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# Clearing the path for biological product commercialization

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**Complex and inconsistent global regulations for agricultural biologicals can make it hard to realize the full scope of commercial opportunities. Aligning commercial and regulatory strategies at the earliest opportunity streamlines the journey to broader market access.**

As the push for more sustainable agriculture increases demand for biologicals, innovation is accelerating. But when it comes to the commercialization of biological products, regulatory complexity and disharmony can slow things down.

While it is generally agreed that biologicals are derived from living organisms or produced using living systems, the way they are classified and regulated varies greatly between markets. This lack of consensus can be a significant obstacle to market entry. Agrichemical companies need to systematically align products with markets' specific registration/authorization demands.

Here, we outline key differences across the United States (US), Canada, Great Britain (GB), and the European Union (EU). We also highlight important State-level considerations in the US. A good understanding of these matters supports and informs innovation and commercialization strategies.



## How are biologicals defined for regulatory purposes?

Agricultural biologicals are typically used in place of, or in combination with, synthetic chemical pesticides and fertilizers to improve the yield and/or health of crops. From a global perspective, the three main categories are biopesticides, biostimulants, and biofertilizers.

The **biopesticide category** is the most mature and well-defined, but there are still discrepancies to account for in multi-market strategies.

In the US, 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 sub-categories: biochemicals, microbials, and plant-incorporated protectants (PIPs). In Canada, the Pest Management Regulatory Agency (PMRA) regulates biopesticides under the Pest Control Products Act (PCPA). The three main sub-categories – microbial, semiochemical, and non-conventional – don't entirely align with those of the US.

In the EU and GB, biopesticide products have historically faced the same regulatory requirements as synthetic pesticides, with separate data requirements expediting the regulatory journey for those using microorganisms as the active substance. However, the EU's December 2025 proposal for streamlining EU food and feed safety legislation indicates that change is coming. The proposal suggests that rules and

procedures will be simplified for plant protection products (PPPs) and biocidal products under the Commission's Vision for Agriculture and Food.

When it comes to **biostimulants and biofertilizers**, the global situation is even more complex.

In the EU, biostimulants have been formally defined and regulated as fertilizing products under Regulation (EU) 2019/1009 (FPR) since 2022. Meanwhile, Canada regulates both biostimulants and biofertilizers through the Canadian Food Inspection Agency, unless they also control pests or disease, in which case dual registration (under two separate regulations) is necessary. This situation is evolving, with a proposed amendment expected that will make it possible to register dual purpose pesticide-supplement products. GB and the US do not have dedicated categories or frameworks for biostimulants.

It's important to note that biostimulants are an emerging class in the US. Biological products with certain intended uses – such as plant nutrition or soil amendment – may be categorized as fertilizing materials. However, a product that influences plant physiology may be considered a plant growth regulator, which falls under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) pesticide regulation.

These differences in definition and classification set the tone for the agricultural biologicals regulatory landscape. The following sections explore further complications across North America and Europe, with guidance on how to navigate them.

## How does the US regulate agricultural biological products?

In the US, agrichemical companies often run into application challenges during the registration of pesticide products, having mistakenly assumed their product would be regulated as a biopesticide. If you're planning to take the biopesticide route to market, it's advisable to 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.

Applying for a Biochemical Classification Determination (PRIA B617) or a non-FIFRA regulated product determination (PRIA M009) is the best way to ensure the appropriate regulatory pathway. 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.

Biostimulant registration in the US can also present unexpected challenges. There's a common misconception that the path to market will be straightforward because they are exempt from EPA registration. However, the opposite is true, as these products must still be registered at the State level prior to sale and distribution. This involves dealing with separate State regulatory authorities and laws that are not in complete alignment, and different – sometimes contradictory – data and labeling requirements.

It's important to understand where a product fits in the State framework so specific components for the registration dossier can be prepared in good time. Otherwise, additional data or efficacy studies may be needed to support the registration process or specific product claims. In some cases, this information takes months or even years to develop. It's incredibly frustrating to discover that something has been overlooked at the start of the State registration process.

Thinking about State registration early, when developing a product's wider registration package, can facilitate easier nationwide rollout. 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.



## How does Canada regulate biopesticides, biostimulants, and biofertilizers?

Many people expect Canada to mirror the US 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 US 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, it's advisable to take advantage of the 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 are 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.



## How do regulatory pathways for biological products differ across the EU and GB?

As it stands, the EU PPP process which covers biopesticides is known for its complexity. Gaining approval of a biological active substance then registering a biopesticide product which contains it can take five years or more. However, new measures proposed in December 2025 include accelerating procedures for biopesticide market access as well as making renewal procedures more targeted and efficient. For example, it has been proposed that approvals for biocontrol active substances are 'unlimited' and that authorization of products containing them would be valid for 15 years.

GB's PPP regulation diverged from that of the EU after Brexit. The Health and Safety Executive (HSE) Chemicals Regulation Division (CRD) oversees the process and aims to make decisions for active substances and products containing them within a three-year timeframe.

In both the EU and GB, when microorganisms are used as the active substance in a biopesticide, separate data requirements apply which may expedite the regulatory journey. Biostimulants also benefit from a simpler path to market, but there are some critical factors to bear in mind.

The EU regulates biostimulants under the FPR, making it possible to obtain a CE mark and access the entire European Economic Area (EEA). For products that could reasonably fall under either the biopesticide or biostimulant category, this poses a regulatory dilemma. Pursuing authorization under the biostimulant category may ease market access, but it comes with limitations. For example, under FPR it is only possible to make claims related to biostimulant effects. Any reference to pest or disease control could trigger reclassification under PPP regulation. Moreover, registering a product as a biostimulant may mean it cannot be marketed as a biopesticide in the future.

In GB, biostimulants do not have to be registered at all. Nevertheless, it is advisable to contact the CRD to determine whether PPP regulation applies on a case-by-case basis.



## How can regulatory insight support biological product commercialization?

Successfully bringing biological products to market starts with a clear understanding of the regulatory landscape, and an appreciation of how it is evolving. In the EU, proposals to simplify biopesticide approvals and renewals suggest a more supportive environment for innovation. But the overall global picture remains fragmented.

For companies targeting multiple regions, navigating this global complexity is a real challenge. However, when decisions are based on robust scientific and regulatory insights it's possible to streamline the path from innovation to market access. Aligning commercial and regulatory strategy from the outset is key.

Sagentia Regulatory's consultants in the US, Canada, EU, and GB support organizations through the full lifecycle of biological product development, from new active substance strategies to product registration and renewal. Get in touch to find out how we can help you move forward with confidence as global frameworks continue to evolve.

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## About Sagentia Regulatory

Sagentia Regulatory, formerly TSG Consulting, provides scientific and regulatory expertise to help clients navigate the technical and compliance challenges of bringing their products to market across multiple jurisdictions. With deep knowledge in environmental science, human health, chemistry and regulatory affairs, Sagentia Regulatory supports innovation and compliance across sectors including crop protection, antimicrobials, biocides, industrial, consumer goods, and more.

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