Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Regulation of products that are or contain polymers under the *Fertilizers Act*

CFIA webinar series
January 14, 2021

Canada

Outline

1. Background and historical perspective
2. Definition of a supplement
3. Revised policy interpretation approach: regulation of polymers
4. Technical requirements
5. Proposed phased-in implementation for products currently in the marketplace: feedback requested
6. Consultative Process
7. Additional sources of information

Legislative authority

A fertilizer is defined in the *Fertilizers Act* as any substance or mixture of substances, containing nitrogen, phosphorus, potassium or other plant food, manufactured, sold or represented for use as a plant nutrient; (engrais)

A supplement is defined in the *Fertilizers Act* as 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; (supplément)

Please note that the definition of a supplement does not specify whether the effects to be conferred by the material are direct or indirect.

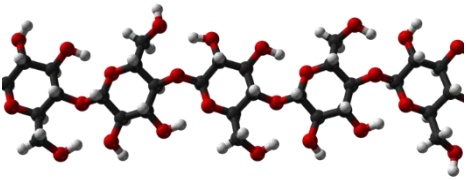



Historical perspective

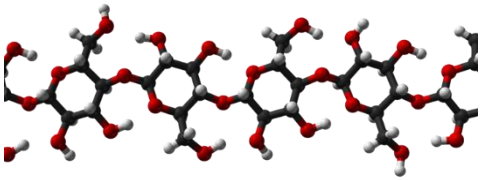
Historically, the CFIA interpreted supplemental properties to mean effects that **directly** impacted the physical condition of the soil (e.g. wetting agents) or resulted in changes to plant morphology, physiology or development that improved its in-field performance (e.g. rhizobial inoculants applied to seed or in furrow).

This narrow interpretation of the definition of a *supplement* presented increasing challenges as new product types and technologies entered the commercial streams.

Additives (indirectly aiding plant growth or crop yield) sold alone did not “fit” the CFIA’s interpretation of either a fertilizer (plant nutrient) or a supplement (with direct effects on the plant or the physical condition of the soil).

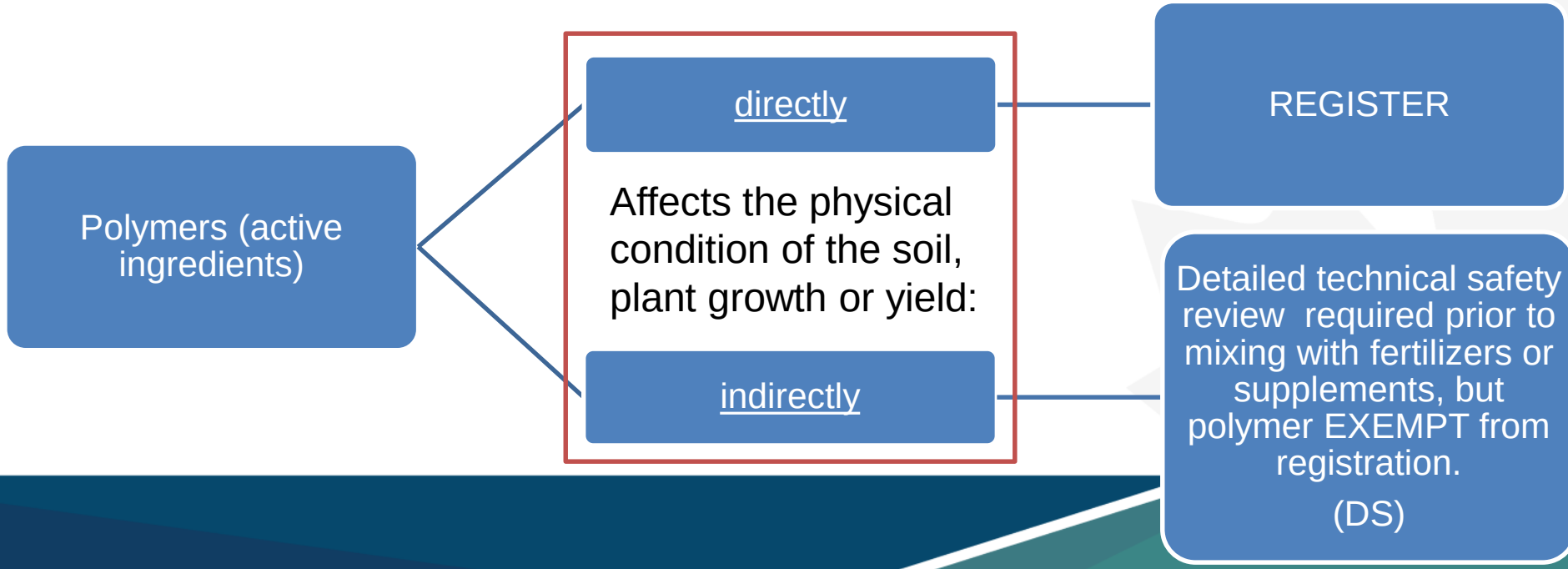


Historical approach: regulation of polymers



To bridge this gap in regulatory oversight and minimize any potential risks the final fertilizer or supplement product might pose to human, plant health or the environment, additives were required to undergo a comprehensive safety assessment before they could be marketed for use with or applied to fertilizers in Canada.

This approach was developed as an alternative to mandatory registration of all individual formulations that contained a given additive.



Evolution of the revised policy interpretation of the definition of a supplement

2016: Pest Management Regulatory Agency (PMRA) announced that, based on their general mode of action, inhibitor products would be regulated under the *Pest Control Products Act*.

July 2017: Fertilizer Canada submitted a position paper to both the CFIA and the PMRA titled: *Nitrogen Management Products: Regulation of Nitrification and Urease Inhibitors in Canada,* in which they recommended that the CFIA should regulate all fertilizers and their additives (including nitrification and urease inhibitors), under the *Fertilizers Act*.

Early 2018: After discussion (industry, PMRA and the CFIA), the PMRA evaluated the scope of CFIA's assessments and deemed it equivalent to PMRA's with respect to safety and environmental endpoints.

This, together with broadening of the interpretation of a *supplement* to include both direct and indirect effects, allowed the CFIA to exclusively regulate urease and nitrification inhibitors under the *Fertilizers Act* without triggering the registration requirement under the PCPA.

Definition of a supplement

A **supplement** means 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.

This definition covers materials that both directly and indirectly affect plant growth, crop yield or impact the physical condition of the soil.

This broader interpretation now forms the lens through which the CFIA identifies and regulates supplement products.

This change also means that all polymer additives that meet the new interpretation of a *supplement* under the *Fertilizers Act* will require registration.

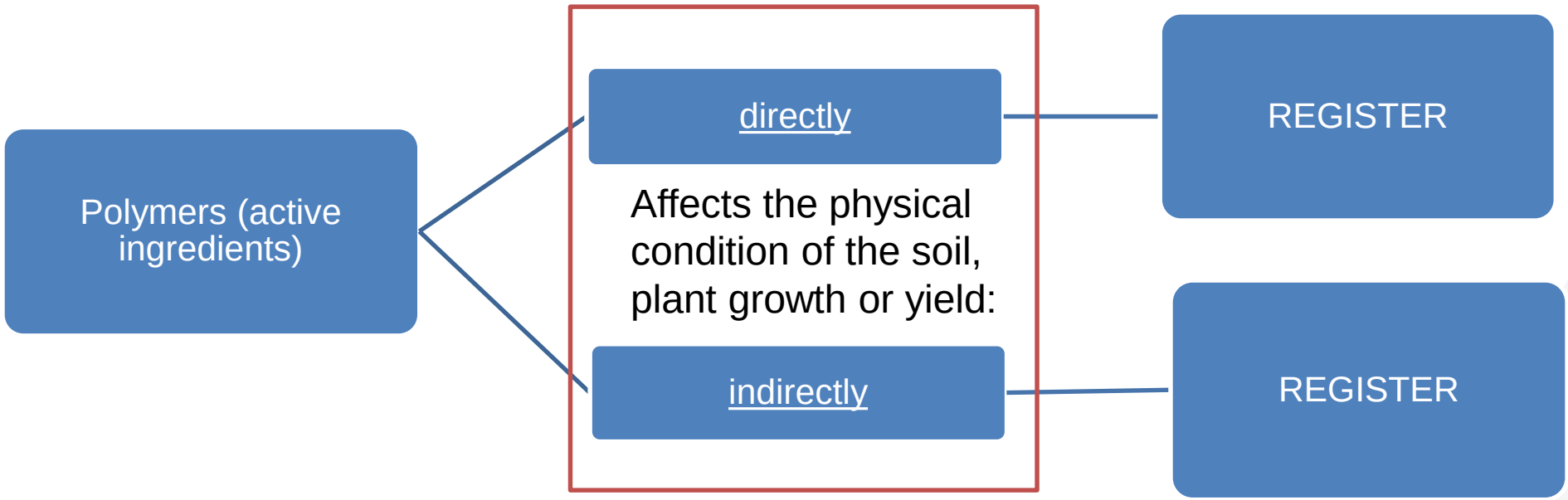
Note regarding biostimulants

While not defined in Canadian legislation, two definitions were recently formalized in the European Union and the USA, respectively.
Both of these definitions include:
products that promote growth and/or improve tolerance to abiotic stress, while excluding products that act on biotic stress (i.e. pests and diseases).

In Canada, materials termed “biostimulants” elsewhere are considered “supplements” under the authority of the Federal *Fertilizers Act* and *Regulations:*

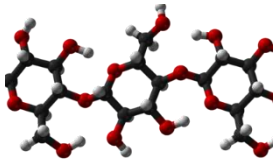
> *any substance or mixture of substances, other than a fertilizer, that is manufactured, sold or represented for use in the improvement of the physical condition of soils or to aid plant growth or crop yields.*

Revised policy interpretation of the definition of a supplement: regulation of polymers

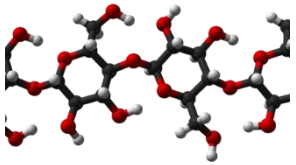


Expanded polymer registration requirement under the *Fertilizers Act* is a direct result of the revised policy interpretation of the definition of a supplement.

When they are active ingredients, polymers are supplements and require registration.



Polymers considered supplements: definition of an active ingredient



Q: Is my polymer considered a supplement? Does it require registration?

A: If it's an active ingredient, it requires registration as a supplement

Active ingredient: means an ingredient of a fertilizer or supplement to which its performance as a fertilizer or supplement is attributed

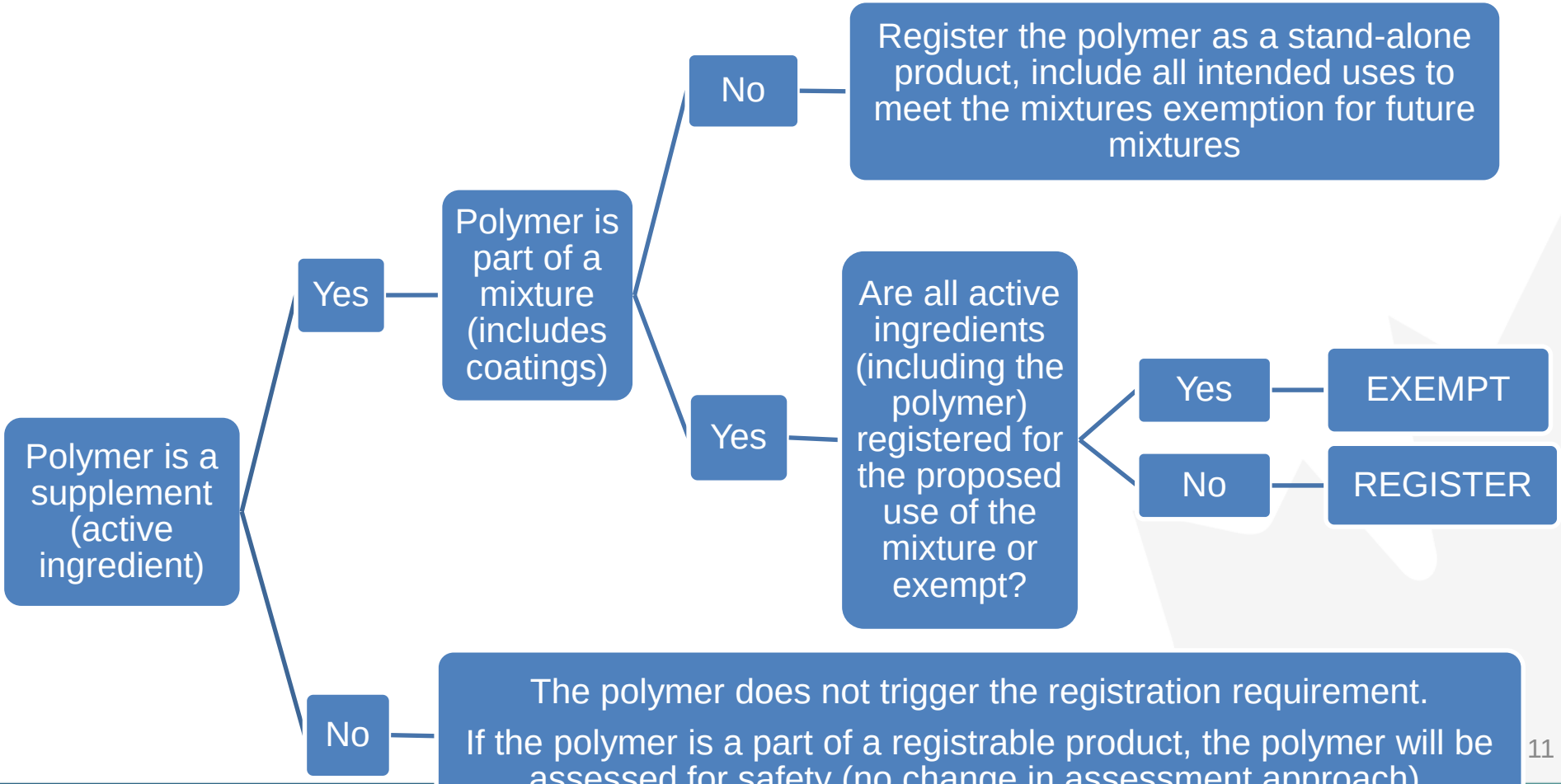
Examples of polymers that are supplements:
-wetting agents
-nutrient release modifying/controlling polymers
-polymers increasing/modifying nutrient availability

Inert ingredient is a substance that is not a fertilizer, supplement or pesticide that is added as a filler or to improve the product's physical characteristics such as sprayability or spreadability, but not to change its performance as a fertilizer or supplement

Examples of polymers NOT considered supplements:
-polymers that lubricate seed or planter systems
-formulation antifoam, antifreeze and polymers applied to prevent seed treatments from peeling

Mixtures

Q: Does my polymer product require registration?



Mixtures continued…

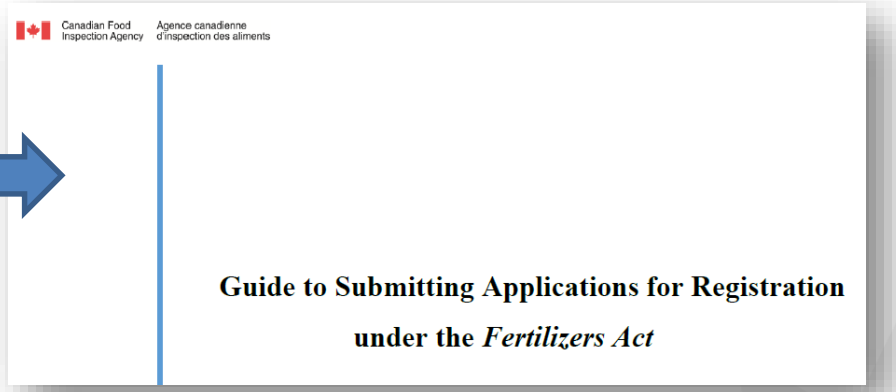
Mixtures are exempt from registration only if each ingredient is exempt from registration, or is registered for the proposed use of the mixture.
Note that the directions for use of the mixture must be consistent with those of the registered ingredient(s). (e.g. target crop, use pattern, application rate, frequency and method)

Product 1: Supplement registered for the proposed use of the mixture	+	Product 2: Exempt material or product registered for the proposed use of the mixture.	=	**Exempt Mixture**
Product 1: a polymer coat for controlled release of nutrients. Registered for use on X,Y,Z nutrients.	+	Product 2: exempt nutrient X	=	**Exempt Mixture**

Technical requirements

Polymers that are active ingredients are **regulated as supplements**.

Follow the Guide to submitting applications for registration under the *Fertilizers Act* for submission requirements.



Guaranteed Analysis

Polymers that are active ingredients must be guaranteed as a minimum percentage in the final product formulation by weight.

The description of the polymer must be in agreement with the corresponding Chemical Abstract Service Registry Number (CAS RN) listing.

Technical requirements

Please note: there are no new safety data requirements.
Polymer products continue to require a Level III risk-based, product specific safety assessment

- **Process of manufacturing or extraction**

relative proportions of monomer(s), cross-linker(s), and catalysts used in the manufacturing process and analytical results to demonstrate the residual levels of these compounds in the final product.

- **Toxicological hazard characterization** for the polymer(s), any other active and inert ingredient(s) and for the residual monomers, cross-linkers, catalysts and any potential degradation products (where applicable).

- **Exposure assessment is required**

If the polymer, any of its ingredients or degradation products are recognized to exhibit (potential) carcinogenicity, mutagenicity, reproductive toxicity, developmental toxicity, teratogenicity or endocrine disruption activity. (hazard criteria outlined in Appendix 4 of the Guide).

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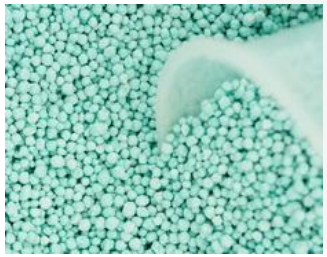
Technical requirements

Please note: there are no new safety data requirements.
Polymer products continue to require a Level III risk-based, product specific safety assessment

- **Food-safety assessment:** Provide a scientific rationale and/or data to address the risk of uptake and incorporation of monomers, cross-linkers and any degradation products in the edible portion of food crops. Where applicable, existing upper tolerances for foods (for example: acrylamide) must be addressed by inclusion in the rationale or risk assessment.
  - If the product containing a polymeric supplement that is not intended for use on food-crops, or if food safety is not adequately substantiated, the statement, **“not for use on food crops”** is required to appear prominently on the marketplace label.





Implementation

All **new** polymer or polymer-containing products:

- require registration as supplements prior to importation and sale in Canada

For all polymer products **currently in commerce in Canada, after undergoing a safety assessment (without registration)** for use with a fertilizer or as a stand-alone supplement product:

- phased in implementation, pending conclusion of the consultative process

Proposed phased-in implementation and enforcement timeline: feedback requested

Year 1

- Stakeholder engagement
- Annual CFPF/FSAC meeting (November)
- Submit applications for registration
- CFIA survey
- Information letters – no immediate enforcement action

Year 2

- No action against products found in the marketplace as long as an application to register the polymer (or mixture) has been received and is in the CFIA registration queue.

Year 3

- Regulated products that are or contain un-registered polymers will be subject to enforcement action.

Consultative Process

Initiate discussion: Draft copy of the notice to industry was shared

Presentation at the Nov 17th annual CFPF workshop

Ongoing discussions with industry associations and bilateral meetings with individual companies

Today's webinar (January 14th, 2020)

CFIA will participate in working groups and feedback/recommendations provided to the CFIA

Phase-in implementation timeline for products already in commerce to be finalized

Notice to Industry to be published
Trade memorandum for polymers (T-4-116) to be published

More Information:

Fertilizer website
https://www.inspection.gc.ca/plant-health/fertilizers/eng/1299165827648/1299165914316

Fertilizer Program Regulatory modernization
https://www.inspection.gc.ca/plant-health/fertilizers/regulatory-modernization/eng/1490851506920/1490851535765

Updated Trade Memoranda
https://www.inspection.gc.ca/plant-health/fertilizers/trade-memoranda/eng/1299873703612/1299873786929

Webinar series

Webinar Title	Topics covered	Date
Exemptions	General exemptions from all provisions of the *Act* and *Regulations*, Exemptions from registration for fertilizers and supplements and associated definitions.	Thursday, January 21, 2021 from 11 to 12 EST
Safety standards	Prohibitions and general safety provisions in the new Fertilizers Regulations, associated definitions, precautionary labelling, CFIA safety standards, determining compliance, tiered safety assessment levels, relevant guidance materials	Thursday, January 28, 2021 from 11 to 12 EST
Labelling and Record keeping	General labelling requirements, product-specific labelling, sample labels, record keeping option, associated definitions and guidance materials	Thursday February 4th , 2021 from 11 to 12 EST

Questions?

Fertilizer Safety Section
c/o Pre-market Application Submissions Office (PASO)
Canadian Food Inspection Agency
59 Camelot Drive
Ottawa, ON K1A 0Y9
Canada
Phone: 1-855-212-7695
Fax: 613-773-7115
cfia.paso-bpdpm.acia@canada.ca