

Strategic Market Access for Biostimulants and Fertilizers in the EU

— Expert Analysis of Regulatory Pathways and Strategic Considerations

By Longjian Huang, Editor at AgroPages, long@agropages.com

When people hear the term “European Union,” many instinctively picture Paris with the Eiffel Tower in the background, or London under the watchful gaze of Big Ben - even though the UK has long since made its dramatic exit. This cognitive bias extends beyond geography; it also reflects a deeper misunderstanding of what the EU truly is. As of 2025, the European Union is a unique political construct comprising 27 member states. It is neither a conventional alliance of sovereign nations nor a fully developed federal system. Rather, it represents an unprecedented experiment in the voluntary transfer of sovereignty: member states have handed over significant authority - such as currency issuance, trade regulation, and environmental standards - to supranational institutions, while firmly holding onto core sovereign powers like military defense and taxation.

This “quasi-federal” character is especially pronounced among eurozone countries: from the European Central Bank’s monetary policy in Frankfurt to competition law rulings issued in Brussels, the economic sovereignty of member states has been deeply woven into the EU’s institutional framework. The experiences of Norway and Switzerland reveal another dimension of European integration. Norway, as part of the European Economic Area, adopts approximately 75% to 98% of EU single market regulations through its agreement with the Union. Despite having no legislative voting rights, it is

nonetheless bound by extensive regulatory alignment. Switzerland, on the other hand, accesses parts of the EU internal market via a series of bilateral agreements, retaining its own currency - the Swiss franc - while selectively harmonizing with EU rules. These two non-member states embody a delicate balance of “close yet distant” relations with the EU’s regulatory system, serving as mirrors that reflect both the reach and the limits of the Union’s influence.

It is this intricate political and economic ecosystem that gives rise to the EU’s distinctive “dual-track” regulatory system. On one track, in pursuit of a unified internal market, regulators in Brussels have crafted a modular regulatory framework designed for broad applicability. On the other, national authorities - shaped by diverse administrative traditions - retain flexibility in implementation, allowing them to tailor regulations to local conditions. This regulatory tension is especially pronounced in the field of agricultural inputs. In the case of biostimulants and fertilizers, it manifests clearly - from the modular architecture of the European Fertilising Products Regulation (FPR) to the varying national requirements for registering organic amendments. The selection of regulatory pathways not only challenges companies’ compliance strategies, but also reveals the underlying power dynamics and negotiations that define the ongoing process of European integration.

Compliance game under dual-track supervision: EU unified framework and member states’ differentiated practices

EU regulatory system: efficiency and limitations of modular design

As the world’s first supranational entity to establish unified regulations for fertilizers, the European Union has developed a distinctive “four-dimensional certification framework” under the European Fertilising Products Regulation (FPR). This framework segments the compliance pathway into four functional modules - A through D - each corresponding to different product categories: Module A covers conventional fertilizers, Module B focuses on organic soil improvers, Module C governs microbial products, and Module D serves as a channel for innovative or non-traditional formulations. Companies must identify the appropriate modules based on their product’s functional claims (PFC) and component material categories (CMC), as these selections determine the depth of data required and the associated certification timeline and cost.

Take microbial fertilizers, for example. Certification under Module C requires the manufacturer to complete three key tests: microbial strain identification, toxicological safety evaluation, and field efficacy validation—each performed by EU-designated laboratories. Upon successful completion, the product is granted the “CE” mark, which acts as a master key, enabling access to all 27 EU member states. With this unified approval and labeling system, products can - in principle - circulate freely across markets from the Baltic to the Mediterranean, potentially significantly lowering cross-border trade barriers. This “one certification, full access” model, when it applies fully,

holds particular strategic value for companies developing innovative biostimulants.

Despite the “streamlined” approach, the modular system still holds complexity. Even with FPR certification, products involving animal by-products (e.g., seaweed extracts) must still comply with the sterilization standards of the Animal By-Products Regulation (ABPR). Moreover, formulations containing novel microorganisms that are not in the existing positive list may trigger a “substantial change” review process of the FPR, which can reset the certification timeline by up to 18 months. Notably, only 4 - 5 categories of well-established products have successfully completed full-module certification to date. It also means that “innovation” is not eased because of a too restrictive framework that does not leave any flexibility. A significant number of biostimulants remain in regulatory gray areas, where compliance is determined case by case - underscoring both the promise and the uncertainty of the EU’s evolving regulatory landscape.

Member States’ Regulatory Systems: Survival Strategies in the Labyrinth of Differences

Under the unified framework established by Brussels, member states still maintain amazing regulatory diversity, forming a three-level regulatory spectrum:

Open market: Germany as an example for a certain type of biostimulants

Germany allows for most microbial products to be placed on the market as “biostimulants”, provided they are in compliance with all relevant provisions of its national fertiliser legislation. Once basic ingredient testing and safety assessments are completed, companies can place their products on the German market under national procedures and bring them to market relatively quickly.

This streamlined regulatory approach has positioned Germany as a key entry point for biostimulant registration within the European Union. Over time, it has fostered a de facto mutual recognition network with several other member states, including Spain and Austria. In practice, products registered in Germany can often be marketed in countries like Spain or Austria by simply submitting a compliance declaration and translated labeling materials.

However, behind this seemingly efficient system lies persistent technical barriers. Austria, for instance, frequently requires that product labels also reference specific clauses of its national “Fertilizer Act,” while Spain may demand additional ecotoxicological data for products containing plant-based extracts. These requirements underscore the underlying tension between the EU’s pursuit of regulatory harmonization and the continued exercise of regulatory sovereignty by individual member states.



Stricter market access: France as an example

For that same category of microbial biostimulants, France has implemented a “dual-review mechanism” that closely mirrors pharmaceutical regulatory standards. Companies are required to submit comprehensive technical dossiers to the National Competent Authority, including genomic data of microbial strains, evidence of intergenerational stability, and environmental safety assessments. Only after a rigorous nine-month scientific review conducted by a panel of experts can a product registration number be granted. This stringent approval process significantly raises the market entry threshold, resulting in higher registration costs for similar microbial products compared to countries like Germany. However, it also creates opportunities for premium-positioned products in specialized market segments.

Comparable “access filters” exist in other EU member states. In Italy, regional agronomic trials are mandated as part of the registration process, while Portugal has established an independent biosafety review pathway specifically for marine-derived ingredients. These country-specific requirements illustrate the diverse regulatory approaches adopted by member states at the implementation level, despite operating under a shared EU framework.

Transitional markets: The Netherlands as an example

The Netherlands has announced that it will fully

abolish its national fertilizer regulations in 2025, making it the first EU member state to fully adopt the European Fertilising Products Regulation (FPR) framework. This policy shift is already setting off a chain reaction across the sector. Products previously on the market under Dutch national standards must undergo modular upgrades to align with the FPR during the transition period. Meanwhile, companies eyeing entry into the Benelux economic zone now face a strategic crossroads: whether to invest early in FPR certification to secure long-term market access, or capitalize on the remaining transition window to capture short-term opportunities.

European market entry strategy: the art of precise breakthrough and dynamic adaptation

When entering the European market, the first and most critical step is to clarify your product positioning and define your target market. A well-structured pathway and realistic timeline are essential for success. Unlike large, homogeneous markets, Europe is characterized by its relatively modest overall market size and pronounced segmentation. This fragmented structure means that survival and growth depend not on blanket coverage, but on identifying a precise niche market and tailoring your product and sales strategy accordingly.

To build a viable European market strategy, the following five aspects deserve careful consideration:

Clarify product positioning and purpose

Start by clearly identifying your product category and intended function:

- Is it intended for plant protection or plant nutrition?
- Does it qualify as a biostimulant or a biocontrol product?
- Which crops is it best suited for?

For instance, if your product is designed for bananas, its potential in Europe may be inherently limited due to the non-existent scale of local banana cultivation (however, bananas are cultivated in, e.g. overseas regions of France, the dom-tom regions). This calls for a realistic assessment of the target crop’s distribution across Europe and may require a strategic adjustment of the product’s application scope or categorization.

Refine the target market countries

Europe is far from uniform - regulatory systems, agricultural practices, and market receptiveness vary significantly across member states.

For example, France, Portugal, and Finland differ markedly in crop structure and farm profiles. Instead of attempting a pan-European rollout, a more practical approach is to select one or two priority countries based on internal resources, market fit, and ease of entry. These countries can serve as pilot markets for product validation and regulatory navigation.

Evaluation of regulatory pathways and registration strategies

To access the entire EU market, you’ll need to assess whether your product qualifies under harmonized EU regulations, such as the Fertilising Products Regulation (FPR). While this path offers broader market access, it also involves higher costs, longer timelines, and more data requirements.

If your product does not yet qualify for EU-wide registration, you can explore national registration as an entry point. This strategy allows gradual expansion from one member state.

For instance, if your primary distributor operates in France or Spain, it’s crucial to deeply understand their local regulatory frameworks and assess compliance early. Upon successful registration in one country, you may leverage mutual recognition mechanisms to enter additional markets. If mutual recognition isn’t viable, consider alternatives such as label modification or formula optimization to meet varying national requirements.

Set a reasonable timeline and budget

Resource planning is key. Companies must clarify their internal expectations:



- Evelyne Gusken, Founder and CEO of sciBASICS, delivered a speech at the 6th Biopesticides, Biostimulants and Biofertilizers Summit (BioEx 2025)

- How quickly do you need to achieve market entry?
- What level of capital and manpower are you prepared to commit?

These questions shape the market entry model - whether to focus efforts on a single strategic country or to test multiple markets simultaneously. Either approach requires thoughtful time and budget allocations to ensure sustainability.

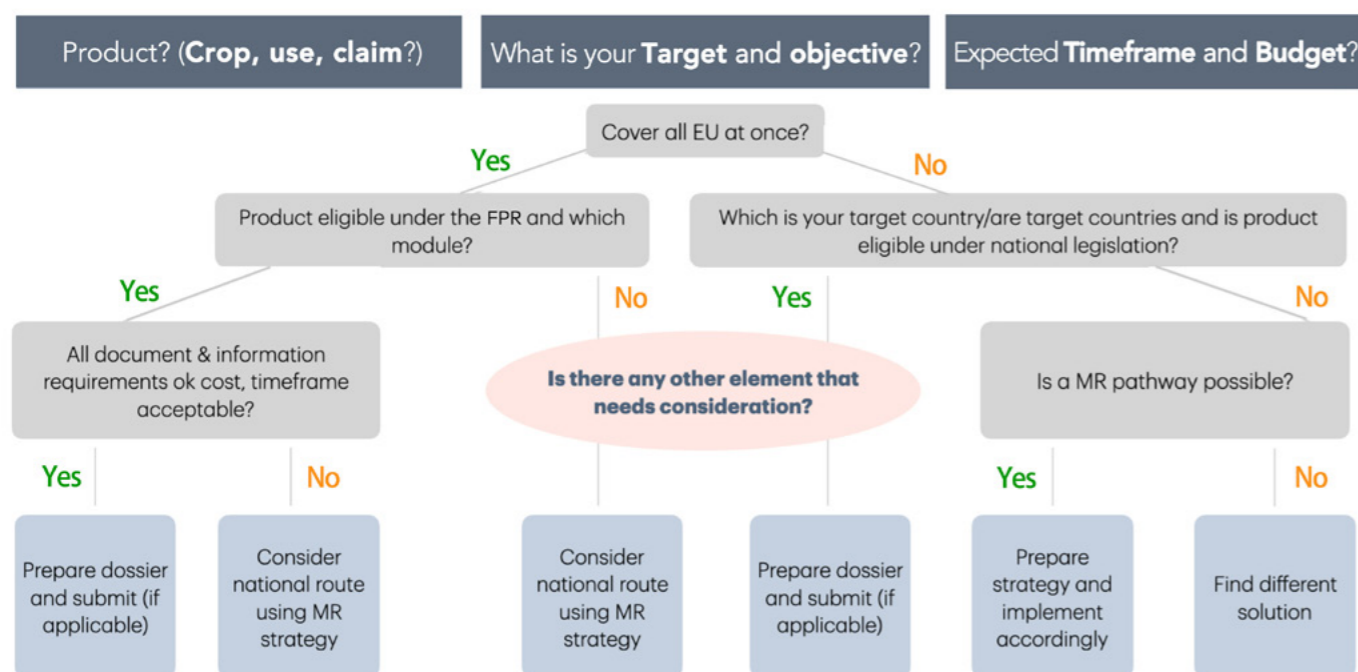
Conduct feasibility studies and path assessment

Before formally launching your strategy, conduct a comprehensive feasibility assessment. Engage with local regulatory consultants, registration experts, and distribution partners to verify the practicality of your proposed entry routes. This step helps prevent wasted resources caused by information asymmetry or overly optimistic assumptions.

Entering the European market is not a one-time event but a systematic endeavor involving resource deployment, regulatory navigation, and strategic execution. The key to long-term growth lies in identifying a market that is “small but strategic”, and advancing step-by-step with a grounded, localized approach.

Have you identified your target markets, refined your product positioning, and aligned your budget expectations? These are essential questions that must be answered before launching your European strategy.

Regulatory strategic considerations



🌱 **Regulatory alchemy in the label game: How sciBASICS solves the EC declaration dilemma**

In a highly regulated and complex market like the EU, even a minor label adjustment can conceal significant uncertainties and compliance risks. A recent success case led by the consulting firm sciBASICS vividly illustrates the timeless truth that “the devil is in the detail” - particularly when navigating the intertwined challenges of functional claims, market access, and regulatory safeguards.

Dual Requirements in a Deadlock

The client in this case is a biostimulant manufacturer seeking to expand into the EU market. Their product has successfully passed the EU Harmonization Regulation (FPR) conformity assessment, received a declaration of conformity, and obtained a legal EC label. At first glance, the process seemed to be on track, but the client’s strategic goal extended beyond mere regulatory compliance - they aimed to add a functional claim to the existing label in order to better showcase the product’s value and gain a competitive edge in the marketplace.

However, complications soon arose. Although the additional claim had been approved at the national level in one member state, it could not be added directly to the existing EC label due to EU regulations. The claim had not been included in the original, unified EU conformity assessment. Moreover, the client was particularly concerned about safeguarding this functional claim to prevent competitors from exploiting it - a common issue

in the agricultural inputs sector, especially when active substances serve multiple functions. The uniqueness and commercial value of such claims can be easily diluted if not adequately protected.

In response to this challenge, the client sought advice from two consulting firms. The first firm recommended revising the EC label or conducting a new GLC efficacy study. This solution, however, came with a substantial price tag of €60,000 - €70,000 and would require at least two years to implement. While this approach would strengthen the claim’s legitimacy and legal protection, it significantly exceeded the client’s budget and timeline expectations.

The second consulting firm suggested leveraging the existing national authorization declaration and extending it to other member states through the mutual recognition procedure. While this approach could potentially cover the entire EU, it would still require additional research in countries like Hungary and Bulgaria. The process was estimated to take anywhere from 6 months to 3 years, with an investment of up to €80,000 or more. Even with this approach, effective protection of the functional claim could not be guaranteed in all EU member states.

The value miracle created by sciBASICS in one month

After careful consideration during the initial consultation, the company turned to sciBASICS for a solution. Instead of providing a “standard answer,” sciBASICS took a more thoughtful and pragmatic approach. They first advised the client to “take a step back” and thoroughly reassess the scope and possibilities of label design and functional claims under EU regulations.

Through an in-depth analysis of current legal texts and regulatory interpretations, sciBASICS discovered that, without altering the product composition or adding new clinical data, the existing labels could be optimized. By adjusting the wording and structure, both the original and new claims could coexist within the compliance framework, avoiding the need for additional scientific studies or new registration procedures. This strategy hinged on a precise understanding of regulatory provisions and expert label design.

The entire project - from needs analysis to implementation - took just one month, resulting in the successful integration of the new claim into the EC label. The product was immediately cleared for sale in all 27 EU countries, with the claim legally protected through careful structural design. All of this was achieved at a cost of only about €2,500.

This case underscores a key insight: in a highly regulated market, success often doesn’t come from high investment or lengthy processes, but from attention to detail and a deep understanding of regulatory interpretation. By leveraging its expertise in EU regulations, sciBASICS enabled the client to achieve the ideal goal of being “fast, stable, and economical” - a perfect example of aligning regulatory compliance with business strategy.

For companies looking to enter the European market, this case offers crucial lessons: never underestimate the power of a single statement on a label, as it could determine your market success; and never overlook the impact of regulatory wording, as it can save years of time and tens of thousands of euros. In the European market, true competitiveness often resides in these “details” that may otherwise go unnoticed.

🌱 **Success is never accidental. Three key principles help you make decisions**

The success of this case was far from coincidental. Its ability to achieve complex regulatory objectives in a short time and at a low cost rested on three core principles:

Start with regulatory foresight.

A comprehensive, upfront understanding of the EU regulatory landscape is essential. By clearly grasping the scope and limitations of the EC label, the boundary of functional claims, and the interplay between national authorizations and EU-wide compliance, companies can allocate resources more strategically - avoiding costly detours and unnecessary duplication. Regulatory awareness is not just the foundation for compliance; it’s the cornerstone of an efficient go-to-market strategy.

Master the details to unlock compliant flexibility.

sciBASICS’ ability to help its client quickly optimize labels and legally consolidate functional claims lies in its

command of regulatory nuance—technical language, legal interpretation, and even layout strategies. In a system that appears rigid, there are always compliant pathways that offer flexibility. The challenge is to identify safe, lawful, and executable solutions within these gray zones - something only possible with deep technical expertise and creative regulatory thinking.

One product, one pathway: avoid the template trap.

Perhaps the most overlooked lesson is that every product - and every route to market—is unique. Even within the same category, differences in formulation, mode of action, or target market can lead to vastly different compliance strategies. There is no universal template. Success requires tailored solutions that account for the specific regulatory, agronomic, and commercial context of each case. Regulations provide the framework, but the route must be custom-designed.

The sciBASICS case reminds us that in a complex ecosystem like the EU, the key to success is not about investing more, but about investing smarter—not just moving fast, but moving in the right direction. I hope today’s discussion offers some useful insights, helping you avoid detours and achieve more with less as you navigate the path to European market entry.



This article was compiled based on Evelyne Gusken's on-site speech at the 6th Biopesticides, Biostimulants and Biofertilizers Summit (BioEx 2025). If you are interested in how biostimulant products can enter the EU market more efficiently and cost-effectively, you can contact Evelyne Gusken, Founder and CEO of sciBASICS, at evelyne@scibasics.com for more details. ^{AP}

Case Study

	1st consultant	2nd consultant	sciBASICS
Target market: all EU Member States	Provide more studies to extent EU label	Proceed with MR from reference authorisation	Make use of labelling possibilities under EU labelling requirements
	Additional efficacy studies (GLP)	Efficacy studies still required in some MS	No additional studies required, making use of what is already there
	2 years	6 months to 3 years to cover all countries	1 month to adapt dossier and artwork label
	€ 60000-70000	€20000 and up to 80000 if additional efficacy studies are required	2500 €
	Claim protected, but timelines and costs !	Claim not protected everywhere, timelines and costs!!	Claim protected, quick, most cost-efficient solution

This is possible when the existing legislative frameworks are mastered and used in a diligent way and to the advantage of companies wishing to place their products on the market.



The 7th Biopesticides, Biostimulants and Biofertilizers Summit (BioEx 2026) is now in the preparation stage.

Inquiries and collaborations are welcome!

Contact: Christina Xie
christina@agropages.com