrient levels in feeds.

### **Feed and Feed Ingredient Registration**

The efficiency of the feed regulatory approval process is affected by the level of regulatory oversight required. Other than feeds that fit within the Table 4 nutritive ranges, feed and ingredients in Canada must be approved and registered. There are three submission categories within which new feeds or ingredients would fit. Categories 2 and 3 require pre-market evaluation of safety and efficacy of their intended and level of use.

#### Category 1: Standard Feed or Ingredient

- Under this category no safety or efficacy data review is required. These feeds include ingredients that have already been approved and are listed in Schedule IV or V of the Regulations; however the nutrient levels do not fit into the Table 4 range requirements.

#### Category 2: New Feed or Ingredients

- Under this category a safety and efficacy data review is required. These feeds and ingredients are already approved and listed in Schedule IV or V but they are being used for a new purpose.

#### Category 3: Novel Feed or Ingredients

- Under this category a safety and efficacy data review is required. These are new feeds and ingredients which have no history of use as a feed or ingredient.

#### *Feed Ingredients*

Approved feed ingredients must be listed in Schedules IV and V of the *Feeds Regulations*. These Schedules are prescriptive and list feed ingredients by type, for example, energy feeds, protein feeds and vitamin products. If a company wants to utilize the feed ingredients for another purpose then the feed ingredient must be approved and registered for that purpose.

In order to add a new feed ingredient to the Schedules a regulatory amendment is required. It is also policy that the Canadian public has an opportunity to comment on any regulatory amendments. In order for this to occur, an intention for approval is published in the Canada Gazette making it quite a lengthy process. Unlike the human food additive regulatory approval process, once a feed ingredient is approved it is put on a list with other feed ingredients and the process of regulatory amendment then occurs once per year or so and not every time a feed ingredient is approved. Companies that receive approval can also start to use the feed ingredients prior to the regulatory amendments.

However, the lag time between having a feed ingredient approved and it appearing on Schedule V or IV can impede innovation across the industry. At times other companies may also be registering a similar feed ingredient and be unaware that it has already been approved because of the lag time. This could result in unnecessary costs and time for those companies.

### *Feeds*

Complete feeds are not listed in Schedules IV and V even though they must be registered and approved prior to marketing.

High regulatory oversight in a minor market such as Canada can lead to fewer new feed and ingredient submissions being made or approved, leading to less innovation in the livestock feeds industry.

The major difference between Canada and the United States in this regulatory process is that the US is more flexible and timely due to the Generally Recognized as Safe (GRAS) process which allows feeds and ingredients with a history of safe use to be used without being formally registered and approved. This process also relieves pressure on the regulatory system as not every product would require time and effort of CFIA. For feeds, the EU and Australia/New Zealand also follow a similar GRAS process (ANAC 2009).

### *Medicated Feeds*

With a growing emphasis on animal nutrition and health, the livestock nutrition industry has developed medicated livestock feeds that have been readily available to the industry. These types of feeds must comply with the *Feeds Act and Regulations* as described above, as well as *Food and Drugs Act* and *its Regulations*.

The *Food and Drugs Act* prohibits the manufacture or sale of all dangerous or adulterated food products anywhere in Canada. The *Act*, “which derives its authority from criminal law, is supplemented by regulations designed to ensure the safety and nutritional quality of foods”.

“All medicated livestock feed imported, manufactured or sold in Canada must meet the standards set out in the CFIA's Compendium of Medicating Ingredient Brochures (CMIB), unless the feed is a veterinary prescription feed (a feed that is manufactured pursuant to a veterinary prescription). The CMIB is a listing of drug premixes that have been assigned a Drug

Identification Number (DIN) and approved for use in livestock feeds by Health Canada” (CFIA, 2010). If the medicating ingredient is not in the CMIB, then the feed manufacturer would have to obtain a valid DIN through the New Drug Submission application and registration process.

The Veterinary Drugs Directorate (VDD) is part of the Health Products and Food Branch of Health Canada. The VDD is responsible for ensuring the safety of foods such as milk, meat, eggs, fish and honey from animals treated with veterinary drugs. They also ensure that veterinary drugs sold in Canada are safe and effective for animals.

### *Functional Feeds*

As in the global food market, the development and formulation of ‘functional’ livestock feeds is growing and has become more sophisticated. Feeds are now developed to not only provide a basic nutrient profile but also to target specific areas such as health, feeding efficiency or animal performance. In many instances, livestock feeds that include functional ingredients are classified as drugs in Canada. When this is the case, these feeds must comply with the *Feeds Act and Regulations* as described above, as well as *Food and Drugs Act and its Regulations*.

It is the view of the industry, however, that CFIA has abdicated many of its responsibilities to VDD instead of managing them themselves since a formal approval mechanism does not exist.

### **Authority to validate or approve product names**

*The Feeds Act and Regulations* provide regulatory authority to validate or approve feed product names despite the fact that this strays beyond health and safety of a product and is not based on science.

### **Administration/Process**

While the CFIA has set its own performance standards of a decision made within 90 days (90% of the time), CFIA rarely meets that standard. Many industry stakeholders have noted that often times it is not the regulatory requirement of submitting a registration application that is the time lag but rather the administration and process of reviewing the submission.

A number of administration and process issues exist (ANAC, 2009):

- Delays by CFIA in responding to registration and renewal applications and no accountability to timelines
- Lack of communication between approval body and applicant
- Lack of objectivity and transparency in the regulatory process
- Lack of consistency in application and interpretation of regulations

### **Summary**

The above discussion shows that there is potential for improvement in the efficiency of the livestock feeds registration process in Canada in both the regulations and the process that administers the regulations.

It was acknowledged by CFIA in 2007 (CFIA, 2007) that the Feeds Regulations were outdated and were impacting the success of the Feed Program within CFIA. It was recommended at that time that the regulations be updated to reflect the current environment and that the regulatory consultative process be more open and transparent.

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.

### **3. Case studies: Experience working within Canada’s Feed Regulatory System**

This section provides evidence through four actual examples provided by Canadian feed and feed ingredient manufacturers that the livestock feed regulatory system in Canada presents problems and lengthy lags for companies seeking approvals for new feed ingredients and companies trying to formulate feeds to comply with the *Feeds Regulations*.

It also quantifies the impact of these deficiencies in the system. The case studies detail the high opportunity costs for the entire supply chain including the manufacturers but also primary agriculture producers seeking to benefit from the use of innovative products.

Having a measure of direct costs and opportunity costs is vital in explaining to regulators why the system is urgently in need of reform<sup>4</sup>. Raising awareness of the urgency for change has been challenging in the absence of comprehensive data that quantifies the real costs caused by delays and inefficiencies within the Canadian feed regulatory system.

#### **3.1 Case A: Dairy Feed Supplement**

Case A involves a dairy feed supplement to be mixed with grains that was solely developed in Canada for which Company A submitted a standard registration and was denied.

#### **Background**

Ketosis<sup>5</sup> is a common metabolic disease that affects fresh cows during the early stages of lactation. Ketosis is “caused by a negative energy balance due to insufficient energy intake to support energy output in milk” (WDD, 2006). This energy imbalance increases the risk of other diseases and ultimately affects milk production. The costs of Ketosis are significant and include milk production losses, treatment costs and in worst cases culling of cows. The cost of treating clinical Ketosis is estimated at \$US 150 per cow and \$US 78 for subclinical Ketosis (WDD, 2006).

Ingredient A has proven to be an effective energy source for fresh dairy cows. When a cow’s energy is depleted during and after pregnancy, Ingredient A can help to restore energy, increase

<sup>4</sup> Appendix A describes the methodology used in estimating the costs to the agri-food value chain.

<sup>5</sup> <http://www.rennut.com/articles/pdf/Ketosis-English.pdf>

glucose levels in the blood, limiting the production of ketones, which will ultimately prevent Ketosis.

Oral drenching of the liquid form of Ingredient A is a typical practice to prevent and treat Ketosis in fresh cows. This method requires skilled personnel, is labour intensive and can cause stress to the animal. Therefore, Company A's clients requested a product that could be handled and administered more easily.

### **Submission Experience**

In 2000, a Canadian firm developed a dry form of Ingredient A - Product A, which is a water-soluble, white, free-flowing powder that consists of 65% of Ingredient A and 35% silicon dioxide. The initial application for the registration of Product A on a carrier for livestock feed took six months to be approved. Product A was approved in the spring of 2001 as a feed ingredient as part of Schedule 4. The Canadian supplier licensed Product A in 2001 to Company A, which mixed Product A with other approved ingredients, and subsequently tried to register it as a supplement in Canada.

In the fall of 2001, Company A submitted a standard registration for a dairy cow supplement. All of the ingredients in the supplement were approved and included in Schedule IV of the Regulations, including Ingredient A, approved as a manufacturing aid (Class 8). Ingredient A is also highly recognized in the industry as a source of energy. However, although all of the ingredients were approved, by design this ruminant supplement did not fall within the strict nutrient ranges of Table IV (which is oriented to complete feeds) and therefore required registration (as spelled out in Trade memo T-3-157). Company A submitted the requirements for a standard registration and explicitly stated that they did not intend to make any nutritional claims. Company A assumed this registration would be timely and transparent since all of the ingredients were already approved.

Along with other concerns, CFIA responded to Company A stating that Product A was not registered as an energy source for cattle, and that Company A would have to make a claim, as it was using Product A for a new purpose. Although Company A did not want to make a claim, it did and stated that Product A was being used as a glucose precursor. Company A referred to references in the Journal of Dairy Science that addressed the ingredient's efficacy as a glucose precursor. CFIA had no disagreements with the science provided by Company A, but came back stating that Ingredient A was not approved for this use and that the supplier of Product A would have to register it as an energy source.

CFIA then responded by informing Company A that the registration submission had been forwarded to the Veterinary Drugs Directorate of Health Canada (VDD) for an opinion on whether the product dealt with disease prevention or treatment, rather than with nutritional supplementation. In fall 2002 (almost 10 months after the application was filed), CFIA notified Company A that the dossier had been returned to CFIA from Health Canada noting "the matter has been turned back to CFIA for any required decision."

Three months after Company A requested a status report on its submission, and more than a year after its submission, CFIA finally responded (in January of 2003) indicating a denial of the dossier because the “supplier provided inadequate data to support the use of Ingredient A as an energy source for cows” and that the feeding ratio constituted a drug use for prevention or treatment of ketosis.

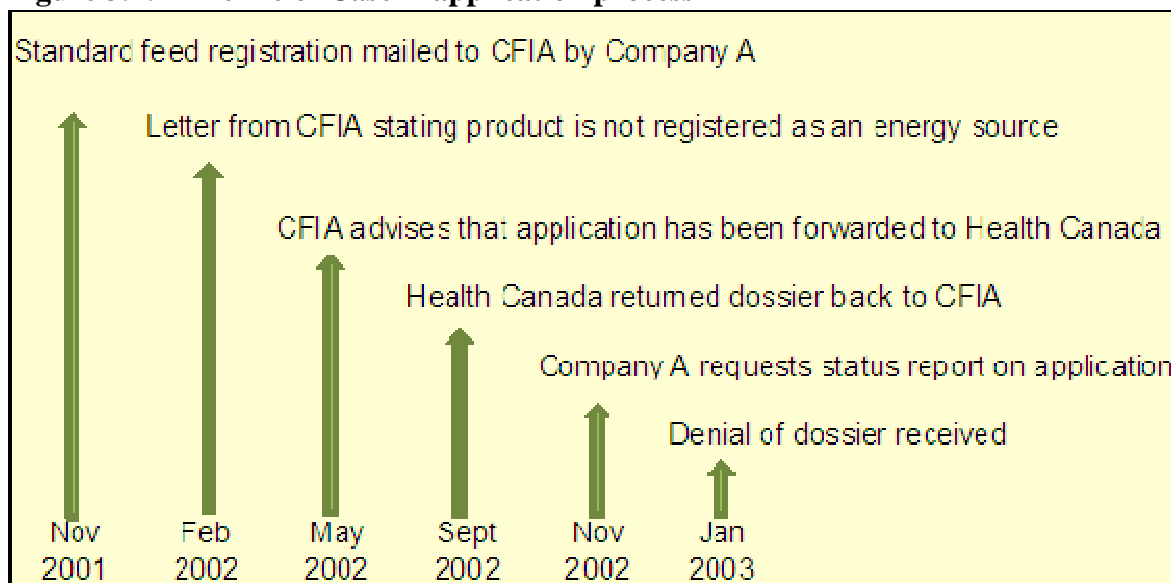
In the end, what was simply a result of following the rules with respect to a ruminant supplement that contained the typical Table IV nutrient array, albeit outside the required ranges, turned into a completely different issue. Instead CFIA concluded that the inclusion rate of the Ingredient A constituted a use of an otherwise approved Schedule IV Part 1 ingredient that they had not approved.

Company A did have the opportunity to apply for a new animal drug application, however it does not think that supplements should be required to be registered as drugs and second, it is a very expensive process for the small Canadian market.

### Supplier Experience

Every three years, approved products must be re-approved. Therefore, in 2003 the Canadian firm that had developed Product A submitted a re-approval application. The submission was immediately referred to the VDD. After only one month the re-approval was denied and the product had to be taken from the market. Subsequently, any feeds and other feed products that were using Product A as an ingredient had to be withdrawn as well.

**Figure 3.1: Timeline of Case A application process**



In Canada, livestock producers can purchase the pure liquid form of food-grade Ingredient A from veterinary drug suppliers or industry-grade Ingredient A from chemical suppliers and mix it with feed without restriction. The cost of Ingredient A in this form would be cheaper than in a

value-added feed product but could also be contaminated. However, would livestock producers be challenged if CFIA inspectors saw this occurring? This allowance puts feed manufacturers at a competitive disadvantage in which they cannot offer a similar product with added value.

This, and the fact that Ingredient A has been approved as an ingredient for livestock feed, show that the issue in this case is not one of safety.

## **Impact and Opportunity Costs**

The denial of Product A on the Canadian market has several implications:

- The supplier company invested an estimated \$50,000 (2002 dollars) in research and development of the product that is now a sunk cost that cannot be recovered.
- In 2002, the supplier of Product A sold 300 tonnes of the product with intentions to expand sales across Canada. The conservative estimate was that about 1,000 tonnes of the product could be sold in Canada. Assuming that the product was sold for \$3/kg and 1,000 metric tonnes would be sold annually, the estimated annual sales loss is \$3 million per year. Assuming a 5 percent discount rate, from 2003 to 2010 the present value of potential losses in annual sales have accumulated to \$28,647,327.
- Based on customer demand for the product and expected sales based on customer adoption rates, Company A had estimated sales of \$600,000 per year. If this submission was a standard submission, as expected by Company A, and the submission was reviewed in a timely manner it was assumed that the supplement would have been on the market by mid-2002. Assuming that Company A has lost sales since mid-2002, the present value of lost sales has accumulated to 5,872,702.
  - It must be noted that Company A will always be able to sell basic feed to the livestock industry in Canada. However the company would like to offer customers innovative technologies within their feed and in this case they were prevented from delivering a better management tool.
- For livestock producers, not having access to one feed product is obviously not a total loss in that there are likely alternatives, however there are still opportunity costs associated with having access to one less tool:
  - This product in particular provided a convenience factor by providing Ketosis prevention and treatment in the form of a supplement requiring less labour, time and equipment requirements than other methods of treatment.
  - Producers may have to recalibrate feed rations to meet their needs if they cannot get all of their requirements from one feed
  - The denial of this product restricts choice in the way a producer chooses to manage Ketosis

## **Summary Issues with Registration of this product**

- Restrictive Table IV nutrient ranges and the lack of recognition of supplements triggered registration of this product.
- Registration requirements of feed ingredients by use have caused CFIA to question whether this product was a drug.
- Lack of transparency; CFIA sent the submission to Health Canada-VDD without prior notification to Company A.
- Untimely responsiveness of CFIA throughout the process.

### **3.2 Case B: Dairy Anionic Supplement**

Case B involves a dairy anionic supplement, which was the flagship product of Company B1, an innovative Canadian animal health company. Product B was approved and sold in Canada for a number of years, but was denied re-approval in 2006.

#### **Product Background**

Calcium deficiency in dairy cows can result in reduced feed intake, poor muscle tone and can lead to ketosis, mastitis and displaced abomasums. Severely calcium deficient dairy cows may suffer from milk fever.

Product B was an anionic supplement for close up dry cows used to prevent calcium deficiency that included chlorinated canola meal as its primary ingredient. Basic research for the product was conducted at the United States Department of Agriculture (USDA). However, research trials for the final product were conducted at the University of British Columbia. In 1998 the product was registered and sold across Canada and in some U.S. states (mainly California and Oregon). The main advantage of Product B was its high palatability. The ingredients of the product were (at the time of its last approval application) soy hulls, beet pulp, hydrochloric acid (HCl), canola meal, ammonium chloride, calcium chloride, lime and silicon dioxide. The active ingredient in Product B is hydrochloric acid.

In 2004, Company B2 expressed interest in the product, and Product B was licensed to Company B2 in 2005. Product B was manufactured by Company B1 and distributed in Canada by Company B1 and in the U.S. by Company B2.

#### **Submission Experience**

The original applications for Product B and chlorinated canola meal were submitted by Company B1 in February 1998. Some additional information on engineering of the product and safety testing were requested by CFIA. Once this was provided to CFIA the application was processed and approved in July 1998. Company B1 felt that the registration process and the approval time were satisfactory.

Every three years, approved products must be re-approved, and Product B was re-approved without problems in 2001 and 2004. In 2006, Product B was reformulated slightly to improve



flowability by including both soy hulls and beet pulp as additional organic carriers for HCl, together with the previously registered ingredient chlorinated canola meal. Since two different mixers were required, the production process changed slightly. According to Company B1, the reformulation did not change the efficacy or any significant nutrient specification of the product. The active ingredient (HCl) stayed the same, only the carriers changed.

Despite the only slight changes, CFIA requested that Company B1 submit a new application for chlorinated grain mix, to reflect the change in the production process. The revised Product B application was submitted in 2006 under the impression that the chlorinated grain mix would not be different from the chlorinated canola meal approval from 1998. However, CFIA returned the application stating that the chlorinated grain mix is not a standard ingredient and that an application for this new ingredient had to be submitted. At this time, Company B1 had been growing at a rate of 10 percent annually as a result of Product B sales.

At the same time, Company B2 applied to CFIA to register Product B in Canada. Their application was unsuccessful. CFIA informed Company B1 in September 2007 that they were no longer allowed to distribute Product B in Canada. As a result, Product B was only manufactured for the US market, but for their Canadian customers, another US product had to be imported from the United States.

Company B2 continued to work on an approval for Product B in Canada. The CFIA replied to Company B2's application for the single ingredient feed approval for chlorinated grain mix. Several issues were mentioned, including:

- Product description and labeling: CFIA recommended that the name should be changed from 'chlorinated grain mix' to another name, since more ingredients than just grain were included in the mix.
- Manufacturing: CFIA requested a precise description of the Hydrochloric Acid (HCl) and what was used to manufacture it and the chemical process used to synthesize it. This included a reminder that only food grade sources of HCl may be used, as industrial byproducts are not permitted.
- Safety Evaluation: CFIA requested a safety evaluation of the chlorinated ingredient, asking for scientific explanations to demonstrate that the maximum levels did not pose a risk for the intended species and that additional toxicity data should be provided from scientific journals or actual toxicity studies. The papers submitted with the application were not sufficient.
- Furthermore, CFIA asked for signed Certificates of Analysis for three different production lots of the HCl to show identity, purity, pH and moisture. Similarly, signed certificates of analysis for three different production lots of the chlorinated ingredient indicating were also required.
- Finally, if the product would make any nutritive claims to treat disease or restore and correct bodily functions, it would be considered as a drug and would need to be approved by Health Canada.

Company B2 had 60 days to address CFIA's concerns. Company B2 addressed the concerns, but not to CFIA's satisfaction, and the approval was denied. Subsequently, Company B2 also

submitted an application for registering HCl as an ingredient and provided significant data on the source and verification of food grade source of HCl. CFIA continued to have questions and it was determined that it would be unachievable to meet CFIA's ongoing requests for further information.

The interesting point here is that these questions were not asked in the initial application in 1998 and that the product did not change. That is, the main active ingredient was still HCl. The license from Company B2 was eventually returned to Company B1 and Company B1 has since been dissolved.

## **Approval in other jurisdictions**

### *United States*

Product B was approved in several U.S. States. The registration required that a label be submitted and cost \$US 25. The US FDA considered the product Generally Recognized as Safe (GRAS). In total the registration took approximately two weeks.

However, if a product that is made in Canada is not registered in Canada, many jurisdictions will not allow its use, hence the loss of registration in Canada made Product B much less valuable around the world.

## **Impact and Opportunity Costs**

The denial of the re-registration of Product B has had several implications:

- At the end of 2007, all Canadian sales were lost. Company B1 estimates that sales would have grown up to \$500,000 by 2010. Assuming a 12 percent annual sales growth rate from 2007, the present value of potential losses in annual sales has accumulated to \$1,416,640.
- Company B1 has experienced sunk costs from investments in R&D, marketing and capital items (mixing equipment, etc...) and estimates these losses at \$250,000.
- As a result of halting production, jobs were lost. The losses for direct production would be approximate 2 FTE (\$100,000 per year).
- For livestock producers, not having access to one feed product is not a total loss as there are alternatives, however there are still opportunity costs associated with having access to one less tool:
  - This product in particular provided a convenience factor by providing calcium deficiency prevention and treatment in the form of a supplement
  - The denial of this product restricts choice in the way a producer chooses to manage calcium deficiency.
  - Producers who were using the product when its registration was pulled were left without a solution until a product was imported from the United States. The recalibration of livestock feed rations can have an effect on animal performance.

## **Summary Issues with Registration of this product**

- Lack of consistency in application and re-approval
  - Product B was approved by CFIA in 1998, without the request for a safety evaluation for the active ingredient HCl and was sold in Canada for many years without problems. However, suddenly, in 2006 an extensive evaluation of HCl was required.
- Registration requirements caused CFIA to question whether this product was a drug.
  - Product B was sold for many years in Canada and producers bought it to prevent calcium deficiency in dairy cows. However, in the re-application, CFIA required that the product should not make any nutritive claims to treat disease or restore and correct bodily functions in order to be approved; otherwise it would be considered as a drug and would need to be approved by Health Canada.

### **3.3 Case C: Enzyme Supplement for Poultry Feeds**

Case C involves an enzyme supplement for poultry feeds, which was developed by Company C. This case study details the lengthy registration process of Product C.

#### **Background**

Company C is a manufacturer of enzyme premixes (feed, food and industrial), pigmenters, flavors, acidifiers and other environmental products. Product C belongs to the group of enzyme premixes and is an enzyme supplement for poultry feeds, designed for diets which use oilseeds and meal with cereal grain. In short, the enzyme increases the omega-3 level in eggs, allowing for a lower inclusion rate of flax in feed rations. Product C is currently available in the Canadian and U.S. market.

#### **Submission Experience**

Company C developed and tested this new enzyme product in Canada. Research was undertaken at the University of Manitoba to verify the response of the enzyme in increasing omega-3 levels in eggs.

In December 2004 a Trademark was filed for a product name that contained the word ‘omega’ with the Canadian Government, which approved the trade name in March 2005. On April 13, 2005, Company C submitted the requirements for a novel feed registration for the poultry supplement, including samples and documentation outlining the description of the active ingredients. However, during the time of application preparation a change to the guidelines occurred, which required that the expiry dates of feeds and supplements be included in the application as well. According to Company C this change in process was not pre-announced by CFIA and, therefore, Company C had to backtrack on samples to verify this change.

CFIA responded to the initial application on April 25, 2005 notifying Company C that the initial name choice, which, as previously mentioned, is trademarked, was not allowed because the

product did not contain omega-3. Instead CFIA suggested a different name that contained the word 'Flax'. However, the product did not contain any flax either, raising the question as to why the initial name that contained the word Omega was not approved.

CFIA informed Company C that if the initial name choice was not changed to a suitable alternative, their file would be closed. In this case, if Company C was still looking for an approval for their enzyme product, they would have had to re-submit the application resulting in more time and money spent. CFIA and Company C eventually agreed to a name change, Product C. Throughout this process, Company C discussed how a name that is acceptable to the trademark arm of the Federal government can be overruled by CFIA.

A final approval decision was received approximately seven months later, on November 7<sup>th</sup>, 2005. However, this approval was only temporary as the CFIA stated that they needed to verify Company C's testing methodologies to verify enzyme activity. Company C would have been able to sell the product from this point on. However, Company C chose not to roll out the new product until the approval was finalized. On December 7<sup>th</sup>, 2005, another request from CFIA was made to provide specific explanations on the methodology used by Company C to verify enzyme activity. Company C had 60 days to respond to the request or CFIA would close the file. Company C responded to CFIA on February 1<sup>st</sup>, 2006. The final approval of Product C was received in June 2006.

Due to the process changes during the application process, the required name change of the enzyme and the non-observance of the 90 day standard application time rule, Company C did not feel that the process was transparent and timely.

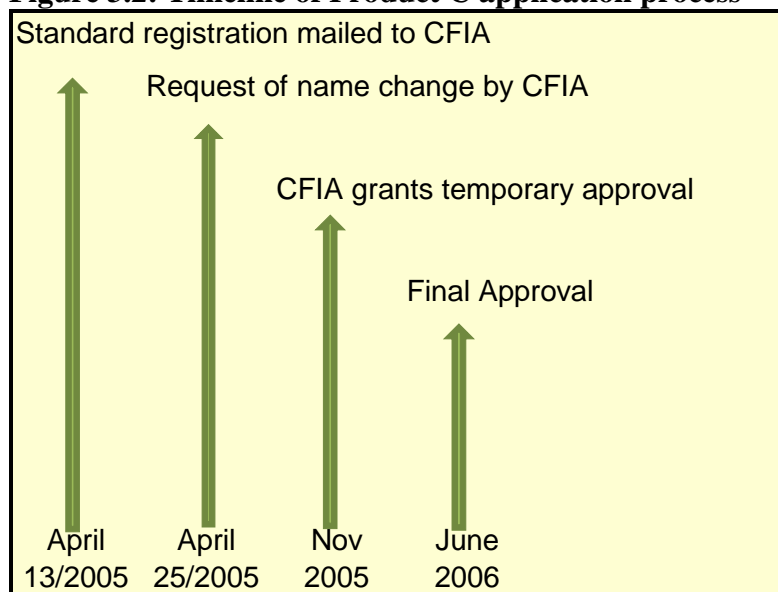
The issues that held this submission back were not ones of feed safety, but rather administrative and proving efficacy.

### **Approval in other Jurisdictions**

Product C has been approved in the United States in the States of Minnesota and Wisconsin. The product was recognized as GRAS in the United States. In both cases, the approval process took two weeks. With the application, the name of the product, the copy of the product label and an application fee of US \$25 had to be submitted.

From experience, Company C can attest that the approval process is much easier and less costly in the USA than in Canada.

**Figure 3.2: Timeline of Product C application process**



### Impact and Opportunity Costs

The lengthy approval process of Product C into the Canadian market had several implications:

- According to Company C, the change in guidelines requiring expiry dates to be submitted was not pre-announced by CFIA. The cost of backtracking on samples to verify this change was approximately \$2,000.
- Overall, Company C estimates that the time spent on sample, assay and documentation preparation by employees dedicated to the file was 3 weeks at an approximate cost of \$4,000.
- Since the trademarked name was not approved by CFIA, the money spent on trademark registration (\$200) and lawyers' fees (\$500) are sunk costs.
- Based on customer demand for the product, and expected sales based on customer adoption rates, Company C had estimated sales of \$50,000 in the first year. If this submission was standard, as expected by Company C, and the submission was reviewed in a timely manner, it was assumed that the supplement would have been on the market by mid-August 2005. However, due to the lengthy approval process, Company C lost approximately 10.5 months in sales. Hence, Company C lost approximately \$56,317 in 2010 dollars in sales.
- According to Company C, poultry producers now spend less on feed, since the flax portion in the ration decreases through the addition of Product C from 15 to 6 percent. Assuming a flax price of \$600/tonne, an enzyme price of \$6.25/tonne, and an annual feed supply that would make use of the enzyme of 96,000 tonnes, farmers could have saved \$3,629,000 in the first 9.5 months.

## **Summary Issues with Registration of this product**

- Lack of communication by CFIA regarding process changes.
- Lack of communication between CFIA and government departments regarding the original trademarked name.
- CFIA's lack of accountability to timelines and their own performance standards.
- In summary, the issues that held this submission back were not ones of feed safety, but rather administrative and proving efficacy.
- Company C is a Canadian firm and will continue to register products in Canada, as their mandate is to provide the Canadian market with products that will reduce costs at the farm gate and will allow Canadian farmers to produce wholesome products utilizing Company C researched and scientifically published products.
  - Many companies have anecdotally suggested that they have given up on registering innovative feed products in Canada – a loss for the agri-food sector. In contrast, Company C has maintained its Canadian focus; in doing so it is at a competitive disadvantage due to the Canadian regulatory system
- The Natural Sciences and Engineering Research Council of Canada (NSERC) has recognized Company C's contributions by granting them the Synergy Award and the Alberta Government granted Company C the ASTEC Award. The NSERC, IRAP, AARDI scientific funding groups continue to partner with Company C in search of new technologies for applications to farm production and to enhance Canadian export sales. Company C finds it unfortunate that the CFIA does not dialogue with these scientific departments and realize that they stifle what in fact these departments are trying to accomplish.

### **3.4 Case D: Phytase Supplement for Poultry and Swine**

Case D involves a phytase supplement for poultry and swine feeds, which was developed by Companies D1 and D2. This case study details the lengthy registration process of Product D.

#### **Background**

Both poultry and swine require dietary phosphorus for normal body maintenance and growth. Phosphorus is an essential element required in many physiological processes in swine (Jacela et al. 2010) and poultry. Phosphorus is abundant in most grains used in livestock feeds, however phosphorus as it exists in grains (in phytate form) is not readily digestible by swine or poultry and a large amount of phosphorus is excreted as waste. Therefore, historically, supplemental inorganic phosphorus was added to swine and poultry diets. Furthermore, phytate has additional unwanted effects as it can decrease the availability and utilization of other essential nutrients in animal diets (Jacela et al. 2010).

Phytase is an enzyme that breaks down phytate in feeds in order to release phosphorus in a form that is available to the animal. The addition of phytase to livestock diets “reduces the need for supplemental inorganic phosphorus and improves the nutritional value of feedstuffs” (Jacela et al. 2010).

Product D is a phytase supplement that releases phosphorus and other nutrients making them readily available and utilized for growth and development in swine and poultry. Product D is manufactured by Company D1 in Denmark that has been operating out of the United States since the 1990s and started selling phytase in the US in the 1990s.

### **Submission Experience**

In 2000, Company D1 submitted a novel ingredient registration to have phytase approved for use in swine and poultry diets in Canada. Over the course of a year Company D1 felt it was making little progress. Therefore, in September 2001 Company D1 asked Company D2 to lead the submission process since they needed a Canadian agent and Company D2 was more familiar with the Canadian regulatory system.

Company D2 understood that this submission required registering the organism first, then the product under a novel registration. CFIA informed Company D2 that there were two primary requirements for the submission:

- Safety assessment – as per the “Guidelines for Safety Assessment of Novel Feeds: Microbial Sources”
- A lab assessment – so that CFIA can reproduce the assay methodology used by the manufacturer.

In October 2001, the CFIA Feed Section held a basic registration workshop at the request of ANAC. The dialogue in the workshop was open and participants discussed specific issues and discontent with the regulatory process. CFIA personnel from various product registrations including Biotech were present and Company D2’s representative was told that the Biotech team had expanded and understood that more guidance was required throughout the registration process. This led Company D2 to be optimistic about an improved submission process.

In May 2002, ANAC arranged a meeting with CFIA to specifically discuss enzyme registration because many of their members were having difficulty getting these products registered.

Discussion topics included:

- Delays in response time from CFIA
- Additional requirements not listed in the Guidelines
- CFIA lab service backlog

Again, Company D2 came away encouraged by the meeting and optimistic that the registration process would improve after receiving assurances from CFIA.

Around the same time, Company D1 developed a new and improved strain of enzyme – in both dry and liquid form. This new strain was submitted for registration. Company D2 contacted CFIA to enquire as the data required for phytase submission.

Between May 2002 and December 2002 CFIA requested additional information and Company D2 provided it as required. In December 2002, Company D2 was given temporary registration for the product until the lab analysis could be assessed. Although Company D2 understood the risk, it went ahead and marketed the product because of strong consumer demand in Canada.

In March 2003, a feed manufacturing client of Company D2 incorporated Product D into a feed product. This client understood that a claim needed to be put on its product and asked Company D2 if they had an efficacy claim for the Product D label.

In discussions with CFIA, Company D2 was also made aware that feeds containing Product D would be considered specialty feeds. As a result, Company D2 was required to submit efficacy data so that other feed manufacturers using the product would not have to submit their own efficacy data. In May 2003 Company D2 submitted the efficacy data so that feed manufacturers could label the feed.

Despite the earlier back and forth communication with CFIA, Company D2 was not made aware that they needed to provide efficacy data to substantiate the phytase claim on the label. Company D2 wonders why at no time throughout the registration process CFIA did not mention that efficacy data was required.

In July 2003 CFIA requested further data. Since the studies that Company D2 submitted were internal studies and not peer reviewed, CFIA required the raw data from the studies be submitted. Company D2 was obliged and submitted the data in September for each species' study from studies that were peer reviewed.

In December 2003 Company D2 received a letter from CFIA stating that CFIA felt that the data in one of the studies did not support the claim, that there was too much analytical variance in the data and therefore Company D2 was required to submit another swine study within 60 days. Company D2 responded to the objections in the letter a month later by refuting the conclusions and refused to submit another study. It seemed obvious to Company D2 that the reviewers were unfamiliar with assessing performance data. The reviewer accepted Company D2's arguments.

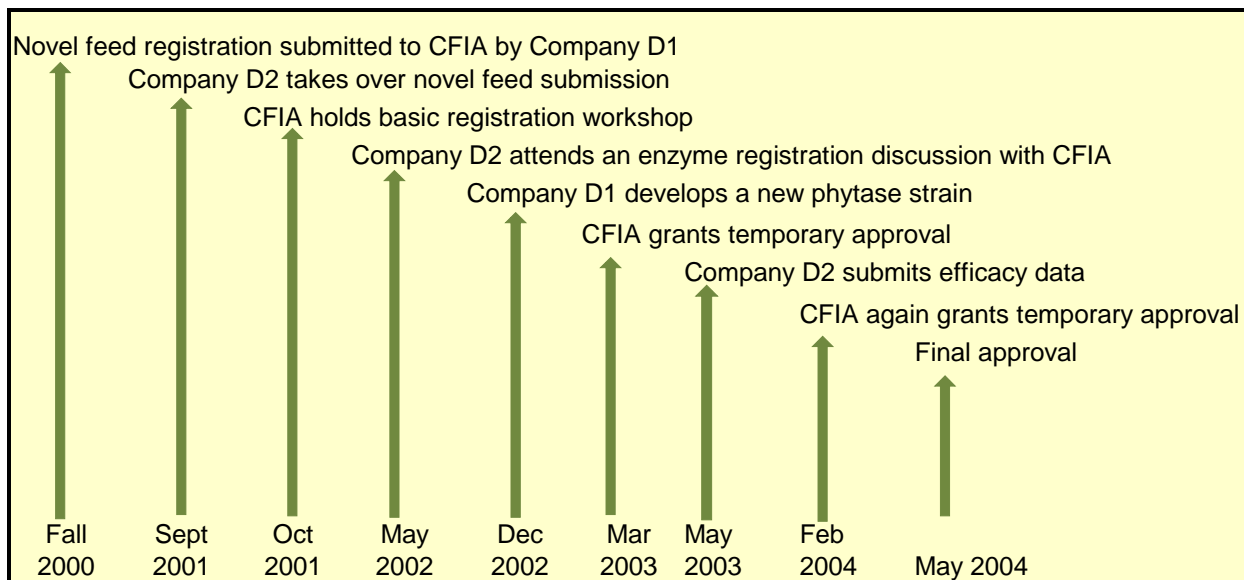
In February 2004 temporary registration with the phytase efficacy claim was granted even though CFIA was still assessing the lab methodology. At this point, due to the length of time the submission had been in process, CFIA required a fresh phytase sample.

The final approval of Product D was received in May 2004.

Due to the continual data requests and the lack of accountability to the 90 day standard application rule, Company D2 felt that the process lacked transparency, communication and timeliness on behalf of CFIA. The issues that prolonged this submission were ones of administration and process, the lack of understanding of the industry and scientific knowledge by CFIA reviewers. Additionally, Company D2 was surprised regarding the difficulty in registering the enzyme since another company had registered a similar product years earlier. Company D2 questions the value of CFIA's involvement in establishing efficacy for this type of product, as the market would not support a product that didn't perform as expected.



**Figure 3.3: Timeline of Product D application process**



### Feed Manufacturer Use of Product D

As described above, the use of this phytase enzyme allows phosphorus nutrients to be more available to the animal and therefore reduces the need for supplemental inorganic phosphates to be added to poultry and swine diets. However, as described in Section 2.2, Table IV nutrient requirements do not accommodate the use of new ingredients and additives. Table IV has a minimum limit on phosphorus of 0.5% content of a complete feed.

Scientific studies of feeding trials using phytase technologies have proven that feeds can be formulated to a lower level of phosphorus, and these technologies, such as Product D, have been registered by CFIA. However, Table IV has not been updated to accommodate this new technology and the result is that feeds that utilize this technology will inevitably not meet Table IV requirements and therefore must be registered. There are likely thousands of feed formulations that are affected and this provides a disincentive to register these products. Technically, feed manufacturers are not being prevented from using phytase by CFIA but the regulations make its use more difficult and costly than necessary.

### Approval in Other Jurisdictions

Product D has been approved in the United States since February 2000 and in the EU since July 2000. Through experience the approval process was much more clear, transparent and timely in these jurisdictions.

In the United States and Europe this product has also been approved for use in duck feeds. However, due to CFIA’s requirement for efficacy studies in ducks and geese, and Company D2’s past experience in getting the product approved for poultry and swine feeds, Company 2 has decided not to conduct studies on ducks and geese as the market in Canada is not big enough to warrant this.

Also in the United States and Europe this product is approved for aquaculture but is not approved for use in Canada. Again Company D2 has made the decision that the registration process is too onerous relative to the market size in Canada. In July 2003 Company D2 inquired about an application for aquaculture approval. CFIA requested chronic toxicology studies different from the mammalian studies that they had – CFIA wanted an acute and a chronic toxicology study conducted in the target species or a ‘sensitive’ species that correlates well with the target species – Company D2 would have likely had to do one for each fresh water and marine species. It was at this time that Company D2 decided the Canadian market was not big enough to justify the costs of the required studies.

As a result of the experience registering Product D in Canada, Company D2 has also made the business decision not to pursue a registration for another product, which is used in poultry and pig diets to help with the digestion of cereals and cereal by-products. This product is available in both the United States and Europe.

Unfortunately, the absence of these products in the Canadian market is a loss for Canadian livestock and aquaculture producers.

### **Environmental Impact**

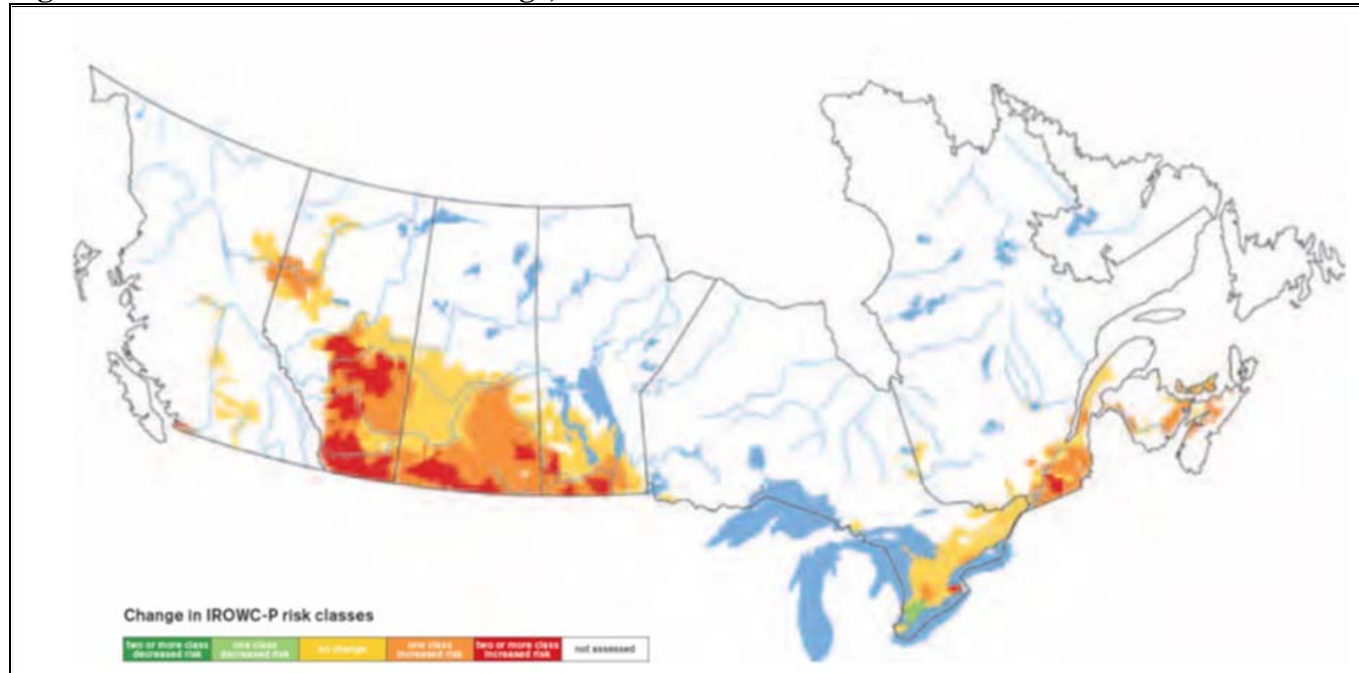
Excessive amounts of phosphorous (P) in manure can lead to the risk of soil phosphorus saturation and result in the contamination of water bodies, which contributes to the eutrophication of rivers and lakes. Eutrophication can lead to *Cyanobacteria* blooms (AAFC, 2010). Aquatic *Cyanobacteria* is also known as blue-green bacteria or “pond scum”, which can develop blooms that are visible as blue-green paint or scum on freshwater and marine environments. Therefore, *Cyanobacteria* decrease water quality and therefore limit water use (Health Canada, 2010).

In general, phosphorous source levels have been increasing in Canadian surface soils because of excessive P application. Very high concentrations of P have been located in regions with intensive agricultural activity (Bochove *et al.* 2010). In order to assess the risk of surface water contamination by phosphorous from Canadian agricultural land over time Agriculture and Agri-Food Canada (AAFC) uses an indicator called: ‘Indicator of the Risk of Water Contamination by Phosphorous’ (IROWC-P). It measures the contamination at the watershed scale<sup>6</sup> and only considers agricultural P risk. Bochove *et al.* (2010) classified farmland into different risk classes from ‘very low’ to ‘very high’. Figure 3.4 shows the changes in risk classes from 1981 to 2006. The amount of farmland that had to be classified into higher risk classes is significant. From 1981 to 2006, 43 percent of the investigated 280 watersheds moved into a higher risk class.

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<sup>6</sup> A detailed description of the calculation of IROWC-P can be found in Bochove *et al.* (2010).  
George Morris Centre

**Figure 3.4: IROWC-P risk class change, 1981–2006**



Source: Bochove *et al.* (2010), p. 89.

Bochove *et al.* (2010), suggest different response options to decrease the risk of water contamination by P. One of them is the use of phytase:

*“For example, appropriate use of the enzyme phytase in monogastric animal feed enables producers to reduce the quantities of P supplement they introduce in the animal ration and, consequently, reduce the P concentration of manures. As the proportion of animals fed with phytase increases nationally, the quantities of P in manure will decrease.”* (Bochove *et al.*, 2010, p. 88).

As mentioned above, Table IV nutrient requirements do not accommodate the use of new ingredients and additives, such as phytase, to its full extent. Table IV has a lower limit on phosphorus of 0.5% content of a complete feed. That is, this amount of phosphorus must be included in a feed ration, even though feed with added phytase could have lower amounts of P but still fulfill nutrient requirements.

Hence, while Agriculture and Agri-Food Canada recommends the efficient use of phytase to reduce the amount of phosphorus in feed, the Canadian Food Inspection Agency dictates a minimum amount of phosphorus. Theoretically, with the addition of phytase, 1 kg of P could be saved for every ton of feed produced for swine and poultry. That would decrease the amount of P excreted in manure, and ultimately, prevent excessive amounts of phosphorus entering Canadian water streams and lakes.

## **Impact and Opportunity Costs**

The lengthy approval process for Product D in the Canadian market had several implications:

- The original application for Product D registration was submitted in the fall of 2000 and it received final approval in May 2004. However, Company D2 began selling the product when it received temporary registration. If this submission was a standard submission, as expected by Company 2 since a phytase enzyme had been approved years earlier, and the submission was reviewed in a timely and knowledgeable manner it was assumed that Product D would have been on the market by January 2001. Therefore, Company D2 lost the potential to sell this product for just over two years before it was approved.

Based on the trend in actual sales data beyond 2003 it is estimated that Company D2 lost approximately \$9,093,739 in 2010 dollars in sales during that period.

- Replacing dicalcium phosphate with Product D provides poultry and swine producers with cost savings. With dicalcium phosphate at 20% P and assuming that all P is available, the 200g/MT recommended dose of Product D will replace 5 kg of dicalcium phosphate in the feed ration. Assuming a dicalcium phosphate price of \$0.70/kg and a list price of Product D of \$8/kg – based on the estimated tonnes of feed supplemented, swine and poultry producers would have saved \$9,655,051 between 2001 and 2003 (NOTE: that this does not account for the cost of rebalancing rations).
- As a result of less phosphorus being excreted, producers require less land for manure disposal thereby reducing manure disposal costs.

### **Summary Issues with Registration of this product**

- Inconsistent and continual requests for more and new data.
  - There are guidelines for submission, not a formalized process, which allows CFIA to continually ask for more data and be inconsistent
  - Data requirements were above and beyond that asked for in any other jurisdiction
- CFIA lack of communication – with respect to informing Company D2 that efficacy data was required to substantiate a label claim.
- Slow responsiveness of CFIA throughout the process
- CFIA lack of understanding
  - No relationship to food, feed and the livestock industry
  - Lack of understanding of feed applications
- Lack of communication that held up the label claim and efficacy review requirements
- For feed manufacturers: restrictive Table IV nutrient ranges with no adaptation to well-known technologies such as phytase triggers all feeds utilizing it to be registered.

### **3.5 Case E: Mineral Supplement**

Case E involves a mineral supplement (Product E) for swine and cattle that has been proven to improve reproductive performance and average daily gain. These production improvements are

supported by published scientific literature. This case study highlights the registration process for swine in Canada.

## **Background**

The global pork market is highly competitive; therefore swine producers are looking for innovative ways to improve productivity and increase profit margins. Product E is a mineral supplement (molecule) that improves average daily gain of growing and finishing swine and increases reproductive performance in gilts and sows.

Company E received patents for this product in the late 1990's. It was then approved for use in the United States for all phases of swine production in 2000. After Product E was approved in the United States, Company E wanted to introduce it to the Canadian market.

## **Submission Experience**

In 2001 Company E submitted a novel registration for Product E. CFIA required that the product be added to Schedule IV as a new ingredient so that Company E could use the new ingredient in swine feeds. Therefore, there were two parts to this application:

1. Application to get the base product/new ingredient approved
2. Application to get the blended product approved in swine diets

The submission package was comprehensive and included efficacy data, safety data, stability data, labels, methods of analysis, and certificates of analysis. Based on past experience Company E felt that the guidelines provided by CFIA required traditional scientific data and nothing above and beyond what had been required in the United States. Company E also communicated with CFIA prior to submitting its registration package to ensure that it would be complete and that CFIA understood the product and its use and was therefore comfortable that the submission process would be relatively smooth.

CFIA responded with questions regarding the submission that left Company E with little confidence in the competence of the reviewers' understanding of basic animal science and basic livestock feeding principles. For example, literature supports that 90% of all commercial pig production in Canada is based on cross breeding, yet CFIA did not accept this information as fact.

Between 2001 and 2005 Company E went back and forth with CFIA in an attempt to get approval for all stages of swine. A face to face meeting was held in mid-2005.

In mid-2005 CFIA approved the product for growing and finishing swine. Company E was surprised by a restricted approval to a certain swine breed since never in any other country had the product been approved for only one class of swine and one specific breed, even though animal trials were conducted across breeds.

CFIA required that Company E conduct more animal trials on further classes of swine to extend the approval. A group consisting of Company E, the ingredient distributor in Canada and a feed

manufacturer met with CFIA face to face to discuss the issue further and determine what was required to get an approval for sows. Again Company E was left with little confidence in the reviewers' and their understanding of the industry that they regulate.

In 2006 Company E provided CFIA with experimental protocols to review for sow studies. It is Company E's policy to provide the regulators with their protocols first in order to get buy in and avoid any surprises, and then provide them with the data following completions of the trial. Again in 2006 Company E accompanied by the same group of industry stakeholders met with CFIA to explain the protocols. At this meeting CFIA in essence agreed to the protocols and as a result Company E conducted trials in sows. It is important to note that these trials took over one year to complete and were not required in other jurisdictions where Company E sought registration.

In late 2007 the trials were finished and Company E went back to CFIA to present the data. Again, Company E presented the data in person first to provide an opportunity for CFIA to ask questions so there would be no surprises when the dossier was submitted. Company E then submitted the trial data.

Throughout 2008 Company E went back and forth with CFIA. Company E would receive a letter stating that they had 60 days to respond to a request for more data or the submission would be cancelled. The time requirements given showed that the reviewers did not understand how long it would take to generate the requested data, given the gestation cycle of swine.

In mid-2009 Company E met face to face with CFIA again to discuss the progress of the submission. In late 2009 Company E was granted temporary registration. It took CFIA four months from the time of the meeting, to send a letter. It should be noted that there was no additional data to review during that time. A temporary registration was granted for sow diets with no label claim. Company E states that the issue of the claim was never discussed in their meetings with CFIA, another surprise.

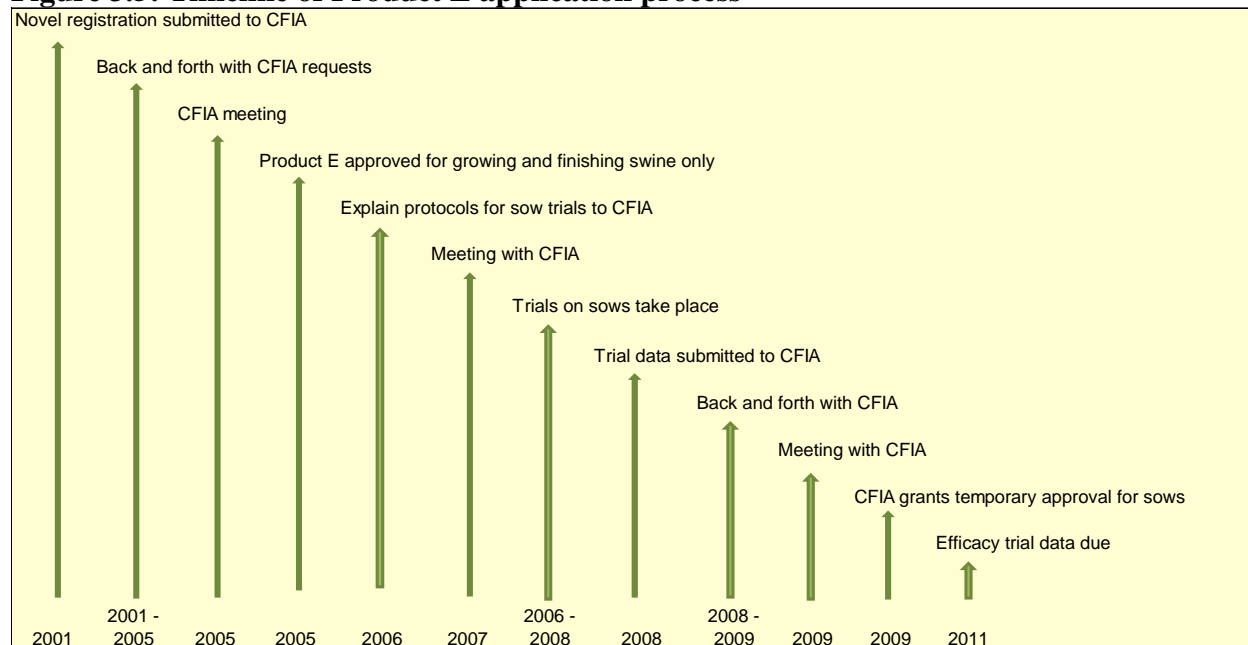
In order for Company E to get an approved claim on the product efficacy, additional trials on sows were conducted. Company E was given 15 months (to early-2011) to conduct efficacy trials on sows.

Once Company E received temporary registration in late 2009 it began selling the product.

In summary, Company E believes that the product registration regulations are clear but that CFIA is not confident enough to make decisions on submissions on a timely basis and therefore continually asks for more data. The pre-submission meetings held with CFIA were intended to circumvent questions and delay in the process once Company E submitted its data but Company E believes that CFIA put no value on the pre-submission meetings. Company E also believes CFIA is hesitant to approve new products for use in Canada.

The issues that held this submission back were not ones of feed safety or lack of product efficacy, but rather administrative issues such as a lack of communication on behalf of CFIA and a lack of understanding animal science and the livestock industry in Canada.

**Figure 3.5: Timeline of Product E application process**



**Product E Patent**

Company E received patents on this molecule in the late 1990’s. However, because Canada has no patent term restorations on feed ingredients, time has ticked away on the patent. Throughout the registration process Company E has continued to pay maintenance fees on the existing patents even though it could not use them. By the time Product E receives full approval there will be less than 40% of the time left on the 20-year patent.

**Approval in Other Jurisdictions**

Product E is approved in at least 18 countries that require regulatory approval. No other country separated the registrations by production class or genetics/breed.

**Countries that have approved Product E**

USA	Argentina	China
Mexico	Brazil	Chile
Guatemala	El Salvador	Dominican Republic
Belarus	Russia	Ukraine
South Africa	Saudi Arabia	United Arab Emirates
Egypt	Morocco	Turkey

After the initial submissions were made in the other jurisdictions, Company E was required to make minor changes on labeling and claims. The changes requested were minor and expected and Company E was not surprised because when necessary they utilized pre-submission meetings similar to their pre-submission meetings with CFIA.

In the United States this product is approved for dairy and beef cattle. However, due to the registration woes in Canada, Company E is uncertain whether or not such a claim extension should be pursued in Canada. This is a significant opportunity cost for cattle producers in Canada.

### **Impact and Opportunity Costs**

Company E's first registration was submitted in 2001. If this submission process was managed efficiently, based on CFIA performance standards it was assumed that the mineral supplement would be on the market by 2002. However, due to the lack of understanding the product and its purpose, a temporary registration was not granted until 2009 for use in sow diets, which represents the primary market opportunity.

The period in which the lag in approving this product for the Canadian market occurred was coincidental with a period of growth for Canadian hog producers and feed manufacturers. Between 2002 and 2007 was a significant growth in the market for hogs in Canada, as illustrated by the increase in sow numbers. There was a market hiccup in 2008 as the Canadian dollar strengthened and hog numbers began to decline. Added to that, the implementation of Country of Origin Labeling has affected the market as well. Therefore, this lengthy regulatory approval process was of great consequence to the hog industry in Canada as the period when it was not approved includes a very positive period for the pork industry.

The lengthy approval process of Product E into the Canadian market had several implications:

- As noted above, it was expected that Product E would be approved and on the market by 2002; instead it was granted registration in 2005 and 2009 for the primary intended market. Therefore Company E lost the potential to sell this product to its target intended market for approximately 7 ½ years before it was approved.
- Based on market share estimates, feed consumption and product dosage, it is estimated that Company E lost approximately \$ 22,349,508 in 2010 dollars in sales during that period.
- Company E's protocol during the registration process is to meet with the regulators to discuss their submissions and any other issues that arise. In this case Company E made numerous trips to CFIA along with other supporting key stakeholders. The time, travel and hotel costs were direct costs paid by Company E.
- Company E has estimated that over the submission period it has required a half-time position to manage the submission. This includes attempting communication with CFIA, managing data requests, animal trial design and management, report writing, dossier preparation and the like. The opportunity cost is significant because this time could have been better spent on new R&D for markets other than Canada which is difficult to enter with 'new' compounds.



- Product E has been proven to improve reproductive performance in sows, by increasing litter size by one pig/sow/year. This is a significant increase in productivity. Producers make investments in sows, therefore the more pigs they can raise and market from these sows, the greater their return on investment.

Based on the number of sows in the country and average revenues per market hog in Eastern and Western Canada, hog producers lost out on potential revenues of \$1,033,350,303 over the eight-year period.

It must be noted that hog production is a cyclical industry and during this period there were both profitable and non-profitable years. In 2004 and 2005 hog producers yielded an estimated net profit of \$22-25/market hog. This is a period of time when Product E could have been marketed where there was very strong profitability.

However, in other periods, due to high feed and input costs among other issues, there were bruising losses. Between 2007 and 2008 producers were losing between \$29-36/market hog. This being acknowledged, producers could gain income when marketing an increased number of pigs and therefore improve return on investment.

In the past few years, the Canadian government has been supporting the hog industry with payments of millions of dollars, while at the same time productive technologies are bogged down in unnecessarily long approval processes.

### **Summary Issues with Registration of this product**

- CFIA personnel did not understand the animal science or the livestock feeding industry.
- Inconsistent and continual requests for more and new data.
  - Guidelines are clear, but the actual process is inconsistent with guidelines.
  - Constant requirement for more data allows CFIA to put off making decisions on products.
- Lack of communication on behalf of CFIA
  - Company E made repeated attempts to open up communication but they were virtually ignored by the regulators.

### **3.6 Case Study Summary**

In summary, the five case studies profiled in this report clearly show that the feed registration system in Canada has had a significant economic impact on the Canadian agri-food sector.

The cases highlight that the inefficiencies with the system stem from both regulation and administration, specifically: the restrictive Table IV requirements that are outdated and restrict modern feed formulation, the lack of a clear framework or process for supplements and other functional ingredients, the requirement for efficacy data and that CFIA regulators are neither communicative, transparent or accountable to performance measures and timelines.

### **Lags Identified in the Case Studies**

- Restrictive Table IV nutrient ranges.
- Lack of formal submission framework for ‘functional’ supplements and other ingredients or products.
- Requirement of efficacy data when a claim is not being made.
- Ability of CFIA to request a name change.
- Lack of transparency in the process.
- Lack of communication by CFIA to applicants.
- Lack of accountability to timelines and CFIA performance measures.
- Lack of consistency in application and re-approval process.

As shown in the box above, the majority of the identified lags within the system have little to do with feed safety. Overall, the current regulatory system, and the way in which it is administered, is incapable of meeting the needs of an innovative feeds industry wanting to provide new products to their clients in a timely manner.

### **Economic Impact**

Table 3.1 shows the direct costs, potential lost sales and opportunity costs to primary producers incurred while participants worked within the feeds regulatory system to get new products approved.

#### *Direct Costs*

Although there is a cost associated with feed registration, case participants agree that there are additional costs, beyond what is required in other jurisdictions, which are deemed unnecessary. The direct costs in Table 3.1 also include sunk R&D costs as a direct result of products being rejected or not re-approved.

#### *Potential Lost Sales*

The potential lost sales shown in Table 3.1 are a result of delays by CFIA in approving/rejecting decisions or a result of a denial that is not based on feed safety.

#### *Opportunity Costs to Primary Producers*

As mentioned above, for livestock producers not having access to one feed product is likely not the end of the world because of available alternatives. However, as the sample of tools that cannot be accessed here grows, it chips away at producers’ abilities to compete with those in jurisdictions that have access to innovative feed products. Table 3.1 also shows that new feeding technologies can also lead to potential cost savings.

The foregone economic activity listed in Table 3.1 resulting from working within the feeds regulatory system is a significant loss to the economy. This study reports on only five cases while it is known that there are many more Canadian feed companies experiencing similar

hurdles and losses while maneuvering through the regulatory system to provide new and innovative products to their clients. It must also be noted that the costs listed here are short term. In the longer term the costs will be higher, as case participants noted that the inefficient regulatory system has caused a disincentive to conduct R&D and have products registered in Canada. In fact, it is impossible to calculate the costs of the regulatory system on the overall economy. But, if companies continue to run into road blocks trying to commercialize new products investment in Canada will decline, less R&D will take place here, and fewer innovative feeding tools will be available to the livestock industry.

**Table 3.1: Summary of Economic Impact of Case Studies**

Case	Direct Costs	Potential Lost Sales to Ingredient and Feed Manufacturers	Opportunity Costs to Primary Producers
A	<ul style="list-style-type: none"> <li>\$50,000 – sunk R&amp;D</li> </ul>	<ul style="list-style-type: none"> <li>\$28.6 million – ingredient supplier</li> <li>\$5.9 million – feed manufacturer</li> </ul>	<ul style="list-style-type: none"> <li>Fewer tools to choose from in managing ketosis – results in labour and equipment costs</li> </ul>
B	<ul style="list-style-type: none"> <li>\$250,000 – sunk R&amp;D</li> <li>*Opportunity cost: 2FTE jobs (\$100,000 per year) at feed manufacturer</li> </ul>	<ul style="list-style-type: none"> <li>\$1.4 million</li> </ul>	<ul style="list-style-type: none"> <li>Fewer tools to choose from in managing ketosis – results in labour and equipment costs</li> <li>Effect on livestock performance from switching products</li> </ul>
C	<ul style="list-style-type: none"> <li>\$4,000 – application preparation beyond requirements of other jurisdictions</li> <li>\$700 – sunk costs due to trademarked name change</li> </ul>	<ul style="list-style-type: none"> <li>\$50,040</li> </ul>	<ul style="list-style-type: none"> <li>\$ 3,629,000 – potential feed costs savings</li> </ul>
D	<ul style="list-style-type: none"> <li>Time and labour of managing onerous process</li> </ul>	<ul style="list-style-type: none"> <li>\$9.1 million</li> </ul>	<ul style="list-style-type: none"> <li>\$9.7 million – potential feed costs savings</li> </ul>
E	<ul style="list-style-type: none"> <li>One half-time position to manage submission</li> </ul>	<ul style="list-style-type: none"> <li>\$22.3 million</li> </ul>	<ul style="list-style-type: none"> <li>\$1.0 billion in potential lost revenues</li> </ul>

## Conclusions

Along with their case study experiences, case participants and other stakeholders provided their general observations regarding the current feeds regulatory system.

- The feeds regulatory system should focus on feed safety
  - In many of the cases above, the time lags and reasons for denial of submissions were not due to safety issues. Instead, CFIA requirements for name changes and administrative delays were largely the culprits. In fact, the delays and denials did not make the feed and livestock industries safer.
  - Efficacy data should only be required when a claim is made.
  - If the regulations focused solely on feed safety, this would free up some time for CFIA.

- The current regulations do not apply to current science
  - The cases clearly show that the regulations have not adapted to the significant developments that have taken place in the feeds industry.
  - For example, Table IV is oriented to complete feeds, and feeding tools such as supplements do not fit within its restrictive nutrient requirements
  - The research on and use of phytase in poultry and swine diets globally has been a significant development in the feed industry. However, Table IV's phosphorous requirements makes phytase use in feed redundant because the Table IV requirements are exempt of criteria such as the use of this new science. This occurs despite the fact that the technology has been proven and registered by CFIA.
- There is a lack of communication among federal government agencies
  - No communication, no sharing of information when a submission must be reviewed by more than one department or when a department has already reviewed a submission.
- Administration improvements are required
  - CFIA personnel should be accountable based on timelines and other performance measures
  - Many of the issues could be resolved by ensuring that cultural and personnel concerns are addressed
  - It was noted by participants that there is an overall sense of arbitrariness from CFIA
  - There is a lack of communication during the application process and a lack of guiding applicants through the process therefore applicants come up against requirements that they were not aware of.
  - CFIA reviewers do not understand the industry they are regulating
- The inefficient regulatory system has caused a disincentive to invest in R&D and have products registered in Canada
  - Anecdotally, many companies have walked away from registering ingredients in Canada since Canada is already a minor market and the extra hassle and cost is not worthwhile.
- The registration process in Canada is so onerous that companies require dedicated regulatory personnel. However, many companies in Canada are not large enough to have personnel solely responsible for regulatory affairs and this creates a real disadvantage for small, innovative, independent firms.
- CFIA labeling requirements for manufactured feed ingredients are much different than the other large global markets making labeling in Canada's small market much more expensive.
  - For feed products manufactured outside of Canada, labels are applied at the time of manufacture to show lot numbers and manufacturing dates. Global labels are set up to comply with US and EU feed regulations.

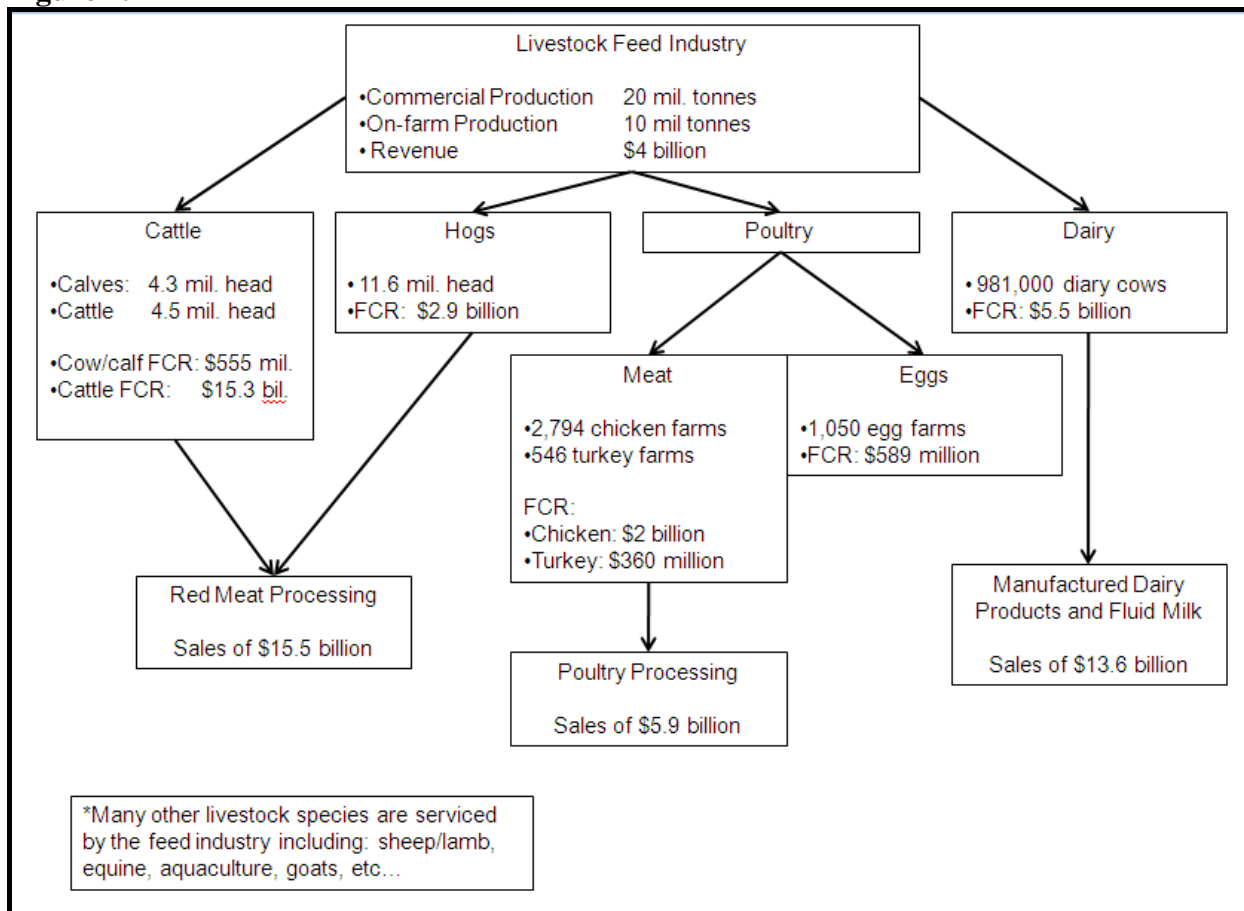
- Canadian labeling regulations are very specific –
  - Ingredients must be listed according to Schedule IV and V descriptions
  - Units/kg are required, which is appropriate for feeds but not feed ingredients such as vitamins, enzymes and other supplements (units/g are utilized in the global labels)
- Because the Canadian labels are inflexible, manufacturers must add a separate Canadian label which is time consuming, costly and logistically difficult (since at the time of manufacturing, the plant does not know where the product is going; therefore, the Canadian labels must be applied at the Canadian distribution centre).

#### **4. Summary and Conclusions**

The feed industry in Canada is a significant contributor to the Canadian economy. Feed represents the most valuable input to livestock production and is also the largest input cost for livestock and poultry producers. Therefore, it is important to ensure that the feed industry has the ability to provide the livestock industry with the newest, most cost effective technologies.

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 an up-to-date and efficient feeds regulatory system, both in regulations and the administration of the regulations.

Figure 4.1



Through the analysis of the five case studies, researchers draw the following conclusions:

The regulatory system is hampered by a power struggle, which obstructs the provision of safety. Several of the examples illustrate this; none more clearly than not accepting a name for a product that included the word omega because the enzyme in question contained no omega-3. To suggest, at the same time, that the product name should contain the word flax, despite the fact that it also contained no flax is a clear indication of the need to resolve serious system issues. Throughout the case studies, this type of inconsistency is continually identified. Unfortunately, this is also true in other case studies of the Health Canada/CFIA system, cited earlier. It is promulgated by a system that continually professes to have too few resources, yet focuses more on the exertion of its power than on issues of importance. It, therefore, illustrates that the system is severely damaged, and must be reformed to act in the public interest.

In essence, the regulatory system fails to promote domestic companies by impeding registration of new innovative products that add value to traditional feed mixes. As a result, it also impedes the primary production sector by not making available or delaying approval of tools that are more cost effective, reduce labour requirements and are more environmentally benign. In the end, the real opportunity cost will be that feed manufacturers will have nothing innovative to offer the livestock industry, and therefore Canadian livestock producers will continue to fall behind their competitors.

The economic impact shown in Table 3.1 is the result of only five case studies, yet there are numerous other examples that could be illustrated from across the industry. The direct and opportunity costs illustrated are short-term costs, but it is the longer-term costs that will be irreversible. Once R&D is lost from a jurisdiction it will be difficult to entice a company to bring it back. As companies get frustrated, there is a loss of desire to register products in Canada. Again, this has significant long-term impacts on the feed manufacturing and livestock industries in Canada.

This study showed that many of the issues affecting the feeds regulatory system are similar to those faced by other industries within the agri-food sector<sup>7</sup>. It also clearly shows that the issues span both the regulations and the administration of those regulations.

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<sup>7</sup> **Brethour, C. et al. 2004.** The Competiveness Impacts of Canada's Agricultural Product Review Regulations. Research conducted by the George Morris Centre. Prepared for the Canadian Animal Health Institute. **Brethour, C. et al. 2005.** Possible Incremental Measures to Address Horticulture Sector Concerns With Pesticide Regulation in Canada. Research conducted by the George Morris Centre. For Agriculture and Agri-Food Canada.; **CANTOX. 2007.** International Comparison on the Management of Health Claims and Novel Foods. CANTOX Health Science International.; **Stiefelmeyer et al. 2008.** Food Regulatory Systems: Canada's Performance in the Global Marketplace: A Case Study Approach. Research conducted by the George Morris Centre. Prepared for Food and Consumer Products of Canada.

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## **Appendix A: Estimating the Economic Impacts**

There are two types of loss accounted for when the economic impacts were estimated in each of the cases: direct losses to the feed manufacturer/feed ingredient supplier and upstream losses to the primary agriculture sector.

### ***Direct Losses to the Livestock Nutrition Company:***

1. The cost of providing additional data and information for Canadian regulators; i.e., information/data that were not anticipated or required for other jurisdictions' approval
2. Lost market potential due to the delayed approval decision. When estimating the lost market potential, the net present value<sup>8</sup> was calculated from the estimated market losses every year the company waited for approval. We have calculated losses up to 2009 (so we can keep with full years). It should be noted that these calculations take into account an appropriate amount of time for the CFIA to provide a decision, based on the CFIA's own service standards of 90 business days (13 weeks). Thus, the calculations of potential market losses start three months after the submission of an application by each company. For example, if Company X submitted an ingredient for approval on January 1, 2008, potential market losses would begin to accumulate on April 1, 2008.

### **Measuring Opportunity Costs in Product Regulatory Approvals**

The delays in product approval and forfeitures of submission described in the case studies create real costs to the livestock nutrition industry. To measure these costs, two related approaches are used.

#### **1. Reference to Other Jurisdictions**

In many cases, feeds and feed ingredients that have been submitted for product regulatory approval in Canada or have been withdrawn from the process have received product regulatory approval in other countries. From these other countries, product sales and growth over time can be observed. Provided that the reference country is analogous to Canada, forgone Canadian sales can be estimated by attributing sales on a per livestock head basis from the reference country to Canada. For example, for a product approved in the US but withdrawn or delayed in Canada, the observed US sales can be converted to a per livestock head basis and then attributed to the Canadian market.

#### **2. Calculation Based on Manufacturer Sales Projections**

A key aspect of the product development process is sales projections for a new feed product being introduced. This is typically done by the manufacturer in tandem with production planning and submission for regulatory approval. Projections will tend to be based on experience and are by nature prospective, but since they can carry great significance are also internally vetted. Where these projections are available, they can be used as a basis upon which

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<sup>8</sup> A discount rate of 5% was used for the net present value calculations.

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to estimate lost sales due to regulatory issues. While they cannot be independently verified, for the reasons stated above they can be very useful. As with the above approach, sales levels are used to estimate lost feed manufacturer and supplier margins.

***Upstream Losses to Primary Agriculture:***

In order to calculate the opportunity costs to livestock producers of not having access to new and functional feeds to improve nutrition or some other targeted performance indicators, we've used health issue and disease costs per animal as well as efficiency costs where appropriate, calculated potential feed cost savings and calculated potential lost opportunities when the products have proven productive gain.