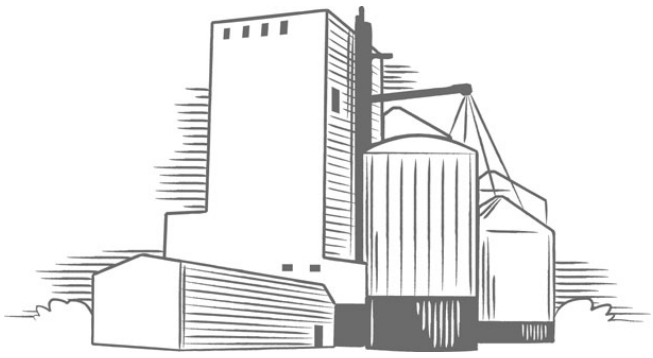
Modernizing the Feeds Regulations

A Proposal for a Risk-Based Approach to Hazard Identification and Control

June 2013



Animal Nutrition Association of Canada

ANAC

Association de nutrition animale du Canada

A. BACKGROUND AND OBJECTIVES

The process for modernizing the Canadian *Feeds Regulations* is currently underway. Four main tracks have been identified in the regulatory renewal effort: 1) feed ingredient classification and authorization, 2) hazard identification and preventive control, 3) feed labelling and, 4) facility licensing/enforcement approaches. The Animal Nutrition Association of Canada (ANAC) offers the following proposal for consideration by CFIA and agri-food stakeholders in the regulatory modernization process relating to regulatory oversight in manufacturing and hazard identification and controls for the commercial feed industry. (The development of criteria for the classification and authorization of feed ingredients was addressed in a separate ANAC paper published in January 2013, entitled "A Proposal by the Animal Nutritional Association of Canada for a Risk-Based Framework for Feed Ingredients", while feed labelling is being addressed in bilateral discussions between government and industry.)

It is ANAC's position that regulatory oversight in manufacturing should be based on the following foundations:

- Safety – maintenance of animal health, protection of the human food supply, and mitigation of environmental risks
- Market access and competitiveness – regulations must not create barriers to innovation and market entry, nor put the Canadian feed industry at a competitive disadvantage with its international counterparts

B. MOVING TOWARD MODERNIZED REGULATION OF FEED HAZARDS

In modernizing the Canadian *Feeds Regulations* as related to manufacturing hazards and controls, the following are recommended:

1. A risk-based facility licensing system
2. An outcome-based regulatory framework predicated on the use of in-house process and systems control programs that are flexible to the organisation, focused on reduction of risk, and aligned with international best practices such as Codex Alimentarius
3. Regulatory oversight scaled on the basis of risk to animals and humans, thus allowing scarce regulatory enforcement resources to be redirected to where they are most needed, such as facilities with minimal or no hazard controls

4. Increased recognition in the new regulatory framework of industry-led HACCP programs, notably ANAC's FeedAssure program, which has been acknowledged by CFIA as meeting all Food Safety Enhancement Program (FSEP) standards (see Appendix I)
5. Industry and government collaboration to develop guidance documents and ensure transparency in the system

The following discussion is offered to expand on ANAC's recommendations.

1. Facility registration/licensing

ANAC proposes that the feed regulatory system require the registration of all feed operations based on their risk profile, regardless of their role in the manufacturing, storage or distribution of feed and feed ingredients. Foreign ingredient or compound feed suppliers should also be subject to registration to ensure they meet Canadian feed safety standards. A publicly available Canadian registry would provide transparency of feed businesses and their activities.

Mandatory facility licensing is similar to the concept currently being proposed by CFIA for the food sector in the inspection modernization process; the same benefits to accountability, enforcement, and traceability would thus be conferred on the feed sector. This would also better align Canada with international trading partners, such as the European Union (EU) and the United States, whereby registration of the business and types of activities undertaken with competent authorities is a condition for manufacture and sale of feeds and their ingredients.

Facility licensing should also use a tier-based approach, taking into consideration safety risks associated with the operating procedures and ingredients of individual facilities as well as accounting for the presence or absence of hazard identification and control systems, such as the FeedAssure program. The highest risk level would have the most rigorous license conditions while the lowest level would require no more than a simple facility identification. This would be very similar to the European licensing system, whereby all feed-related businesses require as a minimum, registration with competent authorities, which essentially requires completion of a declaration. Higher risk operations are also subject to more stringent review prior to approval.

In the Canadian system, ANAC proposes that a facility that manufactures medicated feeds for multiple species and uses ingredients recognized to be potentially hazardous, would be considered high risk. Conversely, one that manufactures feeds without these types of materials would be classified as low risk. For high-risk operations, mitigation procedures would be considered a prerequisite for obtaining a license. Since FeedAssure certification is considered

by both industry and government to be a comprehensive and effective feed safety program, high risk operations having that certification should automatically qualify for licensing. The risk categories defined in CFIA's I-3-93 (four categories based on the use of TSEs, or transmissible spongiform encephalopathy, and medications) are well-established and could also form the initial basis for development of the risk categories used for facility licensing. Risk categories for facilities should be transparent and developed in consultation with industry.

2. Feed hazards and preventive controls

a. Effective means of reducing inherent risk

The concern for better control over hazards in food production has in recent years led to the development of risk management systems that monitor and control production processes throughout the system—from receipt of raw ingredients to delivery of finished products. The adoption by governments and food industries in Canada and around the world of Codex-based HACCP principles and good manufacturing and hygiene practices is seen as an effective way to identify and control hazards and one of the most valuable risk mitigation tools as it focuses on prevention rather than reaction to food safety risks. Where HACCP principles are not specifically part of national regulations (such as is the case in Canada), industry competitiveness is a driving factor in the adoption of recognized programs. Where HACCP principles have been incorporated into the regulations (e.g. in the EU), they serve to level the playing field and ensure adherence to a minimum level of feed safety.

Ideally, all feed manufacturing facilities would be required to have hazard analysis and preventive control systems in place, but this may not be practical due to the diverse nature of the industry and the economic constraints it faces. Facilities with more rigorous feed safety systems in place, however, should be recognized with a reduced enforcement load. Outcome-based regulatory control of feed hazards in a modernized system should be predicated on the use of process and systems control programs in-house rather than principally on product standards compliance, as is the case with the current *Feeds Regulations*. Feed business operators have an important "front-line" responsibility in the daily control and prevention of feed safety issues, while auditing and inspection at varying intervals monitor the effectiveness of the control programs.

b. Hazard assessments and controls specific to the risks of the operations

Hazard identification and prevention should be focused on hazards reasonably likely to occur and those that result in food safety risk. Feed operators are responsible for preventing,

eliminating, or reducing food safety risks to an accepted level through process controls. Hazard assessment should consider the entire feed operation yet be flexible enough to be specific to the facility, ingredients handled, equipment, and individual processes. Control, verification, and monitoring of feed hazards should be outcome-based.

Many types of feed hazards exist, including contaminants and medications at unsafe residue levels. Contaminants include heavy metals, pesticide residues, mycotoxins, and dioxins, for example. Medications require additional attention in the regulations as they are added as a service to feed customers but without appropriate controls, may result in residues that could present a hazard to animal or human health.

The area of biosecurity and intentional introduction of food hazards has been gaining more attention in recent years. For example, the publicly available prerequisite programs for animal feed published as PAS 222 from the British Standards Institute in 2011 has a clause dealing with biosecurity, while it is anticipated that the US Food Safety Modernization Act in a future separate rule will require companies to specifically address bioterrorism and intentional introduction of hazards. It is recommended that this food safety risk be considered separately from other feed safety hazards (i.e. contaminants and medications).

c. Outcome-based regulation of maximum residue limits supported by science

Maximum residue limits (MRLs) for feed contaminants and medications should be established with government and industry collaboration, made publicly available, and regulated through risk-based inspection. These maximum acceptable levels should be considered as outcomes of regulation with industry being responsible for determining the most appropriate means to achieve them. For example, depending on expertise of the staff, some feed mills may find the use of a sequencing guide the easiest means to ensure that medications do not surpass MRLs, while others may be able to conduct their own risk analysis to ensure MRLs are adhered to and sequence feeds accordingly.

As laboratory methods for detecting undesirable substances become increasingly sensitive, there is a greater need to focus on setting scientifically valid limits that would result in harm to humans or animals. Minimizing the levels of undesirable substances and contaminants in food and feed to levels that are as low as reasonably achievable[1] by applying good manufacturing and agricultural practices as well as process controls should be a key objective; however, the concept of zero threshold limits will typically be unachievable or come at an unnecessary

[1] Also known as the ALARA principle, this has been referenced by Codex Alimentarius with regards to risk and contamination.

burden on the feed industry if MRLs are not based on scientific evidence. ANAC recommends that a scientific committee consisting of industry and government experts be established to develop MRL guidelines. This would provide increased transparency to the process and ensure that maximum limits are based on animal and food safety risks.

3. Risk-based regulatory oversight

Regulatory oversight of feed establishments should be based on the risk of the operations, the controls implemented to mitigate risks, and the compliance history. Outcome-based regulatory oversight should therefore result in a decreased inspection burden for facilities which meet the desired outcomes (tier-based). Operations demonstrating reduction of inherent risks via application of hazard and preventive controls, such as applying HACCP principles, would have lower residual risk and would thus gain the maximum benefit from a modernized outcome-based enforcement approach. By adopting a risk-based, systems audit methodology, instead of a traditional on-site inspection approach in all cases, scarce inspection resources could be refocused to facilities that present higher safety risks.

Food safety systems can range from simply identifying hazards and implementing internal procedures and records to mitigate those risks to detailed HACCP plans with regular independent audits from accredited bodies. A systematic mechanism for government to review the value and effectiveness of different feed safety control systems and transparency in the risk profile assessment are thus essential.

ANAC's FeedAssure program received an extensive three-year review that resulted in acknowledgement by CFIA in 2010 that the program meets all Food Safety Enhancement Program (FSEP) requirements (See Appendix I). The agency describes FSEP as "its approach to the development, implementation and maintenance of HACCP systems in all federally registered establishments; it is an effective food safety management system [and] it enhances the establishment's ability to achieve and maintain compliance with the relevant regulatory requirements". No other feed safety programs have received such a detailed examination or acknowledgement by CFIA; and in a risk-based enforcement model, other feed safety programs desiring similar recognition should demonstrate equivalent rigour.

4. Enhanced recognition of FeedAssure

Many industries have implemented industry-specific systems-based approaches founded on HACCP principles in order to better control their risks and strengthen their food safety systems. In Canada, ANAC's FeedAssure program represents the highest level of feed safety. First developed in 1999, the FeedAssure program now certifies over 165 facilities across the country, accounting for more than 70 percent of Canada's commercial feed production. FeedAssure is a voluntary feed safety management and certification program that applies the highest risk-control standards to feed production. Facilities meeting the program requirements obtain a HACCP compliance certificate. To maintain their certification, FeedAssure facilities undergo annual audits by an independent, internationally recognized testing and verification firm. FeedAssure is consistent both in its program requirements and auditing, and new requirements can be adapted and implemented relatively rapidly throughout the industry in response to changing markets or safety risks.

ANAC proposes enhanced regulatory recognition of FeedAssure as a risk-control measure. Focusing government oversight on program compliance to ensure adherence to established HACCP standards and regulatory requirements for these facilities would allow scarce resources to be diverted to operations with no accredited risk control measures in place. In the current regulatory system, however, FeedAssure certified facilities are given inadequate recognition of their hazard control systems during inspections, and are eligible for just one less partial inspection per year.

The CFIA Quality Management Program (QMP) for fish processing represents a modern approach, significantly reducing the frequency of facility inspections and placing greater emphasis on program compliance. The program recognition modelled in the QMP approach should be expanded to FeedAssure and other equally rigorous industry-led programs that are able to demonstrate effective food safety risk mitigation processes.

5. Industry-government collaboration, guidance, and transparency

In moving to an outcome-based approach to regulation, there are several factors crucial to helping industry understand the new rules, and for both government and consumers to have confidence in the feed safety system. These include transparency and industry-government collaboration in the development of regulatory provisions and guidance. Opportunities to reduce the inspection burden could be identified where industry recommends best practices and provides an additional level of monitoring. Where possible, incorporation by reference

should be a feature of the new regulatory framework to allow a more timely response to emerging scientific and commercial developments.

C. CONCLUSIONS

ANAC proposes that a modernized outcome-based regulatory approach to manufacturing hazards and controls should:

1. Include mandatory tier-based registration/licensing of facilities
2. Be predicated on the use of process systems and controls to mitigate risks
3. Include risk-based regulatory oversight
4. Incorporate increased recognition of industry-led HACCP programs, particularly FeedAssure
5. Be founded on collaboration and transparency between industry and government
6. Be modelled, where appropriate, on demonstrably successful international examples.

A number of benefits would result from this approach:

1. Protection of animal and human health, as well as the environment
2. More responsive and adaptable feed hazard control systems focused on prevention of food safety risks
3. Cost-effective regulations based on mitigation of risk associated with manufacturing, storage, and distribution operations
4. Greater alignment with regulatory systems used by international trading partners
5. Promotion of competitiveness and market access for Canadian feed manufacturers and ingredient suppliers.

Appendix I – FeedAssure program recognition letter

Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

AUG 2 0 2010

Mr. Graham Cooper
Executive Director
Animal Nutrition Association of Canada
109 Murray Street, Suite 2
Ottawa, Ontario, K1N 5M5

Dear Mr. Cooper:

On behalf of the Canadian Food Inspection Agency (CFIA), I would like to acknowledge that the FeedAssure/ProQualité™ program meets all Food Safety Enhancement Program (FSEP) standards. The CFIA considers the Animal Nutrition Association of Canada (ANAC) voluntary Hazard Analysis Critical Control Point (HACCP) program FeedAssure™, an industry success story and a very proactive step for the Canadian feed industry in support of food safety.

Yours sincerely,

Cameron Prince
Vice President, Operations

c.c.: Vance McEachern, Executive Director, Operations Strategy and Delivery
Tom Graham, National Inspection Manager, National Inspection Division

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