Overview of the CFIA’s Modernization Agenda

Presentation to the Canadian Animal Health Institute

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Purpose

To provide an update on the CFIA’s modernization activities
• Agency overview
• Update on modernization of the *Feeds Regulations*
A changing environment calls for a new approach

- Canada needs a system that is more:
  - preventive
  - robust
  - transparent
  - supported by modern
technology, tools
  and training

- We are moving to a more preventive system whereby risk and resources are consistently managed across the Agency.

- We are enhancing how we conduct inspections and deliver programs and services.
Our progress

Some modernization activities are already complete:

• Online food labelling tools for industry and consumers
• Web repository for regulatory guidance documents
• Inspection Verification Teams
• Office of Complaints and Appeals
• Central administrative service centres
Path forward
As we transform and enhance the CFIA, we will continue to:

- Consult with staff, external clients and stakeholders
- Focus on open communication and transparency
- Monitor and manage our performance
- Ensure initiatives are integrated and sequenced
- Focus on providing increased access to timely and cost-effective services

Our next steps.....
A modern CFIA…continuously improving

- **What it means**: Building on a strong foundation with new innovative approaches that will consistently manage risk and resources across the CFIA.

New approach to service

Stronger rules

Standard inspections

New ways to manage risk
Changing our service model

Yesterday
- No digital services
- Expertise in silos
- Many communication channels
- Not structured to optimize service delivery for clients

Today
- Modern access to services with “digital-first” approach
- Shared information
- Streamlined and transparent access to information
- Client-focused service delivery

Tomorrow
Changing our service model

- Online tools and resources to help industry comply with requirements
- Timely and plain language information provided in various formats
- “My CFIA” with access to digital services

Progress and next steps
- Summer 2016: New online tools to be tested by select stakeholders
- December 2016: “My CFIA”, with access to new digital services, starts rolling out
Updated user fees and service standards

Yesterday

- Inconsistent
- Based on commodity (plant, animal and food)
- No formal service standards
- Imbalance in cost-sharing for services
- Resources allocated to private sector services
- Based on 1997 dollars

Today

- Streamlined and consistent
- Based on activity (licensing, inspections, etc.)
- Formal service standards tracked and reported
- More balanced cost-sharing
- Resources allocated to highest risk areas
- Indexed for inflation

Tomorrow
Updated user fees and service standards

- User fees and service standards to reflect modern practices and the actual cost of service delivery
- Consistency across all CFIA business lines (food, plants and animals) to ensure equal treatment

Progress to date
- 2016-17 (TBC): Consultation on the proposed service standards and user fees (possibly at the same time as the comment period for the proposed Safe Food for Canadians Regulations)
- 2016-17: Proposal for plant and animal health user fees and service standards to be finalized
- 2017-18 (TBC): New food user fees and service standards anticipated to come into effect
New food rules:
Safe Food for Canadians Act and Safe Food for Canadians Regulations

Yesterday
- Solid foundation
- Separate regulations for food commodities
- Prescriptive
- Complex

Today

Tomorrow
- More robust
- One regulation for all food commodities
- Prevention and outcome based
- Streamlined
New food rules: *Safe Food for Canadians Act* and *Safe Food for Canadians Regulations*

Three key elements based on internationally recognized standards:

- Licensing
- Traceability
- Preventive food safety controls

Progress and next steps
- 2016-17 (TBC):
  - Publication in *Canada Gazette, Part I*
  - Public consultation
New agriculture rules: *Agricultural Growth Act*

**Yesterday**
- Solid foundation
- Limitations for Canadian farmers in global markets
- Enforcement tools in place

**Today**

**Tomorrow**
- More innovative
- Enhanced global market opportunities
- Stronger enforcement tools (e.g., increased penalties)
New agriculture rules: *Agricultural Growth Act*

- Changes to *Plant Breeders' Rights Act* encourage investment in plant breeding and access to foreign seed varieties.
- Updates to *Feeds Act, Fertilizers Act, Health of Animals Act* and *Seeds Act* to include international science in product assessments.
- Consistent set of requirements and authorities across all agricultural statutes, including:
  - Licensing
  - Traceability
  - Preventive safety controls
- All of the CFIA sections of the *Agricultural Growth Act* are now in force except one, amending the definitions of "livestock" and "sell" in the Feeds Act, which occur with the regulatory change.
Feed Regulatory Modernization

Project initiated in 2012 to modernize federal *Feeds Regulations* as part of comprehensive CFIA transformation agenda

Objective - 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

Regulatory framework development and consultation phase completed – April 2016
Next Steps & Project Timelines

Phase 3: Complete consultation on Proposed Framework

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

Phase 5: Final Publication (CG Part II)

Agricultural Growth Act Implementation

Animal Health (including Feed) User Fees Modernization
Feed Regulatory Modernization

Next Steps (2016-17)

✔ Compile and analyse all stakeholder feedback submitted in response to Town Halls & Consolidated Proposal
  • Incorporate feedback into policy decisions to inform regulatory drafting instructions / proposed regulatory text

✔ Continue development of Gazette-ready package for winter/spring 2017 pre-publication
  • Collaborate with RLEAD in preparation of Cost-Benefit Analysis (CBA) and other TBS-required documentation / analyses

✔ Consult on several supporting technical proposals associated with modernized regulatory framework is
  • In particular, a few projects targeting use of AGA authority that enables Incorporation by Reference (IbR)
## Proposed Documents for IbR

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<th>#</th>
<th>Document</th>
<th>Status</th>
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<tbody>
<tr>
<td>1</td>
<td>Collective Feed Ingredient Terms (Labelling)</td>
<td>Consultation completed (2015)</td>
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<td>2</td>
<td>Permissible Claims on Feed Labels</td>
<td>Consultation – Spring 2016</td>
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<tr>
<td>3</td>
<td>Nutrient Guarantees on Feed Labels</td>
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<td>4</td>
<td>Veterinary Biologics in Feeds</td>
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<td>5</td>
<td>Oversight of Weed Seeds in Feeds</td>
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<td>6</td>
<td>Maximum Nutrient Levels in Feeds</td>
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<tr>
<td>7</td>
<td>Maximum Contaminant Levels in Feeds</td>
<td>Consultation – Later in 2016</td>
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<tr>
<td>8</td>
<td>Positive List of Approved Ingredients</td>
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<tr>
<td>9</td>
<td>Compendium of Medicating Ingredient Brochures (CMIB)</td>
<td>IbR in Regulations at present; Consult jointly w/ HC later in 2016 on updated CMIB (AMR)</td>
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Understanding the risk landscape and focussing Agency efforts

Yesterday

- Solid foundation based on traditional business models
- Resource allocation based on service needs within programs
- Decisions based on variety of inputs

Today

Tomorrow

- More systematic, objective, and evidence-based
- Resource allocation based on data and risk-analysis tools and greatest impact
- Decisions also informed by mathematical models
Understanding the risk landscape and focussing Agency efforts

- **Integrated Risk Management Framework** to better understand and manage risk across the Agency and set priorities at all levels of the organization

- **Program Management Framework** to guide the design and management of CFIA programs

- **Establishment-based Risk Assessment (ERA)** model to assess risks with different food-processing establishments

**Progress and next steps**

- Ongoing: Internal consultations on the Integrated Risk Management Framework
- June 2016: CFIA will begin implementing the ERA model in the dairy sector
- October 2016: ERA expanded to fish, seafood, fresh fruit and vegetable sectors
- By June 2017: ERA expanded to all remaining registered sectors
- 2016-17: CFIA will begin applying the Program Management Framework to its program design and management
Enhancing how we conduct inspections

Yesterday

• Prescriptive
• Based on **WHAT** is inspected
• Hardcopy inspection records with various tracking tools
• Decentralized advice and guidance

Today

Tomorrow

• Outcome based
• Based on **HOW** to inspect
• Single digital database for inspection records and tracking
• Nationally consistent advice and guidance
Enhancing how we conduct inspections

The integrated Agency Inspection Model (iAIM):

- defines a standard inspection process for all regulated commodities: plant, animal and food — whether domestically produced, imported or exported
- increases consistency and maximizes opportunities under the digital service strategy

Progress and next steps

- Fall 2014: Centres of Expertise established to provide consistent national advice and guidance to inspectors
- Fall 2015: Initial phase-in of iAIM in select regions and specific commodities for fish, dairy, oil seeds and the current greenhouse export certifications program.
- Fall 2016: iAIM expanded to include target specific commodities related to dairy, fresh fruit and vegetables and permits for specified risk material
- December 2020: iAIM to be fully implemented
Going forward, the CFIA will continue to strengthen and enhance its strong foundation. It will:

- develop programs and inspect based on science and risk
- align with international standards
- feature common activities and standard processes
- support industry compliance with regulations through enhanced tools and services
- provide increased access to timely, cost-effective services
- take advantage of modern technologies
For more information

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Topics To Cover

• Personnel Updates
• Veterinary Biologics Service Performance Standards
• Update on the phased submissions pilot project for vaccines from the USA
• Update on US Single Tier Label Rule
• Update on Good Manufacturing Practices (GMP) implementation
Canadian Centre for Veterinary Biologics (CCVB)
Personnel Updates

• National Manager
  Departure of Dr. Glen Gifford for an OIE assignment
  Dr. Pawan Agrawal is Acting until September, 2016
  Staffing action

• Veterinary Biologics Evaluators
  Dr. Carolyn Cooper has moved to AAFC
  Staffing actions (2)

• VB service delivery will not be affected during the transition
Service performance standards: Initial reviews of new VB product submission review

- Staffing pressures and workload have made it difficult for CCVB to meet all performance standards and to take on new initiatives.
- For FY 2015-16, CCVB reports a backlog for new product submission initial reviews:
  - 50% were completed within service standard of 120 days.
  - Remaining initial reviews completed by 180 days.
Update on the ‘phased submissions’ pilot project for review and approval of vaccines from the USA.

• The CCVB will no longer accept new product submissions for a phased review.
  • Process does not expedite licensing
  • Internal administrative burden
  • Pressure on limited resources
  • Backlog is not resolved

• Phased review of US product submissions will continue on a case-by-case basis for vaccines in support of the CFIA program and for new/emerging diseases.
US Single Tier Label Claim implementation: an update (1)

- New US Rule for label text replaces current 4-levels of efficacy claims with one general efficacy statement.
  - “This product has been shown to be effective for vaccination against (disease) in (animal species).”

- New USDA webpage to summarize efficacy and safety studies.

- Rule to be implemented once related US Labeling and Packaging Rule is approved.

- The CFIA CCVB should be able to accommodate the simplified format for efficacy claims provided the manufacturer's labels meet Health of Animals Regulations requirements and VB labelling guidelines.

- The CFIA CCVB is not establishing a similar, bilingual website of efficacy/safety information in Canada.
Feasibility Review of GMP Implementation

• CCVB initiated a feasibility review of implementing Good Manufacturing Practices for veterinary biologics in Canada.

• Initiative is temporarily ON HOLD due to resource issue.
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