



PLANT PRODUCTS DIVISION	DIVISION DES PRODUITS VÉGÉTAUX	DATE SEPTEMBER 1997	T-4-111
		FERTILIZERS	
TRADE MEMORANDUM			

REGISTRATION OF MICRONUTRIENT FERTILIZERS UNDER THE FERTILIZERS ACT

BACKGROUND

Micronutrient fertilizers must be registered under the *Fertilizers Act* prior to being sold in or imported into Canada. When seeking product registration an Applicant must provide the Plant Products Division with administrative and technical information on its product(s). This guideline has been developed to assist industry in the preparation of a request for product registration, by identifying the standards which micronutrient fertilizers must meet, and the documentation and data which must be provided in support of registration.

Once the information is received, the Plant Products Division will conduct a preliminary review of the product and outline whether any further information is required.

STANDARDS

Products regulated under the authority of the *Fertilizers Act* must be efficacious for every purpose for which they are intended, they must be safe for use as intended (bearing in mind phytotoxicity, food safety, worker safety, and environmental safety) and they must be properly and accurately labelled.

One crucial aspect of micronutrient fertilizers is whether they meet their nutrient guarantee. We recognize that in formulating a product to meet a consistent, guaranteed nutrient level, test results used to confirm this level will generally show slightly more or slightly less nutrient than is guaranteed. Accordingly, a limited degree of variability is acceptable, and specific tolerance limits for this variability are set out in Schedule I of the *Fertilizers Regulations*. (These are primarily testing tolerances rather than manufacturing tolerances.)

Please note that the safety of micronutrient fertilizers is carefully considered at the time of registration. The safety review considers active ingredients, formulants and contaminants (in particular the heavy elements), and may address food safety, environmental safety, toxicity and worker protection. With regard to worker protection, it is necessary that products carry precautionary measures which properly reflect protection against known hazards of the constituent materials.

The *Fertilizers Regulations* stipulates criteria required for the labelling of all fertilizers; if the fertilizer is sold in bulk and does not bear an actual label, the information normally required on the label must appear on the shipping bill or other documentation which accompanies the bulk shipment. The Regulations should be consulted for further guidance on product labelling.

Note: We would like to remind companies of their obligations under the Workplace Hazardous Materials Information System (WHMIS), which involve safety labels and Material Safety Data Sheets (MSDSs), appropriate cautionary statements, ingredient identification, etc . Please refer to Trade Memorandum T-4-104 on Responsibilities of Registrants with respect to the labelling of Feed and Fertilizer Products under the Workplace Hazardous Materials information System (WHMIS) for some additional details and for a list of officials involved in the implementation of WHMIS.

REGISTRATION REQUIREMENTS

1.0 GENERAL

The following requirements apply to all products for which registration under the *Fertilizers Act* is requested.

- 1.1 A completed copy of the "Fertilizer and Supplement Registration Application"; (Please note that a complete list of constituent materials as well as guarantees for the active ingredients must be shown on the application.)
- 1.2 Three copies of the proposed product label carrying the complete Guaranteed Analysis;
- 1.3 An acceptable methods of analysis to identify and quantify the active ingredients (if not already in place with Laboratory Services Division);
- 1.4 Designation of signing authority as outlined in Trade Memorandum T-4-95 entitled "Signing Authority";
- 1.5 If residing outside of Canada, declaration of Canadian Agent; and,

- 1.6 If applicable, statistically significant efficacy data that supports the claims being made regarding the benefits of the product. (This is rarely required for micronutrient fertilizers; please feel free to contact the Plant Products Division for discussion of the applicability of this item to a specific product.)

2.0 MICRONUTRIENT-SPECIFIC

In addition to information on active ingredients and constituent materials as required on the "Fertilizer and Supplement Registration Application", applicants seeking registration of micronutrient fertilizers must provide the following information:

- 2.1 An identification and description of all materials used in the production of the micronutrient fertilizer, including a complete description of the source of these materials (eg. a description of the industrial process from which by-product is obtained and subsequently used in formulating the fertilizer);
- 2.2 A description of the manufacturing and blending processes which convert the above materials into the end-product, including a description of any transformations the materials undergo as a result of these processes; and,
- 2.3 Analyses of the end-product demonstrating (i) the amount of all guaranteed nutrients, and (ii) the concentration of the following elements: arsenic, cadmium, cobalt, lead, mercury, molybdenum, nickel, selenium and zinc.

Four (4) sets of analyses are required for all products. These analyses must be of four different representative samples of the end-product; these four samples must be collected over a period of two months, at intervals of approximately 2 weeks. Each sample analyzed may be a composite sample representative of product generated over the two week interval. Should there be any deviation from these criteria, the applicant must seek approval for an alternate scheme from the Plant Products Division.

An applicant may request permission to provide only 1 set of the above analyses, rather than 4. This request should be based on information pertaining to source materials, manufacturing processes, usage of industrial by-products, historical analyses of the product, etc.

Applicants should recognize that requests to reduce the number of sets of analyses required, or to use a different sampling and analysis scheme, may be denied by Plant Products Division. The two month sampling period and other criteria would remain necessary. Applicants' requests should therefore be timed accordingly.

ASSESSMENT

Once the above requirements for registration have been received, the Plant Products Division will consider the efficacy, safety and labelling of the product. The applicant will be informed as to whether registration has been granted, additional information is required, modification of the product label is required, etc.

FOLLOW-UP MONITORING

Given the well-documented variability in nutrient and heavy element concentrations of several micronutrient fertilizers, it is necessary to monitor registered micronutrient fertilizers for continued compliance with the standards of the *Fertilizers Act and Regulations*. For this purpose, Registrants (i.e. Applicants granted product registration) are asked to provide analyses of guaranteed nutrients and the 9 other above named elements at 6 month intervals. Recommended criteria for sampling and analysis are those identified under section 2.3 above. Requests for submitting fewer samples or for alternate sampling and analysis schemes are also as stated above.

To pursue registration of a micronutrient fertilizer, or for further information on the *Fertilizers Act and Regulations* or on the above data requirements, please contact the Plant Products Division at (613) 225-2342.

This version replaces trade memorandum T-4-111 dated April 1994.
(Administrative changes made to reflect changeover to the Canadian Food Inspection Agency,
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