Canadian Import Regulations - Soil Supplements

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U.S. firms interested in exporting fertilizers and/or soil supplements to Canada should be aware of the current import regulations imposed by the Canadian Food Inspection Agency (CFIA). All fertilizers and supplements that are imported and/or sold in Canada are regulated by CFIA and must first be approved under the *Fertilizers Act and Regulations* prior to entering Canada. The *Fertilizers Act and Regulations* requires that all regulated fertilizer and supplement products must be effective and safe for humans, plants, animals, and the environment. They must also be properly labeled in accordance with CFIA standards. The mandate of the CFIA's Fertilizer Program covers a wide range of products sold for agricultural, commercial, and home and garden purposes.

Before supplements can enter Canada, they must first be pre-approved by CFIA (proving they are safe and efficacious) prior to product registration. Most supplements entering the Canadian market are subject to a research authorization, pre-market assessment and registration prior to being imported and/or sold in Canada. There are however certain products exempt from the aforementioned process, though they still must meet all the prescribed CFIA standards at the time of sale or import.

Research Authorization

Before the applicant is able to register their supplements, they must first obtain a research authorization. Research authorizations must be obtained prior to environmental release of all novel supplements, that is, supplements that are not registered and not exempt from registration or that contain a novel trait.

All applicants requesting a Research Authorization are required to fill out a generic application form which provides CFIA with basic information about the supplement under test and the trial. Based on this information, the Fertilizer Safety Office (FSO) assigns an appropriate research category, identified additional information (if any) required, and requests the appropriate fees. There are three existing research categories**;** “Category A, whereby supplements pose negligible risk to plant, animal, human health and the environment (example; non-Genetically Modified (GM) rhizobia). Category B, applies to novel supplements that have not been previously assessed by the Fertilizer Safety Office, are genetically modified, or in some way represent a potential risk to human health or the environment. Category C, which is reserved for renewals of past exemptions”**.** The cost of the Research authorization differs with each category; $100 for Category C, $250 for Category A, and $500 for Category B. For more information on obtaining a research authorization please see the CFIA Trade Memorandum T-4-103 *Guidelines for research authorizations for testing of novel supplement:* http://www.inspection.gc.ca/english/plaveg/fereng/tmemo/t-4-103e.shtml

Once the appropriate fees are paid and sufficient amount of information is received, a research authorization can then be granted. This step is necessary for all supplements not registered in Canada. It is important to note that for all microbial supplements at least 2 years of supporting trial data must be submitted. While Canadian field trials must be done regardless (via the research authorization process), international research trials conducted outside Canada may be accepted to support product registration/approval. Information on which international trials may be considered in the application process can be found on CIFA's website at: http://www.inspection.gc.ca/english/plaveg/fereng/afge.shtml.

Companies that manufacture and/or import these products may approach the CFIA and request a pre-market assessment. While this pre-market assessment is only optional, it may be useful in order to verify that the product meets the appropriate requirements ahead of time.

Pre-Market Assessment

The CFIA's pre-market assessment is a science based evaluation of the supplement. During this evaluation CFIA assesses the products safety, efficacy, and labeling. In order to properly assess a product CFIA requires supporting documentation; the product label, a list of all ingredients, manufacturing information as well as any supporting trial data available.

During a pre-market assessment a safety and efficacy assessment is performed whereby "supplement ingredients, including the active components, as well as the formulants, carriers, additives, as well as potential contaminants and by-products are thus taken into account. In addition to measuring the desired effect of the supplement, unintended/adverse effects are also examined, including bystander and worker exposure (e.g. retailer, farmer, home owner), safety of food crops grown on land that has been treated with the product, impacts on animals and plants other than the target crop species, and ecosystem effects including impact on soil, biodiversity, leaching to waterways, etc." For more details on pre markets assessments please see CFIA's regulatory oversight at: http://www.inspection.gc.ca/english/plaveg/fereng/ferengfse.shtml

Registering a Supplement

Upon completion of the Research Authorization, and the products safety and efficacy is deemed, a supplement registration form can then be completed. According to industry experts at CFIA, the registration process takes approx. 270 days (this is on a first come first served basis) and costs approx. $C350. The registration form can be found on CFIA's website: http://www.inspection.gc.ca/english/for/pdf/c3778e.pdf. Please note that in order to proceed with the registration step, the applicant must have secured a Canadian agent.

The following info must be submitted for product Registration:

1. A completed copy of the fertilizer and supplement registration application
2. Three copies of the proposed product label
3. Identification of all active ingredients in the supplement
4. The appropriate fees
5. Designation of signing authority (Trade Memorandum T-4-95 *signing authority*)
6. Data proving the efficacy and safety of the product

7. Proof of a Canadian agent if manufacturer is a non-resident

References

Canadian Food Inspection Agency- Forms Catalogue: http://www.inspection.gc.ca/english/for/mpppe.shtml#C3778

Canadian Food Inspection Agency- "Guidelines to Completing the Fertilizer or Supplement Registration Application Form": http://www.inspection.gc.ca/english/plaveg/fereng/afge.shtml

Department of Justice Canada- *Fertilizers Act and Regulations*: http://laws.justice.gc.ca/en/F-10/C.R.C.-c.666

For More Information

The U.S. Commercial Service in Calgary, Canada can be contacted via e-mail at: crystal.roberts@mail.doc.gov; Phone: 403-265-2116; Fax: 403-266-4743; or visit our website: www.buyusa.gov/canada

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