

The Modernized *Fertilizers Regulation* – “exemptions”

QUESTIONS RECEIVED DURING THE WEBINAR ON JANUARY 21ST

1. Does the definition of active ingredient relate to a single material only, or would a previously blended product be considered an active ingredient?

A1: The definition of active ingredient refers to a single material. A previously blended product may contain one or many active ingredients, depending on how many materials are in that blend. If you are including a previously blended product as an ingredient in a "new" mixture, the guarantee on the final mixed product must list all actives (some being re-calculated based on dilution in the new product). It is not acceptable to simply guarantee the presence of that blend as a single "active".

2. Is changing of vendor for ingredient(s) used in the manufacture of a fertilizer or supplement considered a major or minor change?

A2. It depends on the new source of ingredients and whether they pose any additional or new safety risks (this may be inherent to the material itself or coming from potential contamination during manufacture). See section "4.5: Ingredient Source Changing Inquiry" in trade memorandum [T-4-122](#) on the CFIA's fertilizer webpage. This section directly addresses this question.

3. For registration submissions on My CFIA, what is the preferred way to upload multiple supporting documents? It is a little onerous to upload many documents as I believe you can only upload one at a time, and you must exit the upload page and re-enter before adding another. Is it possible to upload a zip file, or perhaps one large combined PDF with all documents?

A3. The application system is built for systematic uploading of requirements which feeds into an organized submission with built-in completeness checks. Therefore, each required upload needs to be completed separately. Where a particular item would be addressed through multiple document uploads (e.g. method of manufacture and detailed Quality Control and Quality Assurance spread across multiple documents), it is acceptable to group those together into a single PDF to facilitate uploading it.

4. Why are seaweed products not in the list as fish residue products?

A4. This is correct, fish meal and fish emulsion are on the List of Materials, while seaweed products are currently not. Seaweed products do not fit under the term and definition of fish meal or fish emulsion.

In order to add seaweed to the [List of Primary Fertilizer and Supplement Materials](#) it must undergo a detailed safety assessment based on publically available data/information. Please note, the List of Materials does not include proprietary formulations or final commercial products. In addition, once on the List, the exemption is available to all companies not only the product proponent that requested the addition. It is up to the

requester of the change to collect and submit all requisite information to CFIA for consideration. We are currently working on a guidance document that will describe the material assessment framework, required data and the process of approving proposed changes. Stakeholders will be consulted before the document is final and in force.

5. Customer-formulated fertilizers? Is that a product formulated one time for a customer or can it be formulated more than once for customer/customers?

A5. To meet the definition of a customer-formula fertilizer in the [Fertilizers Regulations](#) and hence satisfy the conditions of exemption, a customer formula fertilizer must be prepared in response to a written request from the person who will use the product for fertilizing purposes. Customer-formula fertilizers do NOT apply to prepackaged products or products that are prepared in advance of a request in anticipation of a marketplace demand. Also it must not contain seeds or growing media. Please refer to the [Trade memorandum –T-4- 128](#) for more information.

6. Regarding My CFIA: I'm very excited to start using this! It appears that it currently is set up only for registering a new product or for a research authorizations. Renewals or amendments are "Coming Soon!" Do you have a timeline for those types of applications?

A6. Unfortunately we don't yet have a firm timeline that we're able to share at this point. This functionality is part of the next wave of My CFIA implementation. Once these new services are available we will promptly inform the stakeholder community.

7. On the List of Materials, would Fish Bone Meal fall under the definition of Fish Meal as long as it is hydrolyzed and stabilized by drying and contains at least 2% nitrogen? (i.e., wondering if fish bone meal could be considered a component of waste fish rather than whole fish).

A7. In the List of Materials. Fish emulsion and fish meal are defined as:

Fish emulsion (Specify grade)	Whole and waste fish hydrolyzed using enzymes or live steam and stabilized with acid, containing at least 2% nitrogen (Émulsion de poisson)
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Fish meal (Specify grade)	Whole and waste fish hydrolyzed using enzymes or live steam and stabilized by drying, containing at least 2% nitrogen (Farine de poisson (solide))
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The Definitions do not make a distinction between “whole” vs. ‘waste’ – rather the process by which it is manufactured. In either case the product must meet the 2%N minimum.

8. So, a registered blended fertilizer cannot be classified as a registered active ingredient that would contribute to the exemption for registration of the final product?

- A8. A registered blended fertilizer can definitely fit the mixtures exemption if the intended use of the final mixture is consistent with the registered use of the blended fertilizer in question. However, all active ingredients must be carried forward to the final mixture's labelling/guaranteed analysis, and cannot be simplified into a blended active (such as a product name). Guarantee(s) for the actives derived from the registered product being used as an ingredient and those introduced into the new final blend will need to be recalculated to accurately reflect the final mixture.
- 9. Will you be making the ppt available to groups/people not on the call?**
- A9. The PDFs of the presentations in English and in French are attached to this package and can be made available to any stakeholder that has an interest in the topic. The presentations will also be posted on the Fertilizer Canada and FSAC website but the webinar has not been recorded.
- 10. If there are any doubts about a product meeting the specific definition under the List of Primary Fertilizers and Supplements, can we submit a Product Inquiry to get an official letter?**
- A10. Absolutely, you may submit a [Product Specific Inquiry](#) to seek clarification. You can also request a [pre-submission consultation meeting](#). However, please consult and carefully review the definitions (compositional criteria) on the [List of Materials](#) before submitting an inquiry to the CFIA. With respect to products exempt from registration – such as the materials on the List- the onus is on the product proponent (responsible party) to ensure that the product is in compliance with the *Fertilizer Regulations* once in commerce.
- 11. Will an application being submitted under the old regulations be extended to the 5 year extension? We have a pending application thru the old regulations. Will this be on the 3 year registration or the 5 year?**
- A11. Applications received under the old regulations (received by PASO before October 26, 2020) are subject to the three year registration period. At the end of the regulatory transition period these registrations will either lapse or be cancelled if the product is exempt moving forward.
- To bring the product into compliance with new regulations, you will subsequently need to submit for a major amendment under the new regulations at which time you will be granted a 5 year registration. Come October 26, 2023 all fertilizer and supplement products in commerce in Canada must comply with the “new” regulations and this is applicable to new products entering the marketplace as well as those sold previously (old stock). Please allow sufficient time for the major amendment to be completed before the end of the transition period to ensure continuous legal sale of your product in Canada.
- 12. With regards to target crops associated with a registration, can it be broad stroke such as edible crop and non-edible crop rather than specific target crops?**

A12. Target crop groupings on the label are permissible providing a scientific rationale to substantiate their relatedness (taxonomic classification, physiology, anticipated response etc.) is submitted as part of the package. Most importantly, the grouping needs to be specific enough to support a safety assessment including all relevant end points and use patterns (method of application: foliar vs. soil vs. seed; frequency of application etc.). Simple distinction between edible vs non-edible crops is insufficient, however more broad groupings such as garden vegetables, fruit trees/orchards and annual flowers are acceptable.

13. If during production an anomaly occurs resulting in an off-spec (low grade) product thus rendering the fertilizer to no longer meet the definition in List of Materials are these now required to go through a full registration? Example UAN 28% production has an upset resulting in <28% for a short period of time while getting process back in spec. Is there any option to sell/distribute as a low grade/off-spec fertilizer with the appropriate label without going through the registration process?

A13. The short answer is unfortunately “NO”. Materials that do not meet the definition (compositional criteria) prescribed on the List of Materials are not eligible for that exemption, though another exemption in the Regulations may be applicable. In addition, consistency in production is a key determinant of ongoing compliance of the product in the marketplace. If there is an anomalous batch it either should not be sold or you will have to seek registration; in either case the manufacturing process and QC and QA procedures should be in place to ensure that such random errors or variability do not happen.

14. What are the options if the My CFIA portal asks for a Declaration Canadian Resident Agent

A14. If your application is being made from outside of Canada, you will be asked to provide the name and address of a Canadian agent. You must declare this information before moving forward in your application process.

15. It is my understanding that non-plant and animal based materials on the List of Materials do not need to exactly meet the definition listed. I have two questions: 1. Why are there definitions at all for mineral based fertilizer materials? 2. What about plant and animal materials that do not exactly meet the definitions (i.e. soybean oil, or bone meal with more than 14% phosphorus)?

A15. Fertilizer and supplement materials on the List must meet the definition (compositional criteria) in order to use the term and meet the specific exemption; however other exemptions may still apply. If you wish to call a product by the “term” specified on the List you must meet the compositional criteria as well. If they don’t as with your example of bone meal with more than 14% P the material cannot be called bone meal and must satisfy another exemption or it will require registration. Please note that soybean oil is not currently on the List of Materials.

Seed meal (Specify grade and designate as to kind) Seed residue of one or more of soybean, alfalfa, cotton, canola, rape, mustard, and lupine seed, dried and ground, that have been subjected to treatment sufficient to mitigate against the presence and effect of pathogens, containing at least 6% nitrogen, and ground to a fineness (prior to optional granulation or pelletization) whereby at least 40% passes through a 0.149 mm sieve

More generally, the exemption for products that do not contain plant or animal derived materials is a separate provision from the List of Materials [section 3.1 (1) a vs b]. The concept of mineral fertilizer and supplements was repealed from the Regulations as it caused significant confusion in the marketplace and was replaced by *a substance produced by or derived from a living organism*.

16. Consider a fertilizer that is a commonly recognized product with a name that is included on the List of Materials, but does not exactly meet the definition. This fertilizer does not contain, and is not derived from living organisms, per the flow chart. Is it Exempt?

A16. YES, however, the product cannot be named using a term from the List of Materials if it does not meet the specifications provided in the definition.

17. Company is importing MAP into Canada for local sale and for export in bulk. Do they need a label for bulk sales?

A17. First of all, since the product is intended for domestic sale as well as export it is not exempt from all provisions of the *Act* and *Regulations* and may or may not require registration depending on the nature of the product in question. Secondly, the amended Regulations repealed the definition of a *shipping bill* and all products including those imported must be accompanied by a label that meets the labelling requirements in the Regulations (including bilingual labelling). The definitions of a *label* in the *Fertilizers Act* is very broad and it includes *any legend, word, mark, symbol or design applied or attached to, included in, belonging to or accompanying any fertilizer, supplement or package*. Similarly, a *package* includes *a sack, bag, barrel, case or any other container in which fertilizers or supplements are placed or packed*. The latter includes any vessel (truck, railway car, ship etc.) used to transport the product in bulk. For additional information please consult [T-4-130](#).

18. If a mixture is registered, can I use the ingredients in the mixture in other products and not needing to register the other product?

A18. You can use the mixed product in other mixtures as long as the mixture is registered for that use and the end use of the final product falls within the registered use parameters. The exemption does not apply to individual ingredient appearing in a registered product.

19. Could you clarify the status of a plant or animal based ingredient that is being used solely for its nutrient value (and not as a supplement)? i.e. seaweed or shrimp meal

A19. Products that are derived from or contain plant or animal material such as seaweed or shrimp meal require registration as they currently do not appear on the [List of materials](#).

20. Can you please explain the difference between the Experimental Use for supplements 'Research authorizations' under the old regs versus the 'Research Notifications' under the new regs

A20. The research authorization process applied, and continues to apply to novel supplements only (supplements that are not exempt from registration and not registered, or supplements that contain a novel trait). The new "fertilizer research" provisions in the amended *Fertilizers Regulations* enable an individual to conduct research trials on a fertilizer that is not registered and not exempt from registration without having to register it prior to import or release into the environment. This provision was instituted to permit experimental testing of products which previously fell within the purview of the "personal use exemption" which was repealed. Please note that in order to be eligible for the fertilizer research exemption:

- the product must not contain a supplement or a pesticide;
- it must be safe for humans, plants, animals and the environment;
- any residual (unused) product must be disposed of at the end of the trial; and
- any crops to which the unregistered fertilizer is applied are destroyed and do not enter the commercial food or feed chains

21. What is the timeline for adding a material to the List of Materials?

A21. The *Fertilizers Regulations* do not stipulate the frequency with which a document incorporated by reference such as the List of Materials needs to be updated – the terminology used is "from time to time". However as indicated in the answer to question 4 any changes to the List (additions, amendments or deletions) must undergo a rigorous and transparent assessment. In addition, as these assessments are not associated with service fees (are done free of charge) there are no mandated service delivery standards associated with them. These must be carefully managed as not to negatively impact processing of registration related submissions. We are currently working on a guidance document that will describe the material assessment framework, required data and the process of approving proposed changes. Stakeholders will be consulted before the document is final and in force.

22. Can a me-too product be exempt from registration under the new regulations? By stating on the label that it is derived from the original products registration number? Assuming the only change to the product is the name/private label, with the same uses?

A22. Yes, you are correct that most me-too products are now simply exempt under the new regulations, as long as the parent product is itself a mixture and not a single ingredient (to meet the mixtures exemption). In addition to product name, the only additional change is to add a statement to the effect that "this product contains *Fertilizers Act* registration

#XXXXXX” (the parent product) or you may choose to keep records. Me-toos will continue to be available for registered products that are not mixtures and that are therefore not eligible for the exemption for mixtures comprised of registered products or exempt materials.

23. What do you mean by 'The product is further cultured or manipulated once mixed' in the flowchart – Registration requirements for mixtures?

A23. The intent of this provision is to minimize risks associated with microbial populations shifts after various sources are mixed together and subject to sub-culturing or enrichment. In those cases the microbial complement may be very different than that originally evaluated with respect to its safety due to competition, mutation, niche displacement etc. Further manipulation may also lead to contamination with pathogenic organisms that were not present in the original constituent products.

24. The definition for methylene urea states A mixture of methylenediurea and dimethylenetriurea, obtained by reacting urea with formaldehyde, that contains at least 41% nitrogen, and that is a source of slowly available nitrogen (Urée de méthylène). Many MU products on the market are 40-0-0, does this mean they would require registration?

A24. YES unless the compositional criteria for methylenediurea and dimethylenetriurea are amended on the [List of Materials](#).

25. Why is Potassium carbonate not listed on the Primary List? Does this ingredient require registration?

A25. Current inclusions on the List of materials are the result of the technical review of the former Schedule II which was conducted in consultation with the Canadian Fertilizer Products Forum between 2011 and 2013. As a result of the review the list of materials was expanded from 56 to 104 materials. Some were also added to align with international norms more specifically the Uniform Bill in the US (American Association of Control Plant Officials). Change requests to the List may originate from various sources both internal to the CFIA and other Gov. Departments as well as industry proponents. In each case, a change request must be accompanied by publically available data that allows for comprehensive assessment of the material against safety standards. For More info see answer to question 4. Potassium carbonate is exempt as a fertilizer that is not of plant or animal origin. Please refer to the flow-charts in the [registration triggers document](#) for material-specific registration requirement guidance.

26. Is the 30 days for the IQ still working days?

A26. Correct

27. If there is a product already in the marketplace under the Specialty Fertilizer exemption, and now it needs to be registered under the new regulations, can it be

submitted for registration, but still remain in the marketplace during the review period?

A27. Yes, the existing product/packaging that is compliant with the former regulations can continue to be marketed throughout the three year transition period (October 26, 2020 – October 26, 2023). However, all product packaged in accordance with the former regulations (as a specialty fertilizer) must be off the market by October 26, 2023.

28. Since My CFIA is not ready for renewals and I will be working on renewals in Feb, should I just go ahead and do it as a paper copy under the new registration?

A28. Until renewals are available in My CFIA, please continue to submit to PASO by mail or email. Wherever possible, submission of digital files is strongly encouraged as it significantly simplifies the process under remote working environment and thus expedites reviews.

29. Are foliar fertilizers for use on cannabis exempt?

A29. The definition of specialty fertilizer and associated exemptions have been repealed from the *Fertilizers Regulations*. There is also no specific provision in the *Fertilizers Regulations* that would exempt foliar fertilizers used on cannabis from registration. The registration status of the product depends on the nature of the product and its ingredients irrespective of its end use or target crop.

Health Canada recently announced a change in policy interpretation and now permits the use of foliar fertilizer in the cultivation of cannabis (previously not allowed). That decision does not impact whether a fertilizer or supplement requires registration under the *Fertilizers Act*.

30. I have a partner, a biochar producer which has obtain it registration number in 2017, now biochar is excluded from the list, Is it possible for him to keep its registration number on his packaging.

A30. Biochar has been added to the List of Materials and is therefore exempt under the amended regulations. Having said that, until the regulatory transition period is over (October 26, 2023) products that comply with the former regulations are permitted to be sold or imported into Canada. Therefore if your partner has maintained a valid registration number to date, the product may continue to be sold while labelled in accordance with the former regulations until October 26, 2023. After that date, the product will need to be labelled in compliance with the updated regulations. The existing registration number will no longer be valid and cannot appear on the marketplace label.

31. One of the slides notes that Schedule IV - Designation of a Canadian Agent - was repealed. But you state My CFIA requires this information. This is confusing. My company exports from US to Canada. Following up to a previous question and answer. Is a designated agent still required? Thank you.

A31. Yes, the name and address of a Canadian agent is still required under the amended regulations. While the form itself was repealed from the regulations, the information (name and address of a Canadian agent) is still a requirement of registration. If you are applying online through My CFIA, you will be prompted for your Canadian Agent's information in a fillable field. If you submit to PASO, you should indicate the name and address in your application. For the former regulations, we are still using the Designation of a Canadian Agent form.

32. When can we expect you will be making the first update to the List of Primary Materials? We have submitted multiple times with new materials we would like to see on the list.

A32. The short answer to this question is that a change request to add a material to the List requires submission of data, extensive literature review and a safety assessment. It is the responsibility of the requester to collect this information and submit for CFIA review. Please refer also to the response to Question 21.

33. I am unaware of any existing Methylene urea or ureaform fertilizer that meets the specs of definitions on the List of Materials. If I understand correctly, these are still exempt (not derived from living), but they could not be called methylene urea or ureaform. Is that correct?

A33. That is correct. The Materials on the List are only exempt if they meet the definition (compositional criteria) as specified on the List and then they can be called using the "term" from the List. However, fertilizer and supplement products that are not eligible for an exemption under the List of Materials can still be exempt if they meet any other applicable exemption in the regulation. The compositional criteria that are present in the current definition were established following an extensive 2-year review of the former Schedule II of the *Fertilizers Regulations* (now incorporated by reference as the "list of materials") that included extensive consultation through a stakeholder working group (from 2011 to 2013). The definition of a material on the List of Materials (including compositional criteria) can be amended if sufficient rationale is provided (including proof of ongoing agronomic relevance) is submitted along with the change request, so long as that change is shown to more accurately reflect the material as it is commonly recognized by the stakeholder community (both domestic and internationally).

34. If a product meets an exemption, what further action is needed? Do we need to notify CFIA? will we receive an exemption letter?

A34. The action required will depend on the nature of the exemption from registration. In most cases, if the product meets an exemption from registration then no further action is required – you do not have to notify the CFIA once the product reaches the market nor will you receive an exemption letter. However, if the product is exempt because it is a mixture of exempt materials and products registered for the purpose of the mixture, and the proponent has chosen to keep records rather than label the information that demonstrates that it is exempt then the responsible party must keep records of that

information **and** inform 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:

- Product name
- Responsible party
- Location where the record is located:
123 Main St.
City, Province or Territory A1B 2C3
Canada

Please refer to [T-4-131](#) for more information.

Once the product is in the marketplace it may be subject to inspection and if found non-compliant with the Regulations, (registration, labelling, contamination, etc.) it will be subject to enforcement action which may include detention (stop sale) or, in cases of severe or repeated noncompliance, prosecution.