

CFIA Webinar: Regulation of products that are or contain polymers

Questions raised at January 14 webinar:

Q1. Is it true that compliant registration of an individual registerable ingredient includes a full label as if it were to be used as an end use product, even if a registrant hopes to consider it as a "technical" product that is only intended to be used in the formulation of end use products?

A1. Registering individual ingredients (for example polymers) as stand-alone products is a choice available for registrants which enables use of the new mixtures exemption. It is important to note that individual registrable ingredients are not required to be registered as stand-alone products. An applicant may instead choose to register each final product which contains that ingredient.

Whether registering a final, mixed product or a stand-alone ingredient product, each application for registration requires a full, compliant label.

Q2. It was mentioned that we could just register the polymer and indicate what materials we wished to mix it with, however what if a material does not exactly meet the definition set out on the List of Materials (i.e. urea with a biuret % above 1.2%)?

A2. Please list intention to mix each exempt material (by name) or class of materials. Note that if the material does not meet the term set out in the List of Primary Fertilizer and Supplement Materials, that term cannot be used. Additionally, if the material is not listed in the List of Primary Fertilizer and Supplement Materials and does not meet another exemption in the regulations, that ingredient requires registration when sold alone and does not qualify for the mixtures exemption (the final mixture requires registration).

When listing materials, the level of detail provided must be sufficient to conduct a safety assessment for all intended uses. Safety evaluators may request addition of detail to the direction for use at 1st review, if there is a need.

Q3. In terms of timelines, I am struggling with how to begin complying with the new Fertilizers Regulations within the 3 year period seeing as we will not be able to update labels with the registration numbers until our polymers are registered. For example, even if we (or our suppliers) begin the registration process this year, we will need to wait for the registration numbers to be issued before updating many of our finished product labels. One way around this could be for CFIA to issue registration numbers for all previously approved polymer technologies while registrants work to gather and submit any additional information CFIA requires (i.e. updated labels).

A3. Polymer registration is a result of the change in the interpretation of the definition of a supplement which is housed in the Act and applies to all polymers with supplemental qualities (direct and indirect effects) . Polymer registration is not a new requirement under the amended *Fertilizers Regulations*. All "new" polymer products are required to be registered irrespective of the regulatory regime: old vs. new.

The CFIA is consulting on an implementation timeline proposing that products currently on the market will have two years (from the start date of implementation) to submit the application for registration and bring the product into compliance with the labelling requirements. The safety of these materials has already been determined, therefore the process of registration for these products will be relatively quick (for example, where a compliant label is produced, a product can be registered at 1st review).

Note that in any case, all regulated products and their labels must be compliant with the new *Fertilizers Regulations*, come October 26th 2023.

Q4. Will the "Formulaire d'engagement Relative à l'importation d'engrais ou de suppléments au Canada uniquement pour le traitement ensuite l'exportation" still be valid ?

A4. Yes, the form is still valid. It is available by request to PASO (cfia.paso-bpdpm.acia@canada.ca).

Q5. Where is the flow chart for registration triggers?

A5. The registration triggers document, containing the flow-charts, can be found at the following location:

<https://www.inspection.gc.ca/plant-health/fertilizers/registering-fertilizers-and-supplements/fertilizers-and-supplements/eng/1330932243713/1330933201778>

Q6. Does this mean that any mineral based nutrient is exempt from registration even if doesn't meet the exact definition on the list of materials?

A6. As written in section 3.1 (1) of the *Fertilizers Regulations*, the following fertilizers are exempt from registration if they do not contain seeds or growing media:

(a) a fertilizer, unless it contains any of the following:

- (i) a substance produced by or derived from a living organism,
- (ii) a pesticide,
- (iii) a supplement that is not registered and is not set out in the List of Materials,
- (iv) a registered supplement, if its directions for use are not consistent with those of the product,
- (v) a micronutrient fertilizer that is not registered, and
- (vi) a registered micronutrient fertilizer, if its directions for use are not consistent with those of the product.

Q7. If the manufacturer of the polymer coating is different than the manufacturer of the product that is coated, then I'm assuming that the polymer manufacturer is the entity that would have to register the polymer as a stand-alone product, but the manufacturer of the final coated product would be the entity to register the final product if needed. Is that correct?

A7. The answer depends on the circumstance and whether the materials being coated trigger registration.

If the materials intended to be polymer-coated, and all active ingredients in the mixture are exempt, then the manufacturer of the polymer coating may register the polymer as a stand-alone product, ensuring to cover the intended uses (name the nutrients to be coated) in the directions for use. Once the polymer coating is registered, the coated products could meet the mixtures exemption (registered polymer material + exempt nutrient/active ingredients = mixtures exemption applies).

If the materials to be coated, or any active ingredient in the mixture require registration and are not yet registered for the proposed use of the mixture, the final product requires registration. Alternatively, the

polymer could be registered as a stand-alone product and the material intended to be coated could be registered by the respective manufacturers – each including the intended use of the final mixture in the approved label's direction for use. In this alternate case, the two registered products could then be mixed under the mixtures exemption.

Q8. Just to clarify, what statement would we need to put on the label if do not want to wait for the CFIA registration number? (excluding growing media/seeds)

A8. The requirements for record-keeping are fully detailed in [T-4-131: Record-keeping requirements under the *Fertilizers Act* and regulations.](#)

The following is copied directly from Section 3 of this document. Please be sure to read the complete guidance outlined in T-4-131.

“The label of a mixed product **does not** have to identify its exempt or registered ingredients **if**:

- a. the mixture is labelled with a statement indicating that the fertilizers or supplement in the mixture are registered or exempt from registration
- b. the responsible party ([see section 4](#)) maintains records for at least 5 years beginning on the day on which the mixture was last imported, packaged or caused to be packaged, at that party's place of business in Canada or, if they do not have one, at another place of business in Canada ([see section 6](#) for details on what is required in a record)
- c. the responsible party informs the President of the Agency of the place where the record is located by submitting the following information to the CFIA through the PASO email address or by mail (contact information found in section 8):
 - Product name
 - Responsible party
 - Location where the record is located:

123 Main St.
City, Province or Territory A1B 2C3
Canada”

Additionally, for all labeling requirements, please refer to [T-4-130: Labeling requirements for fertilizers and supplements.](#)

Q9. Could you provide a written example of how we would go about registering the coating itself (as opposed to the polymer coated fertilizer)? I.e. how would we phrase the directions for use to capture numerous fertilizer components?

A9. Here is an example of directions for use for a polymer coating:

Direction for Use

This polymer coating will control the release of nutrients and is intended for use with the following nutrients: X,Y,Z either homogeneous or blended.

This supplement is intended for coating nutrients only and should not be applied to crops independently.