

Proposed Licensing and Product Approvals as an Alternative to Individual  
Product Registrations Under the *Fertilizers Act*

CFPF Recommendations  
to the  
Canadian Food Inspection Agency

December, 2017

## Executive Summary

As part of an ongoing review and modernization of the [Fertilizers Regulations](#), the Canadian Food Inspection Agency (CFIA) is considering a licensing option to fulfill its pre-market regulatory oversight of fertilizers and supplements. Authority for a licensing option is possible as a result of amendments to the [Fertilizers Act](#)<sup>1</sup>, afforded by the [Agricultural Growth Act](#). In principle, licensed facilities could seek multiple product approval through an expedited process, as an alternative to individual product registration.

During the Canadian Fertilizer Products Forum (CFPF), held in Ottawa, November 1-2, 2016, CFPF participants agreed to form a new Licensing Working Group to discuss the benefits and limitations of a licensing option, and make recommendations to the CFIA with regard to any further exploration of the option. Membership in the Working Group was on a voluntary basis. Members of the Working Group represent the federal government, blenders, manufacturers, importers, agricultural retailers, and multi-national companies from both the consumer and agricultural sector of the market, and a broad range of products consisting of fertilizer, specialty fertilizer, supplements, and biotech, regulated under the *Fertilizers Act* and *Regulations*.

The cornerstone of licensing would be a [preventive control plan](#) (PCP) – a combination of control measures that, when taken as a whole, provide for a science-based approach to managing risks as part of achieving compliance with regulatory requirements. Preventive control plans are already used by CFIA in administering and enforcing other Acts and Regulations under its purview.

Having considered both the potential benefits and limitations of a licensing regime, the Working Group has concluded that licensing under the *Fertilizers Act*, combined with an expedited product approval process could be a beneficial option to individual product registration, for at least some of the regulated community. However, there are also limitations that make it less attractive to certain sectors at this time. The Working Group believes that licensing should be explored further by CFIA in consultation with CFPF.

Twelve recommendations have been made by the Working Group for future consideration, including the recommendation that the CFIA continue to work with industry stakeholders to develop a detailed proposal for a licensing regime.

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## Introduction

Fertilizers and supplements imported or sold in Canada are regulated by the Canadian Food Inspection Agency (CFIA) under the authority of the *Fertilizers Act* and *Regulations*. The *Fertilizers Act* and *Regulations* are the framework for a science-based approach to decisions supporting the CFIA mission to provide Canadians with a safe, secure source of food. As part of its [Modernization of the regulatory framework](#), CFIA has undertaken a multi-year, staged review of its regulations for food safety, and plant and animal health as part of fulfilling its core mandate to:

- Keep food safe and protect animal and plant resource base;
- Provide the appropriate level of government oversight;
- Deliver services more consistently; and
- Integrate changes in science and technology.

According to the [CFIA Forward Regulatory Plan, 2017-19](#), pre-publication in *Canada Gazette*, Part I, of *Regulations Amending the Fertilizers Regulations* is scheduled for Spring, 2018.

CFIA is considering a licensing option to fulfill its pre-market regulatory oversight, in addition to the current individual product registration process. A licensing option is consistent with the CFIA mandate, delivering regulatory oversight commensurate with the level of risk to human health and the environment. Authority for the licensing option is a result of amendments to the *Fertilizers Act*<sup>1</sup> afforded by the [Agricultural Growth Act](#). While preliminary discussions and surveys of the regulated industry have taken place, the licensing option will not be part of the regulatory amendments scheduled for pre-publication in *Canada Gazette*, Part I, in Spring, 2018.

The CFIA's fertilizer program currently focusses on the final product's compliance, rather than use a [systems-based approach](#) to evaluate the manufacturing process and effectiveness of processing treatment and quality assurance measures. The premise for the licensing option is that the risk of harm to human, animal or plant health or the environment from certain fertilizers and supplements could be determined using other upstream methods such as facility licensing. Providing the option of a system-based approach is consistent with the CFIA [Integrated Agency Inspection Model](#).

The CFIA resources and adherence to service delivery standards will be challenged by cannabis legalization and regulation in Canada because a major increase in applications for micronutrients and plant growth regulators is anticipated. Cannabis legalization further emphasizes the importance of finding other modernization options to ensure that CFIA continues to meet its mandate; a licensing option could alleviate some of the CFIA resource

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<sup>1</sup> Relevant definitions from the *Fertilizers Act*:

**Person 5.2(1)** The Minister may, on application, register a person, or issue a licence to a person, authorizing them to conduct a prescribed activity in respect of a prescribed fertilizer or supplement that has been imported for sale — or that is to be exported or to be sent or conveyed from one province to another — or both register a person and issue them a licence.

**Establishments 5.3(1)** The Minister may, on application, register an establishment as one where a prescribed activity may be conducted in respect of a prescribed fertilizer or supplement that has been imported for sale or that is to be exported or to be sent or conveyed from one province to another.

**Holder (2)** The applicant in respect of an establishment is the holder of the registration.

pressure and workloads associated with increased numbers and complexity of submissions for individual product registration. In consideration of the impact on the fertilizer and supplement industry, CFPF formed a separate Cannabis Working Group to review the implications of [Bill C-45, Cannabis Act](#) and associated regulations on the fertilizer and supplement industry.

*“During the Canadian Fertilizer Products Forum (CFPF), held in Ottawa November 1-2, 2016, it was agreed to form a new CFPF working group to discuss and make recommendations to the Canadian Food Inspection Agency (CFIA) on licensing facilities. In principle, licensing facilities would allow multiple products to be approved under a single license, as an alternate to individual product registration.*

*The proposed working group will engage in dialogue and provide feedback regarding the feasibility and design considerations for a licensing program to work well in the current regulatory environment.” - Peter McCann, CFPF Chair, Letter of Invitation to CFPF members (February 6, 2017)*

## **Group Membership**

The Canadian Fertilizer Products Forum (CFPF) was formed by Fertilizer Canada in 2006 in joint partnership with the CFIA, to act as a consultative body to provide the framework for consultation; resulting in strengthened coordination among federal departments and agencies, increased transparency, and improved stakeholder engagement in the regulatory process. The CFPF provides a forum for the fertilizer & supplements industry to make recommendations to the CFIA for improvements to the regulatory system.

The government-industry Licensing Working Group (Working Group) was formed in 2016 through a volunteer process during the [November 2016 Canadian Fertilizer Products Forum](#) held in Ottawa, Ontario, Canada. Members of the Working Group represent the federal government, blenders, manufacturers, importers, agricultural retailers, multi-national companies from both the consumer and agricultural sector of the market and a broad range of products such as fertilizer, specialty fertilizer, supplements, and biotech, regulated under the *Fertilizers Act* and the *Fertilizers Regulations*.

Rich Adderley, Potash Corp Saskatchewan, served as the Working Group Chair. The CFIA was represented by Ewa Madey, PhD, National Manager, Fertilizer Safety Section. Nadine Frost, [Fertilizer Canada](#), coordinated the group teleconferences and recorded meeting minutes and summaries. A full list of the industry Working Group members can be found in Appendix 1.

## **Objectives of the Working Group**

The CFPF Licensing Working Group, in collaboration with the CFIA, was charged with developing a proposal for licensing persons. Subsequently, the proposal was distributed to the broader CFPF membership at the annual meeting in October, 2017. The proposal will also be made available on the [Fertilizer Canada website](#).

The licensing proposal takes into consideration all products and materials regulated under the *Fertilizers Act* and *Regulations* and not exempt from registration, as well as the regulated

community. Examples of activities and licensing options can be found in Appendix 2; not all will be candidates under the licensing regime for assorted reasons as noted.

This proposal addresses the following:

- Examine whether the mandate of CFIA to assess product safety and risk to human health and the environment can be achieved using upstream evaluation inherent to a licensing regime;
- Identify fertilizer and supplement product types that would be suitable candidates for a licensing regime within the context of the current *Fertilizers Act* and *Regulations*;
- Identify sectors of the regulated community that would be eligible, based on the *Fertilizers Act* and *Regulations*, to utilize the licensing regime;
- Identify barriers to licensing;
- Recommend general principles for the Preventive Control Plans (PCP);
- Identify the benefits and limitations of a licensing regime; and
- Make recommendations with regard to moving forward with a licensing option.

## **Description of the proposed licensing regime and eligible products**

Licensing is a powerful regulatory instrument that can augment or replace individual product registrations for certain product types. Under the *Fertilizers Act*, the CFIA can make regulations to licence a person to perform a specific activity. In addition to licensing, the *Fertilizers Act* provides authority to approve products via an expedited process. This expedited process would apply to products manufactured under a licence.

A licence could be issued to a person (which includes a corporation) authorizing them to perform a regulated activity (e.g. manufacture for the purpose of domestic sale) or a range of activities (e.g. manufacture and/or packaging for sale, importing product for sale, etc.) for a registerable product or products under the *Fertilizers Regulations*. In addition, a licence may be issued to a person to conduct activities in single or multiple physical locations (e.g. a company with multiple manufacturing plants across the country, but not foreign locations).

The cornerstone of licensing would be a [preventive control plan](#) (PCP) – a combination of control measures that, when taken as a whole, provide for a science-based approach to managing risks posed by hazards as part of achieving compliance with regulatory requirements. Preventive control plans are already used by CFIA in administering and enforcing other Acts and Regulations under its purview. The PCP approach builds on existing systems currently used by industry, and would be aligned with requirements already in place for registering products under the *Fertilizers Act* and *Regulations*. The information currently required to substantiate product safety in support of registration would be included in a PCP and would be reviewed and approved by the CFIA prior to issuing a licence. Furthermore, analytical tests conducted at regular time intervals (to be determined based on production parameters) would be required to demonstrate that the PCP is resulting in final products that are compliant. A pre-licence inspection of the establishment could also be required. As part of the inspections, the

operator would be required to maintain appropriate documentation (records) and provide them to CFIA officials on an ongoing basis as required in the PCP, or upon request. Failure to do so may result in cancelling the licence and any other compliance or enforcement action that would be merited.

Products manufactured under a license would obtain an approval number via an expedited review process.

Only products that require registration would be eligible for approval under the licensing regime. Appendix 2 provides a comprehensive overview of product eligibility to the licensing regime.

## **Benefits and limitations of the proposed licensing regime combined with product approval**

### **Benefits:**

- Creates a level playing field for products sold within a Province and those traded inter-provincially;
- Allows the CFIA to take enforcement action against a single product as opposed to against the licence (which would impact all activities covered by the licence);
- Provides a streamlined and expedited approval process for multiple products manufactured in accordance with the same PCP. This approach can significantly reduce administrative burden on both the Agency and the regulated party while maintaining the program safety mandate and facilitating compliance verification;
- Allows licensed toll manufacturing blenders to expeditiously respond to new product business opportunities; and
- Provides options to agricultural and consumer retailers to import fertilizers and supplements provided they are licensed (with an activity-appropriate PCP), and the products are approved.

### **Limitations:**

- Increases administrative burden for companies manufacturing a small number of different products;
- Complexifies and potentially expands the market inspection activities for CFIA;
- Introduces educational gaps with various stakeholders, including the regulated community, retailers, consumers, and compliance officials;
- Increases complexity for the portion of the regulated community utilizing domestic and/or foreign production facilities;

- Increases compliance activities for CFIA with importers such as retailers, who have previously not been active in the regulated community, potentially participating in the licensing option; and
- Complicates compliance for approved products imported by more than one licensed importer.

## **Recommendations**

### **1. Eligibility and Triggers for Licensing of persons**

We recommend that the CFIA define the eligibility criteria for licensing of persons (which includes a corporation) based on the information set out in Appendix 2.

### **2. Preventive Control Plans**

We recommend that the PCP be developed, documented, implemented, and maintained by the licensee. They should be outcome based, providing companies with the opportunity to develop PCPs that are compatible with their operations. The PCP should reflect the current level of oversight indicated by the registration requirements for [Safety Assessment Levels and Information Requirements](#) (Ref.: "[Guide to Submitting Applications for Registration Under the Fertilizers Act](#)")

We recommend that consideration be given to allow licensees to refer to other certifications (e.g. AWSA, ISO 9001, etc.) in their PCP, when information is overlapping.

### **3. Duration of a license**

We recommend that a license be renewable every five years, consistent with the duration of a product registration.

### **4. Cost of licensing and economic considerations**

We recommend that the industry be consulted when proposed fee structures are available, so that a more thorough economic comparison could be done. Licensing must be an economically viable option. It is challenging to provide an economic assessment to compare the current registration structure with a proposed licensing framework until further information is available for the proposed fee structures. Likewise, a fee structure and overall process, will need to be considered for those companies that, once implemented, opt to switch to the licensing regime.

### **5. Process and service delivery standards for issuing, renewing and amending a license**

We recommend that the CFIA define the process of issuing, renewing and amending a license in policy rather than regulations, whenever possible. The processes should be clearly defined and communicated to the regulated parties. Service delivery standards for issuing, renewing and amending a license will require further discussion with CFIA.



## **6. Process and service delivery standards for issuing and renewing a product approval**

We recommend that the service delivery standard for issuing a product approval, based on a valid license, be no more than 45 days, once the request is submitted to the CFIA. We recommend that the renewal of a product approval be made at the time of the license renewal (e.g. every five years).

## **7. Communications plan**

We recommend that the CFIA develop a targeted communication plan for, and with, specific stakeholders, such as the regulated community, agricultural community, consumers, compliance officials e.g., CFIA, inspectors, and the Canadian Border Services Agency.

## **8. Labelling of approved products / record keeping**

We recommend that licensees have the option to print product approval numbers on the label or keep records (associated, for example, with the lot number) to be provided upon request.

## **9. Phase-in of licensing regime**

We recommend that the licensing option be developed and finalized for implementation before the end of the transition period for the *Regulations to Amend the Fertilizer Regulations*. The licensing option will not be part of the regulatory amendments anticipated to be pre-published in *Canada Gazette*, Part I, in Spring, 2018. However, introduction of the licensing option during the regulatory transition period makes it a more viable and meaningful option for those companies wishing to use the licensing option.

We recommend that there be an expedited transition process to license approval for current registrants.

We recommend that the licensing of persons, combined with product approval, be an alternative to the current individual product registration, and not mandatory.

## **10. Confidentiality**

We recommend that within the licensing regime, the CFIA maintain protection of confidential business information and confidential test data.

## **11. Funding**

We recommend adequate funding is allocated to CFIA to develop and implement the license regime without compromising current activities and level of service.

## **Next Steps**

Based on these recommendations, the Working Group recommends that the CFIA continue to work with industry stakeholders to develop a licensing regime.

## **Conclusion**

Licensing of persons, as afforded by the *Fertilizers Act*, combined with an expedited product approval process, could be a beneficial option to individual product registration for both the CFIA and the regulated community, while maintaining the opportunity for intra- and inter-provincial trade. The Working Group believes that this option should be explored further by CFIA in consultation with the Canadian Fertilizer Products Forum.

## Appendix 1: List of CFPF Licensing Working Group Members

<b>Name</b>	<b>Company</b>
1. McCann Peter	Plant Inoculants Canada Inc., CFPF Chair
2. Ewa Madey	CFIA
3. Rich Adderley, Chair	PCS
4. Theresa Wildman	Plant Products Inc.
5. Cody Cruise	TerraLink Horticulture Inc. / Biofert Manufacturing Inc.
6. Lynda Nicol	CAAR
7. Abdel El Hadrami	OMEX Agriculture Inc
8. Rick de Jong	Agro-K
9. Ashley Vickress	NutriAg Ltd.
10. Joanne Steffes	Agrium
11. Carol Morgan	Agrium
12. Suzanne Beattie	Beattie Consulting Services
13. Elisabeth Price	Yara North America
14. Claudine Bégin	Premier Tech
15. Valérie Prémont	Premier Tech
16. Laura Barbison	Master Plant-Prod Inc.
17. Michelle Johnson	The Mosaic Co.
18. Dawne Fuchs	The Mosaic Co.
16. Nadine Frost / Clyde Graham	Fertilizer Canada

## Appendix 2: Eligible Activities for Facility Licensing

Facility Activities <sup>1</sup> eligibility to the licensing alternative to registration						
Product types <sup>4</sup>	Producer <sup>5</sup> of the finished products	Repackaging <sup>6</sup> of finished products (ex. for private label)	Producer of Customer formula products for end user	Distributor or Seller of finished product	Exporter of finished Product to Canada	Importer of finished product
Micronutrients  + Microbial OR Supplement	Registration or Facility License <sup>2</sup>	Me-too Registration or Facility License <sup>2</sup> of precedent product	Exempt from Registration and Licensing 3.1(3)(f)	Assure compliance before sale	Not eligible for licensing; can be registrant with Canadian agent	Registration or Facility License <sup>2</sup>
	Registration	Me-too Registration or Facility License <sup>2</sup> of precedent product	Registration, Licensed Facility or Use products from Licensed or registered sources	Assure compliance before sale	Not eligible for licensing; can be registrant with Canadian agent	Registration or Facility License <sup>2</sup>
Supplement	Registration or Facility License <sup>2</sup>	Me-too registration	Registration, Licensed Facility or Use products from Licensed or registered sources	Assure compliance before sale	Not eligible for licensing; can be registrant with Canadian agent	Registration or Facility License <sup>2</sup>
Microbials	Registration or Facility License <sup>2</sup>	Me-too registration	Registration, Licensed Facility or Use products from Licensed or registered sources	Assure compliance before sale	Not eligible for licensing; can be registrant with Canadian agent	Registration or Facility License <sup>2</sup>
Mineral NPK  Mineral NPK + micronutrient OR Supplement OR Microbial Product	Exempt from Registration and Licensing	Exempt from Registration and Licensing	Exempt from Registration and Licensing	Assure compliance before sale	Not eligible for licensing; can be registrant with Canadian agent	Assure compliance with Fertilizers Act and Regs.
	Registration or Facility License <sup>2</sup> (exempt if micro, supplement or microbial is registered or produced under a license)	Me-too Registration or License of precedent product	Registration, Licensed Facility or Use products from Licensed or registered sources	Assure compliance before sale	Not eligible for licensing; can be registrant with Canadian agent	Registration or Facility License <sup>2</sup>
Non-mineral NPK and non-Sch. II (ex. amino acid chelate, seaweed/kelp, humic acid, cold pressed fish emulsion)	Registration or Facility License <sup>2</sup>	Me-too Registration or License of precedent product	Registration, Licensed Facility or Use products from Licensed or registered sources	Assure compliance before sale	Not eligible for licensing; can be registrant with Canadian agent	Registration or Facility License <sup>2</sup>
Schedule II	Exempt from Licensing and Registration	Exempt from Licensing and Registration	Exempt from Licensing and Registration	Assure compliance before sale	n/a	Assure compliance with Fertilizers Act and Regs.

Schedule II + Micronutrient OR Supplement OR Microbial Product	Registration or Facility License <sup>2</sup> (exempt if micro, supplement or microbial is registered or produced under a license)	Me-too Registration or License of precedent product		Assure compliance before sale	Not eligible for licensing; can be registrant with Canadian agent	Registration or Facility License <sup>2</sup>
Innoculants (live organisms applied to seeds)	Registration of primary product	Further review <sup>3</sup>	Further review <sup>3</sup>	Assure compliance before sale	Not eligible for licensing; can be registrant with Canadian agent	Assure compliance with Fertilizers Act and Regs.
Innoculants (non-viable items ex. a fertilizer applied to seed )	Registration	Me-too registration	Assure compliance before sale	Assure compliance before sale	Further review <sup>3</sup>	Further review <sup>3</sup>
Polymers	Not regulated as stand alone product	N/A	N/A	N/A	N/A	Registration of primary product
Polymer + fertilizer	Registration of primary product	Not covered in Licensing		Assure compliance before sale		
Nano-technology	Registration	Further review <sup>3</sup>	Further review <sup>3</sup>	Assure compliance before sale	Further review <sup>3</sup>	
Fertilizer + Pesticide	PMRA registration first, then CFIA Registration		Exempt from Registration and Licensing 3.1(1)			

<sup>1</sup> Facility Activities:

- a) Acceptable Preventive Control Plans (PCP) are in effect and
- b) Proposed Regulatory Modernization is already in force
- c) Licensing is not an option for products exempt from regulation or registration

<sup>2</sup> To be Eligible for Facility License:

A product is produced under license and together with product approval for an intended purpose.  
Facility will have an approval number for a specific activity that covers product approvals and inter-provincial trade.

<sup>3</sup> further review

Discussion incomplete at this time; CFIA is reviewing

<sup>4</sup> Product Types

Excludes Fertilizers and supplements in any Product Type that will be exempt from regulation or registration as per the proposed Regulatory Modernization

<sup>5</sup> Producer

Manufacturer of finished products; includes creating blends with products that are either exempt, registered or under a Facility License

<sup>6</sup> Repackaging

Strict one-to-one product packaging; no alterations (ex. zinc sulphate bought in bulk and repacked to 2kg with private label)