

Agence canadienne d'inspection des aliments

Canadian Food Inspection Agency



Our vision:

To excel as a science-based regulator, trusted and respected by Canadians and the international community.

Our mission:

Dedicated to safeguarding food, animals and plants, which enhances the health and well-being of Canada's people, environment and economy.

Feed Regulatory Renewal Update for AAFCO

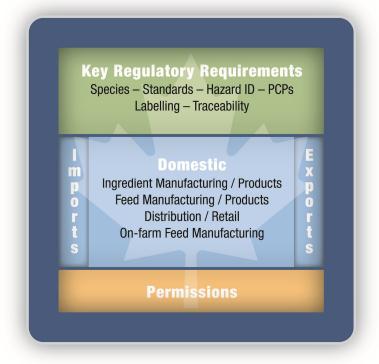
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Purpose / Objectives

To provide an update on:

- current status
- revised timelines
- next steps



Recall objectives for the review of the *Feeds Regulations* ...

Develop a modernized risk- and outcome- based regulatory framework for feeds which:

- ✓ safeguards feeds and the food production continuum
- ✓ attains the most effective and efficient balance between fair and competitive trade in the market
- ✓ minimizes regulatory burden



Legislation Update – *Agriculture Growth Act*

- Tabled by Minister of Agriculture and Agri-Food on December 9, 2013
- Received Royal Assent on February 25, 2015
- Made amendments to CFIA Acts:
 - Agriculture and Agri-Food Administrative Monetary Penalties Act;
 - Feeds Act;
 - Fertilizers Act;
 - Health of Animals Act;
 - Plant Protection Act;
 - Seeds Act;
 - Plant Breeders' Rights Act.



Legislation Update – Feeds Act

Some significant amendments made to *Feeds Act*:

- Incorporation by reference
- Regulation-making authorities to require regulated parties to develop, implement and maintain quality management programs, preventive control plans etc.
- Clear authority to consider information available from the assessment of feeds done by foreign governments / international organizations
- Regulation-making authorities to licence/register establishments and/or operators relative to import, export and domestic activities and products

Current status - Consolidated Proposal

A Consolidated Proposal being distributed/posted for final, pre-*Gazette I* public consultation. The consolidated proposal:

1. Integrates first three modules consulted on

 Demonstrate how feed ingredient assessment & authorization, hazard ID & preventive controls, and labelling will work together to provide a robust, risk-based regulatory framework

2. Includes proposal on facility licensing/enforcement

 Demonstrate how new Agricultural Growth Act (AGA) authorities and the principles of iAIM will apply in a Feed context

3. Addresses additional policy issues, including:

 Proposals regarding scope of species subject to Feeds Regulations, oversight of feed imports & exports, traceability





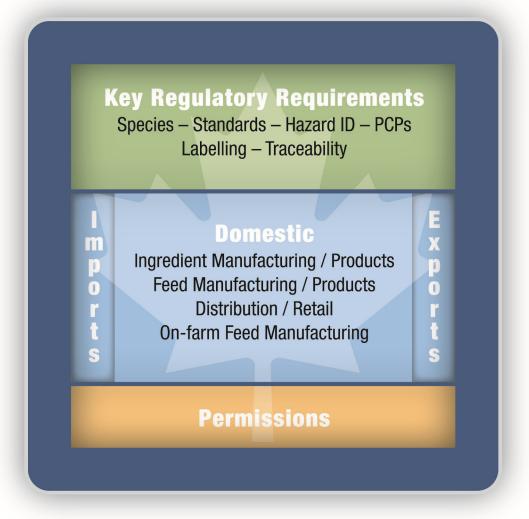
Current status – Consolidated Proposal (con't)

- Posting of Consolidated Proposal anticipated for mid— to late January 2016
- A 45 day consultation period will be provided once proposal posted on CFIA website
 - CFIA will notify FRSG and stakeholders when proposal posted and closing date for comments

Proposal Influenced by...

- US-FDA proposed feed rule (response to FSMA)
- CFIA Integrated Agency Inspection Model (iAIM)
 - Framework of roles/responsibilities of regulated parties to prevent/mitigate risks and CFIA oversight
- Amendments to Feeds Act by the Agriculture Growth Act
- Approaches being taken by Food Programs in preparing modernized food regulations for Safe Food for Canadians Act

Consolidated Framework Proposal



Components of the Consolidated Proposal

- 1. Hazard Identification and Preventive Controls
- 2. Ingredient Assessment and Authorization
- 3. Labelling
- 4. Additional Policy Issues

1. Feed Hazard Identification and Preventive Controls

Current Situation

- CFIA takes a tiered approach, in regulation and administratively, to the identification of hazards and providing guidance on maximum acceptable levels in feed
- Current regulations largely silent on requiring preventive controls/preventive control plans to be in place for feed manufacturing – focus of existing requirements are on BSE transmission prevention

Proposal

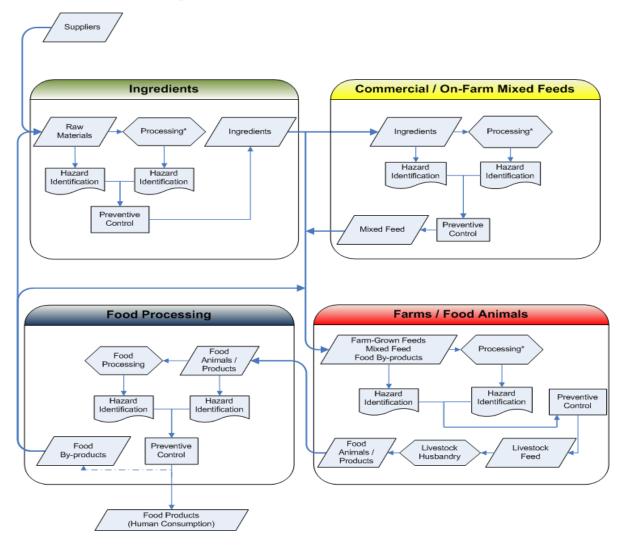
- Require hazard identification and preventive control plans for feed/ingredients along entire feed supply chain
 - Ag Growth Act provides authorities to make regulations in this regard





Feed Hazard ID / Preventive Controls – Anticipated Framework

Feed Supply Chain Continuum
Figure – Hazard ID / Preventive Control



^{*} Processing includes manufacturing, handling, storing and distribution.





1. Proposal - Hazards

- CFIA to continue taking tiered approach to the identification and setting of standards for hazards
 - Revise list of prescribed deleterious substances
 - Add/revise/remove specific hazards and standards identified for all feeds in regulation
 - Retain/revise more outcome-based requirements
 - Include known hazards and limits in ingredient descriptions (Schedule IV and V or lists outside the Regulation)
 - Identify specific hazards and maximum limits in feeds in guidance (build on current RG-8)
- Table 4 to be removed from Regulations; to be replaced with standards/guidance on maximum levels of nutrients that may pose risks to animal or human health or the environment

Proposal – Hazard ID and Preventive Controls

- Regulated parties would be responsible for the identification of hazards associated with their own products and processes along the supply chain (feed and feed ingredients)
 - At a minimum, regulated parties would have to take into consideration the range of known or reasonably foreseeable hazards in feeds and feed ingredients identified by the regulatory framework in doing their own hazard identification
- Regulated parties develop, implement and maintain outcome- and performance-based preventive control plans (PCPs) per the requirements proposed for each preventive control element set out in proposal
 - Not all controls will necessarily apply in all operations
 - Farms again exempted if feeds not for sale, non-medicated





2. Feed Ingredients

Current Situation

- New ingredients are assessed for safety, efficacy, and validation of claims in order to be authorized.
- In some cases, mixed feeds (multiple ingredients) are further assessed for efficacy and claims, and may require registration.

Proposal

- Use broader range of approaches to continue assessment of new ingredients for safety to animals, humans and the environment
- Agency's role in assessing Fit for purpose and Claims with regards to new ingredient characterization and authorization will be focussed more narrowly on safety.

3. Feed Labelling

Current Situation

All feeds must have, or be, accompanied by a label

The labelling requirements generally include:

- Contact information
- Basic information about the feed (name, purpose guarantees, directions, amount)
- Required cautions and warnings (e.g. medications, prohibited material)
- Additional label information typically triggers product registration

Proposal includes:

Increased flexibility (e.g., additional guarantees, allow other label information)

Increased international alignment (e.g., list of ingredients, lot #)

Address gaps in current regulations (e.g., compel caution statements)





4. Additional Policy Issues identified

- 1. Species to which the Regulations apply
- 2. Traceability of feeds
- 3. Oversight of Feed Exports
- 4. Oversight of Feed Imports
- 5. Permissions/Exemptions (Licences, registration)
 - Includes registration of mixed feeds

Additional Work - Current status

- Several supporting projects/proposals associated with modernized regulatory framework are underway
 - In particular, projects targeting use of Agricultural Growth Act
 (AGA) authority that enables <u>Incorporation by Reference</u>
 - Anticipating roll-out of proposals to start early in 2016
- Drafting of drafting instructions has begun in collaboration with RLEAD and Legal Services
- Elements of Cost-Benefit Analysis (CBA) being identified in collaboration with RLEAD

Upcoming Consultations

Feed Regulatory Modernization -

Outstanding Proposals for Consultation

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Proposal Name	Proposed Release Date (Proposed Consultation Timeline)	Communications Strategy	
Consolidated Proposal	December 2015 (mailed to stakeholders)	 Direct e-mail out to stakeholders on AFD distribution list 	
	(45 days once posted (TBD))	 Web mark-up and posting on external site 	
		 Listserv notification to internal Merlin and external site subscribers when posted 	
		 Mail-out of "Industry Notice" to registrants & non-ANAC feed mfrs when posted 	
Feed Ingredient Collective Terms – Summary of Respondent Feedback & CFIA Response (June 2015 proposal being marked-up for posting on external site)	December 2015 (Comments due January 17)	 Direct e-mail out to stakeholders on AFD distribution list 	
		Web mark-up and posting on external site	
		 Listserv notification to external site subscribers when posted 	
		 Mail-out of "Industry Notice" to registrants & non-ANAC feed mfrs when posted 	



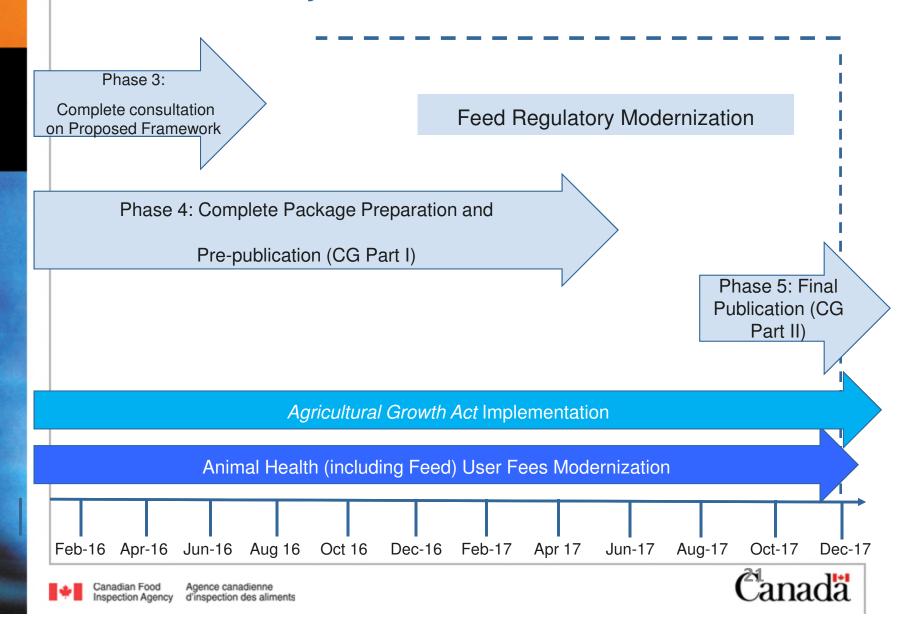
Upcoming Consultations

Feed Regulatory Modernization -

Outstanding Proposals for Consultation

Proposal Name	Proposed Consultation Timeline (2016)	Communications Strategy
Permissible Claims	TBD	
Nutrient Guarantees on Feed Labels (modernized Table 3, Schedule I)	TBD	
Maximum Nutrient Levels (replacement of Table 4, Schedule I) - Swine [±Broiler chickens]	TBD	
Weed Seeds (Review/replacement of Schedule II, Tables 1 and 2)	TBD	
"Non-Feed" Feed Additives proposal (feed-additive vet biologics, pesticides (?))	TBD	
Approved Feed Ingredient List (replacement of Schedules IV/V)	TBD	

Revised Project Timelines



Next Steps

- Stage "Town Hall" information sessions for regional/provincial stakeholder groups not directly engaged in consultations to date
 - Five (5) half-day sessions being planned (BC, AB, ON, QC, ATL)
 - Timeline for sessions February 2016 while consultation period for Consolidated Proposal is open

Next Steps (con't)

- Continue development of Gazette-ready package for 2017 Pre-publication
 - Preparation of regulatory drafting instructions for Department of Justice team to work from
 - Collaborate internally on preparation of Cost-Benefit Analysis (CBA) and other TBS-required documentation / analyses
- Bilateral engagement of US FDA: FSMA animal food safety final rule
 - Final Rule published in Federal Register September 2015
 - Will set stage for potential feed systems recognition process between Canada and US
 - Bilateral meeting with FDA being planned for January 29, 2016

QUESTIONS

