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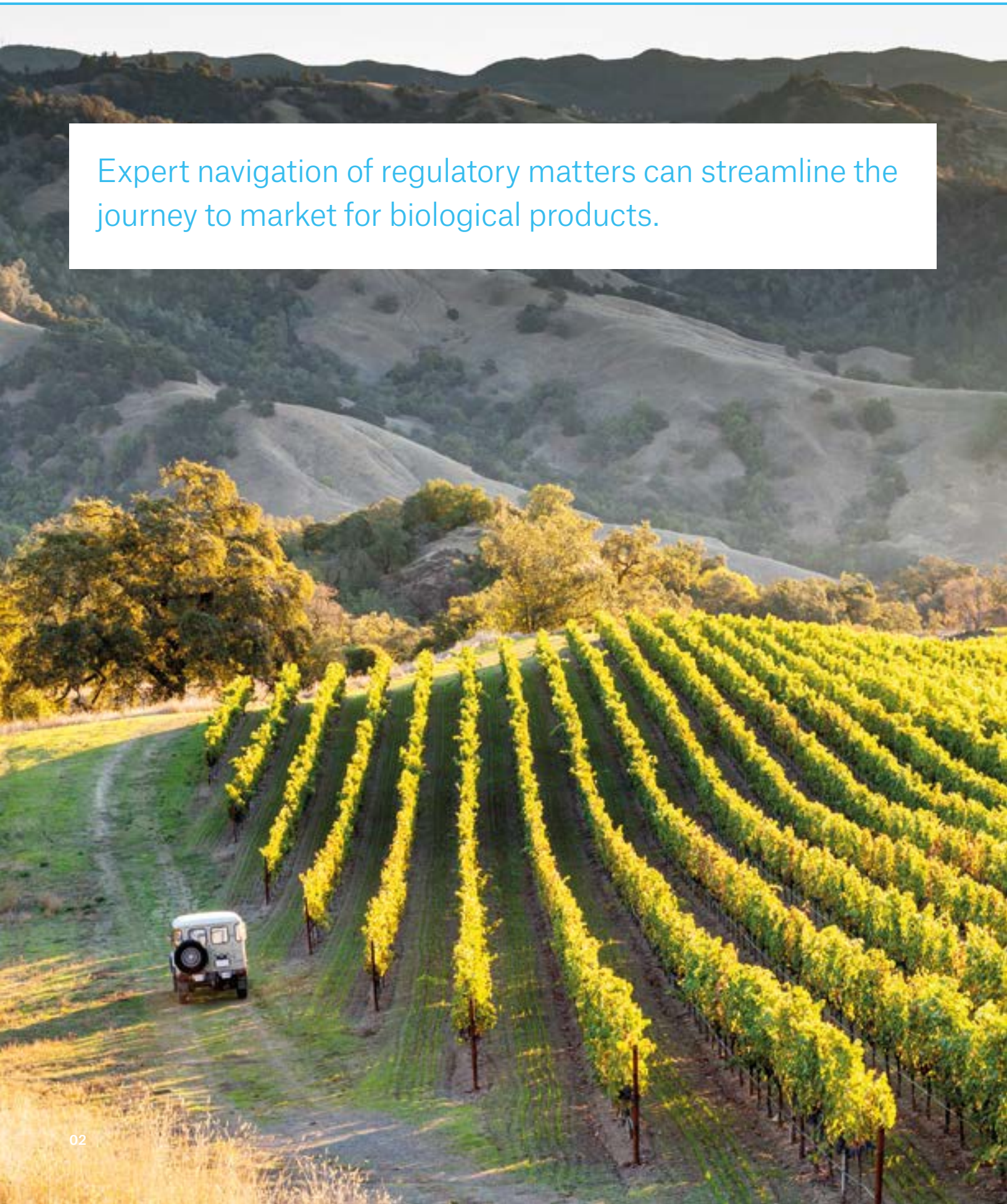
INSIGHT

Five ways to ease the regulatory journey for biological products

Experts from the USA, Canada, and Europe share practical tips for the registration of biopesticide, biofertilizer, and biostimulant products.



Expert navigation of regulatory matters can streamline the journey to market for biological products.

Navigating the complexity of biological product registration

Demand for biopesticides, biofertilizers*, and biostimulants is expanding as attitudes to conventional pesticides and fertilizers change. However, complex and inconsistent global regulations for biologicals make it hard to unlock commercial opportunities.

Firstly, it's important to determine a biological product's category, the route for registration, and associated data requirements at the earliest opportunity. But a varied and changeable global picture for biologicals means this is far from straightforward. Table 1 illustrates the high level of market variation in product classifications.

In this article, five of TSG's regulatory experts share insights on the product registration challenges companies typically face in North America and Europe, and how to resolve them. Their aim is to facilitate cost-effective and efficient national and global regulatory strategies for biological products.

USA	Canada
Biopesticides are regulated by the Environmental Protection Agency (EPA) Biopesticides and Pollution Prevention Division (BPPD) within the Office of Pesticide Programs (OPP). There are three categories: **biochemicals, microbials, plant-incorporated protectants (PIPs).** Plant **biostimulants** are an emerging product class. Biological products with certain intended uses – such as plant nutrition or soil amendment – may be categorized as **fertilizing materials.** However, a product which physiologically influences plant growth and development may be considered a plant growth regulator, which would require pesticide registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).	**Biopesticides** are regulated by the Pest Management Regulatory Agency (PMRA) under the Pest Control Products Act (PCPA). Classifications include: **microbial, semiochemical,** and **non-conventional.** **Biostimulant** products and other biological fertilizing materials are regulated by the Canadian Food Inspection Agency (CFIA) under the authority of the Federal Fertilizers Act and Regulations. However, those which control disease or pests, as per PCPA definitions, are regulated by PMRA. Products with dual properties may be subject to both fertilizer and pest control regulations.
UK (GB, excluding Northern Ireland)	**EU (including Northern Ireland)**
Biopesticide products and active substances face the same PPP regulatory process as conventional pesticides. However, where **microorganisms** are used as the active substance separate data requirements apply to help expedite the regulatory journey. There are no specific regulations for bio-based fertilizing products such as **biostimulants**, soil conditioners, or improvers.	**Biopesticide** products and active substances face the same PPP regulatory process as conventional pesticides. However, where **microorganisms** are used as the active substance separate data requirements apply to help expedite the regulatory journey. Since 2022, plant **biostimulants** and other bio-based fertilizing products have been clearly defined under Regulation (EU) No 2019/1009 surrounding fertilizing products. PPP regulations have been amended to acknowledge this.

Table 1: Regulations for biological products vary between markets

*Biofertilizer is a widely used industry term, but it is not a defined term under current regulations.

USA

"Determine the appropriate requirements for your product before building your application package."

Wendy McCombie suggests engaging with the US EPA's BPPD as early as possible to confirm the regulatory jurisdiction and data requirements for product registrations.

Clients often approach me after they've run into application challenges during the registration of pesticide products. Many assumed their product would be regulated as a biopesticide but didn't obtain a pre-application determination to qualify as a biochemical or have a pre-submission meeting to discuss data requirements. Basing the strategy for a product's testing and registration on the reduced data set for biopesticides can lead to significant data gaps or reliance on studies and test methods that don't satisfy regulatory requirements if it doesn't qualify for BPPD review.

In some cases, the emerging class of plant biostimulants may trigger FIFRA pesticide registration requirements if the product is categorized as having a growth regulator mode of action. This complex area has caused a great deal of confusion across industry due to the regulation of biostimulant products in other countries.

Applying for a Biochemical Classification Determination (PRIA B617) or a FIFRA-regulated product determination (PRIA M009) is the best way to ensure the appropriate regulatory pathway for your product. The review process takes at least six months and the PRIA fee is a few thousand US dollars, but it is well worth the investment to avoid wasted time, energy, and budget on an application package that misses the mark.

Wendy is a Principal Regulatory Consultant. She has a strong track record providing strategies and solutions to the chemical industry, helping companies maintain compliance with Federal and State laws. Highly experienced in government regulations related to chemicals, she holds deep knowledge of the FIFRA regulatory framework for pesticide products and related inert ingredients. Wendy has a BSc in Biology from Gettysburg College.

“Understand state-level registration challenges, and plan accordingly.”

Shannon Bryant-Spas advocates early and proactive planning for state registration of biostimulants.

There’s a common misconception that the path to market for biostimulants is straightforward in the USA because they’re not regulated under FIFRA. In fact, the state registration process is complex, challenging, and time consuming. Dealing with 48 separate regulatory entities is no mean feat. Their laws don’t always align, and labeling and data requirements can also be different or even contradictory.

My advice is to take time to understand where your product fits in the state framework so you can prepare specific components for the registration dossier in good time. Otherwise, you may discover that additional data or efficacy studies are needed to support the registration process or specific product claims. In some cases, this information takes months or even years to develop, so it’s incredibly frustrating to discover something has been overlooked just as you want to get started with registration.

Think about state registration early, when developing a product’s wider registration package. Evaluating composition, then deciding what claims are acceptable and will be allowed, informs label development and helps define the types of data that will be needed. Having a clear understanding of the mode of action and not making too many claims can also expedite the process and make it easier to achieve a single label that is permissible across all states.

Shannon is a Principal Regulatory Consultant and Team Leader, specializing in the state level compliance of products including fertilizers, plant and soil amendments, and organic input materials. Shannon has more than 20 years of experience managing environmentally and chemically-based projects. She has a BA in Chemistry and English from the University of Kansas.

EUROPE

“Apply a strategic mindset to plant protection products.”

Iain Watt advises manufacturers to consider multiple registration options for biological agrochemical products in the UK and EU.

Generally, the registration of PPPs takes longer and is more complex in the EU than in the USA. This is equally true for biopesticides which in the EU are covered by the same regulation and process as conventional chemical PPPs. The end-to-end process for gaining approval of a biological active substance and then registering a biopesticide product which contains it can take more than seven years in the EU. For companies that want to achieve commercial returns sooner, a biostimulant route to market may be more suitable.

Not all products can be neatly categorized as a ‘biopesticide’ or ‘biostimulant’. For those where mode of action is on the borderline, it may be beneficial to focus on the product’s biostimulant claims on the label and access the market more quickly as a biostimulant product. As Erika explains opposite, biostimulants can potentially obtain a CE mark, unlocking access to the entire European Economic Area (EEA). However, it’s worth considering that a biostimulant registration may preclude a product from being marketed as a biopesticide in the future.

In the UK (GB), biostimulants do not have to be registered at all. Nevertheless, it is advisable to contact CRD to determine whether Plant Protection Product Regulation (PPPR) applies on a case-by-case basis.

Post-Brexit, it appears new active substance/PPP registration is more time-efficient in GB than in the EU, with CRD aiming to make decisions for both within a three-year timeframe. Since requirements and criteria closely resemble those of the EU regulation, this could be an effective testing ground for manufacturers looking to secure EU registration for PPPs. EU decision makers may use the GB evaluation as a point of reference to help inform their decision.

Iain is our Head of Plant Protection. He has more than 35 years’ experience in the crop protection sector, working in research, advisory and industry roles, latterly as a Regulatory Affairs Manager supporting a global portfolio of product authorizations. He has a research MPhil, MSc in Applied Entomology and a BSc (Hons) in Zoology. Iain is an active member of the IBMA Natural Substances Professional Group.

“Determine product claims clearly, and as early as possible.”

Dr Erika Arias-Cordero says thinking pragmatically about product claims helps streamline EU registration.

It’s important to understand that claims made about a biological product’s function have a direct impact on the complexity of its registration in the EU.

For instance, plant biostimulants benefit from a dedicated fertilizing product category under Regulation (EU) 2019/1009 which harmonizes quality and safety standards for EU-wide trading of mineral and bio-based fertilizers. If you can demonstrate a product’s conformance with Regulation (EU) 2019/1009, it receives a CE mark which means it can be traded across the EEA without restrictions. However, if a product’s claim includes a pesticidal or other plant protection function defined under PPPR as biocontrol effects, it cannot be classified as a biostimulant, and is therefore not eligible for this regulation.

With borderline products, it is sometimes difficult to determine whether PPP or fertilizer regulation applies in the EU. If it is not possible to submit clear evidence demonstrating that a biostimulant with biocontrol effects satisfies PPP criteria, national level fertilizer product registration is advisable in some cases. This requires demonstration of compliance with national regulations which are inconsistent and may require more comprehensive data.

I would suggest thinking very carefully about composition, function, and claims from a commercial and regulatory perspective, especially for products with combined biostimulant and biocontrol effects. Then you can make an informed decision about whether the simpler route for full EU coverage is permissible and desirable, or if a national approach is more appropriate.

Erika is a Regulatory Consultant and a project manager for the preparation of Biological Assessment Dossiers and CADDY dossiers. Her area of expertise is biological efficacy of PPPs. She has a Masters degree in Horticulture focusing on Plant Protection, and a PhD and postdoc in Microbiology from the Friedrich-Schiller-Universität and the Max Planck Institute of Chemical Ecology.

CANADA

“Be prepared for Canada’s specific data requirements.”

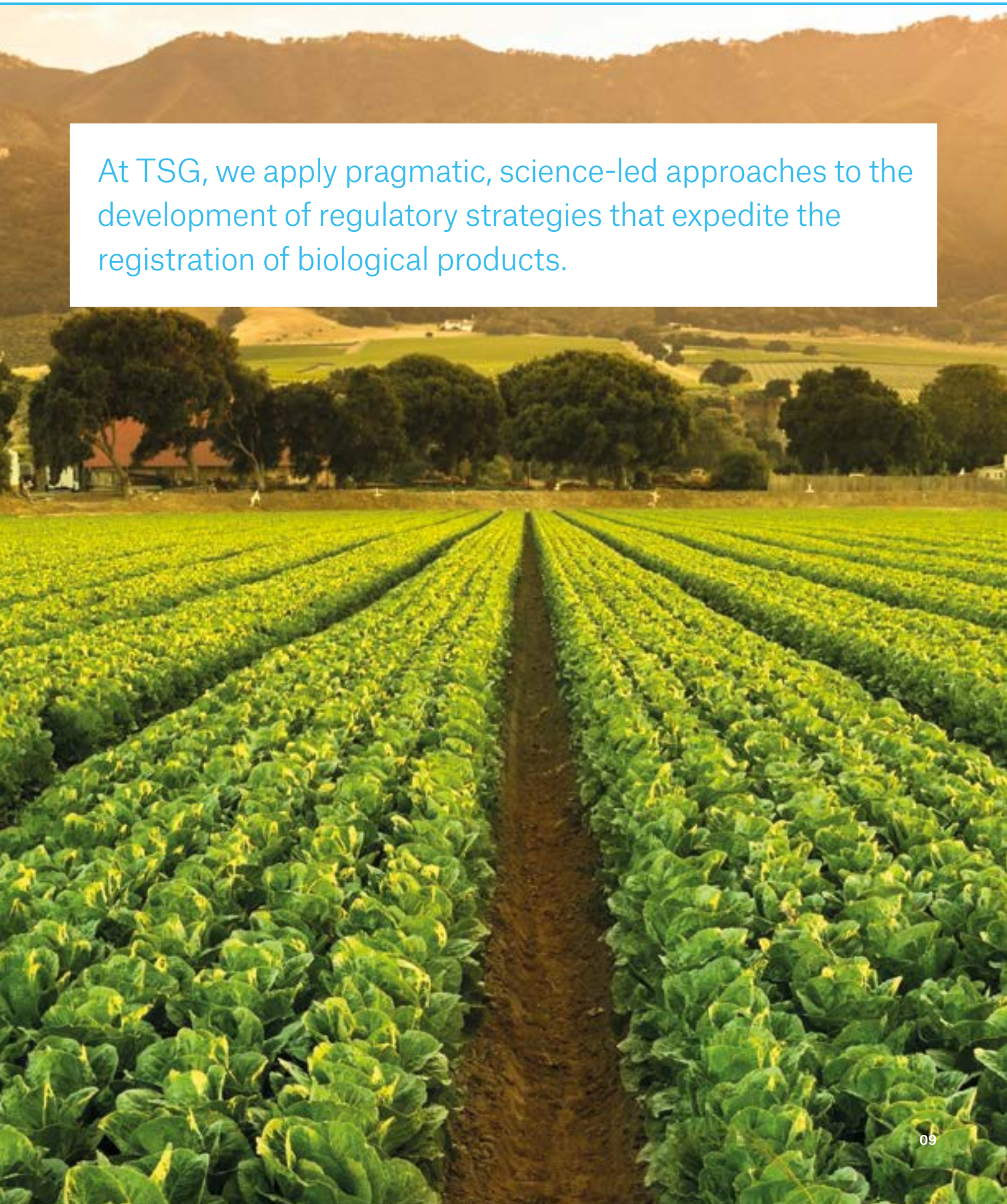
Joseph McCarthy says it’s a good idea to research data obligations for biopesticides, biofertilizers, and biostimulants in Canada before starting product trials.

Many people expect Canada to mirror the USA when it comes to the registration of agricultural biochemicals. In fact, the data requirements are often more stringent and specific.

All pesticides in Canada, including biopesticides, require supporting value (efficacy) data for the registration of any use described on the label. This sometimes takes companies by surprise, as it is not the case in the USA where non-public health claims, such as crop protection, don’t require efficacy data. It’s important to plan for this since efficacy trials must be conducted with Canadian cultivars in regions with equivalent environment/growing conditions to those in Canada. To maximize the chances of getting this right, I always advise companies to take advantage of the Pest Management Regulatory Agency (PMRA) pre-submission process for biopesticides. It’s free, and provides useful details about data requirements for toxicology, exposure, residues, environment toxicology and fate.

Another point to note is that strain level data is required for the origin, derivation, and identification of microbial organisms used in biopesticides, biofertilizers, and biostimulants. This is often considered confidential business information, so it may be hard to obtain from ingredient suppliers. If a product’s commercial strategy is likely to include Canada, it may be prudent to opt for a registered source of microbial organisms. Simply describing ingredients as ‘naturally occurring’ does not relieve the applicant’s obligation to provide safety information surrounding human health and non-target organisms.

Joseph is a Principal Regulatory Consultant and TSG’s lead Canadian Agent. With over 20 years’ experience, he provides service and solutions to clients for a variety of conventional, non-conventional, and pesticide device products in Canada. Joseph has a keen understanding of Canadian regulations including the Pest Control Products Act, Fertilizers Act and New Substance Notification Regulations. He holds a BSc in Chemistry and Environmental Sciences.



At TSG, we apply pragmatic, science-led approaches to the development of regulatory strategies that expedite the registration of biological products.

Let TSG help with your product registration

Our expert consultants provide country-level representation across Europe and North America. They manage data reviews, label preparation and review, national and state-level registration, and other country-specific matters to streamline compliance in target markets.

Efficient, effective regulatory strategies

TSG can navigate the complex regulatory landscape for biological agrochemicals on your behalf. We keep track of ongoing developments and changing obligations so we can identify the most effective regulatory strategy to meet your commercial goals.

Data requirements are complicated and submission processes are often labor-intensive. But we have extensive experience handling them, so we work with confidence and efficiency. Our consultants provide country-level representation in the USA, Canada, UK, France, Germany, and Spain. We also have an established network of associates covering Central and Eastern European countries as well as Latin America and the Asia Pacific region.

Regulatory experience and scientific insight

Many of the regulatory consultants and scientists on our 100-strong global team are educated to Masters or PhD level in their respective field. This underpins the depth and breadth of our specialist consultancy services for biological agrochemicals.

We hold more than 30 years' experience in biochemical and microbial pesticides, and we have supported numerous biopesticide active substances and products through the relevant regulatory processes.

In terms of biostimulants, we have successfully completed a wide range of activities in Europe, the USA, and Canada for products ranging from mineral fertilizers, microbials, and micronutrients to plant improvers, plant strengtheners, and soil amendments.

Environmental sciences

- In-depth scientific knowledge of microbials, biochemicals, botanicals, and semiochemicals
- Ecotoxicology study management and issue resolution
- Environmental risk assessments

Human health

- In-depth scientific knowledge of microbials, biochemicals, botanicals, and semiochemicals
- Residues and dietary risk assessment, and non-dietary risk assessment
- Substance identification, chemical method validation

Regulatory reviews and submissions

- More than 50 experienced users of the IUCLID platform (EU)
- Dedicated teams for Federal and State-level regulatory activities (US)
- Dedicated teams for Canadian federal regulatory activities
- Certification and labeling support for input materials used in organic production (Europe and North America)

Study management

TSG offers full lifecycle management of studies to support biological product registrations, including physical-chemical properties, storage stability, biology, toxicology, environmental fate, and ecotoxicology. We handle technical and strategic matters including the design of study protocols, review of study plans and draft reports, and report finalization. Study monitors oversee programs with technical input from specialists within the human health and environmental sciences teams.

We also provide a literature search and review service covering bespoke searches to address SANCO/2020/12258 (secondary metabolites), as well as helping to overcome challenges in defining an appropriate search strategy.

Get in touch

Contact our experts directly if there's a specific matter you would like to discuss:

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Contact us to discuss how we can support your registration of biological products across national and international markets.

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