The Regulatory Pulse

In conversation with the experts

A guide with regulatory insights on registration of microbial bioproducts

The Journey from Innovation towards Registration

A Case Study of Advanced Agriscience

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Acknowledgement

We sincerely thank Dr. Collin Juurakko, Founder and CEO of Advanced Agriscience, for sharing his experience and valuable insights through this case study, offering a practical perspective on the regulatory journey of a biological product. We also acknowledge the invaluable contributions of our research and publication team whose collaboration makes *The Regulatory Pulse* possible.

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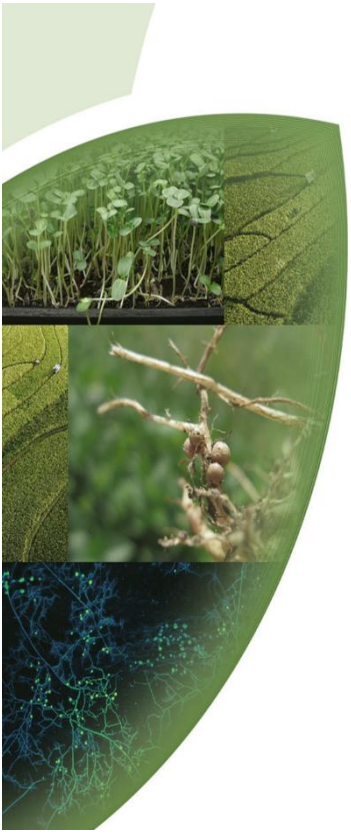
In This Issue



Editor's Note

Bringing a novel agricultural biological from the laboratory to the market involves much more than demonstrating that a technology works. Developers must navigate product classification, regulatory jurisdiction, pre-submission consultation, data requirements, field testing, safety assessment, funding, timelines, and ultimately commercialization.

In this case-study edition of *The Regulatory Pulse*, we follow the regulatory journey of Advanced Agriscience, a Canadian startup developing microbial-based frost-protection products for agriculture. Through an in-depth conversation with the Founder and CEO, Dr. Collin Juurakko, we explore the practical realities of moving an innovative microbial technology from academic research toward regulatory registration.

Beyond the biology of nature's "antifreeze," this conversation offers an unfiltered look into what it takes to register a novel microbial biopesticide in Canada. From navigating a 12-month detour between regulatory agencies (CFIA vs. PMRA) to managing the extreme costs and yearly seasonal constraints of efficacy field trials, Dr. Juurakko's insights serve as an invaluable roadmap for innovators. The case study also highlights how public–private support through ISH enabled his team to access specialized regulatory expertise without building an extensive in-house team.

One of the strongest messages emerging from Dr. Juurakko's experience is that regulatory planning should begin early not after the science is complete. Early regulatory mapping and pre-submission consultations directly inform research decisions, funding needs, and market entry strategies.

We hope this case study provides a practical, actionable roadmap for anyone working to commercialize the next generation of biological crop solutions.

Dr. Jaswinder Kaur

Edited & Compiled by

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Dr. Jaswinder Kaur

Spotlight Interview - In Conversation with

Dr. Collin Juurakko

Molecular Geneticist & CEO of Advanced Agriscience

Dr. Collin Juurakko is a molecular geneticist, entrepreneur, and the Founder/CEO of Advanced Agriscience, a British Columbia-based startup and public benefit company developing frost-protection technology for agriculture. He holds a BScH in Biochemistry and an MSc and PhD in Molecular Genetics from Queen's University in Kingston, Ontario, where his research focused on plant freezing-stress tolerance, ice nucleation, and anti-freeze proteins. He has published several peer-reviewed papers on the topic before transitioning into commercial applications for his research.

Photo credit: Timo Juurakko

Since founding Advanced Agriscience, he has secured funding, recognition, and support from groups including Agriculture and Agri-Food Canada, Ontario Genomics, and the Bill Gates' founded Breakthrough Energy Fellowship. He leads the operations, technical development, and commercialization efforts of the company's flagship frost protection technology with the goal of becoming a great Canadian anchor company and world leader in biological crop protection. Beyond research and running a startup, Collin volunteers to mentor founders and students in STEM.

Frost doesn't wait for paperwork.

Every spring, growers watch the forecast and brace for the nights that can wipe out a season's yield in hours. For Dr. Collin Juurakko, that same urgency has defined his path from freezing-tolerance research at Queen's University to founding Advanced Agriscience — a startup built to fight frost with nature's own antifreeze instead of fossil fuels.

Industry: Agricultural Biologicals
Region/Country: British Columbia, Canada
Founded: 2023
Research Partners: ISH (KPU), UFV and McMaster University
Current Status: Research Permit application submitted to PMRA

Key Development Milestones

Advanced from CFIA exploration to a defined PMRA regulatory pathway within a year while advancing active field-trial permit applications.

Advanced Agriscience

CASE STUDY AT A GLANCE

- **SUSTAINABLE BIOLOGICALS**
- **AFFORDABLE FORMULATIONS**
- **CONVENIENT APPLICATION**
- **PROVEN EFFECTIVENESS**

Four pillars guiding Advanced Agriscience's mission to protect crops, reduce grower risk and build resilience in a changing climate.

Research Begins
Freezing tolerance research begins at Queen's University (2017).

Company Founded
Advanced Agriscience was founded to advance the frost protection technology (2023).

Initial Regulatory Exploration
The CFIA pathway was explored first.

PMRA Engagement
After roughly a year, the appropriate pathway was established with PMRA.

Pre-Submission Consultation
Data requirements for efficacy, ecotoxicology & environmental fate identified.

Partnership for R&D
Collaborated with ISH (KPU), UFV, and growers on efficacy, safety, formulation, production.

Field Trial Permits
Research permit currently under process.

Registration
Commercial registration in Canada, followed by international markets.

Questions & Answers - Insights from the expert

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

1. **Could you please provide a brief overview of your microbial product and highlight what distinguishes it from conventional products currently available in the market?**

Dr. Collin Juurakko: Advanced Agriscience is developing microbial-based products to protect crops against frost damage and improve marketable yields. Unlike conventional frost protection methods that are prohibitively expensive and warm plants by burning fossil fuels and emerging alternatives including synthetic hormones, recombinant proteins, or foam sprays, our microbial products are uniquely differentiated by directly combatting the molecular cause of frost injury using nature's own "antifreeze" to prevent ice crystals from damaging plant tissue. Our approach and novel modes of action can translate to lower costs and easier adoption, less labour and longer lasting protection, broader crop type use and fewer losses for increased yields.

2. **What motivated you to develop this product? Was there a specific problem or market gap you were trying to address?**

Dr. Collin Juurakko: All I've ever wanted to do was build a great company that can make an impact on the world. During my time at Queen's University, Dr. Virginia Walker graciously accepted me into her lab where I did both my MSc and PhD in molecular genetics specializing in freezing tolerance and low-temperature stress in plants. We studied how tolerant plants are able to survive freezing temperatures and the molecular mechanisms behind ice nucleation and frost injury. It was in grad school that I learned about the challenges growers face with frost and the lack of any effective, affordable, or biological protection tools. The real-world applications and potential impacts of our research to support growers and address the market needs that growers consistently tell us about, motivated me to develop this product.

3. **How long has the product been in development? Could you please walk us through the timeline till now?**

Dr. Collin Juurakko: The products have been in active development since 2023 when I founded Advanced Agriscience. But the research began much earlier. I started researching plant freezing tolerance in 2017 as an undergraduate student but research into this field began far earlier. As scientists, we truly stand on the shoulders of giants. After grad school I started the company, built a molecular biology lab, and began collaborating with the Institute for Sustainable Horticulture at Kwantlen Polytechnic University, McMaster University, and the University of the Fraser Valley where the product is in active development. With academic collaborators, we have been engaging with the Pest Management Regulatory Agency (PMRA), developing efficacy datasets in

the greenhouse, safety data, evaluating application rates and timing, and characterizing modes of action as per consultations with the PMRA together with production bioprocesses and formulation development. We're regulated as biopesticides and as such have a much greater burden of proof for data to generate. Our next major milestones are nation-wide field trials on key crops, where growers tell us they have need, before we can register for commercial use in Canada and internationally.

4. **How did you begin the registration process for your microbial pesticide in Canada? Did you engage with PMRA, CFIA, or both? How did you determine which authority was the right one to approach?**

Dr. Collin Juurakko: First we tried to go the Canadian Food Inspection Agency (CFIA) route but that was a dead end. Then we engaged with PMRA and they were willing to discuss our project and determine the correct regulatory path with us. So it was a bit of guesswork based on our products' modes of action, but the PMRA has been supportive and we are grateful. We have also begun engaging with international counterparts as we aim to bring our products to growers worldwide since frost does not respect borders.

5. **How about pre-registration consultation? How much time did it take to get to the right regulatory authority? What challenges did you face while navigating the regulatory framework of Canada?**

Dr. Collin Juurakko: It took at least one year to get directed to the right regulatory authority in Canada. Once we engaged with the PMRA we submitted our request for a pre-submission consultation which gave us all the data requirements for full registration. The major challenges navigating the regulatory framework of Canada are general uncertainty surrounding which agency will be responsible for the product, lengthy timelines, and significant fees as a startup.

6. **What challenges did you face with respect to data requirements, safety assessments, and efficacy testing?**

Dr. Collin Juurakko: So far, the biggest challenges have been the high costs of biological research and getting meaningful funding in Canada to actually gather the required data together with the regulatory timelines to conduct efficacy testing in the field.

7. **Did you work with consultants, contract research organizations (CROs), or other experts to generate data or prepare the dossier? How are you selecting them, and what is your experience working with them?**

Dr. Collin Juurakko: We're working largely with third-party academic institutions to generate the data and prepare the dossier. To date, we've worked closely with the Institute for Sustainable Horticulture at Kwantlen Polytechnic Universities as their expertise and capabilities in developing and registering biological products has enabled us to achieve the success we have as an early-stage startup. The Institute is a fantastic example of public-private collaboration within Canada that enables startups to develop biologicals

without the high-cost burden of all the required infrastructure and expertise. We select our partners largely through our networks and referrals and our experience has been great. As we gear up for registration, we must conduct more in-depth safety studies, multi-season field trials, and environmental fate studies with accredited Contract Research Organizations (CROs) and third parties.

8. **How are you ensuring that your microbial product meets the standards for efficacy, safety, and environmental impact required by Canadian regulators? Are efficacy, toxicology, ecotoxicology, and environmental fate studies all required for your product? Did you get confirmation in pre submission consultation about these studies?**

Dr. Collin Juurakko: Yes, we started with a pre-submission consultation with the PMRA which confirmed all requirements including efficacy, toxicology, ecotoxicology, and environmental fate studies. We continue to base our ongoing research around the described efficacy and safety data requirements. We will ensure our microbial products are compliant and meet the standards described by Canadian and international regulators by conducting all required standardized testing with compliant and permitted third-party partners, then making the data available to regulators within our dossiers.

9. **Are you facing any challenges in generating the required data? Are there any specific studies that are particularly difficult or costly to conduct?**

Dr. Collin Juurakko: Funding and regulatory timelines are the greatest challenge. Biological sciences are incredibly expensive, slow, and difficult. Field trials to generate the necessary real-world data for both the PMRA, and to share with growers and the research community at large, is very expensive and requires permits which take a long time to receive in Canada. Since we are also targeting late spring frost events, we only get one shot per year in Canada and even that is not guaranteed during a field trial at the study site so it adds uncertainty, challenges, and more cost. Toxicology studies required for generating safety data are also extremely expensive, require working with accredited CROs, and there are no providers for some required studies in Canada which adds an additional layer of complexity and cost on our end.

Another important challenge is producing sufficient TGAI for the required research, efficacy, and toxicology studies. Production at a scale sufficient to support these studies can itself be challenging and can become a critical factor in planning the overall product-development timeline, as downstream testing and trials cannot proceed until sufficient TGAI is available.

> Pre-submission consultation is more than a meeting. It is where you map the regulatory journey ahead and lay the foundation for success.


THE SINGLE-SHOT DILEMMA
The Seasonal Field-Testing Reality
For seasonal agricultural innovations, such as spring frost protectants, natural testing conditions occur only once per calendar year in Canada. A minor administrative delay immediately translates into a full 1-year wait for field testing. standstill.
Spring Field Window
Window Missed
+12
MONTHS TO NEXT ELIGIBLE FIELD WINDOW
Regulatory Execution Roadmap
❖ Initiate pre-submission permit discussions months prior.
❖ Submit applications well ahead of target trial season.
❖ Keep buffer time for regulatory reviews and revisions.
❖ Ensure the required permit is in hand before the planned experiment or field-testing window begins.
Treat regulatory timelines as part of your experimental design not as an administrative step that comes afterward.

10. What are some of the most critical eco-toxicology studies required by PMRA, and how do you go about fulfilling these requirements?

Dr. Collin Juurakko: Microbial biopesticides are usually inherently less toxic than broad spectrum conventional pesticides since they are generally highly specific to targets, effective in small quantities, and decompose quickly. However, eco-toxicology studies are still required by the PMRA and international counterparts. Studies impacting pollinators for example are required and we are working closely with our collaborators at the Institute for Sustainable Horticulture to fulfil these critical eco-toxicology studies and others per regulator guidance. Other required eco-toxicology studies include evaluating the impacts on birds, freshwater fish and invertebrates, terrestrial arthropods and invertebrates, and other non-target plants.

11. Did you have any interactions with PMRA after pre submission consultation?

Dr. Collin Juurakko: Yes, since our pre-submission consultations we have had close contact with reviewers at the PMRA to advance our products through field trials, permits and registrations. The PMRA has done a great job being available for discussion and supporting us through the processes and we are appreciative of their efforts to support innovation.

12. What are the total costs associated with registering your microbial product in Canada? Are there any unexpected costs during the registration process which you are considering?

Dr. Collin Juurakko: It will depend on the PMRA and what data requirements they will allow us to waive based on scientific rationales of existing data in the literature, and any small business discount they grant us, if at all. There will certainly be unexpected costs if the PMRA requests additional data and if they don't accept our request for a small business discount. In the latter case, if the PMRA would adopt a similar framework to the US EPA on small business discounts where it is 75% across the board, it could reduce the cost and time burden for both applicants and the PMRA. This is a simple adjustment the PMRA could make to either match or exceed the US, that could improve innovation, biological development, and product registration within Canada. Additional data requirements triggered based on results from toxicology or eco-toxicology studies could also add more costs in the future.

13. What were the biggest challenges you faced during the registration process until now? Are there any regulatory hurdles, a registrant should be particularly aware of when registering a microbial pesticide?

Dr. Collin Juurakko: Time, money, and clarity. You could be waiting over half a year to get an email back where you asked about XYZ from Agency A telling you that Agency A will not allow you to do ABC and they will not offer any suggestions or guidance. So, then you need to try Agency B but first you need to figure out how to get in touch with Agency B because you can't email them; you must navigate a confusing and difficult to use online

portal. Another major hurdle is approvals to conduct field trials. Once you can engage with the correct agency, timelines to get approved to conduct field trials and generate required efficacy data are very lengthy and not within the prescribed time frames stated on the agency website or guidance documents. Moreover, the dataset burden to simply get approved to conduct small plot field trials is also a major barrier and just adds more costs and time before you can even reach field validation. All this adds to the uncertainty and barriers that you must relay to customers and collaborators who are waiting to conduct field trials.

14. What advice would you give to someone preparing to register a microbial product for the first time?

Dr. Collin Juurakko: Engage with all potential agencies early to figure out which agency will regulate you and determine what classification your microbial product will be regulated under ASAP. Build delayed timelines and additional costs to generate more data into your plans. Take advantage of the PMRA and EPA pre-submission consultations. They are a free service designed to help you. Be prepared to hurry up and wait. Make sure you have the capital and strategy prepared to survive the long wait times or be prepared to make sacrifices. An important consideration in microbial product development is to plan Technical grade active ingredient (TGAI) production and scale-up early, ensuring that sufficient material is available for research, efficacy, and toxicology studies and avoiding delays due to material availability.

15. What are some of the key lessons you learned from your experience?

Dr. Collin Juurakko: With regulatory timelines, plan very far ahead and engage very early. Regulatory agencies force you to think in timelines of years, not months, and you have to build your business and life plans around it. For example, once you submit registration packages, you could be waiting around for years without any ability to generate revenue needed to pay staff or operate the business, so you need to have sufficient capital ahead of time or reduce expenses to survive the years of uncertainty. This is even more applicable nowadays when agencies are short-staffed and backlogs continue to grow. As demand for biological products continues to grow, regulatory timelines prevent growers from accessing the newest technologies and stymie large scale benefits to food security and economic growth from innovation.

"Regulatory agencies force you to think in timelines of years, not months, and you must build your business plans around it".

DR. COLLIN JUURAKKO

STRATEGIC COLLABORATION

Accelerating development, Reducing early-stage overhead

Biological research infrastructure and toxicology testing carry substantial capital costs. Advanced Agriscience mitigated this early-stage overhead by partnering with the Institute for Sustainable Horticulture at Kwantlen Polytechnic University (KPU) to generate the efficacy, pollinator safety, and ecotoxicology datasets required for regulatory submission.

Advanced Agriscience

KPU | Institute for Sustainable Horticulture

The Power of Partnership

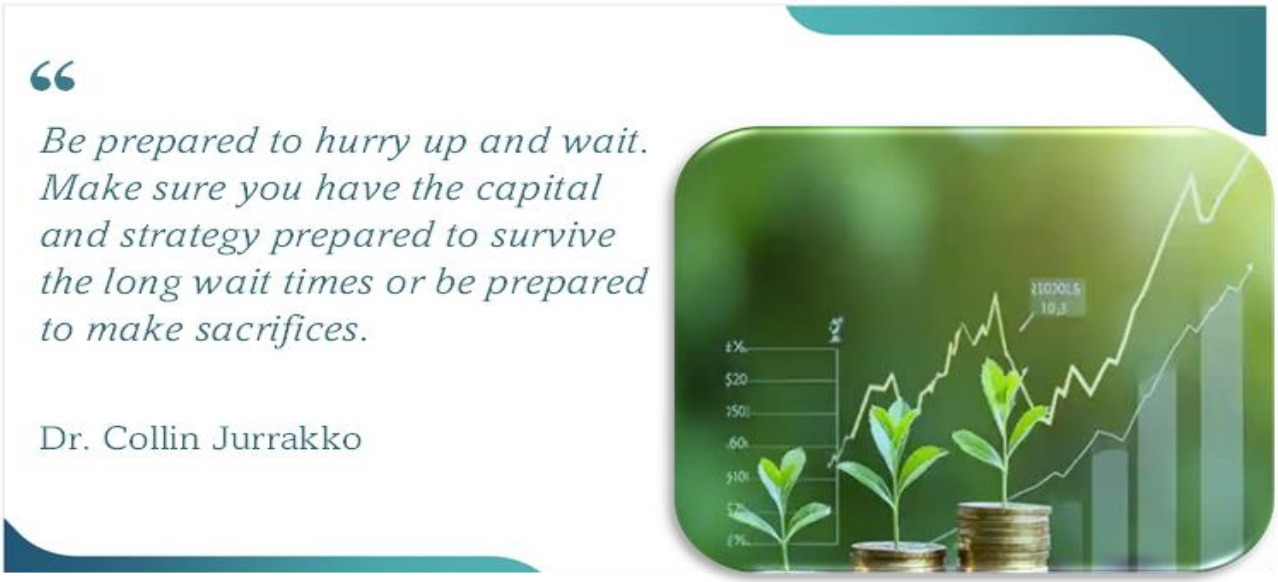
- **Reduced capital overhead**
- **High-quality, regulatory-ready datasets**
- **Faster progress to market**

16. What are your plans for monitoring post-registration? & How will you ensure that your product continues to meet regulatory standards after it's approved?

Dr. Collin Juurakko: We will continue to follow all required regulatory guidelines and conduct necessary monitoring to maintain registrations in Canada and internationally. We will also continue our research to register our products on additional crop types, in additional countries, and iterate product improvement and performance for growers.

17. How do you plan to educate farmers and other end-users about the benefits and proper use of your microbial product?

Dr. Collin Juurakko: We will communicate the benefits, modes of action, and ROI of our uniquely differentiated microbial products through several ways. Research findings, benefits, and proper use of our products will be communicated through field demonstrations, presentations to commodity organizations, and presentations at relevant conferences. Outcomes will also be disseminated through open access preprints and peer-reviewed publications, and we will translate the scientific jargon into digestible lay term white papers for broader accessibility. We will also share research findings in visual formats for non-English speaking audiences and at a glance communication. Just as we engage with growers to select our product names, we will engage with growers to develop clear product labels and materials that communicate proper use and benefits.



18. Looking ahead, what challenges do you anticipate after the product is launched in the Canadian market? What steps are you taking to address those challenges?

Dr. Collin Juurakko: Once we pass all the regulatory barriers, we anticipate adoption and scaling will be the greatest challenges. Here, we are taking steps to build relationships with partners that can help us overcome challenges. We must educate growers by working closely with them, communicate benefits and return on investment, and scale manufacturing and distribution to get our microbials in the hands of growers across Canada and around the world in the most efficient and convenient ways possible.

19. Do you plan to register your product in countries other than Canada?

Dr. Collin Juurakko: Yes, we plan to register our products in any country where frost is an issue for growers. No market size is too small if we are able to bring value to growers. If any readers know of a country where growers face frost challenges and they would like us to register the product there, please reach out to us by email or via the form on our website to let us know. For now, we are focused on Canada and the US to start. We are beginning to explore the registration process in the EU, Australia, Brazil and other major markets with a strong pull for frost protection and biologicals.

20. Are you considering expanding your product line or developing additional microbial product? If so, how will this registration experience influence your approach to future submissions?

Dr. Collin Juurakko: Definitely. We're already working to improve our flagship products with future iterations enhancing and adding modes of action to increase performance and ROI for growers. We also plan to develop our technology into a platform that will allow us to offer a suite of microbial products deploying novel modes of actions targeting abiotic and biotic stressors for cost-effective, safer, and more environmentally friendly alternatives to conventional chemistries. Having this first registration experience will be a huge asset as we build the relationships, knowledge, repeatable processes, and develop the documentation required to successfully register a novel microbial product in Canada and internationally.

> "No market size is too small if we can bring value to growers".
>
> DR. COLLIN JUURAKKO

Key Takeaways

- **Determine the regulatory pathway early.**
  Before investing heavily in product development, identify the likely regulatory authorit and product classification.

- **Use pre-submission consultation strategically**.
  Take full advantage of free pre-submission consultations to establish clear data requirements and design research programs around regulatory

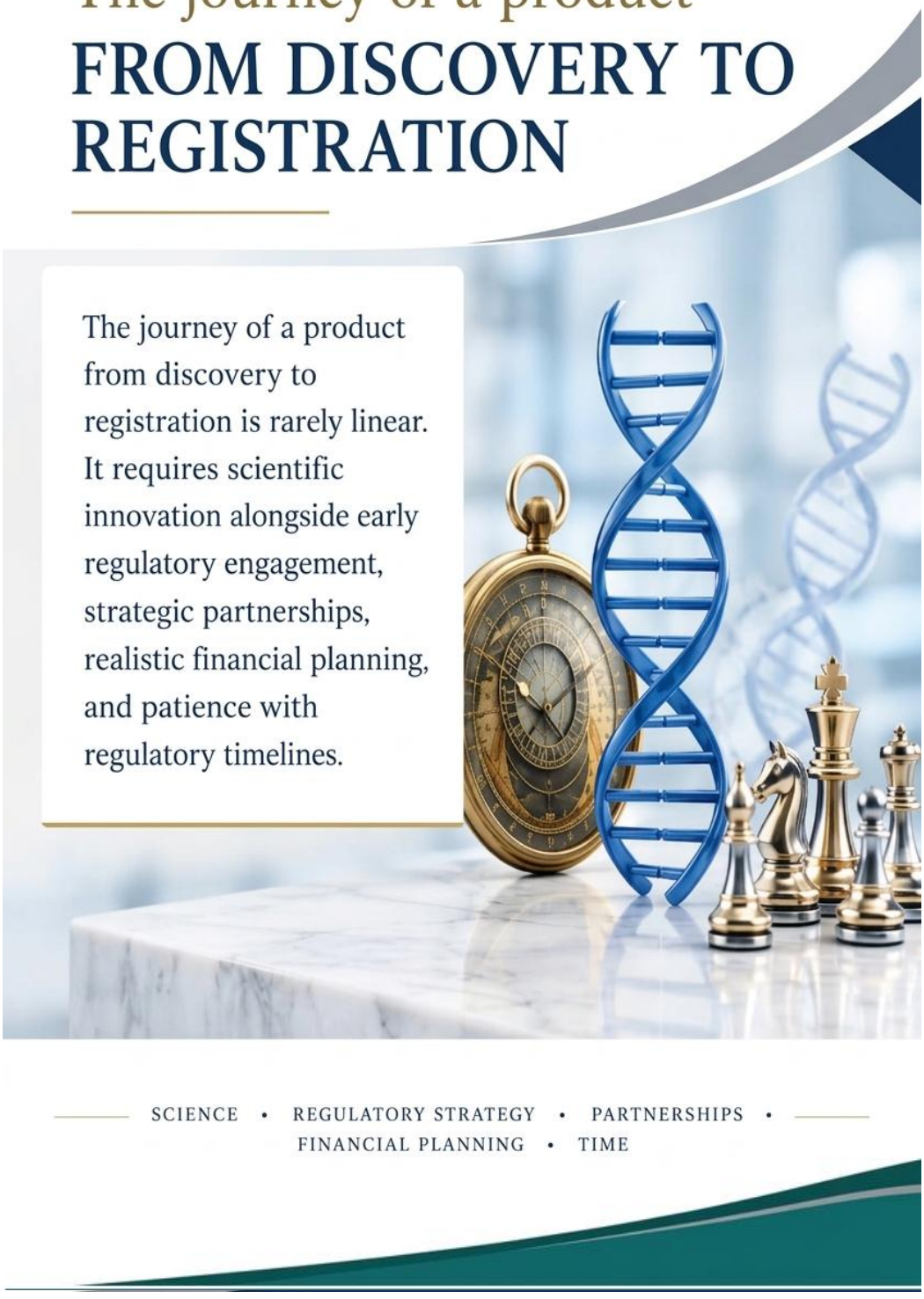
- **Build strong public–private research partnerships.**
  Academic institutions can provide specialized expertise, infrastructure and scientific capabilities that early-stage companies may struggle to access on their own. KPU's Institute for Sustainable Horticulture has been an important part of Advanced Agriscience's development journey.

- **Build regulatory timelines into the business plan.**
  Registration can take substantially longer than anticipated. Developers should plan for delays, additional studies, and associated costs.

- **Budget capital around the calendar, not the clock.**
  Field trial approvals, single-season weather dependencies, and multi-year reviews mea capital strategy must support long periods without commercial revenue.

- **Regulatory readiness should develop alongside scientific innovation**.
  A strong technology alone is not sufficient. Developers must simultaneously build the evidence, documentation, partnerships, funding strategy and regulatory knowledge needed for registration.

- **Advocate for regulatory alignment**.
  Canadian small-business fee structures remain a major barrier compared with frameworks like the US EPA's 75% fee discount — highlighting a need for policy modernization.


The journey of a product
FROM DISCOVERY TO REGISTRATION
The journey of a product from discovery to registration is rarely linear. It requires scientific innovation alongside early regulatory engagement, strategic partnerships, realistic financial planning, and patience with regulatory timelines.
SCIENCE • REGULATORY STRATEGY • PARTNERSHIPS • FINANCIAL PLANNING • TIME

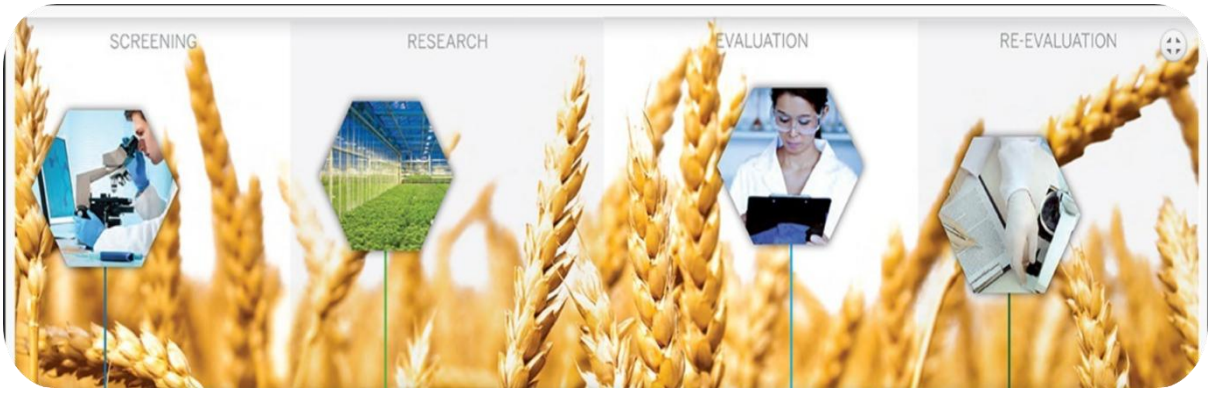
Resources

Canadian Regulatory Resources

- Pest Management Regulatory Agency (PMRA)
  - Guidance for the registration of microbial pest control agents and products [2021]
  - https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/registrants-applicants/submission-consultations.html
  - https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/approach-environmental-risk-assessment.html
- Canadian Food Inspection Agency –
  - Guide to submitting applications for registration under the *Fertilizers Act*
  - CFIA Fertilizer Registration Overview and Application Checklists
- Publications - The Institute for sustainable Horticulture, Kwantlen Polytechnic University
  - https://www.kpu.ca/ish/publications

International Regulatory Resources

- https://www.epa.gov/pesticides/biopesticides#registration
- https://openknowledge.fao.org/items/533c310e-dd22-427d-9b0d-ab764a76f607
- https://www.oecd.org/en/publications/oecd-guidance-to-the-environmental-safety-evaluation-of-microbial-biocontrol-agents_9789264221659-en.html



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