



Animal Nutrition Association of Canada

## Overview of International Feed Regulations

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*August 25, 2010*



## Introduction

*This document provides a brief description of the feed regulations in the European Union, the United States, and Australia and New Zealand. The intent is to focus on recent developments rather than provide a comprehensive analysis. Other key emerging global issues are also discussed. The goal is to draw attention to those areas where Canadian regulatory practice has not kept up with international practices and realities, harming the domestic feed industry's export potential and threatening its survival when faced with more technologically advanced competitors.*

Feed products have for some time received considerable attention from public bodies, but a number of issues are contributing fresh impetus to the drive to reform feed regulations. Continued growth in world population and GDP will lead to increased meat consumption. This in turn will create more demand for feed and supplements and a requirement for better products that are both safer for consumers and for the environment.

On a global scale, it is estimated that annual global feed production is around 614-million tons, but this is only the registered production and often integrated production is not calculated. Furthermore there are an estimated 3,800 feed mills worldwide, which appear to produce 80 percent of all feed. This means an average production of 13,000 tons per mill per year. (Source: <http://www.allaboutfeed.net/feed-around-the-world/> )

The regulatory apparatus in most countries generally divides into three categories:

- Regulation of the content of feed products, including supplemental ingredients and medicinal compounds;
- Regulation of the manufacturing processes of feed products, including distribution; and
- Regulation of the labeling and promotion of products in commercial use.

All three activities share the common purpose of ensuring food safety both for humans and for animals.<sup>1</sup>

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<sup>1</sup> A useful blog on a range of topics is <http://www.allaboutfeed.net/>; Feed International provides current news, [www.fi-digital.com](http://www.fi-digital.com)

Throughout the developed world, food regulatory agencies and the feed industry alike are striving to maintain and improve food safety through the adoption and application of Good Manufacturing Processes (GMP)<sup>2</sup>; Good Agricultural Practices (GAP)<sup>3</sup>; and the Hazard Analysis Critical Control Point system<sup>4</sup>, while improving productivity, efficiency and returns on equity. The Canadian Food Inspection Agency (CFIA) has initiated a compatible program, the Food Safety Enhancement Program (FSEP), but it is under-developed in comparison to feed safety programs in other developed countries and remains secondary to the traditional feed-registration approach.<sup>5</sup>

Although China, Brazil, Argentina and Russia have emerged as rapidly growing feed producers, the following review will include the jurisdictions most relevant to Canada: the United States, the European Union, Australia and New Zealand.

The review will also highlight some of the emerging issues, such as GM products in food stocks, for which an international regulatory regime is being discussed. The question of what risk analysis and liability principles to use in feed regulation is critical and, while examined extensively in several major jurisdictions, is only recently being explored in Canada.

This review will not address pet food issues but concentrate on the regulation of feed products for the major markets of beef, dairy, broiler chickens and eggs, pork and, to a lesser degree, fish and farmed seafood.

Finally the review will identify some of the most important international “best practices” deserving of further consideration as the Government of Canada responds to calls for reform of its dated regulatory regime for feed products, supplements and production.

## **DEFINING FEATURES OF INTERNATIONAL FEED REGULATIONS**

### **Reactive Policy Formation**

Feed regulations can be characterized internationally by two dimensions. First, they are reactive rather than proactive. That is, when a problem, scandal or disaster arises, governments will act to change the policy. In Europe, the dioxin scares of the 1990s, the BSE incidents of the early

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2 See Introduction to GMP inspection process at <http://mygphc.org/pdfs/qpsymp091103GM.pdf>

3 See FAO fact sheet on GAP, <http://www.fao.org/prods/GAP/>

4 The Hazard Analysis Critical Control Point system (HACCP) has become the universally recognized and accepted method for food safety assurance. The recent and growing concern about food safety from public health authorities, food industry and consumers worldwide has been the major impetus in the application of the HACCP system. World Health Organization, [www.who.int/foodsafety/fs\\_management/haccp/en/](http://www.who.int/foodsafety/fs_management/haccp/en/)

5 See the CFIA website on FSEP at <http://www.inspection.gc.ca/english/fssa/polstrat/haccp/haccpe.shtml>

2000s, and ongoing environmental agitation led to a decade-long process of agricultural reform during which the regulations for feed were much revised. In the United States, concerns over the effects of pesticides and growth hormone residues on both consumers and the environment, and the resulting potential for lawsuits, jolted the federal government into an equally protracted reform process.

Australia and New Zealand moved into action during the mid-1990s, when health and environmental concerns in key export markets presaged a potentially precipitous drop in sales. In short, feed regulations specifically and agricultural regulations in general receive government attention after they have received public and media attention. Such regulations are not on any kind of planned maintenance and upgrade schedule.<sup>6</sup>

Another recent example of reactive policy making was the discovery of a toxic substance, melamine, in pet food imported from China into the North American market.<sup>7</sup> This touched off a far more rigorous approach to pet-food regulation. It also highlighted the increasing international nature of feed production, in which untested foreign ingredients can appear in domestic products, requiring a rapid response.

### **Supply-side driven**

A second characteristic is that feed regulations are generally supply-side driven, which means that change is driven by political demand. The public and news media may create a furor over food safety, but they generally turn to their elected representatives for action. The political authorities with responsibility for responding to public concerns have scant technical knowledge, although they receive generally good advice from public servants.

Committees and commissions are struck at the command of ministers, ministries and legislatures. Experts are called in and new policies are delivered to the public, who are less interested in technicalities than in assurance their food will be safer. A comprehensive, regularly scheduled updating of food safety regulations should be the ideal, but in practice policies change only after a problem arises. Canada is now exceptional, having delayed a major overhaul of its feed regulations for more than 25 years.

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<sup>6</sup> See history of press releases in <http://www.ifif.org/>

<sup>7</sup> "Melamine: A Truly Global Case," by Gerald Gutscher at [http://www.ifsqn.com/articles\\_detail.php?newsdesk\\_id=582&t=The+Melamine+Issue+--+A+Truly+Global+Case](http://www.ifsqn.com/articles_detail.php?newsdesk_id=582&t=The+Melamine+Issue+--+A+Truly+Global+Case)

## INTERNATIONAL COMPARISONS

### European Union

The European Union provides possibly the clearest and strongest feed regulations. These are the result of a 15-year consultative process, starting when Europe was struck with dioxin and BSE scares and concluding with the coming into force of new feed regulations in 2010. The agency in charge is the Directorate General for Health and Consumers, with a complementary research role played by the European Food Safety Agency.<sup>8</sup>

A defining feature of the European reforms in the participation of the continental feed industry. The European Feed Manufacturers Association (FEFAC) first came up with a voluntary Manufacturers Code of Conduct (EFMC) in 1998.<sup>9</sup> In 2001, FEFAC added risk-analysis guidelines based on Quality Assurance (QA) and HACCP principles.<sup>10</sup> In 2002/2003, an independent benchmarking exercise was conducted among most of the major EU feed producing nations. Several revisions to the Code of Conduct followed and were largely adopted. Pursuant to hearings of its Standing Committee on the Food Chain and Animal Health, the EU has given EFMC a final positive review as of January 2010.<sup>11</sup> Similarly the FAO has cited EFMC in its good practices guide.<sup>12</sup>

The EFMC was designed to provide principles and standards for every stage in the feed-manufacturing process, allowing full transparency and traceability of all ingredients, including pre-mixtures and additives. By working closely with EU agricultural and safety bodies, the EFMC proponents hoped to achieve continuity with the up-stream and down-stream elements of the food chain. They also hoped to ensure harmonization with existing national feed-safety codes to avoid encouraging trade protectionism under the guise of food safety.

The relationship between the feed manufacturers and the EU proved fruitful. In 2002, the EU passed regulation 178/2002, better known as the *General Food Law*. It incorporated several older directives and added new ones and was amended in following years. By 2005, it was clear that a more integrated policy framework was needed, particularly in feed regulation. Work began on a new regulation to better organize the categories of feed and feed additives, improve transparency and labeling, and expand the coverage of the regulations to non-EU European countries, such as Norway and Sweden.

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8 [http://ec.europa.eu/food/food/animalnutrition/index\\_en.htm](http://ec.europa.eu/food/food/animalnutrition/index_en.htm)

9 See numerous searchable stories in Feed International magazine at [www.fi-digital.com](http://www.fi-digital.com)

10 <http://www.fefac.org/news.aspx>

11 FEFAC newsletter, Jan. 10, 2010.

12 [www.fao.org/docrep/012/i1379e/i1379e03.pdf](http://www.fao.org/docrep/012/i1379e/i1379e03.pdf)

The revised EU feed regulations only recognize four categories of inputs: feed materials, compound feed, feed additives and medicated additives.

Feed materials serve the animals' needs, including energy and nutrients. However, the new regulations have not set out to prescribe minimum and maximum levels, as Canada's regulations do. The EU does ban certain materials from feed products and sets maximum levels of, for example, harmful bacteria. As to the list of acceptable items to include in feed products, the EU has asked FEFAC to provide a list and the justification for each but generally holds that manufacturers are qualified to judge ingredients. In cases of disputed ingredients, the EU and the feed industry have agreed to consult and respect the view of the European Food Safety Agency (EFSA).

The new EU regulations on labeling are more stringent, requiring each ingredient to be listed. However, to avoid the disclosure of intellectual property and to accommodate seasonal variations, the EU does not require manufacturers to provide the exact percentage of each ingredient but to rank them in descending order. Manufacturers are also held legally responsible for the labels and claims of their products. A company that provides inaccurate or misleading information may be subject to civil prosecution under the laws of a specific country. Overall, manufacturers and FEFAC have accepted that liability in exchange for the relative flexibility and simplicity of the new regulations.

The new regulations came into force in November 2010. The EU clearly stated that it hopes the new regulations will continue to encourage research and innovation in the industry, reduce unjustified trade barriers, and boost the export potential of European manufacturers, while providing maximum food safety for consumers.<sup>13</sup>

The text contains modernized provisions covering the following issues:<sup>14</sup>

- “Responsibility of the feed business operators is expanded also to those dealing with pet food, an area in which the recent melamine incidents revealed a gap;
- List with prohibited substances for feed use;
- The obligation to undergo a pre-market authorization procedure for “bio-proteins” (feed materials manufactured by certain procedures) is abolished. Now “bio-proteins” have to comply with the general provisions for feed materials;
- Mandatory labeling particulars for feed materials and mixed feed. In particular, the regulation provides for specific mandatory labeling requirements for feed materials,

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<sup>13</sup><http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/981&format=HTML&aged=0&language=EN&guiLanguage=en>

<sup>14</sup> [www.allaboutfeed.net/.../eu-commission-adopts-new-feed-regulation-id3326.html](http://www.allaboutfeed.net/.../eu-commission-adopts-new-feed-regulation-id3326.html)

compound feed (including pet food) and “dietetic” feed. Any claim attached to a feed must be properly substantiated;

- Solution to the controversial issue of the declaration of feed materials in compound feed (so called “open declaration”) in a balanced way to allow innovation and, at the same time, appropriate information for the customers.
- Creation of a guide to good labeling for farm feed and one for pet food on the initiative of the stakeholders (feed manufacturers and users) and approved by the Commission (Co-regulation).”

The development of EU codes of good labeling practice improves customer information in the field of voluntary labeling provisions. For example, by specifying how much chicken a pet food contains if it is labeled “with chicken” or on how feed additives are labeled.

## United States

The United States has the largest feed safety resources, the strongest scientific research community, and some of the toughest regulations, yet it struggles with a lack of coordination among its myriad federal, state, municipal and aboriginal agencies.<sup>15</sup> The lead agency is the federal Food and Drug Administration (FDA)<sup>16</sup>, operating under the *Federal Food, Drug and Cosmetic Act*.

The domestic food-supply chain is currently overseen by a mix of federal, state, territorial, tribal, and local regulatory and public health agencies that often work independently from one another with different legislative authorities with different objectives and priorities. More than 3,000 state, territorial, tribal, and local regulatory agencies have some responsibility to regulate the retail food and food-service industries. Together, they have inspection authority and oversight of over one million food establishments, including restaurants, grocery stores, cafeterias and other outlets in health-care facilities, schools, and correctional facilities.

The states perform approximately 90 percent of all food safety inspections conducted at food manufacturing and distribution centres. At the federal level, the FDA oversees more than 150,000 registered domestic food facilities including food manufacturers and processors, food warehouses, and grain elevators. The majority of this oversight responsibility is shared with the states. In addition, federal and/or state, territorial, tribal and local authorities oversee more than 2 million farms.

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<sup>15</sup> Indispensable to understanding the U.S. situation is [www.FDA.gov](http://www.FDA.gov), from which much of this description is taken.

<sup>16</sup> The FDA is the federal agency responsible for the food supply, except for meat, poultry, and processed egg products, which are overseen by the U.S. Department of Agriculture (USDA).

The FDA sets national standards for feed in cooperation with state and local partners through a variety of mechanisms: cooperative agreements, contracts, grants, memoranda of understanding and partnerships. For instance, the FDA cooperates with the Association of American Feed Control Officials (AAFCO) and the states to implement uniform policies for regulating the use of feed products<sup>17</sup>.

This includes the establishment of uniform feed ingredient definitions and proper labelling to assure the safe use of feeds. The ingredient definitions are important because feeds and feed ingredients must be correctly and truthfully labelled when they enter the market. Although the FDA has the responsibility for regulating the use of feed products, the ultimate legal responsibility for the production of safe and effective feed products lies with the manufacturers and distributors of the products.

As with human food, the FDA does not approve a feed product before it is marketed. Once a product is ready for market, the FDA will inspect the safety of the product's ingredients, any additives or medicinal supplements, its labeling and conditions of manufacture. The FDA works closely with the Department of Agriculture (DOA), which is responsible for the market food safety of beef, pork, chicken and eggs, for example.

The BSE outbreak of the late 1990s required a high degree of coordination between the FDA and the DOA. Through a program of quarantine, observation and major revisions (1997) to the content of cattle and other feed, the two agencies were able to contain the outbreak. Since the 1997 feed regulation was established, FDA and state inspectors have conducted more than 66,000 inspections involving more than 15,000 firms that handle feed. More than 99 percent of these facilities are in compliance with the regulation.

The Food and Drug Administration (FDA) announced in August 2003 its intention to make its feed-safety program more risk-based and comprehensive. The FDA, with state assistance, worked on an Animal Feed Safety System<sup>18</sup> (AFSS) framework document that identifies the current major processes, guidance, regulations and policy documents that address feed safety and the documents that should be developed to make the agency's feed safety program comprehensive and risk-based. Public meetings were held in September 2003, April 2005, September 2006 and May 2007 to solicit comments. A fourth draft of the AFSS was released in January 2010.

President Barack Obama made an additional commitment to improving food safety on July 7, 2009, by establishing the multiagency Food Safety Working Group. The Working Group is recommending a new approach to food safety focused on preventing harm to consumers and

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17 Update from the FDA-AAFCO Annual Briefing October 28, 2009 at [http://www.aafco.org/Portals/0/Public/presidential\\_update\\_10-28-09.pdf](http://www.aafco.org/Portals/0/Public/presidential_update_10-28-09.pdf).

18 <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalFeedSafetySystemAFSS/ucm196795.htm>

based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery.

The FDA is working on standards that will reflect the prevention-oriented public health principles embraced by the Working Group. In addition, the FDA has said it will work with the food industry to establish quantitative metrics for the controlling factors affecting food safety by incorporating appropriate measures of success.

One important step towards implementing an integrated national food safety system will be the adoption and implementation of the Retail Food Regulatory Program Standards and the Manufactured Food Regulatory Program Standards. The FDA is currently developing process-control regulations for feeds and will investigate the potential for expanding the Retail Food and Manufactured Food Regulatory Program Standards to feed.

#### *Cooperation with industry*

With its focus on human food safety and national standards, the FDA has not engaged industry as much as the EU has. The American Feed Industry Association (AFIA) routinely raises issues that they say could have been resolved earlier had the FDA consulted them.<sup>19</sup> Given the potential for litigation, the issues often involve legal definitions pertaining to possible liabilities.

For example, the AFIA has launched the Safe Feed/Safe Food program. This is a voluntary third-party certification program with standards and practices that AFIA says exceed current requirements. Canadian feed producers also participate in the Safe Feed/Safe Food program. The program is quite rigorous, although possibly not as robust in tracing ingredients and labeling as the EU counterpart. The FDA's participation in the Safe Feed/Safe Food program is considerably less than EU/EFSA participation in the EFMC.<sup>20</sup> However, Safe Feed/Safe Food has made steady progress and has now reached a point of integration with the EU market. EFMC and Safe Feed/Safe Food are clearly emerging as a single global standard.<sup>21</sup>

A closer working relationship between the FDA and AFIA is generally supported by both regulators and the industry; however, the dominant legal liability concerns have slowed progress.

The FDA and the Department of Agriculture clearly have the resources and the policy clarity to match the “farm to fork” program of the European Union in terms of traceability, scientific analysis, labeling and post-sales tracking. The challenge remains coordination, needed to isolate the regulatory regime from legal shocks that can delay and derail the best scientific and industry

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<sup>19</sup> [www.AFIA.org](http://www.AFIA.org)

<sup>20</sup> See Implementation of the new Feed Hygiene Regulation (EC) No 1831/2003 Q&A

<sup>21</sup> See [http://www.feedandgrain.com/web/online/Industry-News/AFIAs-International-Safe-FeedSafe-Food-Certification-Program-Up-and-Running/1\\$2122](http://www.feedandgrain.com/web/online/Industry-News/AFIAs-International-Safe-FeedSafe-Food-Certification-Program-Up-and-Running/1$2122)

initiatives. Given its commercial reality, Canada must take note of the U.S. regulatory regime. The goal should be to get to where the U.S. is headed before it gets there in order to avoid a harmful disruption. The U.S. feed companies and their associations have welcomed the Obama initiatives for the most part, viewing them as supporting their advantage as a highly research-driven, capital-intensive and export-oriented industry.

### **Australia and New Zealand**

Australia and New Zealand have worked to harmonize their feed regulations with those of the EU to avoid disrupting their substantial agricultural food trade with Europe.

Similar features include:

- Rigorous testing of ingredients;
- Traceability of ingredients;
- HACCP risk-analysis principles;
- Detailed labeling; and
- Rapid response incident reporting.

Similarly, Australia has developed a voluntary quality assurance program in cooperation with state and federal authorities. The Stock Feed Manufacturer's Council of Australia operates FeedSafe® as the Quality Assurance Accreditation Program for the Australian stock feed industry.<sup>22</sup>

All full (active manufacturer) members of the SFMCA are required to comply with FeedSafe® to retain their Association membership. The central aspect of FeedSafe® is a Code of Good Manufacturing Practice (GMP), which has been developed in with the Chief Veterinary Officers within each state. The final document has Primary Industries Ministerial Council (PIMC) endorsement.

FeedSafe® requires feed manufacturers to meet minimum standards in relation to:

- Premises and mill buildings
- Personnel training and qualifications
- Plant and equipment
- Raw material sourcing and purchasing
- Raw material quality and storage
- Feed formulation and manufacturing
- Product labeling

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<sup>22</sup> [http://www.sfmca.com.au/feedSAFE/about\\_feedSAFE/](http://www.sfmca.com.au/feedSAFE/about_feedSAFE/)

- Loading, transport and delivery to clients
- Product inspection, sampling and testing
- Customer complaint investigation.

Australia and New Zealand provide comparable models for Canada. Their market structures are similar to Canada's, and their regulatory and legal climates share significant similarities. Australia has received the highest ratings for the safety of its meat exports.<sup>23</sup> FeedSave™ and FeedAssure™ are similar in design. The only difference is the higher development of the former, largely due to government encouragement.<sup>24</sup> Canada has nothing comparable to the FSANZ service charter.<sup>25</sup>

## **EMERGING ISSUES**

### **Genetically Modified Ingredients in Feed**

The issue of genetically modified (GM) foods emerged about a decade ago and has proven quite controversial. Environmental and consumer groups, particularly in Europe and Africa, have taken strong stands against them. With the focus on foods rather than feeds, the export of feeds with GM ingredients has largely grown and remained “below the radar.”<sup>26</sup> The Australian Agrifood Awareness Bulletin provides an analysis of international regulations concerning GM ingredients in feed.<sup>27</sup>

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23 See <http://www.safemeat.au>

24 The difference between government support in Canada and Australia is striking. First, FoodSafe is listed as a National Code of Practice by the FAO, where FoodAssure is not listed or even mentioned, <http://www.fao.org/docrep/012/i1379e/i1379e07.pdf>. Second, Australia and New Zealand maintain a joint independent, regulatory agency, Food Safety Australia New Zealand, FSANZ, that reports to a joint ministerial council, <http://www.foodstandards.gov.au/scienceandeducation/aboutfsanz/theministerialcouncil1551.cfm>

25 “Our main objective – in partnership with national, state and local governments – is to protect the health and safety of people in Australia and New Zealand through the food supply, within policies set by a ministerial council. We encourage participation from individuals and organisations with an interest in the food regulatory system in our standard setting work.”

26 Gruère, G. P. 2006. An Analysis of Trade Related International Regulations of Genetically Modified Food and their Effects on Developing Countries. Environment and Production Technology Division (EPTD) Discussion Paper 147. Washington D.C.: International Food Policy Research Institute. <http://www.ifpri.org/divs/eptd/dp/papers/eptdp147.pdf>

27 [http://www.afa.com.au/biotechpdf/11\\_GM\\_Animal\\_Feed.pdf](http://www.afa.com.au/biotechpdf/11_GM_Animal_Feed.pdf)

**Characteristics of Trade-Related Regulations in Selected Countries in 2006<sup>28</sup>**

<b>Countries</b>	<b>Food safety approval regulations</b>	<b>Labeling regulations</b>
European Union	Process-based mandatory	Stringent mandatory, includes derived products
Brazil, China, Russia	Process-based mandatory	Stringent mandatory, includes derived products
Australia, Japan, Korea, Saudi Arabia, Thailand, Taiwan	Process-based mandatory	Mandatory labeling based on product content
United States, Canada, Argentina, Hong Kong, Philippines, South Africa	Substantial equivalence, mandatory (U.S.: voluntary consultation)	Voluntary for substantial equivalence
Chile, Ecuador, Indonesia, Vietnam	Mandatory (in place or pending)	Mandatory, introduced but not implemented
India, Kenya	Mandatory (in place or pending)	Intention to require labeling
Bangladesh, most African countries	Considering mandatory	No clear position
A few African countries	No	No

The main issue is who will regulate the international trade in GM ingredients, as countries have reserved domestic regulation to themselves. The EU, for instance, has recently announced that each member state will be responsible for deciding their acceptance of GM products, largely eliminating an EU role beyond advisory health-and-safety investigations.

Another emerging question is the transmission of DNA material. Though the amounts are very, very small, concerns have been raised. Working with the scientific community, regulators are looking at ways to better measure the amount of DNA transmitted and to assess its effects, if any.

<sup>28</sup> Source: Gruère, (2006), USDA Foreign Agricultural Service Attaché Reports (2005-2006). Note: Not all countries with a labelling regulation had enforced their regulations as of 2006.

In terms of the export potential of Canadian feeds, the industry will likely have to join forces with the U.S. to dispel some of the unfounded suspicions that have arisen in Africa and the Indian sub-continent, two potentially important new markets.

### **Codex Alimentarius and Feed**

The Codex Alimentarius, or food code, has developed mostly in Europe over the last 100 years. The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme.

The Codex prescribes multiple recommendations in a variety of food safety areas. The original and still current purpose of the Codex is to prevent food standards from being used as protectionist measures. In recent years, the FAO and the WHO, in conjunction with the World Trade Organization, have articulated a more ambitious role for the Codex in hopes of it becoming the global reference point for consumers, food producers and processors, national food control agencies and the international food trade.<sup>29</sup>

The Codex Alimentarius commission has dealt with different aspects of food production and processing that have been important for feed and feeding practices for many years. However, Codex progress was slow in addressing feed problems specifically because discussions were dispersed among several Codex committees that do not have feed as a specific focus or priority.

Due to European problems related to dioxin-contaminated feed and animal products, use of sewage sludge in feed, and BSE, the Codex administration decided to create an ad-hoc intergovernmental task force on feeding. Denmark agreed to host the meetings of this ad hoc task force, which had four years to produce final Codex results. It did not meet the deadline.

The first task force session (June 2000) produced a draft code of practice related to the feeding of animals. This code covers all feeding principles, ranging from grazing/free range feeding and farm-produced feed to commercially produced feed for farm animals and aquaculture.

Discussions on the original draft code and the comments received were somewhat problematic. Many European countries wanted specific requirements in the draft code to address their previous contamination issues and generally ignored the more general concerns of other member countries.

Differences between grazing, farm-prepared feeds, and commercially prepared feeds, (including medicated feeds, nutritive and pharmaceutical additives sold as premixes or contained in bulk

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<sup>29</sup> Feed Tech, Volume 6, Number 1 - [www.AgriWorld.nl](http://www.AgriWorld.nl)

feeds), all needed additional separate discussions and clarification. They did not receive such attention initially and only now are being addressed.

There is no longer an official committee on feed safety in the Codex Commission.<sup>30</sup> Discussions are on-going and, although they do not move at the same pace as national regulators, they have the potential to affect both the terms of trade in feed and national feed regulatory initiatives.

While still in its infancy as a global standard, the Codex may yet emerge as the single most important safeguard against protectionism in the trade in feed products. Recognizing the Codex's potential, Australia and New Zealand have taken a leadership role. Canada serves as an advisor nation to the United States delegation.

### **Globalization of Risk Analysis, Precautions and Liability**

With all regulations, there are international variations in terms of how risks are assessed and analyzed, precautions agreed upon and liability assigned, and feed regulations are no exception. Risk is measurable and therefore subject to mitigation. Steps can be taken to reduce the risk of, for instance, food poisoning to an “acceptable” level as determined by cost and consumer preferences. With good animal husbandry practices, no harmful additives, sanitary rendering techniques, proper transportation, storage and display, a consumer may buy a roasting chicken for a reasonable sum with almost no health risk. However, to move from almost no risk to no-risk would require precautions, treatments and procedures that would make that same chicken prohibitively expensive. On these measures of cost and practicality is where the fashionable “precautionary principle,” (do nothing unless it can be proved to do no harm) fails: harm will always be a possibility even when it is a remote probability.

Each of the jurisdictions surveyed here calculate risks differently and recommend precautions to be taken accordingly. The differences in risk calculation and precautions among countries are relatively slight, based as they are on empirical analysis and scientific inquiry. That the subsequent regulations vary has less to do with the science of risk and how to reduce it and more to do with the legal and financial liability incurred when the almost impossible does happen. Regulations are often a quiet outcome of decisions made as to who pays, not when the unforeseeable happens but when an avoidable mistake occurs—in other words, negligence.

A U.S. judge, Learned Hand, provided a cogent definition of the liability for negligence in a 1947 court case in the State of New York. This case has underpinned much modern thinking on litigation and legislation where consumer food safety is concerned.<sup>31</sup>

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30 See record of 33rd Codex Alimentarius Commission meeting, July 5-10, 2010 at [ftp://ftp.fao.org/codex/Alinorm10/al33\\_03Ae.pdf](ftp://ftp.fao.org/codex/Alinorm10/al33_03Ae.pdf)

31 Hand stated: “[T]he owner's duty, as in other similar situations, to provide against resulting injuries is a function of three variables: (1) The probability that she will break away; (2) the gravity of the resulting injury, if she does; (3) the burden of adequate precautions.”

The Hand formula has been formalized by the economists and lawyers as such: An act is in breach of the duty of care if:  $B < PL$ , where  $B$  is the cost (burden) of taking precautions;  $P$  is the probability of loss; and  $L$  is the gravity of loss. The product of  $P \times L$  must be a greater amount than  $B$  to create a duty of due care for the defendant.

The Hand formula, for all its elegance, faces some serious hurdles in its application to consumer food-safety regulations. First is the question as to who is the owner of the regulations? It is not enough to say simply “the government,” when the government does not face liability in the case of harm.

For example, in Europe, it is exceedingly difficult to bring an action against government for damages for regulatory negligence; indeed, it is prohibited in most European countries. Therefore, in the case of the recent European feed regulations that largely legitimize self-regulation by the feed companies, it is less a case of allowing self-regulation than an admission that, because the companies bear the liability, they should have the responsibility to protect themselves. Not surprisingly, European companies have led the way in voluntary HACCP programs, transparency and labeling, all means to provide at least the legal protection of procedural accountability in a “farm to fork” continuum.

The United States situation is very different. Lawsuits against companies for alleged negligence very often seek joint and several liability against local, state and federal government departments for allowing companies to be negligent in the first place. This explains to some extent the reluctance of the Food and Drug Administration and the Department of Agriculture to endorse the voluntary—and equally as rigorous as Europe’s—transparency, HACCP and labeling programs of the U.S. feed manufacturers association.

In Australia and New Zealand, the liability rules fall somewhere between those of the EU and the U.S., although they incline more towards the former than the latter. Both countries allow for actions of regulatory negligence in the courts. As well, the Australian Senate has taken an active role in investigating allegations about food safety with considerable determination, research and public trust.<sup>32</sup> Yet, they also have a “social utility” proviso to the underlying, if not explicitly recognized, Hand Formula. The “social utility” proviso simply allows for the legal recognition of the argument that while a harm may have occurred, the benefit to society at large of having the activity in first place should be taken into account. At an extreme, even if the charge of negligence is upheld, the actual judgment of liability should not imperil the continued existence of the activity and the solvency of its owners.

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<sup>32</sup> See the March 2010 Australian Senate hearings on beef imports and exports at [http://www.aph.gov.au/senate/committee/rrat\\_ctte/mad\\_cows/first\\_report/c02.htm](http://www.aph.gov.au/senate/committee/rrat_ctte/mad_cows/first_report/c02.htm).

Australia and New Zealand both have large and important food-export industries. It is not difficult to imagine that, in a worse-case scenario, the feed producers could argue for their industry's "social utility."

Since the Australian and New Zealand feed industries, with their substantial export markets, are so highly dependent on having a "clean" reputation, they are far more risk-adverse than their own governments in avoiding even the suggestion of unsafe products or procedures. They worry more about what their customers think than what a court might rule.

## **NEXT STEPS**

This overview of the regulatory regimes of the major developed jurisdictions demonstrates a number of key points.

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

Second, the federal government has yet to fully engage the feed industry in creating the necessary regulatory support for comprehensive, risk-based and transparent "farm to fork" initiatives such as those in Europe and Australia/New Zealand and now being designed by the U.S. The key issues of traceability, transparency, labeling and adaptability have yet to be addressed in-depth. The counterpart to the European and Australia/New Zealand programs in Canada is FeedAssure™, "a feed industry-customized HACCP (Hazard Analysis Critical Control Point) program of processes and controls that bring the highest safety standards to the production of feed."<sup>33</sup>

The international industry consensus of most commercially minded, food-safety-conscious jurisdictions is that an industry-driven, quality-control program that assumes liability risk yet retains entrepreneurial and scientific flexibility is the optimal regulatory model.<sup>34</sup>

To succeed in the international feed market, Canada needs a contemporary regulatory regime attuned to the high standards set in the EU and the U.S. Without a critical appraisal and modernization, Canada's current feed regulations may cause the domestic industry to stagnate.

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<sup>33</sup> See <http://www.feedassure.com/>

<sup>34</sup> For a discussion of the trade-off between self-regulation and liability in the European context, see Paul van der Zeijden and Rob van der Horst, "Self-Regulation in SANCO Policy Areas," EIM, Panteia Group, February 2008 at [http://ec.europa.eu/dgs/health\\_consumer/self\\_regulation/docs/self-reg-SANCO-final.pdf](http://ec.europa.eu/dgs/health_consumer/self_regulation/docs/self-reg-SANCO-final.pdf)

Government cooperation, a public priority on science-based risk-management and a shared plan for consumer-driven transparency and accountability is vital to both the feed industry and to its customers.