New Regulations: Guide to Submitting Applications for Registration under the *Fertilizers Act*

Fertilizer Safety Section
Canadian Food Inspection Agency
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Contents

Abbreviations

ATCC	American Type Culture Collection
CFIA	Canadian Food Inspection Agency
CAS #	Chemical Abstracts Service number
CFU	Colony Forming Unit
CBI	Confidential Business Information
PCDD/Fs	Dioxins and Furans
EPA	Environmental Protection Agency
FSS	Fertilizer Safety Section
GLP	Good Laboratory Practice
IQ	Inquiry
ISO	International Organization for Standardization
LOD	Limit of Detection
LOQ	Limit of Quantification
ED_{50} / EC_{50}	Median Effective Dose / Median Effective Concentration
ID_{50} / IC_{50}	Median Infective Dose / Median Inhibition Concentration
LD_{50} / LC_{50}	Median Lethal Dose / Median Lethal Concentration
LO(A)EL	Lowest Observed (Adverse) Effect Level
MPN	Most Probable Number
NO(A)EL	No Observed (Adverse) Effect Level
OECD	Organisation for Economic Co-operation and Development
PMRA	Pesticide Regulatory Management Agency
PASO	Premarket Application Submissions Office
QA	Quality Assurance
QC	Quality Control
RoA	Results of Analysis
SDS	Service Delivery Standards
SGN	Size Guide Number
TEQ	Toxic Equivalent
WHMIS	Workplace Hazardous Materials Information System

Glossary

Active ingredient
Means an ingredient of a fertilizer or supplement to which its performance as a fertilizer or supplement is attributed.

Fertilizer
Any substance or mixture of substances, containing nitrogen, phosphorus, potassium or other plant food, manufactured, sold or represented for use as a plant nutrient.

Infectivity
The ability of a microorganism to cross or evade natural host barriers to infection (to invade and persist in a viable state or multiply within or on an organism, with or without disease manifestation).

Safety data sheet
A comprehensive technical bulletin detailing physicochemical, compositional, first aid, human health and environmental hazard, toxicological, ecological, precautionary, personal protection/exposure control, handling, storage, disposal, firefighting, accidental release, stability and reactivity, transport and regulatory information on a substance or product.

Microbial toxin
A substance produced by a microorganism that might have a harmful effect on a host organism, irrespective of the presence of the living microorganism.

Microorganism
Bacterium, alga, fungus, protozoan, virus, mycoplasma or rickettsia and related organisms.

Pathogen
Any disease-producing microorganism.

Pathogenicity
The ability of a microorganism to infect a host, establish itself and multiply there, and subsequently inflict injury or damage that might or might not lead to death.

Quality Assurance (QA)
Maintenance of a desired level of quality in a product by means of attention to every stage in the production process to ensure product deficiencies do not arise when the product is being developed.

Quality Control (QC)
Maintenance of standards in manufactured products by testing output samples against the specification to ensure the quality of the final product and to identify deficiencies after a product is developed and before it is released.

Substance
Any distinguishable kind of organic or inorganic matter, whether animate or inanimate. This definition includes a pure culture of a microorganism. A blend of microorganisms or a microbial product is a mixture of substances rather than an individual substance.

Supplement

Any substance or mixture of substances, other than a fertilizer, that is manufactured, sold or represented for use in the improvement of the physical condition of soils or to aid plant growth or crop yields.

Toxicity
Ahe ability of a substance to cause adverse effects on living plants or animals due to its poisonous (toxic) nature.

Toxigenicity
The ability of a microorganism to produce a toxin.

1. Introduction

1.1 Registrations under the *Fertilizers Act*

Fertilizers (essential plant nutrients) and supplements (products other than fertilizers that improve the physical condition of the soil or aid plant growth or crop yield) when imported into or sold in Canada are regulated under the authority of the federal *Fertilizers Act* and regulations administered by the Canadian Food Inspection Agency (CFIA). The *Fertilizers Act* and regulations require that all regulated products be safe with respect to human, animal and plant health and the environment and properly labelled to avoid misrepresentation in the marketplace. Some fertilizers and most supplements require mandatory pre-market assessment and registration prior to importation and sale in Canada. All registrations are valid for 60 months from the date of their issuance. Product proponents wishing to sell or import a registerable product after that date must apply to the CFIA to re-register and remain compliant beyond that time.

Furthermore, no changes to the label, chemical composition or ingredients in the product can be made **if the change can reasonably be expected to affect** its performance as a fertilizer or supplement, its safety or its use, unless the registration is amended accordingly (major or minor amendment). Alternatively, these changes can be made at the time of re-registration. Changes that **will not affect** product identity as a fertilizer or supplement, safety or use can be made without prior approval from the CFIA and they do not require notification. Contact the CFIA if you have any questions about whether or not changes you intend to make to your product(s) trigger a requirement to submit an amendment.

All products regulated under the *Fertilizers Act* and regulations are subject to marketplace monitoring which includes product inspections, sampling and testing as well as label verification. Non-compliant products may be subject to regulatory action including product detention (stop sale) and in cases of serious or repeated non-compliance, prosecution.

Truthful and accurate representation of products in the marketplace is key to consumer protection and prevention of fraud. Products that are supplements need to be represented as such and removal of claims and/or guarantees to avoid registration is not an appropriate corrective action.

1.2 Service Delivery Standards

The file review procedures and associated timeframes (Service Delivery Standards, SDS) for all registration related applications (new registrations, re-registrations, major and minor amendments) are described in Trade Memorandum *T-4-122: Service Delivery Standards for Fertilizer and Supplement Registration*. The service delivery standards include the actual CFIA review time and the queue time since all files are processed in the order they are received. The SDS vary by application type due to the nature and complexity of the assessment required and allow for up to 3 review cycles. Please note that unless there are deficiencies identified in the application, the file may not require all 3 reviews. Therefore, it is critically important that applicants invest the time and effort to familiarize themselves with the registration requirements BEFORE they submit an application to the CFIA.

When deficiencies in the application are identified at the first review stage, the applicants are required to respond to each question posed by the CFIA completely and with sufficient detail to address the deficiency. **Partial responses and responses received past the specified timeframe are considered incomplete and the file will be closed.** In addition, a file will be closed if an applicant discloses new information during the file review process about the product, its composition or manufacturing method, that warrants an additional

review or assessment. If a product proponent still wishes to pursue registration, they would then have to submit a new application for CFIA's consideration and review.

1.3 Purpose of the guide

There are a number of documents available on the CFIA website that are intended to increase awareness and understanding of the regulatory requirements for fertilizer and supplements imported into and sold in Canada. The information requirements detailed in this document are specifically relevant to registerable products and designed to assist prospective registrants in preparing complete and well organized applications to facilitate the file review process and ultimately expedite time to market.

1.4 My CFIA: Electronic application platform

The CFIA now offers digital service delivery through the online platform My CFIA. My CFIA allows you to request, pay for and track the status of services online through a secure account that can be tailored to suit your business model. PASO (pre-market application submissions office) service requests for new fertilizer and supplement registration and research authorization applications are now available online. Guidance documents, videos and step-by-step walk-throughs for how to sign up for an account, manage an account and request services online can be found at www.inspection.gc.ca/mycfia-guidance.

1.5 Application format

Whether applications are electronic or paper-based, the information required to be submitted in support of an application is the same. All tabs required by product type and/or ingredient must be populated in their entirety. These include: 1) Administrative Forms and Fees; 2) Marketplace Label; 3) Product Specification; 4) Results of Analysis; 5) Safety Rationale and Supplemental Data (as identified in **Appendix 1**).

Electronic applications:
The system will prompt for information by providing a brief description of the requirement, appearing in the traditional tab order and organization, as fillable fields and document uploads. Please name uploaded files with the tab number and description of file contents. For example, Tab3_Manufacting_Process.pdf.

Paper-based applications (includes applications received by a method other than MyCFIA):
The information included in the registration package must be organized in form of sections (tabs) for ease of access and review by multiple CFIA evaluators (toxicologists, microbiologists, agronomists, etc.).

For all applications:
It is **not** acceptable to omit a tab or bypass an upload prompt. If a tab is not relevant to the application, a brief written statement is required (for example "This product requires only core product information. As such, all required information has been submitted under Tabs 1, 2 and 3."), included in the file for paper- or uploaded for electronic-based applications respectively. In the electronic system, MyCFIA will not allow a user to advance to the next application requirement until all mandatory fields for the current requirement have been filled.

Applications may reference previous submissions by number, however**, each application must be independent and complete, without requiring the CFIA to pull information from older applications.** Re-registrations, amendments and me-too applications must contain all requisite information to facilitate and expedite file review. Incomplete applications will be closed.

1.6 Safety data requirements

To reduce burden on stakeholders and streamline the information required to support registration under the *Fertilizers Act* and regulations, the CFIA has implemented a tiered approach whereby the extent of the safety data requirements varies depending on the application type, nature of the product and its risk profile. All applications for registration require the submission of **core** product information (Safety assessment Level I), some also require results of analysis (Safety assessment Level II) to allow for verification of consistency in production or effectiveness of treatment as well as purity of the final product with respect to contaminant levels. Products with a higher or unknown risk profile necessitate a full safety assessment (Safety Assessment Level III), for which scientific rationales, supplemental safety data and/or additional results of analysis are required. The requisite assessment level (I, II or III) is determined based on the product ingredients (both active and inert) and their sources, potential residues, contaminants, and degradation by-products as well as the manufacturing process, use pattern and application rate and frequency. Table 1 shows the 3 Safety assessment levels and required information by Tab.

Table 1. Safety assessment levels and information requirements by tab

Assessment level	Tab 1 (Administrative requirements)	Tab 2 (Labelling requirements)	Tab 3 (Product specification)	Tab 4 (Results of analysis)	Tab 5 (Safety rationale and supplemental data)
I	✓	✓	✓		
II	✓	✓	✓	✓	
III	✓	✓	✓	✓[1]	✓

[1] Level III applications may require some or all of the results of analysis

A summary of information requirements for a variety of product ingredients can be found in **Appendix 2**.

Note: The CFIA reserves the right to require additional safety information, data, rationales or results of analysis to support the registration of **any** product regulated under the *Fertilizers Act* and regulations if and when additional safety concerns or questions have been identified during the review of the application.

In addition to familiarizing themselves with this guide, prospective registrants are encouraged to make use of the Inquiry (IQ) process to seek clarification and obtain guidance on the information requirements specific to their product, **prior** to submitting an application for registration. Additionally, product proponents may wish to request a Pre-Submission Consultation meeting with the CFIA, particularly in the early stages of product development, to obtain guidance, advice, and clarification on the regulatory requirements. The IQ and Pre-Submission Consultation processes can assist product proponents in generating appropriate data and information in support of product registration. Refer to *Guidelines for Pre-submission Consultations for Fertilizer and Supplement Products Regulated Under the Fertilizers Act and Regulations* for more details.

2. Application structure and layout

2.1 Tab 1: Administrative forms and fees

This section outlines the core administrative requirements for an application for registration.

2.1.1 - Cover letter

The applicant is required to state the intent of the application, thereby ensuring proper classification. The following must be indicated in the cover letter:

- Application type (for example new registration, re-registration, major amendment, minor amendment);
- Safety Assessment level (for example I, II or III) required (this will be subject to validation by the CFIA and the categorization may change following the pre-screening stage of the application);
- Reference to submission control number of an inquiry (for example 12345IQ) and/or previously granted registration number(s) relevant to the current application, if applicable;
- Intended end-use of the product (for example agriculture, greenhouse, turf, residential lawn, home - indoor, seed inoculation, blending).

The electronic application platform does not support an applicant uploading a cover letter, however, there are data fields to collect all of the information identified above as being required in a cover letter. Any other additional information that the applicant might typically include in a cover letter can be provided to the CFIA through a "notes" field that can be found at the end of the online application. This notes field is provided so that an applicant can identify pertinent information that was not already submitted in the standard application fields.

2.1.2 - Confirm product details (Fertilizer or Supplement Registration Application form)

All sections of the *Fertilizer or Supplement Registration Application* form must be completely and accurately filled out. For electronic applications the form has been replaced by a series of fillable fields. In both cases, the information provided must **exactly** match the label (or label text) that is submitted with the application. For paper-based applications, proponents may reference sections of their application package if there is insufficient room on the application form itself. The CFIA reserves the right to refuse a *Fertilizer or Supplement Registration Application* if the information provided is deemed incomplete. For guidance related to information requested on this form/fillable paper-based applications, please refer to the *Guidelines to Completing the Fertilizer or Supplement Registration Application Form.*

2.1.3 - Signing Authority, Delegated Representatives and Canadian Agents

Before proceeding with the registration of a product, it is necessary to provide the CFIA with signing authority as outlined in: *T-4-95 - Signing Authority, Delegated Representatives and Canadian Agents*. Signing authority is the means of informing the CFIA who they can correspond with regarding the application and for paper-based applications, who may sign the Fertilizer or Supplement Registration Application Form. The CFIA will not divulge any information regarding the application or discuss its status with any person(s) who does not have a valid signing authority. A corporation may also appoint a person to be a delegated representative. A delegated representative may correspond with the CFIA on matters relating to product registration, re-registration or approval, but may not sign application forms on behalf of the corporation.

It is not mandatory that a registrant/applicant reside in Canada. However, for applicants residing outside of Canada, a Resident Canadian Agent must be identified by name and address by filling out the prompted name and address fields in MyCFIA or by filling out the form. The Canadian Agent must co-sign all paper-based registration applications (including any re-registrations, amendments, etc.) and may be sent any related notice or correspondence as appropriate. A Canadian Agent must be a person, not a company, and this

person must be a permanent resident of Canada. An applicant may have more than 1 Canadian Agent on file. Identification as the Canadian Agent does not automatically mean the person has a signing authority on the file and a separate statement (selection of the person in the signing authority field for electronic applications) is required to authorize the CFIA to communicate with the individual regarding the file.

2.1.4 - Registration Fee

In order for the CFIA to process a file, a registration fee is to be paid as per Part 5 of the CFIA's Fees notice.

Fees described in Part 5 of the CFIA's Fees Notice apply to applications made under the *Fertilizers Act* to:

- register;
- re-register;
- amend a registration; or
- assess the safety of a product.

- In cases when the applicant requests a safety assessment only (no registration) the registration fee is not charged and the safety assessment fee is payable when the request is submitted.

In order to ensure consistency in the collection of fees and predictability for regulated parties, the safety fee is applied to **all** Level II and Level III safety assessments as defined in this guide.

Product type	**Registration fees**	**Safety fees**
Major Amendment (AM)	✓	1
Minor Amendment (MA)	✓	
New Registration (NR) Level I	✓	
New Registration (NR) Level II	✓	✓
New Registration (NR) Level III	✓	✓
New Registration (NR) me-too	✓	
Re-registration (RR)	✓	1

[1] Safety fees are charged for a re-registration application or a major amendment in cases where changes to the product's formulation or manufacturing are made, thereby triggering a safety assessment, when not self-identified by the applicant, a CFIA evaluator will notify the applicant of this required fee during at 1st response.

2.2 Tab 2: Proposed marketplace label

Every person who packages, or causes to be packaged, a fertilizer or supplement, or who imports a packaged fertilizer or supplement, must ensure that the package is labelled in accordance with the *Fertilizers Regulations*. **A copy of the product label, or all of the text that is proposed to appear on the product label, must be submitted with the application for registration. The CFIA will accept text-only versions of product labels during the initial review stages, but will not register the product without reviewing and approving the final marketplace label.**

All information required by the regulations must be printed conspicuously, legibly and indelibly in both English and French.

A product label must:

- not include any incorrect or misleading information or symbol that could reasonably be expected to mislead a purchaser with respect to the identity of the product as a fertilizer or supplement, its safety, composition or directions for use
- be consistent with all information provided to the CFIA during the registration process
- clearly define any acronyms used; and
- use metric units of measurement. Equivalent imperial units are permitted to appear in addition to the metric (conversion must be accurate)

No changes may be made to the label, chemical composition or ingredients in a product that would impact its identity as a fertilizer or supplement, its safety, or its use, unless the registration is first amended accordingly.

A package containing a fertilizer or a supplement must be labelled with the following:

2.2.1 Product identity and description

a. The name and address of the manufacturer or registrant or, if a fertilizer or supplement is not registered under the *Fertilizer Regulations*, the name and address of the person who packaged or caused the fertilizer or supplement to be packaged;

b. The name of the fertilizer or supplement. The name of a fertilizer that contains any major plant nutrient must include the grade designation that is stated as a hyphenated numerical series (the numerals must represent guarantees expressed in per cent for total nitrogen, available phosphoric acid and soluble potash listed in that order). **Note:** a fertilizer that is intended for daily feeding and that is not intended for further dilution is not required to have its grade as part of its name;

c. If the fertilizer or supplement is registered, its registration number;

d. If the fertilizer or supplement product is exempt from registration because it appears on the List of Primary Fertilizer and Supplement Materials (List of Materials), the Term (name) for each component, as it appears on the List of Materials, and any other information that is sufficient to demonstrate that the fertilizer or supplement is exempt;

e. the weight of the fertilizer or supplement (volume is also permitted);

f. the lot number of the fertilizer or supplement; and

g. in the case of a supplement in which the active ingredient may deteriorate, the date beyond which the supplement is not intended for use.

2.2.2 Guaranteed analysis

The guaranteed analysis of a fertilizer or supplement must include, if applicable:

Nutrients:

- the minimum amount of total nitrogen, available phosphoric acid and soluble potash, expressed in per cent;
- the minimum amount of each secondary nutrient (calcium, magnesium or sulphur), expressed in per cent on an elemental basis;
- the actual amount of each micronutrient (boron, chlorine, copper, iron, manganese, molybdenum or zinc), expressed in per cent on an elemental basis;
- in the case of an untreated phosphatic fertilizer, the minimum amount of total phosphoric acid and the minimum amount of available phosphoric acid, expressed in per cent;

Microorganisms:

- active microorganisms (except in the case of consortia) must each be listed by genus and species (and strain if available) along with the following information:
  - number of viable cells per gram, or
  - for each microorganism that is not a viable cell, another descriptor of the concentration of that microorganism on a per gram basis
- for microbial consortia: a descriptor of the concentration of viable microorganisms on a per gram basis;

pH adjusters:

- for active ingredient(s) intended to neutralize acidity:
  - the amount of calcium and magnesium, if any, expressed in per cent on an elemental basis
  - its neutralizing value, expressed in per cent of the acid neutralizing capacity of calcium carbonate, and
  - the range of particle sizes of solid materials

- where an active ingredient is an acidifying material intended to increase the hydrogen ion concentration of a growing medium: its acidifying value, expressed in per cent of the basic neutralizing capacity of hydrochloric acid.

Other active ingredients:

- organic matter: the amount expressed in per cent and the moisture content expressed in per cent; and
- any other active ingredient expressed in per cent.

Note: If the active ingredient to be expressed in per cent, is present in a concentration of less than 0.001%, the guaranteed analysis may instead indicate its concentration, on a per gram basis, using another unit of measure.

2.2.3 Directions for use

For a fertilizer, the directions for use must include 1 of the following:

a. complete recommendations, including the intended crop type, the rate, the frequency, and the timing of use; or

b. if the product is intended only for use in blended/formulated fertilizer, a statement such as "Only for Use in Blended Fertilizers" is included on the label; or

c. a statement indicating that the user should seek the advice of the county agricultural representative or a professional agricultural consultant.

Additionally, for all products that contain micronutrients intended to treat a specific nutrient deficiency, a statement must also appear on the label indicating that the product should be used on the basis of a soil and/or tissue analysis.

For a supplement, the complete directions for use are to appear on the product label and include: the intended plant/crop type, the rate, the frequency of application, and the timing of use. If applicable, dilution instructions

2.2.4 Precautionary statements

A statement setting out any precaution that is necessary to mitigate a risk of harm to human, animal or plant health or the environment (except pests) may be required on the label/package of any regulated fertilizer or supplement product. Table 1 and 2 outline precautionary statements that are required when certain ingredients are present in a fertilizer or supplement product. In addition to the statements below, additional product-specific precautionary statements may be required on a case-by-case basis depending on the ingredients in the product, the product's risk profile and its intended use pattern.

The CFIA requires that any hazard or precautionary statements and personal protective equipment requirements that appear on the safety data sheet be incorporated into the product labels. If these are contained within the WHIMS (Workplace Hazardous Materials Information System) box/portion of the label, they need not be duplicated elsewhere on the label. Additional precautionary statements and/or protective equipment requirements may be requested by the CFIA even if they do not appear on the safety data sheet.

Table 2. Precautionary statement requirements based on active ingredients in the fertilizer or supplement product.

Active ingredient	Precautionary statement requirement
viable microorganisms	label may require cautionary statements and/or recommend personal protective equipment, in order to minimize dermal/respiratory sensitization/irritation potential.
supplemental metal (such as cobalt)	"**Caution:** This fertilizer contains (specify name of the supplemental metal) and should be used only as recommended. It may prove harmful when misused."
Boron, copper, iron, manganese, molybdenum or zinc	"**Caution:** This fertilizer contains (specify name of lesser plant nutrient) and should be used only as recommended. It may prove harmful when misused."
Boron content greater than or equal to 0.3% of the final product	"May damage fertility or the unborn child".

Table 3. Precautionary statement requirement for specific materials which may be included in/as fertilizer or supplements.

Fertilizer or supplement is or contains	Precautionary statement requirement
Priority allergens: peanuts, tree nuts, sesame seeds, milk, eggs, fish, crustaceans and molluscs, soy, wheat and triticale, sulphites and mustard.	"**Caution:** This product contains (list all allergens). Adverse reactions may occur in sensitive persons. If skin contact occurs, wash with soap and water. Wear dust mask and protective gloves. If allergic reaction occurs, seek medical attention".
Prohibited material as defined in subsection 162(1) of the *Health of Animals Regulations*	statements indicating that: • feeding the fertilizer or supplement to cattle, sheep, deer or other ruminants is prohibited and punishable under the *Health of Animals Act*, • the fertilizer or supplement is not to be used on pasture land or other grazing areas for ruminants, • the fertilizer or supplement is not to be ingested, and • a person must wash their hands after they use the fertilizer or supplement.

2.3 Tab 3: Product specification

All ingredients in the product (both active and inert) and their sources must be identified and listed under this tab. In addition, a detailed description of the manufacturing process preferably in the form of a flow chart is required together with all relevant quality control/assurance procedures used to ensure consistency in production and purity of the final product. This information is the minimum necessary for CFIA to conduct a preliminary assessment of the product and determine if additional information is required. It is intended for CFIA evaluators only and it is considered and treated as Confidential Business Information (CBI). CBI shall not be divulged or released without explicit authorization (in writing) of the registrant. If the registrant has or anticipates any difficulties in obtaining this information (due to its proprietary nature) it may be submitted by the distributor or manufacturer directly to the CFIA.

2.3.1 - List of ingredients

2.3.1.1 - Input materials

For all materials used in the production of a registerable fertilizer or supplement, except microbial inocula described in section (2.3.1.2), the following information is required:

a. Name of the material
b. Chemical Abstracts Service number (CAS #, if available)
c. Manufacturer
d. Country of origin
e. Source: for example . manufactured (for example dyes, chelators), harvested (for example seaweed, straw, yucca), mined (for example ores), by-product (for example baghouse/electrostatic dust, klinker, slag, electrolysis, ash), recycled organics[1] (for example source separated organics, compost, biosolids,

pulp and paper), synthesized (describe the chemical reaction and any residuals and reaction by-products)

- **f.** Manufacturing/purification processes of the ingredient, if applicable
- **g.** Concentration of the material in the final product
- **h.** Purpose of the material; and
- **i.** Safety data sheets which serve as basis for preliminary safety evaluation, identifying points (such as possible contaminants) which may need to be examined in greater detail. A safety data sheet should also provide a detailed explanation of precautions and protective measures. The Workplace Hazardous Materials Information System (WHMIS) provides criteria for developing a safety data sheet

[1]Recycled organics are required to indicate specific inputs or feedstocks.

Multiple sources of an ingredient may be identified at the time of product registration and used interchangeably during the manufacture of the product. Note: any changes to the ingredients, their sources or their supplier(s) or changes to the formulation after registration require a major amendment unless the CFIA first approves a submitted notification of source change.

2.3.1.2 - Microbial inocula

For products that contain **naturally occurring** viable microorganism(s) the following information is required:

- **a.** Purpose of the microbial strain in the supplement
- **b.** Taxonomic identification of the microorganism to the genus and species level; subspecies, and strain information may also be required depending on the nature of the microorganism),
- **c.** Analytical results (including criteria and raw data) substantiating the taxonomic ID and classification
- **d.** Relationship to known pathogens (for example phylogenetic trees)
- **e.** Origin of the microorganism (when, where and from which material it was isolated) if it is an environmental isolate; or the strain bank accession number and culture certificate if the strain has been deposited in a recognized culture collection, for example American Type Culture Collection (ATCC) or other

Strong and defensible taxonomic identification, preferably to the strain level, is important for the hazard characterization of the microorganism. The choice of methods for microbial identification is at the discretion of the applicant. However, the CFIA recommends that applicants adopt an integrated poly-phasic approach that includes phenotypic analysis (for example analysis of morphological traits or biochemical characteristics) along with molecular tools (for example DNA, RNA or protein based methods), to accurately identify the microorganism. The strengths and weaknesses of the various identification methods should be taken into consideration, such that the methods chosen complement each other to result in a conclusive and definitive identification of the microorganism, and allow for clear differentiation of the organism from any closely related pathogenic and/or toxigenic species and strains.

For a **microbial consortium**, defined as a complex community of microorganisms taken from a single natural environment whose composition is maintained <u>without</u> further manipulation, the following are required:

- **f.** A description of the source, which must be a single natural environment
- **g.** Processing details to support that composition is maintained without further manipulation

Where possible, identification of all individual species in a consortium should be provided. Where precise taxonomic designation is not possible, identification to the level of genus (and possibly family) can be used to describe the major constituents in a consortium. Where taxonomic groupings are identified, the consortium should be screened for hazardous species relevant to the product in question. Product-type and source-dependent indicators should be chosen by the proponent. For example, a product may be screened for species pathogenic to humans such as *Salmonella* sp., *Listeria monocytogenes*, *Vibro* sp., *Campylobacter* sp., *Clostridia* sp., *Bacillus anthracis*, *Pseudomonas aeruginosa*, *Yersinia* sp., *Candida albicans*, *Aspergillus fumigatus*, Faecal coliforms, *Enterococci*, Rotavirus, Norovirus and *Ascaris lumbricoides*. Please note that the Fertilizer Safety Section may request additional indicator screening at the time of review. Pathogenicity tests should be done on the final product formulation.

For additional information, please consult T-4-126 Identification and taxonomic classification of microorganism(s) represented for use as supplements under the *Fertilizers Act*.

For microorganisms modified by molecular biological techniques the following information is required:

- **a.** Flow diagram representing the genetic modification process including:
  - **1.** the map of the construct inserted in the host
  - **2.** location (chromosomal or plasmid)
  - **3.** copy number
  - **4.** cloning vector(s) used
  - **5.** promoter sequences
  - **6.** selectable marker genes including any antibiotic resistance genes
- **b.** Detailed description of the gene product(s), their properties and functions
- **c.** Description of the metabolic pathways altered by the insertion
- **d.** Unintended effects on gene expression (down-regulation or up-regulation of other genes)
- **e.** Stability of the inserted genetic material
- **f.** Horizontal gene transfer potential: capacity to transfer the genetic material between the organism and non-target species, the mechanisms of possible transfer (transformation, transduction or conjugation) and the elements involved (plasmids, bacteriophages, integrative conjugative elements, transposons, insertion sequences, integrons, gene cassettes and genomic islands)
- **g.** Procedures and tests to detect and quantify the modified microorganisms
- **h.** For endophytes, the potential presence of the microbe in the edible portion of the crop must be addressed

Substantiation of the purity of the inoculum is also required and includes:

- **a.** A description of the quality control parameters used to monitor, identity and purify the microorganism from the seed stock (primary inoculum), and the company name and address that keep the seed stock;
- **b.** The manufacturing process and quality control parameters used to monitor the identity and purity of the final inoculum (used as an ingredient in the final product, generally mixed with inert ingredients); and
- **c.** Safety data sheet of the inoculum, if available

2.3.1.3 - Composition of the final product

The identity and relative proportions as weight/weight percentages (totalling 100%) must be provided for **all ingredients** present in the **final product** including all active and inert ingredients, contaminants, residuals, reaction by-products and degradation products.

The input materials may be the same as the final product constituents providing there are no chemical reaction(s) or metabolic by-products generated during the manufacture/storage of the final product prior to sale and no growth of new microorganism(s) is taking place.

Final product safety data sheet should be provided with the application, if available.

2.3.2 - Method of manufacture

A description of the manufacturing process of the final product accompanied by a flowchart used as an overview of the process to determine if there is any potential for secondary reactions, formation of by-products and/or microbial contamination. This description must specify each production step, including point of feedstock incorporation and its proportion by weight and associated conditions, such as temperature, pressure, time, and processing equipment.

2.3.3 - Quality assurance and quality control procedures

In order to substantiate consistency in production and safety of the final product, proponents are required to provide the following details relating to Quality Assurance (QA) and Quality Control (QC) procedures used during manufacture process:

- **a.** Substantiation of the conformance of raw materials to specifications and standards (with analysis or accreditation when applicable)
- **b.** Indication of material(s) being tested (for example raw, intermediary or final product)
- **c.** Specification of analyses and sensitivity of test methods (limits of detection and/or limits of quantification)
- **d.** Identification of “pass” criteria
- **e.** Testing frequency (for example per batch or unit time) and point of sampling during production
- **f.** Monitoring of manufacturing conditions (for example time, pressure, moisture content); and
- **g.** Fate of noncompliant batches/lots (for example reprocessing, disposal)

2.3.4 - Physical characteristics of the final product

For example: granular, liquid, pH, color, odor, size guide number (SGN).

2.4 Tab 4: Results of analysis

The results of analysis required in support of a registration vary depending on product type and the source of ingredients. Examples of ingredient-specific results of analysis that are required to be included in an application are provided in **Appendix 2**. The safety standards and limits for trace metals, dioxins and furans and indicator organisms (*Salmonella* and Faecal Coliform) used by the CFIA to assess product safety and efficiency of treatment or processing are outlined in **Appendix 3**. The upper tolerances around guarantees for fertilizers represented to contain micronutrients are also outlined in **Appendix 3.**

Product samples must be taken at intervals enabling assessment of the consistency in production (for example at regular time intervals, upon receipt of raw materials, per lot/batch, etc.). Applicants are required to indicate the number of batches produced annually. All results of analyses submitted to the CFIA must be printed on laboratory letterhead, bear the signature of the analyst, indicate sample preparation method(s),the test method(s) used together with limits of Quantitation (LOQ) and/or limits of detection (LOD).The results of

analysis must also identify the body that certified/accredited the laboratory. To facilitate file review, results of analysis are to be accompanied by a table with all of the following column headings, identifying for each analysis and sample:

a. name of product and/or constituent material (in full, no abbreviations)
b. laboratory sample identification number
c. manufacturing/sampling date; and
d. type of analysis (for example metals/micronutrients, dioxins and furans, indicator organisms)

2.4.1 – Metals

To demonstrate compliance with the trace metals standards, proponents are required to provide results of analyses for the following 11 metals of concern: As, Cd, Co, Cu, Cr, Hg, Mo, Ni, Pb, Se, and Zn. The number of metal analyses that are required at the time of new registration or re-registration, corresponds to the total number of batches/lots of product manufactured within a 5 year interval preceding the submission of an application for a new or re-registration. This is depicted in Table 4. Analyses provided must be reflective of the batches manufactured over the 5 year period. For example, if 5 analyses are required, it is recommended to submit 1 analysis from each calendar year. Products generated by continuous process require 6 sets of analysis evenly spread over the 5 year interval preceding submission.

Where results of requisite number of analyses are not available (for example because product is not yet being manufactured) please contact the Fertilizer Safety Section for guidance. These will be considered on a case-by-case basis.

Table 4. CFIA Fertilizer Sampling Requirements for Metals Analyses

Number of batches/Lots produced within the 5 years preceding the application	Number of sample analyses required
1	1
2 to 4	2
5 to 9	3
10 to 16	4
17 to 25	5
26+ Schedule to be provided by stakeholder and approved by the CFIA	To be determined

2.4.2 - Dioxins and furans

To demonstrate compliance with the CFIA Fertilizer Dioxin and Furan Standards, proponents must provide 1 set of TEQ dioxins and furans analyses (see **Tables 6 and 7**, **Appendix 3**). Note: Not all level II safety assessments require the submission of dioxin and furan analyses.

2.4.3 - Indicator organisms

Salmonella and Faecal coliforms are currently used by the CFIA as indicators of pathogen contamination and effectiveness of the treatment process. To demonstrate compliance with the CFIA requirements, proponents must provide 4 sets of result of analyses from 4 different lots/batches of the final product for Faecal coliform and *Salmonella.* Samples must be taken at intervals of at least 2 weeks for continuous or semi-continuous batches, or at intervals that correspond to the actual batch manufacture (see **Table 8**, **Appendix 3**).

2.4.4 – Upper tolerances for nutrient guarantees for fertilizers represented to contain micronutrients

To demonstrate compliance with the CFIA upper tolerances for fertilizers represented to contain micronutrients, proponents are required to provide results of analysis for guaranteed micronutrients (B, Cl, Cu, Fe, Mn, Mo, Zn) in addition to the results of analysis for the reportable metals (As, Cd, Cr, Co, Cu, Hg, Mo, Ni, Pb, Se, Zn). The analyses are required both at the time of registration and re-registration to ensure that the actual content of the nutrient in the product does not exceed the guarantee by an amount that is higher than the allowable tolerance (see **Table 9**, **Appendix 3)**. The number of analyses required will be based on the number of batches produced as per the current policy - for details please refer to Table 4 above.

2.5 Tab 5: Safety rationale and supplemental data

Product safety assessments are conducted using the universal 4 step risk assessment framework that is also employed by other CFIA programs (for example plant, animal, food), sister government departments or Agencies (for example Health Canada, Environment Canada, Pesticide Regulatory Management Agency (PMRA)), and international counterparts (for example US Environmental Protection Agency (EPA)). The 4 steps of the framework consist of: hazard identification, dose-response assessment (hazard characterization), exposure assessment and risk characterization.

- *Hazard identification* is a determination of the adverse human health and environmental effects.
- *Dose-response assessment* is a quantification of the relationship between administered/received dose and biological response of an individual or population.
- *Exposure assessment* predicts the anticipated level of human and organism contact and/or uptake and environmental media concentrations that arise as a result of product use.
- *Risk assessment* is a deterministic or probabilistic estimate of the incidence of the adverse human and ecological effects on the basis of the hazard characterization and what is known about exposure; this is the basic risk assessment paradigm (**Risk = hazard multiplied by exposure**).

The safety endpoints detailed in this section are provided as guidance to substantiate the safety of a product with respect to human, plant, and animal health and the environment when the product is used as directed or applied in an amount that is not in excess of the amount that is necessary to achieve its intended purposes. Based on the assessment, additional information may be requested by the CFIA. The safety rationales and supplemental data are **only** required for level III full safety assessments and are determined based on the risk profile of the product. This Tab has been broken down into 3 sections: toxicological risk profile; microbial risk profile; and references and supplemental documentation. **The CFIA strongly recommends that applicants seek assistance/advice from scientific professionals with expertise in human and environmental toxicology and/or microbiology to assist in preparing documentation required under this tab.**

Where there are reasonable scientific grounds to believe that an information requirement identified in this tab is neither necessary, nor applicable to the safety assessment of a product/ingredient, a waiver from the information requirement or elements of it may be requested, and must be accompanied by a sound scientific rationale.

2.5.1 - Toxicological risk profile

2.5.1.1 - Toxicological hazard characterization

For products or ingredients that do not have a well-established history of safe use in fertilizers or supplements, the hazard characterization table in Appendix 4 must be populated. If elements identified in the table are either not applicable or relevant to an ingredient, please provide a literature-supported scientific rationale explaining this determination.

Toxicological hazard characterization may be based on information found in published peer-reviewed scientific literature, international regulatory databases, *in vitro* and *in vivo* toxicity testing/studies and/or, in the absence of experimental data, modelling. Information pertaining to a similar substance may be submitted (surrogate data). Using surrogate data requires a rationale demonstrating similarity between substances for all relevant characteristics (physical, chemical, or toxicological). **Appendix 10** provides a list of useful information resources to aid in the hazard determination.

If other hazard endpoints (for example allergenicity), route-specific hazards (for example pulmonary carcinogenicity with chronic inhalation exposure) or species-specific hazards (for example avian toxicity) are known to the applicant, it is their responsibility to identify them. Additional information may be required by the CFIA depending on risks identified.

<u>High hazard ingredients:</u>
An ingredient is considered **high hazard** if it meets 1 of more of the following criteria (*Hazard criteria identified in Appendix 4*):

- high acute toxicity ($LD_{50} \leq 500$ mg/kg, $\leq 1\ 500$ mg/m^3)
- subchronic toxicity (NO(A)EL ≤ 30 mg/kg bw/d; LO(A)EL ≤ 90 mg/kg bw/d)
- or chronic toxicity (NO(A)EL≤ 10 mg/kg bw/d; LO(A)EL ≤ 30 mg/kg bw/d)
- exhibits carcinogenicity, clastogenicity, mutagenicity, reproductive or developmental toxicity, teratogenicity or endocrine disruption (a positive result)
- or is of high acute aquatic toxicity (lowest $EC_{50}/LC_{50} < 0.1$ppm)

If any of these criteria are met, a toxicological exposure and risk assessment must be conducted (as detailed in sub-tabs 2.5.1.2 and 2.5.1.3).

<u>Ingredients that do not meet any of the hazard criteria:</u>
These ingredients do not require an exposure assessment or risk assessment and completion of sub-tab 2.5.1.2 and 2.5.1.3 is not mandatory.

2.5.1.2 - Toxicological exposure assessment

Applicants must populate **all** fields of the table found in **Appendix 5** for all constituent materials (active and inert), residuals, contaminants and degradation products for which a <u>high hazard level</u> has been identified, as per the endpoint-specific **Hazard Criteria** found in **Appendix 4**. Both direct routes of exposure (occupational mixer, loader, applicator/user) and indirect routes of exposure (by-stander, groundwater, food or feed crop residue, contaminated soil contact and consumption) must be addressed. The choice of appropriate or relevant routes of exposure is based on the intended use pattern of the product (for example agricultural field use vs. potting mixes; ornamental plant species vs. food crops), frequency and rates of application as well as the physicochemical properties of the product and its constituents. These are important factors in determining human, animal, non-target plant and environmental exposure scenarios and must be identified in **Appendix 5**. Applicants must consider worst-case exposure scenarios. Label statements intended to limit exposures such as recommendations for protective equipment to be used, safe handling and disposal procedures, precautionary statements and use pattern restrictions (for example do not use on food crops or grazing lands) as well as post-entry intervals (if applicable) should be integrated in the estimates of

human and environmental exposure. The CFIA considers the custom-applicator scenario as the worst-case frequency of occupational exposure.

2.5.1.3 - Toxicological risk assessment

Applicants must generate estimates of risk (to be populated in **Appendix 5**) by combining the hazard and exposure assessments for each high hazard ingredient under all relevant exposure scenarios characterized in sub–tab 2.5.1.2. The CFIA will review and validate the risk estimate(s) derived by the applicant. Additional information/test data may be required in order to refine the exposure and hazard assessments and/or require mitigation measures such as protective equipment to be used, safe handling and disposal procedures, precautionary statements, use pattern restrictions (for example food vs. non-food crop) and any post-entry intervals, if applicable to facilitate safe use of the product.

2.5.2 - Microbial risk profile

2.5.2.1 - Microbial hazard assessment

A hazard assessment characterizes the microorganism and identifies the potential adverse effects (for example, pathogenicity/toxicity, sensitization, toxigenicity and antimicrobial resistance priority status) towards humans, animals and plants, and the environment. The hazards may be posed by the microorganism itself, its metabolites/toxins or its genetic material.

Source of hazard information include test data, a review of case reports and analytical studies from scientific literature, and research investigations (completed or ongoing). Hazard information considered in the assessment may be for the specific microorganism being assessed, or a suitable surrogate, if there is insufficient information on the specific microorganism and the choice of surrogate is supported by a sound scientific rationale. Factors affecting the severity (degree) of hazard may be strain specific and therefore the assessment must address the factors known or suspected to be produced by the strain, as well as those known or suspected to be produced by other strains of the species (or genus). The severity of hazard may also be affected by the life stage of the organism. For this reason, all stages of the life cycle of the microorganism and their potential effects must be considered.
Ideally, test/study data are used to evaluate the potential adverse effects of the specific microorganism being assessed. Testing typically starts with a maximum hazard dose (maximum label dose/rate). If adverse effects are reported at this dose, a range of lesser doses may be used to establish a dose-response relationship, and ideally to identify an appropriate statistical endpoint, such as median infective, effective or lethal dose or concentration (ID_{50}/IC_{50}, ED_{50}/EC_{50}, LD_{50}/LC_{50}) (Environment Canada, EPS 1/RM/46, March 2005). Recommended methodology for testing the pathogenicity/toxicity of microorganisms on human, animals and plants are available in the "*Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms*" (Environment Canada, Report EPS 1/RM/44, March 2004). **Appendix 11** describes the documents referenced in this section and additional useful information resources. A study report should be prepared for each study. The OECD's Principles of Good Laboratory Practice (GLP) include guidance on reporting study results (OECD; 1998a). The extent of compliance with OECD's Principles of Good Laboratory Practice should be indicated.

Appendix 6 highlights the data required for microbial hazard characterization. We recommend that the applicant uses **Appendix 6** as a checklist to assist in providing all relevant information that is required. The information presented should be referenced, and a copy of each referenced publication/documentation or analytical/study report must be included in the application.

2.5.2.2 - Microbial exposure assessment

An exposure assessment identifies the mechanisms by which a microorganism is introduced into a receiving environment, considers its environmental expression and fate, and estimates the likelihood, magnitude, frequency, duration, and/or extent of human and environmental exposure. Exposure to the microorganism may be direct (for example, through contact with the product) or indirect. Indirect exposure assessment considers how the microorganism is released into the environment through known, proposed or predicted uses, and the environmental fate of the microorganism, its genetic material, toxins and metabolites.

Information considered in the exposure assessment may be for the specific microorganism being assessed, or a suitable surrogate, if there is insufficient information on the specific microorganism and the choice of surrogate is supported by a sound scientific rationale.

Appendix 7 highlights the factors that need to be addressed in order to characterize the exposure to the microorganism. We recommend that the applicant uses **Appendix 7** as a checklist to assist in providing all relevant information that is required.

2.5.2.3 - Microbial risk assessment

The risk assessment conclusion is based on the hazard, and on what is known about the exposure. Considerations for classification of microbial hazard severity and exposure level are summarized in **Appendix 8**. Where appropriate, any preventative risk mitigation measures such as protective equipment to be used, safe handling and disposal procedures, precautionary statements and use pattern restrictions (for example do not use on food crops or grazing lands) as well as post-entry intervals maybe required to minimize worker and environmental exposures.

2.5.3 - References and supplemental documentation

All published information used to fulfill the requirements under **Tab 5** must be **cited in-text** (author/source, year) and also provided in a **list of references** under this sub-tab. Each document must be properly referenced (authors, document name, source, date and page numbers).
Also, copies of all published information referenced under **Tab 5** and analytical results used or mentioned in **Tab 4** and **Tab 5** must be provided under this sub-tab. All models or modelling software employed in support of the safety rationale must be **cited in-text** (model, version) and must also be provided in the **list of references** under this tab.

3. Contact information

Fertilizer Safety Section
c/o Pre-market Application Submissions Office (PASO)
Canadian Food Inspection Agency
59 Camelot Drive
Ottawa, ON K1A 0Y9
Canada
Phone: 1-855-212-7695
Fax: 613-773-7115
Email: cfia.paso-bpdpm.acia@canada.ca

Appendix 1: List of mandatory tabs and sub-tabs

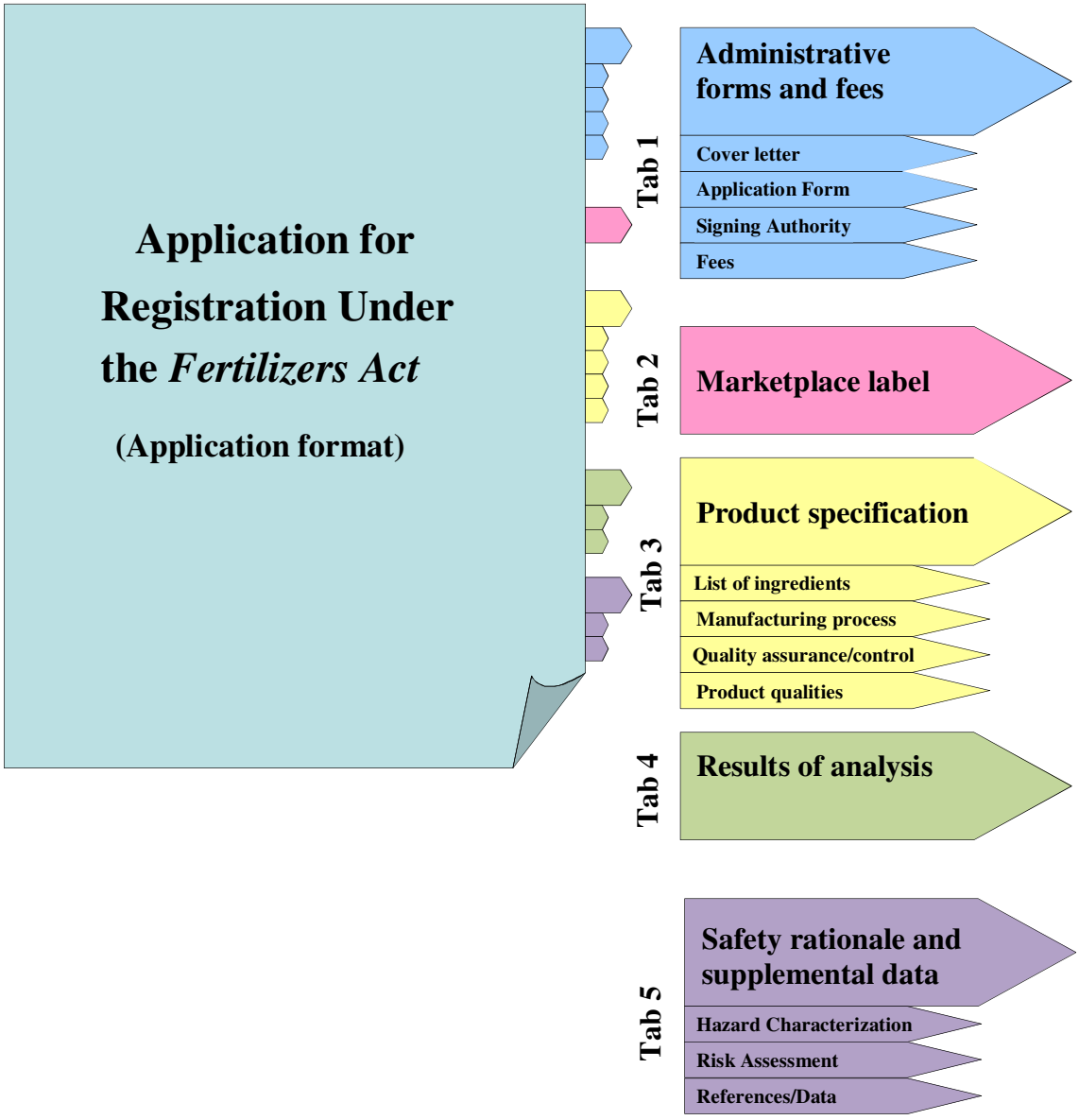

Figure 1: Format of the application. All Tabs are mandatory and omitting any required information will result in the application for registration being rejected at the first response stage. Please adhere to the headings of each tab as identified in the guide.

Appendix 2: Product ingredients and associated safety data requirements

Safety data requirements vary depending on the nature of the product and its risk profile. The presence of an active or inert ingredient in the product may trigger additional safety requirements. The following table details a number of common product ingredients and the associated safety data requirements. Note that all products comprising or containing industrial by-products or recycled organic materials require Tab 4 (Results of analysis).

			Tab 4			
		Tabs 1, 2, 3	Metals	Dioxins Furans	Indicator Organisms	***Tab 5***
Level I	**Indole-3-butyric acid** (IBA) at a concentration not exceeding 1% of the product excluding products for spray application	✓				
	VAMs (Vesicular Arbuscular Myccorhizae) provided the species is substantially equivalent/representative of VAM group	✓				
	Rhizobia (species of the genera *Rhizobium*, *Bradyrhizobium*, *Mesorhizobium* and *Sinorhizobium*) provided the species is substantially equivalent/representative of the rhizobia group, and is not genetically modified.	✓				
	Bacillus subtilis provided the strain is representative of the species, is not genetically modified and does not produce any human enterotoxin.	✓				
Level II	**Mineral derived nutrients**	✓	✓	(1)		
	Micronutrients	✓	✓	(1)		
	Plant extracts and residues	✓	✓		✓	
	Seaweed	✓	✓		✓	
	Fertilizers containing					
	Cement by-products	✓	✓(2)	✓		
	Compost	✓	✓		✓	
	Meals	✓	✓		✓	
	Processed sewage including composts thereof	✓	✓	✓	✓	
	Pulp and paper sludge	✓	✓	✓	✓	
	Wood ash	✓	✓	✓		
	Organic waste	✓	✓		✓	
	Silica	✓	✓			
	Fish fertilizer	✓	✓		✓	
	Biochar	✓	✓			
Level III	**Polymer coated fertilizers**	✓				✓
	Polymeric soil stabilizers	✓				✓
	Wetting agents and surfactants	✓				✓
	Nano-encapsulated fertilizers and nanomaterials (3)	✓				✓
	Plant growth regulators and Plant signalling compounds (for example Gibberellin, Cytokines, NAA, LCOs, Salicylic Acid, Chitosan, Hesperetin, Naringenin) other than Level I IBA as described above	✓				✓
	Registerable supplement(s) that would themselves require a full safety data package, blended with fertilizer.	✓	(4)	(4)	(4)	✓
	Viable microorganism(s) other than those described in Level I	✓			✓	✓
	Metabolites of organism(s)	✓			✓	✓

(1) source dependent
(2) require Thallium and Vanadium testing in addition to analysis of the 11 standard metals.
(3) All products in part or in whole comprised of nano-materials require full safety assessment.
(4) Basic results of analysis required depending on the ingredients.

Note: this does not constitute a comprehensive list of product /ingredient - specific requirements.

Appendix 3: Metals, dioxins/Furans standards and maximum acceptable level of indicator organisms in fertilizers and supplements

Metals Standards

The metals of concern include arsenic (As), cadmium (Cd), chromium (Cr), cobalt (Co), copper (Cu), mercury (Hg), molybdenum (Mo), nickel (Ni), lead (Pb), selenium (Se) and zinc (Zn). Accumulation of these metals in soil over the long term may lead to plant, animal, environmental or human toxicity. The maximum concentration of metals permitted in a product depends on the application rate of the product.

Metals standards are predicated on the maximum acceptable cumulative addition to soils over a 45 year time period, as opposed to the actual concentration of the metal in the product. The 45 year cumulative application approach is intended to account for the persistence of metals in the environment which ultimately determines the level of contamination and thus, long term impacts.

The **maximum acceptable product metal concentration** (in mg metal/kg product) is calculated for each metal using the CFIA standards for maximum acceptable additions to soil and the product's maximum recommended annual application rate. The formula is as follows:

$$1000000\frac{mg}{kg} \times \left[\frac{\textbf{maximum acceptable cumulative metal addition to soil over 45 years}\ (kg\ metal/ha)}{45\ years \times \textbf{annual application rate}\ (kg\ product/ha \cdot yr)}\right]$$

All fertilizers and supplements, including processed sewage, composts and other by-products are required to meet the standards for maximum acceptable cumulative metal additions to soil.

Certain metals such as copper (Cu), molybdenum (Mo) and zinc (Zn) are also **essential plant nutrients**. Products represented to contain (for example guarantee) Cu, Mo or Zn that are used to treat a specific nutrient deficiency are not required to have an application rate specified on the label; rather the label states that the application rate is to be based on a soil or tissue test. In those instances, concentrations of the metal may exceed the metal standard (due to limited frequency of application) and the 95th percentile of the provincially recommended agronomic application rate is used in the calculations. These products must still meet the prescribed labelling standards including representation of the element as a plant nutrient, the associated guaranteed analysis and appropriate precautionary statements. **Table 5** shows the acceptable metals concentrations for products at different application rates.

Table 5. Metals standards and examples of maximum acceptable metal concentrations based on annual application rates

Metal	**Maximum acceptable cumulative metal addition to soil over 45 years** (kg metal/ha)	**Examples of maximum acceptable concentration of a metal based on annual application rate** (mg metal/kg product)		
		4400 kg/ha per year	**2000 kg/ha per year**	**500 kg/ha per year**
Arsenic (As)	15	75	166	666
Cadmium (Cd)	4	20	44	177

Chromium (Cr)	210	1060	2333	9333
Cobalt (Co)	30	151	333	1333
Copper (Cu)	150	757	1666	6666
Mercury (Hg)	1	5	11	44
Molybdenum (Mo)	4	20	44	177
Nickel (Ni)	36	181	400	1600
Lead (Pb)	100	505	1111	4444
Selenium (Se)	2.8	14	31	124
Thallium (Tl) Table Note 1	1	5	11	44
Vanadium (V) Table Note 1	130	656	1444	5777
Zinc (Zn)	370	1868	4111	16444

Table Note 1: Note that not all products require results of analysis for Thallium and Vanadium. These are an example of additional results that may be requested based on product or material type, on a case-by-case basis.

Note: The application rate and the metal concentration must be presented on the same basis (for example both dry weight or both as is).

Note: The Canadian Council of Ministers of the Environment (CCME), Bureau de normalisation du Québec (BNQ) and many provinces also have guidelines for metals in soils, or in sludge, compost, and other products that are land applied. We recommend that you contact your provincial government to obtain additional information.

Note that Selenium and Cobalt are considered supplemental active ingredients as they are not essential nutrients for all plant species. Including Selenium or Cobalt in a fertilizer product formulation makes the product a registrable fertilizer containing a supplement.

A compliance verification tool, an excel spreadsheet that automates metal standard calculations, is available upon request from cfia.paso-bpdpm.acia@canada.ca. It is intended to assist manufacturers/proponents and CFIA inspectors in determining conformance of the final product with the standards.

Dioxins/furans standards

Polychlorinated dibenzo-p-dioxins (dioxins; PCDDs) and polychlorinated dibenzofurans (furans; PCDFs) are highly persistent environmental contaminants. They are found in all living organisms at very low levels and can bioaccumulate in food chains due to their lipophilic characteristics. The CFIA standard for maximum acceptable cumulative addition to soils of dioxins and furans is **5.355 mg TEQ/ha over 45 years** (where TEQ = Toxic Equivalency Quotient). Like the CFIA metals standards, the application rate of a product is a crucial element in determining acceptable product dioxins/furans concentrations and the 45 year cumulative application approach is employed to account for environmental persistence and long-term impacts. **Table 6** lists the congeners to be analyzed in determining total product dioxins and furans concentration.

Table 6. Dioxins and furans congeners for which results of analysis are required in determination of total product dioxins and furans concentration

Compound	**Toxic Equivalency Factors (TEF)**

Chlorinated dibenzo-p-dioxins	
2,3,7,8-TCDD	1
1,2,3,7,8-PCDD	1
1,2,3,4,7,8-HCDD	0.1
1,2,3,6,7,8-HCDD	0.1
1,2,3,7,8,9-HCDD	0.1
1,2,3,4,6,7,8-HCDD	0.01
OCDD	0.0001
Chlorinated dibenzofurans	
2,3,7,8-TCDF	0.1
1,2,3,7,8-PCDF	0.05
2,3,4,7,8-PCDF	0.5
1,2,3,4,7,8-HCDF	0.1
1,2,3,6,7,8-HCDF	0.1
1,2,3,7,8,9-HCDF	0.1
2,3,4,6,7,8-HCDF	0.1
1,2,3,4,6,7,8-HCDF	0.01
1,2,3,4, 7,8,9-HCDF	0.01
OCDF	0.0001
Non-ortho substituted PCBs	
3,3',4,4'-PCB	0.0001
3,4,4',5-PCB	0.0003
3,3',4,4',5-PCB	0.1
3,3',4,4',5,5'-PCB	0.03
Mono-ortho substituted PCBs	
2,3,3',4,4'-PCB	0.00003
2,3,4,4',5-PCB	0.00003
2,3',4,4',5-PCB	0.00003
2',3,4,4',5-PCB	0.00003
2,3,3',4,4',5-PCB	0.00003
2,3,3',4,4',5'-PCB	0.00003
2,3',4,4',5,5'-PCB	0.00003
2,3,3',4,4',5,5'-PCB	0.00003

The **maximum acceptable product dioxins/furans concentration** (in ng TEQ/kg product) is calculated using the CFIA standard for maximum acceptable 45-year cumulative dioxins/furans addition to soil (5.355mg TEQ/ha) and the product's maximum recommended annual application rate as follows:

$$1000000\,\frac{ng}{mg} \times \left[\frac{\mathbf{5.355mg\,TEQ/ha}}{45\ years\ \times \mathbf{annual\ application\ rate}\ (kg\ product/ha \cdot yr)}\right]$$

A maximum product concentration of 100 ng TEQ/kg product is considered protective for workers and bystanders. **Table 7** shows the dioxin/furan acceptable concentrations for products at different application rates.

Table 7. Dioxin and furan standards and examples of maximum acceptable PCDD/Fs concentrations in based on annual application rates

	Maximum acceptable cumulative PCDD/Fs additions to soil over 45 years (mg TEQ/ha)	Examples of maximum acceptable PCDD/Fs concentration based on annual application rates (ng TEQ/ha)	
		4400 kg/ha - yr	**2000 kg/ha - yr**
PCDD/Fs	5.355	27	59.5

A compliance verification tool is available from cfia.paso-bpdpm.acia@canada.ca upon request. The calculator includes functionality for persistent organic pollutants limits.

Indicator organisms

Monitoring for microbial contaminants in fertilizers and supplements must be carried out to provide information on the adequacy of pathogen-reducing processing or sterilization steps and the microbial condition of the final product. Given their widespread presence in the environment, *Salmonella* and Faecal coliform density are used as indicators of microbial contamination and effectiveness of treatment process, a practice aligned with the United States Environmental Protection Agency's Part 503 Rule. The requirement of indicator organism testing allows for detection of any regrowth of bacteria and substantiates the sufficiency of pathogen reduction processes in place.

Table 8. Maximum acceptable level of indicator organisms in fertilizers and supplements

Indicator organism	Level	Minimum detection limit
Salmonella	Not Detectable	less than 1 CFU (Colony Forming Unit) / 25 grams
Faecal Coliforms	1000 MPN (Most Probable Number) / gram solid	less than 2 CFU / gram

Tests for indicator organisms are required to meet the minimum detection limits specified in **Table 8**.

A compliance verification tool is available from cfia.paso-bpdpm.acia@canada.ca upon request. The calculator includes functionality for indicator organism limits.

The CFIA reserves the right to require analyses for additional pathogenic organisms depending on the nature of the product, as assessed on a case-by-case basis.

Please refer to Health Canada's Compendium for Microbiological Analysis for examples of standard methods. To be accepted, a method must be proven to be specific, selective, reliable, and accurate for the active ingredient in the formulated products.

Upper tolerances

To promote safe use and enable compliance verification both at the premarket assessment stage as well as marketplace monitoring and enforcement, upper tolerances for micronutrient guarantees have been established. The tolerances are based on analytical variability associated with product analysis and sampling error as well as attainability based on modern manufacturing practices.

Table 9. Upper tolerances for fertilizers represented to contain micronutrients.

For a given guarantee (left column), the permissible exceedance (numerical value) is added to the guarantee yielding the maximum allowable content (right column).

Guarantee range	Permissible guarantee exceedance
<0.0033	0.0013
0.0033-0.0099	0.0040
0.010-0.032	0.010
0.033-0.099	0.031
0.10-0.32	0.077
0.33-0.99	0.23
1.0-3.2	0.60
3.3-9.99	1.0
≥ 10	10% of Guarantee

Please note that the tolerances vary depending on the range of the micronutrient guaranteed – the tolerance is greater in the low range guarantee and smaller as the concentration in the product is higher. For example, a 0.24% Cu guarantee has a permissible exceedance of 0.077, for a maximum acceptable Cu content of 0.317%. On the upper end 11% Cu guarantee has a permissible exceedance of 10% of the guarantee, in this case 1.1%, for a maximum acceptable Cu content of 12.1%.

Appendix 4: Toxicological hazards characterization

Ingredient identification

Ingredient	
Chemical Abstract Number (CAS#)	
Relative concentration in final product	

Physical chemical properties

Exposure model inputs		**Hazard criteria[1]**	**Value**	**Reference(s)**
Organic carbon partitioning coefficient (K_{oc})				
Log Octanol Water partitioning coefficient (Log K_{ow})				
Water solubility at 25ºC				
Vapour pressure				
Persistence	Air	≥ 2 days		
	Water	≥ 6 months		
	Soil			
	Sediment	≥ 1 year		
Bioaccumulation, Bioconcentration, Biomagnification Factors		>5000		

[1] For each ingredient where any of the hazard criteria are met, proceed to **Appendix 5**

Mammalian hazard profile

Endpoint by Exposure Route		**Hazard criteria[1]**	**Test organism**	**Term**	**Effect**	**Dose**	**Reference(s)**
Oral	Acute (LD_{50}, NOEL, NOAEL)	LD_{50} ≤ 500 mg/kg bw					
	Subchronic LO(A)EL, NO(A)EL	LO(A)EL ≤ 90 mg/kg bw					
		NO(A)EL ≤ 30 mg/kg bw					
	Chronic LO(A)EL, NO(A)EL	LO(A)EL ≤ 30 mg/kg bw					
		NO(A)EL ≤ 10 mg/kg bw					
Dermal	Acute (LD_{50}, NOEL, NOAEL)	LD_{50} ≤ 500 mg/kg bw					
	Irritation/Sensitization						
Inhalation	Acute (LD_{50}, NOEL, NOAEL)	LD_{50} ≤ 1500 mg/m^3					
Ocular	Irritation						
Carcinogenicity		Indication of positive result for these endpoints triggers safety rationale				2	
Clastogenicity and mutagenicity							
Reproductive/Developmental toxicity, Teratogenicity							
Endocrine Disruption							

[1] For each ingredient where any of the hazard criteria are met, proceed to **Appendix 5**

[2] Cancer potency factor (q_1*) is a measure of the relative strength of a non-threshold carcinogen.

Aquatic hazard profile

Category	**Hazard criteria[1]**	**Test organism**	**Term**	**Effect**	**Conc[n]**	**Reference(s)**
Vertebrate (for example. Rainbow trout *(Oncorhynchus mykiss)*, Brook trout *(Salvelinaus fontinalis)*, Fathead minnow *(Pimephales promelas)*, Bluegill sunfish *(Lepomis macrochirus)*)	Acute: Lowest EC_{50} or LC_{50} <0.1 ppm					
Invertebrate (for example Daphnia (*Daphnia sp., Ceriodaphnia dubia),* Zebra fish *(Brachydanio rerio),* Worm *(Lumbriculus variegatus)*)						
Benthic (for example Amphipod *(Hyallela azteca),* Midge larvae *(Chironomus tentans, Chironomus riparius)*)						
Algae (for example *Pseudokrchneriella subcapitata,* Champia parvula)						

[1] For each ingredient where any of the hazard criteria are met, proceed to **Appendix 5**

Appendix 5: Toxicological exposure and risk assessment

Only to be populated for high hazard ingredients (those that meet any of the **Hazard criteria** identified in **Appendix 4)**

Mixer/Applicator

	Assumption/Derivation/Rationale
Exposure Assessment	
Application methodology/equipment	
Application rate	
Area of application (ha)	
Frequency of application	
Expected route(s) of exposure *(for example dermal, inhalation) based on application method and product and constituent physico-chemical properties*	
Mitigative Factors Limiting Exposure	
Personal Protective Equipment *(PPE)*	
Dermal Absorption Factor (if applicable) (% of oral dose) *(DAF)*	Provide value and associated reference
Estimate of exposure, α (mg/kg bw/d)	Show derivation and associated modelling assumptions
Risk assessment	
Critical endpoint and dose, β (mg/kg bw/d) and/or cancer potency factor, q_1* (mg/kg bw/d)$^{-1}$	As identified in **Appendix 4**
Margin of safety (β/α) and/or Incremental Lifetime Cancer Risk (ILCR) (q_1* x α)	

Bystander/Indirect

	Assumption/Derivation/Rationale
Exposure assessment	
Method of exposure *(for example drift, re-entry, soil contact or consumption, potable water, plant residues)*	
Application rate	
Area of application	
Frequency of exposure	
Application setting (for example agriculture, greenhouse, residential)	
Re-entry interval	
Expected route(s) of exposure *(for example dermal, inhalation) based on application method and product and constituent physico-chemical properties*	
Environmental media concentration (ppm) (as required)	Exceedance of persistence screening criteria (**Appendix 4)** must be accounted for in this derivation
Estimate of exposure, α (mg/kg bw/d)	Show derivation, identify model used and associated modelling assumptions
Risk assessment	
Critical endpoint and dose, β (mg/kg bw/d) and/or Cancer potency factor, q_1* (mg/kg bw/d)$^{-1}$	As identified in **Appendix 4**
Margin of safety (β/α) and/or Incremental Lifetime Cancer Risk (ILCR) (q_1* x α)	

Environmental

	Assumption/Derivation/Rationale
Exposure Assessment	
Expected target environmental media *(for example soil, air, aquatic, sediment) based on application method and product and constituent physico-chemical properties*	
Application methodology/equipment	
Application rate	
Frequency of application	
Environmental media concentration estimate, γ (ppm) *(for example impregnated granule, soil, sediment or aquatic concentration)*	Show derivation, identify model used and associated modelling assumptions Exceedance of persistence and/or biomagnification/bioaccumulation/ bioconcentration screening criteria (**Appendix 4)** must be accounted for in this derivation
Organism(s) of concern exposure estimate(s), δ (mg/kg bw/d) *(if applicable, for example avian/terrestrial vertebrate toxicity)*	Show derivation, identify model used and associated assumptions (for example daily soil/granule ingestion rate)
Risk Assessment	
Organism(s) of concern and associated critical environmental concentration(s), ε (ppm)	As identified in **Appendix 4**
Organism(s) of concern and associated critical dose, ζ (mg/kg bw/d) *(if applicable for example avian/terrestrial vertebrate toxicity)*	As identified in **Appendix 4**
Risk quotient (ε/γ)	
Margin of safety (ζ/δ) *(if applicable, for example avian/terrestrial vertebrate toxicity)*	

ε The critical effect is typically the first adverse effect that occurs with increasing dose; the critical dose is the dose at which this adverse effect is observed.

Appendix 6: Microbial hazard characterization (Checklist)

Organism	Hazard	Yes/No	References
Human	Pathogenicity/Toxicity		
	Sensitization/Irritation		
	Dermatophytic potential		
	Toxigenicity[1]		
Mammals	Pathogenicity/Toxicity		
	Sensitization/Irritation		
	Dermatophytic potential		
	Toxigenicity[1]		
Other terrestrial vertebrates (for example birds)	Pathogenicity/Toxicity		
	Sensitization/Irritation		
	Toxigenicity[1]		
Terrestrial plants/crops	Pathogenicity/Toxicity		
	Growth inhibition		
	Post-harvest spoilage		
Terrestrial invertebrates (for example bees, earthworms, springtails)	Pathogenicity/Toxicity		
Aquatic vertebrates (fishes)	Pathogenicity/Toxicity		
Aquatic invertebrates (benthic, epibenthic)	Pathogenicity/Toxicity		
Aquatic plants (algae)	Pathogenicity/Toxicity		
Antimicrobial resistance			
	Hazard	**Yes/No**	**References**
Microorganism	Resistant to medically important antimicrobials[2]		
	Contributes to environmental release of antibiotics[2]		

[1] Hazard of a toxin can be estimated using established chemical models (see **Appendix 4**)

[2] For antimicrobial resistance, hazard is determined by classification as high priority or critical importance by the World Health Organization or Health Canada (see Appendix 11).

Appendix 7: Microbial exposure characterization - Factors to consider

Category	References
Natural occurrence:	
Geographical distribution	
Natural habitats: soils, water, atmosphere, on or inside of living organisms (for example endophyte, epiphyte)	
Hosts (symbiotic, saprophytic or pathogenic relationships)	
Food/feed crops on which the microorganism is found in nature	
Residues on food/feed (accumulation of the microorganism or its metabolites in the edible portion of the plant)[1]	
Physiological properties:	
Growth parameters (for example temperature, pH, osmotic minima, maxima and optima)	
Nutritional dependence, oxygen requirements, energy sources	
Susceptibility to antibiotics, metals and environmental factors such as sunlight and desiccation	
Favorable conditions for toxin production[2]	
Description of the life cycle:	
Characteristics of the different forms of the microorganism during its life cycle (for example motile cells, dormant cysts, spores)	
Mechanism for reproduction and dispersal	
Mechanism for survival (in adverse conditions)	
Potential for dispersal of traits or gene transfer (mandatory for microorganisms modified by molecular biological techniques)	
Unusual properties:	
Unusual properties of the notified strain that differ from the classical description of the species (mandatory for microorganisms modified by molecular biological techniques)	
Product use pattern:	
Crops/plants on which the product is intended to be used	Label
Application methodology/equipment	Label
Application rate	Label
Frequency of application	Label
Expected route(s) of exposure (for example dermal, inhalation, ingestion)	

[1] Residue data are used to estimate the dietary exposure of humans and livestock to microbial toxins.

[2] Exposure to a toxin can be estimated using established chemical models (see **Appendix 5**).

Appendix 8: Considerations for classification of microbial hazard severity and exposure level

Classification	Considerations for classification	
	Hazard severity	**Exposure level**
High	• Significant uncertainty in the identification, characterization or possible effects. • Disease in healthy humans/animals/plants is severe or may be lethal. • Disease in susceptible humans/animals/plants may be lethal. • Lethal or severe (irreversible) effects in laboratory mammals/plants at maximum hazard dose. • Potential for horizontal transmission/community-acquired infection. • Irreversible adverse effects (for instance loss of biodiversity, loss of habitat, serious disease). • Identified as Risk Level II by the Public Health Agency of Canada (ePATHogens Risk Group Database) • Microbes identified as high priority for antimicrobial resistance • Microbes contributing to the release of antibiotics listed as high priority for antimicrobial resistance	• The release quantity, duration and/or frequency are high. • The organism is likely to survive, persist, disperse proliferate and become established in the environment. • Dispersal or transport to other environmental compartments is likely. • The nature of release makes it likely that susceptible living organisms will be exposed. • In relation to exposed organisms, routes of exposure are permissive of toxic or pathogenic effects in susceptible organisms. • Presence of residue on food/feed (microorganism or its toxins).
Medium	• Case reports of human/animal/plant disease in the scientific literature are limited to susceptible populations or are rare, localized and rapidly self-resolving in healthy humans/animals/plants. • Effects at maximum hazard dose in laboratory mammals/plants are not lethal, and are rapidly self-resolving. • Low potential for horizontal transmission/community-acquired infection. • Some adverse but reversible or self-resolving effects. • Microbes listed at a lower priority level for antimicrobial resistance • Microbes contributing to the release of antibiotics listed at a lower priority for antimicrobial resistance	• It is released into the environment, but quantity, duration and/or frequency of release is moderate. • It may persist in the environment, but in low numbers. • The potential for dispersal/transport is limited. • The nature of release is such that some susceptible living organisms may be exposed. • In relation to exposed organisms, routes of exposure are not expected to favour toxic or pathogenic effects.
Low	• No case reports of human/animal/plant disease in the scientific literature, or case reports associated with predisposing factors are rare and without potential for secondary transmission and any effects are mostly mild, asymptomatic, or benign. • No adverse effects seen at maximum dose in laboratory mammals/plants by any route of exposure. • Well characterized and identified with no adverse environmental effects known. • May have theoretical negative impacts for a short period but no predicted long term effect for	• It is used in containment (no intentional release). • The nature of release and/or the biology of the microorganism are expected to contain the microorganism such that susceptible populations or ecosystems are not exposed. • Low quantity, duration and frequency of release of microorganisms that are not expected to survive, persist, disperse or proliferate in the environment where released.

	microbial, plant and/or animal populations or ecosystems. • Has a history of safe use over several years. • Identified as Risk Level I by the Public Health Agency of Canada • Microbes not listed as a concern for antimicrobial resistance • Microbes that do not contribute to the release of antibiotics	

Source: Adapted from ***Environment Canada and Health Canada*** *(2011): Framework for Science-Based Risk Assessment of Micro-Organisms Regulated under the Canadian Environmental Protection Act, 1999*

Note: Combinations of the factors within each generalized hazard severity or exposure level above are possible and would affect the overall hazard or exposure assessment.

Appendix 9: Labelling requirements for fertilizer-pesticides permitted for home and garden uses

i. The headings or statements in bold type must appear on the label, but do not have to be displayed in bold type. The other statements are recommended but not required.
ii. Text in capital letters must be capitalized on the label unless otherwise indicated.
iii. The exact wording of all statements is encouraged but not mandatory as long as the meaning is the same. No contradictory information may appear on the label.
iv. Text in square brackets [ ] is additional information and should not be included on the label.

Corn gluten meal

COMMON NAME:	CORN GLUTEN MEAL
GUARANTEED ANALYSIS:	**Corn gluten meal (actual)**
APPROVED FOR USE:	In specialty lawn/turf fertilizers containing compatible fertilizer constituent materials.
APPROVED CLAIMS:	Pre-emergence inhibition of large and smooth crabgrass, white clover and dandelion seed germination in residential lawns where established perennial ryegrass or established Kentucky bluegrass are the predominant grass species. Pre-emergence inhibition of large crabgrass, white clover and dandelion seed germination in public areas such as sports fields, parks, golf areas, and sod farms, where established perennial ryegrass or established Kentucky bluegrass are the predominant grass species.
APPLICATION RATES:	9500 - 9800 g of corn gluten meal / $100m^2$
DIRECTIONS FOR USE:	**May inhibit weed seed germination when used in conjunction with a sound lawn (or turf) maintenance program.** **Established weeds at time of application will not be inhibited.** **Do not apply the product on newly seeded grass as it may inhibit seeds from germinating, wait until after first mowing when root systems are established.** **If over-seeding or re-sodding in the spring, do not apply the product in the spring. If over-seeding or re-sodding in the fall, do not apply the product in the fall.** **For best results: Apply to established turf twice a year; once in the early spring 2 weeks before weed seed germination, and once in the late summer or early fall after heat stress has passed.** **Apply when soil is moist and when rain is forecasted within 2 days of treatment. If rainfall does not occur within 2 days of treatment, irrigation is required.** **Excessive moisture at time of treatment may reduce the effectiveness of the product.** Do not apply under windy conditions. Product application dates may vary for both the spring and late summer/early fall application from year to year according to weather conditions. The inhibitory effect of the product to weed seeds generally dissipates in five weeks following application. Apply to a mature lawn having a well-developed root mass.

	Large crabgrass seeds germinate when soil temperature reaches 12.8^{0}C.
PRECAUTIONS:	**KEEP OUT OF REACH OF CHILDREN** [on main and secondary panels]. **READ THE LABEL BEFORE USING** [on main panel]. **CAUTION EYE IRRITANT** [on main panel]. **POTENTIAL SENSITIZER** [on main panel]. **May cause sensitization.** **Avoid contact with skin, eyes or clothing.** **Avoid inhaling dusts.** **For good hygiene practice, wear a long-sleeved shirt, long pants, closed footwear and gloves when handling the product.** **It is recommended that a dust mask be worn when transferring the product to the spreader.** **Should not be applied if the applicator or a member of the household has a sensitivity or allergy to corn.**
FIRST AID:	**IF SWALLOWED: Rinse mouth and throat with copious amounts of water. Do not induce vomiting.** **IF ON SKIN/CLOTHING: Take off contaminated clothing. Wash skin with plenty of soap and water.** **IF INHALED: Move to fresh air.** **IF IN EYES: Hold eye open and rinse slowly and gently with water. Remove contact lenses if present, then continue rinsing eye.** **GENERAL: Seek medical attention immediately if irritation or signs of toxicity occur and persist or is severe. Take container, label or product name and registration number with you when seeking medical attention.**
TOXICOLOGICAL INFORMATION:	**Treat symptomatically.**
STORAGE:	**Keep in cool, dry conditions, away from seed, fertilizer and other pesticides.** Keep away from fire, open flame, or other sources of heat.
DISPOSAL:	**Do not re-use empty container. Dispose in accordance with municipal or provincial regulations if applicable. If no such regulations apply, wrap and dispose of empty container with household garbage.**
NOTICE TO USER:	**This product is to be used in accordance with the directions on this label. It is an offence under the *Pest Control Products Act* to use this product under unsafe conditions.**
ACCEPTED COMPATIBLE PESTICIDE ACTIVE INGREDIENTS:	NONE
APPROVED BRANDS OF PESTICIDE PRODUCTS:	Refer to the corn gluten meal section PMRA's approved brands of pesticide products

Ferrous Sulphate

COMMON NAME:	FERROUS SULPHATE
GUARANTEED ANALYSIS:	**Ferrous Sulphate (actual)**
APPROVED FOR USE:	In specialty lawn/turf fertilizers containing compatible fertilizer constituent materials.
APPROVED CLAIMS:	Controls moss in lawns.
APPLICATION RATES:	250 - 980 g of Ferrous sulphate / 100m^2
DIRECTIONS FOR USE:	In lawns: Moss will take over under conditions of poor light, poor drainage and inadequate plant food. Prune trees to open up and reduce shade. Improve drainage with tiling, slit trenching or contouring.

	Fertilize on a regular basis. For immediate control of moss water lawn thoroughly. Spray on recommended rate. Water in to wash off grass blades; then with-hold water for several days. May also be applied at dry rate, but water in thoroughly immediately after application.
PRECAUTIONS:	**KEEP OUT OF REACH OF CHILDREN.** **READ LABEL BEFORE USING** [on main panel]. **Harmful if swallowed.** **Avoid contact with eyes, skin and clothing.** **Avoid breathing dust or spray mist.** **Store in its original container tightly closed and away from children and pets.** Wash hands after use. May stain stone, brick masonry or light coloured sidings. May corrode bare metal. Flush off spills with clear water. Do not use on cement products such as sidewalks, patios, blocks, stucco, etc.
FIRST AID:	IF SWALLOWED : Get medical attention or contact poison control centre. IF IN EYES: Flush with plenty of water and get medical attention or contact poison control centre. IF ON SKIN: Wash with soap and water.
DISPOSAL:	Discard empty container in household garbage.
ACCEPTED COMPATIBLE PESTICIDE ACTIVE INGREDIENTS:	NONE
APPROVED BRANDS OF PESTICIDE PRODUCTS:	Refer to the ferrous sulphate section PMRA's approved brands of pesticide products

Appendix 10: Information resources - Toxicology

Canadian resources

Canadian Centre for Occupational Health and Safety (CCOHS)
Committee on Standards, Equity, health and safety at work (CNESST)

Environment and Climate Change Canada

- Domestic substances list

Health Canada

- First Priority Substances List (PSL1) Assessments
- Second Priority Substances List (PSL2) Assessments

International resources

United Nations

- Food and Agriculture Organization (FAO), The Codex Alimentarius
- International Programme on Chemical Safety (IPCS) INCHEM

United States

- Agency for Toxic Substances and Disease Registry (ATSDR), Toxic Substances Portal
- Centers for Disease Control and Prevention (CDC), The National Institute for Occupational Safety and Health (NIOSH)
- Department of Commerce, National Institute of Standards and Technology (NIST), NIST Chemical WebBook, SRD 69
- Environmental Protection Agency (EPA), Ecotox
- Environmental Protection Agency (EPA), Integrated Risk Information System
- National Library of Medicine, Toxicological Data Network: ChemIDplus

Appendix 11: Information resources – Microbiology

Canadian departments/agencies

Canadian Food Inspection Agency (CFIA)

- Animal pathogens
- Plant Pests regulated by Canada

Environment and Climate Change Canada

- Environment Canada and Health Canada. 2011. Framework for Science-Based Risk Assessment of Micro-Organisms Regulated under the *Canadian Environmental Protection Act*, 1999.
- Environment Canada, Report EPS 1/RM/44. March 2004. Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms.
- Environment Canada, Report EPS 1/RM/46. March 2005 (with June 2007 amendments). Guidance document on statistical Methods for Environmental Toxicity Tests.
- Environment Canada. December 2013. Organisms on the Domestic Substances List (DSL) (Contains several risk group 2 microorganisms).

Health Canada/Public Health Agency of Canada

- Pathogen safety data sheets
- ePATHogen Risk Group Database
- Categorization of antimicrobial drugs based on importance in human medicine
- Canadian antimicrobial resistance surveillance system report (includes priority listing of microorganisms of concern)

International resources

American Type Culture Collection (ATCC)

World Health Organization

- Global priority list of antibiotic-resistant bacteria
- Critically important antimicrobials

OECD (Organisation for Economic Co-operation and Development)

- **OECD (Organisation for Economic Co-operation and Development).** 1998a. Principles of Good Laboratory Practice (as revised in 1997), N°1 – OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, ENV/MC/CHEM(98)17, 41 p., Environment Directorate, Paris, France.
- **OECD (Organisation for Economic Co-operation and Development).** 1999d. The application of the GLP principles to Short Term Studies, N°7 (revised) – OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, ENV/JM/MONO(99)23, 16 p., Environment Directorate, Paris, France.