Update by the CFIA
Animal Nutrition Association of Canada
Annual General Meeting
May 29, 2017

Dr. Michelle Illing, Animal Feed Division
Mr. Craig Price, Western Operations
Topics

• Feed Regulatory Renewal Initiative
• Integrated Agency Inspection Model (iAIM)
• Electronic Services (MyCFIA / AskCFIA)
• Pre-market Service Delivery
• International Cooperation
• Drug vs. Feed Classification
Regulatory Renewal Project:
Next Steps and Timelines

Phase 3: Consultation on Proposed Framework

Phase 4: Complete Package Preparation and Pre-publication (CG Part I)

Phase 5: CG Part II

Feed Regulatory Modernization

Apr-16 Jun-16 Aug-16 Oct-16 Dec-16 Feb-17 Apr-17 Jun-17 Aug-17 Oct-17 Dec-17 Feb-18
Snapshot of CFIA’s Regulatory Plan
January - September 2017

Planned pre-publications*

- Proposed Safe Food for Canadians Regulations
- Agriculture and Agri-Food Monetary Penalties Regulations - SFCR
- Livestock Identification and Traceability – Health of Animals
- Feeds Regulations Modernization

Planned final publications*

- Miscellaneous Amendments Regulations (TBS Coordinated)
- CFIA Fees Notice (SJC Concerns)
- Health of Animals Regulations Humane Transportation (CGII)
- Agriculture and Agri-Food Monetary Penalties Regs – Humane Transportation

*Target month for delivery to Treasury Board for Governor in Council consideration, or to Minister for approval if Ministerial Regulation

4
Modernized Food and Feed Rules: US versus Canada

US – *Final* Human Food Safety Rule

Canada – *Proposed modernized* SFC Regulations

US – *Final* Animal Food Safety Rule

Canada – *Proposed Modernized Feeds Regulations*

IMPLEMENTATION

Final Regulations
Publication timeline – Winter/Spring 2018

Final Regulations
Publication timeline – TBC

Project Next Steps: Phase 4 for CGI publication

1. Prepare CGI package, including:
   
   • preparing proposed regulatory text in collaboration with CFIA Legal Counsel and Department of Justice drafting team;
   
   • drafting Cost/Benefit Analysis (CBA) with Economic Affairs (EA) team
   
   • preparing Regulatory Impact Analysis Statement (RIAS) to accompany proposed regulatory text in CGI

2. Complete preparation and consultation on technical documents proposed for incorporation by reference (IbR)
Technical Proposals – Status of several supporting documents proposed for IbR

<table>
<thead>
<tr>
<th>Document</th>
<th>Status</th>
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<tbody>
<tr>
<td>2. Permissible Claims on Feed Labels</td>
<td></td>
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<tr>
<td>3. Oversight of Weed Seeds in Feeds</td>
<td>Consultations completed – July 2016 - Summary Reports completed</td>
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<tr>
<td>4. Veterinary Biologics in Feeds</td>
<td></td>
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<tr>
<td>5. Nutrient Guarantees on Feed Labels</td>
<td>Consultations completed – July 2016 - Summary Report pending</td>
</tr>
<tr>
<td>6. Maximum Nutrient Levels in Feeds – Swine &amp; Poultry</td>
<td>Swine and poultry proposals released November 1 for consultation;</td>
</tr>
<tr>
<td>Maximum Nutrient Levels in Feeds – Other Species (e.g. Beef &amp; Dairy Cattle, Fish)</td>
<td>Consultation to follow – Spring 2017</td>
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<tr>
<td>7. Maximum Contaminant Levels in Feeds</td>
<td>Consultation to follow – Spring 2017</td>
</tr>
<tr>
<td>8. Positive List of Authorized Ingredients</td>
<td>Consultation to follow – Early 2017</td>
</tr>
<tr>
<td>9. Compendium of Medicating Ingredient Brochures (CMIB)</td>
<td>IbR in Regulations at present; - Consult jointly w/ HC in 2017 on updated CMIB (AMR policy changes)</td>
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Process for reviewing feedback from consultations

• Feedback is compiled and categorized in terms of general comments and subject-specific comments

• All comments are summarized and evaluated against the scope of the published proposals and modifications are incorporated

• A consultation summary report is generated for each proposal consulted on to share the feedback received and communicate what stakeholders can expect to be included in the formal regulatory proposal for publication in the Canada Gazette Part I
Responding to Stakeholder Feedback: Examples

Nutrient Maximum Proposal – Poultry Feeds

### Calcium – Turkey feeds

<table>
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<th>Amended</th>
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<tr>
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<td>2.5%</td>
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<tr>
<td>Grower / Developer / Holding / Finisher / Breeder</td>
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<td>2.5%</td>
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<tr>
<td>Pre-Layer / Layer / Layer Breeder</td>
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### Phosphorus – Chicken feeds

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<thead>
<tr>
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<tbody>
<tr>
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</tr>
<tr>
<td>Grower</td>
<td>1.0%</td>
<td>1.2%</td>
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<tr>
<td>Finisher, Breeder</td>
<td>1.0%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Pre-Layer / Pre-Layer Breeder</td>
<td>0.8%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Layer / Layer Breeder / Layer Broiler Breeder</td>
<td>0.8%</td>
<td>1.2%</td>
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Integrated Agency Inspection Model (iAIM)

- In February 2015, the Agency finalized iAIM containing an inspection approach for all regulated commodities in the food, animal and plant business lines.
- The Wave Project was undertaken to begin implementing the model.
- The Wave strategy involves a series of successive paired waves to test and implement the inspection approach and its supporting elements.
- The opening wave in a pair introduces new elements and tools in limited regions with a limited number of inspectors and industry partners, while the closing wave in a pair is implementation on a national scale.
Integrated Agency Inspection Model (iAIM)

- Commodities were selected based on a number of criteria, including:
  - *CFIA Readiness*: the current inspection approach aligns with iAIM vision
  - *Industry Readiness*: industry is familiar with a systems-based inspection approach

- The iAIM was tested and applied across all three business lines and seven commodities areas:
  - Fish (QMP)
  - Feed (canola oilseed processors)
  - Dairy (FSEP)
  - Dairy (non-FSEP)
  - Greenhouse (export program)
  - Fresh fruit and vegetables (packer, re-packer and fresh-cut operations)
  - Specified risk material permitting
Integrated Agency Inspection Model (iAIM)

What have we learned?

• Found similar overall performance in commodities with no significant differences between Areas or inspectors experience with the procedures.
  – 99% of the criteria assessed showed that the expected outcome of the inspection steps were met.

What happens next?

• Aligning with other inspection modernization initiatives including, but not limited to, *Safe Food for Canadians Regulations*, Feed Regulatory renewal, My CFIA, and Integrated Risk-Based Workplanning.
What is *My CFIA*?

- *My CFIA* is a new digital platform that provides industry with a secure, innovative suite of online services, conveniently accessible 24 hours a day / 7 days a week.

- The service portal provides external CFIA stakeholders with electronic access to a growing list of service requests, including information services, licences, permits, registrations and export certificates.

- This platform will also allow inspectors to electronically capture and report inspection findings for internal purposes (such as data analysis, trend tracking, etc.).
About My CFIA

When did it start?

- My CFIA is being rolled out in four releases – we began gradually on-boarding services on January 9, 2017.

When will it finish?

- Additional services will be available in subsequent releases in Spring, Summer and Fall of 2017.
- The platform will continue to expand to offer additional automated services for years to come.
How does it work?

• Clients can go to the My CFIA web page on the Agency’s external site http://inspection.gc.ca and enrol for a My CFIA account.

• Once they have an account, industry stakeholders have access to services that will be phased in as per the roll-out plan available under “who should enroll” on the My CFIA page http://inspection.gc.ca/MyCFIA

• Self-help learning tools are available to stakeholders in advance of each My CFIA release.

• As we gradually move our services online, traditional channels will still continue to be available during the transition.
How to get involved

• The CFIA will be holding information sessions in the Spring prior to Release 2 of My CFIA.

• Sectoral information sessions will be available via webinar.

• Dates and times will be posted on the My CFIA website:

  http://inspection.gc.ca/MyCFIA
Where can I get more information?

- *My CFIA* web page, linked from the CFIA’s main website, includes:
  - frequently asked questions;
  - how-to guides;
  - a client satisfaction survey; and
  - further detailed information.

- For questions, you can:
  - Call ‘Ask CFIA’ at 1-800-442-CFIA (2342), or;
  - Submit your question via email by completing the feedback form available on our website at [www.inspection.gc.ca](http://www.inspection.gc.ca)
Pre-Market Service Delivery (2016/17)

• Animal Feed Division completed ~2600 product submission files including final labels, novel and new feeds or ingredients, standard feeds, research exemptions, data review and renewals
• For those files subject to the feed service delivery standard, the average days for completion was 97 as compared to 155 in 2015/16

- Additional resources for review capacity and regulatory modernization efforts
- Introduced an innovative and streamlined approach to processing applications for renewals
- Continuous improvement of internal procedures with the Pre-Market Application Submission Office (PASO)
International cooperation: The Convergence Project

- Joint industry/regulator initiative striving to harmonize pre-market submission packages globally wherever possible within the regulatory systems.

- Trilateral at the moment with representation from Canada, United States, and the European Union: includes regulators, feed industry associations, and International Feed Industry Federation (IFIF).

- Looking at adopting a system similar to the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) which has been in place since April 1996
  - VICH is a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration.

- Canada has always been, and continues to be, a strong proponent for this project.
International cooperation: The Equivalence Project

• New authority through the Agricultural Growth Act allows for acceptance of foreign approvals if the foreign assessment is deemed to be equivalent to the requirements under Canadian regulations.

• AFD has been working closely with the US-Food and Drug Administration as well as the European Commission and the European Food Safety Authority (EFSA) to compare data requirements for the pre-market assessment and authorization of feed ingredients.

• Will be sharing details are hoping to have more details to share on the approach and our findings shortly.
Drugs versus Feeds: Finding the right balance for delineating drugs and feed

• Current regulatory approach is not working
  – need for increased flexibility by regulators

• Animal health, food and public safety cannot be compromised

• Consumer protection is part of the CFIA mandate

• Product labelling needs to provide the end users with all the information to ensure the product is used properly and is reflective of the information found to be acceptable by the regulator (i.e., what it is approved for)

• The regulators remain concerned with “out of compliance” advertising with these groups of product

• Harmonize with international feed regulatory frameworks, where possible
Drug Feed Classification Working Group

- Developed a WG to oversee some of these issues
- Meet regularly to discuss classification of grey zone products
- Continue to discuss classes of products that are problematic in terms of classification
- Respond directly to company enquiries – promoting open communication between CFIA and VDD
- Institute measures to decrease time to feedback and increase consistency
- Develop and update Classification Guidance as necessary
What we’re working on

• Recently published 2 Annexes to the Drug/Feed Classification Guidance
• Pilot project for the Classification & Registration of Products as Livestock Feeds
• Exploration into increasing the flexibility for classification of some of the priority products
• Potential for a new category of livestock feed: Gut Modifier
• Discussing grey zone products submitted for classification
Web Publication of 2 Annexes

• Two annexes were produced to clarify the drug vs feed classification:
  1. Products with ‘stress’ claims (Annex D)
  2. Mycotoxin detoxifying agents (MDA; Annex E-1)

• Each of the annexes provide classification criteria & examples of therapeutic vs. feed claims and allow for new classifications as FEED

• Consulted with stakeholders in 2016

• Finalized annexes are now available on the website: http://www.hc-sc.gc.ca/dhp-mps/vet/legislation/guide-ld/classification-eng.php
Exploring the Potential for a Feed Category – Gut Modifier

Recognizes the mode of action on gut microflora and/or gut modification

- Create a category in the new ingredient listing as “Gut Modifier”
  - Currently listed as Cultures under the Miscellaneous Category
  - Production/Performance claims allowed

- Drug/Feed Working Group has met to determine feasibility of the category and potential claims

- VDD and CFIA continue to work together to explore solutions and to formalize the process
Exploring the Potential for a Feed Category: Gut Modifying

Veterinary Drugs:

• Products claiming pathogen reduction or control
• Products claiming to be replacements for antimicrobials
• These products would remain under oversight of HC
• This approach is internationally consistent
• Discussions in Canada – on-going:
  – Labelling statements
  – Guidance documents
  – Industry role
  – Others?
Pilot Project for the Classification and Registration of Products as Feeds

- For products already approved as feed in other jurisdictions
- Aim to determine if data provided to other jurisdictions would be suitable for a similar classification and registration in Canada as a feed
- 1 out of 15 products fulfilled the criteria requirements
- No additional products have been submitted
- We are open to receiving more!
QUESTIONS