Notice to Industry – Regulation of products that are or contain polymers under the *Fertilizers Act*

October 2020

Products that are, or contain, polymers require registration prior to importation or sale in Canada.

Polymers are materials made of long, repeating chains of molecules. These materials have unique properties, depending on the type of molecules being bonded and how they are bonded.

The definition of a "supplement" has been recently reviewed by the CFIA. As a result, it was determined that the scope of the definition extends beyond materials that **directly** affect plant growth, crop yield, or that directly amend the physical properties of the soil.

Therefore, a polymer that **directly or indirectly** acts to improve the physical condition of soils, or to aid plant growth or crop yields is itself considered a supplement. With the exception of mixtures, whether marketed as a stand-alone product or in combination with a fertilizer or supplement (as a coating for example), **products that are, or contain, polymers require registration prior to importation or sale in Canada**.

Mixtures containing polymers are exempt from registration only if:

• all active ingredients in the mixture are either registered for the proposed use of the mixture (with respect to target crop, use pattern, application rate, frequency and method of application) or are exempt from registration (for example. materials on the List of Primary Fertilizer and Supplement Materials (insert link)).

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.

Note that:

- o if the directions for use of a registered product included in a mixture are **not** consistent with the proposed use of the mixture, the final mixed product must be registered.
- o if a mixture contains a product that requires registration but is not registered, then the mixed product requires registration.

Before to the review of the definition of a "supplement", polymers required a comprehensive safety assessment but did not require registration when sold or imported into Canada as stand-alone products prior to sale or import. This notice serves to clarify the current regulatory requirements for products that are or contain polymers.

Phased in implementation and enforcement

All **new** polymer or polymer-containing products and formulations will require registration by the CFIA prior to importation and sale in Canada. To allow the industry to adjust to the registration requirement, proponents will have 12 months from January 1, 2021 to submit a registration package for all **existing** polymer products for use with a fertilizer or as a stand-alone supplement product. A similar approach was adopted with nitrification and urease inhibitors, hence this represents formalizing an industry driven broader interpretation and position.

Focussed stakeholder engagement with members of Fertilizer Canada, the Canadian Fertilizer Products Forum and the Fertilizer and Supplement Advisory Committee will take place prior to publication of the notice.

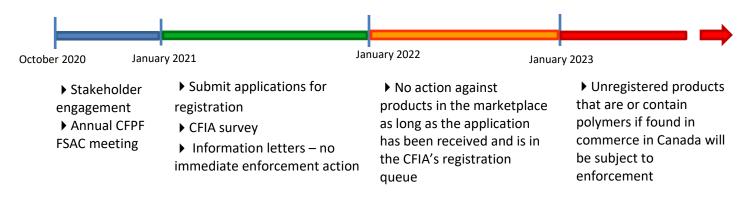
Year 1 (January 1, 2021 – January 1, 2022)

- Proponents will be required to submit applications to register their products under the Fertilizers Act
- The CFIA will conduct a survey of the marketplace focused on polymers containing fertilizers and supplements to better understand the size of the sector and the types of products that are commercially available in Canada (imported or manufactured domestically). However, no immediate enforcement actions will be taken in the marketplace during year 1 phase-in implementation
- During this first year the CFIA will also issue information letters to companies that are found marketing products that are or contain polymers without registration.

Year 2 (January 1, 2022) and onwards:

- Products not registered and for which no application for registration under the Fertilizer Act is actively
 under review, will be deemed in contravention of the act and may be subject to enforcement action (e.g.
 stop sale or detention). During this period the CFIA will <u>not</u> take action against unregistered products
 found in the marketplace for which an application for registration was submitted during year one, and is
 actively under review by the CFIA
- Starting in January 2023 polymers and polymer containing fertilizers and supplements that are not registered will be subject to routine marketplace monitoring and enforcement (if found not compliant with the regulatory requirements).

Timeline:



Registration requirements: Guaranteed analysis

Polymers are active ingredients and 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.

Registration requirements: Safety data

Safety data requirements specific to polymers/products containing polymers, all of which require full safety data assessment (Level III) and are reviewed on a case-by-case basis:

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

If the polymer, any of its ingredients or degradation products meet the hazard criteria outlined in Appendix 4 of the Guide to Submitting Applications for Registration Under the Fertilizers Act; or are recognized to exhibit (potential) carcinogenicity, mutagenicity, reproductive toxicity, developmental toxicity, teratogenicity or endocrine disruption activity, an exposure assessment for the intended use must be provided. Mitigating factors such as recommended personal protective equipment and precautionary statements should be included in the exposure assessment.

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

Learn more about product registration under the Fertilizers Act:

• Guide to Submitting Applications for Registration Under the Fertilizers Act

Contact Information

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