



Canadian Food
Inspection Agency

Agence canadienne
d'inspection des aliments

Guidelines for Pre- submission Consultations for Fertilizer and Supplement Products Regulated Under the *Fertilizers Act and Regulations*

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Introduction

The *Fertilizers Act* is the legislative authority under which the Canadian Food Inspection Agency (CFIA) monitors and controls fertilizers and supplements sold in or imported into Canada. This legislation helps to protect the consumers and the general public against potential health hazards and label misrepresentation, as well as ensuring a fair marketplace. Agricultural fertilizers, specialty fertilizers, fertilizer-pesticides and supplements are all controlled and regulated under the *Fertilizers Act and Regulations*.

To obtain approval of a product for sale in Canada, product proponents must make submissions to the Fertilizer Section of the CFIA. However, often proponents are unsure of how their product is classified, or of the regulatory and policy requirements. Therefore, the Fertilizer Section is encouraging proponents who are experiencing these problems to make inquiries and request a pre-submission consultation meeting. These are intended to serve as communication tools and provide guidance and advice to industry prior to submitting an application package under the *Fertilizers Act and Regulations*. To ensure that the pre-submission consultations follow a standardized process, and the information provided by both the company and the CFIA is recorded and maintained, the following meeting guidelines have been developed.

Purpose

The purpose of the pre-submission consultation is for the Fertilizer Section and/or Fertilizer Safety Office to provide product proponents with guidance, advice, and clarification on the regulatory requirements, current policies and standards for fertilizer and supplement products. This information can then assist product proponents in the preparation of a complete submission that adequately supports the product's safety and efficacy, and meets the prescribed labelling requirements, and can significantly expedite the review process. The meeting can be used to obtain information on products that require registration or pre-market approval, or products that are exempt from registration but are still regulated. These meetings are also intended to serve as a regulatory foresight tool to increase the Fertilizer Program's awareness of industry trends, and innovative products that are currently under development. In this way, the CFIA can ensure that its policies and requirements meet the needs of stakeholders, as well as identify program areas that require review, change and/or improvement.

When to request a meeting

Product proponents, especially those who are unfamiliar with the *Fertilizers Act and Regulations*, or who are unclear how their product is classified, are encouraged to start the process with the submission of an inquiry (IQ). This process and the information to be submitted in support of an IQ are outlined in Appendix A. An inquiry may provide the answers that a proponent requires and eliminate the need for a meeting. However, if a product proponent or the Fertilizer Section and/or Fertilizer Safety Office feel that a more detailed face-to-face consultation is warranted, a pre-consultation meeting may be

requested. This is especially relevant for innovative products where the regulatory and policy requirements may be in transition or in the initial stages of development.

PLEASE NOTE: Having a meeting will NOT affect or change the service delivery standards for submission review once the application is received by the Fertilizer Section/Fertilizer Safety Office.

Procedure for Requesting a Meeting

A meeting request should be made by a product proponent (registrant, importer, manufacturer, Canadian representative etc.) in writing (via e-mail or letter) at least 3 weeks in advance of the meeting. The request can be addressed to either the Client Services Administrator in the Fertilizer Section, or an evaluator in either the Fertilizer Section or the Fertilizer Safety Office. Similarly, if the Fertilizer Section and/or Fertilizer Safety Office wishes to instigate a pre-submission consultation, such a request will be made of the product proponent in writing.

Meeting Inclusions

The meeting can include:

- 1) communication of general information about the Fertilizer Program and the regulatory framework;
- 2) clarification of requirements, policies and administrative processes within the Fertilizer Section and the Fertilizer Safety Office; and
- 3) a discussion of the data/information requirements specific to the product.

Meeting Exclusions

The meeting will **not** include:

- 1) an onsite review or assessment of data, label or other information pertinent to the product;
- 2) a discussion of confidential business information belonging to another company;
- 3) a decision on the acceptability of the data or the product; and
- 4) information regarding pending or current enforcement action(s) and/or complaints submitted against the product proponent/company.

Roles and responsibilities

1) Company representative

Prior to the meeting, the product proponent is required to supply the following information to the Fertilizer Section and/or Fertilizer Safety Office:

- a) Proposed meeting agenda
- b) Draft label
- c) A complete list of ingredients
- d) The manufacturing method
- e) The mode of action for the active ingredient (if known).

The proposed meeting agenda should indicate the length of time required for the meeting, and the specific questions or topics of discussion. This is required to aid the Fertilizer Section and/or Fertilizer Safety Office in preparing for the meeting and compiling all relevant information/requirements for the given product type. The requested information must be submitted, at minimum, 2 weeks prior to the meeting to allow for sufficient review time and preparation. The product proponents are also expected to prepare for the meeting by reviewing the relevant sections of the *Fertilizers Act and Regulations* and applicable Trade Memoranda, which can be found on the CFIA website at:

<http://www.inspection.gc.ca/>

During the meeting, product proponents are invited to present a brief overview of the product as well as record minutes of the meeting. The role of the minute recorder has been assigned to the company representative to ensure that the information they deem important and relevant is captured.

Following the meeting, product proponents are responsible for submitting the minutes to the Fertilizer Section and/or Fertilizer Safety Office for review.

2) Fertilizer Section and/or Fertilizer Safety Office

The Fertilizer Section and/or Fertilizer Safety Office contact will work with the product proponent to arrange a mutually convenient time for a meeting, and coordinate the attendance of the appropriate Fertilizer Section and/or Fertilizer Safety Office representatives. It is the responsibility of the Fertilizer Section and/or Fertilizer Safety Office representatives to prepare for the meeting by reviewing the information submitted by the company.

During the meeting, the role of the Fertilizer Section and/or Fertilizer Safety Office representatives is to provide guidance on the regulatory requirements as prescribed by the *Fertilizers Act and Regulations* and the current policies and standards. Data and/or information requirements specific to the product will also be discussed; however, product-specific advice will be based solely on the accuracy and completeness of the information provided by the company prior to the meeting.

Following the meeting, the Fertilizer Section and/or Fertilizer Safety Office will review and comment on the minutes recorded by the company. The final meeting minutes will be returned to the company representative within 30 days of their receipt. The following disclaimer will be added to the minutes:

Disclaimer

The above advice and guidance provided by the Fertilizer Section and/or Fertilizer Safety Office is based on current CFIA policy and the quality and accuracy of the information supplied by the company prior to the meeting. There may be intervening legislative, regulatory, or policy changes, or significant new

information may come to the attention of the Fertilizer Section or Fertilizer Safety Office, which could affect the validity of the advice provided from this consultation. It is the sole responsibility of the company to keep abreast of any policy or legislation changes that may alter or impact the advice provided. It must be recognized that the advice provided by the Fertilizer Section and Fertilizer Safety Office is not intended to alter or qualify in any way the Agency's authority and responsibility to evaluate and decide on the acceptability of a product in accordance with the Fertilizers Act and Regulations.

The information provided by the company prior to the pre-submission consultation meeting, together with the meeting minutes, will be maintained by the Fertilizer Section and/or Fertilizer Safety Office, and assigned a file submission control number, which can be referenced at a later date when the application package for registration or product approval is formally submitted.

Please be advised that all information contained in the file and/or discussed at the pre-submission consultation meeting will be considered confidential business information. As such, access to the file will be restricted to the applicant/product proponent or person(s) that are granted signing authority by the applicant (for more information on signing authority please consult *Trade Memorandum T-4-95: Signing Authority*).

Contact Information

If you have any questions about pre-consultation meetings, please do not hesitate to contact the Fertilizer Program.

Mail: 59 Camelot Dr.
Ottawa, ON
K1A 0Y9
E-mail: fertilizer@inspection.gc.ca
Phone: 613-773-7189
Fax: 613-773-7163

Appendix A – Procedure for submission of an Inquiry (IQ) to the Fertilizer Section

The Fertilizers Act and Regulations delineates and explains which products require registration, and which products do not require registration. Products that do not require registration may still be regulated under the *Fertilizers Act and Regulations*. Please note that the classification of products and the registration requirements are based largely on the product label, the intended use pattern and the claims made about the effectiveness of the product. In order to determine the particular requirements of a specific product, we encourage product proponents to submit for an Inquiry. Below is a checklist of the information the Fertilizer Section and/or Fertilizer Safety Office require in order to determine if a product requires registration, and what the specific regulatory requirements may be.

Please send this information to the Fertilizer Section to the attention of Client Services Administrator, either by email to fertilizer@inspection.gc.ca, or by mail to: 59 Camelot Drive, Ottawa, ON, K1A 0Y9.

An Inquiry file will be opened, and you will receive a response from an evaluator within 30 working days. The response provided will explain the categorization of the product under the *Fertilizers Act and Regulations*, as well as the requirements specific to that product type. In the event that multiple products are submitted to the Fertilizer Section / Fertilizer Safety Office for Inquiry, the Client Services Administrator will open individual inquiries for each.

Checklist for product specific inquires

Company Name:

Contact Name:

Following information will be required before a product specific inquiry will be answered	
<u>Submission Requirements:</u>	
<input type="checkbox"/>	Cover letter: Explaining the intent of the inquiry.
<input type="checkbox"/>	A copy of the proposed marketplace label .
<input type="checkbox"/>	Constituent materials: <input type="checkbox"/> identification and description of <u>all</u> materials used in the production of the end-product; <input type="checkbox"/> the source of the materials. <input type="checkbox"/> the proportion of the materials
<input type="checkbox"/>	Description of the manufacturing / blending process
<input type="checkbox"/>	Purpose of import (if applicable) or end-use of the product.

