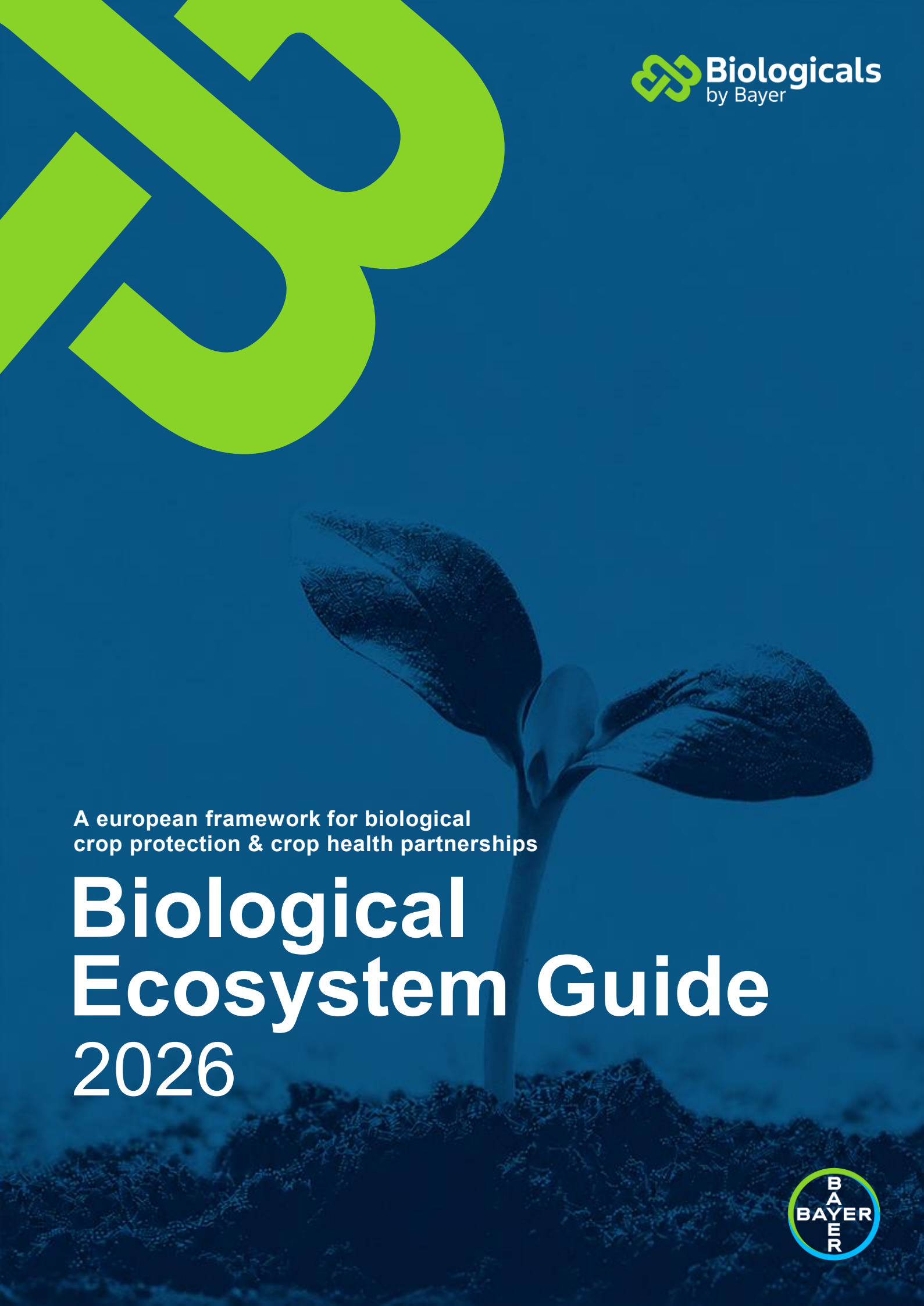
Biologicals by Bayer



A european framework for biological crop protection & crop health partnerships

Biological Ecosystem Guide 2026

BAYER

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Biological ecosystem guide

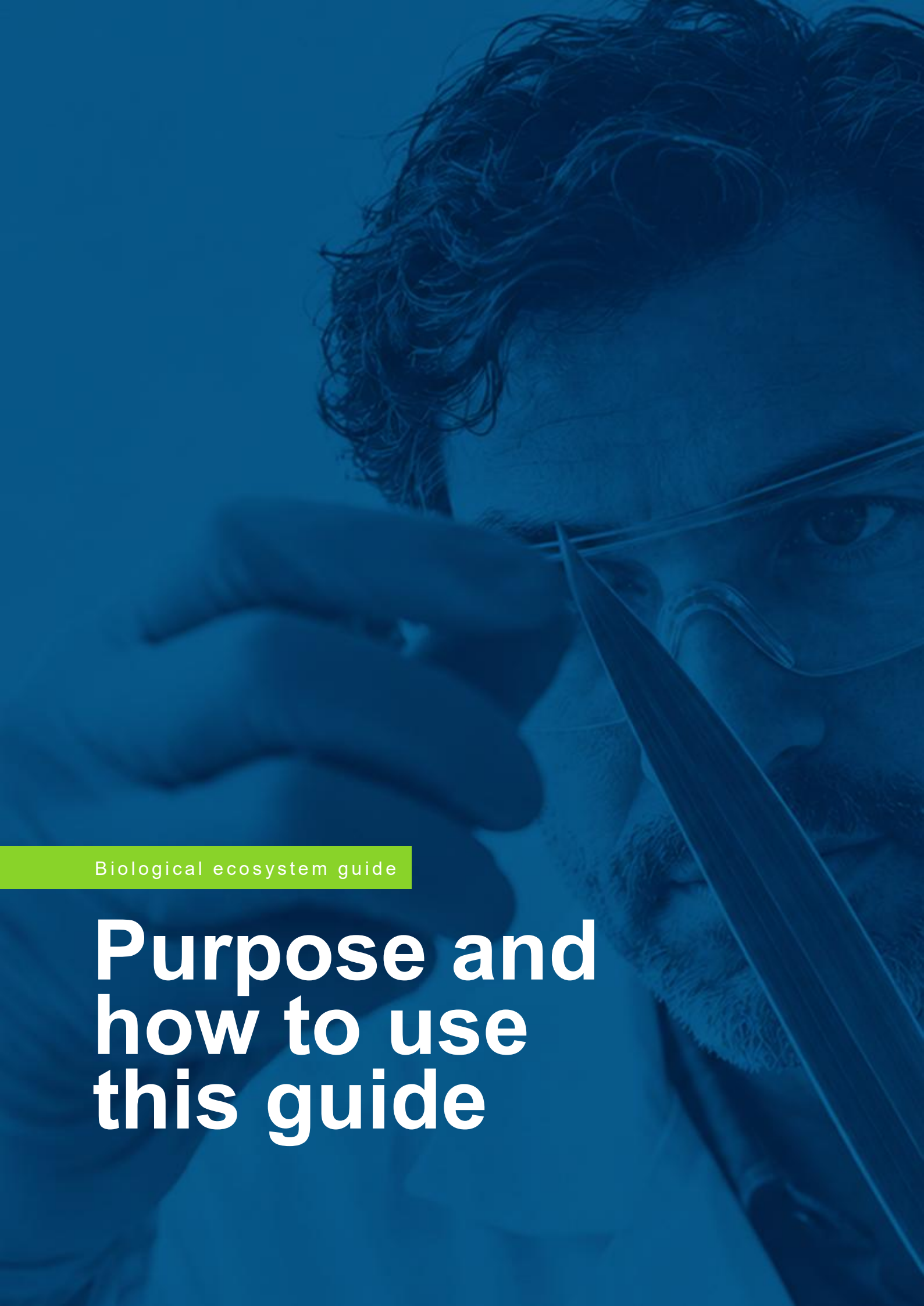
Introduction

Biological ecosystem guide

This Guide provides a practical framework for collaboration and partnership across the agricultural biological ecosystem. It is intended for academics, innovators (start-ups and SMEs) investors and policy makers working to move biological crop protection and crop health solutions from discovery to market.

The Guide is a European complement to the AgPlaybook2.0 (Ag Playbook), which focuses on how to develop Ag biologicals as products, and serves as a roadmap that focuses on the collaboration, evidence generation, investment and partnership considerations that shape whether promising technologies can progress through development to successful registration in the European market.

Turning promising biological innovation into market-ready solutions requires more than science. It requires collaboration, evidence, investment and partnership.



Biological ecosystem guide

Purpose and how to use this guide

Reader value

This Guide helps innovators, startups, investors, ecosystem partners, academics and policy stakeholders understand what evidence, readiness criteria and collaboration models can move promising biological crop protection and crop health solutions from concept toward development, registration and adoption in Europe.

In agriculture, biologicals are increasingly positioned as natural-based complements to conventional (synthetic) crop protection tools, with growing potential under evolving EU rules and market demand.

Adoption and Value Drivers

Recent farmer and retailer surveys point to growing interest in biologicals, while also underscoring that adoption depends on demonstrated value. Growers around the globe are already combining biologicals with chemicals in the form of biological treatments for disease, pest control, or biostimulation. Adoption is expected to rise sharply over the next three to five years as growers need to look for additional tools to support integrated crop management systems.

Key value drivers should include consistent efficacy, compatibility considerations for non-target organisms, relevance to residue-management objectives in food chains, attention to soil health, stronger integrated pest management (IPM) options and resistance management when biologicals are integrated with conventional crop protection programs.

Agricultural Biologicals Are Categorized Into:

- **Biocontrol:** Products that directly manage pathogens, pests, or weeds.
- **Biostimulant:** Products that enhance plant nutrition and tolerance to abiotic stress.

Biocontrol products are regulated in Europe under Regulation EC (European Commission) No 1107/2009, which governs the placing of plant protection products on the market. Biocontrol is not defined in such regulation. In the feed and food simplification omnibus EU commission has proposed the following definition: "micro-organisms, inorganic substances as occurring in nature, with the exception of heavy metals and their salts, or substances of biological origin or produced synthetically that are functionally identical and structurally similar to them such as semiochemicals, biological macromolecules or molecules comprised of components thereof, as well as substances, including of unknown and variable composition, originating from living organisms or derived by biological processes (e.g. extracts from plant products, metabolites produced by micro-organisms).“This broad definition encompasses a wide range of existing, emerging and future technologies.

Biocontrol products encompass a broad range of technologies, including living macro-organisms such as beneficial insects and entomopathogenic fungi or nematodes. Macro-organisms are not addressed further in this document.

- **Micro-organisms (Microbials)**
  This diverse group is mainly composed of bacteria, fungi and viruses. They can be formulated and applied either as living organisms or in inactivated form, often as fermentation-based products.
- **Botanicals, Plant, Algae or Animal Extract**
  This group includes extracts that are either pure, purified or synthetically produced. Pure plant, algae or animal extracts are mixtures of products produced through one of many extraction processes. Some could also be considered as food grade, such as cinnamon oil or garlic extract. Semiochemicals such as pheromones also fall within this group. These substances emitted by plants or animals are used to control pest populations through mating disruption, attraction or baiting. They are produced commonly by chemical synthesis or fermentation processes.
- **Biochemicals**
  Biochemicals as biologicals are a more recent group of technologies that include proteins, peptides, RNAi and antibody technologies. These single entity substances can be versatile from delivering specific and targeted modes of action to broad spectrum modes of action. To date, only a limited number of products in this category have entered the regulatory evaluation process in Europe, though full registration remains pending.

  Note: Certain minerals may also be considered within the Biochemicals category.

Understanding the technology category is only the starting point. To become investable or partner-ready, a biological candidate must also show that its science, evidence package, manufacturability and regulatory pathway can support credible development.

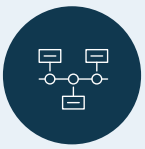
Objectives of the guide

This Guide aims to use an industry perspective to guide innovators, investors and regulators so European farmers can access the most effective biological crop-protection and productivity tools. It focuses on aligning discovery, product development, capital allocation and regulatory pathways to accelerate safe, scalable adoption. For out of EU market, the reference guide is the AgPlaybok 2.0 (Ag Playbook).

Provide strategic guidance and sector insights from a large-scale agricultural company viewpoint to prioritize high-impact biological solutions.

Help discovery efforts target real farm needs and field-scale performance, not just lab potential.

De-risk venture capital decisions by clarifying market potential, adoption barriers and scale pathways so funds flow to the most promising technologies



Streamline regulatory readiness by mapping evidence requirements and recommended dossiers to accelerate approvals while ensuring safety and compliance.

Translate farmer requirements into product and commercialization criteria, ensuring solutions are usable, affordable and agronomically relevant.

Promote scalable, sustainable deployment by highlighting manufacturing, supply chain, distribution and stewardship considerations early in development.

Facilitate cross-stakeholder coordination and sector insights from a large-scale agricultural company viewpoint to reduce friction and accelerate impact of biological solutions.

Measure success with practical benchmarks for discovery-to-farm timelines, investment efficiency and regulatory clearance outcomes.

How to use this guide

As a reminder, this Guide is intended for startups, academic groups, small and midsize enterprises, venture capital investors and industry partners working in the agricultural biologicals ecosystem. Readers can move through the Guide from beginning to end or use the sections most relevant to their role and current decision point:

01

I have a biological product candidate and want to understand whether it is ready for development or partnership.

Start with Section 2, Why Biologicals Matter in Europe; Section 3, From Idea to Partner-Ready Asset; and Section 7, Common Failure Modes.

02

I am preparing for a potential collaboration with an industry partner.

Start with Section 1, Partnerships and Ecosystem Collaboration; Section 3, From Idea to Partner-Ready Asset; and Section 4, Product Evaluation and Evidence Pathway;

03

I am assessing an investment opportunity in agricultural biologicals.

Start with Section 2, Why Biologicals Matter in Europe; Section 5, Regulatory Readiness; Section 6, Commercial Positioning and Farmer Adoption; and Section 7, Common Failure Modes.

Biological ecosystem guide

Partnerships and Ecosystem Collaboration

Biologicals Ecosystem: The Why, Who and How

Building a successful biological ecosystem depends on ensuring connections among academic sectors (open innovation with research centers), startups, subject matter experts, companies, venture capitalists (VCs), public farmer-support organizations, and policy advocates. Each group plays a different role essential to scaling biological crop protection:

- **Academic sector** as a primary source for scouting new potential technologies,
- **Startups and medium sized enterprises** deliver breakthrough biology,
- **VCs fund scale,**
- **public farmer support organizations** drive farmer outreach and adoption, and
- policy advocates define **clear regulatory** and **incentive pathways**.

By maintaining a strong and connected ecosystem, Bayer helps members make coordinated decisions, ensuring the right solutions are at hand to benefit farmers and society through new effective options for crop protection.

Rather than prescribing a single path, this ecosystem emphasizes collaboration, shared information and voluntary approaches that can lower barriers, inform decisions and expand farmer choice.

Key ecosystem elements

Why

to support the emergence and practical use of effective solutions including the best biological and conventional tools intended to improve farm-level outcomes and providing more options for growers.

Who

Academic sector, startups (innovative ideas), VCs (growth capital), public organizations (farmer outreach and extension), policy advocates (guidance and engagement), industry partners (scale, regulatory experience, distribution).

How

- **Interactions:** voluntary data-sharing, collaborative research and field testing, flexible financing arrangements, clear goals and success criteria and cooperative go-to-market efforts.
- **Guiding practices:** shared principles, agreed standards, transparent communication and attention to stewardship that can be adopted gradually.
- **Measuring progress:** potential indicators include farmer interest and -adoption, demonstrated field performance, economic viability, and positive environmental or social signals — used as useful guides rather than strict requirements.

This framing keeps the door open for different models and evolving partnerships while helping participants align around outcomes that benefit farmers and broader society.

Building Strong Partnerships

Partnerships can take many different forms, including collaborations, co-development projects or license agreements. Trust is essential for agricultural biologicals innovation. Trust between industry and innovators reduces friction, enables candid data sharing and aligns incentives around farmer value. Trust is built through repeated behaviors and institutional practices, not a one-time contract.

Key principles

- **Transparency & honesty:** timely, documented updates on timelines, capabilities, and trial results (including negative outcomes).
- **Fair, proportionate intellectual property (IP) & value sharing:** simple term sheets early, detailed agreements later; terms that reward innovation without blocking downstream use.
- **Shared, farmer-centric objectives & governance:** co-created outcome statements revisited at milestones; clear decision rules.
- **Win-win partnership for all parties involved**

Top benefits

- Faster, lower-risk commercialization
- Better, scalable innovations through coordinated capabilities
- Higher farmer adoption and stronger social license
- Greater value opportunities for partners and grower

Main risks & quick mitigations

- **IP lockups / misaligned incentives**
  → proportionate IP clauses, milestone-based options/royalties, mediation.
- **Power asymmetry / decision bottlenecks**
  → explicit governance, escalation paths, protected decision windows.
- **Selective data disclosure**
  → clear data-sharing and confidentiality agreements with tiered openness.
- **Misaligned timelines leading to delays**
  → clear timeline communications and timely responses

Trust is built by repeated transparent actions and simple, fair rules that keep the ecosystem productive and delivers reliable benefits to farmers, companies, and society.

Expectations of Ecosystem Partners

Building effective partnerships in agricultural biologicals requires clarity of purpose, shared incentives and practical structures for collaboration. Shared principles keep partnerships focused on delivering farmer-relevant, scientifically credible, safe and commercially viable biological solutions while managing risk and preserving optionality as science and markets evolve.

In scope:

The ecosystem will focus on collaboration among startups, industry, funders and public organizations to codesign the research and development of biocontrol products for the European farmer. Ecosystem members will enable practical support for innovators by closing knowledge gaps around funding of translational science, harmonizing trial protocols, sharing learnings openly and running joint trainings enabling innovators to make informed choices. These activities will prioritize measurable farmer value, reproducible evidence and responsible stewardship while allowing for flexible, evolving partnerships.

Out of scope:

Closed, anti-competitive exclusivity that blocks collaboration. A professional ecosystem depends on openness and interoperable standards; exclusive practices designed solely to exclude others undermine shared progress.

Biological ecosystem guide

Why Biologicals Matter in Europe

Farmers' Needs and Segment Gaps

According to several sources, the key challenges that European farmers face today are extreme weather conditions linked to climate change, the loss of important crop protection tools resulting from regulatory decision, consumer demands and soil degradation[1].

Extreme weather events, including drought, floods and extreme temperatures, can place crops under significant stress. Some biologicals can help plants respond to these conditions by supporting stress tolerance or improving soil drainage and nutrition with better quality soil structure.

Climate change is also contributing to new and increasing diseases and pest pressures. Biologicals can help fill gaps created by the loss or restriction of conventional crop protection products resulting from regulatory decision by providing solutions that can be used in integrated programs with remaining conventional compounds. Customers demands can also be addressed with biological products used in IPM programs which can be used as approaches that factor in residue outcomes.

The risk of resistance development to remaining single site active ingredients increases. Biologicals have been shown to slow the development of resistance to chemical fungicides when used in IPM programs[2].

Whether biological products improve soil quality, protect against pests or diseases or manage plant stress, these gaps and challenges point to the need for new tools to support food production in Europe.

Having established the farmer and market pressures that create demand for biologicals, the next section clarifies what types of technologies fall within this space and why these distinctions matter for investors, innovators and partners.

			FARMERS NEEDS
BIOCONTROL	Pest Control	Europe	Lepidoptera, Sucking Insects, Coleoptera
		LATAM	Lepidoptera, Sucking Insects
	Disease Control	Europe	Oomycota, Pythium, Septoria
		LATAM	Spot Disease
BIOSTIMULANTS	Nitrogen Optimization	US	Corn
		Europe	Cereals
	Abiotic Stress	US	Uniform Emergence
		LATAM	Crop Perf Enhancer

*January 2026 snapshot

[1]Goffart et. al 2022; Kürklü et. al 2025; Nap et.al 2026; Tita et. al 2025

[2]Bauske et.al 2018; Rotolo et.al 2017; Samaras et. al 2020

Biological ecosystem guide

From Idea to Partner-Ready Asset

Product Requirements

The ultimate objective of an industrial research and development (R&D) program in crop protection is to deliver a safe, effective and reliable product to farmers. Developing a novel biological crop protection agent is a high-risk, long-term financial commitment. Bringing a new active ingredient to market can take up to a decade and cost tens to hundreds of millions of dollars, encompassing R&D, extensive field testing, manufacturing scale-up and regulatory data generation. Before committing to full development, any project or new product must undergo an initial evaluation to de-risk the investment. These principles are technology-agnostic and apply across biocontrol agents, biostimulants, extracts, microbes, peptides and other biological product concepts.

An understanding of where partner companies stand with their projects on the following points will enable a meaningful starting point for discussing partnerships or internal evaluations.

01. **Intellectual Property (IP) and Freedom to Operate (FTO)** – Basic FTO review, Nagoya Protocol compliance and draft IP strategy.

02. **COGs** – Cost of goods aligned with expected performance, manufacturing needs and feasible market pricing.

03. **Mode of Action (MoA)** – Understanding the MoA, excluding any harmful/non-compliant mechanisms

04. **Efficacy** – Robust lab, greenhouse and field data showing meaningful biological effect.

05. **Safety** – No red flags; good human, environmental, and crop safety.

06. **Formulation** – Stable, manufacturable concept, compatible with conventional PPPs

07. **Registrability** – registration path based on data-supported claims, registration status and plans

Intellectual Property and Freedom to Operate

A potential partner should provide available information to support an initial first-pass assessment of legal and commercial feasibility:

- A proposed way to derive **IP protection**, which may include protection of the active, the formulation, or the formulation and production processes.
- Confirmation of ownership and that the asset complies with the **Nagoya** protocol and other access-and-benefit-sharing requirements.

Cost of Goods Sold

When COGs are understood, they should align with realistic market expectations and future positioning, factoring in margin for distribution and the manufacturer (COGs are not equal to the transfer price and the future farm gate price).

Mode of Action (MoA)

An understanding of how the product works strengthens the assessment with respect to regulatory and commercial viability.

General Expectations

- A **description of the Mode of Action (MoA)**, if known, or at minimum a credible hypothesis supported by data and/or literature.
- If known, whether the product acts through e.g., contact, ingestion, systemic or translaminar movement, or indirect mechanisms.
- If information is available, confirmation that the MoA does not rely on antibiotics or other restricted mechanisms.

Efficacy Requirements

To justify internal evaluation, a candidate must demonstrate relevant biological activity in relevant controlled and/or field settings.

- Demonstration of stand-alone activity against relevant targets under **controlled conditions and/or field settings.**
- Replication and statistical rigor to confirm reliability and consistency of performance.
- Comparisons against **appropriate controls and** (if applicable) **relevant commercial benchmarks.**

Safety Requirements

Safety is a non-negotiable prerequisite for internal evaluation and operator safety.

General Expectations

- Absence of safety “red flags” through available literature or partner data.
- No Genetically Modified Organism **(GMO) label** unless explicitly intended and regulatory pathways are established.
- **Initial plant safety (phytotoxicity)** data.

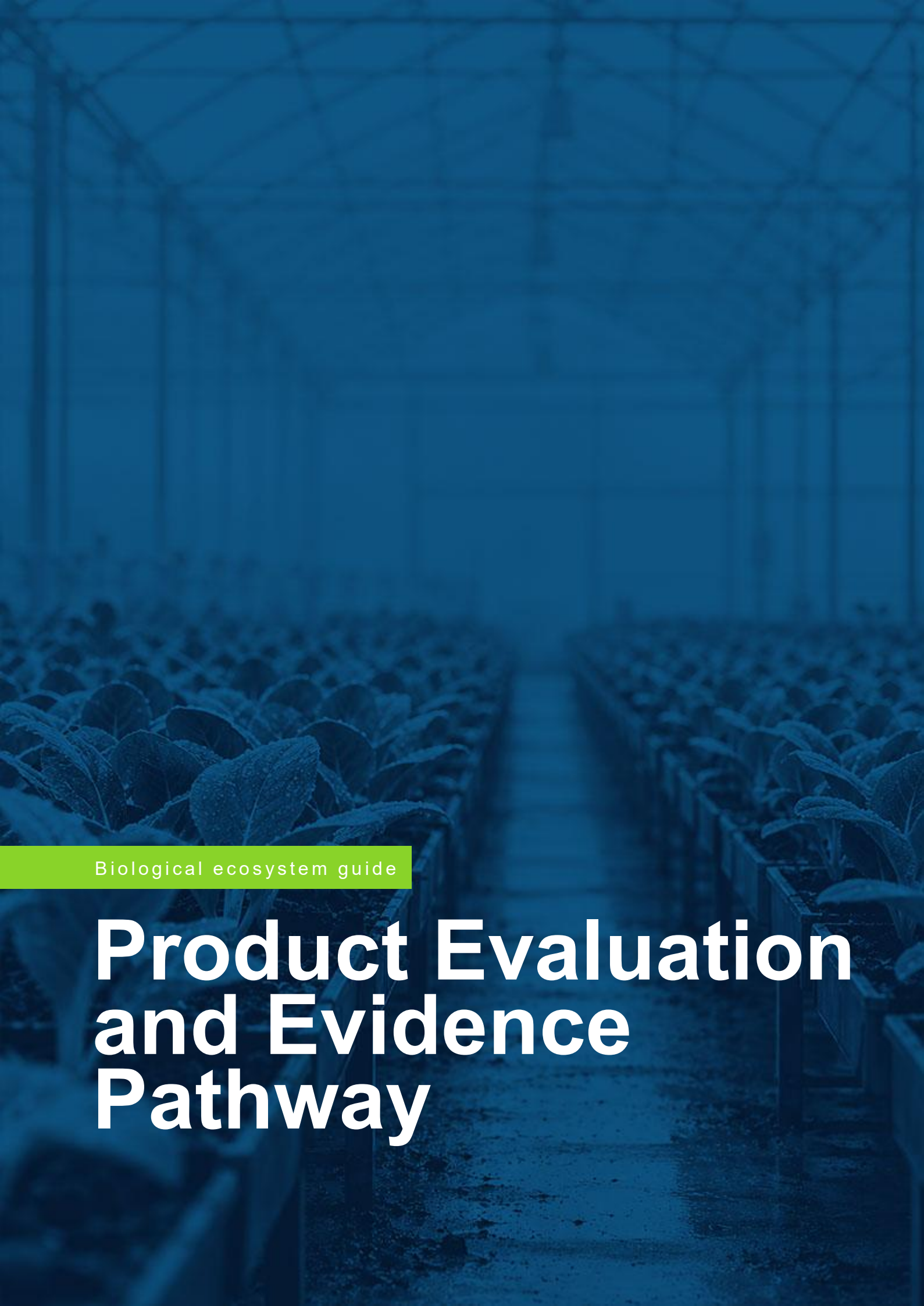
Formulation Requirements

If a candidate is sufficiently characterized, basic manufacturability and testability information will be needed.

Eventually needed

- Evidence of **chemical, physical and biological stability** over time and under typical storage conditions.
- Initial **formulation concept,** including insights into physical behaviour (e.g., solubility, dispersibility).
- Early insight into **production parameters,** even if only high-level (e.g., temperatures, mixing, key constraints).
- Compatibility with key mixing partners, including conventional PPPs, and depending on application methodology.

The criteria above describe what a strong candidate should demonstrate. The following section turns those requirements into a practical risk lens by highlighting the recurring reasons promising biologicals fail to progress.



Biological ecosystem guide

Product Evaluation and Evidence Pathway

This chapter describes two potential paths forward:

01. **data from external partners was presented and is available in such a way that Bayer can take a decision to enter into a collaboration agreement, or**

02. **the results provided are interesting and seem to fit future pipeline needs, however the data did not conform with required standards (e.g., additional controls required, number of replicates and locations insufficient).**

In the latter case Bayer will need to verify the claims on mode of action, targets, and efficacy, as well as confirm handling, formulation, and application instructions are acceptable. This is required to derisk the candidate and prepare for handover for field testing.

Collaboration and data exchange

Early in the process, Bayer aligns closely with external R&D counterparts to support transparent exchange on test systems, product handling experience and general advice. Details on the test systems used to generate initial data (organism strain, life cycle stage, host plant and assay settings) should be provided so results can be confirmed. Prompt sharing of available data will be ensured, including chemical and relevant biological standards, with appropriate statistical analysis to allow joint review and interpretation.

CRO FastTrack program

The CRO FastTrack program is designed to help external innovators generate decision-ready data through qualified contract research organizations. By aligning CRO study designs, controls, data quality expectations and reporting formats with Bayer evaluation needs, the program can shorten the path from external testing to an informed partnering decision. For suitable candidates, this approach may reduce duplication of internal testing, accelerate scale-up discussions and save up to two years in development timelines and evaluation costs. Additional information on participation criteria and study requirements is available upon request.

Testing capabilities

Any relevant scenario can be addressed using Bayer Crop Science's resources. Access is available to 50+ insect species, 30+ plant species (60+ variants) and a collection of more than 15,000 pathogen isolates. Greenhouses, climate and ultra-violet (UV) chambers, a rain tower and multiple application systems are used to select the most suitable setup for the question posed.

Foliar formulation requirements

A basic formulation that is sprayable when diluted in water is required. The formulation must not clog nozzles, cause irreversible phase separation, form flakes or sediment, or react adversely when mixed. A blank formulation (vehicle only) is required for use as a control. Basic dossier information (active concentration, excipients, recommended diluent, handling/storage notes and known incompatibilities) should accompany submissions if available.

Progression to field testing

Progression to Bayer's field program is recommended only after the Bayer team confirm reproducible, biologically meaningful efficacy in lab and greenhouse assays, acceptable handling and stability, appropriate compliance/regulatory permit needs and absence of critical phytotoxicity or safety flags.

Field Data Requirements

Based on greenhouse results, field data against key diseases and pest targets will need to be generated, demonstrating reliable greenhouse to field transferability.

Field trials should be conducted under relevant agronomic conditions of the targeted crop and pest combination, representing key climatic conditions. Untreated controlled plots in the field trials should have sufficient disease and pest pressure during the trials.

Application of the products should be carried out with equipment used by growers in the targeted geography. Clear recommend-dations about stage specific efficacy of the product will help in the analysis of product fit into grower practices that are integrated at a later stage of commercialization.

Eventually, evaluation for crop safety should be conducted with the targeted dose rate and 2x the targeted dose rate at different, critical crop stages to ensure the safety of the product. The trial design should include at least 3 replications with statistical rigor to confirm reliability.

- **Minimum number of 2 to 3 trial sites sites/seasons, disease/pest pressure expectations, 2 commercially relevant standards (one chemical and one biological).**
- **Key metadata to be captured (weather, variety, application method, tank mix details, adjuvants).**
- **Shown efficacy against resistant pathogen or pest when available and applicable.**
- **Data formats from innovators should be compatible so partners can analyze/compare.**
- Optional: Data confirming that the product provides a meaningful contribution within IPM programs.
- Optional: Indications of residual activity, speed of action, and robustness to environmental factors.

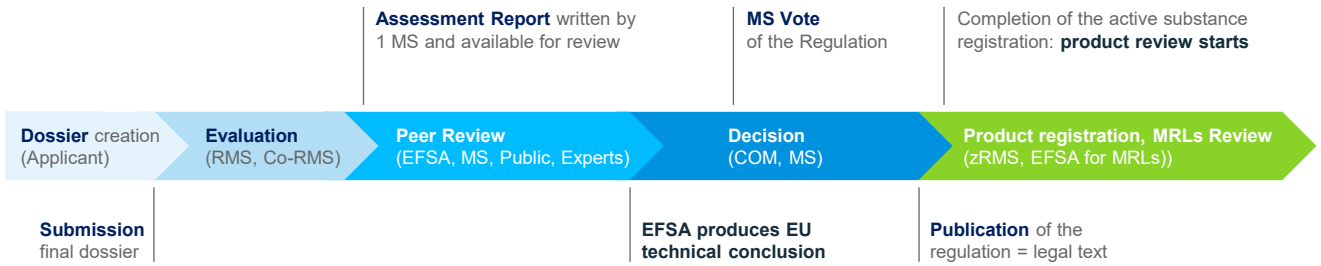
Evidence generation should be planned with regulatory and scale-up considerations in mind. A candidate that performs well in trials still needs a feasible registration strategy, robust manufacturing approach and quality controls that can support commercial use.

Biological ecosystem guide

Regulatory Readiness

General Regulatory Principles for Biocontrol Products

In EU 27, Biocontrol products are regulated under Regulation (EC) No 1107/2009 which governs the placing of plant protection products on the market and was originally designed for conventional crop protection products. The process consists of two main steps: the registration of the active substance at the European level and subsequently the registration of the products at the zonal and member state level with associated Maximum Residue Level (MRL) to be set. After 10 years on the market (or 15 years for low-risk active substance), a renewal process of the active substance will take place, mirroring the process established for new substances.



MS: Member State / RMS: Rapporteur Member State / COM: EU Commission / EFSA: European Food and Safety Agency / zRMS: Zonal Rapporteur Member State / MRL: Maximum Residue Level

Defining a clear regulatory strategy is critical for success. Planning the studies needed to support efficacy and safety evaluation should be anticipated early, and where appropriate, discussed with relevant regulatory bodies. This is especially important for innovative biocontrol products, where unnecessary data packages can add cost and delay, while missing critical studies or data can significantly slow the evaluation process.

For registration of a new active substance, the following items will be worth addressing early in the process:

- **Characterization** of the substance in line with the biocontrol definition
- **Identification** of MoA
- **Literature** review
- **Manufacturing process** description
- **Proposed data waivers** (e.g., such as MRLs)
- **Expected agronomic use patterns** (type of application, indoor / outdoor use, dose rate)
- Foreseen active substance classification **and potential listing as low-risk substance**

Over the last decade, applicants have experienced recurring delays in the EU regulatory process, resulting in unpredictable time to market and affecting return on investment (ROI) calculations. The EU Commission's "Vision for Agriculture" aims to accelerate the introduction of biocontrol products in the EU by amending the current regulation. Currently a feed and food simplification "omnibus" is under discussion as part of the EU legislative process.

Proposed supporting amendments include:

- **Adoption of a broad definition** of biocontrol product supporting innovation
- **Introducing specific schemes*** (such as Provisional Authorization, automatic mutual recognition) to speed access to market in EU for biocontrol products.

*subject to change based on final vote

General Regulatory Principles for Biostimulant Products

A plant Biostimulant is defined as a product stimulating plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:

- **nutrient use** efficiency
- **tolerance** to abiotic stress
- **quality** traits
- **availability of confined nutrients** in soil or rhizosphere

In Europe, Biostimulant can be registered under different schemes.

- **If product is eligible,** the EU Fertilising Products Regulation (FPR) - EC 2019/1009 – should be privileged. Indeed, this scheme offers EU wide registration with EC marked product
- **If the product is not eligible** to EC 2019/1009, then a country-by-country regulatory path would have to be followed, leading to longer time to market.

To be eligible, a product must fulfill certain requirements, including:

- **Product function to be covered** by one of the 7 Product Function Category (PFC)
- **All raw materials to be positively listed** in one of the 15 Component Material Category (CMC)

Biostimulants products cannot claim any biotic stress (pesticidal) control under biostimulant regulation schemes. In case dual actions (Biostimulant and Biocontrol) could be claimed, the product would have first to go through the Regulation EC 1107/2009 for biocontrol products.

Organic Farming

In Europe, organic farming is a relevant complementary market for biocontrol products, driven by food chain demand and policy interest in increasing organic farmland. To be used in organic farming, biocontrol products must be properly listed through the applicable schemes. Once an active substance is approved under Regulation (EC) No 1107/2009, it should be listed in Annex 1 of the Regulation (EU) No 2021/1165. Micro-organisms are eligible by default if they are not of GMO origin. All other technologies must follow the applicable listing procedure.

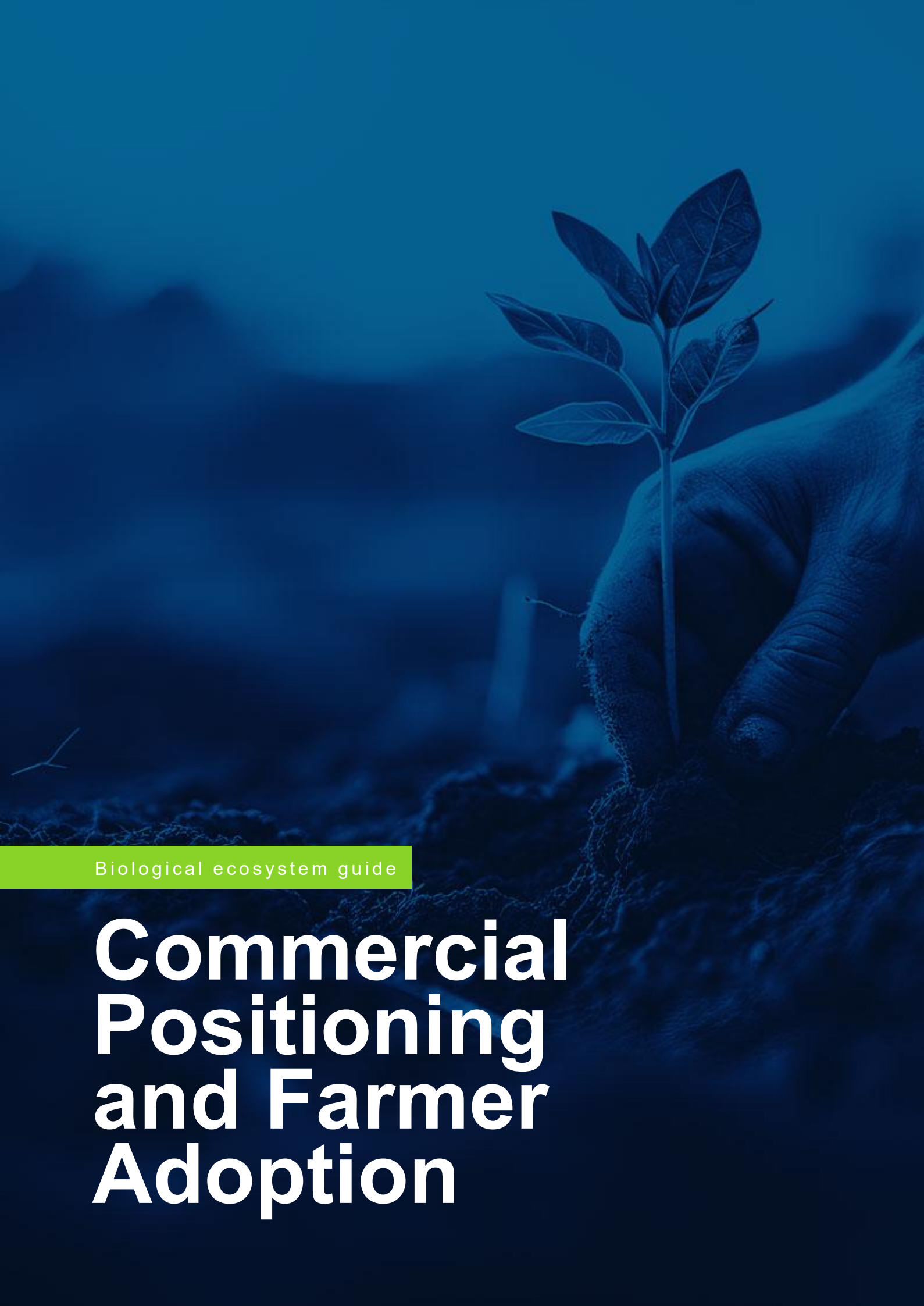
Biocontrol products containing listed active substances should be included in the European Input List of FiBL, the Research Institute for Organic Agriculture. Special attention should be given to the selection of co-formulants that can be included. Finally, where no harmonized process is in place, biocontrol products would have to be certified at country level.

Retailer Secondary Standards

Despite the European regulation enforcing Maximum Residue Levels (MRLs) of Plant Protection Products (PPPs) on food commodities, a large proportion of food retailers have set secondary standards to limit the number of residues on food commodities, independent of safety considerations. To support this market trend, growers must adapt their toolbox to reach those supplementary requirements. Biocontrol products, usually exempt from MRLs, perfectly fit into IPM programs, allowing a level of protection relevant to residue-management considerations to be found in food commodities.

Regulatory approval and scalable production create the permission and capacity to launch, but adoption depends on whether the product fits real crop programs, delivers practical value and can be positioned clearly for growers and advisors.

In Europe, biostimulant and biocontrol success depends on regulatory compliance, market fit, and practical value.



Biological ecosystem guide

Commercial Positioning and Farmer Adoption

Complementing Conventional Products

Biocontrol products can be used in different ways within crop management programs. Because they are positioned as complementary tools to conventional plant protection, understanding their fit within a program including seed, soil or foliar treatments is **crucial for defining a successful value proposition.**

Accurate positioning starts with understanding how farmers manage a crop in specific regions. For each crop and region, a typical program will be defined by Team Bayer. This program represents the most common practices within this given crop and geography. The program should be described with product types, properties, dose rates and timing of application.

Understanding the representative program also means understanding its gaps including secondary diseases or pests not controlled, crop safety (phytotoxicity), limitations in dose rates or number of applications (regulatory), resistance problems, residue management and IPM program requirements. A basic economic evaluation should also be calculated such as cost per hectare (ha) of the current program.

The value of the Biocontrol product should be tangible, and its added value should be perceived practically at farmer level within its conventional program. This value could come from:

- **Resistance management** (preserving the Chemical MoA)
- **Boosting effect** (in tank mix) on difficult pests
- **Complement to a limitation** of use of conventional
- **Application in a window** where conventional products are banned: IPM, pollinators safety, residue management
- **Lack of conventional solution** (registration) on a given problem
- **Late application** for no residue
- **Early application** to decrease the population (e.g., pheromones)

In all cases an economic evaluation should be carried out on the introduction of a biocontrol product in a program with a clear view on the number of applications necessary to provide additional value. This evaluation in cost/ha should be analyzed at marketing level to be sure of the value of the additional cost versus the benefit realized.

Field trials of the Biocontrol product in an IPM program are key to

- **Demonstrate the value** in Yield or Quality of the harvest (return on investment)
- **Explain the (precise) positioning** of the Biocontrol product within the program (threshold of infestation, crop stage or BBCH…)
- **Check and demonstrate** the physio-chemical compatibility in tank with the conventional PPPs
- **Confirm selectivity to the crop** (in local conditions and varieties)

Repeated trials (several years) could be necessary to demonstrate an effect on the level of the population (e.g., pheromones). A focus on the technique and the quality of application may improve the outcome of the trials.

Fostering Adoption

Integrated Solution concept

Grower needs should drive the development of IPM programs to foster the inclusion of biologicals within integrated solutions for healthy and sustainable crops.

Starting from the needs of the customers, solutions must be adapted to the regulatory restrictions and frameworks of each country, particularly in Europe, where growers have lost access to active ingredients that were once widely used to protect crops.

Applications of biostimulants are among the approaches under consideration for climate-related crop resilience challenges. Large agricultural companies take a holistic approach to biologicals, viewing them not as alternatives, but as synergistic components that complement and be integrated into conventional crop protection products, genetics, and, where possible, digital solutions— enabling a more data driven approach.

At the local level, the goal is to design effective, integrated solutions spanning seeds, biologicals, chemical crop protection products and digital tools, in close collaboration with sales and agronomy teams. This cooperation is essential to fully understand growers' needs in each territory.

By combining real agronomic insights with business strategies, we are able to communicate tailored solutions that control pests and diseases and enhance plant health.
The integrated solutions concept inherently requires a tailored solutions approach; therefore, it is crucial to adapt and customize input combinations according to specific local needs, including the integration of biologicals.

Agronomic Commercial Positioning Trials

Ahead commercial launch biological products, including crop protection and biostimulants, should be included in Agronomic Commercial Positioning Trials in each relevant country. These trials allow testing, fine-tuning and adapting integrated solutions to real local conditions and requirements.

Knowledge Transfer across entire Value chain

Ensuring a high level of product knowledge within the agronomy teams is essential. For this reason, close interaction with Bayer agronomists and external partners is crucial to enable effective and efficient knowledge transfer.

To accurately identify and address the needs of the entire agricultural value chain, it is important that tailored solutions extend beyond growers alone. Depending on the crop and geography, key stakeholders such as technicians, consultants, independent agronomists and the food value chain must also be involved.

Key unmet needs in today's agricultural value chain that biologicals can help address include:

- **Reduced availability** and lower efficacy of conventional agrochemicals
- **Increasing pressure** from invasive (alien) species
- **Resistance management** for conventional agrochemicals
- **Climate change impacts,** including drought stress, early bud break exposing crops to frost, and excessive light exposure, for example
- **Demand from the food chain** for low- to zero-residue production
- **Economic sustainability**
- **Shelf-life improvement**

Agronomic Commercial Positioning Trials aim to address these unmet needs and represent the main driver for showcasing the integrated solutions concept directly in the field to growers and other stakeholders. Throughout the season, knowledge transfer is further supported through in-person and online training sessions, category forums and digital communication. This activity is crucial, considering the differences between biological and conventional products, where the right positioning is extremely important to achieve the desired outcome.

For biologicals, knowledge transfer, local agronomical adaptation and farmer proximity represent the three key drivers for successful adoption and for achieving the best results in open-field applications, in line with outcomes observed in R&D and small-plot trials.

Because adoption depends on more than product performance, the final section returns to the broader ecosystem: how innovators, investors, industry partners and public actors can coordinate around evidence, trust and farmer value.

Biological ecosystem guide

Common Failure Modes

A candid page with the

top reasons why biologicals fail:

Inconsistent
field performance / narrow conditions of success

Unclear
identity / characterization

Underpowered
trials, no benchmark, poor statistics, not correctly integrated into a program

Formulation
incompatibility
with real farming practice

Misaligned
claims vs regulatory pathway
…and a mitigation checklist

Once these failure modes are visible, product evaluation can focus on confirming the claims that matter most: **reproducible efficacy, safe handling, realistic field transferability and a credible path toward development.**

Biological ecosystem guide

Conclusion

The Biologicals Ecosystem Playbook

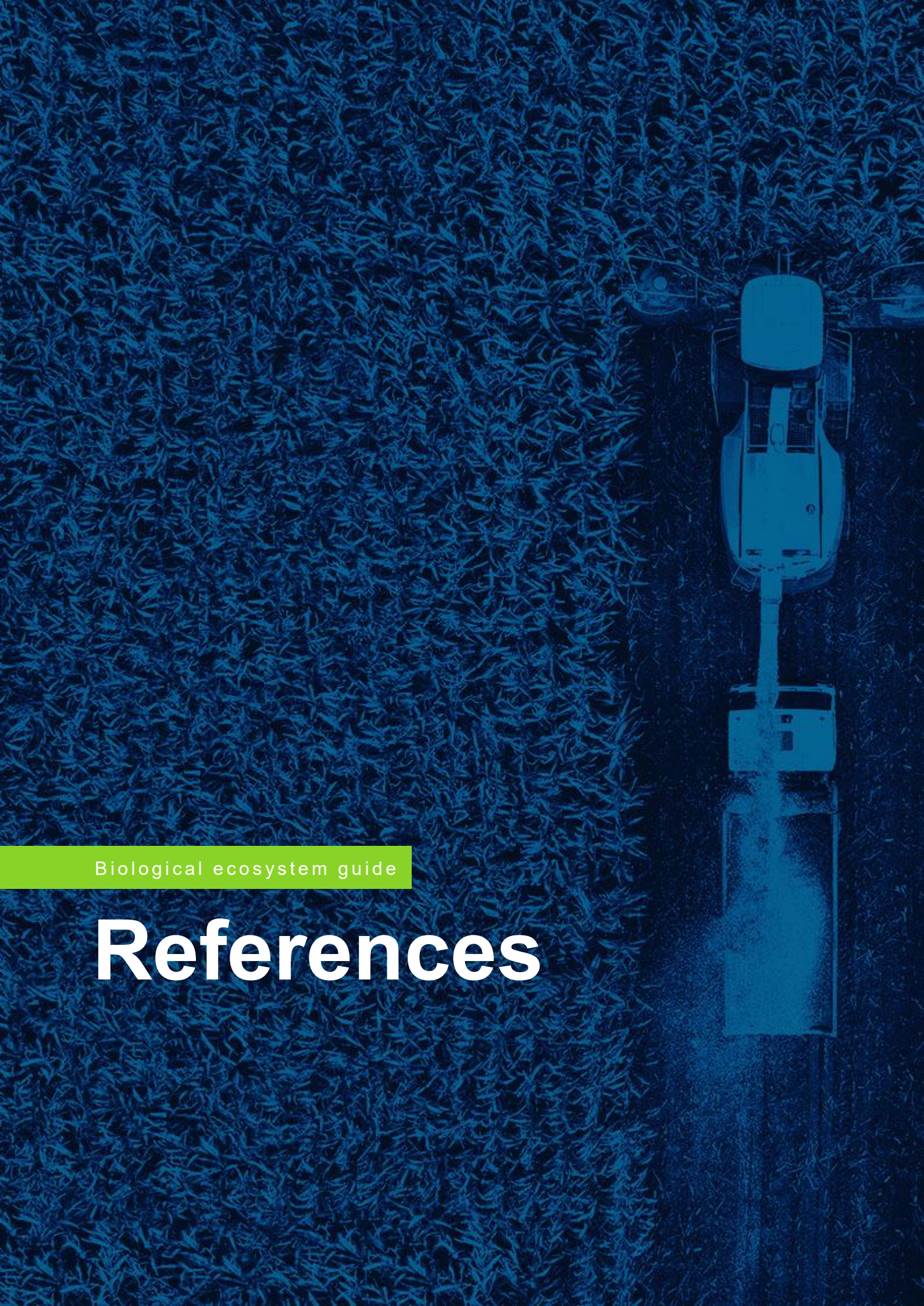
provides a practical framework for fostering collaboration and innovation across the agricultural biologicals sector, emphasizing the importance of building strong partnerships among startups, venture capitalists and public organizations.

By clarifying the critical needs of the farmer, product requirements, partnership expectations, the regulatory landscape and adoption challenges, the Playbook is intended to streamline the development and adoption of biological solutions that enhance crop protection and productivity.

Key principles such as transparency, shared objectives and trust are highlighted as essential for successful collaborations, while the call to action encourages stakeholders to actively engage in the ecosystem to drive sustainable agricultural practices.

As the landscape of agricultural solutions evolves, the Playbook positions biologicals as contributor, alongside other approaches, in addressing the challenges posed by climate change and market demands, ultimately paving the way for a more resilient and environmentally sustainable future in agriculture.

Advancing agriculture through collaboration, resilience, and biological innovation.



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Biological ecosystem guide

Glossary

Glossary

COGs, cost of goods

CRO, contract research organization

EC, European Commission

FiBL, Research Institute for Organic Agriculture (Forschungsinstitut für biologischen Landbau)

FTO, Freedom to operate

GMO, genetically modified organism

ha, hectare

IP, intellectual property

IPM, Integrated Pest Management

MoA, Mode of Action

MRL, Maximum residue level

PPP, plant protection product

QA/QC, quality assurance / quality control)

R&D, research and development

RNAi, Ribonucleic acid interference

ROI, Return on investment

UV, ultra-violet

VC, Venture capitalist

EU Regulation texts mentioned in the document can be found here: EU law - EUR-Lex