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.

Regulatory Modernization - Status Update and Next Steps

Seed Applied Technologies Committee
Canadian Seed Trade Association
Banff, AB, 2014
Overview

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Fertilizer Program

Mandate
To ensure that all fertilizers and supplements, imported into or sold in Canada, are:
• **safe** with respect to human, plant, animal health and the environment; and
• **properly labelled** to promote safe use.

**Note:** efficacy, quality and product performance are no longer regulated by the CFIA – the focus is on **safety**

Regulatory Authority
• *Canadian Food Inspection Agency Act*
• *Fertilizers Act and Regulations*
• *Health of Animals Regulations* (for Enhanced Feed Ban)
• *Canadian Environmental Protection Act* (CEPA 99) Sch. II and IV
Regulated Products

The Fertilizer Program regulates a wide array of fertilizer and supplement products, imported or sold in Canada for agricultural, commercial, and home and garden purposes. These include:

- Farm fertilizers
- Micronutrient fertilizers
- Lawn and garden products
- Chemical supplements and plant growth regulators
- Microbial supplements including legume inoculants
- Waste-derived materials including processed sewage
- Composts

**Fertilizer:** any substance or mixture of substances containing nitrogen, phosphorus, potassium or other plant food, manufactured, sold or represented for use as a plant nutrient.

**Supplement:** any substance or mixture of substances, other than a fertilizer, that is manufactured, sold or represented for use in the improvement of the physical condition of soils or to aid plant growth or crop yields.
Regulated Products

Registration vs. Regulation

Some products are regulated and require registration (e.g. micronutrients and microbial inoculants)
  • Products that require registration must receive a registration number prior to product sale or import into Canada.

Some products are regulated and exempt from registration (e.g. items listed in Schedule II)
  • Products that are exempt from registration are free to enter the marketplace but must meet labelling requirements and safety standards.
**Key Program Activities**

1. **Health and Safety**
   
   **A. Pre-market assessment** of product safety in support of registration/LONO

   - **Potential Chemical Contaminants**
     - Heavy metals
     - Chlorinated organics
     - Endocrine disruptors
     - Pharmaceutical residues

   - **Potential Microbial Contaminants**
     - Toxins
     - Allergens
     - Pathogens

   - **CO₂**

   - **Supplements** → Fertilizers

   - **Food and Feed Safety; and Human Health**

   - **Environmental Health**

   - **B. Development of Safety policies and standards**, including allowable limits for chemical and biological contaminants.

   - **C. Verification** of product compliance with safety standards-heavy metals, pesticide residues and pathogens;

   - **D. Label reviews** for mandatory labelling of safety information and precautionary statements.

   - **E. Verification of records** to ensure compliance of requirements of the Enhanced Feed Ban (joint authority under FzR and Health of Animals Regulations).

   - **F. Research Authorization** for novel supplements
2. Market Access

- **Import Control**: Registration requirement and import inspections
- **Exports**: Although not regulated under the *Fertilizers Regulations*, Canadian approval or letter of free sale often requested by importing country prior to export

3. Consumer Protection

- **Label reviews**: Adequate safety information including precautionary statements to protect the consumer.
- **Guaranteed analysis**: User awareness and safe and sustainable product application (rate, frequency, target crop)
- **Product Inspection**: Marketplace monitoring of regulated products - label reviews, verification of registration, and sampling/testing for contaminants.

4. Other Activities

- International Standard setting
- Stakeholder Engagement
- OGD and FPT Cooperation
- Regulatory research and oversight
In December 2011, the Agency announced a multi-year regulatory modernization plan. It involves a systematic review of the regulatory frameworks for food safety, plant health and animal health.

The regulatory modernization proposal for the Fertilizer Program builds on the recent (April 2013) changes to *Fertilizers Regulations* (removal of efficacy and quality oversight) using innovative approaches:

- **Outcome-based regulations**
- **Removal of prescriptive provisions from the Regulations**
- **Risk-based model – level of regulatory oversight is proportional to product’s risk profile**

The regulatory proposal aims to lessen regulatory burden on products that are deemed safe and have a well-established history of use, and to provide greater flexibility and less red tape for the regulated sector.
Key Elements of Change

• Changes to certain definitions (add/delete or amend) – outside of Schedule II
• General exemptions (clarify exemptions for export, import for manufacturing purpose, repeal “personal use” exemption)
• Revise the exemption from registration (focus on high risk products)
• Streamline labelling requirements:
  • Core mandatory information
  • Guaranteed analysis
  • Bilingual labelling
  • Misleading provisions – narrow the scope to product safety information
• Reduce administrative burden:
  • Remove application form from the Regulations
  • Extend the registration period to 5 years
  • Re-define major and minor amendments
• Policy instruments – tiered registration model
• User Fees Review conducted in parallel
Consultations

• The CFIA co-hosted a regulatory workshop with the Canadian Fertilizer Products Forum (CFPF) on October 16-17, 2012

• Attendees included fertilizer and supplement companies (both domestic and US), industry associations, producer groups, other Government Departments (AAFC and PMRA), provincial representatives (CCME OMAFRA) and CFIA staff (HQ and regional)

• There was overall agreement with the principles, objectives and proposed outcomes of the regulatory modernization initiative

• The comments received at the meeting were considered and incorporated (where possible) into the regulatory proposal

• The proposal was posted for a 60 day public pre-consultation (closed September 17, 2013 – few comments were received)
There was strong AGREEMENT with:

- Safety focus of the regulatory framework
- Maintenance of outcome-based provisions for safety
- Streamlining labelling requirements and the submission format (flexibility)
- Blend of regulatory and policy instruments (revised exemption scheme + tiered registration model)
- Re-defining major and minor amendments

There was a LACK OF CONSENSUS (mixed views) on:

- Future placement of Schedule II
- Mandatory listing of ingredients on product labels
- Personal use exemption
- Bilingual labelling
- Mandatory registration of N, P, K blends containing micronutrients
- Removal of the delineation between specialty vs. farm fertilizers
CFIA Positions

Future placement of Schedule II
- Flexibility and enforceability were considered
- Will remain in the Regulations unless a more appropriate option is available

Personal use exemption
- CFPF surveyed producers in Fall 2012
- Will be repealed given survey response as well as narrow scope of products affected (micronutrients)

Bilingual labelling
- Required by Official Languages Act for health and safety information
- Will be required for core and safety information
CFIA Positions

Mandatory registration of NPK blends with micronutrients
  • Will be required to ensure oversight of micronutrient products
  • Products containing registered micronutrient are exempt

Removal of the delineation between specialty vs. farm fertilizers
  • A reduction in regulatory oversight of the safety of consumer (specialty) fertilizer is not supported
  • Intended to ensure proper oversight for products intended for home and garden applicators where the use patterns and exposure scenarios are very different than in agricultural settings

Mandatory listing of ingredients on product labels
  • Safety risk is highly dependent upon the nature of the material (i.e. ingredients)
  • Will be required to ensure the CFIA can properly implement a risk-based approach and fulfill its safety mandate
  • CFIA to develop and consult on guidelines for ingredient listings
Next Steps and Anticipated Timelines

Regulatory amendment process (spring/summer 2014):

- Drafting instructions (regulatory text)
- Triage statement
- Cost benefit analysis to help determine the impacts (benefits and incremental costs) of the regulatory proposal:
  - Small Business Lens
  - One-for-one
  - Cost/benefit questionnaires
    1) fertilizer and supplement manufacturers and blenders;
    2) Primary producers;
    3) municipalities

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Annex: Risk-Based Approach to Regulation

With the CFIA’s focus on safety and the application of a risk-based approach:

• Regulatory decisions can no longer be based solely on label representation.

• Exemptions from registration must be based on the level of safety risk.

• Safety risk is highly dependent upon the nature of the material (i.e. ingredients).

There is an inherent problem with applying a risk-based approach where the risks are unknown (i.e. what is in the product?)
Annex: Risk-Based Approach to Regulation

Listing of Ingredients:

• Allows the CFIA to properly implement a risk-based system and fulfill its safety mandate, ie. safe for plants, animals, human health and the environment.

• Greater transparency allows consumers to make informed decisions.

• Supports principles of sustainable agriculture.

• Disclosure of ingredients is consistent with other commodities (e.g. food and animal feed).