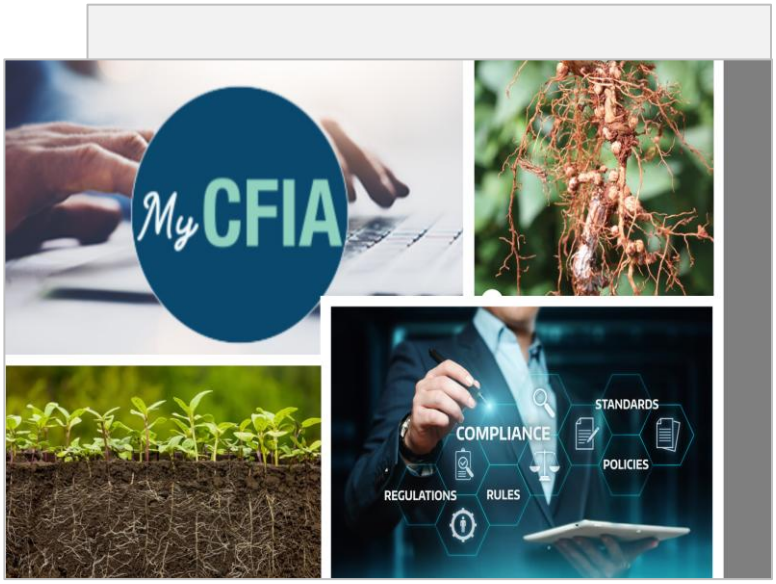
The Regulatory Pulse

In conversation with the experts

A guide with regulatory insights on registration of microbial bioproducts



Navigating the CFIA Registration Framework

Regulatory Guidance for Plant Biostimulants and Microbial Supplements

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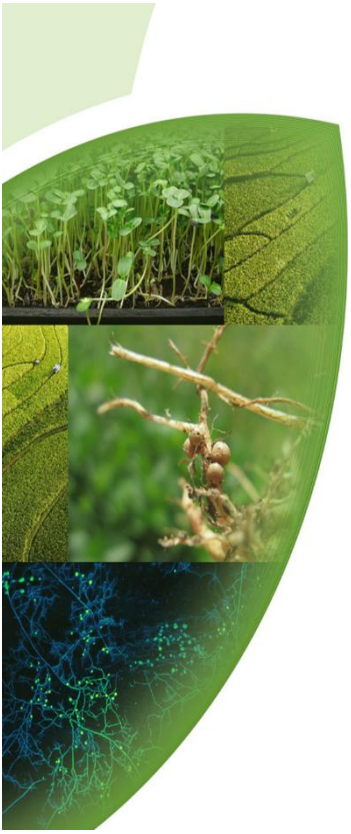

Editor's Note

As Canada's agricultural biologicals sector continues to grow, navigating the regulatory requirements for biofertilizers, biostimulants, and microbial supplements remains a significant challenge — particularly for first-time registrants. In this edition of *The Regulatory Pulse*, we spotlight the Canadian Food Inspection Agency (CFIA) Fertilizer Program, the federal authority responsible for regulating fertilizers and supplements under the *Fertilizers Act* and *Fertilizers Regulations*.

We are pleased to present an exclusive Q&A with the CFIA Fertilizer Safety Section, providing practical, authoritative insights into key aspects of the registration process. Topics include product classification, pre-submission consultations, data requirements, microbial strain identification, labelling expectations, and dossier submission. Whether you are preparing your first registration package or strengthening an existing application, this edition aims to simplify the regulatory landscape and provide clear, actionable guidance.

We hope this resource serves as a valuable reference for industry stakeholders and first-time applicants alike, helping to build confidence, improve submission quality, and support more efficient engagement with CFIA's regulatory pathways.

Dr. Jaswinder Kaur

Edited & Compiled by

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Spotlight Interview - In Conversation with

The Fertilizer Safety Section

Canadian Food Inspection Agency (CFIA)

The Fertilizer Safety Section is part of the Canadian Food Inspection Agency (CFIA) and is responsible for the regulation of fertilizers and supplements under the *Fertilizers Act* and *Fertilizers Regulations*. The Section oversees a wide range of products used in agricultural, commercial, and home and garden settings, including conventional fertilizers, micronutrients, lawn and garden products, and supplements such as microbial inoculants, water-holding polymers, abiotic stress protectants, liming materials, and waste-derived materials (for example, composts and municipal biosolids). Its mandate includes science-based pre-market safety assessments, label verification, and post-market compliance oversight to protect human, animal, plant, and environmental health across Canada.

Additionally, the CFIA conducts marketplace monitoring through inspections, product sampling, and label reviews to verify ongoing compliance, with appropriate enforcement actions taken where necessary. This work is part of CFIA's broader mandate to protect Canada's food supply, safeguard plant and animal health, and support environmental sustainability and economic well-being.

Questions & Answers - Insights from the expert

The following interview was coordinated and edited by Dr. Jaswinder Kaur, Publication Editor.

GENERAL QUESTIONS

1. What kinds of bioproducts require registration with the CFIA?

CFIA: Most supplements and some fertilizers require registration with the CFIA before they can be imported, sold, or distributed in Canada, unless they meet one or more exemptions set out in the Fertilizers Regulations. Whether a product requires registration depends primarily on how it is represented in the marketplace, including its claims, guarantees, composition, and intended use.
Applicants are encouraged to consult the CFIA's Registration triggers for fertilizers and supplements to determine whether a product is subject to registration under the *Fertilizers Act*.

2. Are there specific categories of products that are exempt from registration? Are these exemptions based on ingredients, claims, or both?

CFIA: Yes. Certain fertilizers and supplements are exempt from registration under the Fertilizers Regulations, based on both their composition and how they are represented in the marketplace. To determine whether a product is exempt, applicants are encouraged to consult the decision-making flowcharts on the Registration triggers for fertilizers and supplements webpage. If uncertainty remains after reviewing the flowcharts, a Product specific inquiries (IQ) may be submitted for case-specific guidance. To initiate an inquiry, please send the following information to: cfia.paso-bpdpm.acia@inspection.gc.ca:

- Cover letter:
  - explaining the intent of the inquiry
  - purpose of import/end use (if applicable)
- A copy of the proposed marketplace label in both official languages (English and French)
- Constituent materials:

    - identification and description of all materials used in the production of the final product
    - the source of the materials used
    - proportion of the materials
- Description of the manufacturing/blending process

When this information is received, the Fertilizer Safety Section will open an Inquiry file and provide a response within 30 working days outlining the product's classification under the *Fertilizers Act* and Regulations and the applicable regulatory requirements.

3. Is there a publicly available list of these exempted materials on the CFIA website?

CFIA: Yes. The List of Primary Fertilizer and Supplement Materials on the CFIA website lists fertilizer and supplement materials that are exempt from registration. The list is incorporated by reference into the Fertilizers Regulations and outlines exempt materials along with their specific compositional criteria.

Please note that this is not an exhaustive list of materials that are exempt from registration. Several fertilizers that are not from plant or animal origin and mixtures of exempt and/or registered fertilizers and supplements are also exempt from registration.

Did You Know?

The CFIA evaluates safety, not efficacy

The CFIA does not require efficacy trials or agronomic performance data for registration under the *Fertilizers Act*. Since regulatory modernization in 2013, the CFIA's pre-market assessment has focused on product safety and regulatory compliance. However, any performance claims made on a product label must be truthful, substantiated, and not misleading.

The *Fertilizers Act* prioritizes the protection of human, animal, plant, and environmental health, and the CFIA's assessment is designed to ensure products meet these regulatory requirements before they are marketed.

PRE-SUBMISSION CONSULTATION

4. Would you recommend that companies schedule a pre-submission consultation with CFIA?

CFIA: Applicants should first use the Product specific inquiries (IQ) process to clarify information requirements for their product. If questions remain after completing the IQ process, a pre-submission consultation may be requested. These consultations provide detailed guidance on regulatory requirements and an opportunity to discuss product-specific safety data to support applicants in preparing a complete application for registration. They are particularly beneficial for novel or complex products, such as those containing genetically modified microorganisms or multi-organism consortia.

5. What exactly is a pre-submission consultation with the CFIA, and why is it important for applicants to consider one?

CFIA: A pre-submission consultation is an optional, formal meeting with the CFIA Fertilizer Safety Section intended to provide applicants with guidance and clarification on applicable regulatory requirements, current policies, and standards for fertilizer and supplement products. While many questions can be addressed through the Product specific inquiries (IQ) process, a pre-submission consultation may be appropriate where additional clarification is needed following IQ. These consultations support applicants in preparing a complete submission that adequately demonstrates product safety and meets prescribed labelling requirements, which may help expedite the review process.

6. At what stage of product development or dossier preparation do you recommend scheduling a pre-submission consultation?

CFIA: A pre-submission consultation is best scheduled after completing the Product specific inquiries (IQ) process and before finalizing an application. At this stage,

applicants should have a well-defined product concept, including a proposed marketplace label, its ingredients, intended use, and preliminary safety data. Pre-submission consultations are optional and are not required to submit an application for registration under the *Fertilizers Act*. Applicants are encouraged to consult the Guidelines for Pre-submission Consultations for Fertilizer and Supplement Products Regulated Under the Fertilizers Act and regulations for additional information.

7. How detailed should an applicant's materials be before requesting a consultation? Should they bring a draft dossier or is a concept overview enough?

CFIA: Applicants are not required to submit a complete dossier. However, sufficient information must be provided to allow meaningful guidance, including a draft label, ingredient list, manufacturing overview, intended use, and preliminary safety data.
A simple concept overview is insufficient to enable assessment and guidance related to regulatory and data requirements.

8. In your experience, what are some common issues or misunderstandings that get resolved during a pre-submission meeting which might otherwise cause major delays?

CFIA: Pre-submission consultations allow applicants to clarify regulatory requirements before submitting an application. Common questions, such as product classification, labelling and registration requirements, should first be addressed through the Product specific inquiries (IQ) process. A pre-submission consultation is recommended when more detailed discussion is required, particularly for innovative or complex products. These meetings are often used by applicants to explain product-specific considerations and typically focus on:

- Clarification of regulatory requirements and data expectations to support the safety assessment
- Guidance on microbial identification and hazard characterization, including strain-level considerations
- Considerations for microbial consortia, including composition, maintenance of the original community, and screening for hazardous microorganisms
- Products containing genetically modified microorganisms, where applicants may explain the nature of the modification, its intended function, and any potential safety implications
- Confirmation of the specific information required to adequately support product safety

DATA REQUIREMENT

9. What are the mandatory data requirements for registering a biofertilizer and biostimulant with microbial ingredients?

CFIA: To register a supplement (biofertilizer or biostimulant) containing microbial ingredients, applicants must submit sufficient information to demonstrate product identity, safety, and compliance with labeling requirements. This includes information on microbial composition, taxonomic identification, origin, and relevant analytical data to support classification, as well as data to assess potential risks to human and animal health, plant health, and the environment (For example- pathogenicity, toxigenicity, and infectivity). Product composition, intended use, and labelling information must also be provided to ensure accuracy and prevent misrepresentation in the marketplace.

Applicants are strongly encouraged to consult the Guide to submitting applications for registration under the *Fertilizers Act* for detailed data requirements and instructions prior to submission.

10. Are there specific guidelines or templates available for microbial supplements?

CFIA: Yes, the CFIA provides guidance documents, checklists, and templates for microbial supplements, which are available on its website. Key resources include:

- Guide to submitting applications for registration under the *Fertilizers Act*
- CFIA Fertilizer Registration Overview and Application Checklists
- Trade Memoranda outlining data and safety requirements, such as:
  - T-4-126 – Identification and taxonomic classification of microorganisms for use as supplements
  - T-4-130 – Labelling requirements for fertilizers and supplements
- Technical appendices, including:
  - Appendix 3: Metals, dioxins and dioxin-like compounds standards and maximum acceptable level of indicator organisms in fertilizers and supplements

- Appendix 6: Microbial hazard characterization (Checklist)
- Appendix 7: Microbial exposure characterization - Factors to consider
- Appendix 8: Considerations for classification of microbial hazard severity and exposure level
- Appendix 11: Resources – Microbiology

Applicants are strongly encouraged to consult the CFIA website, for comprehensive and up-to-date requirements prior to preparing and submitting an application.

11. What level of detail is required to confirm strain identity and origin? Are there preferred or required methods for strain identification?

CFIA: Applicants must provide clear and scientifically defensible taxonomic identification for each microorganism. Identification is required at a minimum to the genus and species level, and to the strain level where available, to support hazard characterization. A polyphasic approach is recommended, using complementary methods such as phenotypic characterization and molecular techniques (For example- 16S rRNA or ITS sequencing), supported by appropriate analytical results. All data used to support taxonomic identification, including raw analytical data, must be submitted.

Applicants must also provide information on the origin of each microorganism, either by identifying the isolation source and geographic location or by submitting a strain accession number and culture certificate from a recognized culture collection (For example- American Type Culture Collection).

12. Do the registrants need to provide toxicology or allergenicity data for the microbial strains?

CFIA: Toxicology and allergenicity data are not always required, however, they must be provided where the microorganism does not have a well-established history of safe use or where potential hazards cannot be adequately characterized based on existing information. In such cases, applicants may be required to submit relevant supporting information, including microbial hazard characterization, toxicological data (For example- pathogenicity, toxicity, allergenicity, sensitization potential, etc.), exposure and risk assessments, and/or a scientifically justified rationale supported by surrogate or published data where direct studies are unavailable.

For microbial strains with a documented history of safe use (For example- certain *Bacillus subtilis* strains that do not produce enterotoxins), full toxicology or allergenicity studies may not be necessary. However, applicants must still provide a clear scientific rationale, supported by appropriate evidence, demonstrating that the microorganism does not pose a risk to human or animal health, plant health, or the environment.

13. What are the acceptable limits for microbial contaminants (e.g., coliforms, *Salmonella* etc.)? Are there specific testing methods or labs CFIA recommends or accepts?

CFIA: The CFIA uses *Salmonella* and fecal coliforms as indicator organisms to assess potential pathogen contamination and verify treatment effectiveness in fertilizers and supplements. Compliance is demonstrated using test results from four distinct lots or batches of the final product for both *Salmonella* and fecal coliforms. *Salmonella* must be not detectable, with a detection limit of less than 1 CFU (colony forming unit) per 25 g of product, while fecal coliforms must not exceed 1000 MPN (most probable number) per gram, with a minimum detection limit of less than 2 CFU per gram.
The analysis report must be:

- Printed on laboratory letterhead
- Signed by the analyst
- Include:
  - Sample identification
  - Sample preparation method(s)
  - Test method(s) used, including limits of detection (LOD) and/or limits of quantitation (LOQ)
  - Identification of the certifying or accrediting body for the laboratory

Please note, the CFIA does not recommend specific laboratories, however, it accepts results from accredited laboratories that use validated methods such as ISO, AOAC, or Health Canada's Compendium for Microbiological Analysis.

14. For shelf-life and viability, how much data is needed? Does CFIA expect long-term studies at different storage conditions?

CFIA: The CFIA does not specify requirements for product shelf life. However, product labels must not be misleading, and any stability or shelf-life claims must be substantiated if requested.

15. What are the minimum standards for efficacy data to support product claims? What kinds of efficacy data does CFIA expect, especially for products claiming to improve plant growth or yield?

CFIA: The CFIA does not require efficacy trials or performance data for registration under the *Fertilizers Act*. Since regulatory modernization in 2013, the CFIA has focused on the evaluation of product safety to protect human, animal, plant, and environmental health. While efficacy is not assessed as part of the registration process, all label claims must be truthful, accurate, and not misleading, and applicants are responsible for ensuring that their products perform as claimed.

16. For a crop like tomatoes, which can be grown both in greenhouses and in the field, would greenhouse data alone be sufficient for CFIA approval, or is there a preference for multi-season field trials?

CFIA: The CFIA does not require efficacy data for registration under the *Fertilizers Act*. Greenhouse or field trial data are not mandatory and are not reviewed as part of the registration process. Any label claims must be truthful, accurate, and not misleading.

17. For products based on known microbes with a history of safe use, is a scientific rationale typically enough, or are full toxicological studies still required?

CFIA: For products formulated with well-characterized microbial strains that have a documented history of safe use, a scientific rationale is generally sufficient to support product safety, provided certain conditions are met. Applicants must demonstrate clear taxonomic identification of the microorganism and provide evidence that the strain is not genetically modified, does not produce toxins, and does not exhibit pathogenic characteristics.

Examples of such microorganisms may include *Rhizobium* spp., vesicular–arbuscular mycorrhizae (VAM), and certain *Bacillus subtilis* strains. In these cases, a full toxicological data package is typically not required. However, the CFIA reserves the authority to request additional information or data where safety concerns are identified during the review process.

18. Does the type of microorganism bacteria vs fungi vs viruses vs nematodes change the data requirements significantly?

CFIA: The core data requirements are consistent for all microorganisms, however, the type of microorganism may influence the specific safety information required, as different organisms present different risk considerations.

Data requirements are determined based on product composition and overall risk profile and may vary depending on ingredients. A summary of ingredient-specific safety information requirements is provided in Appendix 2: Product ingredients and associated safety data requirements of the Guide to submitting applications for registration under the *Fertilizers Act*. The CFIA may request additional data, scientific rationales, or analyses during the review process where necessary to address potential safety concerns.

19. What about multi-organism products or microbial consortia- how does CFIA evaluate interactions between ingredients? Is additional risk assessment required for the combination?

CFIA: The CFIA assesses multi-organism products and microbial consortia based on the overall safety profile of the final formulated product intended for import or sale or distribution. The assessment considers the identity, safety, and pathogenic potential of each constituent microorganism, as well as any potential interactions that may influence the overall risk profile.

For microbial consortia, applicants are required to submit information demonstrating that the consortium is derived from a single natural environment and maintained without further manipulation. Information to support safety may include:

- A description of the source environment (for example, soil-based or rhizosphere-associated) and processing steps confirming the original composition is maintained
- Taxonomic identification of individual microorganisms, where possible; where precise identification is not feasible, classification to the genus or family level may be acceptable
- Screening for hazardous microorganisms relevant to the product type and source using appropriate indicator organisms (for example, *Salmonella* spp., *Listeria monocytogenes, Aspergillus fumigatus*, faecal coliforms, enteric viruses, or helminths)
- Molecular characterization supported by appropriate analytical methods and raw data
- Pathogenicity testing conducted on the final product formulation, as applicable

Where the combination of microorganisms, source material, or intended use gives rise to additional safety concerns, applicants may be requested to submit additional supporting data.

20. What about products with dual functions: say, a fertilizer that also claims pest control? Does that trigger separate review by both CFIA and PRD? E.g. *Trichoderma*, which can act as both a biostimulant and a biofungicide, how would this dual functionality affect its regulatory review?

CFIA: Products with dual functionality are subject to specific regulatory requirements depending on their composition and label claims.

Fertilizer-pesticide products may be registered under the *Fertilizers Act* provided they contain a plant-available nutrient and the pesticide component is registered or otherwise authorized by the Pesticide Regulatory Directorate (PRD) under the *Pest Control Products Act*. In such cases, PRD approval must be obtained before applying for registration with the CFIA. Applications will be refused if the pesticide component does not meet PRD requirements. Additional details are outlined in Trade Memorandum T-4-102 – Requirements for fertilizer-pesticides under the *Fertilizers Act*.

For supplement-pesticide products, there is no joint regulatory pathway. Applicants must apply separately to the CFIA and the PRD, resulting in two distinct registrations and separate marketplace labels- one under the *Fertilizers Act* and one under the *Pest Control Products Act*. At present, supplement-pesticide products cannot carry both fertilizer/supplement and pest control claims on a single integrated label. For microorganisms such as *Trichoderma* spp., which may function as both a biostimulant and a biofungicide, regulatory oversight is determined by the claims made on the label and the applicable legislation.

21. How does CFIA treat unique product types like frost protectants or drought resistance products? Are there extra safety or exposure concerns?

CFIA: Products marketed as frost protectants or drought resistance agents are generally regulated as supplements under the *Fertilizers Act* when their primary function is to improve plant growth, yield, or tolerance to abiotic stress rather than to supply plant nutrients.

These products are subject to the same safety assessment framework applied to other supplements, with a focus on potential risks to human, animal, plant, and environmental health. There are no additional safety or exposure requirements solely based on the type of claim, and efficacy data are not required for registration.

Applicants must provide information on product composition, manufacturing process, and intended use, in accordance with the Guide to submitting applications for registration under the *Fertilizers Act*.

22. How should applicants justify claims related to dose, frequency, or method of application if formal efficacy data are not required?

CFIA: As noted above, efficacy data are not required for registration, however, applicants remain responsible for ensuring that all label claims, including those related to application rate, frequency, and method, are truthful, accurate, and not misleading, in accordance with the applicable labelling requirements set out in Trade Memorandum T-4-130 – Labeling requirements for fertilizers and supplements.

Claims should be substantiated, as appropriate, by credible evidence, including scientific literature or a well-documented history of use. The proposed use pattern must be consistent with the product's intended purpose and supported by the overall safety profile established in the submission.

Where applicable, particularly for microbial products, applicants must ensure that any potential risks associated with the proposed use pattern are adequately mitigated through

appropriate label statements (For example- precautionary measures, personal protective equipment, or use restrictions).

23. Can companies use data from a limited number of crops to support broader crop group claims? Is extrapolation across geographies acceptable?

CFIA: The use of surrogate data from representative crops or crop groupings, as well as extrapolation across geographic regions, may be acceptable provided that the approach is scientifically justified and does not result in misleading claims. All label statements must remain compliant with Trade Memorandum T-4-130 – Labeling requirements for fertilizers and supplements.

Applicants are responsible for ensuring that any extrapolation is supported by a sound scientific rationale that considers relevant factors such as crop similarity, agronomic practices, and environmental conditions.

Irrespective of extrapolation, safety considerations must be adequately addressed for all proposed uses. For food crops, this includes consideration of potential exposure pathways, such as the presence of microorganisms or their metabolites in edible plant tissues, where relevant.

24. Does the method of application (for example, soil drench versus foliar spray) affect the data CFIA expects in a submission?

CFIA: Yes. The method of application is a key determinant of exposure pathways and is associated with distinct risk considerations, consequently, it may influence the nature and scope of information required to support the safety assessment.

Applicants must ensure that the proposed use pattern, including application method, rate, and frequency, is clearly described on the marketplace label and aligns with Trade Memorandum T-4-130 – Labeling requirements for fertilizers and supplements.
Submissions should address realistic exposure scenarios associated with the intended method of application, considering the target crop, use setting (For example- field or greenhouse), and potential routes of exposure to humans, animals, plants and the environment.

SUBMISSION PROCESS

25. Does CFIA have a preferred format to help their reviewers navigate submissions more easily?

CFIA: Yes. To support an efficient and consistent review process, the CFIA strongly encourages applicants to follow the prescribed submission structure. All applications must be submitted through the My CFIA digital platform and organized into the following sections:

1. Administrative Forms and Fees
2. Product Details I
3. Product Details II – Other Qualities and Characteristics
4. Product Details II – Safety Assessment
5. Marketplace Label

Supporting documents should be clearly named and organized to reflect their content. Applicants are encouraged to include a cover letter summarizing the application type, proposed safety assessment level, relevant reference numbers, and intended use.

Each application must be complete and self-contained. The CFIA does not retrieve or rely on information from previous submissions. Incomplete or poorly organized applications may be subject to closure without review. Applicants should consult the applicable application checklists to ensure completeness.

26. Once a product is submitted for registration, what is the step-by-step process that CFIA follows? Can you walk us through the key stages? On average, how long does each stage typically take?

CFIA: Following submission, applications undergo a structured, multi-stage review process to assess completeness, compliance, and safety (File review procedures and service delivery standards):

a) **Pre-screening:**
Verification of the proposed safety assessment level and confirmation of submission completeness.

b) **First Review:**
Comprehensive evaluation of the submission, including label review and relevant safety assessments (For example- toxicological and/or microbiological). A deficiency letter may be issued, if applicable.

c) **Second Review:**
Assessment of the applicant's responses to address outstanding deficiencies. Additional clarification may be requested if required.

d) **Third Review (if applicable):**
Final verification that all regulatory requirements have been met prior to decision.

Upon successful completion, a registration decision is issued. Approved products are granted a 60-month registration period. Service delivery standards and indicative timelines are outlined in T-4-122 – Service delivery standards for fertilizer and supplement registration-related submissions under the *Fertilizers Act* and regulations

27. What is the estimated timeline from submission to registration approval?

CFIA: There is no fixed timeline for registration, as processing times vary depending on factors such as:

- Application type (For example- new registration, re-registration, amendment)
- Assigned safety assessment level (I, II, or III)
- Completeness and quality of the submission
- Number and complexity of deficiencies identified during review

Applications are processed in the order received and may involve up to three review cycles. Complete applications that fully meet regulatory requirements may be approved within the first review cycle, however, most applications require additional cycles to address deficiencies.
Applicants should refer to Trade Memorandum T-4-122 – Service delivery standards for fertilizer and supplement registration-related submissions under the *Fertilizers Act* and regulations for information regarding service delivery standards and indicative timelines.

28. How common is it for applicants to receive requests for additional information or clarification from CFIA?

CFIA: Requests for additional information or clarification are common, particularly during the first review cycle. Most applications require at least one round of follow-up to address outstanding requirements.

Common reasons include:

- Missing or incomplete safety data
- Inadequate identification or characterization of microorganisms
- Insufficient detail regarding manufacturing processes or QA/QC measures
- Inconsistencies or non-compliance on the marketplace label

Applicants are required to respond comprehensively within the specified timelines. Failure to do so may result in closure of the application.

29. Are there CFIA-hosted webinars, guidance documents, or checklists for industry applicants?

CFIA: The CFIA provides a range of resources to assist applicants, including:

- CFIA Fertilizer Registration Overview and Application Checklists
- Trade Memoranda (For example- labelling, service standards, regulatory guidance)
- Guide to submitting applications for registration under the *Fertilizers Act*
- Instructional materials available through My CFIA.
- Product specific inquiries
- Registration triggers for fertilizers and supplements
- Guidelines for Pre-submission Consultations for Fertilizer and Supplement Products Regulated Under the *Fertilizers Act* and regulations
- List of Primary Fertilizer and supplement materials

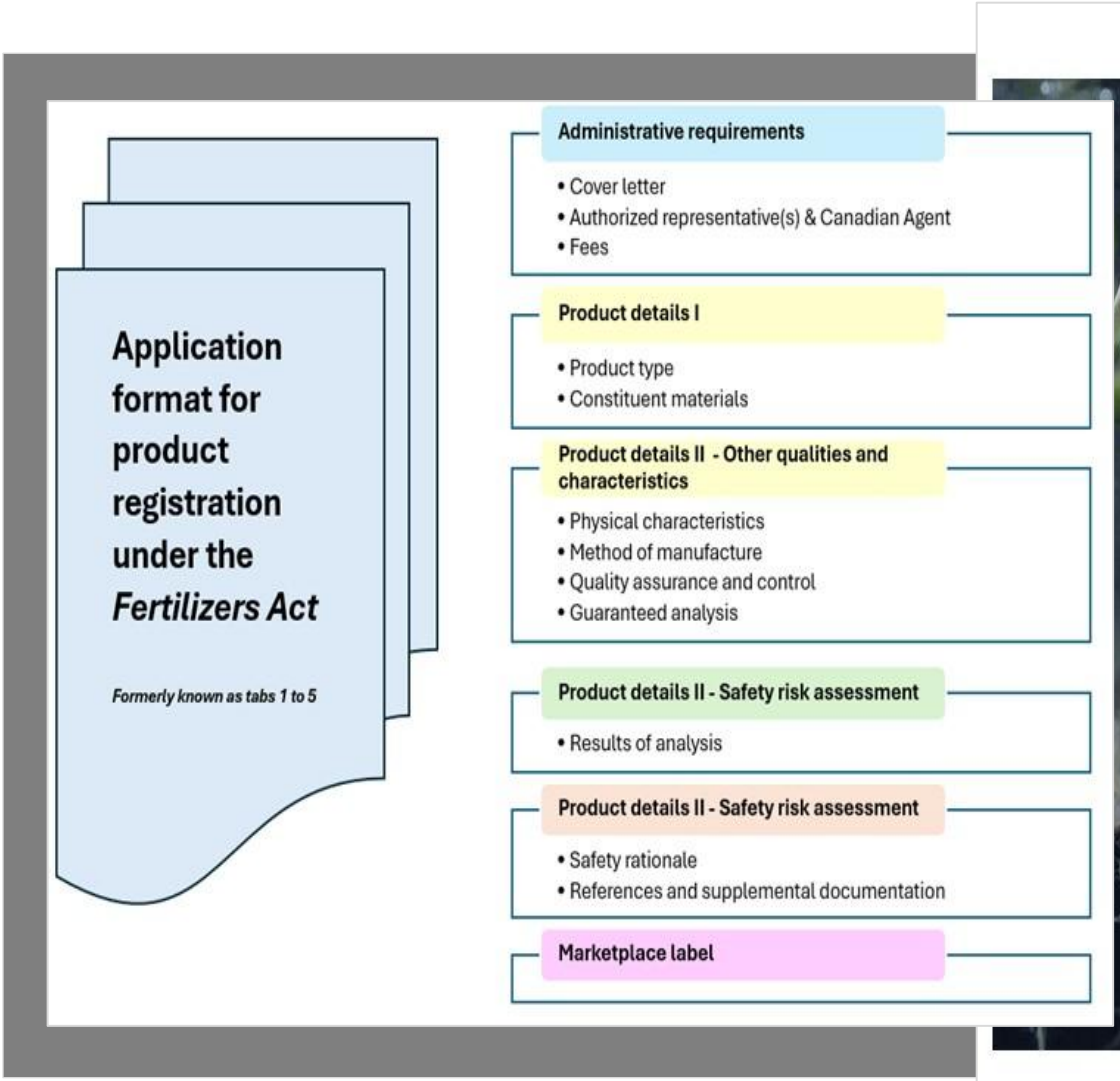
These resources are intended to support applicants in understanding regulatory requirements and preparing complete, compliant submissions.

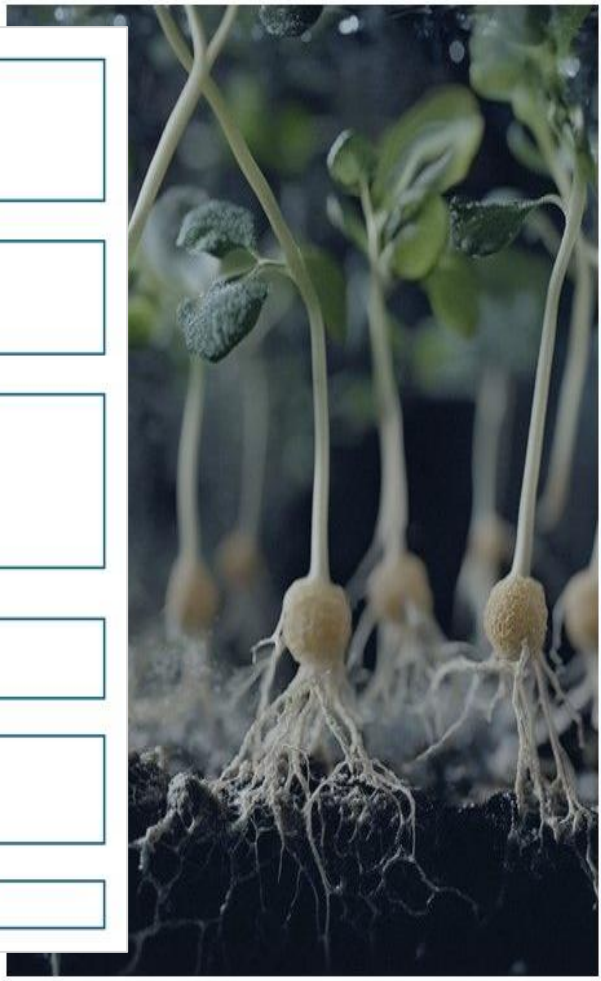
ADVICE FOR NEW REGISTRANTS

The new registrant's **Roadmap to Registration**

1. **Product Concept**
   Define the product idea and intended use.
2. **Product Specific Inquiry**
   Submit a Product- Specific Inquiry (IQ) to obtain case- specific regulatory guidance, if needed.
3. **Pre-Submission Consultation (Optional)**
   Engage with the CFIA for feedback and guidance.
4. **Prepare Submission**
   Compile and finalize all required documents.
5. **Submit via MyCFIA**
   Submit the application through the MyCFIA portal.
6. **Scientific Review**
   Scientific review is conducted by the CFIA
7. **Registration Decision**
   Receive the final decision on your application.

Application format for product registration





30. In your experience, what are the top two or three mistakes, applicants make that lead to delays or rejections?

CFIA: Common issues include:

1. **Incomplete or missing information**: Applicants frequently omit essential details regarding manufacturing processes, quality assurance and quality control (QA/QC) measures. The absence of this information prevents the CFIA from verifying that the product can be consistently produced in a safe manner.
2. **Failure to identify microorganisms to genus and species level**: Failure to identify microorganisms to the appropriate taxonomic level limits the ability to assess pathogenicity, toxigenicity, and antimicrobial resistance.
3. **Improper handling of Confidential Business Information (CBI)**: A complete list of all ingredients, including mixtures, must be disclosed. Where information is submitted as CBI by a third party, proper coordination is necessary to ensure timely review and avoid delays.
4. **Introducing new information during the review process**: Any changes to product composition, manufacturing process, or intended use after submission are considered a new application. This results in the review process being restarted and significantly delays approval.
5. **Misclassification of product type or safety level**: Incorrectly designating the product category (for example- fertilizer versus supplement) or assigning an inappropriate safety assessment level introduces ambiguity and leads to unnecessary review cycles, particularly for complex or microbial products.
6. **Disorganized submissions**: Missing safety data, unclear ingredient descriptions, or improperly named files may impede the review process, cause significant delays, and, in certain cases, result in closure of the application file.

Omitting any required information will result in closure at the first response stage. Each application must be independent, complete, and include all requisite information.

31. Finally, what advice would you give to a small startup or first-time applicant beginning their journey with microbial product registration in Canada?

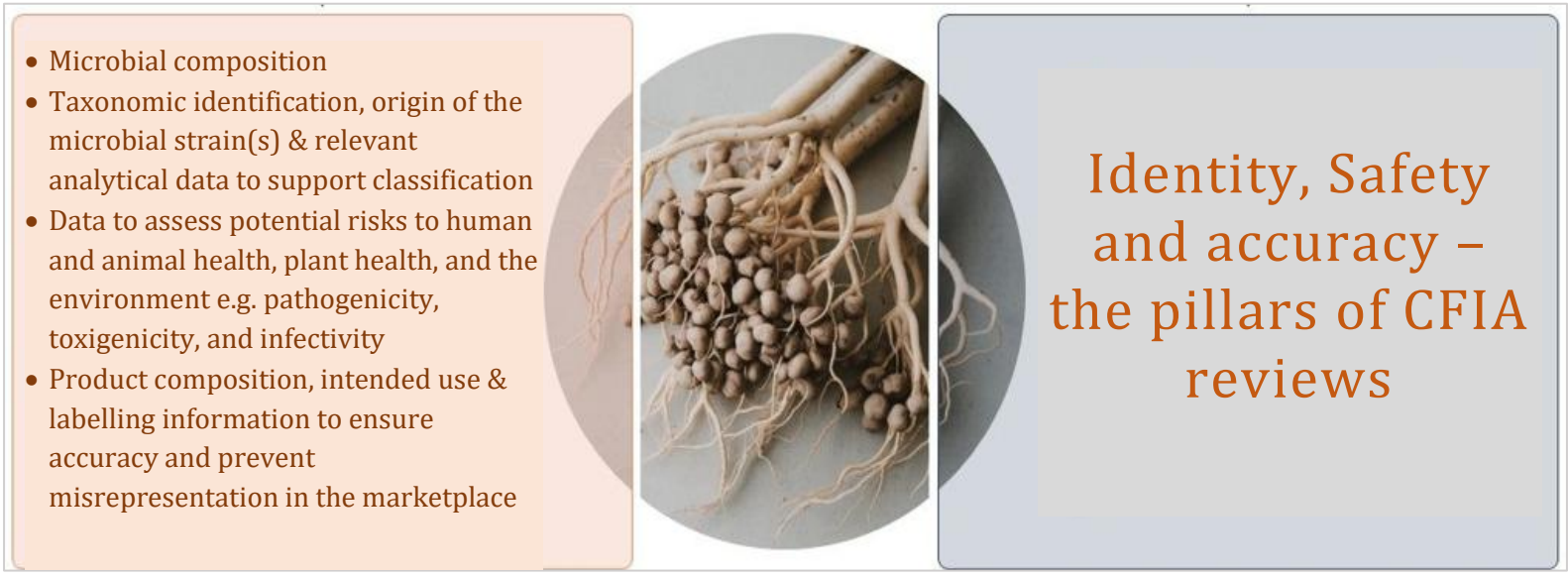
CFIA: For small startups or first-time applicants seeking microbial product registration in Canada, applicants are encouraged to:

- **Confirm regulatory requirements early:** Determine whether registration is required using CFIA guidance and, if needed, submit a product-specific inquiry.
- **Consult relevant guidance:** Review applicable trade memoranda and guidance documents to understand regulatory expectations.
- **Determine the appropriate safety assessment level:** Accurate classification (Level I, II, or III) is important to defining data requirements.
- **Prepare a complete and well-organized submission:**

- Provide detailed manufacturing, QA/QC, and safety information
- Ensure accurate microbial identification
- Disclose all ingredients, including those under CBI (Confidential Business Information) (with proper coordination)
- Avoid introducing changes after submission
- Use clear structure and file naming conventions

- **Plan for timelines:** Regulatory review, particularly for microbial products, can be iterative. A complete and high-quality initial submission is the most effective way to minimize delays.

From strain to shelf
what every submission must prove



Key Takeaways

1 Start with a Product-specific Inquiry IQ

Use an IQ to clarify product classification, regulatory requirements, or application-specific questions before requesting a pre-submission consultation.

2 Efficacy Data not required

CFIA generally does not require efficacy data for registration. All product claims must be truthful, substantiated, and supported by appropriate scientific rationale or evidence.

3 Taxonomic Identification is critical

Identify microorganisms to the genus, species, and strain level using a polyphasic approach, where appropriate. Complete and accurate identification facilitates an efficient safety assessment and helps avoid unnecessary review delays.

4 Toxicology data may not always be required

Data requirements are determined on a case-by-case, risk-based basis. Scientific literature, published information, and other scientifically justified evidence may be sufficient where appropriate, such as well-characterized microorganisms with documented history of safe use.

! Avoid significant changes during review

Major changes to product composition, manufacturing processes, microorganisms, or intended use during review may require substantial reassessment and can significantly delay the registration process. Submit the most complete and final application possible.

6 Submit through My CFIA

Submit applications electronically through the My CFIA portal using the prescribed application format. Incomplete or poorly organized submissions may result in delays or file closure.

Resources

Core guidance

- Guide to submitting applications for registration under the *Fertilizers Act*
- CFIA Fertilizer Registration Overview and Application Checklists
- File review procedures and service delivery standards
- Health Canada's Compendium for Microbiological Analysis

Pre-submission & inquiries

- Product Specific Inquiries (IQ)
- Guidelines for Pre-submission Consultations for Fertilizer and Supplement Products Regulated Under the *Fertilizers Act* and regulations
- Pre-Submission Consultations
- Registration Triggers for Fertilizers and Supplements

Exemptions

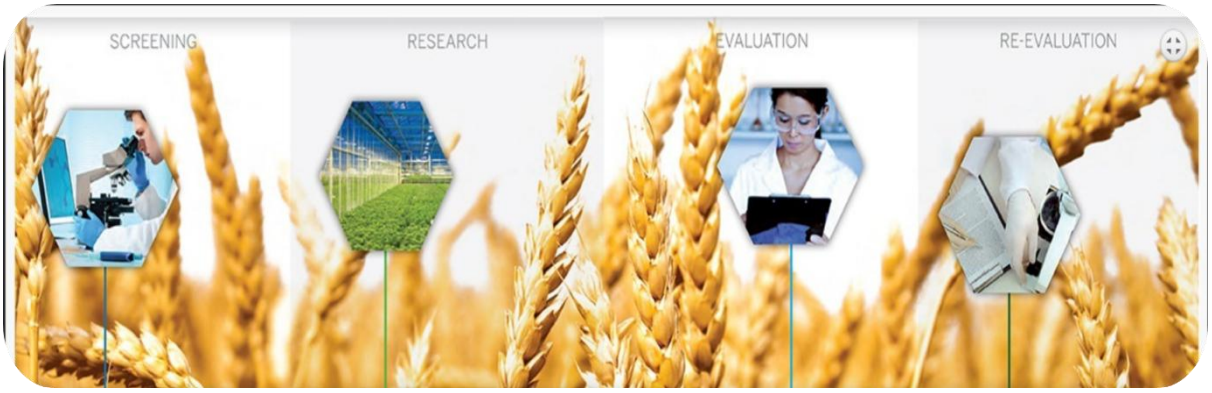
- List of Primary Fertilizer and Supplement Materials

Trade Memoranda

- T-4-102 – Requirements for fertilizer-pesticides under the *Fertilizers Act*
- T-4-122 – Service delivery standards for fertilizer and supplement registration-related submissions under the *Fertilizers Act* and regulations
- T-4-126 – Identification and taxonomic classification of microorganisms for use as supplements
- T-4-130 – Labelling requirements for fertilizers and supplements
- All Trade Memoranda

Submission platform

- My CFIA



Next Issue

Stay tuned for the next issue of
The Regulatory Pulse
on
A case study of an industry partner

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