FROM IDEA TO APPROVED PRODUCT

A Startup's Guide to Regulatory success in the EU

Agrolab CONSULTING

Welcome to reality

This guide is made for startups in the agrochemical and agronomical sector who want to have support on how to move from concept to commercialisation. We will help you bring innovative, compliant products to the market efficiently. We will be your trusted partner on this journey.

You've got the science. You've got the vision. Maybe even a prototype that's showing real promise in the lab or the field. You're not just building a product—you're trying to change the way we grow and nourish a sustainable crop production.

We see you. And we admire what you're doing.

But here's the truth: in the EU, innovation alone doesn't get your product to market. The path from idea to impact is paved with paperwork, protocols, and regulatory requirements. It's not glamorous. It's not fast. And it's not what most founders dream about when they start their journey.

Yet it's absolutely essential.

This e-book is your guide to navigating that reality—not to discourage you, but to enable you. Because when you understand the rules, you can use them to your advantage. When you plan ahead, you save time, money, and credibility. And when you treat the approval process as a strategic asset—not a bottleneck—you unlock real growth.

At Agrolab Consulting, we've walked this road with startups like yours. We know the passion, the pressure, and the pitfalls. And we're here not just as technical experts, but as partners who believe in your mission and want to help you succeed.
Let's get your product out of the lab—and into the world.

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Chapter 1

Beyond product development – what you don't consider in early product development

Turning a promising product into a successful business takes more than scientific ingenuity. It requires a deep understanding of trial design, documentation, and regulatory strategy—elements that are often underestimated in the early stages. These aren't just formalities. They're business-critical assets that determine whether your innovation reaches the market or gets stuck in a cycle of revisions, delays, and missed opportunities. This chapter outlines what founders typically discover too late—and how early regulatory thinking can create a real competitive edge.

You've developed a promising solution. The technical foundation is strong, and you might even be running field trials. But getting from proof-of-concept to market access is about more than showing efficacy.

In the EU, your product's path to market is defined not just by its efficacy or novelty, but by your ability to navigate a complex regulatory environment. If that sounds frustrating, you're not alone. But the sooner you acknowledge it, the more strategic and ultimately successful your journey can become.

The hidden requirements: what catches startups off guard

It's often not the big hurdles that derail a promising project, but the **technical details** that were overlooked early on:

- **Test timing & trial windows:** Some studies, like heavy metal content in Lithuanian fertilisers, must be completed within a set timeframe before registration (e.g. within 6 months). If you miss that window, you risk having to redo work, pay rush fees, or delay submission altogether.
- **Storage stability:** Many startups underestimate the importance of proving how long a product remains stable in storage, especially when it involves living organisms. But without these results, registration can stall, or even fail.
- **Labelling and classification:** Your Safety Data Sheet (SDS), claims, and intended use all need to align with your product's regulatory classification, whether it's governed by the Plant Protection Products (PPP) Regulation (EC 1107/2009), the EU Fertilising Products Regulation (FPR), REACH, or national schemes.

These aren't just checkboxes. They define what you *can legally say* about your product, and what studies are required to say it.

Why trial design is a strategic decision

Too often, startups approach early trials as scientific proof-of-concept exercises, without realising that regulators and investors look for different types of validation.

If your early trial protocol doesn't reflect regulatory expectations (e.g. location, number of repetitions, design standards like GEP), you may end up with data that can't be used in a dossier, and have to start over.

That's not just frustrating, it's expensive.
Designing for both **scientific insight** and **regulatory utility** from day one helps you:

- Reduce cost per data point
- Avoid trial duplication
- Communicate more effectively with authorities and partners
- Demonstrate both efficacy and compliance

Northern Zone basics: what you need to know early

If you're planning to bring a plant protection product to market in the EU, you'll likely fall under **zonal evaluation.** As we are specialists in the **North zone**, we use this area as an example.

This zone includes the countries Denmark, Estonia, Finland, Latvia, Lithuania, Norway and Sweden. While the principle of mutual recognition exists in theory, in practice, national authorities differ in how they interpret and prioritize evaluations.

What that means for your business:

- You'll need a solid strategy for **which country to apply in first**
- Your **data package and trial setup** must align with that country's requirements
- If you're targeting multiple countries, plan for **add-ons, translations, and local deadlines**

Table 1: Northern zone authorities to contact for pesticide approval and evaluation timelines for article 33 and article 40 of the pesticide regulation (EC) 1107/2009.

Country	Authority	Timelines (Northern Zone guidance)	
		New authorization (article 33)	Mutual recognition (article 40)
Denmark	The Danish Environmental Protection Agency (MST)	12 months (+ clock stop*, max 6 months)	120 days (+ clock stop*)
Estonia	Agriculture and Food Board, Plant Protection and Fertilizer Department (PTA)		
Finland	Finnish Safety and Chemicals Agency (TUKES)		
Latvia	State Plant Protection Service, Plant Protection Department (VATZUM)		
Lithuania	Ministry of Agriculture, The State Plant Service (VAAD)		
Norway	Norwegian Food Safety Authority (Mattilsynet)		
Sweden	Swedish Chemical Agency (KEMI)		

** Additional time for the applicant to reply to requests from authorities*

Table 2: Northern zone authorities to contact for fertiliser approval and evaluation timelines.

Country	Authority	Timelines Fertiliser (approx.)
Denmark	The Danish Agricultural Agency	2 months
Estonia	Agriculture and Food Board, Plant Protection and Fertilizer Department (PTA)	2 months
Finland	Finnish Food Authority	2-12 months
Latvia	State Plant Protection Service, Plant Protection Department (VATZUM)	1-6 months
Lithuania	Ministry of Agriculture, The State Plant Service (VAAD)	1-6 months
Norway	Norwegian Food Safety Authority (Mattilsynet)	1 month
Sweden	Swedish Chemical Agency (KEMI)	2 months

Beyond compliance: positioning and timing

Early regulatory planning helps you do more than avoid mistakes. It helps you **position your company strategically**:

- Are you planning to hold the registration or partner with a distributor?
- Will your formulation and dose rate align with existing application methods and equipment on farms?
- Can you time your trial seasons to align with go-to-market plans or funding milestones?
- Does your label support the claims that matter most to the end user?

Your regulatory strategy determines how you fit into the broader value chain. It shapes your pitch to investors, your negotiation with future partners, and even your eventual exit strategy.

Chapter summary: Think regulatory from the start

Universities train you to optimise for accuracy. Investors want to see product-market fit. But regulators? They want to see compliance, clarity, and control.

You don't need to become an expert in EU law, but you do need to:

- Know where your product fits
- Understand the critical documents and timelines
- Design your studies and trials with end-use in mind
- Ask for help early enough to make a difference

This e-book helps startups navigate this terrain, not just to tick boxes, but to build a foundation for faster approvals, lower costs, and better business outcomes.

Product registation pathway

Navigating the regulatory landscape for product approval across multiple EU member states requires a strategic, step-by-step approach. Here's how Agrolab Consulting can streamline the process and ensure your Plant Protection Product reaches the market efficiently.

1. Data Gap Analysis

Identify and Assess Requirements

We evaluate your existing documentation to identify gaps and ensure compliance with North Zone regulations. This includes assessing both necessary studies— such as residue trials, bee studies, and storage stability tests—and your overall adherence to regional standards.

2. Preliminary Risk Assesment

Pinpoint Critical Issues

Our experts conduct a comprehensive risk assessment, identifying bottlenecks and the most critical uses. This step helps in defining the gaps that need to be addressed for successful registration.

3. Endpoint Refinement

Optimise Study Results

If necessary, we refine endpoints (e.g conducting GLP field trials/argumentation), adjust dose rates or add mitigations to achieve the most optimal product label.

4. Conduct GEP and GLP Field Trials

Meet Local Requirements

Conducting field trials in line with GEP and GLP standards is crucial for meeting local regulations. While these trials can be performed by any accredited provider, our GEP and GLP departments are ready to assist, ensuring high-quality results that support your product's registration.

5. Pre-submission meeting

Engage with Authorities Early

Before submission, we arrange a pre-submission meeting with regulatory authorities to discuss potential issues. This proactive step allows us to clarify endpoints, methodologies, and calculations, reducing the risk of rework.

6. Dossier Preparation

Tailor Documentation to North Zone Standards

We meticulously prepare or update all sections of your dossier, ensuring it aligns with the specific requirements of the EU North Zone.

7. Administrative Tasks

Handle Essential Documentation

Our team takes care of all administrative work, including label preparation or translations, cover letters, application forms, completeness checks, and document compilation.

8. Submission to Authorities

Ensure Compliance with Local Protocols

We manage the submission process, compiling and submitting applications through the appropriate channels, such as VATIS for Lithuanian applications.

9. Feedback from Authorities

Manage Follow-Ups Efficiently

Post-submission, we handle all communication with authorities, addressing follow-ups and any additional requirements to keep your application on track.

10. Product Approval

Secure Final Approval

Once your product is approved, we ensure that national labels are fully compliant with the approval letter from the authorities.

11. Post-Approval Services

Expand and Optimize Your Market Presence

After approval, we help you extend and enhance your registration through label extensions (LEX), administrative prolongations, mutual recognitions (Article 40), additional brand names, and more, boosting your market share and competitive edge.

Chapter 2

The expensive mistakes – and how you avoid them

Trial protocols that satisfy an academic need vs. protocols that connect to the regulatory space: Field trials are time-consuming and expensive to conduct, so it is important to plan for early-phase development and proof-of-concept work that also meets regulatory needs. There is a clear advantage to designing trials according to industry and evaluator standards, even in the early phases.
Bringing a product to market in the EU is not just a technical challenge; it is a strategic one. Startups often underestimate the complexity of the regulatory landscape, and the consequences can be costly. This chapter explores the most common blind spots, the price of missteps, and how a clear strategy, supported by expert partners, can save time, money and credibility.

The biggest Blind Spots for startups

Startups entering the EU fertiliser market often fall into predictable traps:

- **Confusing fertiliser and pesticide regulations:** Fertilisers, biocides and pesticides are governed by entirely different frameworks. Fertilisers fall under the FPR, while pesticides are regulated by Regulation (EC) No 1107/2009 and biocides under Regulation (EU) No 528/2012. Each has distinct requirements for data, trials, and approval timelines.

- **Assuming all fertilisers are regulated the same way:** The EU Fertilising Products Regulation (FPR) allows for CE-marked products to circulate freely across member states, but national regulations still apply for non-CE-marked products.

- **Underestimating data requirements:** Many startups overlook the need for validated trial and study data, environmental safety assessments, and conformity documentation.

- **Ignoring deadlines and review cycles:** Regulatory bodies operate on fixed timelines. Missing a submission window can delay market entry by months or even years.

What does it cost to do things in the wrong order?

Mistakes in sequencing, such as starting product development before understanding the regulatory requirements, can lead to:

- **Redundant trials:** Conducting field trials without aligning with regulatory expectations often means repeating them later.

- **Lost time:** Regulatory reviews are slow. A single mistake in your risk assessment, bad trial planning or missing documentation can push your timeline back by 6-12 months

- **Financial waste:** Repeating studies, hiring consultants late, or redoing documentation can easily cost tens of thousands of euros.

> ! A company spent €10,000+ on trials designed purely for evaluation of efficacy. Once they consulted a regulatory expert, they had to repeat those trials with new locations, crops and doserates.

> ! An early-stage startup tested their product on barley using just 2 replicates at one site. That was fine for internal proof of concept. But to qualify as a GEP-compliant trial under EU Northern Zone guidance, they would have needed 4 replicates, 3 sites across 2 seasons, and a standard protocol for yield and crop injury scoring. That oversight delayed their registration by 18 months and cost €35,000 in new trials.

How a lack of strategy leads to rewrites, extra trials, and lost time

Without a regulatory roadmap, startups often:

- **Develop products that don't meet conformity standards:** This leads to rejection or forced reformulation.
- **Miss opportunities for CE marking:** CE marking under the FPR allows for EU-wide distribution, but achieving it requires early planning and engagement with notified bodies.
- **Fail to align with market-specific requirements:** Even with CE marking, some countries have additional rules. A lack of foresight here can block entry into key markets.

Where regulatory consulting creates concrete value

CRO's specialising in regulatory consulting, helps startups avoid these pitfalls by:

- **Mapping the regulatory journey from day one:** Ensuring your product concept aligns with EU and national requirements.
- **Designing, executing or contracting compliant trials:** Saving time and money by getting it right the first time.
- **Managing documentation and deadlines:** Keeping your project on track.
- **Navigating CE marking and national approvals:** Helping you choose the right path for your product and market goals.
- **Completing your dossier:** Performing risk assessments and preparing the product dossier for submission.
- **Supporting in creating and managing labels and label requirements** both before and after registration.

Chapter 3

The plan from day 1 – what the regulatory roadmap looks like

When you want to commercialise your product, we suggest you follow the steps below for a successful product registration.

1 Product concept and classification

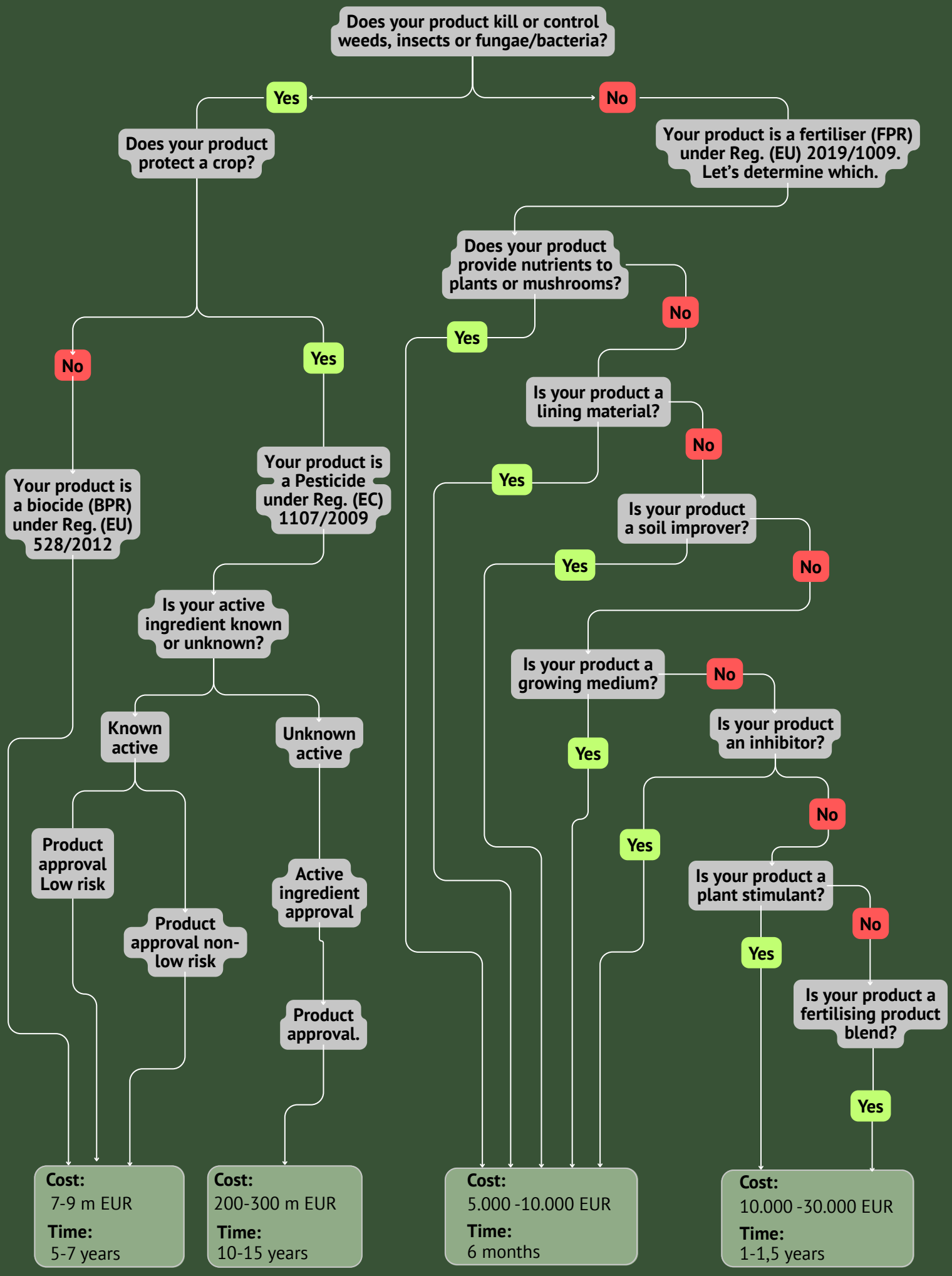
The agronomic function and composition of your product.
You need to know what your product claims are and what mode of action it has. E.g. is it a plant protection product which can control fungal outbreak in cereals or is it a fertiliser that increases the uptake of nutrients through the roots. Depending on the mode of action and the claims of your product, your product falls within different classifications and thereby also need to comply to different regulations. The products in the agrochemical industry are divided into two categories.

a. Plant protection products
b. Fertilizers

There is also a third category, Biocides, which is used to protect structures or humans instead of plants (e.g. hand sanitizer or herbicide on railways). Depending under which category your product falls the regulatory requirements are highly different.

When answering the questions in the flowchart on the following page, it will be clear which category your product falls under.

Flowchart


Does your product kill or control weeds, insects or fungae/bacteria?
Yes
No
Does your product protect a crop?
Your product is a fertiliser (FPR) under Reg. (EU) 2019/1009. Let's determine which.
Does your product provide nutrients to plants or mushrooms?
No
Yes
No
Yes
Is your product a lining material?
No
Yes
Your product is a biocide (BPR) under Reg. (EU) 528/2012
Your product is a Pesticide under Reg. (EC) 1107/2009
Is your product a soil improver?
Yes
No
Is your active ingredient known or unknown?
Is your product a growing medium?
No
Known active
Unknown active
Yes
Is your product an inhibitor?
Product approval Low risk
Yes
No
Active ingredient approval
Product approval non-low risk
Is your product a plant stimulant?
No
Yes
Is your product a fertilising product blend?
Product approval.
Yes
Cost:
7-9 m EUR
Time:
5-7 years
Cost:
200-300 m EUR
Time:
10-15 years
Cost:
5.000 -10.000 EUR
Time:
6 months
Cost:
10.000 -30.000 EUR
Time:
1-1,5 years
COST & TIMELINE

2 Data Generation and conformity assessment

Depending on your product type and claims the data requirements are very different. To show the level of efficacy of your product there are very clear instructions on how to perform the field trials, the number of field trials and location of field trials. There are specific guidelines on how to conduct e.g. biostimulant efficacy trials or Regulatory GEP field trials.
You can follow the link below to find the CEN standards for conducting field trials under the fertilizer regulation: https://agrolab.dk/consulting/cen.
For the EPPO standards on how to conduct field trials for registration purposes of Plant Protection Products, you can follow this link:
https://agrolab.dk/consulting/eppo.
To read more about the requirements of efficacy trials in the North Zone, use this guideline: https://agrolab.dk/consulting/nz-efficacy.

3 Regulatory compliance

Once you have prepared the data package for your product, you need to comply to the administrative requirements e.g. application forms, cover letter, MSDS, labels etc.

Product labels are required to be in local language and compliant to various national requirements. Agrolab Consulting can prepare and translate both fertilizer and PPP labels but also marketing material and other documents for all North Zone countries. We have native speakers in most of the countries and close collaboration with native translators from the Agrochemical industry for the remaining languages.

4 Post Market surveillance

Once your product is on the market in the EU you need to monitor the product performance and compliance. Do customers experience any unforeseen disadvantages or maybe even damage to the crop. Is the product not compatible in a mixture with other products like pesticides or fertilizers or maybe there is an unforeseen advantage when using the product at specific conditions that you have not been aware of. All information from customers is valuable for you as producer/manufacturer and can be used to improve your product or make a new product.

Chapter 4

Approval as a strategic asset

In the fast-paced world of agtech and bio-based innovation, regulatory approval is often seen as a hurdle—something to "get through" on the way to market. But for smart startups, it's much more than that. Regulatory approval is a strategic asset that can unlock funding, partnerships, and acquisition opportunities. In this chapter, we'll explore how a professional approach to compliance builds long-term value.

How a professional approach to approval increases the chances of acquisition or funding

From an investor's point of view, it's not enough to show that your product *might* work. You also need to show:

- That you understand the regulatory classification of your product
- That you've mapped out the necessary studies and documentation
- That you know the time, cost, and risks involved
- That you have a plan to get to market, not just to the next trial.

Products that can't demonstrate a clear route to approval represent **uncontrolled risk**. A startup that is aware of its risks is far more attractive than one still navigating uncertainty.

Why it matters:

- **Due diligence is brutal:** Investors will scrutinise your regulatory status. Missing documentation or unclear classification can kill a deal.
- **Acquirers want plug-and-play assets**: A product that's already approved or close to approval is easier to integrate and scale.
- **Funding depends on milestones:** Regulatory approval is often a key milestone for unlocking the next round of investment.

Why investors and partners value documentation

Documentation isn't just paperwork—it's proof of credibility. It shows that your startup understands the market, respects the rules, and is building something sustainable.

Key documents that add value:

- Regulatory classification and conformity assessments
- Trial protocols and validated results
- Safety and environmental impact data
- CE marking or national approval certificates
- A clear regulatory roadmap with timelines and responsibilities

These documents reduce perceived risk and increase investor confidence.

Thinking ahead - Plan for the future

As a startup you might hyperfocus on the next 6 months. Make sure you think 2–3 years ahead by:

- Mapping regulatory milestones to business goals (e.g., funding rounds, product launches)
- Identifying fast-track opportunities (e.g., mutual recognition, pilot markets)
- Planning for international expansion (e.g., aligning EU approval with other regions)
- Building a data package that scales with future product lines

This forward-thinking approach turns compliance into a growth enabler, not a cost center.

Real-world examples of lost time, funds, or missing approvals

Here are a few anonymised examples of what can go wrong:

- **The "Too Late" Trial:** A startup conducted field trials without consulting regulators. The data didn't meet EU standards, and they had to repeat the entire season—delaying market entry by a year and costing over €20,000.

- **The "Almost There" Acquisition:** A company was in negotiation with a major agri-corp, but the deal fell through when it was revealed that their CE marking was incomplete. The buyer walked away.

- **The "Silent Partner" Problem:** A startup assumed their CRO was handling all documentation. When they applied for approval, they discovered key data was missing. They lost 9 months and had to renegotiate their funding round.

Agrolab Consulting: Your growth partner, not just technical support

We don't just help you tick boxes—we help you build value:

- Strategic guidance from concept to commercialisation

- Investor-ready documentation and regulatory roadmaps

- Preparation of required documentation and field trials

- Risk mitigation through early planning and expert execution

- Positioning support to help you tell a stronger story to partners and funders

We're not just here to help you comply. We're here to help you grow.

Conclusion

Bringing a fertiliser product to market in the EU is no small feat. It takes more than innovation—it takes foresight, strategy, and the right partners.

Here's what we've covered:

- Regulatory missteps are costly, but avoidable with the right guidance.
- Approval is not just a requirement—it's a growth asset that attracts investors and accelerates your business.
- Documentation, data, and deadlines matter, and getting them right early saves time and money.
- You don't have to do it alone—and you shouldn't.

At Agrolab, we specialise in helping startups like yours turn regulatory complexity into competitive advantage. Whether you're still shaping your product or already preparing for approval, we're here to help you think further ahead.

Ready to take the next step?

We invite you to **book a free 1:1 sparring session** with one of our regulatory experts.

In this session, we'll:

- Review your current regulatory status
- Identify potential risks and opportunities
- Outline your next steps toward approval and market entry

You don't need to have it all figured out. In fact, the earlier we talk, the more value we can bring.

Book here

Let's turn your innovation into impact — together.

Checklist

Regulatory Awareness

- [ ] Have you identified whether your product falls under fertiliser or pesticide regulation?
- [ ] Do you know the differences between EU and national regulations?
- [ ] Are you aware of the EU Fertilizing Products Regulation (FPR) and its CE marking process?

Strategic Planning

- [ ] Have you mapped out a regulatory strategy before starting product development?
- [ ] Have you consulted with regulatory experts early in the process?
- [ ] Do you have a timeline that aligns with regulatory review cycles and deadlines?

Data & Trials

- [ ] Have you defined the data requirements for your product category?
- [ ] Are your field trials designed to meet regulatory standards?
- [ ] Have you planned for environmental and safety assessments?

Documentation & Compliance

- [ ] Is your labeling compliant with EU and national rules?
- [ ] Do you have a plan for technical documentation and conformity assessment?
- [ ] Are you prepared for CE marking or national approval pathways

Cost & Risk Management

- [ ] Have you budgeted for regulatory consulting, trials, and documentation?
- [ ] Have you identified potential delays or rework risks?
- [ ] Are you tracking regulatory updates that could affect your product?

Glossary

You might know some of these words; however, we thought we'd gather abbreviations here so we have a common referential point.

BPR

Biocidal product regulation Regulation (EU) 528 / 2012 regulates the placing on the market and use of biocidal products within the European Union.

CMC

Component material categories.
Fertilizers are divived into 11 different CMCs depending on the content of the fertilizer e.g. micro organisms or compost.

CRO

CRO stands for "Contract Research Organization" and is a term for a company, like Agrolab, that supports science industries with outsourced services on a contract basis.

EU North Zone

When registering PPPs we often work in zonal registrations. The EU North Zone consist of Denmark, Sweden, Norway, Finland, Estonia, Latvia and Lithuania. Agrolab covers the entire zone with field stations and collaborators.

FPR

Fertilising Products Regulation.
Regulation (EU) 2019/1009 which lays down the rules for making EU fertilising products available on the market.

PFC

Product function categories.
Fertilizers are divided into 7 product function categories depending on the function of your product e.g. liming material or plant biostimulant.

PPP

PPP stands for "Plant Protection Products". PPPs are herbicides, fungicides, insecticides and Plant Growth Regulators.

REACH

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is a European Union regulation dating from 18 December 2006, amended on 16 December 2008 by Regulation (EC) No 1272/2008

SDS

SDS stands for Safety Data Sheet. It's a document that provides comprehensive information about the hazards of a chemical substance or mixture, including its properties, handling procedures, storage guidelines, and emergency measures.

For more industry specific terms and abbreviations visit our dictionary here:

Visit our dictionary