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# Canada Gazette, Part I, Volume 155, Number 24: Feeds Regulations, 2022

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June 12, 2021

## **Statutory authorities**

Feeds Act
Health of Animals Act
Food and Drugs Act

## **Sponsoring agency**

Canadian Food Inspection Agency

# REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

#### **General Comment**

► View comments for the General Comment section 41 comment(s)

## **Executive summary**

Issues: The Feeds Regulations, 1983 have become outdated. The last comprehensive review of these Regulations took place in 1983 and some ad hoc amendments have been made to the Regulations since then to only address specific issues (e.g. regulating feeds derived from biotechnology, strengthening measures against the spread of bovine spongiform encephalopathy). The Regulations have not kept up with innovation (e.g. they do not require efficient use of feed ingredients to reduce environmental footprints), the management of safety risks, international standards, science and technology. Feed and livestock production sectors in Canada and abroad have also evolved considerably since 1983, operating in an environment influenced by several changing factors such as nutritional awareness, feed manufacturing and distribution, globalization of trade, recognition that feed is an integral component that underpins food production, heightened consumer awareness of food safety, and emergence of new pathogens and disease agents (e.g. bovine spongiform encephalopathy).

The current framework requirements apply mostly to products (e.g. registration, standards and labelling), with few or no requirements that apply to processes (e.g. manufacturing standards and record keeping).

Canada's principal feed industry association, the Animal Nutrition Association of Canada, has signalled a need for regulatory change some time ago.

**Description:** These proposed amendments would repeal and replace the *Feeds Regulations, 1983* of the Canadian Food Inspection Agency (CFIA). Minimizing the health risks for livestock and Canadians associated with livestock feeds manufactured in or imported into Canada is one of the principal anticipated outcomes of the proposal. Feed operators would be required to conduct hazard identification and put in place preventive controls to address risks posed by the identified hazards.

The regulatory proposal would strengthen the ability to protect Canada's food supply as well as the plant and animal resource base, allow the CFIA to take different regulatory approaches (e.g. moving the "livestock" definition under the *Feeds Regulations*, 2022 [proposed Regulations] and removing it from the *Feeds Act*) provided by new regulation-making authorities in the *Feeds Act* made available by the *Agricultural Growth Act*, and address concerns raised by the Standing Joint Committee

for the Scrutiny of Regulations regarding lack of authority for the release of novel feeds and bilingual labelling. In addition, it would increase the consistency of the CFIA inspection system among all commodities by applying inspection oversight on the preventive controls and preventive control plans that are based on risk and would be required of most feed suppliers and distributors along the supply chain.

**Rationale:** The linkages between feed, the safety of food and public health have received an increased focus in recent years. The feed and livestock production sectors in Canada and abroad also continue to evolve. The CFIA has consulted extensively with stakeholders, including a recent consultation to validate potential economic impacts of the proposed regulatory changes with the challenges presented by the COVID-19 pandemic. Most stakeholders indicated that they did not have any concerns with the estimated costs and they remained generally supportive of the regulatory proposal moving forward.

The proposed *Feeds Regulations, 2022* were also identified as a priority under the Government's targeted Regulatory Review Roadmap and 2018 Fall Economic Statement.

The estimated monetized costs of the proposed Regulations would have a present value of approximately \$479.5 million over 10 years. These costs would mostly be associated with the implementation of preventive controls. The estimated monetized benefits would have a present value of approximately \$7.7 million over 10 years, driven by the CFIA resource savings associated with processing fewer product registration applications. The net monetized cost (i.e. costs minus benefit) is estimated to be a present value of \$471.8 million over 10 years.

Even though the feed industry would face additional costs with the proposed Regulations, there would also be many qualitative benefits, including a reduction in feed safety risks for animals, which in turn would translate into reduced food safety risks to consumers. Other qualitative benefits would include a more level playing field for the feed industry, increased international and domestic regulatory alignment, a consistent and more effective feed safety approach to inspection and oversight by the CFIA, and an enhanced reputation for Canada as a global feed safety leader.

► View comments for the Executive summary section 6 comment(s)

## **Issues**

The last comprehensive review of the *Feeds Regulations, 1983* took place in 1983. The current requirements apply mostly to products (e.g. registration, standards and labelling), with few or none that apply to processes (e.g. manufacturing standards and record keeping). While some ad hoc amendments have been made to the Regulations since 1983 to address specific issues (e.g. regulating feeds derived from biotechnology, strengthening measures against the spread of bovine spongiform encephalopathy), the Regulations have fallen largely out of date given the risks and operating environment outlined above. In addition, a number of other domestic and international drivers (e.g. the *Safe Food for Canadians Regulations, Codex Alimentarius' Code of Practice on Good Animal Feeding* and the U.S. *Food Safety Modernization Act*) have increased the need for a comprehensive review of the current regulatory framework.

In 2015, the *Feeds Act* was modernized and included the amendment and addition of several new regulation-making authorities. The *Feeds Regulations, 1983* need to be amended to reflect the broader range of authorities that are now available to the CFIA, in particular

- An authority to incorporate documents containing standards, labelling requirements and other technical requirements by reference in the regulations. This would allow for timely review, consultation and amendment of the documents and their content.
- Authorities to license persons and license or register establishments. Up until these amendments, only an authority to register products has been available.

More recently, the U.S. Food and Drug Administration has implemented a series of human and animal food safety rules that require products to be manufactured using good manufacturing practices and preventive controls to manage known or reasonably foreseeable hazards posing risks to public health. The proposed regulatory amendments would ensure alignment with the Food and Drug Administration's regulatory framework. They would also ensure that a robust market access with the United States is maintained, not only for feed but also for human food.

► View comments for the Issues section 5 comment(s)

## **Background**

## Regulatory authority

The *Feeds Regulations, 1983*, made according to the authorities provided by the *Feeds Act*, set out requirements for the importation, manufacture, and sale of feed (including feed ingredients) in Canada. Feed (defined as "animal food") is also regulated by the *Health of Animals Regulations*, which regulate the use of rendered animal protein products (e.g. animal meat and bone meal, feather meal, tallow, poultry fat) for use in ruminant and other animal feed.

According to these authorities, the CFIA verifies that livestock feed manufactured, sold or imported in Canada are safe for animal health and the environment, effective for animal production, comply with standards, are labelled appropriately and are safe for livestock that would be used for human consumption (meat, milk, eggs).

Livestock producers who manufacture feed for their own animals and do not use medications are exempted under the *Feeds Act* and they are not subject to the requirements under the *Feeds Regulations, 1983*.

## Regulated products

Feeds for the following species of livestock are currently regulated under the *Feeds Act* and the *Feeds Regulations, 1983*:

- Cattle
- Horses
- Sheep
- Goats
- Swine
- Poultry (chickens, turkeys, ducks, and geese)
- Fish
- Foxes
- Mink
- Rabbits

These were the main species being raised commercially at the time the regulations were

developed. Feeds for other species are exempt from the *Feeds Act* and the *Feeds Regulations, 1983* since those species were assumed to not be a significant part of the commercial market.

A wide range of feeds are subject to the regulations, and are grouped primarily into two categories: feed ingredients and mixed feeds (premixes, supplements and complete feeds that contain a combination of approved feed ingredients). The CFIA assesses and approves all feed ingredients for use in livestock feeds. Ingredients represent individual sources of nutrients such as minerals, vitamins, fibre, protein and energy as well as substances that have a function in the feed such as flavours, colours, pellet binders and antioxidants. At present, the CFIA has some 1 250 feed ingredients approved for livestock feeding in Canada.

#### Risks and operating environment

Safe feeds contribute to the production of safe foods of animal origin for human consumption. Feeds contaminated by harmful pathogens (e.g. *Salmonella*), chemical residues (e.g. heavy metals, drug residues, dioxins) or mycotoxins may not only affect the health of the animal, but may also adversely affect the safety of meat, milk, eggs and other animal products used for human consumption. Medicated feeds present potential risks to animals and human health, as well, being implicated in global concerns associated with the increasing incidence of pathogenic organisms becoming resistant to antimicrobial drugs.

As part of the National Feed Inspection Program, the CFIA investigates contamination events predominantly related to issues with medications in feed, but also including other contaminants such as metals or dioxins. In addition, during routine inspections, feeds can be found to be out of compliance. Reports presenting results for the <u>Monitoring program for mycotoxins in livestock feeds</u> and the <u>Salmonella monitoring program</u> are available on the <u>National Feed Inspection Program web page</u>.

The feed industry and livestock producer organizations have worked to establish sector specific, voluntary feed and food safety programs. This collaborative work has been driven by heightened consumer awareness and demands for safe food.

Feed represents a significant input cost to the production of livestock. Feed also plays an important role in contributing to the health and productivity of livestock.

In recent years, the linkages between feed, the safety of food and public health have

received an increased focus. For example, the detection of bovine spongiform encephalopathy in cattle internationally and in Canada has prompted governments to strengthen food safety and animal feeding measures to protect public health as per recommendations made by the World Health Organization.

The feed and livestock production sectors in Canada and abroad continue to evolve, operating in an environment influenced by several trends including

- advanced science and technology in the fields of animal husbandry, nutrition, veterinary medicine, feed manufacturing and distribution;
- globalization of trade and emergence of global supply chains and recognition that feed is an integral component that underpins food production;
- industry restructuring, consolidation and increased competition;
- changes in consumer demands for meat and other animal products;
- heightened consumer awareness of food safety;
- diversification of animals being farmed beyond traditional species (e.g. deer, elk, bison, ostriches, and other species); and
- increased reliance on co- and by-products generated by other industry sectors (e.g. food and beverage processing, food service, distillers' grains from biofuel production) as sources of ingredients for livestock feeds.
- ► View comments for the Background section 5 comment(s)

## **Objective**

The amendments to the *Feeds Regulations, 1983* are required to establish a more robust feed framework that would include hazard identification, preventive controls, traceability, increased record-keeping requirements and licensing. This would enable the CFIA and regulated sectors to better understand and manage risks that livestock feeds pose to human, animal and plant health and the environment. In addition, this would allow the proposed Regulations to align with international frameworks and best practices.

The basis for proposals and consultation to date has followed the objective of developing a modernized regulatory framework based on risk and outcomes for feeds that

- safeguards feeds and the food production continuum;
- creates a fair and competitive market; and
- minimizes unnecessary regulatory burden, where possible.
- ► View comments for the Objective section 2 comment(s)

## **Description**

The proposed Regulations would apply to feed ingredient and mixed feed manufacturers, feed retailers and distributors, feed importers and exporters, as well as on-farm feed manufacturers that sell off the farm or incorporate any drug or other substance that presents a risk of harm to human or animal health or the environment into their feeds.

The regulatory proposal represents a comprehensive review of the current regulatory framework and would result in a range of updated or new requirements for feeds and the regulated parties involved in their production and commerce. The scope of the framework would apply to the domestic supply chain as well as to feeds being imported and exported.

The proposed changes would require feed manufacturers to develop plans to prevent and control potential hazards in livestock feed; introduce licensing requirements for feed sold between provinces, exported and imported for sale; allow faster, easier updates to safety standards based on the latest science; be better aligned with international partners; be based on outcomes, instead of prescriptive requirements that become easily outdated as science and technology change; and reduce the number of feeds that require registration.

## Scope of species — Definition of livestock

The *Feeds Act* was amended in 2015 by the *Agricultural Growth Act* (S.C. 2015, c. 2). Section 53 of this Act replaces the definition of "livestock" with a new definition that provides authority to designate in the *Feeds Regulations, 2022* the animals to which the *Feeds Act* applies. This provision would be brought into force by an order in council at a time that would coincide with the registration of the proposed Regulations, with a delayed coming into force of one year for the new species. The additional species to which the *Feeds Act* and the proposed Regulations would apply are game birds, ratites, bison, water buffalo, cervids, llamas, alpacas, molluscs, crustaceans and bees. Mink and fox would be removed, as they are not considered food producing animals.

## Incorporation by reference

The amendments would include the application of ambulatory incorporation by reference. Incorporation by reference is a drafting technique that may be used to bring the content of an incorporated document into a regulation. Documents incorporated by reference have the same force as the regulation into which it is incorporated. An ambulatory reference refers to the incorporation of a document in such a way as to include any future changes to that document without a need to remake the regulation. The relevant authorities that allow for the use of incorporation by reference are found in section 5.1 of the *Feeds Act*.

The amendments would incorporate by reference nine documents, written, maintained and published by the CFIA

- 1. Canadian Feed Ingredients Table;
- 2. Compendium of Medicating Ingredient Brochures;
- 3. Compendium of Non-Feed Product Brochures;
- 4. Tables of Nutrient Guarantees and Conditions for Feed Labels;
- 5. Tables of Permissible Claims for Feed Labels;
- 6. List of Weed Seeds and Maximum Levels for Feeds;
- 7. Tables of Maximum Nutrient Values for Feeds;
- 8. Tables of Maximum Contaminant Levels for Feeds; and
- 9. List of Prescribed Deleterious Substances.

Updates to these documents would follow the CFIA Incorporation by Reference Policy.

## **Exemptions**

General and specific exemptions for feeds or for persons, from some or all of the provisions of the *Feeds Act* and the *Feeds Regulations, 1983*, would be updated and clarified, including the exclusion of some products intended for animals not being raised for food production (e.g. pet rabbits and fish), for exhibitions, laboratory testing and other non-commercial purposes.

## Permissions (approvals, registrations and licences)

An updated, clearer and broader permissions approach for feed products (approvals and

registrations) and individuals (licensing) would be established in the proposed Regulations.

## 1. Feed ingredient approval

At present, application requirements and assessment processes for feed ingredients and mixed feeds are combined and not well defined. Under the regulatory proposal, the CFIA would maintain its role in assessing the purpose and safety of feed ingredients. All feed ingredients, including novel feeds (new feeds that are organisms or parts or products thereof or feeds that have a novel trait) and new feeds (of chemical origin) would continue to require assessment and approval before they could be placed on the market. In addition, anyone doing research with a novel feed would require approval before they could conduct the research. As part of this approval, industry would need to demonstrate how they would control the novel feed to ensure that it does not present a risk of harm to human or animal health or the environment. These amendments regarding novel feeds would address the Standing Joint Committee for the Scrutiny of Regulations concerns.

A more transparent feed ingredient assessment and approval process would be set out in the proposed Regulations and would have the following features:

- Schedule IV (approved feed ingredients) and Schedule V (approved flavour ingredients)
  would be removed from the *Feeds Regulations, 1983*, combined, updated and replaced
  by the *Canadian Feed Ingredients Table*, which would be incorporated by reference. In
  moving these schedules into a document incorporated by reference, amendments
  could be made from time to time while still requiring public consultation for new or
  modified feed ingredients.
- The number of classes of ingredients would be expanded, which would contribute to more clearly identifying the intended purpose of each feed ingredient (e.g. pellet binders, colours, preservatives).
  - Post-approval conditions would be expanded to apply to all feed ingredients. Currently, post authorization conditions are only required with respect to the release of novel feeds. Expanding the scope of post-approval conditions to approved feed ingredients would provide the CFIA with authorities to reassess and take action on feed ingredients whose safety comes into question following approval. Therefore, an applicant would be required to submit the new information to the Minister for evaluation where there are any changes in risks associated with the feed ingredient after it has been approved.

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## 2. Feed registration

Feed registration requirements and exemptions would be updated, including the reduction in the number of feeds requiring mandatory product registration. The CFIA would require a short list of higher-risk mixed feeds to still be registered, including feeds administered by water, mineral feeds containing medications and feeds bearing labels with languages other than English or French or claims not set out in a list of pre-approved label claims and conditions. In addition, all imported mixed feeds would no longer require registration if they are imported by a licence holder. Instead, it would be required that the feed manufacturers develop and implement preventive control plans. That way, increased responsibility is put on feed manufacturers for the safety of their feed products.

## 3. Licensing of individuals

The proposed Regulations would see the creation of licensing requirements for individuals engaged in activities associated with feeds that are to be sent or conveyed interprovincially, have been imported for sale or are intended for export. This would enhance the oversight of feed imports and exports and improve alignment with the requirements of other CFIA regulations such as the *Safe Food for Canadians Regulations*. Licensing would not be required for individuals that are importing a feed that is not intended to be sold. In this case, the oversight of imported feeds, not for sale, would default to requiring registration rather than the licensing of an individual.

## General and safety standards for feeds

General and safety standards for feed would be updated to better reflect current science, risks, production practices and technology. The following are examples of updated standards:

- A compendium would be established where veterinary health products, veterinary biologics, or other regulated products that may be effective when administered to livestock via their feeds can be listed. This compendium would be incorporated by reference into the *Feeds Regulations*, 2022 to enable timely updates, and
- Standards for a broader range of known or reasonably foreseeable hazards in feeds and prescribed maximum levels in feeds would be identified, based on risks to public, animal and plant health and the environment.
  - Tables of such hazards and maximum levels in feeds (for example for nutrients,

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biological and chemical contaminants, deleterious substances and weed seeds) would be established in documents that would be incorporated into the modernized framework by reference. This would enable the timely review and revision of these standards as scientific and risk knowledge continues to evolve.

## Labelling

Labelling requirements would be updated to reduce prescriptiveness and rigidity, provide better information to purchasers and address concerns by the Standing Joint Committee for the Scrutiny of Regulations regarding official languages obligations (i.e. health and safety labelling requirements to appear in both official languages). Improved flexibility would be provided by allowing additional information, such as claims and guarantees, to be added to the label without requiring the feed to be registered. To increase the traceability of feeds through the supply chain (in the event recalls are necessary), feeds would need to be labelled with a lot number / identification code. Under the proposed Regulations, it would continue to be prohibited for feed labels to be misleading or not be truthful. For example, the label should not deceive or mislead the purchaser with regards to the composition, usefulness or purpose of the feed. The information presented on the label would need to correspond to the purpose of the feed and guarantees would need to accurately reflect its contents.

Amendments would serve to reduce the regulatory burden on stakeholders while increasing responsiveness to industry changes by improving the clarity, transparency, and flexibility of the proposed Regulations. For example, pre-approved claims and optional (non-mandatory) guarantees on labels would be permitted if they comply with requirements set out in documents listing claims and guarantees to be incorporated by reference in the modernized framework. This would mean registration of feeds bearing such claims or guarantees by the CFIA, as is the case at present, would no longer be required.

Mandatory bilingual labelling requirements would be required for any label information that could impact the health and safety of the purchaser or livestock to be fed with the feed product. This would include medication information, and caution and warning statements.

Finally, it is proposed that when a feed is manufactured using a feed ingredient or mixed feed which has a caution or warning statement on its label, or for which there is a maximum inclusion rate of a feed ingredient, this information would need to be transferred onto the label for any other feed that includes the feed ingredient or mixed feed in its formulation.

#### Feed hazard identification and preventive controls

Under the proposed Regulations, regulated parties would be required to conduct a hazard identification (e.g. biological, chemical and physical hazards) for the feeds they manufacture. In addition, they would be required to develop, implement, and maintain a written preventive control plan to demonstrate how the preventive controls (e.g. cleaning and sanitation, pest control, conveyances, equipment, contaminated material, interior of the facility, movement of persons, and water, steam and ice) and other requirements (e.g. packaging and labelling) are met. Regulated parties would have the flexibility to apply the preventive controls and other measures with an approach based on outcomes that demonstrate their operations and feeds comply with the proposed Regulations.

There would be an exception where feed operators would not be required to prepare, keep or maintain a preventive control plan when the feed is approved for research or experimental purposes. In addition, the *Feeds Act* does not apply to livestock producers that make feed for their own animals provided that the feed does not contain any medications; therefore, they would not be subject to the proposed Regulations.

All feed manufacturers who are required to have a preventive control plan would be required to have a written plan. An exception from having a written plan in the *Safe Food for Canadians Regulations* is provided to small businesses and is based on an analysis of the food safety risks. Similar to the food businesses (meat, milk, eggs and fish) that do not qualify for the exception under the *Safe Food for Canadians Regulations*, feed stakeholders would not be exempt by regulations from the requirement to develop a written plan. The majority of affected stakeholders are considered small businesses and they feed livestock species that may eventually become part of the food supply chain as meat and animal products (milk, eggs, fish). As the meat and animal products processors are not exempt from *Safe Food for Canadians Regulations*' requirements, the feed manufacturers would not be exempt from the *Feeds Regulations*, *2022* requirements.

The most effective way to reduce or eliminate risks posed by livestock species being fed with contaminated feed and introduced into the food supply chain as meat and animal products (milk, eggs, fish) is to address risks early in the food supply chain at the feed production level. Risks introduced in the food supply chain would have an impact on an exponentially larger number of food operators and food products as it travels through the food supply chain through these livestock species fed with contaminated feed.

The hazard identification and preventive control plan approach reflect internationally recognized standards and management-based requirements, such as hazard analysis and critical control points principles and good manufacturing practices in the European Union and preventive control plans in the United States.

## **Traceability**

New traceability requirements would require more detailed record-keeping requirements to better support risk management along the feed supply chain, especially where timely responses to incidents of risks to public, animal or plant health or the environment are involved.

► View comments for the Description section 12 comment(s)

## Regulatory development

#### Consultation

Since 2012, the CFIA has done a considerable amount of consultation in advance of completing this proposal, including

- Bilateral meetings and multilateral workshops with stakeholder groups (2012–13);
- Establishment of an industry-government steering group the CFIA provided regular briefings on an ad hoc basis to national feed industry and livestock producer organization members;
- Three online consultations on proposals regarding the key elements of the framework (2013–14);
- Eight in-person public town hall meetings across Canada (2016) to promote awareness and invite feedback on the posting of a (ARCHIVED) comprehensive consolidated regulatory framework proposal;
- Fourteen online consultations on proposed technical standards (2016–18); and
- Consultation prior to prepublication in the Canada Gazette, Part I (fall 2020).

Copies of the proposals and consultation summary ("What We Heard") reports are posted on the CFIA <u>Livestock Feed Consultations on Proposed Regulatory and Policy Changes web page</u>.

Initially, the CFIA engaged most-affected stakeholders by way of bilateral discussions and multi-stakeholder meetings, and less-affected stakeholders by way of an online discussion paper and survey. By July 2012, the CFIA had held 29 bilateral meetings with stakeholder groups and government partners. A two-day, multi-stakeholder workshop was also held, in September 2012. There was general support from stakeholders for using the Codex Alimentarius' *Code of Practice on Good Animal Feeding* (PDF) as a basis for safeguarding the feed supply.

As a result of this preliminary consultation, an industry-government Feed Regulatory Steering Group was formed, comprising members representing commercial feed manufacturers, major national livestock producer associations, the CFIA, and Health Canada's Veterinary Drugs Directorate. The Feed Regulatory Steering Group has been the first point of contact for the CFIA to solicit input or feedback on regulatory modernization topics, and technical working groups formed on an ad hoc basis to discuss aspects of the feed regulatory modernization process. Meetings of the Feed Regulatory Steering Group were held on an ad hoc basis as the CFIA worked to develop different elements of the modernized framework in stages and sought the steering group's feedback as the elements took shape.

In 2013–14, consultation documents were prepared and posted on the CFIA website and circulated to industry stakeholders to consult on specific components of the feed regulatory modernization (i.e. labelling, feed ingredient assessment and approval, and hazard identification and preventive controls).

In 2016, a consolidated proposal was released on the CFIA website and circulated to industry stakeholders to provide a comprehensive overview of the proposed regulatory direction, to address comments and feedback received during previous consultations, and to address additional components that were not included as part of previous consultations. In addition, eight town hall sessions were held across Canada to meet face-to-face with stakeholders and share the information from the Consolidated Proposal.

Between 2016 and 2018, technical standards proposals were developed and shared with stakeholders for review and comment to address specific components of the proposed Regulations that would be incorporated by reference (e.g. required guarantees and permissible claims on feed labels, veterinary biologics used in feeds, weed seed standards for feeds).

In addition, from September 30 to November 15, 2020, stakeholders were consulted on the proposed changes to the Feeds Regulations, 2022. The purpose of the online consultation was to gather feedback and confirm support from industry on the proposed regulatory framework for livestock feeds; to validate potential economic impacts of the proposed regulatory changes, especially with respect to the challenges presented by the COVID-19 pandemic; and to determine where additional guidance would be required. The consultation was developed with the participation of the Animal Nutrition Association of Canada (ANAC). Stakeholders were given an advance copy of the consultation document before it was posted on the CFIA Consultations and Engagement website for comments. Further, to increase response, external and internal listsery messages were sent out and the public and stakeholders were also informed through social media. In total, 36 sets of written comments were received from this consultation. Six sets of comments were received from government organizations (federal and provincial), 11 sets of comments were received from livestock producer associations, 6 sets of comments were received from feed industry associations, 12 sets of comments were received from individual feed companies, and 1 comment was received from an international certification company. Of the comments received from individual feed companies, almost half were from small feed businesses.

#### **Support from stakeholders**

Overall, the fall 2020 consultation resulted in a continued confidence by the CFIA that there is broad support to move forward quickly with this regulatory initiative.

Stakeholders are supportive of a more outcome- and risk-based approach that allows for innovation and flexibility. The following topics/areas were supported by many respondents:

- The use of incorporation by reference to allow for timely updates of general and safety standards in feeds. In particular, updating the maximum contaminant levels allowed in feed, maximum nutrient values in feed, list of permissible claims, Canadian Feed Ingredients Table (list of approved feed ingredients), and Compendium of Non-Feed Product Brochures (e.g. veterinary health products allowed in feed);
- More flexibility in the approval and registration process, in which fewer mixed feeds
  would require product registration; allowing that non-feed products be added to feed,
  and allowing permissible claims on a feed label without requiring product registration;
- Increases in labelling flexibility;

- Requirement to have a preventive control plan (PCP), especially as some expressed that they had some type of PCP already or were part of an on-farm food safety program or hazard analysis and critical control points—type certification program;
- Delayed and staggered approach for some new and amended regulatory requirements coming into force.

Stakeholders expressed some concerns about the exemption in the *Feeds Act* and the Regulations provided to livestock producers making feeds on farm, and the proposed requirement for bilingual labelling of health and safety-related information. For these concerns, the CFIA is limited in applying regulations by the scope of the exemption provided to livestock producers in the *Feeds Act*. The proposed bilingual labelling obligations are in response to concerns raised by the Standing Joint Committee for the Scrutiny of Regulations regarding respecting bilingual labelling obligations applied under the *Official Languages Act*.

In addition, a few concerns were raised regarding preventive control plans for small commercial feed mills, record-keeping requirements at feed retail outlets, and maximum standards for certain contaminants (e.g. dioxins). These concerns were mostly raised by individual stakeholders and some small businesses. In order to obtain a better understanding of these concerns and to determine the manner in which they can adequately be addressed, outreach and engagement with stakeholders would be undertaken in parallel to the comment period in the *Canada Gazette*, Part I. More time and effort will be spent on engaging with the small feed businesses to understand the impacts that these regulatory changes would have on the small feed business communities. Prepublication of the proposed Regulations in the *Canada Gazette*, Part I, where stakeholders could view the regulatory text, would present this opportunity to further consult with stakeholders. Based on more detailed feedback and better understanding of the root of the concerns, the proposed Regulations can be changed to address these outstanding issues.

## Modern treaty obligations and Indigenous engagement and consultations

As required by the <u>Cabinet Directive on the Federal Approach to Modern Treaty</u>
<u>Implementation</u>, the proposal's possible treaty implications were assessed. No such implications were identified, including with respect to the issue of jurisdiction.

#### Instrument choice

A range of regulatory and non-regulatory options was considered, including the baseline scenario and any other feasible regulatory and non-regulatory actions. The regulatory proposal was chosen as the instrument of choice to address the issue.

## Baseline scenario (no change)

In the baseline scenario, the CFIA would continue to administer the highly product-based regulatory framework that applies to feeds in domestic and import trade and does not benefit from more up-to-date approaches that are based on risk and outcomes. This option would not provide a more level playing field of oversight of domestic and imported feeds (i.e. in which most domestic feeds would remain exempted from registration, but all imported mixed feeds would continue to require it). In addition, the CFIA would retain the majority of the responsibility for confirming the compliance of imported feeds via the registration process, which is required before a product can be imported. The registration of such imported feeds is considered to be burdensome by industry and not "World Trade Organization-friendly" by the U.S. feed industry. Furthermore, it does not align well with the principles and outcomes of the Integrated Agency Inspection Model that sets out a standardized and consistent approach to inspection oversight.

The CFIA would continue to exempt feeds for export from Canada from the scope of the *Feeds Act* and Regulations. While this option would maintain the minimal level of regulatory burden on feed exporters and align with the U.S. approach, it may serve to limit broader market access for Canadian livestock feeds internationally, given the limited level of government oversight that would apply to feeds in export trade.

## Regulatory proposal (preferred option)

The regulatory proposal would see a comprehensive, complete and robust renewal of the *Feeds Regulations, 1983* that would include more transparent feed approval and registration requirements, updated product standards, new manufacturing standards that require preventive controls, new traceability requirements and updated labelling requirements. Similar to the *Safe Food for Canadians Regulations*, this option would require that operators of establishments who send or convey feeds across provincial borders, who export feeds or engage in activities related to feeds that have been imported for sale have a licence and comply with any conditions set out in the licence.

In addition, this regulatory option aligns with principles of the Integrated Agency Inspection Model. The Integrated Agency Inspection Model principles are based on the premise that industry is responsible for its products and processes and must demonstrate ongoing compliance with legislative requirements and that approaches should be flexible to accommodate the complexity and size of an operation. A consistent regulatory approach between CFIA-regulated commodities would allow for a more consistent inspection and enforcement approach. Such an approach is beneficial to stakeholders and the CFIA, as it allows for a greater understanding of compliance requirements and enforcement outcomes. The regulatory proposal also aligns with desired outcomes such as licences and preventive control plans, and allows for a combination of oversight mechanisms for imports (via a licence or by product registration with the CFIA).

► View comments for the Regulatory development section 7 comment(s)

## Regulatory analysis

## Benefits and costs

This section assesses the incremental impacts (i.e. benefits and costs) resulting from the difference between the baseline and regulatory scenarios. The baseline scenario describes the situation under the current regulatory framework and what it would look like in the future if the proposed Regulations did not come into force. The regulatory scenario describes the alternate situation should the regulatory proposal come into force. The complete descriptions of the baseline and regulatory scenarios and the methodology used to assess the incremental impacts (including detailed assumptions) are fully documented in a cost-benefit analysis report, which is available from the CFIA by request.

#### Affected stakeholders

The following stakeholders would be affected by the proposed Regulations:

- commercial feed manufacturers who produce complete feeds, supplements, specialty feeds, and premixes;
- ingredient manufacturers for whom ingredients may be the principal product (vitamins, minerals, anti-caking agents) or by-product of another process (e.g. brewing, oilseed grinding, food processing, animal or fish rendering);

- on-farm feed manufacturers for whom feed represents a key input to their operation, and who produce medicated feed solely for their own use; and
- feed retailers/distributors that are exclusively sellers of feeds or retail outlets that may sell feeds in addition to other farm goods such as fertilizers, pesticides, and farm equipment.

The number of affected stakeholders is represented by the number of establishments (see Table 1).

**Table 1: Number of affected establishments** 

Total number of establishments
480 <sup>a</sup>
2 619
17 123 <sup>b</sup>
1 500 ª
21 722

<u>a</u> CFIA inspection database.

Statistics Canada's 2016 Census of Agriculture estimated that there are 85 615 farms in Canada that are raising live animals such as cattle and pigs. CFIA subject matter experts estimated that approximately 20% of these farms are making medicated feeds on site and may potentially be impacted by the proposed changes.

## Baseline versus regulatory scenario

Due to the scope of the proposed amendments, only key elements of the baseline and regulatory scenarios are described below.

## 1. Proposed licensing regime

There is currently no licensing regime under the *Feeds Regulations*, 1983. The proposed licensing regime would apply to stakeholders that import for sale or export feed and/or convey feed from one province to another. As well, a licence would need to be renewed

every two years.

**Table 2: Proposed licensing regime** 

Baseline scenario	Regulatory scenario
No licensing regime	New licensing regime would apply to stakeholders that import for sale or export feed and/or convey feed from one province to another

#### 2. Proposed preventive control and preventive control plan requirements

The feed industry has worked to establish sector specific, voluntary feed and food safety programs in recent years (e.g. FeedAssure®). These voluntary programs are based on hazard analysis and critical control points principles, the focus being largely on food safety risks and controls. The proposed preventive control and preventive control plan requirements are also based on hazard analysis and critical control points principles and would be mandatory across the feed industry. None of the voluntary feed and food safety programs currently fully meet the proposed requirements, as these requirements would be broader in scope.

Table 3: Proposed preventive control and preventive control plan requirements

Baseline scenario	Regulatory scenario
May or may not be enrolled in voluntary feed safety program, such as FeedAssure®	Mandatory preventive controls and preventive control plans

## 3. Proposed product registration requirements

Registration of certain mixed feeds would still occur. However, fewer mixed feeds would require mandatory registration than at present, as the CFIA proposes to shift more responsibility for compliance to regulated parties (as part of the proposed preventive controls and preventive control plan requirements).

## 4: Proposed product registration requirements

Baseline scenario	Regulatory scenario
Registration required if any feed ingredients and mixed feeds are new, modified or have health purposes to animals	Reduced product registration

#### 4. Proposed labelling requirements

Labelling regulatory requirements currently exist for all feeds and feed ingredients. For the proposed regulatory change, all feeds would still require a label with basic labelling information. Additional proposed labelling requirements would include an identification code and bilingual health and safety information.

**Table 5: Proposed labelling requirements** 

Baseline scenario	Regulatory scenario
Basic labelling requirement (e.g. product type) for all feeds and feed ingredients	Additional identification codes and bilingual health and safety information

## 5. Proposed traceability requirement

There would be two tasks performed by affected stakeholders under the proposed traceability policy. Stakeholders would first need to develop a traceability template and then use it to perform the required record keeping. The approach, which is based on outcomes, would allow for flexibility in the type/format used for the template. Stakeholders covered by the proposed requirements would have to keep the following basic traceability information on each feed supplied to them or by them: feed product name, identification code, business name and address, date of purchase or sale, and contact person. Therefore, the traceability template could simply entail using these data elements as category headers in a paper-based or electronic document. Additional guidance documents would also be provided to affected stakeholders to assist with the development of the template.

Currently, the majority of the establishments already have the traceability templates. It was estimated that 94% of commercial feed manufacturers, 99% of feed ingredient manufacturers, 99% of on-farm feed manufacturers and 98% of feed retailers already keep traceability records. It is therefore assumed that these regulated parties have already developed a template. <sup>1</sup> However, not all of these regulated parties have all of the basic record-keeping practices necessary to facilitate timely feed safety investigations, recalls or withdrawals of non-compliant feeds from livestock before they are consumed. The proposed traceability record-keeping requirements would apply the international standard for traceability established by the Codex Alimentarius to everyone who sells feeds. The Codex standard calls for traceability of feed one-step forward to the immediate customer and one-step back to the immediate supplier.

#### **Table 6: Proposed traceability requirements**

Baseline scenario	Regulatory scenario	
Voluntary	Mandatory for everyone who sells feeds	

#### Description of benefits and costs

This section provides a list and brief description of all the benefits and costs. The listing is broken up into categories based on benefits and costs that were monetized and those that were assessed qualitatively.

#### 1. Monetized benefits for industry

#### a. Reduction in product registrations

The proposed Regulations would reduce the number of products required to be registered with the CFIA; thus, the industry would avoid the time required to prepare and submit required documents to the CFIA.

#### b. Avoidance of product registration fees

The proposed Regulations would reduce the number of products required to be registered with the CFIA; thus, the industry would avoid ongoing fees associated with product registration.

#### 2. Monetized benefits for the CFIA

#### a. Reduction in product registrations

The CFIA would have to process fewer applications for product registration.

#### 3. Qualitative benefits for Canadians

#### a. Improved quality and safety of feeds for animal and human health

Feeds represent significant costs for the production of livestock and also play an important role in contributing to their health and productivity. The proposed regulatory requirements would improve the quality and safety of feed and feed ingredients, which would lead to a reduction of contaminated feeds and recalls. Any such reduction in contaminated feed would reduce the feed safety risk to animals and to consumers of food products of animal origin.

#### b. Increased public confidence in feed quality and safety

Consumers, food processors and livestock producers would have increased confidence in the quality and safety of the feed, as it would be produced in a manner that is more likely to ensure feed safety. In addition, there would be increased confidence in the feed supply chain due to the traceability requirements, as products could be identified and traced more easily.

#### 4. Qualitative benefits for industry

#### a. More level playing field for feed industry

Currently, some establishments are required by their associations to maintain a feed safety plan and traceability records (while others are not). This is one example of why operations vary across commercial feed manufacturers and ingredient manufacturers. To address these regulatory inconsistencies, the proposed Regulations would establish consistent requirements for all operations. This would provide a more level playing field for the industry as a whole.

#### b. More timely and improved market access

With reduced product registration, commercial feed manufacturers and ingredient manufacturers would have more timely access to domestic markets. Moreover, the CFIA would provide a publicly available list of permissible claims and guarantees, which would allow specialty or other mixed feeds to be exempt from product registration. Also, domestic and imported feeds would be treated equally by the CFIA in terms of the need for registration and the associated requirements (if applicable).

#### c. Increased labelling flexibility

There would be more flexibility provided for claims, non-mandatory guarantees and labelling statements on feed labels. Manufacturers of mixed feeds could choose to provide additional label information to highlight specific qualities of their feeds, such as additional nutrient guarantees or product claims that presently trigger product registration. This approach would enable innovation and allow manufacturers to differentiate their feeds in a competitive environment.

In addition, requiring that health and safety information (e.g. caution and warning statements) be in both English and French languages may help feed manufacturers access some Canadian markets more easily where only English or French is used.

#### d. More efficient and effective feed safety recalls

Traceability requirements would allow recalls to be conducted in a more efficient and effective manner. This is because the traceability information would be more readily available and precise than with the current regulatory requirements. The proposed traceability requirements would reduce the duration of feed recalls or feed safety investigations and minimize unnecessarily wasted feed through improved targeting of affected feed products in comparison with the baseline scenario.

#### 5. Qualitative benefits for the CFIA

#### a. Improved feed and food safety approach

Currently, the CFIA uses different regulatory approaches to achieve compliance with respect to the safety of livestock feed and foods of animal origin intended for human consumption. In the regulatory scenario, there would be a consistent CFIA feed and food safety approach based on risk, outcomes and regulatory oversight. An example of this would be the proposed preventive control and preventive control plan requirements, which would be enforced for both food producers/processors (who supply food by-products for feed production) and feed establishments.

#### b. Improved knowledge and additional enforcement tool

The CFIA would have improved knowledge of the feed industry based on the activities for which a licence is required. In addition, the CFIA would be able to request additional information about which establishments are involved in higher and lower risk activities. This would allow the CFIA to better allocate existing resources based on an establishment's risk level.

The proposed licensing requirement would also provide the CFIA with an additional enforcement tool, including the potential for licence suspension or cancellation.

#### 6. Monetized costs for industry

#### a. Licence applications

In the regulatory scenario, there would be licensing requirements for businesses that are involved with feeds imported for sale, or feeds exported or being conveyed from one province to another. Licences would need to be renewed every two years. The administrative costs associated with licence applications would be the time spent to prepare and submit required documents to the CFIA.

#### b. Development and modification of preventive control plans

Businesses that do not currently have any feed safety program would be required to develop preventive control plans. Additionally, businesses that currently have a feed safety program in place would need to modify their programs to be fully compliant with the proposed regulatory requirements.

#### c. Implementation of preventive controls

Costs would include implementation of preventive controls, training for employees and record-keeping. The magnitude of this cost would be dependent on current industry practices, since some establishments have already implemented many of the proposed requirements.

#### d. Review of preventive control plans

This cost would include the time spent to review the preventive control plans annually.

#### e. Label modification

Businesses would have to spend time modifying their current labels to include bilingual health and safety information and an identification code if this information is not currently on their feed labels.

#### f. Development of traceability template

Businesses would have to spend time developing a new traceability template to keep traceability records. This template could entail creating a simple tracking spreadsheet or paper-based documentation.

#### g. Traceability record-keeping

Businesses would have to spend time keeping records on each feed commodity supplied to and from them.

#### 7. Monetized costs for the CFIA

#### a. Compliance promotion

The CFIA would bear transitional costs for the following three activities:

- developing and updating compliance promotion materials;
- updating and designing new training materials for the CFIA inspection staff; and

• delivering training to the CFIA staff on implementing the proposed regulatory changes and modernized inspection program.

#### Methodology

This section briefly describes the methodology, key data sources and key assumptions used to estimate the monetized benefits and costs.

#### 1. Model parameters and assumptions

The key assumptions and parameters that were used in this cost-benefit analysis include the following:

- the analysis covered a 10-year time period from 2022 to 2031;
- a discount rate of 7% was used;
- all monetary values are represented using 2017 prices;
- the Standard Cost Model was used to monetize the time required to perform a task.
   The Standard Cost Model uses the following formula: ACTIVITY COST = PRICE × TIME × POPULATION × FREQUENCY;
- wage rates were obtained via the Treasury Board of Canada Secretariat Regulatory Cost Calculator and accounted for overhead costs;
- the number of businesses would be constant over the 10-year time period  $\frac{2}{7}$ ;
- the proposed transitional provisions <sup>3</sup> would provide cost savings for businesses; and
- for the purpose of this analysis, the fees charged to businesses are assumed to reflect 10% of the CFIA costs of providing the service.

#### 2. Key data sources

The key data sources that were used in this cost-benefit analysis include the following:

- the CFIA inspection database
- CFIA data on registered establishments that currently implement a hazard analysis and critical control points-based feed safety program
- The U.S. Food and Drug Administration proposed rule: *Current Good Manufacturing*Practice and Hazard Analysis and Risk-based Preventive Controls for Food for Animals

  (2013)

- the <u>Safe Food for Canadians Regulations</u> cost-benefit analysis
- Statistics Canada's Canadian Business Counts and the 2016 Census of Agriculture
- an industry survey conducted by the CFIA 4

#### Monetized benefits and costs

The approaches used to monetize the most significant impacts are discussed below. The "One-for-one rule" section contains details on the monetized administrative costs and benefits.

## 1. Monetized benefits for industry

## a. Reduction in product registrations

There are approximately 2 000 product registration applications received annually by the CFIA, including 1 200 initial applications and 800 renewal applications. CFIA subject matter experts estimated that there would be a 41% reduction for both initial and renewal applications.

Based on survey results, it takes 1.5 hours, on average, to prepare and submit the required documentation for an initial product registration application package and 30 minutes for a renewal application package.

## b. Avoided product registration fees $\frac{5}{}$ , $\frac{6}{}$

The fee for a new application is \$179, and the fee for a renewal application is \$31.

#### 2. Monetized benefits for the CFIA

#### a. Reduction in product registrations

Due to the reduced number of applications, the CFIA would avoid resource costs associated with processing applications. Savings were calculated using processing costs minus application fees.

## 3. Monetized costs for industry

#### a. Implementation of preventive controls

Preventive control tasks would include training, performing feed safety–related activities and record-keeping. The magnitude of this cost would be dependent on current industry practices. Businesses with a feed safety program (see Table 7) are already implementing

some of the proposed activities. However, they would require some additional time to be fully compliant with the proposed requirements. Businesses without a feed safety program would begin to implement preventive controls and the amount of time required was assumed to be the same as the amount of time required for survey respondents who are already implementing feed safety programs.

**Table 7: Current industry status on the feed safety program** 

Affected stakeholders	With feed safety program	Without feed safety program	Total
Commercial feed manufacturer	384	96	480
% share	80	20	100
Ingredient manufacturer	1 309	1 309	2 618
% share	50	50	100
On-farm feed manufacturer	14 555	2 568	17 123
% share	85	15	100
Feed retailer/distributor	150	1 350	1 500
% share	10	90	100

Table 8 below presents the survey results used to estimate the time required for the implementation of preventive controls.

**Table 8: Survey results on implementation of preventive controls** 

Affected stakeholders	Current training hours/year	Additional training hours/year	Current hours/week for implementation	Additional hours/week for implementation	Current record- keeping hours/week
Commercial feed manufacturers	4.7	0.9	21.7	4.7	9.5
Ingredient manufacturers	3.9	1.6	11.1	6.8	6.0

On-farm feed manufacturers	1.2	0.2	6.3	1.2	3.2
Feed retailers/distributor	3.3	0.7	2.5	1.0	2.5

It was assumed that regulated parties would start to gain efficiency in implementing these preventive control activities over time. It is expected that small businesses would face greater challenges in understanding and fulfilling their compliance obligations than larger establishments. Therefore, the analysis assumed that small businesses would spend 50% less time implementing preventive controls starting in year three while medium-to-large businesses would spend 50% less time starting in year two.

#### b. Label modification

A feed label would need to include the bilingual health and safety information and identification codes. It would be a one-time cost because the industry survey results showed that this information could be added into the computer system once and automatically applied to all future feed labels.

According to CFIA subject matter experts, all affected parties would need to make changes to their feed labels to meet the proposed requirements. Therefore, the survey collected data on the number of affected labels and the additional time required to adjust the current labels to be fully compliant. These survey results are summarized in the following table:

**Table 9: Survey results on label modification** 

Affected stakeholders	Average number of affected labels per establishment	Additional hours/bilingual label	Additional hours/label identification code	Other costs <sup>a</sup> /label (\$)
Commercial feed manufacturers	535.5	0.4	0.1	26.5

<u>a</u> Costs associated with the modification, such as buying new software, extra printer and ink.

ink.

Ingredient manufacturers	14.7	0.3	0.1	0
Feed retailers/distributor	3.0	0.3	0.1	0
<ul><li><u>a</u> Costs associat</li></ul>	ed with the modification	ı, such as buying new	software, extra printe	er and

It is important to note that there would be efficiency gains from incorporating all of the requirements at the same time. This is consistent with the findings from other CFIA proposed regulatory labelling initiatives. The analysis assumed that total hours would be reduced by 50% if all of the changes were incorporated at the same time.

#### c. Development of traceability template and traceability record-keeping

Businesses would have to develop a traceability template to keep traceability records. This template would need to include only basic information (e.g. feed product name and date of purchase/sale) for each feed product supplied to/by them. Based on CFIA subject matter experts, it is assumed that this information would take an average of five minutes to create as additional guidance documents would also be provided to affected stakeholders to assist with the development of the template.

The traceability record-keeping cost was estimated based on the amount of additional time that a business would need to keep all of the purchases and/or sales record (see the "One-for-one rule" section for more information).

#### **Estimated result**

#### Cost-benefit statement

Number of years: 10 years (2022–2031)

Base year for costing: 2017

Present value base year: 2022

Discount rate: 7%

Table 10: Cost-benefit statement (Canadian dollar [Can\$], 2017 prices)
Monetized costs

Impacted stakeholder	Description of cost	Year 1	Year 5	Year 10	Total (present value)	Annualized value
CFIA	e.g. compliance promotion, licensing processing, and the resource costs associated with applications (i.e. net of fees received)	1,068,573	0	4,290,169	16,644,232	2,369,764
Feed industry	e.g. licence applications, development and modification of preventative control plans, implementation of preventative controls, review of preventative control plans, label modification, development of traceability template, traceability record-keeping	0	52,082,778	52,590,478	462,888,788	65,904,950
All stakeholders	Total costs	1,068,573	52,082,778	56,880,647	479,533,020	68,274,714

#### Monetized benefits

Impacted stakeholder	Description of benefit	Year 1	Year 5	Year 10	Total (present value)	Annualized value
CFIA	e.g. reduction in product registration fees	883,176	883,176	883,176	6,637,272	944,998
Feed industry	e.g. reduction in product registrations, avoided product registration fees	142,589	142,589	142,589	1,071,588	152,570
All stakeholders	Total benefits	1,025,765	1,025,765	1,025,765	7,708,860	1,097,568

## Summary of monetized costs and benefits

Impacts	Base year	Other relevant years	Final year	Total (present value)	Annualized value
Total costs	1,068,573	52,082,778	56,880,647	479,533,020	68,274,714
Total benefits	1,025,765	1,025,765	1,025,765	7,708,860	1,097,568
NET IMPACT			471,824,160	67,177,146	

## **Qualitative impacts**

## Canadian public:

• Enhanced animal and human health and safety benefits

## Industry:

- Improved quality and safety of feed products
- More level playing field for feed industry
- More timely and improved market access
- Increased labelling flexibility, accessibility and information

• More efficient and effective feed safety recalls

Consumers and livestock producers:

• Increased confidence in feed supply chain

#### CFIA:

- Better traceability
- Improved consistency in the CFIA feed/food regulatory approach
- Improved knowledge and additional enforcement tool

The following table shows all monetized costs and benefits by category.

## Table 11: Monetized costs and benefits by impact (Can\$, 2017 prices)

Notes: The analysis covered a 10-year time period (2022–2031). Values were calculated using 2022 as the base year and a 7% discount rate.

Monetized impact by category	Total present value	Annualized value
Review time	3,035,136	432,135
Preventive controls and preventive control plans	434,795,915	61,905,157
Traceability	17,420,939	2,480,350
Labelling	5,793,573	824,875
Licensing	112,596	16,031
Licensing fees	1,730,629	246,403
CFIA resource and implementation costs	16,644,232	2,369,764
Total costs	479,533,020	68,274,714
Reduction in product registration	334,113	47,570
Avoided product registration fees	737,475	105,000
CFIA resource savings	6,637,272	944,998
Total benefits	7,708,860	1,097,568
Net cost (i.e. costs minus benefits)	471,824,160	67,177,146

## Sensitivity analysis

A sensitivity analysis is the portion of the analysis that attempts to deal with the uncertainty that is inherent in the estimates and in predicting the future. Sensitivity analysis involves changing key parameters and assumptions and assessing how this affects the costs and benefits of the regulatory proposal.

The first approach for the sensitivity analysis was to vary the discount rate used to estimate the annualized values. The medium estimate of 7% used in the cost-benefit analysis was changed to 3% and 10%.

The second approach was to vary the costs for on-farm feed manufacturers. This is because the number of affected on-farm feed manufacturers is the largest group among all stakeholders; thus, any variation in their costs would significantly affect the total costs of the proposed Regulations. Moreover, the CFIA did not receive any survey responses from onfarm feed manufacturers with costing data related to the preventive controls and preventive control plan requirements. Therefore, the analysis utilized the survey results for commercial feed manufacturers as a starting point for estimating the costs to on-farm feed manufacturers.

However, the costs associated with preventive controls and preventive control plans to onfarm feed manufacturers would be significantly lower than for commercial feed manufacturers for the following reasons:

- most on-farm feed manufacturers are exempt from the proposed regulatory changes, as they do not sell feeds off the farm and they only make non-medicated feeds;
- on-farm feed manufacturers often make single ingredient feeds or make feeds for single species; thus, their preventive control plans are expected to be less complex than commercial feed manufacturers; and
- on-farm feed manufacturers should not require significant expenditure on equipment to be able to comply with the proposed Regulations.

The medium estimate used in the cost-benefit analysis assumed that on-farm feed manufacturers would experience 70% less cost than commercial feed manufacturers. The sensitivity analysis then used the following rates:

- low: 50% less cost than commercial feed manufacturers; and
- high: 90% less cost than commercial feed manufacturers.

The results of the sensitivity analysis are shown in the following table. The range of the annualized net costs is between \$41.5 million to \$94.5 million.

Table 12: Sensitivity analysis cost-benefit summary (Can\$ millions, 2017 prices)

Notes: Numbers may not add up due to rounding. Values were calculated using 2022 as the base year and a 7% discount rate.

Discount rates	Annualized benefits	Annualized costs	Net monetized cost (i.e. annualized costs minus annualized benefit)
Medium (on- manufacture		turers assume 70	0% less costs than commercial feed
Medium <sup>a</sup> (7%)	1.1	68.3	67.2
Low (3%)	1.06	65.1	64.0
High (10%)	1.13	70.6	69.5
Low (on-farn	n feed manufacture	rs assume 50% le	ess costs than commercial feed manufactures)
Medium (7%)	1.1	92.4	91.3
Low (3%)	1.06	88.0	86.9
High (10%)	1.13	95.6	94.5
High (on-far manufacture		ers assume 90% l	less costs than commercial feed
Medium (7%)	1.1	44.6	43.5
Low (3%)	1.06	42.5	41.5
High (10%)	1.13	46.0	44.9
<u>a</u> This	row represents the (	CBA findings.	

## Conclusion

The proposed repeal and replacement of the *Feeds Regulations, 1983* would support the protection of public health as well as that of animal health, reduce feed safety risks for animals and consumers, and create a level playing field for the feed industry. Other benefits include increased international and domestic regulatory alignment, a consistent and more effective feed safety approach to inspection and oversight by the CFIA, and an enhanced reputation for Canada as a global feed safety leader.

The estimated monetized benefit of the regulatory proposal would be \$7.7 million (present value) over 10 years (or \$1.1 million annualized). Industry would have fewer products that require registration, fewer fees to pay and less time spent on filling out registration forms for new feeds and renewals. The benefits to the CFIA are fewer resources to provide product registration services to industry.

The estimated monetized costs would be \$479.5 million (present value) over 10 years (or \$68.3 million annualized). The main component for the monetized costs for businesses is the proposed requirement for them to adopt and implement preventive control plans, representing 83% of the total costs. The CFIA would incur resource costs associated with processing licence applications, and for planned compliance promotion activities such as presentations and town hall meetings.

The overall result would be a net cost (i.e. costs minus benefit) of \$471.8 million (present value) over 10 years (or \$67.2 million annualized).

#### Small business lens

The small business lens applies as there would be costs for small businesses when complying with the proposed Regulations. Approximately 94% of affected stakeholders are considered small businesses.

The CFIA has undertaken significant consultation with stakeholders, including small businesses, since 2013. The CFIA is sensitive to the needs of small businesses and is aware of the importance of finding the right balance between feed safety and costs to businesses. Therefore, the CFIA has included in its regulatory proposal some flexibility that is expected to reduce the potential costs to small businesses.

The following provisions would be included as part of the proposed regulatory change:

eighteen-month delay for the proposed licence requirements to come into force;

- one-year delay for certain proposed requirements (e.g. labelling, traceability, preventive controls, preventive control plans) to come into force; and
- the requirement for the full list of ingredients on the food label would be removed from the *Feeds Regulations*, 1983.

In addition, the CFIA would provide the following to help small businesses with compliance:

- plain language guidance documents;
- preventive control plan templates;
- brochures and glossary of labelling terms;
- a comprehensive compliance-promotion strategy;

The incremental monetized cost would be approximately \$58.7 million annualized for all small businesses, or \$3,497 per impacted small business. The administrative costs include time for the revision of the *Feed Regulations, 2022*, for licence applications and for record keeping (preventive controls, preventive control plans and traceability). Compliance costs include the development and modification of preventive controls and preventive control plans, development of a traceability template, modification of labelling, and licensing fees. The incremental monetized benefits would be \$143,416 because of fewer product registrations, hence, fee savings to industry, as well as less time spent on filling out registration forms for new feeds and renewals. The resulting net cost would be \$58.7 million for all small businesses or \$3,497 per impacted small businesse.

# Table 13: Small business lens summary (Can\$, 2017 prices)

Number of small businesses impacted: 16 798 <sup>a</sup>

Number of years: 2022–2031

Base year for costing: 2022

Present value base year: 2017

Discount rate: 7%

# **Compliance costs**

Activity	Annualized value	Present value
PCP development and modification	5,386,005	37,829,047

PCP implementation (training and conducting)	36,953,130	259,543,321
PCP maintenance (review plan)	1,471,644	10,336,213
Traceability development	136	958
Labelling modification	796,871	5,596,886
Licence fees	183,547	1,289,154
Total compliance costs	44,791,333	314,595,580

#### **Administrative costs**

Activity	Annualized value	Present value
Regulatory review time	413,132	2,901,665
PCP implementation (record keeping)	11,158,123	78,369,985
Traceability implementation	2,373,118	16,667,787
Licence application	11,942	83,873
Total administrative costs	13,956,314	98,023,309

## **Total compliance and administrative costs**

Note: The analysis covered the 10-year period of 2022–2031. Figures may not add up to totals due to rounding. Values were calculated using 2022 as the base year and a 7% discount rate.

Total cost (all impacted small businesses)		
Total cost (all impacted siliali busilesses)	58,747,647	412,618,889
Cost per impacted small business	3,497	24,564
<u> </u>	·	
<u>a</u> On average, 1 business represents 1.25 es	stablishments.	

## One-for-one rule

The one-for-one rule applies, as the proposal results in an incremental increase in administrative burden on business. The proposal repeals the existing Regulations and

replaces them with a new regulatory title, which results in no net increase or decrease in regulatory titles.

The administrative burden would involve licensing applications and record keeping, resulting from the implementation of preventive controls and traceability requirements. However, businesses would benefit from some administrative relief, as fewer feeds would require registration (see Table 14).

Table 14: List of all administrative cost/benefit impacts

Impact category	Why is it administrative impact?	Administrative costs imposed or avoided
Initial review of the <i>Feeds Regulations, 2022</i>	Familiarization with the new information obligation	Costs imposed
Licensing applications	Authorizations	Costs imposed
Preventive controls — implementation (record keeping)	Collecting and retaining data	Costs imposed
Traceability — purchases/sales record keeping	Collecting and retaining data	Costs imposed
Product registration	Authorizations	Avoided cost

The net annualized administrative costs (i.e. costs minus benefits) would be approximately \$7,226,332, which equates to an annualized net administrative cost per impacted business of \$416 (see Table 15).

# Table 15: Estimated annualized values of administrative impacts for the one-for-one rule (Can\$, 2012 prices)

Note: 2012 prices, 2012 present value base year, 7% discount rate. On average, 1 business represents 1.25 establishments.

Net annualized administrative costs (i.e. costs minus benefits)	7,226,332
Annualized administrative costs per business (\$2012)	416

These estimated impacts were based on information gathered from industry surveys, reasonable assumptions, and consultation with stakeholders and CFIA subject matter

experts. The assumptions used to estimate the administrative impacts are as follows:

- There would be initial licence application costs that would then be ongoing for businesses, as a licence would have to be renewed every 2 years. It was assumed that it would take an individual 15 seconds to fill out a data field. The estimated time to fill out an initial licence application is 20 minutes, based on a licence mock-up form. The renewal application would require the same amount of time as the initial application;
- Preventive controls record keeping would be an ongoing cost for those businesses that are currently without any feed safety program. The amount of time spent was obtained through surveys (see Table 8). The analysis assumed that record keeping would be performed by a non management employee on a weekly basis;
- Review of the proposed administrative burden requirements would be one-time costs
  for all businesses. For the proposed Regulations, the CFIA would design interpretive
  guidance and "plain language" examples to help reduce reviewing time. The analysis
  therefore estimated that on average, a small business would require 3 hours to review
  the proposed Regulations, while a medium-to-large business would require 4 hours. It
  was assumed that the review would be performed by a manager;
- Product registration would be an ongoing benefit for businesses, as fewer applications would have to be submitted to the CFIA. According to the survey results, it takes an individual (i.e. a manager) 1.5 hours, on average, to prepare an initial product registration application package, and 30 minutes to prepare a renewal application package; and
- The analysis assumed that a non management employee would keep records of purchases and sales. Ongoing cost and time estimates were obtained through a survey (see tables 16.1 and 16.2).

Table 16.1 Industry survey results on time spent to keep purchases and sales records for small businesses

Activity Commercial feed manufacturer (hr/year)	Ingredient manufacturer (hr/year) <sup>a</sup>	On-farm feed manufacturer (hr/year) <sup>b</sup>	Feed retailer/distributor (hr/year)	
---	--	--	-------------------------------------	--

Keep purchase records	220	32	69	200
Keep sales records	110	31.5	N/A	200

- The survey only received one response from small ingredient manufacturers. Therefore, the analysis decided to omit the result realizing that using one result may not be appropriate as a representative of all the ingredient manufacturers. The analysis assumed small ingredient manufacturers would use 50% less time than a medium-to-large ingredient manufacturer.
- The analysis did not receive any baseline and costing data from on-farm feed manufacturers. The Feed Program subject matter experts estimated that on-farm feed manufacturers are likely to experience 70% less impacts compared to commercial mills, as the scale of the production by on-farm feed manufacturers is much smaller than commercial mills.

# Table 16.2 Industry survey results on time spent to keep purchases and sales records for medium-to-large businesses

Activity	Commercial feed manufacturer (hr/year)	Ingredient manufacturer (hr/year) <sup>a</sup>	On-farm feed manufacturer (hr/year) <sup>b</sup>	Feed retailer/distributor (hr/year)	
Keep purchase records	838	64	251.4	400 <sup>c</sup>	
Keep sales records	1 693	63	N/A	400 <sup>⊆</sup>	

- The survey only received one response from small ingredient manufacturers. Therefore, the analysis decided to omit the result realizing that using one result may not be appropriate as a representative of all the ingredient manufacturers. The analysis assumed small ingredient manufacturers would use 50% less time than a medium-to-large ingredient manufacturer.
- The analysis did not receive any baseline and costing data from on-farm feed manufacturers. The Feed Program subject matter experts estimated that on-farm feed manufacturers are likely to experience 70% less impacts compared to commercial mills, as the scale of the production by on-farm feed manufacturers is much smaller than commercial mills.
- The survey did not receive any results from medium-to-large retailers/distributors.

  Therefore, the analysis assumed that these establishments may spend twice as much time as small retailers/distributors to keep records due to difference in business size.

## Regulatory cooperation and alignment

Feed safety is a shared responsibility between the federal government, livestock producers, ingredient and commercial feed manufacturers and processors, feed retailers/distributors, and many other stakeholders. The CFIA enforces the *Feeds Act* and the *Feeds Regulations*, 1983 with the assistance of the Canada Border Services Agency.

At the federal level, Health Canada is responsible through the *Food and Drugs Act* for approving veterinary drugs, defining manufacturing standards for approved drugs, and coordinating the assessment of the impact of the use of veterinary drugs on antimicrobial resistance and developing appropriate control strategies. The CFIA also collaborates with Health Canada in responding to the *Federal Action Plan on Antimicrobial Resistance and Use in Canada*, which maps out a coordinated, collaborative federal approach to responding to the threat of antimicrobial resistance. The Action Plan also involves participation from the Public Health Agency of Canada, Agriculture and Agri-Food Canada, the Canadian Institutes of Health Research, the National Research Council of Canada, and Innovation, Science and Economic Development Canada. Provinces, territories, and other stakeholders also play a key role by virtue of their responsibility for the delivery of health care, the approval of antimicrobials for medical coverage, and the regulation of antimicrobial use in agriculture

and veterinary medicine. The CFIA verifies, through inspection and sampling, that medicated feeds manufactured or sold in Canada meet the standards set by Health Canada as per the *Compendium of Medicating Ingredient Brochures* or have been prescribed by a veterinarian.

Of the provinces and territories, only British Columbia and Quebec have regulations pertaining to livestock feed. In both cases, the scope of the regulations is limited to medicated feeds and mostly pertains to record keeping.

Internationally and domestically, there has been increased focus on the linkages between feed and the safety of food over the last decade. Since the detection of Canada's first native-born case of bovine spongiform encephalopathy in 2003 and subsequent bovine spongiform encephalopathy cases, international delegations have been coming to Canada regularly to see first-hand the control measures in place to protect against the transmission of this disease. Their evaluations of Canadian animal and food production systems, the nature of feeds, feed controls and feeding practices have become an integral part of their assessment of Canada's overall health and food safety systems.

The proposed amendments are based upon many internationally recognized standards and requirements, including preventive controls (e.g. good manufacturing practices), standards and guidelines. Recommendations established by national and international authorities have also been taken into account, including from

- Health Canada and United States Food and Drug Administration
- National Research Council
- European Food Safety Authority and European Commission
- Codex Alimentarius
- World Health Organization (WHO) and the World Health Organization International Agency for Research on Cancer
- Food and Agriculture Organization of the United Nations (FAO) [e.g. Joint FAO/WHO Expert Committee on Food Additives].

This has the effect of aligning Canadian feed requirements with those of Canada's trading partners.

The CFIA uses all these guidelines to maintain international harmonization when prioritizing which hazards require standards, and therefore which should be prioritized for

incorporation by reference into proposed regulations.

## Strategic environmental assessment

In accordance with the *Cabinet Directive on the Environmental Assessment of Policy, Plan and Program Proposals*, a preliminary scan concluded that a strategic environmental assessment is not required.

## Gender-based analysis plus

The proposed regulatory amendments would affect various stakeholder groups in very different ways. It is important to provide an analysis of the distribution of the costs and benefits among stakeholder groups to help understand the differentiated impacts. This analysis is focused on the distribution of potential economic impacts of the regulatory amendments to the feed industry, by geographic region and province in Canada.

The analysis was performed by identifying the regional locations of the establishments (Table 17). The annualized value is shown in Table 18. This value was obtained by applying the share of establishments by the province to the total costs carried by each stakeholder. Since Ontario and Quebec have the greatest number of feed manufacturers, these two provinces would likely experience more impacts from the proposed regulations, accounting for almost 60% of the total costs.

# Table 17: Provincial distribution of feed manufacturers (share of establishments by provinces and territories, %)

Note: Percentages may not add up to 100 due to rounding.

Affect	ted stakeholders	АВ	ВС	МВ	ON	QC	SK	Atlantic <u>a</u>	Territories <u>b</u>	Canada
<u>a</u> Atlantic includes New Brunswick, Prince Edward Island, Nova Scotia and Newfoundland and Labrador.										
<u>b</u>	Territories includes Nunavut, Northwest Territories and Yukon Territory.									
<u>C</u>	Calculated using the CFIA inspection database.									

Commercial feed manufacturer <sup>c</sup>	14	4	7.4	33.5	27.5	7	6.4	0	100
Ingredient manufacturer	8.1	12.9	3.6	27.4	23.7	2.4	21.6	0.3	100
On-farm feed manufacturer	13.4	9.4	5.5	22.3	37.4	5.1	6.7	0	100
Feed retailer/distributor	11.5	15.5	5.3	36.6	23.2	4.3	3.6	0	100
Total	13.0	9.7	5.4	23.4	35.7	4.9	7.9	0.1	100

- <u>a</u> Atlantic includes New Brunswick, Prince Edward Island, Nova Scotia and Newfoundland and Labrador.
- <u>b</u> Territories includes Nunavut, Northwest Territories and Yukon Territory.
- Calculated using the CFIA inspection database.

# Table 18: Total industry annualized costs distributed by region (Can\$ millions, 2017 prices)

Note: Figures may not add up to totals due to rounding.

Affected stakeholders	AB	ВС	МВ	ON	QC	SK	Atlantic <u>a</u>	Territories <u>b</u>	Canada
Commercial feed manufacturer <sup>c</sup>	0.7	0.2	0.4	1.7	1.4	0.3	0.3	0.0	4.0

- <u>a</u> Atlantic includes New Brunswick, Prince Edward Island, Nova Scotia and Newfoundland and Labrador.
- <u>b</u> Territories includes Nunavut, Northwest Territories and Yukon Territory.
- Calculated using the CFIA inspection database.

Ingredient manufacturer	1.4	2.3	0.6	4.9	4.2	0.4	3.9	0.0	14.2
On-farm feed manufacturer	4.8	3.4	2	8	13.5	1.8	2.4	0.0	28.8
Feed retailer/distributor	0.8	1.1	0.4	2.7	1.7	0.3	0.3	0.0	5.9
Total	7.8	7.0	3.4	17.2	20.8	2.9	6.8	0.0	65.9

- <u>a</u> Atlantic includes New Brunswick, Prince Edward Island, Nova Scotia and Newfoundland and Labrador.
- <u>b</u> Territories includes Nunavut, Northwest Territories and Yukon Territory.
- Calculated using the CFIA inspection database.

## Rationale

Modernization of the feed regulatory framework would reaffirm that the necessary level of protection for Canadians is maintained, while enabling regulated industries to adapt as practices, technology and science evolve. The CFIA anticipates that the modernization of the *Feeds Regulations, 1983*, developed via extensive consultation with stakeholders, would bring benefits to the feed industry and other regulated parties, small business owners, users, producers and consumers. The flexibility provided by an approach based on outcomes is intended to support innovation, reduce regulatory burden, where possible, and enable a risk-based approach to feed safety in Canada.

The proposed regulatory amendments would reflect internationally recognized standards and management-based requirements while also adhering to the guiding principles of the CFIA modernized Integrated Agency Inspection Model.

Safe feeds contribute to the production of healthy livestock and safe foods of animal origin for human consumption (e.g. milk, meat, eggs). Feeds contaminated by harmful pathogens (e.g. *Salmonella*) and chemical residues (e.g. heavy metals, drug residues, dioxins) may adversely affect the safety of animals used for human consumption. Medicated feeds present risks to animal and public health given global concerns associated with the

increasing incidence of pathogenic organisms becoming resistant to antimicrobial drugs.

Livestock feeds and feed ingredients are also pathways for pests and diseases to be transmitted to animals and plants (e.g. bovine spongiform encephalopathy, insects, and weed seeds in grain products). Consequently, controls on the production of feeds play an important role in protecting human, animal and plant health. The expanded scope of species would ensure that feeds are safe for animals being used for human consumption and would help safeguard the food production continuum.

To mitigate risks, feed hazards must be identified and assessed prior to manufacturing, distribution, and feeding of livestock. Assessments must consider both the safety to livestock as the primary consumer of the feed and the safety to humans as the consumers of the food of animal origin. It is necessary to update prescribed deleterious substances and the list of specific hazards and standards identified for feeds; identify specific hazards and maximum limits in feeds in guidance documents; and include known hazards and limits, where appropriate, in ingredient descriptions that are currently set out in Schedule IV of the *Feeds Regulations, 1983*.

The industry must anticipate and take necessary measures to address the hazards that can be present in feed, on the equipment, or in the establishment and its facilities where feed is manufactured. The proposed Regulations would represent a significant stride in augmenting the regulated industry's responsibility and accountability, and the application of hazard identification and prevention measures is a clear raising of the bar for feed safety in Canada. Hazard identification and preventive controls would be adaptable over time to address new or emerging hazards that pose risks to feed and food safety.

Feed ingredient approvals and mixed feed registration requirements would be based on feeds that present higher risks to human, animal or plant health or the environment. This would result in a significant reduction in product registration as well as a reduction in the administrative burden. A robust, more transparent feed ingredient assessment and approval process would focus on safety and purpose while being supported by scientific data.

The CFIA and its regulated parties must be able to rapidly respond to and mitigate emerging feed and food safety risks. Information gaps within the feed supply chain can lead to a less efficient response to a feed safety incident. The use of licensing as well as traceability requirements for domestic, imported and exported feed would enhance consumer protection during a feed safety incident by providing more accurate information

to facilitate the rapid identification of the origin and movement of a feed through the feed supply chain.

Labels play an important role in the safe and proper use of feeds by livestock producers. Proper labelling allows a purchaser and user of a feed to distinguish one feed from another and provides information on what the feed is and how it is to be used as part of a feeding program. Feeds that are not labelled, or that do not have the appropriate information on the label, may be unintentionally used in a manner that is not safe and may pose risks to animal health, food safety, or the environment. The regulation of labels also helps to ensure a fair and level playing field for both purchasers and businesses. Consistent information means consumers can trust what is on the label. For the industry, everyone has the same requirements and competes based on merit, not unfounded label claims.

The CFIA is proposing to implement bilingual labelling requirements on feed labels to promote accessibility of pertinent health and safety product information on labels for all Canadians in accordance with the requirements of the *Official Languages Act*. Section 26 of the *Official Languages Act* requires that where labelling requirements relate to the health, safety or security of members of the public, the required information should appear in both official languages.

The current feed regulatory framework does not offer as broad or flexible a range of compliance and enforcement approaches as some of the more up-to-date regulatory frameworks the CFIA administers. The level of oversight should correspond to the level of risk associated with the product or process and the degree of control demonstrated by the regulated party. The approach proposed in the Regulations would be flexible enough to encompass a range of compliance verification activities. Furthermore, response to non-compliance must be predictable, transparent, graduated and based on risk. The proposed Regulations would enable the implementation of this approach.

The CFIA re-examined and further consulted on the proposed Regulations in the context of the COVID-19 pandemic and the economic recovery. Stakeholders indicated that they did not have any concerns specific to the projected costs for this regulatory proposal.

► View comments for the Regulatory analysis section 8 comment(s)

# Implementation, compliance and enforcement, and service standards

## **Implementation**

The proposed Regulations will come into force on the day on which they are registered in the *Canada Gazette*, Part II. However, to provide the industry with time to adjust to the proposed Regulations, the CFIA is proposing a delayed coming into force for some provisions and transitional provisions for others.

## Coming into force

There would be a delay for the coming into force of certain regulatory requirements, including

- 18 months for licence requirements, non-compliant feed being imported and export certificate or documentation; and
- one year for the species to which the proposed Regulations apply, preventive control
  and preventive control plan requirements, recall procedures, complaints, traceability,
  and some import-related requirements.

### Transitional provisions

To provide time for industry to transition to the new regulatory requirements, a feed may continue to be labelled in accordance with the former Regulations or meet the standards in the former Regulations for a period of one year after the proposed Regulations come into force. In addition, applications for registration or exemption received before the proposed Regulations come into force would be dealt with in accordance with the former Regulations, and any registration issued under the former Regulations would continue to be valid. There are also provisions related to notification of release and retention of documents that continue to follow the former Regulations for feeds that have already been manufactured.

Alternatively, industry would have the option to follow some of the new regulatory requirements as soon as they come into force. However, using a combination of new and old requirements on the same product label would be prohibited.

The CFIA recognizes that guidance material would assist in the successful implementation of the proposed Regulations. Guidance documents should facilitate compliance with the Regulations. The CFIA is developing a new suite of regulatory guidance documents that would improve the format, content and accessibility of its guidance material. Some of the documents will be available to industry and the inspectorate when the proposed Regulations are prepublished in the *Canada Gazette* and the rest will be available by the

coming-into-force date. These documents will update or replace existing manuals to help industry to comply with the *Feeds Act* and the *Feeds Regulations*, 2022.

The CFIA will also provide model systems as tools to promote compliance. Model systems provide examples that when properly applied have been demonstrated to achieve compliance with regulatory requirements. These would initially be drawn from existing guidance and systems recognized by the CFIA, but in time could include other validated generic models or programs.

Implementation of the proposed Regulations would also be supported by the Agency's online Digital Service Delivery Platform to apply for permissions (such as registrations and licences) and other services (e.g. export certificates) electronically.

In addition to the proposed regulatory amendments, the CFIA has initiated a project to consider the equivalency of feed ingredient assessment and approval systems employed in other jurisdictions (in the United States and the European Union to start). If a determination of equivalency is achieved for a foreign jurisdiction, regulated parties seeking Canadian approval for new or modified ingredients that have already been approved in that jurisdiction could submit a less detailed application for assessment by the CFIA. The CFIA will consult separately with industry and other stakeholders on this once the development of a proposed approach is completed.

# Compliance and enforcement

The CFIA would continue to enforce the regulatory requirements of livestock feeds and would implement a redesigned feed regulatory compliance program to take into account the principles of the Integrated Agency Inspection Model, new regulatory requirements, standards, and other considerations (e.g. licensing requirements that follow the process and system tools of the *Safe Food for Canadians Regulations*). The CFIA is collaborating with academia and industry representatives to construct and implement an establishment-based risk assessment model for feed establishments that would better identify the relative risks of different establishments and the inspection frequencies to be applied. Consequently, an updated training program for CFIA inspection staff would be designed, developed and delivered to support the implementation of the regulatory amendments. The CFIA would implement the redesigned program and would continue to enforce feed regulatory requirements by way of pre-market, marketplace and post-market inspection activities aligned with the updated regulatory framework and product, process and establishment

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risks.

The proposed amendments would operate under existing complaint and appeal mechanisms. The CFIA uses an incremental process to manage complaints and appeals, which ranges from discussions with CFIA employees to the submission of a formal complaint to the CFIA Complaints and Appeals Office.

The CFIA uses a range of tools to verify compliance, including inspections, surveillance, sampling, and testing. When non-compliance is determined, the CFIA takes enforcement action commensurate with the seriousness of the non-compliance. Under the proposed Regulations, the Minister may suspend or cancel a licence. For example, a licence could be suspended, upon notice, if there is a risk of harm to animal or human health or the environment that may result if the licence holder continues to conduct an activity that is identified in the licence. This enforcement tool would be in addition to other compliance and enforcement tools and measures available to inspectors, including penalties such as the issuance of an administrative monetary penalty under the *Agriculture and Agri-Food Administrative Monetary Penalties Act*.

#### Service standards

With respect to service standards for the review of applications for feed ingredient approvals and product registration, the CFIA has been reporting on performance for efficacy, livestock, human and environmental safety reviews on an annual basis. There are several initiatives tied to regulatory modernization (e.g. reducing the number of feed types requiring mandatory registration) and other non-regulatory initiatives (e.g. the equivalency of feed ingredient assessment and approval systems employed in other jurisdictions discussed above, the creation of a Digital Service Delivery Platform), and these initiatives are expected to have a positive impact on performance of the current service standard. In addition, reporting on a different set of service standards is being contemplated by the CFIA going forward. If changes are made to the standards, the CFIA will consult stakeholders and implement the changes as a separate exercise from regulatory modernization.

► View comments for the Implementation, compliance and enforcement, and service standards section 7 comment(s)

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## PROPOSED REGULATORY TEXT

Notice is given that the Administrator in Council proposes to make the annexed *Feeds Regulations*, 2022 pursuant to

- (a) section 5  $\frac{a}{}$  of the Feeds Act  $\frac{b}{}$ ;
- **(b)** subsection  $64(1)^{c}$  of the *Health of Animals Act*  $\frac{d}{d}$ , and
- (c) subsection 30(1)  $\stackrel{e}{=}$  of the Food and Drugs Act  $\stackrel{f}{=}$ .

Interested persons may make representations concerning the proposed Regulations within 90 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Laura Scott, National Manager, Feed Program Coordination and Outreach Section, Canadian Food Inspection Agency, 59 Camelot Drive, Ottawa, Ontario K1A 0Y9 (tel.: 613-773-7527; email: <a href="mailto:laura.scott@canada.ca">laura.scott@canada.ca</a>).

Ottawa, May 27, 2021

Julie Adair

Assistant Clerk of the Privy Council

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# Feeds Regulations, 2022

# Interpretation

#### **Definitions**

**1 (1)** The following definitions apply in these Regulations.

#### Act

means the Feeds Act. (Loi)

## Agency

means the Canadian Food Inspection Agency established by section 3 of the *Canadian Food Inspection Agency Act.* (*Agence*)

#### cattle

means animals of the species Bos taurus or Bos indicus. (bœuf)

#### caution statement

means a statement concerning animal health hazards or safe product handling or storage. (précaution)

## complete feed

means a mixed feed that, when used for the type of livestock and for the purposes stated on the label, provides all of the nutrients necessary for the maintenance of life or for promoting production, except water and, in the case of ruminants and horses, roughage. (aliment complet)

#### contaminant

means any micro-organism, chemical substance, extraneous material or other substance that may present a risk of harm to human or animal health or the environment, including any substance that is not permitted under these Regulations or that does not comply with any limits or levels provided under these Regulations. (*contaminant*)

# custom medicated feed

means a medicated feed that is manufactured in accordance with a veterinary prescription and contains a medicating ingredient that

- (a) is not set out in the *Compendium of Medicating Ingredient Brochures* for the species of livestock for which the feed is intended; or
- **(b)** is of a brand, level or compatibility that differs from that set out in the *Compendium* of *Medicating Ingredient Brochures* in respect of that particular ingredient, for the species of livestock for which the feed is intended. (*aliment médicamenté sur mesure*)

#### customer formula feed

means a mixed feed that is manufactured by a feed manufacturer

- (a) for feeding their livestock; or
- (b) in accordance with a written order that is signed by a purchaser if
  - (i) the order states the name of each single ingredient feed, medicating ingredient set out in the *Compendium of Medicating Ingredient Brochures* or type of product set out in the *Compendium of Non-Feed Product Brochures*, and their respective amounts, to be used in the manufacture of that feed or to be added to other mixed feeds that conform to the standards prescribed in these Regulations,
  - (ii) the feed does not contain a *pest control product* as defined in subsection 2(1) of the *Pest Control Products Act*, and
  - (iii) the feed is not intended for resale. (aliment préparé selon la formule du client)

## disposed of in a safe manner

means disposed of, other than by human or animal consumption, in a manner that does not present a risk of harm to human or animal health or the environment. (*disposition* sécuritaire)

## flavouring agent

means a mixed feed that is composed predominantly of flavour ingredients listed in the *Canadian Feed Ingredients Table* and that is added to a feed to enhance its flavour. (*agent de saveur*)

# holder of the approval

means a person who has been provided with a written notice under subsection 9(1) confirming that approval of a feed that is manufactured by or for a government, academic or private research establishment for research or experimental purposes has been given. (titulaire de l'approbation)

# identification code

means any combination of letters or figures or letters and figures by which a lot of feed can be traced during manufacture and distribution. (code d'identification)

## medicated feed

means a mixed feed that contains a medicating ingredient. (aliment médicamenté)

# medicating ingredient

means a drug for which a drug identification number is assigned under subsection C.01.014.2(1) of the *Food and Drug Regulations* or for which a letter of authorization for use in emergency treatment has been issued to a veterinarian under subsection C.08.010(1) of

those Regulations and that is intended

- (a) for use in the prevention or treatment of disease in livestock; or
- **(b)** to affect the structure or any function of the body of the livestock. (*substance médicatrice*)

## mineral feed

means a mixed feed that is composed predominantly of mineral elements or inorganic nutrients. (aliment minéral)

## mixed feed

means a feed that contains at least two single ingredient feeds. (aliment mélangé)

## novel feed

means a feed that is an organism, a part of an organism or a product of an organism, or that consists of parts or products of an organism, and that

- (a) is not listed in the Canadian Feed Ingredients Table; or
- **(b)** has a novel trait. (aliment nouveau)

#### novel trait,

in respect of a feed that is an organism, a part of an organism or a product of an organism, or that consists of parts or products of an organism, means a characteristic of the feed that

- (a) has been intentionally selected, created or introduced into the feed through a specific genetic change; and
- **(b)** based on valid scientific rationale, is not substantially equivalent, in terms of its specific use and safety for human or animal health or the environment, to any characteristic of a similar feed that is listed in the *Canadian Feed Ingredients Table*. (*caractère nouveau*)

## percentage

or **%**, with respect to any product, means the percentage by mass of the product. (pourcentage or **%**)

# poultry

means chickens, turkeys, ducks and geese. (volaille)

# premix

means a mixed feed that provides micro-ingredients, including vitamins or minerals, and that is intended to be further diluted and mixed with other ingredients to produce a supplement or complete feed. (*prémélange*)

#### **President**

means the President of the Agency. (président)

## principal display panel

means the part of the label applied to all or part of any side or surface of a feed that is displayed or visible under normal or customary conditions of sale or use. (espace principal)

## processing

includes the use of a feed for the purpose of manufacturing another feed or the mixing of a feed with another feed. (*transformation*)

## registrant

means a person who has been issued a registration certificate under section 11. (*titulaire de l'enregistrement*)

#### ruminant

means an animal of the suborder *Ruminatiae* and includes an animal of the family *Camelidae*. (*ruminant*)

## single ingredient feed

means any substance or mixture of substances that has been approved for feeding to livestock and that is listed in the *Canadian Feed Ingredients Table*. (aliment à ingrédient unique)

# specialty feed

means a mixed feed that does not provide any nutritional value and that is used to improve or facilitate

- (a) the preservation of any feed with which it is mixed prior to feeding or during storage;
- (b) the qualities, flowability or pelleting of any feed with which it is mixed;
- (c) ingredient dispersion or distribution in any feed with which it is mixed;
- (d) ingestion, acceptability or digestion by livestock of any feed with which it is mixed;
- (e) the quality or availability of nutrients in any feed with which it is mixed; or
- **(f)** the absorption of nutrients by livestock of any feed that is fed to it. (*aliment spécialisé*)

# supplement

means a mixed feed that provides a significant source of nutrients in order to improve the nutritional value of the total diet and that is intended to be

- (a) fed undiluted in addition to other feeds;
- (b) offered on a free-choice basis with other feeds that are available separately; or

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(c) further diluted and mixed to produce the total diet. (supplément)

#### total diet

means the ration consisting of all feeds, including roughage, that are offered daily to livestock. (ration totale)

#### trace mineral salt feed

means a mineral feed that is composed of salt (NaCl) and trace minerals. (complément d'oligo-éléments et de sel)

# veterinary prescription

means an order prescribing a medicated feed issued by a veterinarian licensed to practise in the province in which the feed is to be fed to the livestock to be treated. (*ordonnance*)

## warning statement

means a statement concerning human health hazards. (mise en garde)

#### **Definition of livestock**

- **(2)** For the purposes of the definition *livestock* in section 2 of the Act, the following animals, which are domestically raised or kept, are designated as livestock:
  - (a) cattle, sheep and goats;
  - (b) bison, water buffalo, cervids, llamas and alpacas;
  - (c) swine;
  - **(d)** poultry;
  - (e) ratites, pigeons, pheasants, partridges, quail, grouse, guinea fowl and pea fowl;
  - (f) horses and rabbits;
  - (g) bees;
  - (h) finfish intended for human consumption as food; and
  - (i) molluscs and crustaceans intended for human consumption as food.
  - ► View comments for the Interpretation section Ocomment(s)

# **Incorporation by Reference**

# **Documents incorporated by reference**

- **2 (1)** The following documents, prepared by the Agency and published on its website, and as amended from time to time, are incorporated by reference into these Regulations:
  - (a) Canadian Feed Ingredients Table;
  - **(b)** Compendium of Medicating Ingredient Brochures;
  - (c) Compendium of Non-Feed Product Brochures;
  - (d) Tables of Nutrient Guarantees and Conditions for Feed Labels;
  - **(e)** Tables of Permissible Claims for Feed Labels;
  - (f) List of Weed Seeds and Maximum Levels for Feeds;
  - **(g)** Tables of Maximum Nutrient Values for Feeds;
  - (h) Tables of Maximum Contaminant Levels for Feeds; and
  - (i) List of Prescribed Deleterious Substances.

#### **Inconsistency**

**(2)** In the event of an inconsistency between a provision of these Regulations and any document incorporated by reference into these Regulations, that provision prevails to the extent of the inconsistency.

# **Words and expressions**

- (3) For the purposes of interpreting any document prepared by the Agency that is incorporated by reference into these Regulations, words and expressions that are used but not defined in that document have the same meaning as in these Regulations.
  - ► View comments for the Incorporation by Reference section 0 comment(s)

# **Exemptions**

# **Exemption from Act and Regulations**

- **3 (1)** The following feeds are exempt from the application of the Act and these Regulations:
  - (a) a feed that contains a new drug the sale of which is permitted by section C.08.005 of the *Food and Drug Regulations* for the purpose of clinical testing or by section C.08.013 of those Regulations for the purpose of conducting experimental studies;
  - **(b)** a feed, other than a novel feed, if

- (i) it is grown on a farm, it is sold by the grower and
- (ii) it does not contain any substance that presents a risk of harm to human or animal health or the environment, including any deleterious substance listed in the *List of Prescribed Deleterious Substances*;
- **(c)** a complete feed, other than a novel feed, that is packaged in containers having a net mass of not more than 10 kg and that is intended for feeding to livestock, other than livestock intended for human consumption as food;
- (d) a feed, other than a novel feed, that is in the form of samples having a net mass of not more than 1 kg and that is,
  - (i) intended for the purpose of marketing promotion at exhibits, conferences or trade shows, if the samples are labelled "Not for Sale / Non destiné à la vente" and are disposed of in a safe manner or are exported, or
  - (ii) intended for the purpose of testing at a laboratory in Canada, if the samples are labelled as such and are disposed of in a safe manner or are exported;
- **(e)** a feed, other than a novel feed, that is imported with imported livestock, if that feed is consumed only by that livestock while the livestock is temporarily in Canada and any remaining feed accompanies the livestock when the livestock is subsequently exported or is disposed of in a safe manner;
- **(f)** a feed, other than a novel feed, that is imported and that is intended only for consumption by imported livestock while the livestock is temporarily in Canada, but does not accompany that livestock when the livestock is imported, if
  - (i) the importer has provided to the Minister, before the feed is imported, the following information in respect of each feed:
    - (A) its name,
    - (B) a list of its ingredients,
    - (C) the address where it will be sent,
    - (D) the species and number of livestock for which it is intended,
    - (E) the quantity required to be sent to the imported livestock,
    - **(F)** the date on which it is to be imported and its port of entry into Canada,

- **(G)** the date on which the livestock for which it is intended is to be imported and the livestock's port of entry into Canada, and
- **(H)** the date on which any remaining feed is to be exported and its port of exit from Canada or the date on which it is to be disposed of in a safe manner,
- (ii) any remaining feed is exported or disposed of in a safe manner, and
- (iii) the Minister confirms in a written notice provided to the importer that the information and documents have been received and that the feed is exempt from the Act and these Regulations; and
- **(g)** a feed, other than a novel feed, that is manufactured in Canada by or for a government, academic or private research establishment for research or experimental purposes if
  - (i) it is fed to livestock owned by or under the direct supervision of the establishment, and
  - (ii) the establishment has and implements a plan in writing that provides that any remaining feed and livestock products produced from the feed must be disposed of in a safe manner.

# Feed not exempted under paragraph (1)(g)

- (2) In the case of a feed that is manufactured by or for a government, academic or private research establishment for research or experimental purposes, that is not otherwise exempted under paragraph (1)(g) and that is intended to be fed to livestock owned by or under the direct supervision of the establishment, the following requirements do not apply:
  - (a) in respect of the feed,
    - (i) the registration requirement set out in subsection 6(1),
    - (ii) the requirement to conform to the standards set out in sections 35 to 40, and
    - (iii) the packaging and labelling requirements set out in sections 43 to 55;
  - **(b)** in respect of a person who manufactures, stores, processes, packages, labels or sells the feed that is to be exported or to be sent or conveyed from one province to another, the requirement to hold a licence under subsection 18(2); and
  - (c) in respect of a person who manufactures, stores, packages, labels or sells the feed,

the requirements respecting preventive controls set out in sections 56 to 61.

## **Certain products or substances**

- (3) Any medicating ingredient, any pest control product registered under the *Pest Control Products Act* and any type of product set out in the *Compendium of Non-Feed Product Brochures* for which there is an approved brand are exempt from the application of the definition *feed* in section 2 of the Act.
  - ► View comments for the Exemptions section 0 comment(s)

## **Deleterious Substances**

#### **Prescribed substances**

- **4** For the purposes of subsection 3(2) of the Act, the substances listed in the *List of Prescribed Deleterious Substances* are prescribed as deleterious substances.
  - ► View comments for the Deleterious Substances section 0 comment(s)

# **Approval and Registration of Feeds**

# Feeds to Be Approved or Registered

# Feeds that must be approved

- **5 (1)** For the purposes of paragraph 3(1)(a) of the Act, the following feeds must be approved:
  - (a) any feed that has a novel trait;
  - **(b)** any feed, other than a mixed feed, that is not listed in the *Canadian Feed Ingredients Table*;
  - **(c)** any single ingredient feed that is listed in the *Canadian Feed Ingredients Table* and whose description differs from that set out for that feed in that Table, including with respect to
    - (i) its purpose,
    - (ii) its composition, including any hazard inherent in the feed, its structure, its nutritional quality or its physiological effects,

- (iii) the process by which it is manufactured, and
- (iv) the species or class of livestock for which it is intended and the usage rate; and
- **(d)** any feed that is manufactured by or for a government, academic or private research establishment for research or experimental purposes, other than a feed that is exempted under paragraph 3(1)(g).

## **Exemption from approval**

(2) Any feed that is not referred to in subsection (1) is exempt from approval.

## Feeds that must be registered

**6 (1)** For the purposes of paragraph 3(1)(a) of the Act and subject to subsections (2) and (3), all feeds must be registered.

## **Exemption from registration**

- **(2)** The following feeds are exempt from registration:
  - (a) any mixed feed, other than a specialty feed or custom medicated feed, that is manufactured in Canada and that is not
    - (i) designed to be administered in water,
    - (ii) intended for use as a flavouring agent,
    - (iii) a mineral feed or a trace mineral salt feed that contains one or more medicating ingredients, or
    - (iv) a feed that contains a *pest control product* as defined in subsection 2(1) of the *Pest Control Products Act*;
  - **(b)** any mixed feed, other than a specialty feed or custom medicated feed, that is imported for sale and for which a licence has been issued under subsection 5.2(1) of the Act, and that is not referred to in any of subparagraphs (a)(i) to (iv);
  - **(c)** any specialty feed that is listed in column 1 of Table 3 of the *Tables of Permissible Claims for Feed Labels* that meets the conditions set out in columns 3 and 4 of that Table for the approved claim set out in column 2;
  - (d) any custom medicated feed manufactured in Canada if
    - (i) the sale of such feed is authorized under section C.08.012 of the Food and Drug

## Regulations,

- (ii) the amount of feed manufactured does not exceed the amount that would normally be consumed by the number of animals prescribed to receive the feed during the prescribed period of medication,
- (iii) the veterinary prescription under which the feed is manufactured contains information respecting
  - (A) the date on which the prescription is issued,
  - **(B)** the name and address of the person for whom the feed is to be manufactured and of the person by whom it is intended to be used,
  - (C) the name and level of each medicating ingredient in the feed,
  - (D) the type and amount of feed to be manufactured,
  - **(E)** the number, species, production type and age or weight of the livestock for which the feed is intended,
  - **(F)** any special manufacturing instructions, including any necessary facility cleanup warnings,
  - **(G)** directions for use of the feed, including feeding instructions and the period of medication during which it is to be fed to the livestock, and
  - (H) caution statements and warning statements, if applicable, and
- (iv) a copy of the veterinary prescription is in the possession of the manufacturer of the feed prior to the delivery of the feed; and
- (e) any feed that is listed in Part 1 of the Canadian Feed Ingredients Table.

#### **Conditions**

- (3) The exemption of the feeds referred to in subsection (2) applies only if
  - (a) the guarantees shown on the label are set out in the *Tables of Nutrient Guarantees* and *Conditions for Feed Labels*;
  - **(b)** the claims shown on the label are set out in the *Tables of Permissible Claims for Feed Labels*; and
  - (c) any information shown on the label of the feed does not appear in a language other

than English or French.

## **Application and Requirements**

## **Application for approval or registration**

**7 (1)** An application for approval or registration of a feed must be made to the Minister in a form approved by the President.

## **Elements required**

- (2) Subject to subsection (4), any application referred to in subsection (1) must be accompanied by
  - (a) three copies of a proposed label to be used with the feed if the application is submitted by mail, or one copy of such label if the application is submitted electronically;
  - (b) a sample of the feed;
  - **(c)** the name of the feed that complies with sections 50 and 51, as well as any other name or registration or reference number used to identify the feed;
  - **(d)** a description of the feed, including a list of ingredients and the purpose for which it is intended;
  - (e) directions for use of the feed;
  - (f) the name and address of each location where the feed is manufactured;
  - (g) specifications, concerning, among other things,
    - (i) the usefulness, purity and quality of the feed and the homogeneity of the mix, and
    - (ii) any component, the amount of which must be guaranteed in the feed;
  - **(h)** the identification and description of any contaminant in the feed, as well as the methodology and analysis for the detection of the amounts of those contaminants;
  - (i) reports of any analysis conducted on representative samples drawn from three different and recent lots of the feed, to support any information referred to in paragraphs (g) and (h);
  - (j) a description of the production methods, including details of
    - (i) the formulae used in the manufacture of the feed,

- (ii) the steps of the feed manufacturing process and any variation in the process resulting from the source of any ingredient or additive in the feed or the location where it is manufactured,
- (iii) the type and capacity of the equipment used in the manufacture of the feed, and
- (iv) quality control procedures to assure mix uniformity and to prevent contamination of subsequent lots of feed manufactured in the same place;
- (k) evidence, including the results of any scientific investigation conducted,
  - (i) demonstrating the safety of the feed for the species of livestock for which it is intended, as well as other species of livestock that may be exposed to it, and for humans and the environment,
  - (ii) demonstrating the efficacy of the feed when used for its intended purposes and according to its directions for use,
  - (iii) demonstrating the stability of the feed under normal storage conditions,
  - (iv) demonstrating that any guarantee shown on the label, other than those set out in the *Tables of Nutrient Guarantees and Conditions for Feed Labels*, conveys useful information to the purchaser of the feed, and
  - (v) supporting any claim on the label of the feed that is not set out in the *Tables of Permissible Claims for Feed Labels*;
- (I) scientific analysis that shows whether there are significant changes in the chemical, biological or physical composition of livestock products when the feed is used; and
- (m) a summary of all the elements provided in support of the application.

### Additional information — novel trait

- (3) In the case of a feed with a novel trait, an application for approval must be accompanied by the following additional information:
  - (a) the identification and characterization of the novel trait and, if the novel trait is introduced from another species, details of the host and donor organisms and the methods of introduction of the novel trait into the feed, if applicable;
  - **(b)** the identification and characterization of the feed with a novel trait resulting from the introduction of the novel trait, including details relating to expression of the novel

trait and the stability of the introduction of the novel trait into the feed, as well as a comparison of the characteristics of the feed with those of any other feed;

- **(c)** any other information, including the results of any scientific investigation and test data in respect of the novel trait that are relevant in identifying whether the feed presents a risk of harm to human or animal health or the environment, that is in the applicant's possession or to which the applicant ought reasonably to have access; and
- **(d)** the name of any Canadian government agency, of a government of a foreign state or of a subdivision of a foreign state or of an international organization, or association, of states that has been provided with information in respect of the feed with a novel trait and the purpose for which the information was provided.

## Information — research or experimental purposes

- **(4)** In the case of a feed that is manufactured by or for a government, academic or private research establishment for research or experimental purposes, an application for approval referred to in subsection (1) must be accompanied by the following information:
  - (a) the name of the feed;
  - **(b)** a description of the feed, including a list of ingredients and the purpose for which it is intended;
  - **(c)** the species of livestock for which it is intended and the number of livestock required to conduct the research;
  - (d) the quantity of feed required to conduct the research;
  - **(e)** the research protocol, including a statement of the purpose, objectives and duration of the research and a justification of the quantity of feed and number of animals required;
  - **(f)** the name and address of the establishment where the research will take place, including the name and contact information of the person supervising the research;
  - **(g)** if the establishment has a written plan that provides that any remaining feed and livestock products produced from the feed must be disposed of in a safe manner,
    - (i) a description of the precautions and confinement measures to be taken with respect to the feed and livestock products,

- (ii) a monitoring plan to be applied for the duration of the project, and
- (iii) a contingency plan in case of accidental interaction of the feed or livestock products with any other feed or livestock products that are not the subject of the research;
- **(h)** if the establishment does not have a written plan that complies with paragraph (g), the information referred to in paragraphs (2)(g) to (j), subparagraph (2)(k)(i) and paragraph (2)(l);
- (i) if it is an imported feed, the date of its importation and its port of entry; and
- (j) a summary of all the elements provided in support of the application.

## **Scientific investigation**

- (5) If any scientific investigation has been conducted under paragraphs (2)(k) or (3)(c), the applicant must provide the following information:
  - (a) the scientific research methods used;
  - (b) the statistical methods used to analyze the results of the investigation;
  - (c) the conditions under which the investigation was conducted; and
  - **(d)** the quality control and quality assurance measures taken in conducting the research and analysis.

### **Evaluation and Decision of Minister**

# Approval or registration of feed

- **8 (1)** Once an application for approval or registration of a feed under subsection 7(1) is evaluated, the Minister must approve or register the feed if the following requirements are met:
  - **(a)** the elements referred to in subsections 7(2) to (5), as applicable, have been provided to the Minister;
  - **(b)** the applicant has submitted to the Minister a label that complies with the requirements of these Regulations; and
  - (c) the feed is found to be in compliance with the Act and these Regulations.

#### **Evaluation of risk**

**(2)** For the purposes of paragraph (1)(c), the Minister must evaluate the risk of harm presented by the feed to human or animal health or the environment, including whether the feed is toxic or capable of becoming toxic.

#### Toxic feed

- (3) A feed is toxic or capable of becoming toxic if it enters or may enter the environment in a quantity or concentration or under conditions that
  - (a) have or may have a harmful effect on the environment;
  - **(b)** constitute or may constitute a danger to the environment on which human or animal life depends; or
  - (c) constitute or may constitute a danger in Canada to human or animal life or health.

#### **Notice of refusal**

**(4)** If the requirements set out in subsection (1) are not met, the Minister must notify the applicant in writing of the refusal to approve or register the feed and provide the reasons for the refusal.

## Approval — Listing and Cancellation

## **Notice of approval**

**9 (1)** If a feed is approved by the Minister under section 8, a written notice confirming that approval has been given and specifying the purpose for which it is given must be provided to the applicant.

# Listing in Canadian Feed Ingredients Table

- (2) If a feed is approved by the Minister, other than a feed that is manufactured by or for a government, academic or private research establishment for research or experimental purposes,
  - (a) the feed must be listed in the *Canadian Feed Ingredients Table* as a single ingredient feed and accompanied by a description; or
  - **(b)** if the feed is already listed in that Table, it must be accompanied by a new description.

#### **Cancellation**

**10 (1)** Subject to subsections (2) to (5), the Minister may cancel the approval of a feed that is manufactured by or for a government, academic or private research establishment for research or experimental purposes if there are reasonable grounds to believe that, in respect of that feed, there has been a contravention of the Act or these Regulations.

#### **Factors**

- **(2)** In deciding whether to cancel an approval in accordance with subsection (1), the Minister must take into account the following factors:
  - (a) whether cancellation of the approval is necessary in order to respond to a risk of harm to human or animal health or the environment;
  - **(b)** whether cancellation of the approval is unnecessary because corrective action has been taken or is expected to be taken in a timely manner without risk of harm to human or animal health or the environment; and
  - **(c)** whether there have been contraventions of the Act or these Regulations in the past in respect of the feed.

### **Conditions for cancellation**

- (3) The Minister may cancel an approval only if a written notice has been provided to the holder of the approval that
  - (a) sets out the grounds for the cancellation and the period within which corrective action must be taken in order to avoid the cancellation of the approval; and
  - **(b)** specifies that the holder of the approval must, within 30 days after the date of mailing of the notice, notify the Minister in writing that they wish to have an opportunity to be heard respecting the proposed cancellation.

# **Notice of hearing**

**(4)** Within 30 days after the day on which the Minister receives the notice that the holder of the approval wishes to have an opportunity to be heard, the Minister must notify the holder of the approval in writing of the time and place of the hearing to determine whether the approval is to be cancelled.

#### **Grounds for cancellation**

(5) The Minister must not cancel the approval unless

- (a) the holder of the approval has been provided with an opportunity to be heard in respect of the proposed cancellation; and
- **(b)** the holder of the approval has failed to take corrective action in respect of the feed within the period set out by the Minister in the notice provided under paragraph (3)(a) or within any longer period that is granted by the Minister at the hearing.

#### **Notice of cancellation**

**(6)** The Minister must notify the holder of the approval in writing of the cancellation of the approval and the date on which it takes effect.

## **Registration — Number, Certificate and Cancellation**

## **Assignment and issuance**

**11** If a feed is registered by the Minister under section 8, a registration number must be assigned to that feed and a registration certificate must be issued to the applicant.

## **Use of registration number**

**12 (1)** It is prohibited for any person to use a registration number assigned to a feed unless they are the registrant of the feed.

## False registration number

(2) It is prohibited for any person to use a false registration number in respect of any feed.

# **Expiration of registration**

**13** Every registration expires on the date indicated on the registration certificate.

#### Surrender of certificate

**14** A registrant may surrender a registration certificate by submitting a written notice to the Minister; the registration becomes invalid as of the day on which the notice is received by the Minister.

## **Cancellation of registration**

**15 (1)** Subject to subsections (2) to (5), the Minister may cancel a registration in respect of a feed if there are reasonable grounds to believe that, in respect of that feed, there has been a contravention of the Act or these Regulations.

#### **Factors**

- **(2)** In deciding whether to cancel a registration in accordance with subsection (1), the Minister must take into account the following factors:
  - (a) whether cancellation of the registration is necessary in order to respond to a risk of harm to human or animal health or the environment;
  - **(b)** whether cancellation of the registration is unnecessary because corrective action has been taken or is expected to be taken in a timely manner without risk of harm to human or animal health or the environment; and
  - **(c)** whether there have been contraventions of the Act or these Regulations in the past in respect of the feed.

#### **Conditions for cancellation**

- (3) The Minister may cancel a registration only if a written notice has been provided to the registrant that
  - (a) sets out the grounds for the cancellation and the period within which corrective action must be taken in order to avoid the cancellation of the registration; and
  - **(b)** specifies that the registrant must, within 30 days after the date of mailing of the notice, notify the Minister in writing that the registrant wishes to have an opportunity to be heard respecting the proposed cancellation.

# **Notice of hearing**

**(4)** Within 30 days after the day on which the Minister receives the notice that the registrant wishes to have an opportunity to be heard, the Minister must notify the registrant in writing of the time and place of the hearing to determine whether the registration is to be cancelled.

#### **Grounds for cancellation**

- (5) The Minister must not cancel the registration unless
  - (a) the registrant has been provided with an opportunity to be heard in respect of the proposed cancellation; and
  - **(b)** the registrant has failed to take corrective action in respect of the feed within the period set out by the Minister in the notice provided under paragraph (3)(a) or within

any longer period that is granted by the Minister at the hearing.

#### **Notice of cancellation**

**(6)** The Minister must notify the registrant in writing of the cancellation of the registration and the date on which it takes effect; the registration certificate becomes invalid as of that day.

#### **Renewal or Amendment**

## Application for renewal or amendment of registration

**16 (1)** Any application to renew or amend an approval or a registration must be made to the Minister in the same manner as an application for approval or for registration referred to in section 7 and is considered to be an application for approval or for registration for the purposes of these Regulations.

## No change in respect of a feed

**(2)** The holder of the approval or a registrant must not make a change in respect of an approved or registered feed unless the approval or registration of the feed has been amended by the Minister on application made in accordance with subsection (1).

#### **New Information**

#### **Provision to Minister**

**17 (1)** If, after approval or registration of a feed, a person becomes aware of any new information that the feed may present a risk of harm to human or animal health or the environment, the person must immediately provide the new information to the Minister.

#### **Evaluation and decision**

- (2) If, on the basis of the new information, the Minister determines, in re-evaluating the feed,
  - (a) that it does not present a new risk of harm to human or animal health or the environment, the Minister must maintain the approval or registration of the feed; or
  - **(b)** that it does present a risk of harm to human or animal health or the environment, the Minister must
    - (i) in the case of a feed that has been approved, other than a feed that is

manufactured by or for a government, academic or private research establishment for research or experimental purposes, amend the description of the feed in the *Canadian Feed Ingredients Table* to respond to the risk, or remove the feed from that Table and no longer consider it to be approved under subsection 8(1),

- (ii) in the case of a feed that has been approved for research or experimental purposes by or for a government, academic or private research establishment, cancel the approval in accordance with section 10, or
- (iii) in the case of a feed that has been registered, cancel the registration in accordance with section 15.

### **Notice of amendment**

- (3) The Minister must give public notice of the Minister's determination under subparagraph (2)(b)(i) to amend the description of the feed in the *Canadian Feed Ingredients Table* or remove the feed from that Table and the date on which the amendment or removal takes effect.
  - ► View comments for the Approval and Registration of Feeds section 0 comment(s)

## **Licences**

#### **Prescribed Feeds and Activities**

## Section 3.1 of the Act — import for sale

**18 (1)** For the purposes of section 3.1 of the Act, a prescribed feed that has been imported for sale is any feed other than a feed registered under section 8, and the prescribed activities that a person is prohibited from conducting in respect of that prescribed feed, unless the person is authorized to conduct that activity by a licence, are storing, processing, packaging, labelling and delivering.

## Section 3.1 of the Act — export and interprovincial trade

(2) For the purposes of section 3.1 of the Act, a prescribed feed that is to be exported or to be sent or conveyed from one province to another is any feed other than a feed registered under section 8 or manufactured by a livestock producer and intended for feeding their livestock, and the prescribed activities that a person is prohibited from conducting in respect of that prescribed feed, unless the person is authorized to conduct that activity by a

licence, are manufacturing, storing, processing, packaging, labelling and selling.

## **Exception**

- **(3)** A licence is not required to conduct any prescribed activity referred to in subsection (2) if it is being conducted at
  - (a) a rendering plant operating under a permit issued under section 160 of the *Health of Animals Regulations*; or
  - (b) a grain elevator.

## **Definition of** *grain elevator*

- (4) For the purposes of paragraph (3)(b), a grain elevator means any premises
  - (a) constructed for the purpose of handling and storing grain received directly from producers, otherwise than as a part of the farming operation of a particular producer, and into which grain may be received, at which grain may be weighed, elevated and stored and out of which grain may be discharged; or
  - **(b)** constructed for the purpose of handling and storing grain as part of the operation of a flour mill, feed mill, seed cleaning plant, malt house, distillery, grain oil extraction plant or other grain processing plant, and into which grain may be received, at which grain may be weighed, elevated and stored and out of which grain may be discharged for processing or otherwise.

## Issuance, Renewal and Amendment

# Subsection 5.2(1) of the Act — import for sale

**19 (1)** For the purposes of the issuing of a licence under subsection 5.2(1) of the Act, a prescribed feed that has been imported for sale is any feed, and the prescribed activities in respect of that prescribed feed are storing, processing, packaging, labelling and delivering.

# Subsection 5.2(1) of the Act — export and interprovincial trade

**(2)** For the purposes of the issuing of a licence under subsection 5.2(1) of the Act, a prescribed feed that is to be exported or to be sent or conveyed from one province to another is any feed, and the prescribed activities in respect of that prescribed feed are manufacturing, storing, processing, packaging, labelling and selling.

## **Application**

**20** An application for the issuance, renewal or amendment of a licence must be made to the Minister in a form approved by the President.

#### **Conditions**

- 21 The Minister may issue, renew or amend a licence if
  - (a) the information submitted in the application is complete, truthful and not misleading; and
  - **(b)** the conduct of the activity in respect of which the application is made does not present a risk of harm to human or animal health or the environment.

#### Refusal

- **22** The Minister may refuse to issue, renew or amend a licence if, in the five years before the day on which the application is made, the applicant
  - (a) has had a licence suspended or cancelled; or
  - **(b)** has been convicted of an offence committed under the Act or under any of the provisions of Parts I.1 and XIV of the *Health of Animals Regulations*.

### **Notice of refusal**

**23** If the Minister refuses to issue, renew or amend a licence, the Minister must provide a written notice to the applicant and provide the reasons for the refusal.

#### Place of business

**24** A licence holder must conduct the activities identified in their licence, other than delivery or sale, in a place of business identified in their licence for the activities.

# Amendment — inability to conduct activity

**25 (1)** If a licence holder is unable to conduct an activity identified in their licence in a place of business identified in the licence, the Minister may amend the licence to remove the authorization to conduct that activity in that place of business.

#### **Notice of amendment**

**(2)** The Minister must notify the licence holder in writing of any amendment to the licence and the date on which it takes effect.

# **Expiry, Surrender, Suspension and Cancellation**

## **Expiry**

**26 (1)** A licence expires two years after the date of issuance or renewal that is specified in the licence unless the licence has been surrendered or cancelled before that date.

## **Expiry** — amendment

(2) If the Minister amends a licence, its expiry date remains unchanged.

#### Surrender

**27** A licence holder may surrender their licence to the Minister and that licence becomes invalid on surrender, if it is not subject to a cancellation procedure.

## **Grounds for suspension**

- 28 The Minister may suspend a licence if
  - (a) the licence holder does not comply with any provision of the Act, other than subsection 8(2), with any provision of these Regulations or with any of the provisions of Parts I.1 and XIV of the *Health of Animals Regulations*; or
  - **(b)** a risk of harm to human or animal health or the environment may result if the licence holder continues to conduct an activity that is identified in the licence.

# **Conditions for suspension**

- 29 (1) The Minister must not suspend a licence unless the licence holder
  - (a) has been provided with a written report that sets out the grounds for the suspension and the period within which corrective action must be taken in order to avoid the suspension; and
  - **(b)** has failed to take corrective action within that period.

# **Notice of suspension**

**(2)** The Minister must notify the licence holder in writing of the suspension and the date on which it takes effect.

# Suspension — risk of harm

**30 (1)** Despite section 29, if there is a risk of harm to human or animal health or the environment that may result if the licence holder continues to conduct an activity that is identified in the licence, the Minister may suspend the licence immediately after the licence

holder is provided with a written report that sets out the grounds for the suspension.

## **Notice of suspension**

(2) The Minister must notify the licence holder in writing that their licence is suspended and that the suspension takes effect immediately.

## **Duration of suspension**

**31** The suspension of a licence must be lifted if the Minister determines that corrective action has been taken.

#### **Grounds for cancellation**

- 32 The Minister may cancel a licence if
  - (a) the licence holder fails to take corrective action within 90 days after the day on which the licence is suspended, unless a longer period is granted by the Minister at the written request of the licence holder;
  - **(b)** the licence holder continues to conduct an activity that is identified in their licence while the licence is suspended;
  - **(c)** the licence holder does not comply with any provision of the Act, other than subsection 8(2), with any provision of these Regulations or with any of the provisions of Parts I.1 and XIV of the *Health of Animals Regulations* and, since its issuance or renewal, the licence
    - (i) has already been suspended for non-compliance with that provision, or
    - (ii) has already been suspended twice;
  - **(d)** the licence holder was not in compliance with subsection 8(2) of the Act in respect of their application for the issuance, renewal or amendment of the licence or at any time during the period of validity of the licence; or
  - **(e)** the licence holder ceases or is unable to conduct all of the activities that are identified in their licence in any place of business that is identified in that licence.

#### **Conditions for cancellation**

**33 (1)** The Minister must not cancel a licence unless the licence holder has been notified in writing of the grounds for cancellation and has been provided with an opportunity to be heard in respect of the cancellation.

#### **Notice of cancellation**

- **(2)** The Minister must notify the licence holder in writing of the cancellation and the date on which it takes effect.
  - ► View comments for the Licences section 0 comment(s)

### **Standards**

#### **General Provisions**

#### No risk of harm

**34 (1)** A feed must not present a risk of harm to human or animal health or the environment.

## Mixing of feed presenting a risk

(2) It is prohibited for a person to mix a feed that presents a risk of harm to human or animal health or the environment with another feed for the purpose of bringing the feed into compliance with the requirements of the Act and these Regulations.

## **Exception**

- (3) Subsection (2) does not apply if
  - (a) the person referred to in subsection (2) makes a written request for authorization to mix the feed to the Minister;
  - **(b)** the request is accompanied by information respecting the risk and the measures that will be taken to respond to the risk;
  - **(c)** the Minister determines, on the basis of the information provided, that the mix does not present a risk of harm to human or animal health or the environment; and
  - (d) the Minister provides to the person a written authorization to mix the feed.

#### **Prohibited content**

- 35 A feed must not contain or present, as the case may be,
  - (a) seeds of weeds at a level
    - (i) that would individually or cumulatively exceed the maximum percentage set out

in column 2 of the *List of Weed Seeds and Maximum Levels for Feeds* for the species of weed referred to in column 1, or

- (ii) that could present a risk of harm to animal health or the environment;
- **(b)** screenings sold or offered for sale that would individually or cumulatively exceed the maximum percentage of seeds of weeds set out in column 3 of the *List of Weed Seeds* and *Maximum Levels for Feeds* for the species of weed referred to in column 1;
- (c) mould or damage from heat or any other cause that would
  - (i) render it unfit for consumption by livestock, or
  - (ii) cause it to present a risk of harm to human or animal health when fed in proportions commonly used;
- (d) any product of animal origin, including a fish or a bird, that is not fresh or sound or that has not been properly processed in accordance with good manufacturing practices;
- (e) proteins in any form derived in Canada
  - (i) from *specified risk material*, as defined in section 6.1 of the *Health of Animals Regulations*, except in accordance with a permit issued under section 160 of those Regulations for the purposes of section 6.4 of those Regulations, or
  - (ii) from the carcasses of any ruminants, other than cattle, that died or were condemned before they otherwise would have been slaughtered for human consumption as food;
- (f) proteins in any form derived from the carcass of an animal other than
  - (i) a fish, crustacean, mollusc or insect, or
  - (ii) a food animal, as defined in section 1 of the Safe Food for Canadians Regulations, that was slaughtered for human consumption as food or was raised for slaughter for human consumption as food;
- **(g)** any nutrient referred to in the *Tables of Maximum Nutrient Values for Feeds* in an amount exceeding the maximum amount set out in those Tables for the species of livestock for which the nutrient is intended;
- **(h)** a fat that is or may contain a fat derived from a ruminant and containing more than 0.15% insoluble impurities;

- (i) any extraneous substance except in amounts that are unavoidable even if good manufacturing practices are followed;
- (j) bacteria of the genus Salmonella that present a risk of harm to human or animal health;
- **(k)** any contaminant referred to in the *Tables of Maximum Contaminant Levels for Feeds* at a level exceeding the maximum level set out in those Tables for the species or class of livestock for which the feed is intended;
- (I) an ingredient, supplement or premix that was formulated for a different species;
- **(m)** any substance that could, when fed in quantities commonly used or as specified in the directions for use and in consideration of the total diet, result in the production of an article of *food*, as defined in section 2 of the *Food and Drugs Act*, that is prohibited from sale under section 4 of that Act; or
- (n) any substance, other than those referred to in paragraphs (a) to (m), that presents a risk of harm to human or animal health or the environment when fed in quantities commonly used or as specified in the directions for use and in consideration of the total diet.

## Suited for purpose

**36** A feed must be uniformly mixed and have the chemical and physical composition necessary for it to be suited for the purpose for which it is intended.

### **Mixed Feeds**

#### Content

- **37** A mixed feed must contain only
  - (a) single ingredient feeds listed in the *Canadian Feed Ingredients Table* that conform to the description set out in that Table for those single ingredient feeds and that are used for a purpose consistent with the applicable class for those feeds in that Table;
  - **(b)** medicating ingredients set out in the *Compendium of Medicating Ingredient*Brochures for which the brand, claim, level, compatibility with another ingredient, if any, and species of livestock for which they are intended are those set out for those ingredients in that Compendium, unless the feed is a custom medicated feed;

- **(c)** pest control products registered under the *Pest Control Products Act* for the purpose of mixing with the feed; and
- **(d)** product types set out in the *Compendium of Non-Feed Product Brochures* for which the brand, claim, inclusion level and approved species of livestock for which they are intended are those set out for those product types in that Compendium.

#### Premix — content

- **38** A premix must contain only
  - (a) inert single ingredient feeds that facilitate a uniform distribution of microingredients;
  - **(b)** single ingredient feeds, other than those referred to in paragraph (a), that are used in small quantities measured in milligrams or micrograms;
  - (c) medicating ingredients referred to in paragraph 37(b);
  - (d) pest control products referred to in paragraph 37(c); or
  - (e) product types referred to in paragraph 37(d).

#### Mineral feed — content

- **39** A mineral feed
  - (a) must contain at least 40% crude ash; and
  - (b) must not provide significant amounts of nutrients, other than minerals.

# **Chop feed**

- 40 A chop feed must be obtained by grinding, chopping or crushing
  - (a) grains of wheat, rye, barley, oats, corn, buckwheat, flax, field peas, field beans, triticale, milo, canola or soybeans either alone or in combination with one another;
  - (b) Mixed Feed Oats described in the Canadian Feed Ingredients Table; or
  - **(c)** cereals grain screenings grade 1 or 2 or pulse grain screenings grade 1 or 2 described in the *Canadian Feed Ingredients Table*.

# **Single Ingredient Feeds**

## Chopped, crushed or ground grain

**41** Chopped, crushed or ground grain sold as a feed or as an ingredient of a feed must meet, at a minimum, the characteristics set out in Schedule 3 to the *Canada Grain Regulations* for the lowest grade established by those Regulations for that kind of grain.

## Single ingredient feed set out in Table

- **42** A single ingredient feed sold or imported under an approved name set out in the *Canadian Feed Ingredients Table* must conform to the description of that feed set out in that Table.
  - ► View comments for the Standards section 0 comment(s)

# **Packaging**

### **Packaging requirements**

- **43** A package for a feed must
  - (a) be suitable for its intended use and appropriate for the feed;
  - **(b)** protect the feed against moisture, loss, damage, contamination and deterioration during normal handling, storing and conveying;
  - (c) be clean and in a sanitary condition;
  - (d) be of sound construction; and
  - (e) not impart any undesirable substance to the feed.
  - ► View comments for the Packaging section 0 comment(s)

# Labelling

## **General Provisions**

#### **Location of label**

**44 (1)** Any feed that is manufactured, sold or imported must have a label affixed to it or to a package containing it or, if the feed is shipped in bulk, attached to or printed on any document, including the invoice, shipping bill or statement of account delivered with the shipment.

## **Exception**

(2) Subsection (1) does not apply to a customer formula feed if the feed is manufactured by a feed manufacturer for feeding to their livestock.

#### **Content of label**

- **45 (1)** Subject to subsection (4), the label referred to in subsection 44(1) must contain
  - (a) the name of the feed, in compliance with sections 50 and 51;
  - **(b)** the name and address of the person who manufactured the feed, or caused it to be manufactured, or, if any, the registrant;
  - (c) an identification code;
  - (d) the net amount of the feed
    - (i) expressed as the mass or volume in the package or shipment, or
    - (ii) in the case of a package of feed containing feed that is in the form of individual servings, expressed as the number of units in a package and the mass or volume for each unit;
  - **(e)** a statement of the guaranteed analysis made in accordance with subsection 52(1) and, if applicable, subsection 52(2);
  - **(f)** directions for use, including details to permit the safe and effective use of the feed for its intended purpose by users with no specialized knowledge of the purpose and use of the feed, and
    - (i) in the case of a feed whose sodium content is designed to limit or regulate the intake of that feed by beef cattle or sheep, an indication that adequate water must be provided to the animal, and
    - (ii) in the case of a custom medicated feed, the prescribed period of medication, as indicated on the veterinary prescription;
  - **(g)** if the feed is registered, the registration number;
  - **(h)** if the feed contains a product type set out in the *Compendium of Non-Feed Product Brochures*, the following information as set out in that Compendium in respect of each product type present in the feed:
    - (i) the approved brand for, and actual amount of, the product type, immediately after the feed name,

- (ii) the approved claim for the species of livestock for which the feed is intended, when the product type is used at the level indicated in the Compendium for that claim,
- (iii) any warning statement applicable to the product type and, in the case of a feed that contains more than one product type with a warning statement that contains different withdrawal times, the warning statement containing the longest withdrawal time, immediately after the headings "Warning" and "Mise en garde" and clearly separated from other information shown on the label,
- **(iv)** any caution statement applicable to the product type, immediately after the headings "Caution" and "Précaution" and clearly separated from other information shown on the label,
- (v) any directions for use, and
- (vi) any other information that must be added as a note; and
- (i) if the feed contains *prohibited material* as defined in subsection 162(1) of the *Health of Animals Regulations*, the following statement, clearly separated from other information shown on the label:

"Feeding this product to cattle, sheep, deer or other ruminants is illegal and is subject to fines or other punishme;nt under the *Health of Animals Act.* / Il est interdit d'en nourrir les bœufs, moutons, cerfs et autres ruminants et des amendes ou autres peines sont prévues à cet égard par la *Loi sur la santé des animaux*.".

#### **Additional information**

- (2) The label referred to in subsection 44(1) must also contain
  - (a) in the case of a single ingredient feed, any statement, including any caution statement or warning statement, set out for that feed in the *Canadian Feed Ingredients Table*;
  - (b) in the case of a mixed feed,
    - (i) the name of each single ingredient feed used in the feed or, except in the case of a feed that is registered and is labelled with a claim that is not set out in the *Tables of Permissible Claims for Feed Labels*, the following statement:

"A list of the ingredients used in this feed may be obtained from the manufacturer or the registrant. / La liste des ingrédients de cet aliment peut être obtenue du fabricant ou du titulaire de l'enregistrement.", and

- (ii) any caution statement or warning statement set out in the *Canadian Feed Ingredients Table* in respect of each single ingredient feed used in the formulation of that feed;
- **(c)** in the case of a medicated feed, other than a custom medicated feed, the following information as set out in the *Compendium of Medicating Ingredient Brochures* for each medicating ingredient present in the feed:
  - (i) the name and actual amount of the medicating ingredient, immediately after the feed name,
  - (ii) the approved claim for the species of livestock for which the feed is intended, when the medicating ingredient is used at the level indicated in the Compendium for that claim,
  - (iii) any warning statement applicable to the medicating ingredient and, in the case of a feed that contains more than one medicating ingredient with a warning statement that contains different withdrawal times, the warning statement containing the longest withdrawal time, immediately after the headings "Warning" and "Mise en garde" and clearly separated from other information shown on the label,
  - (iv) any caution statement applicable to the medicating ingredient, immediately after the headings "Caution" and "Précaution" and clearly separated from other information shown on the label,
  - (v) any statement on the prudent use of the medicating ingredient, and
  - (vi) any other information that must be added as a note; and
- (d) in the case of a custom medicated feed,
  - (i) the name of the person for whom the feed was manufactured,
  - (ii) the name of the veterinarian who issued the veterinary prescription,
  - (iii) immediately after the feed name, the name and actual amount of each medicating ingredient present in the feed, and

(iv) any applicable caution statement or warning statement indicated on the veterinary prescription in respect of each medicating ingredient present in the feed, immediately after the headings "Warning" and "Mise en garde" or "Caution" and "Précaution", as the case may be, and clearly separated from other information shown on the label.

## Feed manufactured in another country

(3) If a feed that is manufactured in a foreign state bears a label that shows the name and principal place of business of the person in Canada for whom the feed was manufactured for resale, the name and principal place of business of that person must be preceded by the words "imported by" or "importé par" or by the words "imported for" or "importé pour", unless the geographic origin of the product is stated on the label.

#### **Customer formula feed**

- **(4)** In the case of a customer formula feed, the label referred to in subsection 44(1) must contain
  - (a) if the feed does not contain a medicating ingredient,
    - (i) the information referred to in paragraphs (1)(a), (c), (d), (f), (h) and (i) and subparagraph (2)(b)(ii),
    - (ii) the name and address of the person who manufactured the feed,
    - (iii) the name of the supplier of the formula; and
  - (b) if it contains a medicating ingredient,
    - (i) the information referred to in paragraphs (1)(a) to (d), (f), (h) and (i), subparagraph (2)(b)(ii) and paragraph (2)(c), and
    - (ii) the name of the supplier of the formula.

# **Request for list of ingredients**

**46 (1)** If the name of each single ingredient feed used in a mixed feed is not contained on the label under subparagraph 45(2)(b)(i), any person may, within three years after the day on which the mixed feed is manufactured, make a written request to the manufacturer or registrant to obtain the name of each single ingredient feed used in that feed.

#### **Provision of information**

(2) The manufacturer or registrant must provide in writing the information referred to in subsection (1) within three business days of the day on which the request is received.

## Restrictions — information, guarantee or claim

#### 47 A label must not contain

- (a) any information or guarantees which do not fully describe the usefulness of the feed;
- **(b)** any information or mark that would tend to deceive or mislead a purchaser, including any expression, word, figure, depiction or symbol that may reasonably be considered to imply that a feed contains any substance that it does not in fact contain or that it does not contain any substance that it does in fact contain; or
- (c) any claim, unless
  - (i) it is set out in column 2 of the *Tables of Permissible Claims for Feed Labels* and the conditions set out in columns 3 and 4 of those Tables are met for the types of claims set out in column 1 of those Tables, or
  - (ii) it has been evaluated for the purpose of approving or registering the feed and has, based on the evidence provided with the application, been found to be satisfactory.

# Language of label — information required

- **48 (1)** The information required to be shown on the label of a feed must be printed conspicuously, legibly and indelibly in English or French or both languages, except the following information, which must be shown in both English and French:
  - (a) in the case of a medicated feed, other than a custom medicated feed, the information referred to in paragraphs 45(1)(f) and (2)(c); and
  - **(b)** in the case of any other feed for which a caution statement or warning statement is required to be shown on the label, that caution statement or warning statement.

# **Language of label — optional information**

(2) Any optional information printed on the label that is provided to prevent any risk of harm to animal or human health or the environment, including any caution statement or warning statement that is useful to the purchaser of the feed or any information that is included in the preventive control plan under paragraph 60(1)(a), must be printed in both

English and French.

#### Placement of information on label

**49 (1)** Subject to subsection (2), any information required to be shown on a label must appear on the principal display panel.

## **Exception**

**(2)** The directions for use, guaranteed analysis statement and list of ingredients may be provided on an insert that is enclosed in, or attached to, the package, if there is a reference on the principal display panel to where that information is located.

#### Presentation of information on label

**(3)** A label must not contain any variation in the character, size, colour or placement of the printing that obscures or emphasizes any part of the information required to be shown on the label unless such variation is to draw attention to the caution statements or warning statements required to be shown on the label.

## **Naming Feeds**

#### Suitable name

**50** The name of a feed required to be shown on the label of a feed must not tend to deceive or mislead a purchaser.

# Mixed feed for single species or class

**51 (1)** A mixed feed formulated for a single species or class of livestock must have as part of its name the name of the species or class of livestock and the purpose for which the feed is intended.

## Feeds not formulated for species or class

- **(2)** A feed that is not formulated for a single species or class of livestock must have as part of its name
  - (a) its general nutritional or functional classification; and
  - **(b)** the name of each species of livestock for which it is intended, unless the feed is formulated for all species or classes of livestock, in which case it must have as part of its name the word "livestock" or the words "animal de ferme".

#### **Identical names**

**(3)** If the name of a feed is identical to that of another feed of the same manufacturer but is different in terms of its guaranteed level of protein, the brand of the feed must be different from the brand of the other feed or the percentage of protein content must form part of the name of each feed.

#### **Premix**

**(4)** If a feed is a premix, the word "premix" or "prémélange" must form part of the name of the feed.

## **Supplement**

(5) If a feed is a supplement, the word "supplement" or "supplement" must form part of the name of the feed.

#### **Customer formula feed**

**(6)** If a feed is a customer formula feed, the words "customer formula" or "formule du client" must form part of the name of the feed.

## Single ingredient feed

(7) If a feed is a single ingredient feed, the name of the feed must be one of the names approved and set out for that ingredient in the *Canadian Feed Ingredients Table*.

# **Guaranteed Analysis**

## **Mandatory guarantee**

- **52 (1)** The guaranteed analysis statement required to be shown on the label of a feed must include
  - (a) in the case of a single ingredient feed, any guarantee that is set out in the *Canadian Feed Ingredients Table* for that feed; and
  - **(b)** in the case of a mixed feed, the guarantees that are set out in column 2 of Table 1 of the *Tables of Nutrient Guarantees and Conditions for Feed Labels* for that feed.

## **Optional guarantee**

(2) In the case of a mixed feed, the guaranteed analysis statement may also include a guarantee, other than a guarantee referred to in paragraph (1)(b), if the guarantee

- (a) is set out in column 1 of Table 2 of the *Tables of Nutrient Guarantees and Conditions* for *Feed Labels* in accordance with the particulars set out in columns 2 to 4 of that Table for that guarantee; or
- **(b)** has been evaluated for the purpose of registering the feed and has, based on the evidence provided with the application, been found to be satisfactory in that it conveys useful information to the purchaser of the feed.

## **Individual serving**

**53 (1)** In the case of a mixed feed that is in the form of an individual serving, the guaranteed analysis statement referred to in section 52 may include an indication of the amount per individual serving of each guaranteed nutrient.

#### **Moisture content**

**(2)** For the purposes of section 52 and subsection (1), and unless specified on the label, the guaranteed analysis statement must be based on the feed as it is fed to livestock and take into account its maximum moisture content.

## Minimum guaranteed amount

**54 (1)** If the guarantee specifies the minimum amount of a substance in a feed without specifying the maximum amount, the actual amount of the substance in the feed must not exceed the minimum guaranteed amount by more than 10%.

## Maximum guaranteed amount

**(2)** If the guarantee specifies the maximum amount of a substance in a feed without specifying the minimum amount, the actual amount of the substance in the feed must not be less than 90% of the maximum guaranteed amount.

#### **Units of Measurement**

#### **Metric units**

**55 (1)** All units of measurement shown on a label of a feed must be expressed in metric units in accordance with the *Weights and Measures Act*.

#### Other units of measurement

(2) Other units of measurement may be shown on a label if

- (a) the quantities expressed in metric units are shown first; and
- **(b)** the quantities expressed in other units of measurement are equivalent to the quantities expressed in metric units.

#### **Definition of** *metric unit*

- (3) For the purposes of subsections (1) and (2), *metric unit* means any unit of measurement that is set out in Schedule I to the *Weights and Measures Act*.
  - ► View comments for the Labelling section 0 comment(s)

### **Preventive Controls**

## Interpretation

#### **Definitions**

**56** The following definitions apply in this section and sections 57 to 61.

## acceptable level

means a level of a biological, chemical or physical hazard that does not present a risk of contamination of a feed. (*niveau acceptable*)

#### control measure

means a measure that can be applied to prevent or eliminate any biological, chemical or physical hazard that presents a risk of contamination of a feed or to reduce the hazard to an acceptable level. (*mesure de contrôle*)

# critical control point

means a step at which the application of a control measure is essential to prevent or eliminate any biological, chemical or physical hazard that presents a risk of contamination of a feed or to reduce the hazard to an acceptable level. (*point de contrôle critique*)

## equipment

means equipment, in a facility, that is used in connection with an activity that is regulated under the Act. (*équipement*)

## facility

means a location, excluding a conveyance, where a feed is manufactured, stored, packaged, labelled or sold. (*installation*)

# **Biological, Chemical and Physical Hazards**

## **Identification and analysis of hazards**

**57 (1)** A person who manufactures, stores, packages, labels, sells or exports a feed must identify the biological, chemical and physical hazards that are present in that feed and analyze those hazards to determine whether they present a risk of contamination of that feed.

### **Control of hazards**

**(2)** The person referred to in subsection (1) must prevent, eliminate or reduce to an acceptable level the hazards identified as being present in the feed by using control measures that are shown by evidence to be effective, including any treatment or process that is necessary for the feed to comply with section 35.

#### **Factors**

- **(3)** In identifying and analyzing the hazards referred to in subsection (1), the person referred to in that subsection must consider the effect of any factor relevant to the safety of the feed, including
  - (a) the formulation of the feed;
  - (b) the ingredients of the feed, including raw materials;
  - (c) the level of any inherent contaminant in the feed;
  - (d) the procedures for manufacturing, processing, packaging and labelling the feed;
  - (e) the storage and distribution of the feed;
  - (f) transportation practices;
  - (g) the intended or reasonably foreseeable use of the feed;
  - (h) the condition, function, design and sanitation of the facility and equipment;
  - (i) employee hygiene; and
  - (j) meteorological conditions.

## **Preventive Control Plan**

# Preparing, keeping and maintaining

**58 (1)** A person who manufactures, stores, packages, labels, sells or exports a feed must

prepare, keep and maintain a written preventive control plan that meets the requirements set out in section 60 for any of those activities.

## **Exception**

- **(2)** Despite subsection (1), a preventive control plan is not required to be prepared, kept or maintained for any activity conducted by that person in respect of a feed that is a cultivated farm crop that
  - (a) is unprocessed and will be manufactured, processed or treated for use as a grain, oil, pulse or sugar; and
  - **(b)** has a label applied or attached to it that bears the words "For Further Preparation Only" or "pour conditionnement ultérieur seulement".

## **Implementation**

**59** Any person that is required to prepare, keep and maintain a preventive control plan must implement that plan.

### **Content** — hazards

- **60 (1)** The preventive control plan must include the following information:
  - (a) a description of the biological, chemical and physical hazards that are identified under section 57 as presenting a risk of contamination of a feed, of the control measures for preventing or eliminating those hazards or reducing them to an acceptable level and of the evidence that shows that the control measures are effective;
  - **(b)** a description of any critical control point, including, for each,
    - (i) the related control measures and the evidence that shows that the control measures are effective,
    - (ii) a description of the critical limits,
    - (iii) the procedures for monitoring the critical control points in relation to their critical limits, and
    - (iv) the corrective action procedures; and
  - **(c)** the procedures for verifying that the implementation of the preventive control plan results in compliance with the provisions of the Act and these Regulations.

### Content — measures to be taken

- (2) The preventive control plan must describe the measures that will be taken to ensure that
  - (a) the cleaning and sanitation of a facility and of any equipment are conducted in a manner that does not present a risk of contamination of a feed;
  - **(b)** a facility is protected against the entry of any animal that presents a risk of contamination of a feed and that any such measures do not present a risk of contamination of that feed;
  - **(c)** no substance in a facility presents a risk of contamination of a feed and no substance is handled or used in a manner that presents such a risk;
  - (d) any sanitizer or non-feed chemical or biological agent in a facility
    - (i) is properly and clearly identified,
    - (ii) is suitable for its intended use, and
    - (iii) is handled and used in accordance with the manufacturer's instructions;
  - **(e)** any agronomic input, pet food or veterinary drug in a facility is properly and clearly identified;
  - **(f)** any conveyance that is used to manufacture or convey a feed to or from a facility and that is unloaded or loaded at the facility
    - (i) is designed, constructed, used and maintained to prevent, eliminate or reduce to an acceptable level any risk of contamination of the feed,
    - (ii) is constructed of, and maintained using, materials that are suitable for their intended use and do not present a risk of contamination of the feed,
    - (iii) is equipped with instruments to control, indicate and record any parameters that are necessary to prevent, eliminate or reduce to an acceptable level any risk of contamination of the feed,
    - (iv) functions as intended,
    - (v) is accessible for cleaning, sanitizing, maintenance and inspection,
    - (vi) is of sound construction and in good repair,
    - (vii) if necessary, is calibrated in accordance with the manufacturer's instructions,

- (viii) does not contain or has not contained any animal, any pest control product as defined in subsection 2(1) of the Pest Control Products Act or any other material or substance that presents a risk of contamination of the feed unless the conveyance is adequately sanitized, and
- (ix) is clean and in a sanitary condition at the time of unloading or loading;
- **(g)** any equipment that is used in the manufacturing, storing, packaging or labelling of a feed
  - (i) meets the requirements set out in subparagraphs (f)(i) to (vii), and
  - (ii) is appropriate for the feed and for the activity being conducted;
- **(h)** any equipment or conveyance in a facility that is used to handle contaminated materials, waste or any other thing that is not intended for a feed, unless that equipment or conveyance does not come into contact with those materials, that waste or those things,
  - (i) is used only for that purpose and identified as being reserved for that purpose, or
  - (ii) meets the applicable requirements set out in paragraph (g);
- (i) any risk is prevented, eliminated or reduced to an acceptable level for
  - (i) any land that forms part of a facility and that presents a risk of contamination of a feed, and
  - (ii) any facility located near any place or thing that presents a risk of contamination of a feed;
- (j) the interior of a facility is
  - (i) designed to minimize the accumulation of contaminants, including dust, dirt, micro-organisms and feed residues and to permit effective maintenance, cleaning and, if applicable, sanitizing,
  - (ii) designed, constructed and maintained in such a manner that
    - **(A)** the size and layout is adequate to accommodate the activity being conducted and the equipment used in the activity,
    - (B) the entry of insects, rodents and other vermin is minimized, and
    - (C) any floors, walls, ceilings, windows and doors are smooth, non-absorbent and

impervious to moisture, except if those floors, walls, ceilings, windows or doors do not present a risk of contamination of a feed,

- (iii) constructed of, and maintained using, materials that are suitable for their intended use and appropriate for the feed and for the activity being conducted, and
- (iv) of sound construction and in good repair;
- **(k)** a facility or conveyance where a feed is manufactured, stored, packaged or labelled is designed, constructed and maintained in such a manner that the movement of persons and things within, into and out of it is controlled;
- (I) the movement of persons and things referred to in paragraph (k) does not present a risk of contamination of a feed;
- **(m)** physical or other effective means are used to separate incompatible activities in order to prevent contamination of a feed;
- (n) physical or other effective means are used to separate a feed from
  - (i) anything that presents a risk of contamination of the feed,
  - (ii) any feed that does not meet the requirements of the Act or these Regulations, and
  - (iii) anything that is manufactured, stored, packaged or labelled in a facility and not intended or sold for use as a feed;
- (o) any feed that does not meet the requirements of the Act or these Regulations is identified as such and placed in a designated area when it arrives at a facility;
- **(p)** the feed referred to in paragraph (o) does not contaminate any other feed that is in the facility;
- (q) a facility has means for the removal and disposal of contaminated materials and waste and, if necessary to prevent contamination of a feed, is equipped with a drainage, sewage and plumbing system that functions as intended;
- **(r)** contaminated materials and waste are removed and disposed of at a frequency that is sufficient to prevent contamination of a feed and in a manner that does not present a risk of contamination of the feed;
- (s) any water that might come into contact with a feed must not present a risk of

contamination of that feed;

- (t) any steam or ice that might come into contact with a feed must not present a risk of contamination of the feed;
- **(u)** any system that supplies water is not cross-connected with any other system, unless measures are taken to prevent, eliminate or reduce to an acceptable level any risk of contamination of a feed as a result of the cross-connection;
- (v) any treatment of water, steam or ice is conducted in a manner that does not present a risk of contamination of a feed;
- (w) any unloading and loading of a feed from or onto a conveyance at a facility is conducted in a manner that does not present a risk of contamination of the feed;
- (x) any storing of a feed is conducted in a manner that does not present a risk of contamination of the feed;
- **(y)** any storing of conveyances, equipment, sanitizers, agronomic inputs, veterinary drugs, chemical agents, packaging materials, labels or any other thing that is used in the manufacturing, storing, packaging or labelling of a feed is conducted in a manner that does not present a risk of contamination of the feed;
- (z) any person who is involved in the manufacturing, storing, packaging or labelling of a feed has the competencies and qualifications that are necessary to carry out their duties;
- **(z.1)** any person who enters or is in an area where a feed is manufactured, stored, packaged or labelled wears clothing, footwear and protective coverings that will prevent, eliminate or reduce to an acceptable level any risk of contamination of the feed; and
- (z.2) a facility and any equipment are clean and in a sanitary condition.

## **Content** — other requirements

(3) The preventive control plan must include a description of the measures for ensuring that the applicable requirements set out in sections 34 to 55, 62 to 65, 70 and 72 are met.

# Retention period — documents

- **61** Any person that is required to prepare, keep and maintain a written preventive control plan must keep
  - (a) a copy of each version of the preventive control plan for three years after the day on

which that version ceases to be implemented; and

**(b)** supporting documents that show evidence of the information recorded under section 60 and documents that substantiate that the preventive control plan has been implemented with respect to that section, for three years after the day on which they are prepared.

### ► View comments for the Preventive Controls section 0 comment(s)

## Investigation, Complaints and Recall

## Investigation — risk of harm

**62 (1)** Any person that manufactures, stores, packages, labels, sells or exports a feed and who suspects on reasonable grounds that the feed presents a risk of harm to human or animal health or the environment or does not meet the requirements of the Act or these Regulations must immediately investigate the matter.

#### **Notification**

(2) If the investigation establishes that the feed presents a risk of harm to human or animal health or the environment, the person must immediately notify the Minister and immediately take action to respond to the risk.

## **Complaints** — procedure

**63 (1)** Any person that manufactures, stores, packages, labels, sells or exports a feed must prepare, keep and maintain a document that sets out a procedure for receiving, investigating and responding to complaints that relate to the feed.

# **Complaints** — implementation

(2) On receipt of a complaint, the person must implement the procedure, prepare a document that sets out the details of the complaint, the results of the investigation and the actions taken based on those results and keep the document for three years after the day on which the actions are completed.

### Recall procedure

**64 (1)** Any person that manufactures, stores, packages, labels, sells or exports a feed must prepare, keep and maintain a document that sets out a recall procedure that enables the

effective recall of the feed, the name of a contact person who is responsible for the procedure and the name of a contact person who is responsible for conducting recalls.

## **Recall** — implementation

- (2) If a feed is recalled because it presents a risk of harm to human or animal health or the environment, the person referred to in subsection (1) must
  - (a) immediately implement the recall procedure; and
  - **(b)** prepare a document that sets out the details of the recall, including any information that substantiates its effectiveness, and keep the document for three years after the day on which the recall is initiated.
  - ► View comments for the Investigation, Complaints and Recall section 0 comment(s)

# **Requirements Specific to Certain Activities**

#### Manufacture of Feeds

#### Mixed feed

**65 (1)** Any person that manufactures a mixed feed must keep a copy of the mix sheet for a period of three years after the day of manufacture of each lot as well as a copy of the mix formula for a period of three years after the last day of manufacture of that feed.

#### Customer formula feed or custom medicated feed

(2) If the feed is a customer formula feed or a custom medicated feed, the person who manufactures that feed must have a copy of the customer formula or the veterinary prescription under which the feed is manufactured in their possession during the manufacture of that feed and keep that copy for a period of three years after the last day of manufacture of that feed.

# Single ingredient feed

(3) Any person that manufactures a single ingredient feed must keep a document containing the name of the feed, its identification code, its date of manufacture and the quantity manufactured for a period of three years after the day of manufacture of each lot of the feed, and keep a copy of any mix formula for a period of three years after the last day

of manufacture of the feed.

## **Import of Feeds**

#### Information

- **66 (1)** Any person that imports a feed must, before or at the time of the import, provide to the Minister, in a form approved by the President, the following information:
  - (a) their name and address;
  - (b) the name and address of the person from whom the feed is received;
  - (c) the name of the country of origin;
  - (d) the address of the first destination of the feed in Canada; and
  - (e) a description of the feed, including its name and quantity.

## **Exception**

**(2)** Despite subsection (1), the Minister may authorize the person who imports the feed, at their written request, to provide the information after the time of import, at the time specified by the Minister.

## **Further inspection**

**67** If, during an inspection that is conducted at the time of the import of a feed, the inspector determines that a further inspection is required, the person who imports the feed must keep it at the address referred to in paragraph 66(1)(d) until the further inspection is completed.

# Same level of protection

**68** The person who imports a feed must demonstrate that the feed imported has been manufactured, stored, packaged and labelled in a manner and under conditions that provide at least the same level of protection as that provided by subsections 57(1) and (2) and sections 60 to 64.

# Non-compliant feed

- **69** Any person may import a feed, other than a novel feed, that does not meet any of the requirements set out in sections 6 and 34 to 47 of these Regulations if
  - (a) a label that bears the words "Imported for Export" or "importé pour l'exportation" is

applied or attached to the feed or accompanies it;

- **(b)** the feed is intended to be stored, processed, packaged or labelled for the purpose of exporting it; and
- **(c)** the activities referred to in paragraph (b) are conducted by the holder of a licence issued under section 5.2 of the Act.

## Manufacture or Sale for Export or Export of Feeds

## Non-compliant feed

- **70** Any person may manufacture or sell a feed, other than a novel feed, that is intended to be exported and that does not meet any of the requirements set out in sections 6 and 34 to 47 of these Regulations if a label that bears the word "Export" or "exportation" is applied or attached to the feed or accompanies it and if
  - (a) in the case where the foreign state to which the feed is exported has a different requirement on the same matter as the unmet requirement, the person prepares a document that substantiates that the foreign state's requirement has been met; or
  - **(b)** in the case where the foreign state to which the feed is exported has no requirement on the same matter as the unmet requirement, the person prepares a document that sets out the specifications for the unmet requirement as stipulated by the person in the foreign state for whom the exported feed is intended.

## **Export certificate or document**

**71 (1)** An application for the issuance of a certificate or other document referred to in section 5.5 of the Act must be made to the Minister in a form approved by the President.

#### **Conditions for issuance**

(2) The Minister may issue a certificate or other document referred to in section 5.5 of the Act in respect of a feed that has been manufactured, stored, processed, packaged, labelled, sold or delivered by the holder of a licence issued under section 5.2 of the Act if the licence holder complies with all the conditions to which the licence is subject.

## **Inspection before export**

(3) The Minister may require that an inspection be conducted of any feed in respect of which a person has applied for a certificate or other document referred to in section 5.5 of

the Act, for the purpose of deciding whether to issue the certificate or other document.

► View comments for the Requirements Specific to Certain Activities section

O comment(s)

## **Traceability**

#### **Documents**

- **72 (1)** Any person that manufactures, stores, packages, labels, sells, imports or exports a feed must, if they provide the feed to another person, including as a sale at retail, prepare, keep and maintain documents that set out the following information:
  - (a) the name of the feed;
  - (b) its identification code;
  - **(c)** the name and address of the person who manufactured the feed or caused it to be manufactured;
  - **(d)** the date on which the feed was provided and the name and address of the person to whom it was provided;
  - **(e)** if they were provided the feed by another person, the name and address of that person and the date on which it was provided; and
  - **(f)** if the feed is a mixed feed, the name of any feed, substance or product referred to in section 37 contained in the mixed feed and, if they were provided the incorporated feed, substance or product by another person, the name and address of that person and the date on which it was provided.

## **Retention period of documents**

(2) The documents must be kept for three years after the day on which the feed was provided to another person and must be accessible in Canada.

## **Request for documents**

**73 (1)** If the Minister believes on reasonable grounds that a feed presents a risk of harm to human or animal health or the environment, any person that is required to prepare, keep and maintain documents must, at the Minister's request, provide the Minister with any document referred to in subsection 72(1), or any part of such a document.

#### **Production of documents**

- (2) The person referred to in subsection (1) must provide the documents
  - (a) within 24 hours after receipt of the request, or within
    - (i) any shorter period that is specified by the Minister, if the Minister believes that it is necessary in order to identify or respond to a risk of harm to human or animal health or to the environment associated with the feed, or
    - (ii) any longer period that is specified by the Minister, if the Minister believes that the document is not necessary for a recall that is or may be ordered under subsection 19(1) of the *Canadian Food Inspection Agency Act*; and
  - **(b)** if provided electronically, in a single file and in text that is capable of being imported into and manipulated by standard commercial software.
  - ► View comments for the Traceability section 0 comment(s)

## Samples for Analysis

## Requirements

**74 (1)** A sample of feed taken by an inspector for analysis must be representative of the lot of feed from which it is taken and be of sufficient size to be satisfactory for analytical purposes.

## Packaged feed — more than 5 kg

**(2)** If the feed to be analyzed is in packages of more than 5 kg, samples approximately equal in size must be taken from not fewer than 10 separate packages of the feed or, if the lot contains fewer than 10 packages, samples approximately equal in size must be taken from each of the packages.

## Packaged feed — 5 kg or less

(3) If the feed to be analyzed is in packages of 5 kg or less, one unbroken package may constitute a sample.

## **Damaged feed**

(4) If a portion of the feed that is to be analyzed appears mouldy or otherwise damaged in a manner to affect its suitability for feeding purposes, separate samples may be taken of the

undamaged portion and the damaged portion.

#### **Bulk feed**

- **(5)** If the feed to be analyzed is in bulk, samples of approximately equal size must be taken from not fewer than 10 separate sections of the bulk.
  - ► View comments for the Samples for Analysis section 0 comment(s)

## **Tolerance Limits**

## **Nutrient guarantee**

**75 (1)** The tolerances set out in column 3 of Table 1 of the schedule must be applied to the analysts' results of the analysis for the purpose of determining the accuracy of the guaranteed analysis shown on the label under paragraph 45(1)(e) for the nutrients set out in column 1.

## Medicating ingredient guarantee

- (2) The tolerances set out in column 2 of Table 2 of the schedule must be applied to the analysts' results of the analysis for the purpose of determining the accuracy of the guaranteed amount shown on the label under subparagraphs 45(2)(c)(i) and (d)(iii) for a medicating ingredient set out in column 1 that is present in a feed.
  - ► View comments for the Tolerance Limits section 0 comment(s)

## Seizure and Detention

## **Detention tag**

**76 (1)** Any article seized under section 9 of the Act may be detained by an inspector at any place by attaching a detention tag to the article or to any part of it.

#### **Notice of detention**

**(2)** If an article is detained in accordance with subsection (1), an inspector must provide a notice of detention to its owner or to the person in possession of it.

#### **Prohibition**

(3) It is prohibited for a person to alter or remove a detention tag or to sell or move any

detained article unless an inspector gives written authorization to the person to do so.

#### **Notice of release**

(4) If an article is released under subsection 9(2) of the Act, an inspector must provide a notice of release to the person to whom the notice of detention was provided.

#### **Forfeited articles**

- **(5)** Any article forfeited under subsection 9(3) or 9.1(3) of the Act must be disposed of in the following manner:
  - (a) in the case of a feed that is fit for feeding to livestock, it must be
    - (i) sold and the proceeds deposited to the credit of the Receiver General, or
    - (ii) donated to a *registered charity* within the meaning of subsection 248(1) of the *Income Tax Act*;
  - **(b)** in the case of a feed that is not fit for feeding to livestock, it must be disposed of in a safe manner; and
  - **(c)** in the case of an article other than a feed, it must be sold and the proceeds deposited to the credit of the Receiver General.
  - ► View comments for the Seizure and Detention section 0 comment(s)

#### **Transitional Provisions**

## **Definition of former Regulations**

77 In sections 78 to 84, *former Regulations* means the *Feeds Regulations, 1983* as they read immediately before the day on which these Regulations are registered.

**Exemption** — paragraph 3(b) of former Regulations

78 (1) Paragraph 3(b) of the former Regulations continues to apply in respect of a feed referred to in that paragraph for the 12-month period that begins on the day on which these Regulations are registered.

**Exemption** — paragraph 3(c.1) of former Regulations

(2) Paragraph 3(c.1) of the former Regulations continues to apply in respect of a feed referred to in that paragraph on or after the day on which these Regulations are

registered provided that the importer of the feed has submitted to the President, before the day on which these Regulations are registered, the information referred to subparagraph 3(c.1)(i) of the former Regulations for approval by the President for the importation and accepted responsibility for the disposal in a safe manner of all livestock produced from the feed in accordance with subparagraph 3(c.1)(ii) of the former Regulations.

#### **Notification of release**

79 (1) If, before the day on which these Regulations are registered, a notification for an authorization for the release of a novel feed has been provided to the Minister under paragraph 4.1(1)(a) of the former Regulations, accompanied by the undertaking referred to in paragraph 4.1(1)(b) of those Regulations and the information set out in section 4.2 of those Regulations, and a decision has not been made by the Minister under subsection 4.3(1) of those Regulations, the Minister must approve the feed under section 8 of these Regulations if the requirements set out in paragraphs 8(1)(b) and (c) are met.

#### Notice of refusal

(2) If the requirements set out in paragraphs 8(1)(b) and (c) of these Regulations are not met, the Minister must provide written notice of the refusal to approve the feed to the person providing the notification and provide the reasons for the decision not to approve the feed.

#### **New information** — release

(3) If, at any time after receiving authorization from the Minister for the release of a novel feed under paragraph 4.3(1)(a) of the former Regulations, a person becomes aware of any new information that the feed may present a risk of harm to human or animal health or the environment, the person must make an application for approval for that feed in accordance with section 7 of these Regulations.

#### Pending application to register a feed

80 Every application to register a feed made to the Director in accordance with section 6 of the former Regulations that is pending on the day on which these Regulations are registered must be dealt with in accordance with the former Regulations.

## Validity of registration certificate

81 A registration certificate issued under section 9 of the former Regulations that is valid immediately before the day on which these Regulations are registered is deemed to have been issued under section 11 of these Regulations.

**Cancellation of registration certificate** 

82 Section 12 of the former Regulations continues to apply in respect of a registration certificate on or after the day on which these Regulations are registered if, before that day, the Minister has sent the notice referred to in subsection 12(2) of the former Regulations to the registrant by registered mail.

Retention of documents — manufacture before coming into force

83 (1) Subsections 15(1) and (4) of the former Regulations continue to apply in respect of any of the feeds referred to in those subsections if they were manufactured before the day on which these Regulations are registered.

Retention of documents — manufacture on or after coming into force

(2) Section 65 of these Regulations applies in respect of any of the feeds referred to in that section only if they are manufactured on or after the day on which these Regulations are registered.

#### Content of feed

84 (1) Nothing in these Regulations prohibits the manufacture, sale or import of a feed that does not comply with the standard set out in section 35 of these Regulations if it complies with the standard set out in section 19 of the former Regulations.

Mixed feed or single ingredient feed

(2) Nothing in these Regulations prohibits the sale or import of a feed that does not comply with the standard set out in section 42 of these Regulations if it complies with the standard set out in section 22 of the former Regulations.

## Labelling

(3) Nothing in these Regulations prohibits the manufacture, sale or import of a feed the labelling of which does not comply with the requirements set out in sections 44 to 55 of these Regulations if the labelling of that feed complies with the requirements

set out in sections 24 and 26 to 33 of the former Regulations.

#### **Cessation of effect**

- (4) Subsections (1) to (3) cease to have effect 12 months after the day on which these Regulations are registered.
  - ► View comments for the Transitional Provisions section 0 comment(s)

## **Consequential Amendments**

**Health of Animals Act** 

**Health of Animals Regulations** 

85 Section 113 of the *Health of Animals Regulations*  $\frac{7}{2}$  is replaced by the following:

**113** Section 112 does not apply to any feed approved or registered under the *Feeds Act*.

## **Food and Drugs Act**

**Food and Drug Regulations** 

86 Subsection C.01.014(2) of the *Food and Drug Regulations*  $\underline{^8}$  is replaced by the following:

**(2)** Subsection (1) does not apply in respect of a veterinary health product, a *study drug* as defined in section C.03.301 or a *medicated feed* as defined in subsection 1(1) of the *Feeds Regulations*, 2022.

## 87 The definition *dilute drug premix* in subsection C.01A.001(1) of the Regulations is replaced by the following:

## dilute drug premix

means a drug for veterinary use that results from mixing a drug premix with a *feed*, as defined in section 2 of the *Feeds Act*, to such a level that at least 10 kg of the resulting mixture is required to medicate one tonne of *complete feed*, as defined in subsection 1(1) of the *Feeds Regulations*, 2022, with the lowest approved dosage level of the drug. (*prémélange médicamenteux dilué*)

## 88 Paragraph C.01A.001(2)(b) of the Regulations is replaced by the following:

**(b)** a medicated feed as defined in subsection 1(1) of the Feeds Regulations, 2022;

## 89 Subsection C.08.012(2) of the Regulations is replaced by the following:

- **(2)** For the purpose of this section, *medicated feed* has the same meaning as in the *Feeds Regulations*, 2022.
  - ► View comments for the Consequential Amendments section 0 comment(s)

## Repeal

90 The *Feeds Regulations*, 1983  $\frac{9}{2}$  are repealed.

► View comments for the Repeal section 0 comment(s)

## **Coming into Force**

#### Registration

91 (1) Subject to subsections (2) and (3), these Regulations come into force on the day on which they are registered.

First anniversary of registration

- (2) The following provisions come into force on the first anniversary of the day on which these Regulations are registered:
  - (a) paragraphs 1(2)(b), (e), (g) and (i); and
  - (b) sections 43, 56 to 61, 63, 64, 66 to 68, 72 and 73.

18 months after registration

- (3) Sections 18 to 33, 69 and 71 come into force on the day that, in the 18th month after the month in which these Regulations are registered, has the same calendar number as the day on which they are registered or, if that 18th month has no day with that number, the last day of that 18th month.
  - ► View comments for the Coming into Force section 0 comment(s)

## **SCHEDULE**

(Section 75)

► View comments for the SCHEDULE section 0 comment(s)

## **Tolerance Limits**

## **TABLE 1**

# Tolerances to be applied to the analysts' results of the analysis on nutrients in feed under subsection 75(1)

	Column 1	Column 2	Column 3
	Nutrient	<b>Guaranteed Amount</b>	Permitted tolerances not to exceed
1	Calcium (Ca), Magnesium (Mg), Sodium (Na), Potassium (K), Sulphur (S), Salt (NaCl)	(a) 1% and under	A deficiency or excess of 0.2% of the feed
		(b) Over 1%	A deficiency or excess of 20% of the guaranteed amount
2	Zinc (Zn), Copper (Cu), Manganese (Mn), Iodine (I), Cobalt (Co)	All amounts	A deficiency or excess of 20% of the guaranteed amount
3	Fluorine (F)	All amounts	An excess of 20% of the guaranteed amount
4	Phosphorus (P)	(a) 5% and under	A deficiency or excess of 20% of the guaranteed amount
		(b) Over 5%	A deficiency of 10% or an excess of 20% of the guaranteed amount
5	Iron (Fe)	All amounts	A deficiency of 20% or an excess of 40% of the guaranteed amount
6	Crude protein (mixed feed)	(a) 24% and under	A deficiency of 1.0% of the feed
		(b) Over 24%	A deficiency of 1.5% of the feed
	Crude protein (single ingredient feed)	All amounts	A deficiency of 0.8% of the feed

7	Equivalent crude protein	(a) 5% and under	An excess of 1.0% of the feed
		(b) Over 5% and up to and including 25%	An excess of 20% of the guaranteed amount
		(c) Over 25%	An excess of 5% of the feed
8	Crude fat	All amounts	A deficiency or excess of 0.5% of the feed
9	Crude fibre	(a) 5% and under	A deficiency or excess of 0.5% of the feed
		(b) Over 5% and up to and including 15%	A deficiency or excess of 10% of the guaranteed amount
		(c) Over 15%	A deficiency or excess of 1.5% of the feed
10	Vitamin A, Vitamin E	All amounts	A deficiency of 20% of the guaranteed amount
11	Vitamin D	All amounts	A deficiency of 25% of the guaranteed amount
12	Sugar (invert)	(a) 24% and under	A deficiency of 1.5% of the feed
		(b) Over 24%	A deficiency of 2% of the feed
13	Pepsin digestible protein	All amounts	A deficiency of 10% of the guaranteed amount

## **TABLE 2**

# Tolerances to be applied to the analysts' results of the analysis on medicating ingredients under subsection 75(2)

Column 1	Column 2
Medicating Ingredient	Permitted tolerances not to exceed

1	Medicating ingredients except antibiotics	A deficiency or excess of 20% of the guaranteed amount	
2	Antibiotics	A deficiency or excess of 25% of the guaranteed amount	

► View comments for the Tolerance Limits section 0 comment(s)

## Privacy notice statement

## **Footnotes**

<u>a</u> S.C. 2015, c. 2, s. 56

<u>b</u> R.S., c. F-9

<u>c</u> S.C. 2015, c. 2, ss.95(1) to (6)

<u>d</u> S.C. 1990, c. 21

<u>e</u> S.C. 2016, c. 9, s. 8

<u>f</u> R.S., c. F-27

- Section 170.1 of the *Health of Animal Regulations* states that every person who imports, manufactures, packages, labels, stores, distributes, sells or advertises for sale any animal food for ruminants, equines, porcines, chickens, turkeys, ducks, geese, ratites or game birds shall establish and maintain written procedures to facilitate an effective recall of the animal food and keep records. Thus, the businesses that are engaged in these activities should have a traceability template in place right now. These businesses include
  - 450 out of 480 commercial feed manufacturers (94%) inspected by the CFIA;
     and
  - 1 468 out of the 1 500 feed retailers (98%) inspected by the CFIA.

On-farm feed manufacturers who import feed products would also be subjected to the same recall requirement under the *Health of Animal Regulations*. It is also assumed that they are purchasing feed products and would therefore be collecting this information for other purposes (such as keeping track of their business expenses for tax purposes). Thus, the majority of them should have a traceability template in place to keep their records right now.

The CFIA has limited knowledge about the ingredient manufacturers. However, a CFIA industry survey showed that 100% of ingredient manufacturers can trace 100% of their purchase and sales records. This suggests that they should have a traceability template in place already to be able to keep their records. The CFIA decided to use a 99% compliance rate considering the possibility that there may be some ingredient manufacturers that are not captured by the survey and do not have a traceability system now.

According to CFIA subject matter experts, the growth of establishments in the feed manufacturing industry is more in line with the growth of the Canadian livestock sector. Statistics Canada's 2016 Census of Agriculture shows that the number of animals has remained static in the past 10 years; thus, it may hinder the future growth of the feed industry. Moreover, expanding to foreign markets has not been the focus of the feed manufacturing industry as the industry is mainly domestic-oriented. Therefore, the analysis kept the number of establishments unchanged over the 10-year period.

- To provide the industry with time to adjust to the proposed Regulations, the CFIA is proposing a delayed coming into force of 18 months for licence requirements and of one year for certain other requirements (starting from the date that the proposed Regulations are published in the *Canada Gazette*, Part II).
- The CFIA conducted an industry survey in March 2017 to gauge the impact of the proposed regulatory changes. Surveys were distributed to national associations such as the Animal Nutrition Association of Canada and provincial associations such as Alberta Beef Producers, who sent the surveys to their members. In total, there were 127 survey responses received by the CFIA.
- Calculated as weighted average based on current types of applications submitted. In reality, fees would vary depending on the types of renewal ranging from \$10 to \$50 per application.
- <u>6</u> The current fees are listed on the registration application form see <u>Application</u> for Feed Registration or Renewal form [CFIA 0009] (PDF)
- <u>7</u> C.R.C., c. 296; SOR/91-525, s. 2
- 8 C.R.C., c. 870
- 9 SOR/83-593