

The Synthesis on Microbial Approaches for Low- and Zero-Pesticide Crop Protection

The agricultural sector is facing an increasing need to develop more sustainable production systems that can maintain crop productivity while reducing negative impacts on the environment and human health. Intensive reliance on chemical plant protection products has raised concerns about biodiversity loss, soil and water contamination, impacts on non-target organisms, and the development of pesticide resistance. Consequently, reducing the use of, and the risks associated with, chemical plant protection products has become an important objective of European agricultural and environmental policies. This creates a need for effective biological and preventive approaches that can complement or, where possible, replace conventional chemical inputs. In this context, the biological intensification of crop production (“biologisation”) and the development and wider adoption of microbial-based solutions are becoming increasingly important.

The concept of the plant as a holobiont provides an important biological basis for this approach. Plants do not function as autonomous organisms but as complex biological systems associated with diverse communities of microorganisms. The plant and its associated microbiota form an integrated functional system in which microorganisms can influence plant nutrition, growth, stress tolerance, disease resistance, and interactions with other organisms. The plant microbiome can therefore be considered an integral functional component of plant biology and an important reservoir of biological functions that can be harnessed in sustainable crop production.

Against this background, a video meeting was held on Thursday, 10 September at 16:00 via MS Teams, with experts from Poland, Serbia, Switzerland, and Slovakia, to exchange experiences on the current use and development of microbial approaches in crop production and their potential to reduce or eliminate pesticide use. This report was prepared based on the discussion held during the meeting and complemented by a review of relevant scientific literature and the applicable European Union regulatory framework. The discussion focused on practical experience, regulatory and market barriers, the use of microbial plant protection products and biostimulants, mechanisms of action, plant resistance and preventive approaches, and differences between national systems. The following sections summarize the main issues raised during the discussion and place them in the context of the available scientific literature and European regulatory framework.

Regulatory framework for microbial plant protection products and microbial plant biostimulants

The following regulatory issues were identified during discussions with experts from several European countries and subsequently compared with the applicable European Union legislation. The discussion highlighted that microbial products used in crop production may fall under substantially different regulatory frameworks depending on their intended function. Particular attention was therefore given to the distinction between microbial plant protection products and microbial plant biostimulants; the microorganisms that may be used in these

products; requirements for their identification and safety assessment; and the implications of recent changes in EU legislation.

Microbial plant protection products

At the EU level, there is no separate legal product category formally called "microbial plant protection product". Rather, a microbial plant protection product is a plant protection product that contains a microorganism as the active substance. Plant protection products are regulated primarily under Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. The regulation covers products intended, among other purposes, to protect plants or plant products against harmful organisms, influence plant life processes, preserve plant products, or destroy or prevent the growth of undesired plants or plant parts (<https://eur-lex.europa.eu/eli/reg/2009/1107/oj>).

The regulatory framework for microorganisms was substantially updated in 2022. Commission Regulation (EU) 2022/1438 introduced specific approval criteria for active substances that are microorganisms, while Commission Regulation (EU) 2022/1439 introduced specific data requirements for microorganisms used as active substances. Commission Regulation (EU) 2022/1440 introduced specific data requirements for plant protection products containing microorganisms. These provisions have applied since 21 November 2022 (<https://eur-lex.europa.eu/eli/reg/2022/1438/oj>; <https://eur-lex.europa.eu/eli/reg/2022/1439/oj>; <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R1440>).

The changes were introduced because microorganisms require a different assessment approach from other active substances. The legislation explicitly recognizes the importance of their biological and ecological characteristics, including pathogenicity, infectivity, production of metabolites of concern, and the potential transfer of antimicrobial-resistance genes. The updated framework was also intended to facilitate the approval of microorganisms as active substances and the authorization of plant protection products containing them. This framework has resulted in a relatively broad range of microorganisms being available for use as active substances in plant protection products. According to the European Commission, more than 60 microorganisms are currently approved as active substances for use in plant protection products in the EU (<https://eur-lex.europa.eu/eli/reg/2022/1438/oj>; https://food.ec.europa.eu/plants/pesticides/micro-organisms_en).

Viruses are included within the EU regulatory definition of micro-organisms used as active substances in plant protection products. However, they are biologically distinct from bacteria and fungi and therefore subject to specific considerations within the risk-assessment framework, including criteria regarding their potential low-risk status. Their highly specific host range is particularly relevant for targeted pest control. An example discussed by the experts is the use of baculoviruses against the codling moth (*Cydia pomonella*) in apple production, where the virus targets the pest with high specificity.

The data requirements for microorganisms are therefore considerably more specific than a general assessment of an active substance. These requirements are specified in Part B of the Annex to Regulation (EU) No 283/2013, as amended by Regulation (EU) 2022/1439 for active substances that are microorganisms, and in Part B of the Annex to Regulation (EU) No

284/2013, as amended by Regulation (EU) 2022/1440, for plant protection products containing microorganisms (<https://eur-lex.europa.eu/eli/reg/2022/1439/oj>; <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R1440>).

An important consequence of the updated framework is the emphasis on strain-level identification. For an active substance that is a microorganism, the legislation requires that the microorganism be unequivocally identified to species and named at the strain level, be deposited in an internationally recognized culture collection, and be assigned an accession number. The same principle is explicitly reflected in the requirements for the formulated plant protection product: each microorganism subject to an application must be identified to species and named at strain level, together with other relevant designations where applicable (<https://eur-lex.europa.eu/eli/reg/2022/1438/oj>; <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R1440>). Thus, strain identity forms part of the formal identification requirements for microbial active substances and products. This is particularly relevant when considering the traceability, consistency, and safety assessment of microbial products.

Experts provided examples of microbial plant protection products already authorized for practical use. These include products based on *Pseudomonas*, *Trichoderma*, *Bacillus*, and *Beauveria*, used against soil-borne and foliar pathogens as well as insect pests. Examples for Poland include *Pseudomonas* sp. DSMZ 13134 against *Rhizoctonia solani* in potato, *Trichoderma asperellum* T34 against seedling and root diseases, *Bacillus amyloliquefaciens* D747 against selected diseases, and *Beauveria bassiana* against insect pests. These examples illustrate that microbial plant protection has progressed beyond experimental research to authorized practical applications, although availability remains crop- and target-specific.

Microbial plant protection products can act through several complementary mechanisms. These include competition with pathogens for nutrients and colonization sites; production of antimicrobial compounds; direct antagonism, parasitism, or predation; production of lytic enzymes; siderophore-mediated competition for iron; interference with pathogen signaling and virulence; and induction of plant defense responses. Microbial products may therefore provide both direct effects on target pathogens or pests and indirect effects mediated through the plant and its associated microbiome.

Data availability and market uptake

Eurostat pesticide sales statistics report quantities of active substances placed on the market, expressed in kilograms, rather than quantities of commercial formulated products. Microbial active substances differ from conventional chemical substances because they consist of viable microorganisms, whose concentration and biological activity are commonly expressed using viable counts such as colony-forming units (CFU), rather than solely by mass. Although microbial products themselves are marketed in kilograms or liters, there is currently no harmonized EU methodology for converting measures such as CFU into kilograms of microbial active substance. Consequently, microbiological active substances (F06 and I05) are not included in Eurostat's disseminated pesticide-sales totals, limiting direct EU-level comparison of the sales of microbial and conventional active substances. More detailed information may nevertheless be available through national databases and registers.

Microbial plant biostimulants

Regulation (EU) 2019/1009 establishes the harmonized EU framework for EU fertilizing products. Within this framework, plant biostimulants constitute one of the functional product categories (PFC 6). A plant biostimulant is defined as an EU fertilizing product whose function is to stimulate 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, or availability of confined nutrients in soil or rhizosphere (<https://eur-lex.europa.eu/eli/reg/2019/1009/oj>).

Within PFC 6, the Regulation distinguishes between microbial plant biostimulants (PFC 6(A)) and other plant biostimulants (PFC 6(B)). A microbial plant biostimulant is a plant biostimulant consisting of a microorganism or a consortium of microorganisms, as defined in CMC 7 of Annex II (<https://eur-lex.europa.eu/eli/reg/2019/1009/oj>).

Under the EU-harmonized framework of Regulation (EU) 2019/1009, a microbial plant biostimulant (PFC 6(A)) shall consist of a microorganism or consortium of microorganisms listed in CMC 7. CMC 7 currently covers *Azotobacter* spp., mycorrhizal fungi, *Rhizobium* spp., and *Azospirillum* spp. The product may also contain non-harmful residual elements of the production medium and, under the specified conditions, dead or empty-cell microorganisms.

Other substances such as plant extracts, algae, enzymes, chitin, *Bacillus* spp., or *Trichoderma* spp. are not included in CMC 7 and therefore cannot simply be incorporated into an EU-harmonized PFC 6(A) product under this category.

Thus, the EU-harmonized microbial biostimulant category is considerably narrower than the broad scientific concept of “microbial biostimulant.”

And separately, national products outside the EU-harmonized framework are a different question — that's where we need to examine the legislation of individual Member States rather than extrapolate from Regulation 2019/1009. Also, a fertilizing product blend (PFC 7) can contain two or more EU fertilizing products from PFC 1 to PFC 6. Therefore, a microbial plant biostimulant can be one component of a broader EU fertilizing-product blend, but that is legally distinct from saying that arbitrary additional substances are part of the PFC 6(A) product itself.

The regulation specifies that microorganisms used under CMC 7 must have undergone no processing other than drying or freeze-drying, subject to the detailed requirements of the regulation (<https://eur-lex.europa.eu/eli/reg/2019/1009/oj>).

Microorganisms such as *Bacillus* spp. and *Trichoderma* spp., although widely studied and used in microbial plant protection, are not included in the current CMC 7 list for EU-harmonized PFC 6(A) microbial plant biostimulants. However, this does not necessarily mean that products containing these microorganisms cannot be marketed as biostimulants in an EU Member State.

This distinction illustrates an important regulatory difference. The EU framework for microbial plant protection products provides a mechanism for the scientific assessment and approval of a broad range of microorganisms as active substances, whereas the harmonized category of microbial plant biostimulants under PFC 6(A) currently relies on the much narrower CMC 7 list.

The regulation also establishes specific requirements for the composition and labeling of microbial plant biostimulants. All intentionally added microorganisms must be indicated, and where microorganisms comprise several strains, the intentionally added strains must be indicated. Their concentration must also be declared in an appropriate form, such as colony-forming units per gram or millilitre where appropriate (<https://eur-lex.europa.eu/eli/reg/2019/1009/oj>).

The distinction between microbial and non-microbial plant biostimulants is also important. A non-microbial plant biostimulant (PFC 6(B)) is a plant biostimulant other than a microbial plant biostimulant. Therefore, the presence of a plant-derived substance, extract, or other non-microbial component does not, by itself, make a product a microbial plant biostimulant. The regulatory classification depends on the applicable product category and its composition and function (<https://eur-lex.europa.eu/eli/reg/2019/1009/oj>).

Regulatory implications for low- and zero-pesticide production

A microorganism may have several scientifically demonstrated effects, such as antagonism towards pathogens, stimulation of plant defense, promotion of nutrient uptake, or improvement of plant tolerance to stress. However, the biological mechanism alone does not determine the regulatory category. The intended function, product composition, and applicable legislation determine the regulatory pathway.

The 2022 amendments introduced criteria and data requirements specifically adapted to microorganisms and were intended to facilitate access to biological alternatives to chemical plant protection products while maintaining requirements for human, animal, and environmental safety (https://food.ec.europa.eu/plants/pesticides/micro-organisms_en).

Issues identified through the expert discussion beyond the regulation

The expert discussion also identified several practical and scientific issues relevant to implementing microbial approaches in low- and zero-pesticide systems. For instance, formal registration does not necessarily translate into effective availability on the national market. The Serbian example illustrated a situation in which a product may appear on a national list of registered products but nevertheless be difficult or impossible for farmers or researchers to obtain because it is not being imported or distributed. This suggests that regulatory approval should be considered separately from market availability, distribution, and practical accessibility.

Preventive approaches and enhancement of plant defense

Apart from regulatory issues, the expert discussion emphasized the importance of shifting from approaches based solely on post-disease intervention to preventive strategies that enhance plant resilience and natural defense mechanisms.

One example discussed was the use of chitin and chitin-containing materials derived from crustacean shells. Chitin and its derivatives have been investigated as elicitors of plant defense responses and may activate defense-related signaling pathways and other

mechanisms associated with pathogen resistance. Scientific literature supports the general concept discussed during the meeting that microbial or microbiome-related approaches can contribute to crop protection not only through direct antagonism of pathogens but also through priming or induction of plant defense.

This approach is particularly relevant to low- and zero-pesticide systems because it aims to reduce the probability or severity of disease rather than relying exclusively on curative interventions. Rather than relying exclusively on post-infection interventions, microbial and microbiome-related approaches may help strengthen plant resilience and activate endogenous plant defense mechanisms.

Soil, rhizosphere, and microbiome-based approaches

The experts also discussed approaches based on the soil and rhizosphere microbiome, including the use of materials such as biochar, humic substances, and spent mushroom substrate (SMS). Such approaches may modify the soil environment and support beneficial microbial communities rather than acting exclusively by introducing a single microbial strain. This is relevant to the concept of naturally disease-suppressive soils and to the development of microbiome-informed approaches to crop protection. SMS is a biologically transformed lignocellulosic matrix whose traits include chitin, nutrients, enzymes, and microbial consortia that regulate pathogen suppression and plant immune modulation (Khan et al. 2026).

Such approaches are conceptually different from the direct application of a microbial plant protection product. Their potential contribution lies in modifying the soil environment and microbial community in ways that may support plant growth, nutrient availability, resilience, and natural disease suppression.

This distinction is important for the development of microbiome-based strategies: the objective may not necessarily be to introduce a single "beneficial microorganism", but rather to support or modify microbial communities and their functions within the plant–soil system.

Disease-suppressive soils provide an important example of a microbiome-based approach. Naturally occurring microbial communities can reduce the development or severity of particular soil-borne diseases through mechanisms including competition, antibiosis, parasitism and stimulation of plant defense. This shifts the focus from identifying a single microorganism to understanding and supporting biological processes within the soil and rhizosphere that contribute to disease suppression.

Microbial consortia and functional approaches

Another issue concerned the potential future role of microbial consortia. Combining microorganisms with complementary functions may offer advantages over using individual strains, particularly when plant health depends on multiple interacting processes. This perspective also supports a shift from individual microbial strains towards microbial consortia and microbiome-informed approaches, including the support of naturally occurring beneficial microorganisms and management practices that favor beneficial microbial functions.

From the perspective of low- and zero-pesticide production, this raises an important research question: whether future microbial products should be designed primarily around

individual strains with clearly defined functions, or around consortia and microbiome-informed approaches that provide several complementary functions.

However, the regulatory framework remains an important consideration, as the registration and assessment of a consortium may be more complex than those for an individual microorganism. For instance assessing multiple microorganisms and their interactions may be more complex than assessing a single strain. This is an area where scientific development may outpace the regulatory framework.

Summary

The expert discussion highlighted the broad potential of microbial approaches for low- and zero-pesticide crop protection. Microbial plant protection products can act through diverse mechanisms, including direct antagonism of pathogens and pests, production of antimicrobial compounds, competition, and induction of plant defense. Microorganisms may also contribute to plant nutrition, stress tolerance and the functioning of the plant–soil–microbiome system. Their effectiveness, however, is strongly dependent on environmental conditions, formulation, application strategy and timing.

The discussion also identified regulatory and market access as important barriers to wider adoption. The EU regulatory framework for microbial plant protection products has become more specific following the 2022 amendments, including requirements for the identification of microorganisms and strains, as well as for safety assessment. At the same time, the harmonized EU framework for microbial plant biostimulants is considerably narrower, as it is linked to the microorganisms listed in CMC 7 of Regulation (EU) 2019/1009. National differences in regulatory requirements, product registration and availability may further affect access to microbial solutions.

Experiences from Poland, Serbia, Slovakia, and Switzerland illustrated that regulatory approval does not necessarily guarantee practical availability or widespread use. The experts also emphasized the importance of preventive approaches, including enhancing plant defense and managing the soil and rhizosphere microbiome. Examples such as chitin-based approaches and disease-suppressive soils illustrate the potential to support endogenous biological processes rather than relying exclusively on post-infection interventions.

Overall, the discussion suggests that the transition towards lower pesticide use is unlikely to depend on a simple one-to-one replacement of chemical pesticides with individual microbial products. A broader approach that combines prevention, plant resilience, beneficial microbial communities, targeted microbial products, and potentially microbial consortia and microbiome-informed management may offer greater long-term potential. At the same time, further research, improved formulations, appropriate regulatory pathways, reliable efficacy assessment and better market availability will be needed to translate this potential into wider agricultural practice.