The Regulatory Pulse

In conversation with the experts

A guide with regulatory insights on registration of microbial bioproducts

Pre-Submission Consultation for Biopesticides

Unlocking the value of early dialogue with PMRA

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In This Issue

Editor's Note

Welcome to the second edition of *The Regulatory Pulse* - a publication designed to share regulatory insights on microbial bioproducts. In this edition, we delve into one of the most valuable yet sometimes underutilized tools available to applicants: the Pre-Submission Consultation. Focusing specifically on microbial biocontrol products, this edition provides guidance on engaging with Health Canada's Pest Management Regulatory Agency (PMRA) prior to submission.

The journey from product development to regulatory approval can be complex, particularly for new registrants or those developing innovative, low-risk, or microbial products. A well-timed pre-submission consultation can save time, reduce costs, and significantly improve the quality of an application. In this interview, Dr. Deborah Henderson, Director of the Institute for Sustainable Horticulture, shares insights on the purpose, process and strategic advantages of Pre-Submission Consultation.

Our goal in publishing this edition is to demystify the consultation process, highlight best practices, and encourage applicants to engage with PMRA early and effectively. Whether you are a first-time applicant, an experienced registrant, or considering joint reviews with international partners, the guidance shared here offers a roadmap to smoother submissions and more predictable outcomes.

We hope this edition serves as a practical reference, empowering you to make the most of this free regulatory support service and helping bridge the gap between policy and practice.

Dr. Jaswinder Kaur

Edited & Compiled by

Dr. Deborah Henderson
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Spotlight Interview - In Conversation with

Dr. Deborah Henderson

Director, ISH & BC regional Innovation Chair

Deborah Henderson has been the Director of the Institute for Sustainable Horticulture (ISH) since 2005 and BC Regional Innovation Chair since 2009 at Kwantlen Polytechnic University. She received her PhD from the University of British Columbia (UBC) and established E.S. Cropconsult Ltd. to offer IPM and research services to both conventional and organic agriculture in the Fraser Valley.

At ISH, Deborah leads an active research program focused on biological and non-chemical management strategies for pests and diseases, advancing agriculture toward ecologically sound alternatives. Her team develops microbial biocontrol solutions and environmentally sustainable bioproducts in partnership with agricultural industry stakeholders, with the goal of expanding the toolbox of bioproduct options for growers. In addition to her research leadership, Deborah has developed recognized expertise in navigating Canada's regulatory system for pest control products. Drawing on her applied research and regulatory experience, she has guided multiple projects through pre submission consultations, helping to bridge the gap between product innovation and regulatory approval. This combination of scientific, practical, and regulatory expertise uniquely positions her to support the advancement of sustainable pest management solutions from the lab to the field.

Questions & Answers - Insights from the expert

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

1. What is a pre-submission consultation?

Dr. Deborah Henderson: A pre-submission consultation is a free service provided by Health Canada's Pest Management Regulatory Agency (PMRA). It's intended to offer regulatory guidance to applicants before they apply to register or amend a pest control product. The guidance is a written document which helps registrants to generate and submit a complete, high quality application package.

One can request a pre-registration consultation for planning work from the beginning of developing a data package or later for further questions related to a data requirement, like guidance on a study protocol that you plan to carry out to address a requirement. Before submitting a request for a pre-registration

consultation, make sure you review PMRA's policy documents related to this. (see Resource section)

2. What is the primary goal of the pre-submission consultation?

Dr. Deborah Henderson: The valuable thing about a pre-submission consultation is that it provides a tailored, product-specific roadmap document to support the development of a complete and high-quality application package for the registration of a pest control product.

While many general questions can be addressed through PMRA's publicly available policy documents (see Resources), certain cases—especially those involving non-conventional products, novel uses, or complex formulations—may require customized direction.

3. So, is it about getting product-specific clarity before submission?

Dr. Deborah Henderson: Exactly. At your first consultation, PMRA will provide a list of exactly what requirements your product will need to meet, along with fees, timelines and forms. They also share relevant policy links to guide applicants.

4. What is the process to initiate a pre-submission consultation with PMRA?

Dr. Deborah Henderson: To initiate a pre-submission consultation with the PMRA, you must complete and submit a Pre-submission Consultation Request Form (Form #6117), a Statement of Product Specification Form (Form #6003), and a draft product label. You may not have information for everything on the form, but you can leave some parts blank or just make your best guess at the time. These documents can be sent via email, mail, or through the Electronic Pesticide Regulatory System (e-PRS). These forms cover the purpose of the consultation, a description of your product or active ingredient, your questions (which could simply be to please provide a list of required data requirements for your described product by checking all the boxes listing the kinds of information PMRA is able to provide).

5. Is this mandatory for everyone?

Dr. Deborah Henderson: Not mandatory, but strongly recommended, especially for new applicants, microbial products, or complex cases. Early consultation helps align your data strategy with PMRA's expectations.

6. Once the request is submitted, what are the next steps in the pre-submission consultation process?

Dr. Deborah Henderson: Once the request has been submitted, PMRA assigns a pre-submission number and sends an acknowledgment of receipt to the applicant. A Pre-Submission Coordinator will be assigned to your request, who reviews the package to ensure all required components are included. If any information is missing or clarification is needed, the coordinator will contact you to request the necessary details.

After this internal review, the coordinator will provide a written response to the applicant using PMRA's Pre-Submission Guidance Template**.** This document will address the questions outlined in the original request and include information on the applicable submission category**,** fees**,** timelines**,** and data requirements.

If the applicant has follow-up questions or requires clarification after reviewing the guidance, they may contact the Pre-Submission Coordinator with their pre-submission number in the subject line.

7. What forms are part of a pre-submission consultation package?

Dr. Deborah Henderson: There are a few key documents

Pre-submission Consultation Request Form (form #6117) that outlines the purpose of the consultation and allows applicants to identify specific questions or regulatory issues.

Proposed Product Label – showing the use directions, including specific pest/host combinations and claims relevant to Canada. You don't have to have a complete list at this stage, but an example or two of target pests or diseases will help the coordinator decide which regulator to assign it to. "Claims" refer to what the label says the product will do – for example "control", "suppress", "prevent build up" of the target pest/pathogen.

Statement of Product Specification Form (form 6003) to confirm the formulation details, including the active ingredient(s) and formulants (if you know them). Early-stage consultations usually refer to the active ingredient if formulation has not been developed yet.

Additional information as required for Microbial and Low-Risk/Non-Conventional products registrants should also provide any supporting data that helps PMRA assess the microbial pesticide, including strain characterization, mode of action, efficacy, safety, environmental fate and formulation details if available. If this is not your first request for a consultation, include summarized study results, key references and specific regulatory questions you must clarify

data requirements. The applicants can also refer to Regulatory Directive (DIR2001-02), Guidelines for the Registration of Microbial Pest Control Products.

8. And applicants can use electronic submission systems, right?

Dr. Deborah Henderson: Yes, the e-PRS or the e-Index Builder is recommended to speed up processing. To use the e-PRS Secure Web Portal, applicants must first enroll by completing the enrolment package and submitting it via email to PMRA-ARLA.REG.CON@hc-sc.gc.ca**.** Once approved, they receive an activation key and can access the portal using a Government of Canada GCKey or SecureKey. The step-by-step enrolment instructions are available in the e-PRS Secure Web Portal Enrolment Guidance document. If electronic submission isn't possible, applicants may also submit their documents as PDF or Word files via email.

9. Can the registrants submit draft study protocols for review and feedback?

Dr. Deborah Henderson: Yes, if you have any doubt about the protocol requirements of a study, or the product is novel, non-conventional, or low-risk. Early submission of protocols allows PMRA to provide high-level feedback on whether the proposed studies are likely to meet regulatory expectations. This can help applicants avoid unnecessary revisions or delays later in the registration process. Study protocols are the subject of several PMRA guidance documents however so usually the requirements are clear.

10. Is it helpful to include preliminary data (e.g., identity, efficacy, safety) or marketing intent with PMRA at this stage?

Dr. Deborah Henderson: Yes. Providing preliminary data on efficacy or safety or any other if you have, can help PMRA better understand the context of your request and offer more targeted guidance. Similarly, sharing your intended market position or label claims can assist in defining the product's value and inform discussions around data requirements, particularly for value assessment.

11. What is Value assessment and how does PMRA evaluate the "value" of a microbial pesticide during the pre-submission consultation stage?

Dr. Deborah Henderson: A value assessment basically looks at whether your microbial pesticide will be useful, for instance does it work, does it fit into real pest management programs and does it offer something helpful or different from what's already on the market? For example, if it replaces an old class pesticide, it has "value" to the environment and human health. PMRA wants to understand the practical benefit of your product, even if your data is still preliminary. PMRA uses your proposed benefits, intended claims and early information on use patterns or market gaps to understand the product's potential role. Even preliminary details help them frame the value assessment and anticipate what data may be needed later.

12. What are the requirements for label language and use instructions?

Dr. Deborah Henderson: The draft label submitted with your pre-submission package must include:

- Specific pest/host claims
- Clear and complete directions for use
- Appropriate safety and precautionary statements
- Data to support all claims (if you have data yet)

Labels must be tailored for the Canadian market and all claims must eventually be supported by appropriate scientific evidence to ensure they meet regulatory standards. Hint 1. – don't promise the earth in your draft label because you'll have to prove it one day. Hint 2. For safety precautions, you can look at other labels of similar products and say what they say. For example, do not apply within XX meters of a water way, applicator covers all skin, wears a respirator, eye protection, gloves and takes care to avoid spills etc.

13. What types of claims are allowed (e.g., suppression vs. control)?

Dr. Deborah Henderson: Efficacy claims must match the strength of the supporting data. PMRA distinguishes between control, suppression, and prevention. If you don't have the data yet, be conservative.

14. Approximately how many days does it take until a registrant can expect to receive pre-submission consultation guidance?

Dr. Deborah Henderson: PMRA aims to process 90% of consultations within 80 calendar days after receiving a package. This timeline begins once a complete package is received and ends when the applicant is issued the written guidance. This timeline, however, may be extended if PMRA requires additional information from the applicant. To avoid delays, applicants should ensure that as much of the required documentation and details are provided at the time of submission.

15. If a registrant is interested only in information regarding the value requirements for his product. Can they request a value-only pre-submission consultation?

Dr. Deborah Henderson: Yes. A value-only pre-submission consultation is possible. If you have specific questions regarding the value requirements for product registration, check the appropriate box in the pre-sub form. It is very important to provide as much information as possible about the following:

1. the product directions for use (application rate or rate range, timing of initial application and re-application, and maximum number of seasonal applications, if applicable).
2. what crops or use sites the product is to be applied on.
3. what pests it will be used to manage; and
4. what the expected level of control will be for each of the pests.

Additional value-related information can be found in Regulatory Directive (DIR2013-03), Value Assessment of Pest Control Products and in other Guidance Documents found on PMRA website. Consult these first, they may answer your questions.

16. At what stage of product development, the pre-submission consultation should be done?

Dr. Deborah Henderson: We recommend that applicants request a pre-submission consultation early in the product development process even at the stage where they may have little more than the name of the biological or active ingredient. Ideally, this should occur before initiating key studies, such as toxicity testing, which is costly. Remember, at this point you may not be able to put in all of the information the form asks for, so either leave it blank or make a guess (what do similar products have on their labels?).
Engaging early allows applicants to gain a clear understanding of regulatory expectations, including which data are required and which may not be necessary. This helps companies with limited budgets be efficient and reduces the risk of generating unnecessary or inadequate data.

17. Will PMRA provide written confirmation or minutes summarizing the consultation?

Dr. Deborah Henderson: Yes. PMRA will provide a written response using the Pre-Submission Consultation (PSC) guidance template. This document will summarize the discussion, outline data requirements, provide timelines, and confirm the proposed category classification. It will be your roadmap for planning the work to get the new product registered.

18. We know that microbial products are generally considered safer or low-risk products. Does PMRA offer any kind of tiered review pathways or expedited processes to help bring these types of products to market faster?

Dr. Deborah Henderson: Yes, PMRA does offer streamlined or tiered review processes for certain categories of products, particularly those classified as low-risk or biopesticides. These types of products often have favourable safety profiles and pose minimal risk to human health and the environment, so PMRA has developed specific guidance to help accelerate their review.

For example, products that qualify as biochemicals, microbials or non-conventional pest control products may be eligible for reduced data requirements and shorter review timelines, provided they meet PMRA's criteria. This is part of an effort to encourage innovation and facilitate the registration of products that support more sustainable pest management. Registration fees are lower too!

A pre-submission consultation helps confirm eligibility for these expedited pathways.

19. How many pre submission consultations can a registrant seek?

Dr. Deborah Henderson: There is no set limit to the number of pre-submission consultations a registrant can request. PMRA encourages applicants to seek guidance as often as needed. Registrants may request multiple consultations as

product development progresses or as new questions arise. A consultation advice is valid for 24 months, so if you miss that deadline for submitting a registration package, you need a new consultation to make sure you have any requirement updates.

20. How can registrants stay informed about regulatory changes?

Dr. Deborah Henderson: The registrants can stay up to date by subscribing to PMRA's email notifications, regularly visiting the PMRA website, and reviewing updates to Regulatory Directives and guidance documents.

21. Finally, how can a registrant get the most out of a pre-submission consultation?

Dr. Deborah Henderson: Prepare the right consultation request at the right time. Plan a first consultation when you begin the process. It will orient you to what data you need and even help you develop a timeline. For example, if you want 12 months of stable self-life, it would be best to start shelf-life trials early so you don't have to wait a year if that is the last data piece you need. Subsequent consultations should be planned for when milestones are reached and when new guidance will help to focus your efforts and budget on the important data requirements remaining. For example, once efficacy has been validated (you know the product does what your label claims), and a literature review suggests no toxic elements produced by this microbial, then invest in the mammalian toxicity trials. A product that works and is non-toxic is on its way to registration. Alternatively, if your new product has the potential for producing toxic metabolites, you want to explore that before investing in field efficacy trials.

General or vague inquiries will result in general responses – like the first consultation which will result in the data table indicating which requirements are mandatory and which are conditional. In contrast, a focused request will yield more comprehensive, customized guidance tailored to the product. E.g. if a registrant has a product with Bacillus strain, the question can be "Given that my *Bacillus* strain is intended for foliar use on greenhouse cucumbers to suppress powdery mildew, do I need additional non-target plant studies?" PMRA can give much more targeted guidance that directly applies to your product and intended uses.
Once the written pre-submission guidance has been received and reviewed, applicants may request further clarification if needed, using their submission number.

22. So, in short, a well-prepared consultation saves time, aligns expectations, and sets the foundation for a successful registration.

Dr. Deborah Henderson: Exactly. Early, informed engagement makes all the difference.

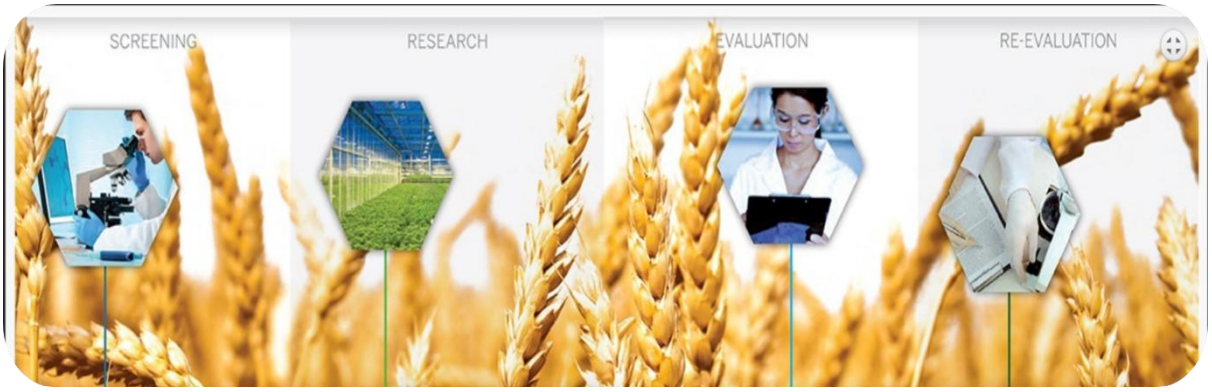
Key Takeaways

- **Early engagement** before key studies begin helps align data generation with PMRA expectations, saving time and resources.
- **Preparation is key** - A well-prepared package with clear questions, draft labels, and product details ensures meaningful and specific feedback.
- **Strategic checkpoint**- The Pre-Submission Consultation is more than a regulatory step; it is a strategic opportunity to align your product development with PMRA's expectations from the outset.

Resources

- https://www.kpu.ca/ish/publications
- Guidance for the registration of microbial pest control agents and products [2021]
- https://pest-management.canada.ca/forms
- Regulatory Directive DIR2006-02: Formulants Policy and Implementation Guidance Document
- Statement of Product Specification Form instructional video
- Guidance for completing the Statement of Product Specification Form (Form 6003)
- https://www.canada.ca/content/dam/hc-sc/documents/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/new-plant-protection-products-label-amendments/new-plant-protection-products-label-amendments-eng.pdf

💡 The Pre Submission Consultation is not just a meeting it is your chance to set the foundation for success.



Next Issue

Stay tuned for the next issue of
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on
VALUE ASSESSMENT

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