

Biologicals Market Intelligence



Products & Research: 2024

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Biological Crop Protection Products Introduction

Definitions of biopesticide, bio-aligned, and biostimulant products

When analysing biologicals and the biostimulants industry, one of the most fundamental challenges is accurately defining the taxonomy and associated product classes and determining which product types should be considered biological. There are several definitions of a biological product. They may vary by organisation or stakeholder and depend on the market view of such products, their specification, target market, the interests of the parties involved, and regulatory oversight.

AgbioInvestor defines biological crop protection (CP) products as follows:

ABI'S DEFINITION OF BIOPESTICIDE/BIOCONTROL AGENTS (BCA) PRODUCTS

'Products with efficacy in controlling pests for use in growing harvestable produce that are derived from a natural or biological source **without subsequent chemical modification**'.

Throughout this report and in AgbioInvestor's other future biologicals publications, the terms 'biopesticide' and 'biocontrol agent' (BCA) may be used interchangeably but have the same meaning.

Harvestable produce is any annual or perennial crop from which a harvest is taken, including grains, pulses, fruits, vegetables, forage, silage, and industrial crops. Therefore, products for non-crop uses, including turf, ornamentals, animal health, pasture, and vector control, are not considered part of the biological CP market.

The following examples are included in this definition:

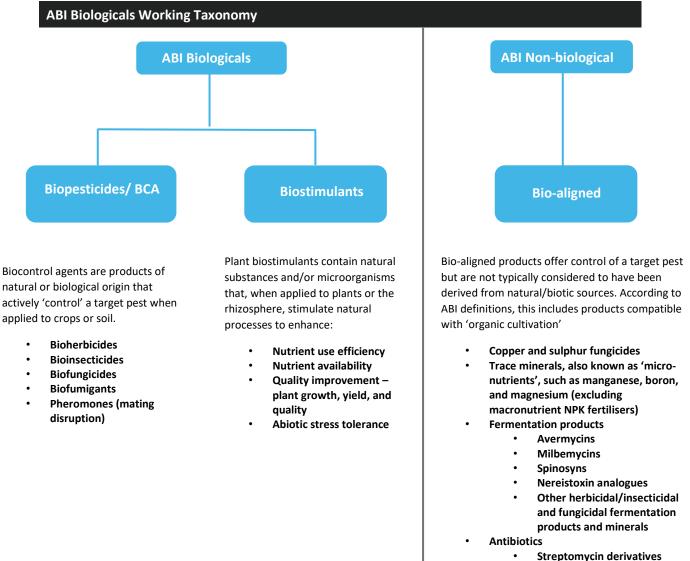
- Plant extracts, such as neem oil, that have been 'harvested' and potentially processed.
- Insect pheromones with sex-disrupting activity (excluding attractants).
- Naturally occurring predators, including aphid predators such as ladybirds.
- Living microorganisms that act as entomopathogens, such as the fungus Beauveria bassiana.

ABI'S DEFINITION OF BIO-ALIGNED PRODUCTS

'Products with efficacy in controlling pests for use in growing harvestable produce derived from a natural or biological source and that have since undergone subsequent modification or are atypical from biological processes'.

The term 'bio-aligned' has been chosen to reflect the subtle distinction necessary to differentiate product classes, such as copper and sulphur fungicides, which have traditionally been used in organic agriculture but have unique regulatory and environmental profiles compared to biopesticide products. Although they have a natural source, fermentation products and bacterial extracts such as avermectins, milbemycins, and spinosyns often undergo subsequent modification and are often positioned as biochemical alternatives to chemical CP. The term 'bio-aligned' also includes additional herbicidal, insecticidal, and fungicidal fermentation products and minerals, like:

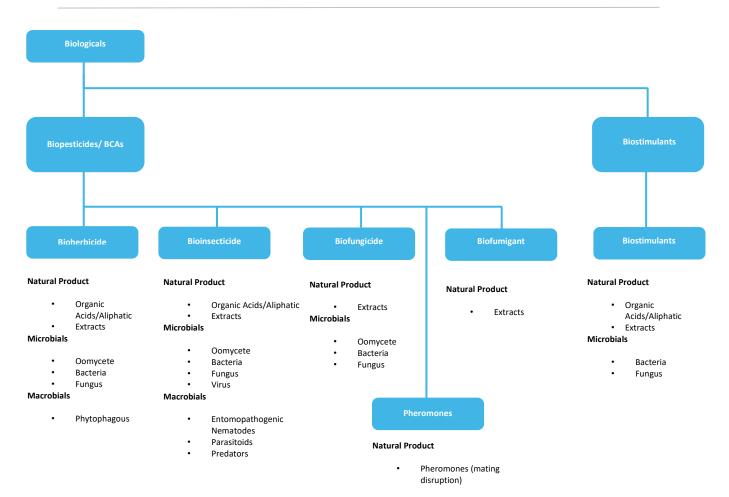
- Copper and sulphur fungicides.
- Fermentation products.
- Mineral products and other basic substances that could potentially be found within living organisms (e.g. potassium bicarbonate).

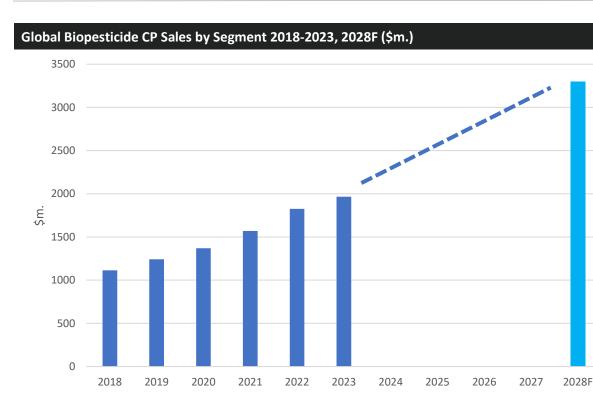


 Abiotic stress treatments derived from clays and minerals (e.g. kaolin clay barriers)

Developing the above broad biopesticide classifications into their constituent 'activity classifications' (bioherbicides, bioinsecticides, biofungicides, pheromones, and biofumigants) shows that the subclassifications describing the biochemical character of the active ingredients (AIs) fall into one of four classifications: natural products, inorganics, microbials, and macrobials. Similarly, when considering the classification of biostimulants, natural products and microbials sufficiently cover the products identified within ABI's comprehensive product database and market research. Notably, in line with the abovementioned definitions, inorganic minerals have been excluded from taxonomy and added to the 'bio-aligned' classification.

Biological Products





The biological CP market is expected to continue its strong growth – likely outpacing the overall CP market – driven by the following:

- **Organic production:** Increased consumer demand for organic produce has driven the need for naturally derived CP products, as organic growers still require pest control to maintain yields and quality.
- **'Green' legislation:** Legislators are increasingly turning to biological CP products to reduce reliance on toxic chemical pesticides and lower environmental chemical loading.
- **Efficacious new technology:** Traditionally, biological CP products have had demonstrably lower efficacy than conventional chemical products, particularly in open and variable environments such as fields. However, growers are increasingly using emerging technologies with comparable efficacy (e.g. new actives or enhanced formulations).
- Increased market reach: The biological CP market has traditionally been characterised by numerous small companies with new lead technologies focused on niche markets in a few core (often domestic) markets. With consolidation and enhanced distribution reach (such as through licensing and distribution agreements with industry majors), the geographic reach (in acreage) of biological products is expected to increase.
- **Novel mode of action:** Compared to conventional chemicals, biological CP products often have new and diverse modes of action that are particularly suitable for resistance management.
- **'Bridge' hybrid products:** Many companies are beginning to combine biologicals with conventional products because biological products bring new modes of action while conventional products are often very effective. These hybrid product concepts are expected to enhance grower trust in biological CP products and potentially act as a 'bridge' from a vast conventional market to a future market with a greater share of biological technology.
- **Regulation:** Stringent regulatory requirements (particularly governing toxicity and environmental safety) are driving approvals of biologicals as older conventional technologies leave the market.

Despite such advances, the biologicals market continues to be held back by a lack of field efficacy for certain products compared to chemical products, high regulatory costs, and inadequate grower understanding of how biologicals differ from conventional products in use and efficacy. However, there are indicators that this is changing with improvements to grower education, product quality assurance, and grower sentiment.

In addition, sales of the leading AI by value (the bacterial insecticide *Bacillus thuringiensis*) are increasingly hindered by resistance concerns and the continued uptake of in-plant *Bt* traits (e.g. in Chinese maize by the mid-2020s). Plant biostimulants containing substances or microorganisms that – when applied to plants or the rhizosphere – stimulate natural processes to enhance nutrient uptake, nutrient efficiency, tolerance to abiotic stress, crop growth, yield, and quality are increasingly perceived as vital to achieving sustainable production targets and tackling challenging production conditions.

The overall development of the biopesticides and biostimulants segments will ultimately be determined by the industry's overall success in adequately positioning the products as integrated pest management strategies rather than single products. This highlights a need for sufficient research and development to understand the products' overall modality, synergies, timing, shelf life, and resistance management considerations.

Sufficient production capacity must also be developed to support the overall industry growth. There is a significant opportunity for biostimulants to supplant some chemical fertiliser usage by improving the overall efficiency of uptake of macronutrients already in the soil zone and lowering the application volumes of chemical NPK fertilisers. This could, in turn, create opportunities for row crops; however, due to the broad-acre nature of such crops, the growth-limiting factors will be raw material availability and production capacity rather than grower uptake or regulation. Due to the biological source of the vital biostimulant classes, such as seaweed extracts, another critical consideration will be the sustainability of cultivating kelp and associated species in the marine environment and maintaining stocks of naturally occurring organisms. This may create challenges involving local regulation by environmental protection agencies, creating a need to obtain permits and licences for cultivation and harvesting.

Biological Product Sectors

Macrobials, microbials, and natural products all exert pathogen-control activity, while semiochemicals and biostimulants do not.

The biological crop protection market can be broadly defined based on pesticidal activity and the source of active ingredients. In this report, the biologicals market is defined according to the definitions below:

Bioherbicides

Products with efficacy against unwanted plants that are derived from natural or biological sources, such as the plant-derived non-selective contact herbicide pelargonic acid.

Bioinsecticides

Products derived from the natural sources listed below that have efficacy against arthropods (e.g. insects and mites), gastropods (e.g. snails), nematodes, and other invertebrate animal pests of crops:

- **Macrobials:** Natural non-microbial predators or parasites, primarily of arthropods; these include wasps, beetles, and mites that prey upon pest species. These often mimic the roles of natural in-field beneficial insects.
- **Microbials:** Microbial pathogens of the pests outlined above, including bacteria, fungi, and viruses.
- **Natural Products:** Products derived from natural sources, such as animal or plant extracts that have activity against the pests listed above; these include fatty acids for aphid control or neem oil, derived from neem seeds.

Biofungicides

Naturally derived products that have efficacy against disease-causing pathogens of crops such as fungi and water moulds:

- **Microbials:** Microbial predators/pathogens/parasites of the pests outlined above; these include bacteria, fungi, and viruses that compete with or infect crop pathogens.
- Natural Products: Naturally derived products from sources such as animal or plant extracts

 that have activity against the pests listed above; these include tea tree oil extracts used for fungal control.

Biologicals: Others

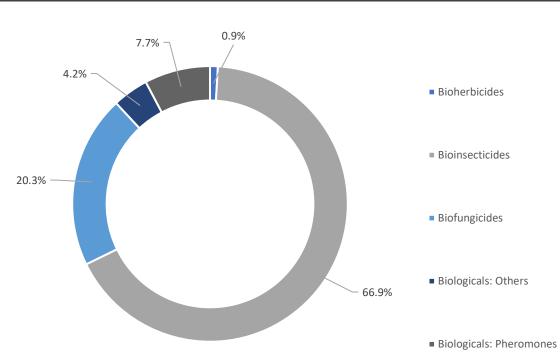
Naturally derived fumigants and plant growth regulators (not including synthetic plant hormones), such as the mustard-derived biofumigant allyl isothiocyanate.

Sales of these various biological crop protection product groupings are outlined below, with the inorganic fungicides copper and sulphur and fermentation products added to provide context for related products.

Biostimulant Market and Forecast							
US\$m.							
Туре	2018	2022	2023	2028F	2023/ 2022 (%)	2023/2018 (% p.a.)	2028F/ 2023 (% p.a.)
Bioherbicides	6	16	18	36	12.5	25.4	14.9
Bioinsecticides: Macrobials	138	210	222	344	5.5	10.0	9.2
Bioinsecticides: Microbials	339	510	564	836	10.6	10.7	8.2
Bionematicides: Microbials	178	292	301	592	3.0	11.1	14.5
Bioinsecticides: Natural Products	157	212	228	381	7.5	7.7	10.8
Bioinsecticides	812	1224	1315	2153	7.4	10.1	10.4
Biofungicides: Microbials	121	268	292	525	9.0	19.2	12.4
Biofungicides: Natural Products	41	97	107	201	10.3	21.3	13.4
Biofungicides	162	365	399	726	9.3	19.8	12.7
Biologicals: Others	53	78	83	131	6.2	9.2	9.6
Biologicals: Pheromones	80	142	152	252	6.9	13.5	10.7
Biological: Others Total	134	220	235	383	6.7	11.9	10.3
Biological Crop Protection	1113	1825	1966	3298	7.7	12.0	10.9
Crop Protection Market	58165	74755	74806	81266	0.1	5.2	1.7
Conventional	54506	69471	70510	75263	1.5	5.3	1.3
Share Bio CP to Crop Protection Market	1.9	2.4	2.6	4.1			

At ex-manufacturer prices, the biological crop protection market was worth an estimated \$1,966 million in 2023, with its leading sector being bioinsecticides, representing 66.9% (\$1,315 million) of the biological crop protection market total, as shown in the chart below. Microbial bioinsecticides are particularly important, due largely to sales of the highest-value biological product, *Bacillus thuringiensis*. Biofungicides are the next most significant product category at 20.3%; these sales mostly consist of microbials such as *B. subtillis, B. amyloliquefaciens*, and *Trichoderma* spp. Bioherbicides constitute a minor share of only 0.9%, with a much larger market in the biological non-crop space, although sales are beginning to increase in bio crop protection as well. Other product categories (biofumigants, and mating-disruption pheromones) represent 11.9% of the total.





Bioherbicides

Sales Performance of Bioherbicides						
Year	Bioherbicide Sales (\$ m.)	Total Herbicide Sales (\$ m.)	Share of Bioherbicides to Total Herbicides (%)	Share of Total Herbicides to Total Crop Protection (%)		
2018	6	23,646	0.52	40.65		
2022	16	31,547	0.88	42.20		
2023	18	31,017	0.92	41.46		
2028F	36	32,390	1.09	39.86		
1-yr Change (%)	12.5	-1.7				
5-yr CAGR (% p.a.)	25.4	5.6				
5-yr CAGR Forecast (% p.a.)	14.9	0.9				

Introduction

Bioherbicides are naturally or biologically derived products used for controlling unwanted plants. Traditionally, the bioherbicide market for crop protection has been very minor, due to the availability of a wide range of low-cost and efficacious chemical herbicides. Furthermore, organic production methodologies have been aimed at broadly reducing the use of chemicals, pushing growers towards alternative non-chemical weed control methods such as strimming, mowing, or ploughing. Whereas mechanical methods can effectively control weeds (albeit at greater labour outputs and costs), these are not options for disease and insect pest control. Consequently, there is a larger base requirement for biofungicides and bioinsecticides.

Bioherbicides: Key Information							
Active Ingredient (AI)	Туре	Source	Spectrum	Timing	Rate (Kg _{Al} /Ha)	Usage	Companies
Alternaria destruens Strain 059	Microbial	Fungus	Selective (Dodder)	Soil Pre-em	2.5	Non-Crop (Ornamentals), Crop (F&V)	Loveland
Colletotrichum gloeosporioides f. sp aeschynomene and fermentation medium	Microbial	Fungus	Selective (Northern Jointvetch)	Post-em, (Aerial, Ground)		Crop (Rice, Soybean)	University of Arkansas
Corn Gluten Meal	Natural Product	Maize extract	Annual & Perennial BLW and GRA	Foliar		Non-Crop (Home & Garden <i>,</i> Turf)	Gardens Alive
<i>Fusarium oxysporum</i> f. sp. strigae strain DSM 33471	Microbial	Fungus	Witchweed (<i>Striga</i> hermonthica)	Seed treatment		Maize	Toothpick Company
Live Chlamydospores of Phytophthora palmivora	Microbial	Oomycete	Selective (Strangler Vine)				Sumitomo Chemical
Pseudomonas fluorescens, strain D7	Microbial	Bacteria	Selective (Grasses)	Foliar		Crop (Cereals), Non- Crop (Rangeland)	Sumitomo Chemical
<i>Puccinia thlaspeos</i> strain Woad (Dyer's Woad Rust)	Microbial	Fungus	Selective (Dyer's Woad)	Foliar		Non-Crop (Rangeland)	Greenville Farms

Note: BLW = Broadleaf Weeds, GRA = Grasses

Products

This section outlines some of the key bioherbicide products, detailing company involvement in their development and their use spectrum.

Natural Products

Corn Gluten Meal

Corn gluten meal is a protein derived from maize kernels and is used in residential situations to prevent the emergence of grasses and broadleaf weeds. The products currently registered in the USA are both from Gardens Alive, including the granular formulation Wow Plus.

Microbials

Alternaria destruens Strain 059

Alternaria destruens Strain 059 is a naturally occurring fungus that parasitises species of Dodder (*Custuca* spp.), which itself is a parasitic plant species targeting a large range of crop plants. *A. destruens* was isolated from swamp dodder in 1986 and found to infect and suppress dodder throughout its life cycle. The product was formerly available in the USA in two formulations from Sylvan Bioproducts: Smolder G was applied to soil in a granular formulation, while Smolder WP was a foliar spray formulation. However, the registration for these products is no longer active.

Colletotrichum gloeosporioides f. sp aeschynomene

The fungus *Colletotrichum gloeosporioides* f. sp. *aeschynomene* ATCC strain 20358 has been used as a biopesticide since the 1980s, when it was developed by the University of Arkansas under the Collego brand. This product is targeted at control of Northern jointvetch in rice and soybeans in the southern United States. Although it was applied to nearly 10,000 hectares of rice in Arkansas prior to 1993, this AI has limited commercial significance.

Live Chlamydospores of Phytophthora palmivora

Live chlamydospores of the oomycete *Phytophthora palmivora* MWV (PC Code 111301) have been registered in the USA for the control of *Morenia orderata* (strangler vine) in citrus trees since 1981. This oomycete infects the roots of milkweed strangler vine plants, beginning to kill the vine 6–10 weeks after application. This product was developed by the Sumitomo Chemical subsidiary Valent Biosciences as Devine Mycoherbicide, with Encore Technologies retaining the license to the product, although its US registration was cancelled in 2020 at the request of the registration holder (Valent).

Pseudomonas fluorescens, strain D7

Pseudomonas flourescens strain D7 is a ubiquitous soil bacterium whose herbicidal activity in grasses was discovered by USDA scientists. The North Carolina, USA-based biopesticide company Verdesian Life Sciences introduced the active ingredient as D7 in the USA in 2015 for managing downy brome in non-crop settings, as well as in alfalfa, cereals, and grass seed. D7 can be applied aerially, as a seed treatment, or in-furrow; it is packaged in a freeze-dried form.

Sites in Washington state have found that natural populations of cheatgrass showed reduced seed production (16–64%), shoot mass (0–54%), and plant density (0–35%) less than a year after

application. However, more recent studies have suggested that achieving results in the field may require several years of application.

Fusarium oxysporum f. sp. strigae strain DSM 33471

Is a bioherbicide based on *Fusarium* for the control of the parasitic weed *Striga spp.*, particularly *Striga hermonthica*. Striga affects some 300 million people and 40 million farms, mostly within Africa. Kichawi Kill Spore Powder (*Fusarium oxysporum f. sp. strigae* strain DSM 33471) developed by Dr. David Sands (a plant pathologist) has been brought to market through partnerships between NGOs and the Toothpick Project to distribute the product across Africa. Current partners include the Liberty Initiators Network, Welthungerhilfe, and FIPS-Africa. The product shows clear host specificity (crops such as sorghum, pearl millet, maize, rice, fonio, cotton, groundnut, cowpea and okra)

The *F. oxysporum* strain was originally isolated from a wilting *striga* plant in Kenya and was virulence enhanced to over produce the amino acids leucine, methionine and tyrosine. Leucine and tyrosine have an herbicidal effect, whilst ethylene produced by soil microbes from methionine triggers the germination of *striga* seeds in the soil. Additionally, the strain has been improved to be resistant to the fungicide captan, which is commonly used to treat maize seed in Kenya. Seed coating tests conducted on 25 striga-infested small holder farms spread out in six counties of western Kenya reported yield increases of up to 88%. A second trial carried out by the Kenyan Agricultural and Livestock Research Organization showed a 93% reduction of emerged striga plants.

The final product is inoculated primary mycelium on small wooden dowels (hence "toothpick"). Secondary inoculum is then self-produced in the villages using this dowel provided by Toothpick Company Ltd. The formulated product has some disadvantages, which are a complicated production process, a very short shelf life, requires refrigeration and high application rate. Additionally, the product has to be applied manually and therefore can only be used in manual production, leaving out the opportunity for farmers of using mechanisation. For this reason, efforts have been made to formulate the active ingredient *Fusarium oxysporum f. sp. Strigae* strain DSM 33471 as a powder and to use it as a seed coating agent.

Representative Pricing of Kichawi Kill Spore Powder					
Package Size	Maize Seed	Acres	Kenyan Shillings	USD*	\$/ha
80g	10 kg Seed	1 Acre	2,000	15.2	37
40g	5 kg Seed	0.5 Acre	1,000	7.6	37
16g	2 kg Seed	0.2 Acres	400	3.0	37

*Rate correct as of May 2024

The above limitations couple with the relatively high cost of application of around \$37/ha may limit the widespread adoption of the technology without significant subsidies and governmental/NGO support. Glyphosate typically has a ~\$10/ha application costs, glufosinate ~\$22/ha and s-metolachlor ~\$15/ha.

Regulatory Situation

Six bioherbicide active ingredients have been registered in the USA, with none of these currently having a registration in the EU. The active ingredients registered in the EU are all of 'bio-aligned' character, that is to say organic acids, basic substances and minerals. The regulatory situation for bioherbicides based on microbials and plant extracts is generally favourable since they offer an alternative to chemical herbicides.

In Europe, although the process for biopesticide registration is broadly like that of conventional crop protection, there are simplified requirements for microbials which are assessed for compliance with low-risk criteria. The assessment of these ingredients takes 120 days, and the approval is valid for 15 years instead of 10 years. Product authorisation can be granted at a lower fee. In the USA, the EPA classifies biopesticides as 'reduced-risk pesticides' and as such they qualify for fast-track registration.

Class in 059 Fungus
in 059 Fungus
eum strain HQ1 Fungus
eum strain PFC 2139 Fungus
rioides f. sp. Aeschynomene Fungus
Phytophthora palmivora MWV Microbial
l strain' on rust-infected pieces Fungus
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Information correct as of May 2025

Company Involvement

Traditionally, company involvement in bioherbicides has been relatively limited in the crop protection space, with many of the key active ingredients having been developed by universities or by innovative small companies with limited market reach. Bioherbicides have only relatively recently gained wider acceptance and marketing by larger companies in the industry. This has perhaps stemmed from the relatively limited market opportunity offered by bioherbicides to date in the crop protection space. By contrast, involvement has been greater in non-crop uses (for example, Bayer with pelargonic acid/glyphosate mixtures).

Profarm (formerly MBI)

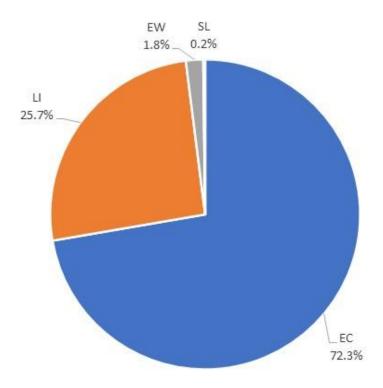
Profarm has developed several bioherbicides based on plant extracts and microbes, and is actively researching new bioherbicidal AIs. This company references an existing business based on thaxtomin and sarmentine, although the company noted in its financials that the vast majority of its sales in the crop protection space are from biofungicides, bioinsecticides, and bionematicides, while sales of its bioherbicide portfolio are relatively minor. A number of bioherbicide products have been mentioned to be in R&D for a number of years but have yet to achieve a notable penetration into the market.

The table below outlines key active ingredients along with the companies offering those products.

Bioherbicide Active Ingredients and Key Companies Involved				
Al	Key Companies			
Alternaria destruens Strain 059	Sylvan BioProducts			
<i>Colletotrichum gloeosporioides</i> f. sp aeschynomene and fermentation medium	University of Arkansas			
Corn Gluten Meal	Gardens Alive			
Live Chlamydospores of <i>Phytophthora palmivora</i> <i>Puccinia thlaspeos</i> strain woad (dyer's woad rust)	Sumitomo Chemical Greenville Farms			
Sermentine	Profarm (formerly MBI)			
Thaxtomin	Profarm (formerly MBI)			

Formulation Types – Value Share

The below chart(s) are derived from the biological focussed market research that AgbioInvestor conducted, and illustrates the value share attributed to various formulation type codes.



Code	Description	Code	Description
AE	Aerosol dispenser	LI	Liquid
AL	Other liquids to be applied undiluted	LS	Solution for seed treatment
СВ	Bait concentrate	ME	Micro emulsion
CS	Capsule suspension	OD	Oil dispersion
DC	Dispersible concentrate	SC	Suspension concentrate
DF	Dry flowable	SL	Soluble concentrate
DP	Dustable powder	SP	Water soluble powder
EC	Emulsifiable concentrate	VP	Vapour releasing product
EW	Emulsion, water in oil	WG	Water dispersible granule
FS	Flowable concentrate for seed treatment	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment
10			

LC Liquid concentrate

Research and Development

A number of companies are actively researching bioherbicide candidates, with the most important characteristics being to target a broad spectrum of activity, favourable cost of production, field stability, compatibility with spray programs and of course efficacy. The lack of any major bioherbicides beyond niche applications and the increased need for low-toxicity, high-efficacy products has driven R&D into bioherbicidal active ingredients.

Some example companies active in bioherbicide R&D include: Profarm (formerly MBI), Mustgrow, and Plant Advanced Technologies.

Profarm (formerly MBI)

In 2021, the company noted that it had screened more than 12,000 microbes. From this, it was noted that the company had discovered approximately 500 bioherbicidal microbes that they could further develop through its genomics, bioinformatics and synthetic biology systems. From this R&D program, Marrone Bio noted that it had three bioherbicide candidates in its R&D portfolio. The first two leads MBI-005 and MBI-011, had received regulatory approval from the U.S. EPA, and were having formulation technology refined. The third lead known as MBI-014/015 was noted to have been progressed to advanced stages of development. The company also noted that results indicate that MBI-014/015 has herbicidal properties estimated to be 50-to-100 times more active than leading chemical alternatives.

Thaxtomin (MBI-005) is a compound produced by *Streptomyces sp.* that was developed by MBI under the Opportune brand. Its phytotoxic characteristics have been known in academia since at least 1998. The end-use product is based on heat-killed, non-viable bacteria of the *Streptomyces acidiscabies* strain RL-110T—which was initially isolated from scab-infected potatoes in Maine and New York—as well as spent fermentation media. Thaxtomin exerts its activity by disrupting cellulose biosynthesis (similar to isoxaben and dichlobenil); it displays selective control of broadleaf weeds and sedges in post-emergence application, with safety on turf, wheat, corn, and rice, as well as broad-spectrum activity in pre-emergence applications. MBI received a US patent for the product in 2013, covering pre-and post-emergent use for broad-spectrum weed control in cereals, pasture, and turf and has since marketed the product in the USA.

Sarmentine (MBI-011) is a single pyrrolidine compound isolated from a Chinese pepper (*Piper longum*), although it can be made synthetically. While sarmentine is used in Chinese medicine and in cosmetics, the company MBI discovered its herbicidal potential and received a US patent in 2013 for its use as a bioherbicide. This product shows burndown activity with similar effects to pelargonic acid, although subsequent characterisation in 2015 found that this AI has activity through a complex process and is associated with multiple mechanisms of action. MBI has noted, however, that formulation is a key consideration for sarmentine's efficacy, with MBI eventually gaining a registration in 2014 for the product as a 50% EC formulation applied at a rate of around 24 L/Ha. This product has been available for the control of annual and perennial grass and broadleaf weeds in many crop situations, as well as home and garden, turf, and ornamental settings.

In 2018, MBI submitted its MBI-014 bioherbicide to the US EPA for approval. MBI-014 is a waterdispersible microbial herbicide derived from the bacterium *Burkholderia rinojensis* (strain A396) that utilises a novel mode of action in the post-emergent control of a range of weeds such as palmer amaranth, waterhemp, and others in the pigweed family (*Amaranthacae*). MBI-014 is reportedly suitable for use in conjunction with other herbicides for organic production. The company noted positive 2019 field trials for the same active ingredient in MBI-015, a liquid formulation targeted at conventional crops. These field trials utilised commercial rates of the product and demonstrated control of *Palmer amaranth* (a primary pest in Midwestern field crops in the USA) that was nearly as effective as post-emergent conventional chemical products. The company was also issued a US patent covering claims related to pre- and post-emergent herbicidal activity for the bioherbicide.

In December 2021 MBI acquired the exclusive rights to strains of *Streptomyces acidiscabies* from Novozymes. This is expected to accelerate the commercialisation of the second-generation of MBI's MBI-006 bioherbicide. The strains were developed and licensed from Novozymes and will optimise MBI-006's use rate, reduce production costs and enhance performance. MBI-006 reportedly offers higher efficacy at lower use rates in comparison to MBI-005 and has an uncommon mode of action inhibiting the formation and repair of plant cell walls, reducing the likelihood of resistance developing. The herbicide is targeted at pre- and post-emergent use on broadleaf weeds, grasses and sedges, and can be mixed with most chemical products and fertilisers. The first generation MBI-006 is expected to launch in 2024/25 for organic and specialty crops, turf, ornamentals and the home and garden market. The second generation of MBI-006 will be targeted at row crops and is expected to be commercially available in 2027/28.

MustGrow

MustGrow Biologics is a Canadian biopesticide company focussed on developing biopesticide solutions using extracts from mustard seed, leveraging mustard's natural defence mechanisms against pests. In 2021, MustGrow isolated and concentrated thiocyanate, a mustard extract that has been found to be soil-active; it is translocated in plants as a systemic, non-selective bioherbicide. The related allyl-thiocyanate has been developed by Isagro as the biofumigant Dominus in the USA; however, it has not yet been marketed specifically for its bioherbicidal properties.

While the non-selective nature of this product is important, perhaps of greater interest are its selective properties, distinguishing it from competitors in the bio-aligned herbicide space such as pelargonic acid, which has contact activity. The only truly non-selective *and* systemic conventional chemical herbicides of significant commercial value on the market today are glyphosate, glufosinate, paraquat, and diquat, all of which have had regulatory issues in some regions. Thus, thiocyanate would likely have significant market potential if it could act as a non-toxic alternative. Furthermore, the soil-active nature of thiocyanate stands out from glyphosate, the leading herbicide active ingredient in the crop protection market by value.

In proof-of-concept studies, thiocyanate killed 100% of small weeds and weed seeds in pre-plant application, with activity across the whole plant. MustGrow has also identified its mode of action and—although further greenhouse tests continue—has filed for method-of-use and composition-of-matter claims related to this product.

Greenhouse weed treatment studies have also commenced with this new bioherbicide extract.

Plant Advanced Technologies

Plant Advanced Technologies is a French company focussed on the identification, optimisation, and production of active plant compounds for use in a variety of industries. In 2019, in association with the public bodies INRA and ITEPMAI, this company launched a new bioherbicide discovery programme called HerbiScan.

The HerbiScan programme utilised PAT's Target Binding technology, in which a mixture of substances are added to the target protein of interest (e.g. a protein site for an herbicidal mode of action). The non-bound compounds are then removed, with the bound ligands then desorbed from the target protein and identified. Ligands are reportedly identified within two hours and are characterised

directly using mass spectrometry, which allows for a large number of tests over a short period of time and facilitates the usage of the often-complex mixtures of compounds characteristic of plant extracts.

The HerbiScan programme aims to discover new molecules with herbicidal activity from extracts of plant origin; characterise the herbicidal activity of these molecules (efficacy and selectivity) on greenhouse-grown weeds; determine the toxicological profiles of these new molecules in order to retain only those with a favourable profile; and finally validate the herbicidal effects in field trials on field crops.

PAT announced in 2021, through a collaboration with Kyoto University and the University of Lorraine, the discovery a new class of plant enzymes—aromatic O-prenyltransferases— that are involved in a plant defence mechanism. These reportedly have potential across all of the company's target markets, including crop protection.

Topical RNAi Technology

A number of companies with biotech seeds businesses such as Syngenta and Bayer have utilised RNAinterference (RNAi) in stacked trait systems such as SmartStax Pro and VT4PRO corn from Bayer and Vorceed Enlist corn from Pioneer. These traits express RNAi molecules that control insect pest. However topical RNAi application has also been researched as a means of silencing genes responsible for the production of weed resistance proteins in the field. Following this treatment, the conventional herbicide may be applied again to allow weed control, thereby reactivating the herbicide efficacy. The main downside of topical RNAi is that unlike in-plant RNAi where the plant biosynthesises (expresses) the RNAi molecules, topical RNAi must be synthesised which is typically higher cost than other resistance management strategies.

On Apr 30, 2025 GreenLight Biosciences announced successful greenhouse and field trials of its RNAbased bioherbicide, reportedly demonstrating effective control of horseweed (*Conyza canadensis*), a major weed in no-till soy farming. The lead candidate has been selected from more than 180 prospects using proprietary AI-enabled tools, and the company plans to begin work on submission dossiers for regulatory review ahead of a planned global launch.

Moa Technology

In 2024 Moa Technology, a UK-based agricultural biotech company, formed a 10-year strategic partnership with the global life sciences and consumer care company Croda International. The partnership aims to develop next-generation bioherbicides for land-based farms, leveraging Croda's library of natural compounds based on the marine microbiome and the company's manufacturing capabilities, with Moa's herbicide screening platform.

Also in 2024, Moa Technology, a UK-based agricultural biotech company, formed a long-term collaboration agreement with Biomar Microbial Technologies. Through the partnership, Moa Technologies will gain access to Biomar's library of natural marine compounds and will utilise its proprietary Galaxy platform to screen and identify candidate compounds for further herbicide development.

In 2025, Moa Technology, a UK-based agricultural biotech company, partnered with Italian firm NAICONS, a Milan-based biotech company specialising in the discovery and development of bioactive molecules, to search for new biological herbicides. Under the terms of the partnership, Moa will screen 70,000 microbial extracts from NAICONS' natural product library using its proprietary platform to identify safe, effective herbicide candidate molecules. Moa also gains exclusive development rights to any new herbicide leads, with both companies to share any potential future value from licensing and commercialisation.

Market Outlook

The market outlook for bioherbicides is positive in the sense that any products that can be brought to market with robust efficacy against at least a few select weed species may see favourable product uptake. So far this has mostly been limited to niche situations, where there are fewer chemical alternatives, or where there are specific resistance issues or integrated pest management considerations. A good example of this is the control of witchweed (*Striga hermonthica*), a parasitic weed that impacts staple food crops in many parts of Africa. By the time striga weeds have emerged, the damage to the root zone has already commenced. Due to the longevity of seeds in the soil, one important tool for tackling *Striga* is a bioherbicide which triggers suicidal germination of the *Striga* seeds (see above).

Such specific use cases may justify the often-considerable premium that bioherbicides cost over their conventional counterparts. For the bioherbicide segment to truly supplant the conventional herbicide market, it would be necessary for the products in the segment to possess multiple attributes that compete with that of conventional herbicides, such as cost, tank mix compatibility, machinery compatibility, favourable shelf life, stable formulations, crop selectivity and safety. The gold standard up to this point for which all non-selective herbicides are judged is of course glyphosate. Given the current uncertainty around the long-term use of the AI, any product which could replicate glyphosate attributes would likely become a major breakthrough, however so far this has not been achieved, despite some promising candidates in at least some of the key performance indicators. Another key consideration will be that bioherbicides that have demonstrated poor efficacy are likely to tarnish the brand identity of the company selling the product, as well as future sentiment and uptake.

Regardless of the fate of glyphosate in many markets, there is a growing opportunity for using bioherbicides in organic agriculture as alternatives to other toxic active ingredients. The EU Green Deal (and similar legislation in other countries), which aims to reduce reliance on chemicals in agriculture, could drive bioherbicide usage in the longer term, however we have seen these targets watered down and there is currently significant uncertainty surrounding the future direction of sustainability targets in the EU. The future adoption of bioherbicides will not just be determined by the sustainability targets, but fundamentally how efficacious the product is and other important metrics such as cost, shelf life and selectivity.

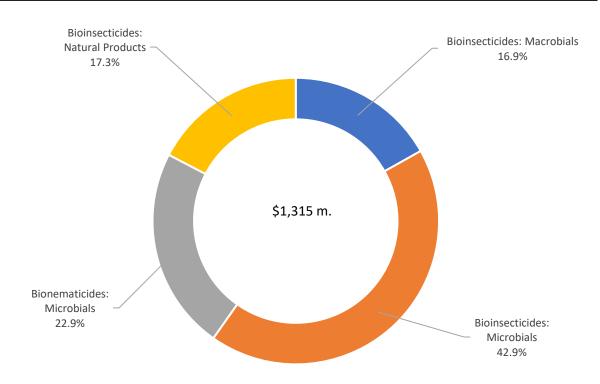
Taking these factors into account, we expect that the market for bioherbicides in crop protection will increase by 14.9% per annum between 2023 and 2028 (constant currency and pricing), albeit from a small base.

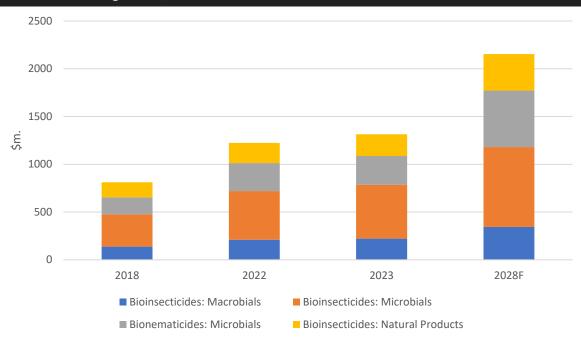
Biological Insecticides

Sales Performance of Biological Insecticides						
Year	Bioinsecticide Sales (\$ m.)	Total Insecticide Sales (\$ m.)	Share of Bioinsecticide to Total Insecticides (%)	Share of Total Insecticides to Total Crop Protection (%)		
2018	812	16,796	72.93	28.88		
2022	1,224	21,566	67.07	28.85		
2023	1,315	21,737	66.86	29.06		
2028F	2,153	24,446	65.28	30.08		
1-yr Change (%)	7.4	0.8				
5-yr CAGR (% p.a.)	10.1	5.3				
5-yr CAGR Forecast (% p.a.)	10.4	2.4				

CCP = Conventional crop protection

Segment Split 2023





Sales of the Leading Classes, 2018-2022-2023-2028F

Introduction

In this report, biological insecticides are defined as follows: natural products such as plant extracts; microbial products such as viruses or bacteria and their proteins; and macrobials such as living predators of certain pests—these are used for the control of arthropods such as insects and mites, as well as nematodes and molluscs. Fermentation products such as abamectin, emamectin, and spinosad are not included since these are generally synthetically produced versions of natural compounds. Pheromones used for mating disruption are also included since they are typically based on naturally occurring substances, but this report excludes pheromones used in insect traps.

The market for biological insecticides has increased significantly in recent years, growing by 10.1% per annum between 2018 and 2023 to an estimated \$1,315 million. Increases in organic production systems, regulations against conventional technologies, and a perceived need for 'natural' alternatives in some markets have all driven this growth. In the EU, where regulation has precluded the use of many conventional chemical products, and where the number of newly approved active ingredients is low compared to other markets, biological alternatives are being promoted for their perceived safety and 'natural' character. Nevertheless, the number of new biological active ingredients reaching the market in the EU remains low, and the market has not developed as some had anticipated. Key factors behind this are that biological pesticides undergo the same regulatory processes as conventional chemicals, requiring numerous studies and significant capital to complete a successful product registration. Many new biological products have been developed by small companies, including those that have emerged from academia. These companies often lack the necessary resources to bring such products to market. Therefore, new introductions have generally relied upon larger companies supporting new biological AIs through either licensing agreements or acquisitions. The pressing need for new technologies in the EU is expected to drive introductions in the coming years, with EU regulatory authorities aiming to promote combinations of biological and conventional chemical products as 'hybrid' solutions, both to increase efficacy and to assist in resistancemanagement programs.

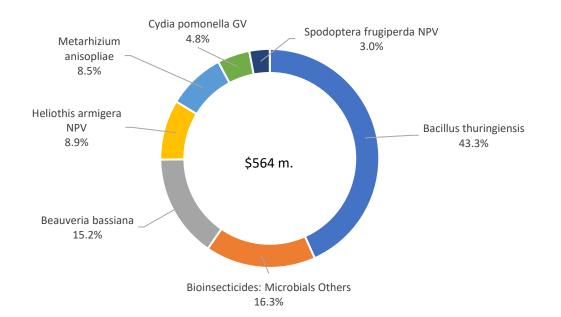
A key issue with biological insecticides is their sometimes-limited efficacy in field settings, with living organisms such as bacteria often requiring a relatively stable environment to remain viable and some viral products degrading under light. As such, biological products have often found their primary application in speciality crop sectors, such as in greenhouses, or as seed treatments, where the application environment is more controlled or stable. However, to truly become alternatives to conventional chemicals, these products must be efficacious in field settings.

A clear driver of growth has been the increased use of seed-treatment products such as *Bacillus firmus*, a nematicide with significant use in the USA for protecting high-value GM seed. Another driver has been increased usage of macrobial products to control pests such as mites, many of which have rapidly evolved resistance to conventional chemical products. Increased uptake in key regions such as the EU—in response to the regulation of older technologies, growth in organic production systems, new product introductions, and the effect of multinational investment in research and acquisitions—is expected to benefit the bioinsecticides market in the coming years. Therefore, we expect the overall bioinsecticide market to increase at an average annual rate of 10.4% per annum between 2023 and 2028 in real terms.

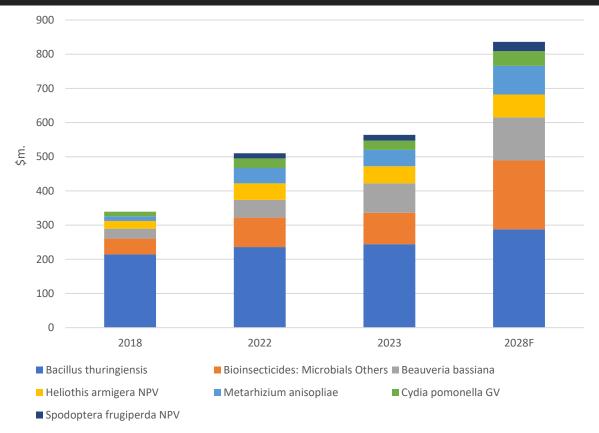
Bioinsecticides: Microbials

Sales Performance of Microbial Bioinsecticides								
Year	Microbial Bioinsecticide Sales (\$ m.)	Total Insecticide Sales (\$ m.)	Microbial Bioinsecticides Share of Bioinsecticides (%)	Microbial Bioinsecticides Share of Total Insecticides (%)				
2018	339	16,796	41.78	2.02				
2022	510	21,566	41.66	2.36				
2023	564	21,737	42.90	2.59				
2028F	836	24,446	38.83	3.42				
1-yr Change (%)	10.6	0.8						
5-yr CAGR (% p.a.)	10.7	5.3						
5-yr CAGR F (% p.a.)	8.2	2.4						

Leading Products 2023



Leading Biopesticides: Bioinsecticides: Microbials							
AI	YOI	Timing	Main Crops	2023 Sales (\$ m.)	2028F Sales (\$ m.)		
Bacillus thuringiensis	1970	Foliar	Maize, Rice, Soybean, Cotton, F&V	244	288		
Beauveria bassiana	-	Foliar	Soybean, F&V, Maize	86	126		
Cydia pomonella GV	-	Foliar	Pome Fruit	27	43		
<i>Heliothis armigera</i> NPV	-	Foliar	F&V, Cotton, Rice	50	67		
Metarhizium anisopliae	-	Foliar	Sugarcane, F&V, Potato	48	84		
Spodoptera frugiperda NPV	-	Foliar	Cotton, Maize, Soybean	17	27		



Sales of the Leading Als 2018-2022-2023-2028F

Introduction

Microbial insecticides are biological pesticides based on bacteria, viruses, and other microscopic organisms or their proteins; these have activity against nematodes, molluscs, or arthropod pests such as insects and mites. One of the first microbial insecticides to be developed was *Bacillus thuringiensis*, which remains the leading active ingredient in terms of sales, although numerous products are now available. Other significant bacterial products include *Bacillus firmus*, used for a nematicidal seed treatment; *Lysinibacillus sphaericus*, which is used against mosquitoes; and *Chromobacterium subtsugae*, which is used on speciality crops against multiple insect pests. Several entomopathogenic (insect-targeting) soil fungi have also been developed as insecticides: the mould *Paecilomyces lilacinus*, which is also an effective nematicide; *Beauveria bassiana*, which is used to control insects by causing white muscadine disease in target pests; and *Metarhizium anisopliae*, a parasite of primarily beetle larvae. Furthermore, Baculoviruses such as Granuloviruses (GVs) and Nuclear Polyhedrosis Viruses (NPVs), which target specific insect pests, have been developed and introduced with some commercial success; currently, *Heliothis armigera* NPV, *Helicoverpa zea* NPV, and *Cydia pomonella* GV are the leading products.

The market for microbial bioinsecticides grew by an average of 10.7% per annum between 2018 and 2023 to an estimated \$564 million, primarily driven by rapid sales growth for *Beauveria bassiana*, and *Heliothis armigera* NPV, *Metarhizium anisopliae*, *Cydia pomonella* GV. Sales in 2023 increased significantly, rising by 10.6% year-on-year.

Products

Numerous products are in the marketplace, many of which are individual strains of existing species with varying efficacy against target pests. Generally, these actives can be split into bacteria, fungi, and viruses, as outlined in the taxonomy classification provided earlier in this section.

Bacteria

Bacterial insecticides represent the single largest bioinsecticide group by value, with *Bacillus thuringiensis* and its associated sub-strains representing the largest single species worth an estimated \$236 million in 2022. Key sub strains include *Bacillus thuringiensis–aizawai*, *Bt–galleriae*, *Bt–israelensis*, *Bt–kurstaki*, *Bt–tenebrionis*, and *Bt–thoworthy*. Each of these strains tends to act against specific insect larvae, owing to its production of unique endotoxins with efficacy against different insect gut membranes. As an example, *Bacillus thuringiensis–galleriae* strain SDS-502, which has recently been registered in North America, produces a Cry8Da protein active against scarab beetles, while the initial introductions of *Bacillus thuringiensis–tenebrionis* produced a CryIIIA protein active against beetle larvae such as Colorado Potato Beetle.

In addition, *Bacillis papillae*, *Bacillus amyloliquefaciens*, *Bacillus sphaericus*, and *Bacillus subtilis* all have insecticidal properties or strains. Some, such as *B. subtilis*, have additional applications in competing against plant pathogenic fungi.

More minor in overall sales terms are other bacterial insecticides such as *Burkholderia rinojensis, Chromobacterium subtsugae, Empedobacter brevis, Paenibacillus popilliae, Photorhabdus luminiscens, Serratia entomophila, Streptomyces* spp., and *Wolbachia pipientis.*

Bacillus thuringiensis

The insecticidal activity of *Bacillus thuringiensis* (*B.t.*) was originally discovered by Japanese scientists in the early 1900s, although the first commercial sale of the product (Sporeine) came decades later in the 1930s in France. This product had very limited commercial significance until the 1970s, when its deployment as a biological alternative to conventional chemical controls began to increase. *B.t.* is a soil bacterium that was originally discovered in silkworms; it occurs naturally in the digestive systems of Lepidopteran insects. Its insecticidal action is through crystal protein endotoxins, which are produced during sporulation. GM crops have been developed that contain genes encoding for these endotoxins, enabling these plants to produce the insecticidal protein, thereby conferring insect resistance. The scale of these GM technologies is such that they account for the vast majority of *B.t.* usage. Nevertheless, sprayable *B.t.* remains the single most important biological insecticide, with application on a wide variety of crops plagued by *Lepidopteran* pests.

The leading crop sector for *B.t.* sales in 2023 was fruit and vegetable crops, particularly in China, as well as rice, cotton, soybean, pome and stone fruit, and vines.

Its use is concentrated in the Asia-Pacific region, particularly China, although significant sales are also made in Brazil, the USA, Mexico, Spain, Italy, and Australia. Key manufacturers include Sumitomo Chemical, which markets the product under the DiPel brand, and Certis USA, which sells this AI in the Trilogy and Agree brands, among others. Several strains and subspecies of *B.t.* exist, with new strains being developed to overcome resistance development.

For this analysis, all strains have been classified as *B.t.* Sales of *B.t.* increased at an average annual rate of 2.6% per annum between 2018 and 2023 to an estimated \$244 million.

Key events over the last few years have included:

- July 2021 Bharat Certis AgriScience, formerly Bharat Insecticides, launched the biological insecticide Delfin (*Bacillus thuringiensis var. Kurstaki* Serotype 3a, 3b, SA II).
- May 26, 2022 Adama launched the biological fungicide / nematicide product Protege (*Bacillus thuringiensis* strain CNPSo 3915 / *Bacillus velezensis* strain CNPSo 3602 / *Bacillus amyloliquefaciens* strain CNPSo 3202) in Brazil. The product is targeted at the control of the pathogenic fungus *Rhizoctonia solanil* and root-lesion nematode (*Pratylenchus brachyurus*) in soybean and sugarcane.
- Sep 15, 2022 The Brazilian biological crop protection company Biotrop Soluções Biológicas launched the biological nematicide / fungicide Biomagno (*Bacillus amyloliquefaciens* strain CNPSo3202 / *Bacillus thuringiensis* strain CNPSo3915 / *Bacillus velezensis* strain CNPSo3602) in Brazil. The product is targeted at the control of the pathogenic fungus *Rhizoctonia solani* and root-lesion nematode (*Pratylenchus brachyurus*) on a range of crops.
- May 31, 2023 The Brazilian company Bionat Soluções Biológicas, part of the Essere Group, announced it was to invest in its manufacturing capabilities. Following the investment, the company anticipates that it will be able to produce enough bacteria-based products to treat approximately 10 million hectares. Bionat's products include the bioinsecticide Lepthure (*Bacillus thuringiensis* strain S234).
- Nov 20, 2023 Helena Agri-Enterprises announced the launch of Enertia (*Bacillus thuringiensis* strain EX297512). Enertia is an enzyme-based, biological soybean seed treatment product designed to enhance soil health and nutrient availability through root development. Additionally, the product has been formulated to enhance compatibility with traditional insecticide/fungicide products.
- May 20, 2024 the biological crop protection company Biohelp received approval in Austria for the bioinsecticide Novodor FC (*Bacillus thuringiensis*), intended for use on potatoes and aubergine.
- Aug 22, 2024 the Brazilian biologicals company Biotrop launched the bioinsecticide Biobrev Full (*Bacillus thuringiensis* strain CCTB22 / *Bacillus thuringiensis* strain CCTB25 / *Brevibacillus laterosporus* strain CCT492). The product is targeted at the control of lepidopteran pests including soybean looper (*Chrysodeixis includens*), fall armyworm (*Spodoptera frugiperda*), and tomato leafminer (*Tuta absoluta*).
- Sep 26, 2024 Syngenta launched the biological insecticide Costar (*Bacillus thuringiensis* subsp. kurstaki strain SA-12) in Argentina for use on vine. The product provides control of lepidopteran insect pests, including European grapevine moth (*Lobesia botrana*).
- Dec 10, 2024 The US EPA received applications from Syngenta and FMC to register pesticide products containing active ingredients not included in any registered pesticide products:
 - FMC Corporation *Bacillus thuringiensis* strain RTI545 at 100%: insecticide and nematicide for manufacturing into end-use pesticide products.
 - FMC Corporation *Bacillus thuringiensis* strain RTI545 at 9.59%: insecticide and nematicide for use as a commercial and on-farm seed treatment.

Other Bacillus Species

A range of other *Bacillus* species are used as bioinsecticides or bionematicides with more limited sales:

- Bacillis papillae Marketed by Rincon Vitova for control of Japanese beetle grubs in turf.
- **Bacillus amyloliquefaciens** Marketed by a range of companies such as Sumitomo Chemical (Aveo), FMC (Ethos), and Nufarm (Trunemco, acquired from BASF) for control of nematodes (see bionematicide: microbials section) in field crops, often as seed treatments.

- **Bacillus sphaericus** Marketed by Biodalia for mosquito control as Sefralit in the public health sector.
- Bacillus subtilis Marketed by a plethora of companies, including UPL (Biowork), Bion Tech (Biobac), and Nippon Soda (Agrocare) for nematode control (see bionematicide: microbials section), often in fruit and vegetable crops.
- Burkholderia rinojensis Albaugh markets Burkholderia rinojensis in North America as the seed treatment BIO_{ST} Nematicide for soybean cyst, root knot, reniform, Colombia lance, and sting nematodes in soybean, corn, and cotton; it markets BIO_{ST} Insecticide for wireworms, corn rootworm, and seed corn maggot.
 - Feb 27, 2024 the US EPA received applications to register pesticide products containing active ingredients not included in any registered pesticide products:
 - Marrone Bio Innovations Inactivated Burkholderia rinojensis A396 cells and spent fermentation media at 100%. Proposed for manufacturing use.
 - Marrone Bio Innovations Inactivated Burkholderia rinojensis A396 cells and spent fermentation media at 94.46%. Proposed for use indoor and outdoor agricultural use on crops and ornamentals, seed treatment, and indoor and outdoor residential use.
 - Mar 12, 2025 Bioceres Crop Solutions and its subsidiary ProFarm Group received US EPA registration for their RinoTec biological insecticide/nematicide technology (inactivated *Burkholderia rinojensis* strain A396 cells and spent fermentation media). RinoTec, which has already been approved for commercialisation in Brazil, is a novel bacterial agent that reportedly demonstrates activity against plant-parasitic nematodes, wireworms, whitefly, thrips, mites, lepidopterans, and other key foliar and below-ground pests
 - Mar 14, 2025 Eléphant Vert renewed its agreement with Pro Farm Group regarding the distribution of biocontrol products in Africa. Under the renewed agreement, the companies will develop and market the Pro Farm Group range of biocontrol products, while expanding its presence in East African countries such as Ethiopia and Tanzania, Tunisia and Algeria. The distribution will primarily focus on biocontrol products including Venerate (*Burkholderia rinojensis*).

Chromobacterium subtsugae

Profarm (formerly Marrone Bio Innovations) markets the bioinsecticide Grandevo (*Chromobacterium subtsugae* strain PRAA4-1) for foliar (aerial or ground), chemigation, soil treatment, or backpack/hand sprayer application on a range of crops including fruits, vegetables, and nuts. Grandevo WDG focusses on speciality and row crops, while Grandevo CG (Cultivated Garden) targets ornamentals and greenhouses. These products are effective against armyworms, aphids, Asian citrus psyllid, mites, spotted wing drosophila, thrips, and whiteflies, with multiple modes of action such as repellence, ingestion, and reproduction disruption.

Chromobacterium subtsugae strain PRAA4-1 was isolated from Eastern Hemlock in central Maryland, USA, and its insecticidal activity was discovered by the USDA. MBI subsequently introduced the product through a co-licensing agreement (presumably with the USDA) through which the other party receives royalty fees in mid-single digits of net sales. Exclusivity and royalty agreements are tied to the expiry of underlying patents, with the patent related to the license expected to expire from 2024. Profarm ferments Grandevo at its in-house manufacturing facility but uses a third-party contractor for formulation. In 2021, MBI received approval for Grandevo WDG (*Chromobacterium subtsugae* strain PRAA4-1T) bioinsecticide for use in New Zealand and Chile.

• Mar 14, 2025 Eléphant Vert renewed its agreement with Pro Farm Group regarding the distribution of biocontrol products in Africa. Under the renewed agreement, the companies will develop and market the Pro Farm Group range of biocontrol products, while expanding its presence in East African countries such as Ethiopia and Tanzania, Tunisia and Algeria. The distribution will primarily focus on biocontrol products including, Grandevo (*Chromobacterium subtsugae*).

Empedobacter brevis

Empedobacter brevis (formerly *Flavobacterium brevis*) strain GXW15-4 is a gram-negative bacterium commonly found in soil, meat, plants, and water. It can act as an insecticide against *Lepidopterans*, with target pests including diamondback moth, *Prodenia litura*, and *Cnaphalocrocis medinalis*. Its mode of action is through the production of insecticidal toxins when ingested.

The Chinese company Zhenjiang Runyu originally developed products based on this active ingredient, which was discovered in 2001. The original Chinese patent relating to its use as an insecticide was filed in 2004. Zhenjiang Runyu gained Chinese registrations in 2012 and launched the product throughout China in 2013, setting up field tests in several other countries, including Korea and Japan. As of 2012, the company had plans to introduce products based on this AI in 25 countries, including the USA and the EU.

Paenibacillus popilliae

Paenibacillus popilliae (formerly *Bacillus popilliae*) is a natural pathogen of several Coleopteran pest larvae, notably the Japanese beetle (*Popillia japonica*), from which the bacteria gained its binomial name (*P. popilliae* was isolated from *P. japonica* in the late 1930s). This bacterium exerts insecticidal effects initially by being present in the soil as spores that are ingested by beetle larvae. The bacteria then multiply after being ingested as spores and prevent the larvae from becoming adults. Once the bacterial population density increases within the pest, spores are released to the surrounding soil, killing the pest. These spores can accumulate in the soil and reduce Japanese beetle populations significantly.

Japanese beetle control is the key outlet for *Paenibacillus popilliae* products, particularly in the USA, where this pest is an invasive species impacting numerous ornamental and amenity plant species, including grasses, roses, and trees. These spores have been utilised since the 1940s in parks and gardens, with St. Gabriel Organics being a key producer offering two key registrations: Milky Spore Powder and Milky Spore Granular. The granular and powder formulations are both sprinkled onto soil, with the intention of inoculating the soil throughout the year with multiple applications between spring and autumn, when the larvae are active.

Serratia entomophila

Serratia entomophila is a bacterial pathogen of the Coleopteran insect Costelytra zealandica, which is native to New Zealand and a pest of pasture. AgResearch New Zealand discovered *S. entomophila*'s insecticidal properties and developed a liquid formulation containing this AI, launched as Invade in 1990, with manufacture being conducted by Industrial Research Ltd. This product works by inoculating pasture with the bacteria, which colonise grass roots. Larvae that ingest this bacterium whilst feeding on grass roots will stop feeding and develop 'amber disease', followed by death.

Streptomyces spp.

Several *Streptomyces* species are used as bioinsecticide active ingredients, including *Streptomyces rochei* and *Streptomyces albus*. The Indian company T. Stanes has introduced *Streptomyces* spp. in

Stanomyte, which is intended for controlling all mite species and is active through infecting, parasitising, and colonising their eggs and larva. Camson Seeds, an agrobiotechnology company based in Bangalore, India, has also developed insecticides based on *Streptomyces* spp., including the Aygis brand, developed to control Lepidopteran pests in arable and fruit and vegetable crops.

- Feb 11, 2020 The Canadian Pest Management Regulatory Agency (PMRA) granted re-approval of the microbial pest control agent *Streptomyces* strain K61, and its associated end-use products, for use in the country provided that label amendments are implemented.
- Feb 25, 2021 MustGrow Biologics received regulatory approval from Health Canada's Pest Management Regulatory Agency (PMRA) for the biofungicide CannaPM (*Streptomyces spp*). The product was registered for the suppression of powdery mildew on cannabis and hemp crops. MustGrow obtained the exclusive rights to this product in Canada for cannabis and hemp cultivation in 2019.

Fungi

As with bacteria, a large number of species and strains have been commercialised as insecticides. These are often naturally occurring entomopathogens (entomo = insect, pathogen = disease-causing organism) of insect pests. Such fungi can be cultivated and applied as spores to insect populations; they then attack these insects, much as they would if the insect had encountered such a disease in the wild.

Beauveria bassiana

Beauveria bassiana is an entomopathogenic soil fungus that causes white muscardine disease in insects. It has been used for years as a biological control agent of a range of pests including termites, whiteflies, and other insects. The leading suppliers are Koppert with Boveril, which use the ESALQ PL63 strain for control of whitefly, coffee borer, brindle mite, and weevil, as well as Ballagro, which offers the IBCB66 strain in Ballveria for whitefly control.

Koppert became a significant supplier in Brazil after acquiring the microbial pesticide developer Itaforte BioProdutos, which was involved with the product, in 2012. BASF also markets this AI, having received approval for Velifer (strain PPRI 5339) in Germany in 2017 and Canada in 2018. Certis USA uses *Beauveria bassiana* strain GHA in the product BoteGHA, after acquiring LAM International in 2017. In 2019, the EU commission approved the PPRI 5339 and IMI389521 strains for use in the region, with an expiry set for 19th February 2029.

- Mar 15, 2021 the Canadian Pest Management Agency granted registration for the sale and use of the insecticide active ingredient *Beauveria bassiana* strain ANT-03. The registration will allow growers additional means of controlling Colorado potato beetle on potato, tomato, bell pepper, and aubergine; tarnished plant bug on spinach, Chinese cabbage, lettuce, celery, strawberry, raspberry, and blackberry; and chinch bug, European chafer and Japanese beetle larvae in turf. The registration meant that the products BioCeres F WP, BioCeres F GR, and BioCeres D GR, which contain the technical grade active ingredient, were approved for sale in the country.
- May 5, 2021 Andermatt Biocontrol's Tunisian distribution partner, Aloha Agriculture, gained Tunisian registration for Bb-Protec (*Beauveria bassiana*), which is targeted at the control of sucking pests in fruit and vegetable crops.
- Sep 14, 2021 Andermatt received a label extension for its biological insecticide Eco-Bb (*Beauveria bassiana*, strain R444) in South Africa. The product was registered for use to

suppress Mealybug on pome fruit (apples, pears), citrus and grapes, and Red spider mite on stone fruit (peaches, plums, nectarines, cherries).

- Oct 14, 2021 Bee Vectoring Technologies (BVT) and Biogard entered into a licensing agreement concerning Biogard's biological insecticide *Beauveria bassiana* ATCC 74040. Under the terms of the agreement, BVT will develop a biological insecticide solution for delivery to crops through BVT's proprietary bee vectoring platform using Biogard's active substance registration. This could be either stacked alongside BVT's own biological fungicide, *Clonostachys rosea* strain CR-7 (CR-7), for a complete fungicidal plus insecticidal solution for certain crops or used as a standalone when some diseases are not present. The agreement was intended to allow BVT to generate revenue from the EU for the first time and was also the company's first product expansion by in-licensing a third party-biological for use in the company's bee vectoring system.
- Mar 28, 2022 Canada's Pest Management Registration Agency (PMRA) granted registration for the sale and use of *Beauveria bassiana* CFL-A (technical grade active ingredient) for control of emerald ash borer.
- Apr 27, 2022 Symborg, a Spanish biological crop protection company, received approval from the European Commission for the bioinsecticide *Beauveria bassiana* 203. The product is reportedly highly tolerant of adverse conditions and remains effective against agricultural pests in such conditions. This approval follows Symborg's acquisition of Glen Biotech earlier in 2022.
- Jul 18, 2022 Certis Biologicals announced it was to begin directly marketing its BotaniGard (*Beauveria bassiana*) and Mycotrol (*Beauveria bassiana*) bioinsecticides in the USA from October, when its previous distribution agreement with BioWorks was to end. The products, which are marketed to nurseries and greenhouses, offer control of aphids, thrips, weevils, whiteflies and other insects.
- Aug 2, 2022 De Sangosse Brasil (DSB), a subsidiary of France's De Sangosse Group, entered the Brazilian biologicals market through the launch of its Bio Solutions portfolio including Papillon (*Beauveria bassiana* strain IBCB 66) biological insecticide / acaricide
- Oct 18, 2022 Corteva launched the biological insecticide Tezpetix Beauve (*Beauveria bassiana*) in Brazil. The product is intended for use on maize to control maize leafhopper (*Dalbulus maidis*).
- Nov 11, 2022 Canada's Pest Management Registration Agency (PMRA) granted registration for sale and use of *Beauveria bassiana* strain R444 Technical, and Bassidor (formerly called Bb-Protec), containing the technical grade active ingredient *Beauveria bassiana* strain R444. It is approved for control of two-spotted spider mite and whitefly on a wide variety of greenhouse-grown ornamental and food crop plants, including plants grown for transplanting, and cannabis grown in greenhouses and enclosed structures.
- Dec 5, 2022 Syngenta launched several new products in Chile, including the bioinsecticide Botanigard (*Beauveria bassiana* strain GHA ATTC). Other products launched by the company include fertilisers, biostimulants and nutritional correctional products.
- Mar 20, 2023 Syngenta launched three new bioinsecticides in Italy including Arbiogy (*Beauveria bassiana* – ATCC 74040) which can be used on vines, stone fruit, floral and ornamental crops, and is targeted at the control of thrips, mites, leafhoppers (including scaphoid), whiteflies, fruit and cherry flies.
- May 26, 2023 The São Paulo sugarcane farmers' association Canaoeste announced it was to construct a new biologicals manufacturing facility in Sertãozinho. The plant focuses on the

production of a bioinsecticides based on the fungi *Metarhizium anisopliae* and *Beauveria* bassiana.

- Nov 16, 2023 OHP, a subsidiary of American Vanguard, entered an agreement with Certis Biologicals to be a key distributor of its products for US non-crop markets, including nursery, greenhouse, turf, ornamental and cannabis markets. The agreement includes the commercialisation of Certis' BotaniGard (*Beauveria bassiana*) and Mycotrol (*Beauveria bassiana*) products, whilst OHP gained exclusive access to Certis' pipeline of new technologies for non-crop markets and comes as part of American Vanguard's strategy to expand its GreenSolutions portfolio.
- Jan 8, 2024 UPL launched the bioinsecticide Tackler (*Beauveria bassiana*) in Brazil, targeted at broad-spectrum pest control, including whitefly (*Bemisia tabaci*), corn leafhopper (*Dalbulus maidis*), wireworm (*Diabrotica speciosa*), coffee borer (*Hypotenemus hampei*) and sugarcane weevil (*Sphenophorus levis*) in various crops. The product has a reported storage shelf-life of up to 10 months at ambient temperature.
- Apr 2, 2024 BASF received a new label registration for the bioinsecticide/miticide Velifer (*Beauveria bassiana* strain PPRI 5339) in the US. The product can be used in dips and drench applications, in addition to soil-directed sprays, in commercial greenhouses, with the expanded label also including new crops, covering fruit and nut trees, vines, brambles, and bushberries.
- Apr 30, 2024 Biogard, launched the bioinsecticide Naturalis (ATCC 74040 strain of *Beauveria bassiana*) in Italy for the control of weevils (*Otiorynchus* spp.) in table grapes.
- Oct 10, 2024 Syensqo announced it was launching its microbial formulation technology, AgRHEA LifeXtend Plus, designed to enhance shelf life in support of sustainable agriculture practices. The product is a ready-to-use solution, which includes a carrier, co-dispersant and rheology agent for the formulation of microorganisms, and has reportedly significantly improved the shelf life of *Beauveria bassiana* and *Paecilomyces lilacinus*, in viability studies.
- Apr 1, 2025 Health Canada's Pest Management Regulatory Agency (PMRA) approved the registration of *Beauveria bassiana* strain ANT-03 and BioTitan WP, which contains the active ingredient. BioTitan WP is authorised for reducing tarnished plant bug populations on outdoor industrial hemp and for decreasing whiteflies, aphids, and thrips on outdoor ornamentals, including transplants.
- Apr 16, 2025 BioWorks received approval from the US EPA for the bioinsecticide Principle WP (*Beauveria bassiana* strain BW149), with subsequent registrations expected in all 50 states. The product is labelled for indoor and outdoor use, foliar spray, soil drench, dipping, and aerial applications, and is targeted at the control of various hemipteran, coleopteran and lepidopteran pests in multiple crop sectors, including fruit and vegetables, cereal grains and oilseeds.

Interest in these products has increased in Brazil following significant sales development in recent years. Notably, Kimberlit Agrociências has established the Bionat brand and opened a new factory in Olímpia, São Paulo, to support its operations. Bionat expects to receive registrations from the Brazilian Ministry of Agriculture for the commercialisation of *Beauveria bassiana* for the control of whitefly and the brindle mite. Furthermore, Agrivalle launched a new EC formulation of this AI as Auin in Brazil for the control of cucurbit beetle (*Diabrotica speciose*) in crops including soybean, beans, potatoes, and tomatoes.

The leading crop outlets are sugarcane, soybeans, maize and F&V crops. Sales of *Beauveria bassiana*based insecticides have increased significantly in recent years, reaching \$86 million in 2023, having risen by an average of 24.2% p.a. since 2018.

Beauveria brongniarti

Beauveria brongniarti has been developed as a bioinsecticide for control of longhorn beetles in orchards. The final product, Biolisa, consists of fibre bands impregnated with *Beauveria brongniartii* cultures that are wound around the bases of trees.

Metarhizium anisopliae

Metarhizium anisopliae is an entomopathogenic soil fungus that causes green muscardine disease in insects. Koppert, and Ballagro are leading suppliers, with the biggest country market being Brazil, India, and Vietnam. This AI is useful for controlling thrips, whitefly, mites, and aphids, amongst other pests, with the primary crops being sugarcane and fruits and vegetables. Sales were estimated at \$48 million in 2023, having grown from just 14 million in 2018 (+28.7% p.a. 2018-2023).

- Aug 2, 2022 De Sangosse Brasil (DSB), a subsidiary of France's De Sangosse Group, entered the Brazilian biologicals market through the launch of its Bio Solutions portfolio. The company's Bio Solutions portfolio currently encompasses 7 products including Paragran (*Metarhizium anisopliae* strain IBCB 425) biological contact insecticide
- May 25, 2023 Dhanuka Agritech entered the agricultural biologicals market through the launch of its new BiologiQ portfolio in India. The company's BiologiQ portfolio currently encompasses 3 products including Whiteaxe (*Metarhizium anisopliae*) bioinsecticide for the control of white grub, termites, and borers.
- May 26, 2023 The São Paulo sugarcane farmers' association Canaoeste announced it was to construct a new biologicals manufacturing facility in Sertãozinho. The plant was to focus on the production of a bioinsecticide based on the fungi *Metarhizium anisopliae* and *Beauveria bassiana* for the control of sugarcane spittlebug (*Mahanarva fimbriolata*) and sugarcane weevil (*Sphenophorus levis*). The new facility was to have a capacity to produce 100,000 litres of product for spraying and is intended to provide a more affordable solution for Canaoeste's members.

Paecilomyces spp.

Several species of the fungal genus *Paecilomyces* are used as insecticides for their entomopathogenic insecticidal or nematicidal properties. *P. lilacinus* is used for control of nematodes, and *P. fumosoroseus* is used to control insects such as whitefly, thrips, aphids, and spider mites. Prophyta, which was acquired by Bayer in 2013, developed *P. lilacinus* strain 251 for its end-use product BioAct, a leading product. Ballagro's Nemat has significant sales in Brazil for nematode control in soybeans. Overall, sales of *Paecilomyces* spp. were estimated at \$81 million in 2023.

- Mar 24, 2020 Futureco Bioscience received new authorisations for its bioinsecticide NOFLY WP (*Paecilomyces fumosoroseus* strain FE 9901) in the US. The product has been approved for outdoor and residential crops in the country. NOFLY has been previously authorised in several other countries,
- Mar 4, 2022 The European Commission renewed the approval of the microorganism *Purpureocillium lilacinum* strain 251 until 28th February 2037. *Purpureocillium lilacinum* strain 251, which was formerly approved in the EU as *Paecilomyces lilacinus* strain 251,
- Jun 8, 2022 Futureco Bioscience and Nufarm expanded their distribution agreement for Futureco's bioinsecticide NOFLY WP (*Paecilomyces fumosoroseus* strain FE 9901) to include the Belgian and Dutch markets, expanding on a similar previous agreement covering Spain. The product was to be distributed as part of Nufarm's NuBio umbrella brand.
- Oct 10, 2024 Syensqo announced it was launching its microbial formulation technology, AgRHEA LifeXtend Plus, designed to enhance shelf life in support of sustainable agriculture practices. The product is a ready-to-use solution, which includes a carrier, co-dispersant and

rheology agent for the formulation of microorganisms and has reportedly significantly improved the shelf life of *Beauveria bassiana* and *Paecilomyces lilacinus*, in viability studies.

• November 27, 2024 The European Commission extended the approval periods for 13 active ingredients due to ongoing delays in the procedure for evaluating the approvals. This included *Paecilomyces fumosoroseus* strain FE 9901 to 31st May 2027.

Verticillium spp.

Verticillium is a genus of entomopathogenic fungi that are used for control of aphids, with *Verticillium lecanii* being a leading commercial species. Sales were estimated at \$17 million in 2023. Several companies are active with species in this genus, notably Stanes, in vivo (via Dudutech), Koppert (with their leading Mycotal brand), Indore Biotech, and UPL.

Hirsutella thompsonii

The mite-specific pathogen *Hirsutella thompsonii* has been developed as a pesticide against the coconut mite (*Aceria guerreronis*) since the year 2000, and has been commercialised by Hindustan Antibiotics as Mycohit.

Lagenidium giganteum

Lagenidium giganteum is an oomycete species that parasitises mosquito larvae, which it generally encounters in the breeding stages in fresh water. Due to its natural parasitic behaviour and the ease of its culture (in large fermentation tanks using inexpensive media), *L. giganteum* has been commercialised as a mosquito-control product since 1997, initially by ArgaQuest as Laginex, with these assets having since passed to Bayer.

Viruses

Cydia pomonella GV

Cydia pomonella GV (Granulosis Virus) is a viral-based product that targets codling moth (*Cydia pomonella*), a significant pest of fruit and vegetables, especially pome fruit such as apples and pears. Certis USA is a significant supplier through Cyd-X, which was launched in the USA in 2012. Andermatt Biocontrol and Arysta are also significant market players, offering Madex and Carpovirusine, respectively. Recent registrations for this AI include Andermatt Biocontrol receiving approval in Sweden and Israel in March 2020 for its *Cydia pomonella* granulovirus (CpGV)-based bioinsecticide product Madex Top, intended for use in pome fruit orchards to control codling moth (*Cydia pomonella*). With the addition of these two countries, Andermatt's Madex Top is now registered in 16 countries.

In September 2020, the Canadian company BioTEPP received approval from the California Environmental Protection Agency for its biological insecticide Virosoft CP4 (*Cydia pomonella* granulosis (CpGV-CP4)). This product has been approved for use against codling moth and oriental fruit moth (*Grapholita molesta*) in various fruit and nut crops, including apple, pear, plum, prune, nectarine, apricot, and nut trees.

- May 5, 2021 Andermatt Biocontrol received registration for Madex Pro (*Cydia pomonella* granulovirus), also known as Madex Top, in Lithuania and Latvia for the control of codling moth (*Cydia pomonella*) in apple, pear, quince and walnut orchards. The product, which is reportedly safe for humans, bees, and other beneficial insects, was to be distributed by Agrimatco Vilnius in Lithuania and by Agrimatco Latvia in Latvia.
- Nov 11, 2021 The Canadian Pest Management Regulatory Agency (PMRA) approved the registration of the active ingredient *Cydia pomonella* granulovirus isolate V-22 and the bioinsecticide Madex HP, which contains the active ingredient. Certis' Madex HP is targeted

at the control of codling moth and oriental fruit moth on pome and stone fruits and can be used by organic growers and in integrated pest management programs.

• July 11, 2024 the Andermatt Group acquired BioTEPP Inc., a Canadian biological pest control company. Following the acquisition, Andermatt intends to expand the reach of BioTEPP's flagship granulovirus-based biopesticide Virosoft CP4 (*Cydia pomonella* granulosis (CpGV-CP4)). Virosoft CP4 is targeted at the control of codling moth and oriental fruit moth larvae.

Sales of these products have increased significantly in recent years, benefitting from their use in resistance-management programs, growing from an estimated \$14 million in 2018 to \$27 million in 2023, with the market estimated to have increased by an average of 14.8% per annum over this period as a result of new market introductions and increased use in organic production.

Heliothis armigera NPV

Heliothis armigera NPV (Nuclear Polyhedrosis Virus) is a virus specific to the cotton bollworm, one of the most significant pests worldwide due to its high reproductive capacity and ability to feed on a broad range of crops. This pest is particularly important in cotton and fruit and vegetable production. Andermatt is a significant supplier in this arena through its Helicovex product, which was approved in the USA in 2015 and in Canada in 2018.

Sales were estimated at \$50 million in 2023 rising by an average of 17.5% since 2018.

Other Products

As discussed previously, several Baculovirus products are important in this class, while some fungalbased products are important in certain markets.

Spodoptera fruigiperda nucleopolyhedrovirus

Sales were estimated at \$17 million in 2023, representing an increase of 13.3% over 2022.

- January 8, 2020 Australia-based biological pest control company AgBiTech gained approvals for its bioinsecticide Fawligen in Sri Lanka, the Ivory Coast, and Bangladesh in 2020. Their product contains a high concentration of *Spodoptera fruigiperda* nucleopolyhedrovirus (NPV) and is targeted at the control of Fall Armyworm (*Spodoptera frugiperda*) and Beet Armyworm (*Spodoptera exigua*).
- Jan 23, 2020 AgBiTech entered into a distribution agreement with UPL through which UPL will distribute AgBiTech's baculovirus bioinsecticides Fawligen and Heligen in multiple African countries.
- May 18, 2020 AgBiTech has received approval for its baculovirus bioinsecticide Fawligen in Bangladesh.
- Oct 21, 2020 AgBiTech has received approval for its baculovirus bioinsecticide Fawligen in the lvory Coast.
- Jan 8, 2021 The Queensland Department of Agriculture and Fisheries (DAF) in Australia received approval to import the baculovirus bioinsecticide Fawligen for research purposes, in an effort to combat fall armyworm (FAW) populations, under local conditions and in various crops.
- Jan 11, 2021 AgBiTech entered into a distribution agreement with Golden Agri Inputs Limited (GAIL), part of the Flour Mills of Nigeria group, regarding AgBiTech's baculovirus bioinsecticide Fawligen. Under the agreement, GAIL was to become the exclusive distributor of the product in Nigeria.
- Jan 25, 2021 AgBiTech launched its baculovirus-based bioinsecticide Cartugen in Brazil.
- Mar 2, 2021 AgBiTech received approval for its baculovirus bioinsecticide Fawligen in Kenya.
- Jun 23, 2021 Andermatt Biocontrol and the Brazilian agricultural research company Embrapa announced the launch of the biological insecticide Spodovir in Brazil. The product, jointly

developed by both companies through a partnership first established in 2015, is a baculovirusbased insecticide containing a formulation of *Spodoptera fruigiperda* nucleopolyhedrovirus and is targeted at the control of Fall Armyworm (*Spodoptera frugiperda*). Spodovir has been registered in Brazil for use on crops including maize, soybean, sorghum, cotton, rice, vegetables, and pasture.

- Jan 5, 2022 AgBiTech announced that its baculovirus bioinsecticide Fawligen had been registered in Ghana.
- Apr 19, 2022 UPL launched the baculovirus bioinsecticide Fawligen in Ghana and the lvory Coast for use on maize. Fawligen, developed by AgBiTech, contains a high concentrate formulation of *Spodoptera fruigiperda* nucleopolyhedrovirus (NPV) and is targeted at the control of Fall armyworm (*Spodoptera frugiperda*). UPL entered into a distribution agreement with AgBiTech in 2020 to distribute AgBiTech's baculovirus bioinsecticides Fawligen and Heligen in multiple African countries
- May 11, 2022 AgBiTech entered into a distribution agreement with UPL through which UPL's Natural Plant Protection unit (see AgbioNews Jun 29, 2021) was to distribute AgBiTech's baculovirus bioinsecticides Fawligen and Heligen in California, Arizona and Hawaii.
- Dec 9, 2022 Koppert launched the baculovirus bioinsecticide Buick (*Spodoptera fruigiperda* nucleopolyhedrovirus) in Brazil.

Chrysodeixis includens nucleopolyhedrovirus

- 2020 In partnership with the local distributor Glymax, AgBiTech launched its bioinsecticide Surtivo Soy in Paraguay in 2020. The product contains a pre-mix of baculovirus (*Chrysodeixis includens* Nucleopolyhedrovirus isolate #460/*Helicoverpa armigera* Nucleopolyhedrovirus ABA-NPV-U) and is targeted at lepidopteran pests, including cotton bollworm (*Helicoverpa armigera*), corn earworm (*Helicoverpa zea*), tobacco budworm (*Heliothis virescens*), and soybean looper (*Chrysodeixis includens*).
- Jul 29, 2021 Andermatt Biocontrol announced the launch of the biological insecticide Loopovir in Brazil. The product is a baculovirus-based insecticide containing a formulation of Chrysodeixis includens nucleopolyhedrovirus (ChinNPV) and is targeted at the control of the soybean looper (*Chrysodeixis includens*).
- Feb 22, 2023 UPL and the Australia-based biopesticide company AgBiTech expanded their existing distribution partnership in the US. Through the collaboration, UPL's Natural Plant Protection (NPP) business unit will now distribute AgBiTech's entire portfolio of biosolutions in the US, including five nucleopolyhedrovirus (NPV)-based bioinsecticides two of which are based on *Chrysodeixis includens* Nucleopolyhedrovirus:
 - Chrysogen (*Chrysodeixis includens* Nucleopolyhedrovirus isolate #460) intended for the control of resistant soybean looper (*Chrysodeixis includens*) and cabbage looper (*Trichoplusia ni*).
 - Surtivo (*Chrysodeixis includens* Nucleopolyhedrovirus isolate #460 / *Helicoverpa zea* Nucleopolyhedrovirus strain ABANPV-U) for the control of corn earworm (*Helicoverpa zea*), tobacco budworm (*Heliothis virescens*) and soybean looper (*Chrysodeixis includens*).
- Mar 7, 2023 Koppert launched the baculovirus bioinsecticide Diplomata Evo in Brazil, with the product based on *Chrysodeixis includens* nucleopolyhedrovirus and *Helicoverpa armigera* nucleopolyhedrovirus. Diplomata Evo is targeted at the control of soybean looper (*Chrysodeixis includens*) and cotton bollworm (*Helicoverpa armigera*).
- Aug 22, 2024 The Brazilian biologicals company Biotrop has launched the bioinsecticide Biobrev Full (*Bacillus thuringiensis* strain CCTB22 / *Bacillus thuringiensis* strain CCTB25 / *Brevibacillus laterosporus* strain CCT492). The product is targeted at the control of lepidopteran pests including soybean looper (*Chrysodeixis includens*), fall armyworm

(*Spodoptera frugiperda*), and tomato leafminer (*Tuta absoluta*). Biotrop was acquired by Biobest earlier this year (see AgbioNews Jan 8, 2024).

Helicoverpa armigera nucleopolyhedrovirus

- In September 2020, Andermatt Biocontrol's partner in North Macedonia, Magan-Mak, received approval for Andermatt's baculovirus product Helicovex (*Helicoverpa armigera* nucleopolyhedrovirus–HearNPV). This product has been approved in North Macedonia for use in vegetables and field crops to control multiple *Helicoverpa* species.
- Oct 6, 2020 The Australia-based biological pest control company AgBiTech, in partnership with the local distributor Glymax, launched its bioinsecticide Surtivo Soy in Paraguay, representing the company's first product to be launched in the country. The product contains a pre-mix of baculovirus (*Chrysodeixis includens* Nucleopolyhedrovirus isolate #460 / *Helicoverpa armigera* Nucleopolyhedrovirus ABA-NPV-U) targeted at the control of lepidopteran pests, including cotton bollworm (*Helicoverpa armigera*), corn earworm (*Helicoverpa zea*), tobacco budworm (*Heliothis virescens*), and soybean looper (*Chrysodeixis includens*). AgBiTech expects to bring together a portfolio made up of 5 additional products for lepidopteran control in Paraguayan soybeans by the end of 2021.
- Jul 8, 2021 Andermatt Biocontrol's distribution partner Caltech S.A. received registration in Paraguay for the baculovirus product Helicovex (*Helicoverpa armigera* nucleopolyhedrovirus – HearNPV), to be marketed in the country under the trademark Verpavex. The product has been registered for use on a variety of crops for the control of *Helicoverpa spp*.
- Mar 7, 2023 Koppert launched the baculovirus bioinsecticide Diplomata Evo in Brazil, with the product based on *Chrysodeixis includens* nucleopolyhedrovirus and *Helicoverpa armigera* nucleopolyhedrovirus. Diplomata Evo is targeted at the control of soybean looper (*Chrysodeixis includens*) and cotton bollworm (*Helicoverpa armigera*).
- Jun 5, 2023 The European Commission extended the approval periods for several active ingredients due to ongoing delays in the procedure for evaluating the approvals. The approval period is extended to 31st October 2025 for *Helicoverpa armigera* nucleopolyhedrovirus

Regulatory Situation

The regulatory situation for biological pesticides is generally more lenient in most country markets than for conventional chemical products, with the natural origin generally seen as having a more favourable environmental profile. However, the high cost involved in registering a new active ingredient for use has a limiting effect on the ability of many small companies to pursue registration. As a result, we anticipate smaller companies looking to take a position in the biologicals sector in the EU to pursue licensing and distribution agreements, in a similar manner to the approach many R&D led Japanese companies approach the market. As a result, interest from larger companies has seen several acquisitions and licensing agreements related to smaller biological product developers.

As mentioned previously, the EU has recently adopted new rules aimed at simplifying the approval and authorisation process for biological plant protection products which contain microorganisms. Under the new rules, which were effective from November 2022, the regulatory requirements for these products will be primarily based on the biological and ecological properties of each microorganism. It is hoped that this will make the regulatory requirements for microorganisms more fit-for-purpose and flexible, leading to streamlined application dossiers, more straightforward risk assessment, and shorter timelines to gain access to the EU market.

Microbial Insecticides Approved for Use in the EU and USA		
Approved in EU	Approved in USA	
Adoxophyes orana GV		
Bacillus firmus		
Bacillus thuringiensis*	Bacillus thuringiensis*	
Beauveria bassiana*	Beauveria bassiana*	
Chromobacterium subtsugae	Chromobacterium subtsugae	
Cydia pomonella GV	Cydia pomonella GV*	
Helicoverpa armigera NPV	Helicoverpa armigera NPV	
Isaria fumosorosea	Isaria fumosorosea*	
Lecanicillium muscarium		
Metarhizium anisopliae	Metarhizium anisopliae*	
Paecilomyces lilacinus		
Pasteuria nishizawae	Pasteuria nishizawae	
Spodoptera exigua SeMNPV**	Spodoptera exigua NPV*	
Spodoptera littoralis NPV		
	Bacillus popilliae*	
	Helicoverpa zea NPV	
	Lagenidium giganteum	
	Myrothecium verrucaria	
	Nosema locustae	
	Pasteuria usgae	
	Spodoptera frugiperda NPV	

The table below shows the microbial insecticides approved for use in the EU and USA:

Note: Green = approved, red = not approved. Information correct as of May 2025. * Multiple strains. ***Spodoptera exigua multicapsid* nucleopolyhedrovirus (SeMNPV), isolate BV-0004.

Company Involvement

The companies that hold involvement in the biological control market differs from the conventional chemistry-based market significantly. The comparatively low research and development costs involved in new product development have allowed a significant number of small to medium-sized companies to enter the market.

There is also a significant variety of company types, with many choosing to focus on research and development only, then opting to licence-out products to companies with sufficient distribution capabilities. Alternately, several medium and larger-sized companies have opted to build their portfolios through partnerships and acquisition, rather than research and development. For multinationals, BASF is involved through *Bacillus firmus* following its acquisition of the Votivo seed treatment brand from Bayer in 2018; Sumitomo Chemical is an important company for *Bacillus thuringiensis*; whilst Syngenta sells *Pasteuria* spp. for nematode control, gained through the acquisition of Pasteuria BioSciences in 2012.

The following table highlights the key companies marketing key microbial insecticide active ingredients.

Active orinciple	AI	Companies
Bacteria	Bacillis popillae	Rincon-Vitova
	Bacillus amyloliquefaciens	FMC, Bion Tech
	Bacillus sphaericus	Biodalia
	Bacillus subtilis	Varsha
	Bacillus pumilus	Bayer, Varsha
	Bacillus thuringiensis	Varsha, Vita Bee Health
	Bacillus thuringiensis - aizawai	Andermatt, FMC, Mitsui & Co., Sumitomo Chemical, Many Others
	Bacillus thuringiensis - galleriae	Phyllom BioProducts
	Bacillus thuringiensis - israelensis	Ajay Biotech, Amvac, Sumitomo Chemical, Rincon-Vitova
	Bacillus thuringiensis - kurstaki	Sumitomo Chemical, Mitsui & Co., many others
	Bacillus thuringiensis - tenebrionis	De Sangosse, Sumitomo Chemical
	Bacillus thuringiensis - thoworthy	Lallemand
	Bacillus thuringiensis - kurstaki	MaduProfarm (MBI) Sustainable Agriculture (Andermatt)
	Burkholderia rinojensis	Albaugh, PROFARM (MBI)
	Chromobacterium subtsugae	PROFARM (MBI)
	Empedobacter brevis	Point Andina
	Paenibacillus popilliae	Arbico, Rincon-Vitova
	Photorhabdus luminiscens	Nirmal Organo Bio Tech
	Serratia entomophila	Wrightson Seeds
	Streptomyces spp.	Rodonit, Stanes, Veguma
	Wolbachia pipientis	Mosquito Mate
ungi	Beauveria bassiana	Agrivalle, Ballagro, Biocontrol (Nitro), many others
	Beauveria brongniarti	Nitto Denko, Idemitsu Kosan
	Hirsutella thompsonii	Hindustan Antibiotics
	Isaria fumosorosea (formerly Paecilomyces fumosoroseus)	Biobest, Futureco, Koppert, Mitsui & Co.
	Lagenidium giganteum	Bayer
	Lecanicillium lecanii (formerly Verticillium lecanii)	Ballagro, Dudutech (in vivo), Koppert, Stanes, Lage y Cía (lallemand)
	Lecanicillium muscarium	UPL (Arysta), BioSur, Koppert
	Metarhizium anisopliae	Ballagro, Biocontrol (Nitro), Biotech International, Biovalens (Vittia), Earth BioSciences, EcoScience, Farroupilha (Lallemand), Genica (Nitro), ICIPE, Indore Biotech, Itaforte, Koppert, Lallemand, Novozymes, Probioagro, Real IPM (Biobest), Rincon-Vitova, SiProfarm (MBI)ose, Stanes, Terminex, TZ Biotech, UPL, Varsha, Vitta
	Metarhizium anisopliae - acridium	BASF, Biological Control Products, Earth BioSciences, NPP , SGB
	Metarhizium anisopliae – anisopliae	BASF, Bionema
	Metarhizium anisopliae, Beauveria bassiana, Paecilomyces lilacinus	Orus Biotech, Sanagro
	Metarhizium anisopliae, Beauveria bassiana and Isaria fumosorosea	Agrobionsa

Metarhizium brunneum	Futureco
Metarhizium flavoviride	Becker Underwood
Metarhizium rileyi	Andermatt
Nosema locustae	Beneficial Insect Company, Biocontrol Network, M&R Durango, Rincon-Vitova
Paecilomyces fumosoroseus (Isaria fumosorosea)	Agri Life, Agrobionsa, Bio Best, Futureco, GAP Del Peru, Mitsui & Co., Natural Industries, Sipcam, SOLAGRO (Soluciones Agrosostenibles), Stanes, Sumitomo Chemical, UPL
Pochonia-chlamydosporia	Rizoflora
Verticillium lecanii (Lecanicillium lecanii)	Agri Life, Agrobionsa, Arysta, Biotech International, Indore Biotech, Koppert, Stanes, UPL, Varsha

Active principle	AI	Companies
Virus	Adoxophyes orana GV	Andermatt, Arysta, CBC , Intrachem, Biogard
	Agrotis segutum GV	Open Natur
	Anagrapha falcifera	Mitsui & Co. (Certis)
	Andraca bipunctata GV	Unknown
	Anticarsia gemmatalis	Agroggen S/A Bio Ag
	Anticarsia gemmatalis	AgBiTech, Nitral Urbana
	Autographa californica NPV	AgBiTech, Agricola El Sol, Andermatt, Mitsui & Co. (Certis)
	Chrysodeixis includens NPV	AgBiTech
	Chrysodeixis includens NPV,	AgBiTech
	Helicoverpa armigera NPV	Agoirech
	Chrysodeixis includens	Andermatt
	nucleopolyhedrovirus	Andermatt
	Codling moth granulosis virus	Agrichem Bio (Rovensa)
	Cryptophlebia leucotreta Npv	MaduProfarm (MBI) Sustainable Agriculture (Andermatt)
	Cryptophlebia leucotreta granulovirus	Andermatt
	Cydia pomonella granulosis	Agrichem Bio (Rovensa), ALSSAS, Anasac, Andermatt, Arysta, Bayer, Biobest, Biosani,
	virus	BioTEPP, CBC , Mitsui & Co. (Certis), Colin Campbell Chemicals, Fargro, INTA, Intrachem,
	Virus	Natural plant protection, NPO Vector, Rincon-Vitova, Serbios, Sumitomo Chemical, UPL
	<i>Cydia pomonella</i> Granulovirus	Gowan (Spain)
	<i>Cydia pomonella</i> granulovirus	Andermatt, MaduProfarm (MBI) Sustainable Agriculture (Andermatt)
	Dendrolimus punctatus cytoplasmic polyhedrovirus	Unknown
	Ectropis obligua	Unknown
	Helicovepa armigera NPV	AgBiTech, Agri Life, Agrichem Bio (Rovensa), Ajay Biotech, Andermatt, ArgiCheProfarm (MBI)o, Arya BioTech, Bio Pest Control Industries, Bio-control Laboratory, Biotech Industries, Biotech International, CBC , Mitsui & Co. (Certis), Chitra Agri Organics, Department of Agriculture, Farmagro, FMC, Ganesh Bio Control Systems, Gujarat Chemicals and Fertilisers Trading, Haarit Bio Control, Hari Agri-Tech, Indore Biotech, J.R. Biocontrol Laboratories, Jyothiraditya Bio Solutions, K.S.N. Bio. Tech, Kalapavruksha Biosystems, Keyun Biocontrol, Krishi Vikas Sahakari Samiti, MaduProfarm (MBI) Sustainable Agriculture (Andermatt), Margo Biocontrols, Microplex, Multiflex Biotech, Nufarm, Om Agro Organic, Pest Control (India), Rincon-Vitova, Sai Agrotech, Sipcam, Sugway Agri Biotech and Research Foundation, Vaibhav Laxmi Bio Control, Vector Control, Vidarbha Biotech
	Helicoverpa armigera NPV	Dudutech (in vivo), Koppert
	Helicoverpa zea NPV	CCAB (in vivo)
	Laphygma exigua NPV	Unknown
	Lymantria dispar multiple NPV	Andermatt, Sylvar Technologies, USDA Forest Service
	Mamestra brassicae NPV	Arysta, BioTEPP, NPO Vector, NPP
	Mamestra configurata NPV	BioTEPP
	Neodiprion abietis NPV	Andermatt, Sylvar Technologies
	Neodiprion sertifer/N. lecontei NPV	Canadian Forestry Service, Oxford Virology, Sylvar Technologies, USDA Forest Service, Verdera (Lallemand)
	Orygia pseudotsugata NPV	USDA Forest Service
	Phthorimaea operculella granulovirus	Andermatt
	Pieris rapae granulosis virus	Unknown
	Plodia interpunctella granulosis virus	AgriVir
	Plutella xylostella granulosis virus	Keyun Biocontrol
	Spodoptera exigua NPV	Agrichem Bio (Rovensa), Andermatt, Applied Chemicals (Thailand), Bicolor SL, Brinkman, Mitsui & Co. (Certis), Keyun Biocontrol, Rincon-Vitova
	Spodoptera falcifera NPV	Prophyta (Bayer),

Spodoptera frugiperda NPV	AgBiTech, Andermatt, Bioma Indústria Comércio e Distribuição - EIRELI, Mitsui & Co. (Certis), Grupo Vitae, Promip Manejo Integrado de Pragas, SiProfarm (MBI)ose
Spodoptera littoralis NPV	Agri Life, Agrichem Bio (Rovensa), Ajay Biotech, Andermatt, CBC, Indore Biotech
Spodoptera litura NPV	Agri Life, Biotech International

In 2020 American Vanguard acquired the biological crop inputs provider Agrinos. This acquisition came as part of the company's strategic objective to expand its global presence in the biological crop inputs market, particularly for products that contribute to improving soil health. Agrinos' intellectual property includes nearly 50 patents issued and nearly 100 pending worldwide.

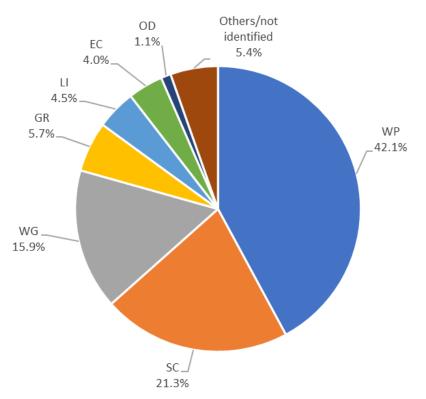
American Vanguard, based in Davis, California, currently operates two manufacturing facilities: a microbial input manufacturing facility in Oregon and a biostimulant manufacturing facility in Mexico.

Along with recent M&A activity, several companies have entered into collaborations aimed at enhancing their operations. These include an alliance between Invaio Sciences and the University of California (UC-Riverside)—centred on a licence agreement for a novel technology developed at the university—and a partnership between AlgaEnergy and Concentric Ag Corporation. As part of the latter agreement, AlgaEnergy became the exclusive global distributor of Concentric's microbial product Synergro and its cell-free microbial metabolite product Synergro M2.

Other partnerships include NewLeaf Symbiotics forming an alliance with the digital agriculture company IN10T to test its M-troph microbial product line, Terrasym, with farmers. As part of this collaboration, NewLeaf will utilise IN10T's FarmerTrials Network to analyse the Terrasym product line's impact on root development, plant health, yield, and other agronomic benefits in maize and soybeans.

Formulation Types – Value Share

The below chart(s) are derived from the biological focussed market research that AgbioInvestor conducted, and illustrates the value share attributed to various formulation type codes.



Code	Description	Code	Description
AE	Aerosol dispenser	LI	Liquid
AL	Other liquids to be applied undiluted	LS	Solution for seed treatment
СВ	Bait concentrate	ME	Micro emulsion
CS	Capsule suspension	OD	Oil dispersion
DC	Dispersible concentrate	SC	Suspension concentrate
DF	Dry flowable	SL	Soluble concentrate
DP	Dustable powder	SP	Water soluble powder
EC	Emulsifiable concentrate	VP	Vapour releasing product
EW	Emulsion, water in oil	WG	Water dispersible granule
FS	Flowable concentrate for seed treatment	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment
LC	Liquid concentrate		

Research and Development

The research and development of new microbial insecticides centres around the discovery of new fungi, bacteria, and viruses that show insecticidal activity, along with the development of new strains of existing organisms that have improved efficacy or the improvement of formulations to increase efficacy in the field and usability for growers.

Indigo and Anheuser-Busch

Indigo and Anheuser-Busch, the largest end-user of rice in the US, extended their partnership through the 2020 growing season to provide additional digital and technological support for growers. This partnership aims to reduce water use, nitrogen use, and greenhouse gas emissions in rice cultivation. Growers who utilised Indigo's portfolio of solutions through the partnership, including microbial products and agronomic support, in the production of rice for Anheuser-Busch reportedly achieved water-use and nitrogen efficiencies, as well as reductions in emissions.

Vive Crop Protection and A&L Biologicals

Vive Crop Protection and A&L Biologicals, a subsidiary of A&L Canada Laboratories, formed a collaboration for developing new biopesticide products using Vive's Allosperse nanotechnology delivery system and A&L's novel microbial-based biopesticide technologies. Their collaboration is part of a Sustainable Development Technology Canada (SDTC) project entitled 'Targeted Delivery of Biopesticides'. SDTC is an independent federal foundation that helps Canadian companies develop and deploy competitive clean technology solutions to help solve some of the world's most pressing environmental challenges: climate change, clean air, clean water, and clean soil.

AlgaEnergy and Concentric Ag

AlgaEnergy entered into a two-part partnership agreement with the microbial and plant nutrition crop inputs developer Concentric Ag Corporation, with part of the collaboration aimed at developing a new biological product through the combination of Concentric's microbial technologies and AlgaEnergy's proprietary microalgae technologies.

Lavie Bio

In addition to these partnerships, Lavie Bio, the ag-biologicals subsidiary of Evogene, announced in October 2020 a positive trial result for two of its leading biofungicide candidates: LAV311 and LAV312. These products, which were tested for the control of bunch rot diseases in vineyards located in target locations in Europe and the US, reportedly demonstrated significantly better efficacy and consistency than existing comparable commercial biological benchmarks and were competitive with commercial chemical benchmarks. Following successful trials, both products will enter Development Stage 2, aimed at further advancing their formulation and fermentation and broadening their spectrum of target crops and diseases. Both LAV311 and LAV312 were developed by utilising the company's Biology Driven Design platform, which is intended to provide an optimised combination of live microbial strains, formulations, and fermentation technologies.

Valent BioSciences

Other developments include the creation of a new biologicals research unit in Japan by Sumitomo Chemical's subsidiary, Valent BioSciences, at Sumitomo's Health & Crop Sciences Research Laboratory (HCRL) in Takarazuka, Hyogo, Japan. The new Biorational Research Unit will initially focus on biopesticide discovery, field application of plant growth regulators (PGRs) in Japan, and various projects related to arbuscular mycorrhizal fungi (AMF).

Sumitomo Chemical recently realigned its subsidiaries, including Valent BioSciences, to strengthen its biorational business, which encompasses products and microbes derived from natural sources, as well as natural products themselves, such as microbial pesticides, plant growth regulators, and microbes for soil health.

Nihon Nohyaku

Jun 15, 2023 Nihon Nohyaku entered a joint-development agreement with the microbial product developer Boost Biomes to develop novel bioinsecticides. The agreement aimed to leverage Boost's proprietary technology platform, which uses high-throughput DNA sequencing, selective enrichment and informatics to identify products with key commercial applications.

Amvac

Nov 7, 2023 American Vanguard Corporation, through its wholly-owned subsidiary Amvac Chemical Corporation, expanded its North American partnership with NewLeaf Symbiotics. Under the expanded partnership, which now includes distribution in Argentina, Brazil, Ukraine, and China, both companies will collaborate to develop and bring to market biological crop solutions. Amvac will leverage its international market access and sales teams in Latin America and Ukraine, whilst NewLeaf will provide its proprietary microbial library, R&D capabilities, and current product offerings, including naturally occurring microbes. The extended partnership is intended to help accelerate the expansion of Amvac's GreenSolutions biologicals portfolio and enable NewLeaf to secure wider market penetration for its pink-pigmented facultative methylotroph (PPFM) technology.

NewLeaf Symbiotics

Dec 20, 2023 NewLeaf Symbiotics raised \$45 million in a Series D funding round led by new investor Gullspång Re:food with participation from Otter Capital Partners LP, S2G Ventures, Leaps by Bayer and others. NewLeaf intends to use the funding to accelerate its efforts with its pink-pigmented facultative methylotroph (PPFM) technology and adjacent technologies in the areas of biostimulants and microbial inoculants, biocontrol, nitrogen use efficiency and methane mitigation. Its plans for 2024 include a new EPA-registered biopesticide technology that is reported to repel corn rootworm in

maize, new biostimulant technologies for peanut and cotton, and continued research and development around rice yield, nitrogen efficiency and methane reduction impact.

Andermatt

May 9, 2024 Andermatt entered into a partnership with the distribution company Key Industries to test the regulatory pathway for novel biopesticides in New Zealand. Through the project, Andermatt's bioinsecticide Plutex (*Plutella xylostella* granulovirus) will be taken through the regulatory pathway. Launched in 2023, Plutex is targeted at the control of diamondback moth (*Plutella xylostella*) and has undergone field trials in crops such as cabbage, cauliflower and canola.

FMC

May 10, 2024 FMC entered into a research collaboration with AgroSpheres, a developer of biodegradable microencapsulation technologies suited for biological pesticides. The collaboration intends to accelerate the discovery and development of novel bioinsecticides, leveraging AgroSpheres' expertise in RNAi biomolecules, including its patented AgriCell manufacturing technology, and FMC's high throughput testing, evaluation, and commercialisation capabilities.

FMC Ventures invested in AgroSpheres in 2023 in their Series B funding round to improve the delivery, stability, and efficacy of biopesticides based on RNA interference technology.

Isomerase

Jan 29, 2025 Isomerase, a UK-based synthetic biology company, formed a strategic partnership with the biological pest control solutions developer BugBiome, focused on the discovery of novel targeted bioinsecticides via insect behavioural screening. As part of the partnership, BugBiome will gain non-exclusive research access to Isomerase's collection of approximately 7,000 proprietary actinomycete strains. These strains are reported to have demonstrated a range of activity, including cytostatic, enzyme inhibition, and virus inhibition. BugBiome will then utilise its AvidX insect behavioural screening platform to evaluate the actinomycete strains to identify actives that effectively deter important crop pests while protecting beneficial organisms and minimising environmental impact. In addition, BugBiome has the option to secure exclusive commercial rights to strains of particular interest.

Market Outlook

The biological sector is a fast-paced growth market. As a result, increased organic production, in part driven by large-scale regulatory shifts in key growing regions (notably Farm to Fork in the EU), offers strong future development potential for any product that can demonstrate a good level of efficacy. The sector does, however, suffer from intense competition that can exert downward pressure on profitability. Larger multi-nationals looking to move into a new market will often find a significant number of regional or country market players already present in that market, thus creating challenging conditions for product development in key markets.

The recent decision by the EU to adopt new rules to simplify the approval and authorisation process for microorganism-based biological plant protection products is expected to encourage the development and introduction of new products in the region, to the benefit of the overall biological crop protection market.

The growth potential in the biological pest control sector is reflected by continued investment, with significant funding recently being secured. NewLeaf Symbiotics received a \$45 million investment to advance its pink-pigmented facultative methylotroph (PPFM) technologies, and successfully launched its PPFM TS201 solution, aimed at corn rootworm control in 2024. Meanwhile, BioConsortia raised

\$15 million to support the development of its microbial products, including solutions aimed at controlling nematodes and soil insect pests.

The microbial market represents the largest sector within the 'pure' biologicals industry, with a significant amount of growth derived from a smaller number of very large products, notably *Bacillus firmus* and *Bacillus thuringiensis*. These older technologies continue to dominate the sector, with *Bacillus firmus* expected to continue achieving solid growth in coming years through the inclusion of the product in seed treatments and uptake in key markets such as Brazil.

It should also be noted that in the insecticide segment, there are several new conventional chemistries that have been brought to market, many of which will compete with bioinsecticide uptake, due to their often-new mode of action, lower resistance factors, competitive cost with microbials, broad spectrum of activity, often rapid activity, stable shelf/formulation life and lower use rates compared to older chemistries. Good examples include some of the newer generation diamide insecticides such as tetraniliprole from Bayer and broflanilide from Mitsui Chemicals Agro/BASF, the latter of which comes from an entirely novel mode of action classification. One such opportunity, however, is for microbials to be offered in hybrid bio/conventional mixtures, lessening the competitive impacts, however it can still be expected that there will be significant opportunities for both bioinsecticides as well as newer conventional insecticides.

With consumer and regulatory habits continuing to shift, as well as the emergence of new target pests in various geographies, it seems inevitable that the microbial sector will continue to experience a pullthrough effect from these shifts. As such, the value potential for larger or more research and development-focused companies will continue to grow. New defining technologies, including advanced formulations or hybrid mixtures involving a biological and conventional mix, seems a likely area where companies will seek to differentiate themselves in such a crowded market, while economies of scale and established distribution capabilities will aid large to multi-national sized companies.

As mentioned above, another area where growth potential exists is through shifts in pest pressure, with the persistence of Fall armyworm throughout Africa and Asia Pacific offering a potential outlet for companies that have a bioinsecticide solution in place. Fall armyworm is a significant pest, and its identification in these markets is likely to stimulate significant increases in insecticide use as farmers seek to minimise the pests' impact on crops.

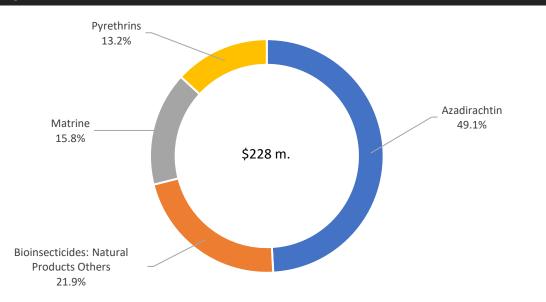
The sector does, however, face challenges to future market growth, notably through the increased incidences of B.t. resistance in key pests; a factor that holds the potential to limit growth to a degree.

As a result of the above factors, we expect the market for microbial bioinsecticides to increase at an average annual rate of 8.2% per annum between 2023 and 2028, significantly ahead of the overall insecticides market, which is anticipated to see average growth of 2.4% p.a. in the same timeframe.

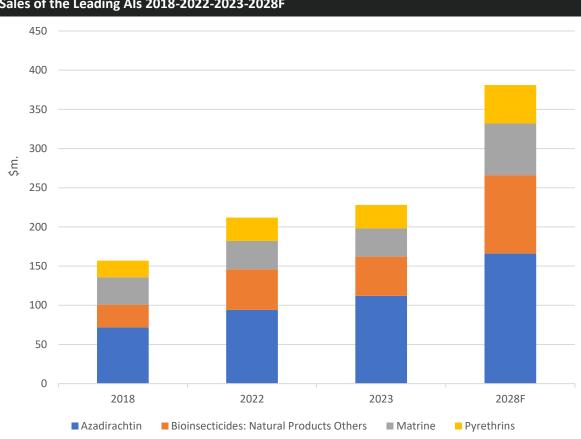
Bioinsecticides: Natural Products

Sales Performance of Natural Product Insecticides				
Year	Natural Product Insecticide Sales (\$ m.)	Total Insecticide Sales (\$ m.)	Natural Product Insecticides Share of Bioinsecticides (%)	Natural Product Insecticides Share of Total Insecticides (%)
2018	157	16,796	19.34	0.93
2022	212	21,566	17.32	0.98
2023	228	21,737	17.34	1.05
2028F	381	24,446	17.70	1.56
1-yr Change (%)	7.5	0.8		
5-yr CAGR (% p.a.)	7.7	5.3		
5-yr CAGR F (% p.a.)	10.8	2.4		





Leading Bioinsecticides: Natural Products						
AI	YOI	Timing	Main Crops	Rate (Kg/Ha)	Sales 2023 (\$ m.)	Sales 2028F (\$ m.)
Azadirachtin	1968	Foliar, Soil	Rice, Cotton, Pome fruit, F&V	0.03 - 0.05	112	166
Matrine	-	Foliar	F&V, Rice, Pome fruit		36	66
Pyrethrins	-	Foliar	F&V, Vine, Pome Fruit		30	49



Sales of the Leading Als 2018-2022-2023-2028F

Introduction

Natural-product insecticides are naturally derived compounds with demonstrated activity against arthropod pests, such as insects and mites, nematodes, or molluscs. The majority of products in this class are plant extracts, animal extracts, naturally occurring proteins, or natural oils. Azadirachtin, which is derived from seeds of the neem plant (*Azadirachta indica*) is a significant product in this class, along with neem oil. Many plant-derived products have reached the market, such as extracts of thyme and nettle, and oils from mint, soybean, orange and sesame. The nematicide matrine, which is derived from the traditional Chinese medicinal herb *Sophora flavescens*, and Chrysanthemum-derived pyrethrum are moderately commercially significant. Natural acids and proteins, terpenes, and naturally occurring sodium- and potassium-based products with insecticidal activity have also been developed. Most natural-product insecticides have their primary application in diverse fruit and vegetable markets, with their perceived safety and 'natural' origin making them a strong fit for organic production. Sales in this class have been estimated at \$228 million in 2023 representing a rise of 7.5% over the previous year. In the longer term since 2018 sales of the segment have increased by an average of 7.7%. Real terms forecasts for the segment are growth of an average of 10.8% per annum to 2028.

Products

Azadirachtin

Azadirachtin is a tetranortriterpenoid limonoid derived from seeds of the neem plant (*Azadirachta indica*); it was first isolated from neem seeds in 1968. Azadirachtin displays broad-spectrum insecticidal activity through multiple modes of action, such as insect growth regulation, impacts on sterility, and disruption of cellular processes, while also exerting antifeedant activity in a range of pests. Its key markets are Spain, India, the USA, France, and Italy, where it is used on fruits and vegetables, cotton, vines, and pome and stone fruit. A significant manufacturing base exists in India for azadirachtin, as well as for neem oil, which contains the active ingredient.

- In 2018, Coromandel International acquired EID Parry's biological pesticides business, including the company's US-based subsidiary Parry America, for ₹3,380 million (approximately \$53 million). EID Parry is active in the manufacture and sale of neem oil-based azadirachtin insecticides, biostimulants, micronutrients, and microbials; it operates an R&D facility and an azadirachtin manufacturing facility in Tamil Nadu. Coromandel expects this acquisition to provide access to the US and European crop protection markets, with its Parry America business active in sourcing technical azadirachtin from Indian companies for formulations that are then sold across North and South America.
- Oct 3, 2019 Terramera received approval in California for its OMRI-listed biological insecticide / fungicide Rango (cold pressed neem oil). Rango is approved for the control of insects, mites, nematodes and a range of fungal diseases in a range of crops including bulb and fruiting vegetables, cucurbits, legumes, berries, pome fruit, citrus, tree nuts, cereals and grains and forage crops. The product was launched in other regions of the USA in 2018.
- Apr 18, 2023 Terramera launched the biological insecticide/fungicide Socoro (cold-pressed neem oil) in the US. The product, which gained US approval in March 2023, is registered for the control of foliar and soil insects and fungal diseases in cereal grains, maize, cotton, forage, legumes, peanuts, potato, oilseed crops, soybeans and other row crops. Socoro can be applied in-furrow or foliar and is labelled for use as a standalone product, a tank mix partner or in a program rotation.

- Dec 8, 2023 Terramera received approval in Mexico for its biological insecticide / fungicide Trifecto, for use on F&V in both organic and conventional farming. The product, which contains 70% cold pressed neem oil, is intended for the control of insects, mites, and diseases. Trifecto is labelled for use as a standalone, a tank mix partner, or in a program rotation.
- Oct 8, 2024 Rovensa Next registered its bioinsecticide product Kuneka (Karanja oil and Neem extract) in Perú. The product is registered for use on avocado, mandarin, and vines to control various insect pests.

Certis USA, Gowan, and Sipcam Oxon are some of the leading marketing companies in this sector.

- In 2018, Certis USA completed the construction and start-up of a new facility for formulating and packaging azadirachtin at its factory in Wasco, California. The new facility expanded the company's capacity to produce the azadirachtin bioinsecticide Neemix 4.5.
- Aug 12, 2022 the biological crop protection company Trifolio-M acquired a 10% stake in Andermatt Romania, a subsidiary of Andermatt Group. The share acquisition supported the introduction of Trifolio-M's NeemAzal-T/S (azadirachtin) in the Romanian market. NeemAzal T/S is targeted at the control of sucking and chewing pests such as aphids, whiteflies and thrips in potatoes, vegetables, tree fruits, berries, vines and ornamentals.
- Mar 20, 2023 Syngenta launched Bemotius (azadirachtin) in Italy for use on apple trees, citrus fruits, vines, strawberries, floral/ornamental and numerous horticultural crops, and is targeted at the control of aphids, scale insects, whiteflies, leaf miners, thrips and flies, Colorado potato beetle, and lepidopteran larvae.
- Mar 28, 2024 Lithos Crop Protect, an Austrian start-up company involved in the development, approval and marketing of biological crop protection agents and biostimulants, launched the bioinsecticide Aza (azadirachtin) in Austria. The product is targeted at the control of pests such as the Colorado potato beetle, aphids, whiteflies and thrips in tomatoes.
- May 21, 2024 The European Commission extended the approval periods for 16 active ingredients due to ongoing delays in the procedure for evaluating the approvals. The approval period was extended to 31 January 2027 for azadirachtin.

Sales of azadirachtin have increased significantly in recent years to an estimated \$112 million in 2023, with its broad spectrum of insect control and multiple modes of action driving its use in resistance-management programs.

Matrine

Matrine, an alkaloid derived from the traditional Chinese medicinal herb *Sophora flavescens*, is used as a nematicide, insecticide, and miticide in a range of crops. Chinese manufacturers are the dominant suppliers, with sales estimated at roughly \$36 million in 2023 – flat over 2022.

 Aug 25, 2021 Avgust launched the insecticide MatrinBio (matrine) in Russia, representing the company's first biological product in the country. The product's active ingredient is an alkaloid extracted from plants of the genus Sophora. MatrinBio is targeted at the control of a wide range of pests, including spider mite, whitefly, aphids, thrips and bed bugs in the indoor and outdoor production of tomato, cucumber, rose, soybean and vine.

Pyrethrins

Pyrethrins are derived from *Chrysanthemum cinerariifolium*, which also forms the basis of the pyrethroid insecticides (synthetic analogues of pyrethrin). Sales of pyrethrins for crop protection were

estimated at \$30 million in 2023, with Sumitomo Chemical being a leading supplier, having added to its business by acquiring the Australian company Botanical Resources Australia in late 2017.

- Apr 5, 2019 Biological pest and disease control company Biobest launched the bioinsecticide Spyro (pyrethrins / piperonyl butoxide) in the Netherlands. Spyro has been authorised for use on tomato, cucumber, pepper, eggplant and courgette, with the registration being held by the manufacturer PelGar International.
- In 2023 the Canadian Pest Management Regulatory Agency (PMRA) made a re-evaluation decision regarding pyrethrins, determining that continued registration of most uses of pyrethrins is acceptable, with additional risk mitigation measures. The risk mitigation measures focus on risks to human health and environmental impacts. Some of the key updated mitigations include:
 - Increased personal protective equipment (PPE)
 - Limit on the amount of active ingredient handled per day for commercial-class products
 - o A 2-hour re-entry interval after indoor residential applications
 - Precautionary statements to protect pollinators and the environment
 - Spray buffer zones
- Dec 6, 2023 Rovensa Next, Rovensa Group's global biosolutions business, announced the launch of Tec-Fort (pyrethrins derived from *Tanacetum cinerariifolium sin. Chrysanthemum cinerariaefolium Vis*) in Peru, reportedly representing the first pyrethrin-based bioinsecticide in the country. The product, which provides broad-spectrum control of a range of pests including thrips, whiteflies and budworm, works by contact and ingestion, disrupting neural transmissions once inside the pest. In addition, Tec-Fort is formulated using the company's Promicell Technology, which is designed to enhance product stability in the field, combining the pyrethrins with antioxidants, adjuvants and other natural co-formulants. The pyrethrins are encapsulated inside lipidic capsules called micelles, which protect the pyrethrins from rapid degradation by ultraviolet rays.
- Jun 24, 2024 Syngenta launched the bioinsecticide Pyerevert (pyrethrin derived from *Chrysanthemum cinerariaefolium*) in Spain for use on a range of fruit and vegetable crops. The product is targeted at the control of a range of pests including aphids (*Aphidoidea* spp), whiteflies (*Aleyrodidae* spp), thrips (*Thysanoptera* spp), leafhoppers (*Cicadellidae* spp) and bunch moths (*Tirathaba mundella*).
- Oct 8, 2024 Rovensa Next received product registration for its biological insecticide product Santem (pyrethrin extracts) in Colombia. The product is targeted for use on various fruit tree crops, including banana, lemon, and orange, for the control of thrips and aphids.
- Nov 21, 2024 The biological crop protection company Seipasa received a label extension for its bioinsecticide Pirecris (pyrethrins) in Spain, with the product now also approved for use on pome and stone fruit trees, berries and persimmon. Pirecris is targeted at the control of aphids, whitefly and *Cicadellidae* (leafhoppers).
- Apr 9, 2025 Seipasa received a further label extension in Spain for the bioinsecticide Pirecris (pyrethrins), with the product now approved for use on citrus fruits, nut trees (almond, hazelnut, walnut, pistachio and chestnut), cherry and plum trees. Pirecris is targeted at the control of aphids, whitefly, *Cicadellidae* (leafhoppers) and spotted vinegar fly (*Drosophila suzukii*).

Regulatory Situation

As with microbial products, the regulatory situation is generally favourable for insecticides in the natural products class. The table below summarises the natural-product insecticides approved for crop protection in the EU and USA.

In the USA the EPA classifies biopesticides as 'reduced-risk pesticides' and as such they qualify for fast-track registration.

In the EU a plant extract pesticide is defined as a 'botanical active substance' which consists of:

"...one or more components found in plants and obtained by subjecting plants or parts of plants of the same species to a process such as pressing, milling, crushing, distillation and/or extractions. The process may include further concentration, purification and/or blending, provided that the chemical nature of the components is not intentionally modified/altered by chemical and/or microbial processes."

Botanical active substances have to be approved under Regulation (EC) No 1107/2009 and a dossier has to be compiled according to the data requirements as laid down in Regulation (EU) No 283/2013 (active substance) and Regulation (EU) No 284/2013 (plant protection product). Therefore, unlike microbial pesticides where there are some reduced requirements/provisions, plant extracts are subject to the same process as that of the conventional pesticides.

Natural Product Insecticides Approved in the USA and EU		
EU	USA	
Azadirachtin (<i>Margosa</i> extract)	Azadirachtin	
Fatty acids C7-C18 and C18 unsaturated potassium salts	Fatty acids***	
Kaolin	Kaolin	
Pyrethrins	Pyrethrins	
Tagetes oil	Tagetes oil	
Thyme oil	Thyme herbs	
Capric acid	Capric acid	
Caprylic acid	Caprylic acid	
Carbon dioxide	Carbon dioxide	
Hydrolysed proteins		
Maltodextrin		
Oleic acid	Oleic acid	
Orange oil	Orange oil (Limonene)	
Sodium chloride	Sodium chloride	
Terpenoid blend QRD-460		
	Capsaicin	
	Chenopodium ambrosioides var. ambrosioides	
GS-omega/kappa-Hxtx-Hv1a (spider venom peptides)	GS-omega/kappa-Hxtx-Hv1a (spider venom peptides)	
	Iron Phosphate	
Methoprene	Methoprene*	

Mint oil	Mint oil
	Neem Oil*
Potassium silicate	Potassium Silicate
	Quillaja saponaria saponins
	Sesame*
	Sodium Ferric EDTA
	Sorbitol octanoate
Soybean oil	Soybean oil

Note: Green = approved, orange = pending approval, * = multiple related products. Information is correct as of May 2025. Purple = registration review ***Some under registration review, some re-registration

Company Involvement

Many of the registered natural-product active ingredients in the USA have limited commercial significance for very niche applications. Consequently, they are often supplied by small companies with relatively limited marketing capacity and reach. Gowan, Certis, Bayer, and Sumitomo Chemical are larger companies involved in this class, with Gowan supplying products based on azadirachtin, capsaicin, and fatty acids, and Bayer having acquired AgraQuest. Bayer also distributes fatty acids (marketed as Flipper) to control sucking pests in Europe, with the company having gained the license from the UK biological crop protection company Alpha Biocontrol.

As with other biological products, there are a wide number of companies with involvement in the natural products segment. Although the majority of these companies are small and medium-sized players, generally with a focus on regional activities, there are several large companies with involvement in the sector.

Bayer, through its Biagro business, has a relatively significant number of natural products within its biological portfolio, as does Sumitomo Chemical through its Valent and MGK subsidiaries, whilst Syngenta also commands a strong market position.

Several significant medium-sized regional players have also taken a position in the sector, including Rovensa, Certis (Mitsui & Co), Marrone Bio Innovations (now part of Bioceres as ProFarm) and the US-based company, Gowan.

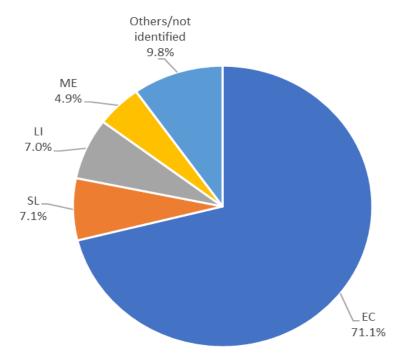
Al Azadirachtin	Key Companies Certis, Rallis, Sipcam, many
	Certis Ballis Sincam many
	certis, Railis, Sipearit, marty
Capsaicin	Soil Technologies
Chenopodium ambrosioides var. ambrosioides	Bayer, Rovensa
GS-omega/kappa-Hxtx-Hv1a (spider venom peptides)	Brandt, Vesteron
Hydrolysed proteins	Adama, Bioiberica, Gowan
Maltodextrin	Certis
Matrine	Adama, Chinese companies, many
Mint oil	Brandt, EcoMight, Vegalab
Neem Oil	Brandt (Monterey Lawn & Garden)
Nettle extract (<i>Urtica</i> spp.)	Chemie
Orange oil	Rovensa
Pyrethrins	Copyr, Rovensa, Sumitomo Chemical, many

Quillaja saponaria saponins	Botanical Solutions, Natural Response
Sesame*	Brandt
Soybean oil	Cretis, Drexel, Xeda
Tagetes oil	PI Bioscience
Terpenoid blend QRD-460	Bayer
Thyme Oil	Agro Micro Biotech, Botano Health, Laboratoire M2
Thyme Oil	Agro Micro Biotech, Botano Health, Laboratoire M2

* Multiple analogous products.

Formulation Types – Value Share

The below chart(s) are derived from the biological focussed market research that AgbioInvestor conducted, and illustrates the value share attributed to various formulation type codes.



Code	Description	Code	Description
AE	Aerosol dispenser	LI	Liquid
AL	Other liquids to be applied undiluted	LS	Solution for seed treatment
СВ	Bait concentrate	ME	Micro emulsion
CS	Capsule suspension	OD	Oil dispersion
DC	Dispersible concentrate	SC	Suspension concentrate
DF	Dry flowable	SL	Soluble concentrate
DP	Dustable powder	SP	Water soluble powder
EC	Emulsifiable concentrate	VP	Vapour releasing product
EW	Emulsion, water in oil	WG	Water dispersible granule
FS	Flowable concentrate for seed treatment	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment
LC	Liquid concentrate		

Research and Development

Extracts of certain plants do have insecticidal activity; however, it is rare that an active ingredient that is highly efficacious, active through multiple modes of action, and has a very broad spectrum of activity, is derived from this route.

Formulation development to increase efficacy or enable greater product stability is also an important area of research; for example, Seipasa developed Pirecris, a patented formulation of pyrethrum which replaces the synergist piperonyl butoxide with a natural compound that inhibits the degradation of pyrethrin molecules.

Research and development within the natural product segment is primarily achieved through a wide number of small companies, as shown in the 'key companies' table above. There are, however, more companies at the larger end of the market taking a position in the sector, notably Sumitomo Chemical, Adama, Bayer, and Rovensa.

Research and development of natural-product insecticides is generally performed by small companies, as illustrated in the 'Key Companies' table above. While extracts of certain plants do have insecticidal activity, it is rare that an active ingredient is highly efficacious, active through multiple modes of action, and broad-spectrum—as well as a natural product. Research continues nonetheless, driven by the need for new biological products to replace older technologies. For example, Vesteron developed a novel, natural insecticidal active ingredient based on spider venom. Formulation development to increase efficacy or enable greater product stability is another important area of research. For example, Seipasa has developed Pirecris, a patented formulation of pyrethrum that replaces the synergist piperonyl butoxide with a natural compound that inhibits the degradation of pyrethrin molecules.

- Apr 7, 2021 Vestaron submitted its new bioinsecticide Basin for US EPA approval. Basin contains a new peptide-based active ingredient which is active on the nicotinic acetylcholine receptor (nAChR), similar to the previously approved Spear. The product provides activity at a distinct site, allowing it to be added to integrated pest management programs. Vestaron expects Basin to provide a zero-day pre-harvest interval and be maximum residue limit exempt, whilst offering an alternative to synthetic chemistries for use in fruit, nuts and other high value field crops targeting lepidopteran pests.
- Jun 21, 2021 IBI-Ag, which is focused on the development of a new class of bioinsecticides, completed an investment round for the optimisation of its first product and expansion of the product portfolio spectrum. Investors in the round included the Bayer Trendlines Ag Innovation Fund, set up by Bayer Crop Science and the innovation commercialisation company Trendlines; Agriline; and the Trendlines Group.
- IBI-Ag focuses on the development of natural, single domain antibody insecticides aimed at increasing crop production whilst minimising harm to farmers, consumers, and the environment. Single domain antibodies have the potential to act as a novel type of active ingredient due to their small size, stability, high-affinity, high-specificity, ease of manipulation and production.
- May 24, 2023 The Brazilian agricultural biotechnology company Sempre AgTech has developed a bioinsecticide based on double-stranded RNA (dsRNA), classified as non-GM by the Brazilian biosafety regulatory agency CTNBio. The sprayable bioinsecticide is targeted at the control of brown stink bugs (*Euschistus heros*) and green-belly stink bugs (*Diceraeus melacanthus*). Sempre AgTech expects to commercialise products based on this technology from 2026.

- Jun 29, 2023 The Australian agtech company Bio-Gene Technology was granted a Notice of Allowance for an additional patent in the US crop market. The patent relates to the use of Bio-Gene's of flavesone, and related molecules, to control highly damaging aphid pests, including the green peach aphid (*Myzus persicae*) and the Russian wheat aphid (*Diuraphis noxia*), in crops and extends the patent protection for Bio-Gene's technology to 2040.
- Aug 4, 2023 The Australian agtech company Bio-Gene Technology was granted a new US patent (No. 11712039) extending the use of Bio-Gene molecules, including the bioinsecticide Flavocide, to control all resistant pests in all significant environments. Flavocide is based on the beta-triketone molecule flavesone, which is a natural product found in a number of plant species. This builds on a previous patent, which covers the use of Bio-Gene's flavestone and related molecules to control resistant insects in an agricultural environment. The patent is expected to expire in December 2039.
- Apr 23, 2024 Bayer signed an agreement with the UK-based company AlphaBio Control, through which Bayer gained an exclusive licence for a new biological insecticide discovered by AphaBio. The bioinsecticide is targeted at use against coleopteran insects such as cabbage stem flea beetle (*Psylliodes chrysocephala*), including on arable crops such as oilseed rape and cereals. The product is targeted for initial launch in 2028 pending further development and registration. Bayer and AlphaBio Control partnered in 2019 for the commercialisation of FLiPPER (carboxylic acid potassium salts C14-C20), a bioinsecticide also developed by AlphaBio.
- Sep 2, 2024 the Australian agtech company Bio-Gene Technology and Rallis India announced the successful completion of pilot-scale production trials of pre-commercial quantities of the bioinsecticide Flavocide (flavesone). Rallis has produced several hundred kilograms of the product, demonstrating high yield and consistent quality, validating the production process at scale and establishing proven standard operating procedures for future large-scale manufacturing. The companies will now progress with the remaining studies to support its regulatory application for Flavocide.
- Oct 21, 2024 BASF entered into a strategic partnership with AgroSpheres to co-develop and commercialise a novel bioinsecticide. The companies are currently working together to develop biological crop protection products leveraging AgroSpheres' patented AgriCell manufacturing technology, which reportedly enables the production of encapsulated biomolecules with improved stability, field persistence, and targeted delivery. BASF and AgroSpheres also plan to accelerate the development of this product line and launch a pipeline powered by AgriCell technology.
- Mar 10, 2025 the UK-based agricultural technology company Solasta Bio achieved two key
 milestones regarding the approval and commercialisation of its neuropeptide-based insect
 control products. Solasta received patent allowances from the US and European Patent Office
 for its novel peptide candidates, strengthening the company's intellectual property position
 and commercial strategy. In addition, Solasta's lead peptide candidates have received
 a favourable biochemical-like regulatory classification from the US EPA, which is expected to
 accelerate the approvals procedure and minimise associated costs. This follows the close of
 an oversubscribed \$14 million Series A funding round in 2024

Market Outlook

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Changing consumer behaviour, shifts in regulatory oversight towards naturally derived technologies, and a ramp-up in organic areas all contribute to increased demand for products that are perceived as being of natural origin. It seems likely in markets with a strong regulatory approach, particularly in the EU, that these products will continue to gain prominence.

Azadirachtin, the leading product from the class for crop protection use, has strong potential, with multiple modes of action, a broad spectrum of activity and a safe and natural profile lending it to the introduction in a wide array of crop sectors.

In a similar fashion to the microbial insecticide segment, natural product-based insecticides are also likely to face at least some competition from newer conventional chemistries. However, there are product opportunities to either market hybrid products between those biologicals and conventional chemistries, as well as positioning of biologicals alongside conventional insecticides in tank-mixing and/or overall spray programs.

A key advantage that plant and natural product derived insecticides have over microbial bioinsecticides, is that since they are often stable extracts of natural material, and therefore not living organisms, they are less sensitive to the products they are mixed with in prospective spray programs. One downside, however, is that due to the natural feedstock that is used to produce them, which may itself have natural variability, there may be issues surrounding the consistency of product composition year-on-year, which of course can create issues with product efficacy, grower sentiment as well as product regulation.

As a result of the above factors, we expect sales to increase at an average rate of 10.8% per annum between 2023 and 2028, which is at a rate slightly ahead of that of the microbial bioinsecticide segment.

Bioinsecticides: Macrobials

Sales Performance of Macrobial Insecticides				
Year	Macrobial Insecticide Sales (\$ m.)	Total Insecticide Sales (\$ m.)	Macrobial Insecticide Share of Bioinsecticides (%)	Macrobial Insecticide Share of Total Insecticides (%)
2018	138	16,796	16.95	0.82
2022	210	21,566	17.15	0.97
2023	222	21,737	16.86	1.02
2028F	344	24,446	15.98	1.41
1-yr Change (%)	5.5	0.8		
5-yr CAGR (% p.a.)	10.0	5.3		
5-yr CAGR F (% p.a.)	9.2	2.4		

Introduction

Macrobials are non-microscopic organisms used to control arthropod pests, primarily insects and mites. Generally, these are natural predators of specific pest species (often aphids and mites), such as parasitic wasps or predatory mites or beetles, which have been commercialised for use by growers. These are usually provided as eggs, larvae, or adult organisms that growers can introduce to their crops. Application is often in controlled environments where climatic conditions are more stable, such as greenhouses. Therefore, these sales are limited largely to niche markets. Nevertheless, sales have grown significantly in recent years due to growth in the fruit and vegetable sector, and resistance development to chemical technologies, particularly in mites. A prominent advantage of macrobials is that developing resistance to natural predators is much less likely. Sales increased at an average annual rate of 10.0% between 2018 and 2023, to an estimated \$222 million.

The principle of macrobial pest control is the use of insects to control pests, although there are multiple mechanisms by which this can be achieved:

- 1. Parasitoids lay their eggs on or within the bodies of pests, resulting in the host's death. They include parasitoid bees, bugs, flies, mirids, and wasps.
- 2. Predators eat insects; they include predatory mites, aphids, beetles, bugs, flies, gall midges, lacewings, ladybirds, midges, snails, and thrips.
- 3. Entomopathogenics, such as nematodes, live parasitically inside an infected host, eventually causing its death.
- 4. Phytophagous organisms, such as beetles, caterpillars, flies, gall midges, mites, and weevils, feed on specific plant material, thereby stunting growth and acting as herbicides.

Clearly, a high degree of specificity is necessary to avoid cancelling out any benefits.

Products and Companies

A plethora of products exist in this category, with parasitic wasps and predatory mites, bugs, and beetles all being important. Koppert, Arysta LifeScience (now UPL), Bioline (now In Vivo), Praxis, Rincon-Vitova, Bioline, and Arbico are among the leading providers, although macrobials are sold by a wide range of companies, with predatory insects being produced by several insectary companies for subsequent distribution.

Some of the products currently available to growers are outlined in the table below.

Entomopathogenic Nematodes	Pests Controlled
Heterorhabditis bacteriophora	Weevils, beetles, Chafer bugs
Heterorhabditis indica	Small hive beetle, fungus gnats, root weevil, western flower thrips, and
Heterorhabditis megidis	select grubs Weevil beetles and weevils, beetles, wireworms, mole cricket
Phasmarhabditis hermaphrodita	Slugs, Chafer grubs
Steinernema carpocapsae	Flea larvae, cutworms, banana moth, weevils, codling moth, oriental frui
	moth
Steinernema feltiae	Sciarid, thrips, weevil larvae, black fly
Steinernema glaseri	White grubs
Steinernema kraussei	Weevils and grubs
Steinernema riobrave	Grubs, beetles, weevils
Steinernema scapterisci	Mole crickets
Phytophagous	Weeds Controlled
Beetles	
Agapeta zoegana	Spotted and diffuse knapweed
Agrilus hypericin	Hypericum spp.
Aphthona flava	Euphorbia spp
Chrysolina hypericin	St. John's wort
Chrysolina quadrigemina	St. John's wort
Longitarsus jacobaeae	Common ragwort
Microlarinus spp.	Puncture vine
Oberea erythrocephla	Leafy spurge
Oberea shirahatai	Japanese honeysuckle
Sphenoptera jugoslavica	Diffuse knapweed
Caterpillars	
Hyles euphorbiae	Euphorbia spp.
Leucoptera spartifoliella	Scotchbroom
Tyria jacobaeae	Common ragwort
Flies	
Urophora quadrifasciata	Spotted and diffuse knapweed
Gall midges	
Spurgia esulae	Leafy spurge
Vites	
Aceria malherbae	Bindweeds
Weevils	
Apion fuscirostre	Scotch broom
Apion ulicis	Gorse
Bangasternus orientalis	Yellow star-thistle, purple star-thistle
Rhinocyllus conicus	Nodding thistle
Trichosirocalus horridus	Carduus and Cirsium spp.

Macrobial Insecticides and Target Pests		
Parasitoids	Pests Controlled	
Bees		
Metaphycus helvolus	Scales	
Pediobius foveolatus	Mexican bean beetle larvae	
Chabara Abraco	Aphids	
Bugs		
Halyomorpha halys (Stink bug)	Thrips	
Flies		
Lydella thompsoni	European corn borer	
Mirids		
Tupiocoris cucurbitaceus	Whitefly, tomato moth, aphids, mites	
Nematodes		
Deladenus siricidicola	Sirex woodwasp	
Wasps		
Acerophagus flavidulus	Mealybug (Pseudococcus viburni).	
Amitus spiniferus	Woolly aphids	
Anagrus atomus	Leafhoppers	
Anagrus epos	Leafhoppers	
Anagyrus fusciventris	Mealybugs	
Anagyrus pseudococci	Mealybugs	
Anagyrus vladimiri	Mealybugs	
Anaphes flavipes	Cereal leaf beetles	
Anaphes iole	Plant bugs	
Anaphes nitens	Eucalyptus snout beetle	
Anastatus tenuipes	Cockroaches	
Aphelinus abdominalis	Aphids	
Aphelinus asychis	Aphids	
Aphelinus mali	Aphids	
Aphidius colemani	Aphids	
Aphidius ervi	Aphids	
Aphidius gifuensis	Aphids	
Aphidius gifuensis	Aphids	
Aphidius matricariae	Aphids	
Aphytis lignanensis	Scale Insects	
Aphytis melinus	Scale Insects	
Aprostocetus hagenowii	Cockroaches	
Bathyplectes curculionis	Alfalfa weevil	
Bracon hebetor	Caterpillars, moth larvae	
Cales noacki	Citrus woolly whitefly	
Cephalonomia tarsalis	Beetles	
Coccidoxenoides perminutus	Mealybugs	
Coccophagus spp.	Soft scale insects	
Comperia merceti	Cockroaches	
Comperia merceti Cotesia flavipes	Cockroaches Sugarcane borer Iarvae (<i>Diatraea saccharalis)</i>	

Bioinsecticides: Macrobials

Parasitoids	Pests Controlled
Wasps, continued	
Cotesia marginiventris	Lepidoptera
Cotesia melanoscela	Lepidoptera
Cotesia plutellae	Lepidoptera
Curvy Encarsia	Whitefly
Dacnusa sibirica	Leafminer
Diadegma semiclausum	Diamond-back moth
Diglyphus isaea	Leaf miners
Encarsia formosa	Whitefly
Ephedrus cerasicola	Aphids
Eretmocerus californicus	Whitefly
Eretmocerus hayati	Silverleaf whitefly nymph
Eretmocerus mundus	Whitefly
Glyptapanteles liparidis	Gypsy moth
Goniozus legneri	Navel orange worm, carob moth
Habrobracon hebetor	Moth larvae
Lariophagus distinguendus	Beetles, weevils
Leptomastidea abnormis	Mealybugs
Leptomastix algirica	Phenacoccus solani
Leptomastix dactylopii	Citrus mealybugs
Lysiphlebus testaceipes	Aphids
Macrocentrus ancylivorus	Oriental fruit moth, strawberry leafroller
Metaphycus barletti	Mediterranean black scale
Metaphycus flavus	Soft scale insects
Metaphycus helvolus	Citrus black scale, soft scale insects
Metaphycus stanleyi	Soft scale insects
Meteorus spp.	Various caterpillars
Microctonus aethiopoides	Alfalfa weevil
Microplitis plutellae	Diamond-back moth
Microterys nietneri	Soft scale insects
Nagyrus pseudococci	Mealybugs
Necremnus artynes	Tomato leafminer
Necremnus tidius	Tomato leafminer
Neodryinus typhlocybae	Planthoppers
Palmistischus elaiseis	Heliothis virescens, helicopter, S. frugiperda, Helicoverpa spp, Agrotis spp
Pediobius fovelatus	Mexican bean beetle, squash bug nymphs
Pentalitomastix plethorica	Navel orangeworm
Praon volucre	Aphids
Psyllaephagus pilosus	Eucalyptus psyllid
Telenomus podisi	Brown stink bug, Helicoverpa spp., Chrysodeixis includens
Tetrastichus howardi	Diatrea saccharralis
Thripobius semiluteus	Greenhouse thrips
Torymus sinensis	Chestnut gall wasp (<i>Dryocosmus kuriphilus</i>).

Parasitoids	Pests Controlled
Wasps, continued	
Trichogramma achaeae	Various Lepidoptera, Tuta absoluta
Trichogramma brassicae	Lepidopteran caterpillar eggs
Trichogramma evanescens	Lepidopteran caterpillar eggs
Trichogramma galloi	Diatrea saccharralis (Sugarcane borer)
Trichogramma minitum	Tree crop Lepidopteran caterpillar eggs
Trichogramma ostriniae	Various Lepidoptera
Trichogramma platneri	Codling moth
Trichogramma pretiosum	Various Lepidoptera
Trichogrammatoidea bactrae	Various Lepidoptera
Trichospilus diatraeae	Diatrea saccharralis
Sitobion avenae	Aphids

Predators	Pests Controlled	
Mantis		
Tenedera aridifolia sinesis	Many	
Aphids		
Aphidius colemani	Aphids	
Aphidius ervi	Aphids	
Beetles		
Atheta coriaria (Dalotia coriaria)	Fungus gnats, Shoreflies, Thrips pupae	
Calosoma sycophanta	Gypsy moth	
Carcinops pumilio	Flies	
Chilocorus kuwane	Scale Insects	
Chilocorus nigritus	Scale Insects	
Chilocorus stigma	Scale Insects	
Coleomegilla maculata	Aphids, mites, small larvae, and insect eggs	
Cryptolaemus montrouzeiri	Mealybugs	
Cybocephalus nipponicus	Scale Insects	
Dalotia coriaria	Shore flies, fungus gnats, moth flies, springtails, aphids, spider mites	
Delphastus catalinae	Whiteflies	
Delphastus pusillus	Whiteflies	
Rhizophagus grandis	Bark beetles	
Rhyzobius forestieri	Olive scale	
Rhyzobius lophantae	Scale insects	
Rodolia cardinalis	Cottony cushion scale	
Serangium parcesetosum	Citrus whitefly	
Flies		
Coenosia spp.	Whitefly, leaf miner, gnats	

Episyrphus balteatus	Aphids
Ophyra hydrotaea aenescens	Flies
Sphaerophoria rueppellii	Thrips, spider mite, and whitefly
Gall midges	
Feltiella acarisuga	Spider mites
Lacewings	
Micromus angulatus	Aphids
Micromus variegatus	Aphids
Chrysoperla carnea	Aphids, mites, whitefly, and thrips
Chrysoperla rufilabris	Aphids, mites, thrips, and moths
External Chrysoperla	Aphids, mites, whitefly, psyllids, and scale insects.
Micromus variegatus	Foxglove Aphid
Sympherobius marmoratipennis	Mealybugs

coris nemoralis A	Aphids, psyllids
ocoris brevis A	Aphids, whiteflies
hus hesperus V	Nhitefly, thrips, moth eggs, Two-spotted spider mite
pris punctipes N	Many
eseius liturivorus T	Thrips
olophus caliginosus V	Nhiteflies, spider mites, aphids, thrips, moth eggs
iocoris tenuis V	Nhiteflies, leafminers, thrips, Red spider mite
albidipennis T	Thrips
<i>armatus</i> T	Thrips
<i>insidiosus</i> T	Thrips
laevigatus T	Thrips
<i>majusculus</i> T	Thrips, whitefly, aphids
niger T	Thrips
<i>strigicollis</i> T	Thrips
enus relictus L	ygus bugs
us maculiventris L	epidoptera and Coleoptera
us nigrispinus C	Caterpillars
lea japponica A	Aphids
alosiphum padi A	Aphids
oris flavipes N	Many
renardii A	Aphids, mealybugs, caterpillars, thrips
irds	
a bipunctata A	Aphids
a coccifly A	Aphids
orus nigritus S	Scales
olaemus montrouzieri S	Scale insects, mealybugs

Cycloneda spp.	Aphids, mites, fruit flies, small caterpillars, psyllids
Eriopis chilensis	Aphids
Hippodamia variegata	Aphids
Harmonia axyridis	Aphids
Hippodamia convergens	Aphids
Rhyzobius lophanthae	Scales
Stethorus punctillum	Spider mites
Midges	
Aphidoletes aphidimyza	Aphids
Feltiella acarisuga	Spider mites

Predators, continued	Pests Controlled
Mites	
Amblydromalus limonicus (Typhlodromalus limonicus)	Whitefly and thrip larvae, mites
Amblyseius andersoni	Mites
Amblyseius barkeri	Thrips
Amblyseius californicus (Neoseiulus californicus)	Mites
Amblyseius cucumeris (Neoseiulus cucumeris)	Thrips
Amblyseius degenerans	Thrips
Amblyseius fallacis	Mites
Amblyseius montdorensis	Thrips, whitefly, mites
Amblyseius swirskii	Thrips larvae, whitefly larvae and eggs
Amblyseius womersleyi	Spider mites
Cheyletus eruditus	Mites
Euseius gallicus	Whitefly, thrips
Gaeolaelaps gillespiei	Fungus gnats, Western flower thrips
Galendromus annectens	Spider mites
Galendromus helveolus	Spider mites
Galendromus occidentalis (Metaseiulus occidentalis)	Spider mites
Hypoaspis aculeifer (Gaeolaelaps aculeifer)	Sciarid flies, bulb mites, thrips pupae, collembola, and nematodes
Hypoaspis gillespieii	Gnat and shore flies
Hypoaspis miles (Stratiolaelaps scimitus)	Sciarid flies, springtails, mites, thrips pupae, and nematodes
Macrocheles robustulus	Thrips pupae; eggs, larvae, and pupae of Sciarid fly; Lyprauta larvae
Mesoseiulus longipes (Phytoseiulus longipes)	Two-spotted spider mites
Metaseiulus occidentalis	European red mite, Two-spotted spider mite
Orius strigicollis	Thrips, aphids, mites
Phytoseiulus macropilis	Red spider mite (Tetranychus urticae)
Phytoseiulus persimilis	Two-spotted spider mites
Stratiolaelaps scimitus (Hypoaspis miles)	Fungus gnat, root aphids, spider mites, and thrips

Transeius montdorensis	Thrips, whitefly, mites, small arthropods
Typhlodromus pyri	Mites
Snails	
Rumia decollata	Slugs and snails
Thrips	
Franklinothrips orizabensis	Avocado thrips
Franklinothrips vespiformis	Thrips
Haplothrips brevitubus	Various
Scolothrips sexmaculatus	Mites

The below table(s) on key active ingredients and key companies is derived directly from AgBioInvestor's exclusive primary market research study that surveyed biological- and biostimulantgrowers, which were conducted for the first time in 2023 and profiled the 2022 agricultural market. The market research surveyed many key agricultural markets for biologicals, including: USA, Mexico, Chile, Brazil, Argentina, France, Italy, Spain and Turkey. The Als have been ranked by farm-gate value (\$m.). Quantification of these data and much more biological market research can be found in the separate subscription product AgbioInsight.

Key Companies with Involvement in Macrobials

AI	Key Companies		
Amblyseius swirskii	Koppert		
Trichogramma spp.	Bioline Agrosciences		
Phytoseiulus sp.	Biobest		
Phytoseiulus persimilis	Agrobio		
	Koppert		
Nesidiocoris tenuis	Agrobio		
Trichogramma pretiosum	Koppert		
	Topbio		
Aphidius colemani	Sautter & Stepper		
Sphaerophoria rueppellii	Agrobio		
Trichogramma galloi	Koppert		
Trichogramma Brassicae	De Sangosse		
Steinernema Carpocapsae	BASF		
Steinernema feltiae	Koppert		
Neoseiulus californicus	Koppert		

Regulation

Within the USA the EPA has determined that macrobial-based pest control organisms such as insect predators, nematodes, and macroscopic parasites are exempt from the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Similarly in the EU macrobials (insects, mites and nematodes) are exempted from registration under Regulation (EC) No 1107/2009 in most European countries.

In China, macrobials have been exempted from registration since 2017, whilst in Japan, the country requires the registration of all biological CP products, including macrobials. However, natural enemies such as parasitoid wasps and predaceous insects are exempt.

Research and Development

Within the macrobial pest control space the species used are typically well established, and therefore the majority of research and development surrounds the optimisation and development of existing species. This includes genetic engineering to enhance the effectiveness of the macrobial species such as increasing resistance to environmental stresses and lifespan improvements. Selective breeding can also be used to enhance desirable traits in the species including improved predation and parasitism rates.

Much of the research development surrounding macrobials is centred around further optimisation of mass production techniques, as well as storage, packaging and formulation technologies. Application strategies such as drone spraying and smart release technologies are another area of development, to be used in conjunction with digital ag technologies to monitor pest infestations, and also generate recommendations on precision application to include timing, location and usage alongside other pesticide/biopesticide prescriptions. Decision support systems are one branch of digital ag that can assist farmers and agronomists with optimal windows for application based on pest population dynamics and environmental conditions.

A number of companies are active in macrobial R&D:

Koppert

Amblyseius swirskii: A predatory mite used for controlling thrips, whiteflies, and spider mites. Recently, efforts have been made to enhance its effectiveness in different climatic conditions and crop environments.

Trichogramma brassicae: An egg parasitoid wasp used primarily against lepidopteran pests. Recent developments have focused on improving its mass-rearing and release methods.

BioBee

BioPersimilis (*Phytoseiulus persimilis*): This predatory mite is highly effective against spider mites. BioBee has been working on optimizing its breeding to ensure higher survival rates and effectiveness in various agricultural settings.

BioAphidius (*Aphidius colemani*): A parasitoid wasp targeting aphids, with recent improvements aimed at increasing its parasitism efficiency and adaptability to different aphid species.

Bioline Agrosciences

Phytoseiulus persimilis: Continued improvements in the breeding and deployment of this predatory mite for spider mite control.

Amblyseius andersoni: A predatory mite used against a range of pests including thrips, spider mites, and some other small insects. Bioline has focused on enhancing its performance in various environmental conditions.

Andermatt Biocontrol

Steinernema carpocapsae: An entomopathogenic nematode used for controlling a variety of soildwelling pests. Andermatt has developed more robust strains that are effective across a broader range of temperatures and soil types. *Metarhizium anisopliae*: A fungal pathogen that targets a wide range of insects. Recent developments include formulations that improve its shelf life and effectiveness in field conditions.

BioBest

Macrolophus pygmaeus: A predatory bug used against whiteflies, thrips, and spider mites. BioBest has been working on improving its adaptability to various crops and environmental conditions.

Bombus terrestris (Bumblebee): For pollination services, BioBest has optimized the breeding and maintenance of these bumblebees to ensure better performance in diverse agricultural settings.

Some other recent developments in R&D include:

- Oct 5, 2022 Koppert launched a new formulation of its Larvanem and Sportnem-H insect control products, which are based on beneficial nematodes. The new formulation, based on 100% biodegradable formulants, is reported to improve the products' solubility and compatibility with existing spraying and irrigation systems. Larvanem (*Heterorhabditis bacteriophora*) is targeted at the control of weevils and other coleopteran and lepidopteran pests on a wide range of crops, whilst Sportnem-H (*Heterorhabditis bacteriophora*) is intended for the control of chafer grubs and other coleopteran pests in lawns.
- Nov 16, 2022 Koppert introduced two insect control products, Capirel (*Steinernema feltiae*) and Casea (*Steinernema carpocapsae*), which are based on beneficial nematodes. Both products are targeted at the control of various dipteran, coleopteran, lepidopteran hymenopteran, and heteropteran pests in pome and stone fruits, soft fruit, potatoes, and several outdoor vegetables.
- Dec 13, 2022 Koppert launched the macrobial bioinsecticide Mirical (*Macrolophus pygmaeus*) in France. The product, which is a predatory insect, is designed to offer biological control of whitefly, a destructive pest in many greenhouse vegetable crops. The insect is a generalist predator that prefers whitefly (*Trialeurodes vaporariorum*), the tobacco whitefly (*Bemisia tabaci*), the eggs and caterpillars of the tomato leaf miner (*Tuta absoluta*) and other lepidopteran pests, while also offering control of weaver spider mites (*Tetranychus urticae*), aphids and leafminer larvae (*Liriomyza spp.*). The product was commercially launched in France for the 2023 season, with expansion into other geographies expected to follow.
- Jan 25, 2023 Koppert announced the launch of the macrobial bioinsecticide Nezapar (*Trissolcus basalis*) in the Netherlands, Belgium, France and Hungary. The product, which is a parasitic wasp, is designed to offer biological control of the Southern green stink bug (*Nezara viridula*), a destructive pest in many greenhouse crops. Koppert has undertaken successful trials of the product in Spain, France, Hungary, the Netherlands and Belgium. Previously, Southern green stink bug control could only be achieved using conventional chemical solutions.
- Mar 14, 2023 Koppert launched the macrobial bioinsecticide Tripar (*Trichogramma brassicae*) in France. The predatory insect, a parasitoid wasp, is intended to offer control of European corn borer (*Ostrinia nubilalis*). Koppert has also partnered with the agricultural drone company Aero Vision to offer growers a drone application service for Tripar and other products.

- Jul 24, 2023 Brazil approved Bioln Biotecnologia's macrobial bioinsecticide Bioln-Longicau-D (*Diachasmimorpha longicaudata*). The product, which is a parasitic wasp, has been registered for use in both organic and conventional farming for the control of several fruit fly species, including *Anastrepha spp.*, carambola fruit fly (*Bactrocera carambolae*), and Mediterranean fruit fly (*Ceratitis capitata*).
- Jan 22, 2024 Bioline AgroSciences launched the macrobial insecticide products Bugline Duo (Amblyseius cucumeris / Amblyseius andersoni / Amblyseius californicus / Amblyseius swirskii / Amblyseius montdorensis) and Gemini Duo (Amblyseius cucumeris / Amblyseius andersoni / Amblyseius californicus / Amblyseius swirskii / Amblyseius montdorensis) for use in greenhouse vegetables and floral crops, including cucumbers, strawberries aubergines, cut flowers and ornamentals. Bugline Duo is reportedly the first commercialised release system that deploys two species of complementary predatory mites, designed to improve efficiency and application times. Both Bugline Duo & Gemini Duo target several pest types, including thrips, red spider mites, tarsonemidae, spider mites, white flies and russet mites.
- Apr 5, 2024 Koppert launched the macrobial bioinsecticide Capyphor in Poland. The product, which is based on the beneficial nematode *Heterohabditis bacteriophora*, is intended for use on fruit & vegetable crops to control insect pests including wireworms (*Agriotes spp.*) and flea beetles (*Phyllotreta spp.*).

Market Outlook

The outlook for macrobial insecticides seems generally positive, although much smaller in size in comparison with the microbial and natural product segments.

As with other biological products, the favourable environmental profile for products of this group finds a good fit with markets where strong regulatory oversight continues to remove conventional chemistry solutions, as well as demand in markets such as the speciality crop sectors where organic production is increasingly prevalent.

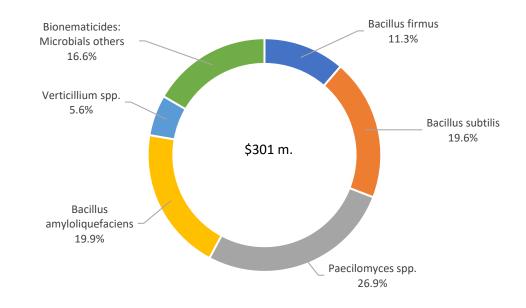
The usage of macrobials in open field settings, although still a small percentage of the overall macrobial usage, is expected to gain momentum in the coming years. However, due to the unique challenges surrounding the optimum timing of application, lack of knockdown activity, weather volatility, population dynamics, narrow control spectrum, and of course, cost, it is expected that the majority of sales of macrobials will remain in protected settings such as high-value horticulture crops grown in glasshouses.

As a result, we expect sales of macrobial insecticides to increase at an average rate of 9.2% per annum between 2023 and 2028 in real terms (constant currency and pricing).

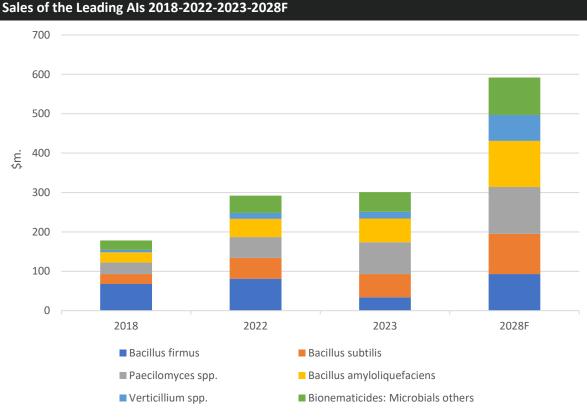
Bionematicides: Microbials

Sales Performance of Microbial Nematicides								
Year	Microbial Nematicide Sales (\$ m.)	Total Nematicide Sales (\$ m.)	Microbial Nematicide Share of Bioinsecticides (%)	Microbial Nematicide Share of Total Insecticides (%)				
2018	178	16,796	21.93	1.06				
2022	292	21,566	23.87	1.36				
2023	301	21,737	22.90	1.38				
2028F	592	24,446	27.50	2.42				
1-yr Change (%)	3.0	0.8						
5-yr CAGR (% p.a.)	11.1	5.3						
5-yr CAGR F (% p.a.)	14.5	2.4						

Leading Products 2023



Leading Biopesticides: Bionematicides: Microbials								
AI	ΥΟΙ	Timing	Main Crops	Rate (Kg/Ha)	Sales 2023 (\$ m.)	Sales 2028F (\$ m.)		
Bacillus firmus	2010	Seed Treatment	Maize, Soybean, Cotton	0.005 - 0.025	34	93		
Bacillus subtilis	2000	Seed Treatment, Soil		1 - 3.4	59	102		
Paecilomyces spp.		Soil	F&V, Potato	-	81	119		
Bacillus amyloliquefaciens	1943	Seed Treatment, Soil		0.07 - 0.84	60	117		
Verticillium spp.		Soil	Soybean, Maize, F&V	-	17	66		



Introduction

Sales of microbial bionematicides increased to \$301 m. in 2023 an increase of 3.0% over the previous year. Over the previous 5 years sales have increased by an average of 11.1% in nominal terms.

Nematodes are microscopic roundworms of the phylum nematoda and are therefore distinct from true insects and acari such as ticks and mites.

Many of the species described in this section will also have insecticidal activity and/or miticidal activity *in addition to* their nematicidal activity. For the purpose of market segmentation, an estimation has been made based on the value of use of these strains for nematicidal purposes.

Nematodes feature a cosmopolitan distribution in an abundance of biological environments and systems, and they can be found in almost all ecosystems including marine, freshwater, the Earth's lithosphere and soil. Most species of nematode feed on microorganisms, however in an agricultural context, nematodes can cause severe losses.

Crop nematodes mostly affect roots and stems, and far less commonly leaves and fruits/seeds. Species, such as root-knot nematodes (*Meloidogyne* spp.), cyst nematodes (*Heterodera* spp. and *Globodera* spp.), and lesion nematodes (*Pratylenchus* spp.), primarily inhabit and feed on plant roots where they may cause damage by feeding on root tissues, leading to symptoms such as galling, necrosis, and reduced root function. Stem and bulb nematodes such as *Ditylenchus dipsaci*, as the names suggest, infest the stems, bulbs, and tubers of plants leading to swelling, distortion, and decay of affected plant tissues.

The two most common genera of crop infesting nematodes include root-knot nematodes (*Meloidogyne* spp.) and the lesion nematodes (*Pratylenchus* spp.) which can infect, feed on, and reproduce on an extremely broad range of crops and plant species.

Meloidogyne species can be found in a vast range of countries, including major agricultural areas such as the USA (particularly southern States), Brazil, China (particularly Guangdong, Fujian, and Hainan provinces), India (particularly Andhra Pradesh, Karnataka, Tamil Nadu, and Maharashtra), Australia (particularly Queensland, New South Wales, and Victoria) and southern Europe (particularly France, Spain, Italy, and Greece).

Pratylenchus species can also be found in most key agricultural regions and crops, including the USA (Southeast, Midwest, and Pacific Northwest), Brazil (the Cerrado and the southern states of Paraná, São Paulo, and Minas Gerais), Argentina, Colombia, Chile, Peru, China (Heilongjiang, Jilin, Liaoning, and Henan provinces), India (Andhra Pradesh, Karnataka, Tamil Nadu, and Maharashtra), Australia (New South Wales, Queensland, Victoria, and Western Australia), the EU (Spain, Italy, France, and Germany); as well as Africa (Nigeria, Kenya, South Africa, and Egypt).

Some nematodes may feed on foliage, although it should be noted that this far less common compared to root and stem infestations. When this does occur however, leaves may become discoloured, stippled, and abnormal in structure. Infested fruits, seeds and reproductive parts may also be damaged by feeding leading to tissue deformities, reduced yield, and seed contamination.

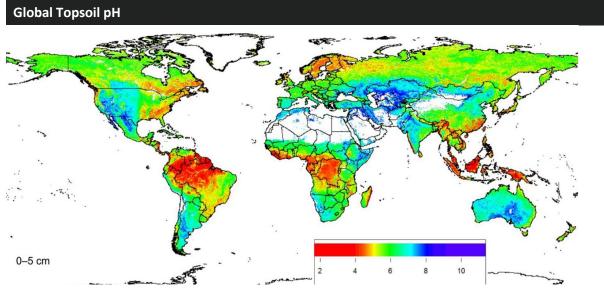
Due to the invisible nature of nematodes growers who are less aware of this type of pest may not have sufficient plans in place to control nematode pressure. Chemical crop protection classes such as the organophosphate and carbamate insects that also provide control of nematodes have increasingly come under regulatory scrutiny in recent years. In addition, the fumigant nematicides such as methyl bromide have also been banned in many markets such as the EU. This means that growers now have a smaller tool kit to control nematodes, at least by chemical means. The growing awareness of nematodes, as well as a greater push towards integrated pest management practices and availability and acceptance of biopesticides, is driving strong demand for microbial bionematicides. Climate change also has the potential to create changing distribution patterns of nematodes, and enhanced overwintering leading to greater populations season-on-season.

In addition to chemical and biochemical/microbial control, various control methods may be used for nematode infestations including crop rotation to species that are less susceptible to certain species of nematode, reducing subsequent populations. This may be through those crops expressing certain repellent phytocompounds, potentially achieved through breeding of varieties with enhanced expression of these compounds. Soil solarisation may be used in countries with high levels of incident UV radiation during the off season or where fallow periods are present. Clear plastic film is applied to the soil to create a warming effect that assists with killing of nematode populations.

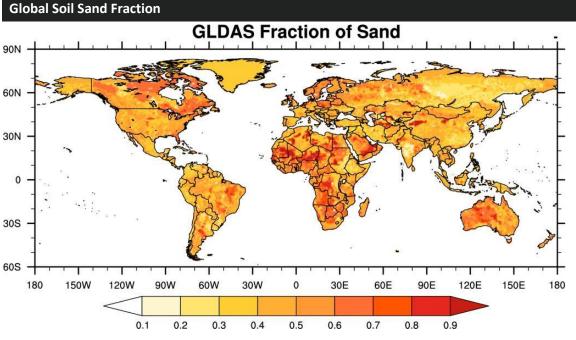
Biofumigation is an interesting practice, in that it relies on natural material but is not included in the scope of biopesticides (traded products) since it works by the growing of certain cover crops such as brassicas (e.g., mustard, rapeseed), that are ploughed into the soil prior to sowing of the next season's crop. Compounds found in the cover crops such as glucosinolates and isothiocyanates when incorporated into the soil, help to reduce nematode, insect and disease pressure. Similarly, improvements to soil structure such as by adding composts, manure, and biochar can help enhance the microbial bioflora. Trade brassica extracts can be found under the biological others: others segment profile (see below).

Plant nutrition, either through biostimulants or through chemical micro/macro fertilisers, can also play an important role given that crops that are generally in better health will be able to better resist nematode infestations, be adequately able to synthesise allelochemicals (defence compounds) and grow faster. For example, potassium plays many roles in plants, including effects on water retention and on cell walls. Sufficient potassium levels facilitate thicker cell walls and provide more tissue stability, whilst also improving resistance to lodging, pests and disease.

In terms of soil types, nematodes generally favour sandy soil where populations may increase significantly more rapidly than in loamy sand or sandy loam with clay soils less affected. Nematodes also appear to survive the winter better in the more fine-textured as opposed to the more coarse-textured soil. Soils higher in soil organic matter and with good structure are generally more conducive to nematode movement, which is important from a field distribution perspective. Water levels need to ensure soil is moist but not overly waterlogged, whilst tropical and subtropical regions have higher soil temperatures suitable for reproduction. Soil pH is also important, generally *Meloidogyne spp.* and *Pratylenchus* spp. prefer pH that is slightly acidic – somewhere approximately 4.5-5.5, but neutral conditions are also somewhat conducive.



0-5 CM, Source: PLOS ONE 9(12): e114788.



Source: NASA Global Land Data Assimilation System (GLDAS)

From the above maps it is evident that the key agricultural areas with both acidic soil and a high degree of sand fraction are within parts of Brazil, Australia, sub-Saharan Africa, and the south eastern USA, all of which have generally favourable temperatures for reproduction across at least a significant part of the year. Areas with a lower proportion of sand fraction but neutral to acidic pH and a warm climate include India and parts of Southeast Asia such as Indonesia, Malaysia, Papua New Guinea, Thailand, Vietnam and southern provinces of China.

Taking these environmental factors into consideration, it is clear that Brazil's combination of climate, soil geochemistry and strong growth of the biologicals industry fuelled in part by favourable biopesticide registrations will generate strong growth of bionematicides in the coming years, particularly as grower sentiment improves and more efficacious products come to market.

Products and Companies

Bacillus firmus

Bacillus firmus is a bacterium with activity against a range of nematodes. It was developed by Bayer as a seed treatment for various crops, with the most important in sales terms being maize and soybean. This product is often applied alongside clothianidin as Poncho/VOTiVO in the USA, the primary market for the product.

Bayer launched Poncho/VOTiVO 2.0 in the USA in 2018 to good success in maize crops, with other introductions taking place in limited areas through select seed partners, including Beck's Hybrids. Poncho/VOTiVO 2.0 provides control of a range of insect and nematode pests, boosting yield potential by increasing soil nutrient availability. This product was later transferred to BASF as a result of anti-trust requirements related to Bayer's acquisition of Monsanto. Since then, BASF has announced a \$70 million expansion at its facility in Sparks, Georgia, USA to directly produce much of the company's seed-treatment range, including Poncho Votivo 2.0 for maize.

Sales of *Bacillus firmus* have increased significantly since its introduction in 2010, as growers have adopted the GM seeds treated with this product. Its nematicidal activity provides another layer of protection on top of the GM insect-resistance traits that often protect against *Lepidopteran* (above-ground) and *Coleopteran* (below-ground) pests. Outside of the USA, minor sales are made in Italy for various fruits and vegetables, while the product has also been introduced in Brazil, although sales remain relatively minor at present.

- Aug 26, 2020 BASF announced a \$70 million expansion at its facility in Sparks, Georgia, USA to allow for the production of seed treatment formulations. The expansion includes a new formulation unit, laboratory expansion and a climate-controlled warehouse. The facility will directly produce BASF's seed treatment portfolio, including the seed treatment system Poncho Votivo 2.0 (clothianidin / Bacillus firmus) for maize.
- Dec 3, 2021 BASF launched the bionematicide seed treatment Votivo Prime (*Bacillus firmus* strain I-1582) in Brazil, representing the company's first bionematicide commercialised in the country. The product is intended for use on soybean, maize, rice, wheat and cotton to control root-legion nematode (*Pratylenchus brachyurus*) and root-knot nematode (*Meloidogyne javanica*).
- Apr 19, 2023 BASF's insecticide seed treatment Poncho Votivo (clothianidin / *Bacillus firmus*) has received a label extension in Ukraine. The product is now approved for use on sunflower to control soil-borne and seedling pests, including nematodes. Poncho Votivo was previously approved for use on maize, winter oilseed rape, and sugar beet.

• Oct 24, 2023 BASF introduced the insecticide seed treatment Poncho Votivo Precise (*Bacillus firmus* strain I-1582 / clothianidin) in the US for use on soybeans. The product is targeted at the control of nematodes, as well as key early-season insects including aphids, seed corn maggots, bean leaf beetle, white grubs and grape colaspis.

Sales are estimated to have decreased from around \$68 million in 2018 to \$34 million in 2023. Yearon-year, sales decreased 58.0% in 2023. This can largely be attributed to Corteva's strategic moves with the company shifting to their own *Bacillus amyloliquefaciens* as part of their seed treatment platform and no longer offering Poncho/Votivo.

Bacillus subtilis

- Sep 16, 2019 FMC announced the launch of its biological nematicide seed treatment Presence (*Bacillus subtilis / Bacillus licheniformis*) in Brazil for use against root-knot nematode (*Meloidogyne Incognita*) and root-lesion nematode (Pratylenchus brachyurus) in soybean, maize, bean, and cotton crops. The product, which was developed in collaboration with Chr Hansen, reportedly also provides plant health benefits including improved water use efficiency, plant emergence and stand establishment. FMC initially gained approval for Presence from Brazilian authorities in 2017
- Aug 25, 2020 The Brazilian biologicals company Biotrop launched its biological nematicide Furatrop in Brazil. The product, based on Bacillus subtilis strain CNPSo 2657, is targeted at the control of nematodes in various crops, including soybean, maize, sugarcane and cotton. Furatrop also reportedly accelerates the germination and initial development of crops, in addition to providing nutritional benefits.
- Nov 10, 2021 UPL launched the microbiological nematicide Biobac (Bacillus subtilis strain Y1336) in Brazil for use on sugarcane to control root-knot nematode (Meloidogyne incognita). The product, which is already available in the country for use on more than 50 crops, is also intended for the control of various diseases, including grey mould (*Botrytis cinerea*) and those caused by *Rhizoctonia solani*.
- Jun 23, 2022 FMC launched a new brand identity for its Plant Health business, Biologicals by FMC. As part of the new brand launch, FMC launched the biofungicide/bionematicide Zironar (*Bacillus licheniformis* strain FMCH001 / *Bacillus subtilis* strain FMCH002) in the US.
- Aug 2, 2022 De Sangosse Brasil (DSB), a subsidiary of France's De Sangosse Group, entered the Brazilian biologicals market through the launch of its Bio Solutions portfolio. The company's Bio Solutions portfolio currently encompasses 7 products including:
 - Messenger (*Bacillus subtilis* strain ATCC 6051 / *Bacillus licheniformis* strain ATCC 12713 / *Purpureocillium lilacinum* strain CPQBA 040-11DRM 10) biological nematicide
- Oct 27, 2022 Chr. Hansen received approval in Brazil for the bionematicides Unnat and Nimaxxa (both based on *Bacillus paralicheniformis* strain CH2970 / *Bacillus paralicheniformis* strain CH0273 / *Bacillus subtilis* strain CH4000). The products have been registered for the control of root-knot nematode (*Meloidogyne incognita*), soybean cyst nematode (*Heterodera glycines*) and root-lesion nematode (*Pratylenchus brachyurus*).
- Oct 30, 2023 FMC launched the bionematicide seed treatment Presence Full (*Bacillus subtilis* strain FMCH002 / *Bacillus licheniformis* strain FMCH001) in Brazil for use on soybean, maize, cotton, and beans. The product, which can also be applied in-furrow, is targeted at the control of root-knot nematodes (*Meloidogyne incognita, Meloidogyne javanica*), lesion nematodes (*Pratylenchus brachyurus, Pratylenchus zeae*), and soybean cyst nematode (*Heterodera glycines*).

- Feb 5, 2024 the Brazilian biotechnology company Superbac gained Brazil approval for the biological nematicide Supershield (*Bacillus subtilis / Bacillus amyloliquefaciens / Bacillus velezensis / Bacillus licheniformis*). The product, was expected to be made commercially available during 2024, is intended for the control of lesion nematodes (*Pratylenchus brachyurus, Pratylenchus zeae*), soybean cyst nematode (*Heterodera glycines*), and root-knot nematodes (*Meloidogyne incognita, Meloidogyne javanica*).
- Feb 23, 2024 Bionat Soluções Biológicas (Bionat), a subsidiary of Essere Group, launched the biological nematicide Peregrino (*Bacillus subtilis / Bacillus velezensis*) in Brazil for the control of root-knot and lesion nematodes. The product was developed in partnership with Luiz de Queiroz College of Agriculture (Esalq), a unit of the University of São Paulo (USP).
- Jul 30, 2024 UPL obtained an expanded registration for the bionematicide Nimaxxa (*Bacillus paralicheniformis* strain CH2970 / *Bacillus paralicheniformis* strain CH0273 / *Bacillus subtilis* strain CH4000) in Brazil to include biostimulant activity. The product, first launched in 2023, has undergone regulatory testing and has been published by the Ministry of Agriculture and Livestock (Mapa) as a biostimulant. The product reportedly enhances root structure and nutrient availability, benefiting crop development.
- Sep 25, 2024 The biologicals company Agrivalle received a label expansion for the bionematicide Profix (*Bacillus subtilis* strain ATCC 6051 / *Bacillus licheniformis* strain ATCC 12713 / *Paecilomyces lilacinus* strain CPQBA 040-11 DRM 10) in Brazil. The product is now also registered for the control of cyst nematode (*Heterodera glycines*) and root-knot nematode (*Meloidogyne exigua*).
- Dec 20, 2024 UPL gained approval from the US EPA for its bionematicide seed treatment Nimaxxa (*Bacillus paralicheniformis* strain CH2970 / *Bacillus paralicheniformis* strain CH0273 / *Bacillus subtilis* strain CH4000) for season-long nematode protection in soybeans and maize. The product, which is reported to be effective against the most damaging nematodes, including soybean cyst nematode (*Heterodera glycines*), root-knot nematode (*Meloidogyne incognita*) and reniform nematode (*Rotylenchulus reniformis*), will be available for the 2025 season.

Sales in 2023 were estimated at \$59 million, representing an average increase of 18.5% per annum since 2018.

Paecilomyces spp.

- Aug 19, 2019 As part of an ongoing collaboration between Certis USA and Bayer, Certis USA is to take over the sales and distribution of Bayer's MeloCon WG (*Paecilomyces lilacinus*) bionematicide which is targeted at the control of nematodes in fruit, vegetable, vine, tuber, row and ornamental crops.
- Mar 4, 2022 The European Commission renewed the approval of the microorganism *Purpureocillium lilacinum* strain 251 until 28th February 2037. *Purpureocillium lilacinum* strain 251, which was formerly approved in the EU as *Paecilomyces lilacinus* strain 251, is a ubiquitous, saprobic filamentous fungus commonly isolated from soil, decaying vegetation, insects and nematodes. Strains of *Purpureocillium lilacinum* are used in plant protection products due to their nematicide activity
- May 26, 2022 Bayer announced the launch of its nematicide solution Control Prime in Spain for the cultivation of greenhouse tomatoes. The solution consists of four products including: BioAct (*Paecilomyces lilacinus*), a biological nematicide.
- Jun 8, 2022 Futureco Bioscience and Nufarm expanded their distribution agreement for Futureco's bioinsecticide NOFLY WP (*Paecilomyces fumosoroseus* strain FE 9901) to now

include the Belgian and Dutch markets, expanding on a similar previous agreement covering Spain. The product will be distributed as part of Nufarm's NuBio umbrella brand. NOFLY is targeted at the control of a range of pests including whiteflies, aphids, thrips, and some caterpillars. The product has received approval in several countries, including Italy (2013), Spain (2017), Cyprus (2018), France (2020), the US (2020) and Guatemala

- Jun 6, 2023 Dhanuka Agritech launched the biological insecticide Nemataxe (*Paecilomyces lilacinus* strain P1-1-MTCC 5175) in India. Strains of the filamentous fungus *Paecilomyces lilacinus*, also known *as Purpureocillium lilacinum*, are used in plant protection products due to their nematicide activity. Dhanuka recently launched its new BiologiQ portfolio of biological products in India.
- Sep 24, 2024 the Brazilian biological crop protection company Ballagro introduced the bionematicide Nemat Stellus (*Paecilomyces lilacinus* strain URM 7661 / *Pochonia chlamydosporia* strain URM 8121) in Brazil. The product is targeted at the control of root-knot nematode (*Meloidogyne javanica, M. incognita*), reniform nematode (*Rotylenchulus reniformis*), soybean cyst nematode (*Heterodera glycines*), common spiral nematode (*Helicotylenchus dihystera*), and root-lesion nematode (*Pratylenchus brachyurus*).
- Sep 25, 2024 the biologicals company Agrivalle received a label expansion for the bionematicide Profix (*Bacillus subtilis* strain ATCC 6051 / *Bacillus licheniformis* strain ATCC 12713 / *Paecilomyces lilacinus* strain CPQBA 040-11 DRM 10) in Brazil. The product is now also registered for the control of cyst nematode (*Heterodera glycines*) and root-knot nematode (*Meloidogyne exigua*).
- Oct 10, 2024 Syensqo announced it was launching its microbial formulation technology, AgRHEA LifeXtend Plus, designed to enhance shelf life in support of sustainable agriculture practices. The product is a ready-to-use solution, which includes a carrier, co-dispersant and rheology agent for the formulation of microorganisms, and has reportedly significantly improved the shelf life of *Beauveria bassiana* and *Paecilomyces lilacinus*, in viability studies.

Sales in 2023 were estimated at \$81 million, representing an average increase of 22.7% per annum since 2018.

Photorhabdus luminiscens

Photorhabdus luminiscens is a bacterium found in the intestinal tract of the nematode *Heterorhabditis indica*. These bacteria and nematode species are thought to have a symbiotic relationship in which the bacteria are released into the host's gut membranes after the nematode enters insect pests. Here, the bacteria rapidly multiply, killing the insect with endotoxins. The nematode and bacteria are then free to multiply within the deceased pest.

Scientists at the International Centre for Genetic Engineering and Biotechnology in New Delhi, India, originally developed this active ingredient in the formulated products Bioprahar and Biowooly Kill, which were launched through Nirmal Organo Biotech Ltd. in 2005.

Key challenges in the development of the AI include making a viable formulation, which does not require a cold chain and demonstrates robust performance in open field settings. The company noted that the formulation was developed with emulsifiers and stabilisers so that it remains biologically active for a longer duration. Its shelf life is over a year with no drop in the potency or efficacy of the formulation.

These challenges are of course not exclusive to the AI, and highlights some of the key issues faced by developers of biological crop protection products, such as maintaining efficacy and viability in both commercial (ag retailers, distribution) and field settings.

Pochonia chlamydosporia

Pochonia chlamydosporia strain CP-10 was developed as a bionematicide by Rizoflora Biotechnology, a spin-off of the Brazil-based Laboratory of Biological Control of the Federal University of Viçosa. This fungus parasitises nematode eggs, reducing nematode populations of *Meloidogyne, Heterodera, Rotylenchulus, Pratylenchus,* and other genera by hindering recruitment of subsequent generations. This fungus also has root zone associations with plants, and also reportedly solubilises and increases the absorption of phosphorus, nitrogen, and potassium. Stoller acquired Rizoflora in 2016 and subsequently launched the product as Rizotec, which is marketed for nematode control in a variety of crops in Brazil.

For soybeans, Rizotec is applied in-furrow or directly to the soil; in maize and cotton, only in-furrow application is recommended. In semi-perennial and perennial crops, such as fruit trees (guava, papaya, fig, banana, etc.), and in coffee, Rizotec is applied to the soil below and around the plant canopy. In vegetables, Rizotec is sprayed on the bed and incorporated into the soil (e.g. by hoeing), as well as direct application to seedling planting holes.

- In 2019, Stoller entered into an agreement with Corteva, under which Corteva was to offer Rizotec to its sales and distribution network for sugarcane in Brazil, with customers being given technical and expert support from Stoller. Corteva noted that this was its first entry into bionematicides and announced its intention to make further launches in other markets around the world.
- Feb 22, 2024 Amvac and Biotor Labs, a Nicaragua-based developer of biological control solutions, introduced the bionematicide Klamic (*Pochonia chlamydosporia*) in Mexico for the control of nematodes in various crops. The product, which is already available in Nicaragua, Honduras, Dominican Republic, Costa Rica, and Panama, is expected to receive Mexican approval by the beginning of 2025. Amvac and Biotor Labs expanded their Global Product Evaluation and Exclusive Option contract through to July 2024
- Sep 24, 2024 the Brazilian biological crop protection company Ballagro introduced the bionematicide Nemat Stellus (*Paecilomyces lilacinus* strain URM 7661 / *Pochonia chlamydosporia* strain URM 8121) in Brazil. The product is targeted at the control of root-knot nematode (*Meloidogyne javanica*, *M. incognita*), reniform nematode (*Rotylenchulus reniformis*), soybean cyst nematode (*Heterodera glycines*), common spiral nematode (*Helicotylenchus dihystera*), and root-lesion nematode (*Pratylenchus brachyurus*).

Streptomyces kathirae

Aug 15, 2023 Indigo Ag announced the commercial launch of its first bionematicide seed treatment for the US market. The company's biotrinsic Z15 product, based on the non-sporulating bacteria *Streptomyces kathirae*, is labelled for use on maize and soybeans for the control of soybean cyst nematode and other plant-damaging nematodes. The product is also reported to enhance root growth and vegetative growth, improving nutrient use efficiency and supporting yields.

Bionematicides Approved for Use in the EU and USA				
USA	EU	AI	Activity	Class
Registration Review	Approved	Bacillus amyloliquefaciens strain MBI 600	Fungicide / nematicide	Bacteria
Registered	Pending	Bacillus licheniformis strain FMCH001	Fungicide / nematicide	Bacteria
Registered	Pending	Bacillus subtilis strain FMCH002	Fungicide / nematicide	Bacteria
Registered		Burkholderia (pseudomonas) cepacia type Wisconsin isolate/strain J82	Fungicide / nematicide	Bacteria
Registered		Burkholderia (Pseudomonas) cepacia type Wisconsin isolate/strain M54	Fungicide / nematicide	Bacteria
Registered		Diallyl disulfide	Fungicide / nematicide	Plant Extract
	Approved	Garlic extract	Insecticide / nematicide	Natural Product
Registered		Glutens, corn	Nematicide	Plant Extract
Registration Review		Metarhizium brunneum (formerly known as Metarhizium anisopliae) Strain F52	Nematicide	Fungus
Registered		Oriental mustard seed (Brassica juncea)	nematicide/fungicide	Plant Extract
Registered	Approved	Pasteuria nishizawae Pn1	nematicide	Bacteria
	Approved	Plant oils / Clove oil	Fungicide / herbicide / insecticide / nematicide	Natural product
	Approved	Purpureocillium lilacinum PL 11	Nematicide	Fungus
Registered	Approved	Purpureocillium lilacinum strain 251 (former Paecilomyces lilacinus strain 251)	Nematicide	Fungus
Registration Review		Sesame plant, ground	Nematicide	Plant Extract

Note: Green = approved (EU) registered (USA), orange = pending approval, purple = registration review, light blue = reregistration blue = pending registration. Information is correct as of May 2025.

Some of the products currently available to growers, and the main pests that they control are outlined in the table below. This has been derived from AgbioInvestor's biological market research study.

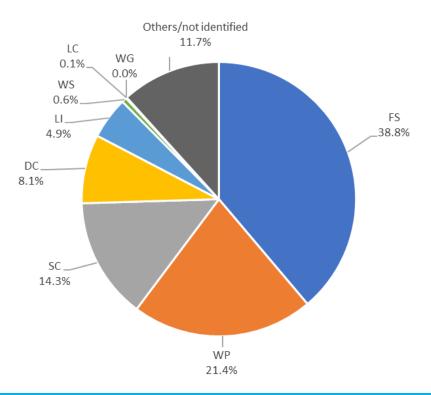
Microbial Nematicides and Pest	Targets
Strain	Pests Controlled
Burkholderia spp. strain A396	
Awl (<i>Dolichodorus spp</i> .) nematodes	Sting (Belonolaimus spp.) nematodes
Dagger (Xiphinema spp.) nematodes	Stunt (Tylenchorhynchus spp.) nematodes
Pin (<i>Paratylenchus spp</i>) nematodes	Ring (Bursaphelenchus spp.) nematodes
Root-knot (<i>Meloidogynespp.</i>) nematodes	Soybean cyst (<i>Heterodera glycines</i> } Nematodes
Lance (Hoplolaimus galeatus, Hoplolaimus columbus) nematodes	Stubby-root (<i>Paratrichodorus spp</i> .) nematodes
Lesion (<i>Pratylenchus spp</i> .) nematodes	Reniform (Rotylenchulus spp.) nematodes
Bacillus methylotrophicus strain UFPEDA20	Root-knot nematodes (Meloidogyne incognita)
Bacillus firmus Strain I-1582	Meloidogyne spp.
	Root-knot nematodes (Meloidogyne incognita)
Pasteuria nishizawae Strain Pn1	Sugar beet nematode Heterodera schachtii
	Cyst nematodes from the genera Heterodera and Globodera
<i>Pochonia chlamydosporia</i> strain Pc 10	Root-knot nematode (Meloidogyne javanica)
	Root-knot nematodes (Meloidogyne incognita)
Purpureocillium lilaciunum Strain 251	Root-knot nematodes (<i>Meloidogyne incognita</i>)
Bacillus amyloliquefaciens strain PTA-4838	Dagger nematode (Xiphinema Americanum)
	Lance nematode (Hoplolaimus galeatus)
	Needle nematode (Longidorus sylphus)
	Root lesion nematode (<i>Pratylenchus brachyurus</i>) Sting nematode (<i>Belonolaimus longicaudatus</i>)
	Stubby-root nematode (<i>Trichodorus allius</i>)
	Root-knot nematode (<i>Meloidogyne incognita</i>)
Burkholderia spp.	Root-knot nematode (<i>Meloidogyne incognita</i>)
Bacillus subtilis UFPEDA 764	Root knot nematode (<i>Meloidogyne exigua</i>)
Bacillus amyloliquefaciens isolate SIMBI BS 10 CCT 7600	Root-lesion nematode (<i>Pratylenchus brachyurus</i>)
Paecilomyces lilacinus isolate UEL Pae 10	Root-knot nematode (<i>Meloidogyne incognita</i>)
Streptomyces sp. strain SYM00257	Root Knot Nematode <i>Meloidogyne spp.</i> Cyst Nematode <i>Heterodera spp.</i>
Bacillus firmus	Rodopholus similis, Xiphinema index, Heterodera sp., Ditylenchus sp., Tylenchulus semipenetrans and Meloidogyne sp.
<i>Bacillus amyloliquefaciens</i> isolate IMA 411	Meloidogyne incognita
	Pratylenchus brachyurus
<i>Bacillus amyloliquefaciens</i> strain UMAF6614	Root lesion nematodes (<i>Pratylenchus brachyurus</i>) and galls (<i>Meloidogyne incognita</i> and <i>Meloidogyne javanica</i>)

The below table(s) on key active ingredients and key companies is derived directly from AgBioInvestor's exclusive primary market research study that surveyed biological- and biostimulantgrowers, which were conducted for the first time in 2023 and profiled the 2022 agricultural market. The market research surveyed many key agricultural markets for biologicals including: USA, Mexico, Chile, Brazil, Argentina, France, Italy, Spain and Turkey. The AIs have been ranked by farm-gate value (\$m.). Quantification of these data and much more biological market research can be found in the separate subscription product AgbioInsight.

Key Companies with Involvement in Microbial bionematicides			
AI	Key Companies		
Burkholderia spp. strain A396	MBI		
Bacillus methylotrophicus strain UFPEDA20	Lallemand		
Bacillus amyloliquefaciens	Sumitomo Chemical		
Bacillus firmus Strain I-1582	Bayer		
	BASF		
Pasteuria nishizawae Strain Pn1	Syngenta		
Pochonia chlamydosporia strain Pc 10	Rizoflora		
Purpureocillium lilaciunum Strain 251	Bayer		
Bacillus amyloliquefaciens strain PTA-4838	Corteva		
	Sumitomo Chemical		
Burkholderia spp.	MBI		
Bacillus subtilis UFPEDA 764	Lallemand		
Bacillus amyloliquefaciens isolate SIMBI BS 10 CCT 7600	Simbiose		
Paecilomyces lilacinus isolate UEL Pae 10	Ballagro		
Streptomyces spp. strain SYM00257	Indigo Ag		
Bacillus firmus	BASF		
Bacillus amyloliquefaciens isolate IMA 411	Comdeagro		
Bacillus amyloliquefaciens strain UMAF6614	Koppert		

Formulation Types – Value Share

The below chart(s) are derived from the biological focussed market research that AgbioInvestor conducted, and illustrates the value share attributed to various formulation type codes.



Code	Description	Code	Description
AE	Aerosol dispenser	LI	Liquid
AL	Other liquids to be applied undiluted	LS	Solution for seed treatment
СВ	Bait concentrate	ME	Micro emulsion
CS	Capsule suspension	OD	Oil dispersion
DC	Dispersible concentrate	SC	Suspension concentrate
DF	Dry flowable	SL	Soluble concentrate
DP	Dustable powder	SP	Water soluble powder
EC	Emulsifiable concentrate	VP	Vapour releasing product
EW	Emulsion, water in oil	WG	Water dispersible granule
FS	Flowable concentrate for seed treatment	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment
LC	Liquid concentrate		

Research & Development

Research and development of novel bionematicides has focussed on selecting new strains that have broad spectrum efficacy against a range of key agriculturally relevant nematode species such as root-knot nematodes (*Meloidogyne spp.*), cyst nematodes (*Heterodera spp.* and *Globodera spp.*), lesion nematodes (*Pratylenchus spp.*), root-lesion nematodes (*Pratylenchus spp.*), stubby-root nematodes (*Trichodorus spp.* and *Paratrichodorus spp.*), reniform nematodes (*Rotylenchulus reniformis*), dagger nematodes (*Xiphinema spp.*), sting nematodes (*Belonolaimus spp.*), soybean cyst nematode (*Heterodera glycines*) and corn rootworm nematode (*Diabrotica spp.*).

Efforts have also been made to improve the formulation technology, as well as the development of a range of new formulation technologies aimed at improving the stability, shelf life and compatibility with other pesticides.

We are increasingly seeing more hybrid products, with a good example being BASFs Poncho/Votivo (*Bacillus firmus* strain I-1582 / clothianidin) which is a major product in the US for use on soybeans. The product is targeted at the control of nematodes, as well as key early-season insects. We are likely to see even more hybrid bionematicide products in the future, as well as greater integration into precision and in-furrow application technologies, particularly closed transfer systems where products come premixed ready for application into sprayers.

- Oct 25, 2022 The US-based soil and plant health company Holganix was granted a patent by the US Patent and Trademark Office for its microbial bionematicide technology, which is currently still in development. The company's bionematicide utilises soil microbes to reduce plant parasitic nematodes, including soybean cyst, corn lesion, tomato root-knot, lance, and sting nematodes.
- May 10, 2023 Plant Health Care was granted the first stage of approval for its new PREtec product PHC68949 in Brazil. PHC68949 is a novel bionematicide designed to amplify a plant's natural defence against nematodes. The Brazilian Ministry of Agriculture, Livestock and Food Supply (MAPA) has accepted the efficacy of PHC68949 and approved the conditions for its use in soybean cultivation in Brazil.

MAPA approval is the first step of regulatory approval in Brazil, and the product will now be evaluated by the Brazilian Health Regulatory Agency (ANVISA) and the Brazilian Institute of Environment and Renewable Natural Resources (IBAMA). Subject to the relevant approvals, the company intends to initially launch the product for use in soybeans, before expanding to other crops in Brazil.

- Jul 27, 2023 Solvay established a partnership with the University of São Paulo (ESALQ-USP Escola Superior de Agricultura Luiz de Queiroz) aimed at developing bioinsecticides, biofungicides, bionematicides and inoculants for use in different crops. The partnership will leverage ESALQ-USP's expertise in biopesticides, bioprocesses and agronomic applications, and Solvay's knowledge in formulations for the agricultural sector.
- Sep 4, 2023 Agrobiológica Sustentabilidade, the biologicals-focused subsidiary of the agribusiness Crop Care Holding, opened a new R&D facility in Itápolis, São Paulo. The facility, announced in 2022, will focus on the research and development of biological products, including bionematicides, bioherbicides, biofungicides and bioinsecticides, for the Brazilian and wider Latin American market.
- Sep 25, 2023 Plant Health Care (PHC) submitted applications to the regulatory agency in Mexico for the commercialisation of two peptide products, PHC25279 and PHC68949, for use on major crops. Both products are derived from PHC's PREtec (Plant Response Elicitor)

technology platform. The bionematicide PHC68949 is reported to enhance a plant's natural defence pathways to provide protection against plant parasitic nematodes. In Mexico, the product will be positioned for use in tomato, aubergine, pepper and other crops within the *Solanaceae* family and in cucurbits to provide protection against root-knot nematodes (*Meloidogyne spp.*) and other pathogenic nematode species, with additional label claims against plant parasitic nematodes to be added in the future.

- Nov 1, 2023 Vitales, a Brazilian agricultural biopesticides company headquartered in Uberaba, Minas Gerais, entered a partnership for the development of biological technology with Microbial Biotechnology Laboratory (Labim), of the Center for Biological Sciences (CCB). Universidade Estadual de Londrina (UEL), through Labim, formalised a cooperation agreement with Vitales to carry out research for the production of fungicide and bionematicide products for a reported R\$ 250 million (\$49.8 million) over the next two years.
- Jun 12, 2024 The Spanish biologicals company Futureco Bioscience was granted a European patent (EP 3934428 B1) for a new microbial bionematicide active ingredient, *Metabacillus halosaccharovorans* strain B410. Studies have reportedly shown that the B410 strain inhibits the hatching of nematode eggs and is particularly effective against root-knot nematodes (*Meloidogyne incognita, M. javanica, M. arenaria*) as well as potato cyst nematodes (*Globodera rostochiensis* and *Globodera pallida*). The first formulation of the active ingredient has been designed as an oil dispersion (OD) and obtained using a scalable manufacturing approach using liquid fermentation technology.

Market Outlook

The outlook for bionematicides is particularly strong, and expected to grow at a rate that is ahead of the microbial bioinsecticide and natural product based bioinsecticide market. This can largely be attributed to a greater grower awareness of the need to tackle nematode pressure as well as generally fewer chemical options due to regulatory pressure on older organophosphate and carbamate insecticides. As mentioned above nematode pressure is generally greatest where there is a combination of factors, including moderately acidic soil pH, high sandy soil character and warm winter soil temperatures. This firmly places Brazil as one of the key areas for nematode pressure, as well as parts of sub-Saharan Africa. Due to Brazil's focus on developing the biologicals market through support for regulatory processes, agronomy university extensions and training, bionematicides are increasingly featured in integrated pest management strategies. This coupled with greater grower awareness, sentiment and crucially product availability has driven the market in recent years and is expected to continue doing so at a rate above that of both the conventional market, but also the average for the bioinsecticide segment.

There have also been a number of new conventional nematicide product launches in recent years including cyclobutrifluram from Syngenta and fluazaindolizine from Corteva, both of which operate via novel modes of action. There does exist the potential for bionematicides to be complementary to these in the overall segment, both in isolation, but also from mixture product launches.

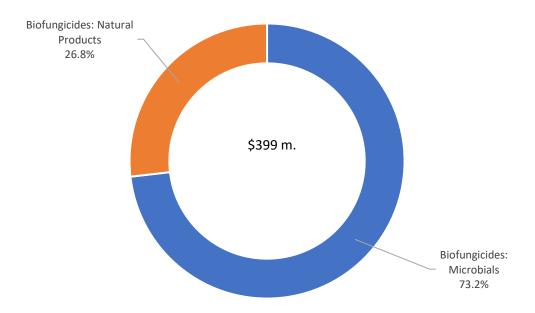
Taking this into account, it can be expected that the segment will increase at a rate of 14.5% p.a. over 2023-2028 (constant currency and pricing).

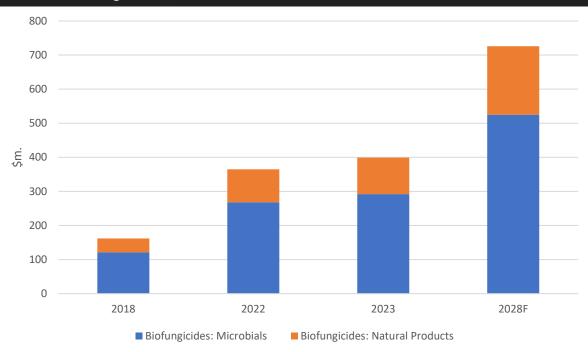
Biological Fungicides

Sales Performance of Biological Fungicides				
Year	Biofungicide Sales (\$ m.)	Total Fungicide Sales (\$ m.)	Share of Biofungicides to Total Fungicides (%)	Share of Total Fungicides to Total Crop Protection (%)
2018	162	15,927	14.54	27.38
2022	365	19,453	20.00	26.02
2023	399	19,878	20.29	26.57
2028F	726	21,992	22.01	27.06
1-yr Change (%)	9.3	2.2		
5-yr CAGR (% p.a.)	19.8	4.5		
5-yr CAGR Forecast (% p.a.)	12.7	2.0		

CCP = Conventional crop protection

Segment Split 2023





Sales of the Leading Classes, 2018-2022-2023-2028F

Introduction

This section covers biofungicides derived from microbial species (predominantly *Bacillus amyloliquefaciens, Trichoderma* spp., *Bacillus pumilus* and *Bacillus subtilis*) and natural product based products (including plant extracts such as *Reynoutria sacchalinensis* and *Melaleuca alternifolia*)

As microbial biofungicides are often living organisms, efficacy can pose a challenge in field settings, while shelf life can also be a problem. As a result, the key markets have historically been those with more controlled environments, such as greenhouses or seed treatments, where environmental stability benefits microbial establishment and activity. The drive for biological alternatives to conventional chemistries has increased interest in the sector in recent years, with several multinationals introducing products in this class.

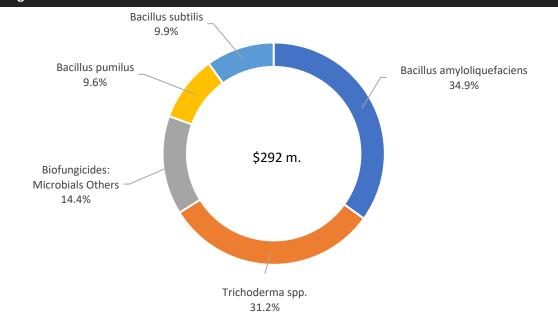
The market for microbial biofungicides increased by an average of 19.2% per annum between 2018 and 2023 to reach \$292 million, driven primarily by rapid growth for *Bacillus amyloliquefaciens* strain QST713 in Bayer's Serenade product range, which was acquired along with AgraQuest; this product is used to control *Botrytis cinerea* in grapes and other fruits.

The natural product biofungicide segment has increased at a rate of 21.3% per annum over the period 2018-2023 to reach \$107 million. This has largely been driven by increased product availability through company investment in R&D, as well as acceptance by growers.

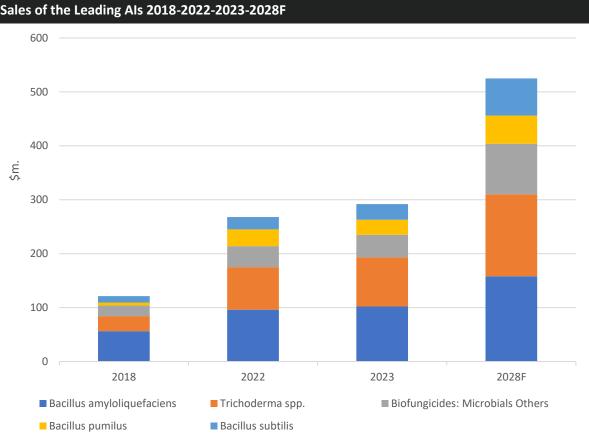
Biofungicides: Microbials

Sales Performance of Microbial Biofungicides				
Year	Biofungicide Sales (\$ m.)	Total Fungicide Sales (\$ m.)	Microbial Biofungicide Share of Biofungicides (%)	Microbial Biofungicide Share All of Total Fungicides (%)
2018	121	15,927	74.85	0.76
2022	268	19,453	73.42	1.38
2023	292	19,878	73.18	1.47
2028F	525	21,992	72.31	2.39
1-yr Change (%)	9.0	2.2		
5-yr CAGR (% p.a.)	19.2	4.5		
5-yr CAGR F (% p.a.)	12.4	2.0		

Leading Products 2023



Leading Biopesticides: Microbial Biofungicides Sales Sales Rate YOI Timing Main Crops 2028F (\$ 2023 (Kg/Ha) (\$ m.) m.) Vine, Pome / Stone Bacillus 1943 Foliar 0.07 - 0.84 102 158 amyloliquefaciens (F) Fruit, F&V F&V, Soybean, Cereals, Trichoderma spp. -Foliar 91 152 Vine **Bacillus pumilus** Seed Treatment 28 52 Soybean --Foliar, Seed Bacillus subtilis (F) 2000 Maize, Soybean, F&V 1 - 3.4 29 69 Treatment, Soil



Sales of the Leading Als 2018-2022-2023-2028F

Introduction

The microbial biofungicide segment is currently smaller than that of the microbial insecticide segment but is growing at a faster pace, largely down to more efficacious product entering the market coupled with greater grower acceptance. The segment is currently exemplified by a number of *Bacillus* species such as Bacillus amyloliquefaciens, Bacillus subtilis, Bacillus pumilus and Trichoderma species.

Microbial fungicides typically work by a number of mechanisms including:

- **Competitive inhibition** biopesticides that are competitive inhibitors (alongside other modalities the biopesticide may have) are active only indirectly against pathogenic bacteria and fungi by out-competing the rival species for available space on the surface of the plant leaves, stems, or root tissues. They may also consume any nutrients needed for the crop pathogen to replicate. This modality relies upon the biofungicide being applied alive to the plant so that it can replicate, creating potential challenges surrounding shelf life, storage conditions, tank-mix compatibility, correct product application timings, and general field conditions. Examples of such products include Actinovate (Streptomyces lydicus strain WYEC 108) and Serifel (Bacillus amyloliquefaciens strain MBI 600).
- **Bio-film formation** as the name suggests, biofilms are microbial structures that occur on • leaf/plant tissues as surface-attached communities. They typically consist of microbial cells embedded in a self-produced extracellular matrix composed of polysaccharides, extracellular DNA and other components. Biofungicides with this mode of action may protect crops via forming a barrier biofilm that actively prevents pathogens from infecting plant tissue or growing on leaf surfaces, stems, roots and reproductive bodies.

- **Parasitism** some microbial biofungicides exhibit a parasitic action by infecting and feeding on the target crop pathogens. This could include degrading fungal hyphae or spores, limiting future reproduction and nutrient absorption of the pathogen and therefore supressing further disease proliferation.
- Induced Systemic Resistance (ISR): ISR is a plant defence response that is induced following interactions with beneficial microbes, such as rhizobacteria, mycorrhizal fungi, or non-pathogenic fungi. These may stimulate the production of phytoalexins as well as other changes such as cell wall composition, and the production of proteins such as chitinases and glucanases due to disease response.

Challenges in Segment Definition

It should be noted that this is one grey area between biostimulation and biocontrol, since the application of microbes is triggering or stimulating a biotic stress response. The definition of the market size for microbial biofungicides includes species that have been shown to trigger ISR, such as *Tricoderma*, *Pseudomonas* and *Bacillus*, non-pathogenic *Fusarium* and mycorrhizal fungi such as *Glomus spp.* and *Rhizophaguss spp.*. However, this does not include products in the biostimulant segment, many of which are microbial species that promote overall plant health with regards to abiotic stress and biotic stress. These are excluded depending on how the product is registered and positioned. Also Induced Systemic Resistance (ISR) is not to be confused with Systemic Acquired Resistance (SAR) that is induced following exposure to pathogens or pathogen-derived molecules, such as elicitors.

Products

Bacillus amyloliquefaciens

B. amyloliquefaciens is a soil bacterium with activity against a range of diseases such as *Botrytis*, *Sclerotinia*, *Xanthomonas*, and *Erwina*, reportedly through multiple modes of action: preventing spore germination, disrupting cell membrane growth, and competing with pathogens for space on leaf surfaces. This product benefits from its compatibility with a number of widely used organic products such as copper (a bactericide) and sulphur, with the majority of sales being in maize, soybeans, horticulture, vine, tree fruit/nuts, as well as other F&V and specialities. The largest country markets for this product are the USA, Brazil, Mexico, France and Italy.

Several suppliers are important in this sector. Bayer Crop Science is a significant player through its Serenade brand (*B. amyloliquefaciens* strain QST713), which has been re-classified as *B. amyloliquefaciens* due to a taxonomic revision (it was earlier identified as *B. subtilis*). Other notable companies include BASF, which distributes Serifel (*B. amyloliquefaciens* strain MBI600) in Italy and Chile; Certis USA, which holds a global license (excluding Japan) for Kumiai's *B. amyloliquefaciens* strain D747 and sells the product as Double Nickel; and Valent, which has an agreement with LidoChem to develop *B. amyloliquefaciens* strain PTA-4838, with a launch occurring in 2017 in the USA as the nematicide Aveo.

In addition, several notable recent developments are listed below:

- Jan 27, 2021 BASF's biological fungicide Serifel (*Bacillus amyloliquefaciens* strain MBI600) received a label expansion in Canada, with the product now approved for use on a range of fruiting, leafy, root and cucurbit vegetables, including potatoes. For potatoes, the product is targeted at the control of early blight (*Alternaria solani*) and the partial suppression of soilborne *rhizoctonia* stem canker or black scurf (*Rhizoctonia solani*) in-furrow. Serifel was previously registered in the country for use on grapes to control powdery mildew and botrytis.
- Apr 23, 2021 Koppert Biological Systems launched the biological industrial seed treatment BioTSI Koppert in Brazil. The product, which combines the microbial fungicide and nematicide Trianum DS (*Trichoderma harzianum*, strain T22) and the nematicide Veraneio (*Bacillus amyloliquefaciens*, strain UMAF6614), is intended to protect crops against fungi and root nematodes and reportedly results in improved plant health and vigour due to increased root volume.
- Jun 4, 2021 Marrone Bio Innovations (MBI) entered into a distribution agreement with the Canadian plant nutrition company ATP Nutrition. Through the agreement, ATP will distribute MBI's Stargus Biofungicide in Canada for use on broad acre crops, primarily canola, dry beans, peas, soybeans and sunflower. The product, which is based on an MBI-discovered strain of *Bacillus amyloliquefaciens* (F727) that has been re-classified as *Bacillus nakamurai*, was launched in Canada in 2020
- Jun 22, 2021 Andermatt Biocontrol received Californian regulatory approval for the biofungicide AmyProtec 42. AmyProtec 42 is a soil-applied biological product containing *Bacillus amyloliquefaciens* strain FZB 42 for the management of *Rhizoctonia* on potatoes, *Sclerotinia* on leafy greens, and soil-borne diseases on strawberries. The product was approved in Canada in 2020
- Aug 4, 2021 The Brazilian company Agrivalle launched the biofungicide Twixx-A in the country for use on soybeans, maize, beans, and cotton. The product, based on *Bacillus amyloliquefaciens*, is reported to be the first multi-site biofungicide introduced in the country across these crops, and is targeted at the control of foliar diseases such as Anthracnose, White Spot and Target Spot.
- Aug 20, 2021 Syngenta launched the biological fungicide Taegro (*Bacillus amyloliquefaciens* strain FZB24) in Portugal. The product is registered for use in greenhouse and outdoor horticultural crops, including aubergine, courgette, cucumber, lettuce, tomato, pepper, melon, watermelon, strawberry, potato, and vine. Taegro is a broad spectrum biofungicide targeted at controlling fungal diseases including powdery mildew, downy mildew, grey rot, *sclerortinia* and alternariasis in fruit and vegetables.
- Aug 25, 2021 Sumitomo Chemical launched the biological nematicide seed treatment Aveo (*Bacillus amyloliquefaciens* strain PTA-4838) in Brazil. The product is targeted at the control of soybean cyst nematode and can be used in areas where resistance issues are prevalent.
- Sep 27, 2021 Novozymes announced the launch of three new biological products for the US market: BioniQ (*Penicillium bilaiae* / *Bacillus amyloliquefaciens* / *Trichoderma virens*), an inoculant for row crops that strengthens roots, enhances nutrient availability and improves yield; TagTeam BioniQ Pro (*Penicillium bilaiae* / *Rhizobium leguminosarum* / *Bacillus amyloliquefaciens* / *Trichoderma virens*) and TagTram BioniQ Chickpea (*Penicillium bilaiae* / *Rhizobium leguminosarum* / *Bacillus amyloliquefaciens* / *Trichoderma virens*), inoculants that improve stress tolerance, nutritional availability and efficiency, and enhance yield in pulse and chickpea crops; and Taegro 2 (*Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24), a broad-spectrum foliar fungicide for use on fruit and vegetable crops, which provides protection against a wide range of soil borne and foliar pathogens.
- Oct 1, 2021 The European Commission approved the biological fungicide active ingredient *Bacillus amyloliquefaciens* strain AH2, submitted by Probelte, as a low-risk active substance until 31st October 2036.

- Oct 15, 2021 The China Pesticide Registration Evaluation Committee has approved two of Bayer's pesticide products: Vayego (tetraniliprole) and Serenade (*Bacillus amyloliquefaciens* QST713). *Bacillus amyloliquefaciens* QST713 has been approved for control of strawberry grey mould until 2026.
- Feb 8, 2022 FMC received label extensions for the insecticide/fungicide Ethos XB (bifenthrin/ *Bacillus amyloliquefaciens* D747). The extension permits liquid in-furrow-ready application of the products on sunflower crops. Both products are targeted for army cutworm and wireworm, while Ethos XB is also effective in the suppression of root and crown diseases caused by *Pythium, Rhizoctonia, Fusarium,* or *Phytophthora*.
- May 26, 2022 Adama launched the biological fungicide / nematicide product Protege (*Bacillus thuringiensis* strain CNPSo 3915 / *Bacillus velezensis* strain CNPSo 3602 / *Bacillus amyloliquefaciens* strain CNPSo 3202) in Brazil. The product is targeted at the control of the pathogenic fungus *Rhizoctonia solanil* and root-lesion nematode (*Pratylenchus brachyurus*) in soybean and sugarcane.
- Jun 29, 2022 Dillon Biotecnologia launched the biofungicide Bactel (*Bacillus amyloliquefaciens*) in Brazil. The product is targeted at the control of a range of diseases on various fruit crops.
- Jul 13, 2022 Corteva announced the expansion of its seed treatment portfolio in Canada with the introduction of two new seed treatment packages under its LumiGEN brand for maize and canola crops. The packages are expected to be available to growers in time for the 2023 growing season.
 - LumiGEN for maize includes the fungicide Lumiscend Pro (ethaboxam / inpyrfluxam / metalaxyl), targeted at various seed and soil-borne diseases including *Pythium*, *Rhizoctonia*, *Fusarium* and corn head smut species. In addition, the package includes the biological nematicide Lumialza (*Bacillus amyloliquefaciens* strain PTA-4838), providing control of a variety of nematodes including sting, needle, lance, stubby-root, root-knot, dagger and lesion.
- Aug 2, 2022 De Sangosse Brasil (DSB), a subsidiary of France's De Sangosse Group, entered the Brazilian biologicals market through the launch of its Bio Solutions portfolio. The company's Bio Solutions portfolio currently encompasses 7 products:
 - Restrict (*Bacillus amyloliquefaciens* strain CPQBA 040-11DMR 01 / *Bacillus amyloliquefaciens* strain CPQBA 040-11DMR 04) biological fungicide
- Sep 15, 2022 The Brazilian biological crop protection company Biotrop Soluções Biológicas launched the biological nematicide / fungicide Biomagno (*Bacillus amyloliquefaciens* strain CNPSo3202 / *Bacillus thuringiensis* strain CNPSo3915 / *Bacillus velezensis* strain CNPSo3602) in Brazil. The product is targeted at the control of the pathogenic fungus *Rhizoctonia solanil* and root-lesion nematode (*Pratylenchus brachyurus*) on a range of crops.
- Sep 28, 2022 BASF added two new products to its Canadian crop establishment portfolio including Nodulator IP Plus (*Bacillus subtilis* strain BU1814 / *Bacillus amyloliquefaciens* strain MBI 600 / *Bradyrhizobium japonicum* strain 532C) for the 2023 season.
- Sep 29, 2022 The Canadian Pest Management Agency granted registration for the sale and use of the active ingredient cis-jasmone and the nematicide seed treatment Trunemco (cis-Jasmone / *Bacillus amyloliquefaciens* strain MBI-600) for use as a seed treatment in soybean and maize. Nufarm's Trunemco is a patented combination of a biochemical active ingredient and a microbiological component which, in addition to providing control of nematodes, is also reported to improve root systems, vigour and canopy closure. The product works by priming plant physiological responses and stimulating defence mechanisms to manage nematodes. Nufarm acquired Trunemco from BASF in February 2019.

- Oct 20, 2022 Sumitomo Chemical launched a new platform in Brazil encompassing the company's portfolio of seed treatment products including the biological nematicides Aveo EZ (*Bacillus amyloliquefaciens* strain PTA-4838) and Loyalty Bio (*Bacillus amyloliquefaciens* strain MBI 600). The Seed Protection platform includes both industrial seed treatments and on-farm seed treatment products.
- Dec 20, 2022 De Sangosse received registration in Brazil for Restrict (*Bacillus amyloliquefaciens* strain CPQBA 040-11DRM 01 / *Bacillus amyloliquefaciens* strain CPQBA 040-11DRM 04), a multisite biofungicide representing the latest product available through the company's Bio Solutions line. The bacteria produce the metabolites surfactin, marihysina, heptamycin and nobilamide, which act on structures within the fungal cell, disrupting pathways essential for processes such as respiration and protein synthesis. The product offers control of foliar diseases including Anthracnose (*Colletotrichum lindemuthianum / Colletotrichum truncatum*), Target spot (*Corynespora cassiicola*), *Phaoeosphaeria* leaf spot (*Phaeosphaeria maydis*) and *Ramularia (Ramularia areola*), in various crops including soybean, cotton, maize, sugarcane and various fruits and vegetables.
- Jan 24, 2023 Canada's Pest Management Registration Agency (PMRA) granted registration for the sale and use of MBI-110 TGAI and Stargus Biofungicide, containing the technical grade active ingredient *Bacillus amyloliquefaciens* strain F727. The products have been approved for the control of grey mould on indoor-grown cannabis and to suppress or partially suppress certain diseases on field-grown hemp, grape, tomato, potato, red (garden) beet, sugar beet, cabbage and brussels sprouts.
- Feb 2, 2023 The soil fertility and plant health company DPH Biologicals launched the biofungicide seed treatment BellaTrove Companion Maxx ST (*Bacillus amyloliquefaciens* strain ENV503) in the US. The product has been approved for use on various crops, including maize and soybeans, for the prevention, control or suppression of soilborne pathogens, including *Rhizoctonia spp., Pythium spp.,* and *Fusarium spp.* BellaTrove Companion Maxx ST works by stimulating a plant's natural defences against pathogens and reportedly also improves nutrient uptake and root health.
- Mar 10, 2023 Corteva launched the biological inoculant Utrisha P (*Bacillus amyloliquefaciens* strain FZB45) in the US. The product is intended to improve below-ground phosphorus availability and can be used on various crops, including maize, soybeans, wheat, potatoes, tomatoes and strawberries.
- Sep 21, 2023 The European Commission amended the maximum residue levels (MRLs) in pesticides for *Bacillus amyloliquefaciens* (strain AH2), *Bacillus amyloliquefaciens* (strain IT-45) and *Purpureocillium lilacinum* (strain PL11) in or on food and feed of plant and animal origin. For all three, no specific MRLs have been set, therefore, a default value of 0.01 mg/kg applies. All three strains were approved as low-risk active substances, with all found to be non-pathogenic to humans, not expected to produce toxins relevant to human health, and pose negligible risk to humans through metabolites.
- Nov 7, 2023 Certis Biologicals established a distribution agreement with Belchim Crop Protection Canada (Belchim CPC). Through the agreement, Belchim CPC will be the exclusive distributor of Certis' biofungicide Double Nickel 55LC (*Bacillus amyloliquefaciens* strain D747) and biological plant activator LifeGard WG (*Bacillus mycoides* isolate J) in Canada. Double Nickel 55LC is intended for the control of diseases including powdery mildew, *Sclerotinia spp.*, and *Botrytis spp*.

- Nov 29, 2023 Mycorrhizal Applications, a subsidiary of Valent BioSciences, launched the biological fungicide AmyloShield (*Bacillus amyloliquefaciens*, PTA-4838) in the US for the control of pathogens such as powdery mildew, botrytis, downy mildew. The product is intended for use in a wide variety of plants, such as ornamentals, interior plants, fruits, vegetables, herbs, hemp, and turf.
- Nov 29, 2023 Corteva received a label expansion for the biological nematicide Lumialza (*Bacillus amyloliquefaciens* strain PTA-4838) in Brazil. The product can now be used in seed treatments to control root-knot nematodes (*Meloidogyne javanica*) in soybeans, lesion nematodes (*Pratylenchus zeae*) in maize, and reniform nematodes (*Rotylenchulus reniformis*) in cotton.
- Jan 9, 2024 Certis Biologicals launched the biofungicide product Convergence (*Bacillus amyloliquefaciens* strain D747) in the US. The product is intended for use on row crops for the control of soil borne fungal and bacterial diseases caused by *Pythium, Rhizoctonia, Fusarium* and *Phytophthora*, and also provides an additional mode of action against foliar diseases, including tar spot, rusts and leaf spots.
- Jan 10, 2024 Syngenta announced plans to launch 4 new products in Switzerland: including the biofungicide Taegro (*Bacillus amyloliquefaciens* strain FZB24) which is targeted at the control of powdery mildew in vines and vegetables.
- Jan 30, 2024 The Canadian Pest Management Regulatory Agency (PMRA) completed the reevaluation of *Bacillus amyloliquefaciens* strain MBI 600 and *Bacillus subtilis* strain QST 713. Under the authority of the Pest Control Products Act, Health Canada determined that continued registration of products containing *Bacillus amyloliquefaciens* strain MBI 600 and *Bacillus subtilis* strain QST 713 is acceptable, based on the evaluation of available scientific information, which found that the use of the products meets current standards for the protection of human health and the environment and has acceptable value when used with label updates.
- Feb 5, 2024 The Brazilian biotechnology company Superbac received approval in Brazil for the biological fungicide Superguard (*Bacillus amyloliquefaciens*). The product is recommended for the control of damping-off (*Rhizoctonia solani*), white mold (*Sclerotinia sclerotiorum*), and fusarium wilt (*Fusarium oxysporum*).
- Feb 5, 2024 The Brazilian biotechnology company Superbac announced its entry into the biological crop protection market with the registration of two products in Brazil including the biofungicide Superguard (*Bacillus amyloliquefaciens*). Superguard is recommended for the control of damping-off (*Rhizoctonia solani*), white mold (*Sclerotinia sclerotiorum*), and fusarium wilt (*Fusarium oxysporum*).
- Apr 2, 2024 Certis Biologicals and Certis Belchim announced their first cereal seed treatment biofungicide Toltek (*Bacillus amyloliquefaciens* strain D747). The product, which has been approved in France, is reportedly the first biofungicide registered in Europe for the control of Take-All disease (*Gaeumannomyces tritici*) and will be distributed by Certis Belchim. Further authorisations are pending in Germany, Belgium, Czechia, Ireland, and the UK.
- Jun 3, 2024 Syngenta launched the biofungicide Taegro (*Bacillus amyloliquefaciens* strain FZB24) in Denmark for the control of various fungal diseases, including powdery mildew and grey mould, in fruit and vegetable crops. This represents Syngenta's first biological crop protection product to be introduced in the country.

- Jan 28, 2025 The European Commission extended the approval periods for 23 active ingredients due to ongoing delays in the procedure for evaluating the approvals. The approval period has been extended to 31st August 2027 for *Bacillus amyloliquefaciens* subsp. *plantarum* D747.
- Jan 30, 2025 Syngenta launched the biofungicide Taegro (*Bacillus amyloliquefaciens* strain FZB24) in Ukraine for the control of various fungal diseases, including powdery mildew (*Erysiphales spp.*), grey mould (*Botrytis cinerea*), *Alternaria*, late blight (*Phytophthora infestans*) and bacterial diseases, in fruit and vegetable crops.
 Taegro was developed in collaboration with Novonesis (formerly Novozymes), and has been
- launched in several countries in Europe and Latin America. Jan 30, 2025 Amvac entered into a regional distribution agreement with the agricultural
- biologicals company DPH Biologicals. Under the long-term agreement, Amvac will resell DPH Biologicals' key products in the US, including the biocontrol product BellaTrove Companion Maxx (*Bacillus amyloliquefaciens* strain ENV503)
- Mar 14, 2025 Eléphant Vert renewed its agreement with Pro Farm Group regarding the distribution of biocontrol products in Africa. Under the renewed agreement, the companies will develop and market the Pro Farm Group range of biocontrol products, while expanding its presence in East African countries such as Ethiopia and Tanzania, and North African countries such asTunisia and Algeria. The distribution will primarily focus on biocontrol products Majestene (*Burkholderia rinojensis*), Venerate (*Burkholderia rinojensis*), Grandevo (*Chromobacterium subtsugae*) and Reysana (*Bacillus amyloliquefaciens*).
- Apr 28, 2025 Nufarm launched the biofungicide seed treatment Pretium SDS (natamycin) in the US for use on soybean. The product is targeted at the control of red crown rot (*Calonectria ilicicola*) and *Fusarium virguliforme*, the causal agent of Sudden Death Syndrome (SDS). Pretium SDS will be offered as an optional add-on to Nufarm's nematicide seed treatment Trunemco (cis-Jasmone / *Bacillus amyloliquefaciens* strain MBI-600).

Sales increased by an average of 19.2% per annum between 2018 and 2023 to \$292 million, driven by new introductions, increased use in organic cultivation systems, and use in integrated pest management programmes.

Bacillus subtilis

Bacillus subtilis is a soil bacterium sold mostly in the Asia-Pacific region and Central and South America for use on fruits and vegetables, sugarcane, cotton, and soybeans. A few companies are now active with *Bacillus subtilis*: Idemitsu Kosan sells it in Japan; FMC sells it in a mixture with *B. licheniformis* as CHR Hansen's Nemix C for sugarcane in Brazil; and Arysta sells *B. subtilis* strain Y1336, from the Taiwanese company Bion Tech, in Japan.

Recent developments involving this bacterium include the following:

- Apr 21, 2021 FMC and Syngenta entered into a commercial agreement whereby Syngenta was to distribute FMC's new biological seed treatment for use on maize and soybean in Canada. The seed treatment, which Syngenta was to commercialise under the brand name Draco (*Bacillus licheniformis / Bacillus subtilis*), offers control of pests such as *Rhizoctonia* and nematodes. The product also reportedly provides biostimulant activity which improves water utilisation by the roots and enhances plant performance.
- Jul 29, 2021 Rovensa's biocontrol business Idai Nature gained label expansions in Mexico for two of its biofungicide products, Rador (*Bacillus subtilis spp.*) and Naturdai Mim (*Mimosa* and *Quercus* extracts). The label for Rador has been expanded to cover the control of powdery mildew in berries and table grapes.

- Sep 6, 2021 Idai Nature, a member of the Rovensa Group, launched the biological fungicide Portento (*Bacillus subtilis* – strain IAB / BS03) in Spain. The product, which was launched in France last year, is registered for use against Scab in pome fruit trees, Powdery Mildew in cucurbits and Downy Mildew in lettuce and related plants. Portento has both preventive and curative action against fungi, acting as a shield against the proliferation of diseases in the plant.
- Sep 7, 2021 Seipasa, a Spanish company specialising in the development and formulation of biologicals, announced the launch of its Seitylis biofungicide in Spain. The product, which is based on a strain of *Bacillus subtilis*, provides preventative and curative action against a broad range of diseases such as oidium, mildew and mottling by forming a biological, protective barrier on the plant's leaves and by activating its integrated defence system. Seitylis reportedly has a short safety period and is suitable for use in organic farming. Crop use includes a range of fruit and vegetables, including lettuce, zucchini, cucumber and pome fruit.
- Sep 27, 2021 Novozymes announced the launch of five new biological products for the US market including Taegro 2 (*Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24), a broad-spectrum foliar fungicide for use on fruit and vegetable crops, which provides protection against a wide range of soil borne and foliar pathogens.
- Nov 5, 2021 The Canadian Pest Management Agency granted registration for the sale and use
 of two biological strains, *Bacillus velezensis* strain RTI301 and *Bacillus subtilis* strain RTI477, in
 addition to the biofungicide products Ataplan and Arolist, which contain the active
 ingredients. The products have been registered for the suppression of seed rot and seedling
 blight in maize, soybean and sunflower, and for suppression of sudden death syndrome of
 soybean.
- Dec 14, 2021 The Brazilian biologicals company Biotrop Soluções Biológicas launched its biological fungicide Bombardeiro in Brazil. The product, based on *Bacillus subtilis* strain CNPSo 2720, *Bacillus velezensis* strain CNPSo 3602 and *Bacillus pumilus* strain CNPSo 3203, is targeted at the control of brown spot (*Septoria glycines*) on a range of crops, including soybean.
- Dec 23, 2021 China's Jiangsu Academy of Agricultural Sciences (JAAS) and Trust Chem Crop Protection launched a joint venture, Trust Chem Biopesticide Research Institute of Jiangsu Academy of Agricultural Sciences. Trust Chem purchased biopesticide patents of JAAS and the two entities were to cooperate in the research, development and marketing of biopesticides. Activities are expected to initially focus on *Lysobacter capsici* and *Bacillus subtilis*.
- Jun 1, 2022 AgBiome obtained approval for its Theia (*Bacillus subtilis*) fungicide from the US EPA following its submission in 2020. The product has been developed through the company's Genesis platform and represents the second proprietary product released by the company. The fungicide provides protection against a broad-spectrum of foliar and soil diseases including powdery mildew, and fusarium in fruit and vegetable crops.
- Jun 6, 2022 The Spanish biological crop protection company Seipasa received approval in France for its Fungisei (*Bacillus subtilis* strain IAB/BS03) biofungicide. The product is targeted at the control of diseases including *botrytis*, powdery mildew and mildew in a variety of crops including berries, vine, tomato, chili pepper and horticultural crops. Fungisei has also been registered in Mexico in 2020, Turkey, and Peru (2019) under an agreement with Agritop Peru.
- Jul 22, 2022 AgBiome received state registrations for its biofungicide product Theia (*Bacillus subtilis*) in Arkansas, Delaware, Georgia, Idaho, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nevada, Oklahoma, South Carolina, Utah, Vermont and West Virginia. This follows the product receiving EPA approval earlier in 2022.

- Aug 2, 2022 De Sangosse Brasil (DSB), a subsidiary of France's De Sangosse Group, has entered the Brazilian biologicals market through the launch of its Bio Solutions portfolio. The company's Bio Solutions portfolio currently encompasses 7 products including the biofungicide Restrict (*Bacillus amyloliquefaciens* strain CPQBA 040-11DMR 01 / *Bacillus amyloliquefaciens* strain CPQBA 040-11DMR 04).
- Aug 11, 2022 AgBiome received further state registrations for its biofungicide Theia (*Bacillus subtilis*), in North Carolina, Texas and Arizona. The product was initially granted US EPA Approval in June 2022. The fungicide provides protection against a broad-spectrum of foliar and soil diseases including powdery mildew, and fusarium in fruit and vegetable crops.
- Aug 17, 2022 FMC introduced the biofungicide Provilar (*Bacillus velezensis* strain RTI301 / *Bacillus subtilis* strain RTI477) in Brazil for the control of white mould in cotton, soybean and bean crops. The product will be offered through the company's recently launched Biologicals by FMC brand.
- Sep 28, 2022 BASF added the product to its Canadian crop establishment portfolio: Nodulator IP Plus (*Bacillus subtilis* strain BU1814 / *Bacillus amyloliquefaciens* strain MBI 600 / *Bradyrhizobium japonicum* strain 532C).
- Oct 4, 2022 The Spanish biological crop protection company Seipasa launched the biofungicide Fungisei (*Bacillus subtilis* strain IAB/BS03) in Portugal, with the product to be distributed in the country by Jovagro. Fungisei is targeted at the control of diseases including botrytis, powdery mildew and mildew, in a variety of fruit and vegetable crops. Fungisei has also been registered in France (2022), Mexico (2020), Turkey, and Peru under an agreement with Agritop Peru (2019).
- Oct 27, 2022 AgBiome's biofungicide Theia (*Bacillus subtilis*) received state registration in Florida, with the product now approved in more than 40 US states. The product was initially granted US EPA approval in June 2022, and was recently approved in North Carolina, Texas and Arizona (2022). The fungicide provides protection against a broad-spectrum of foliar and soil diseases including powdery mildew, and fusarium in fruit and vegetable crops.
- Dec 12, 2022 The Spanish biological crop protection company Seipasa launched the biofungicide Fungisei (*Bacillus subtilis* strain IAB/BS03) in Spain. Fungisei is targeted at the control of a range of diseases including botrytis, powdery mildew and mildew, in a variety of fruit and vegetable crops. The product has also been introduced in Portugal (2022), France (2022), Mexico (2020), Turkey, and Peru under an agreement with Agritop Peru (2019).
- Dec 13, 2022 Bayer received registration in Canada for the biological fungicide Minuet (*Bacillus subtilis* strain QST 713). The product is approved for soil-applied use on potatoes and other vegetable crops to offer protection against rhizoctonia root rot, black scurf, and stem canker. The product also offers protection against pink rot and root rot caused by *Fusarium, Phytophora and Pythium spp.*
- Mar 21, 2023 AgBiome's biofungicide Theia (*Bacillus subtilis* strain AFS032321) received state registration in California. The product provides protection against a broad spectrum of foliar and soil diseases, including powdery mildew and fusarium in fruit and vegetable crops. Theia was initially granted US EPA approval in June 2022 and has since received registration in more than 40 US states.
- Jul 11, 2023 Seipasa obtained new phytosanitary registrations for its products Pirecris (pyrethrin) and Fungisei (*Bacillus subtilis* strain IAB/BS03).
 Fungisei has been registered in Italy, Greece, Croatia, Cyprus and Bulgaria to protect against powdery mildew, mildew, *Botrytis* and soil diseases in various fruit and vegetable crops. The product has also been introduced in Spain (2022), Portugal (2022), France (2022), Mexico (2020), Turkey, and Peru under an agreement with Agritop Peru (2019) and also has registrations in the USA, Ecuador, Morocco, Tunisia and Ivory Coast.

- Aug 31, 2023 FMC and Girassol Agrícola, a Brazil-based provider of agricultural seeds, entered into an agreement through which Girassol Agrícola was to supply cotton seeds treated with FMC's seed treatment Presence Full (*Bacillus licheniformis / Bacillus subtilis*) and seed protector Permit Star (dietholate). Presence Full is intended for the control of gall nematode (*Meloidogyne incognita*) and lesion nematode (*Pratylenchus brachyurus*)
- Aug 31, 2023 FMC launched the biofungficide Entazia (*Bacillus subtilis*) in India. The product is targeted at the control of bacterial leaf blight in rice crops.
- Oct 17, 2023 FMC launched the biofungicide seed treatment Ataplan (*Bacillus velezensis* strain RTI301 / *Bacillus subtilis* strain RTI477) in Brazil. The product, which can also be applied infurrow, is targeted at the control of soil-borne diseases, including *Fusarium spp., Rhizoctonia spp., Pythium spp.*, and *Colletotrichum spp.*
- Nov 13, 2023 FMC announced that it was to launch the insecticide / biofungicide Ethos Elite LFR (bifenthrin / *Bacillus velezensis* strain RTI301 / *Bacillus subtilis* strain RTI477) in the US in 2024. The product is intended for use on a range of crops including maize, soybeans, cotton, peanuts, tomatoes, and canola, to provide broad spectrum control of early-season diseases and soil-borne pests. Ethos Elite LFR, which is formulated with FMC's Liquid Fertiliser Ready (LFR) technology, will be available on a limited commercial basis for the 2024 crop season with a complete launch scheduled in 2025.
- Mar 20, 2024 Certis Biologicals announced the acquisition of multiple assets from AgBiome, including Theia (*Bacillus subtilis* strain AFS032321). Theia is intended for the control of soilborne and foliar diseases such as *Alternaria*, blight, *Phytophthora*, powdery mildew and *Pythium* in a variety of crops including citrus, cucurbits, grapes, stone fruits and fruiting vegetables.
- Apr 23, 2024 The Chilean biocontrol manufacturing company Bio Insumos Nativa launched the biofungicide Nacillus Max (*Bacillus subtilis* strain N5 / *Bacillus licheniformis* strain Copihue / *Brevibacillus parabrevis* strain N4) in Brazil for the control of early blight (*Alternaria solani*). Sumitomo Corporation recently announced plans to invest in Bio Insumos Nativa, with the company representing the main supplier of biocontrol products offered by Sumitomo's Summit Agro South America subsidiary
- Jun 26, 2024 Rovensa Next launched the biofungicide Milarum (*Bacillus subtilis* strain IAB/BS03) in Brazil. The product is registered for the control of downy mildew (*Pseudoperonospora cubensis*) and late blight (*Phytophthora infestans*).
- Jun 26, 2024 Rovensa Next launched the biofungicide Ospo Vi55 (*Bacillus subtilis* strain IAB/BS03) in Brazil. The product is targeted at the control of powdery mildews (*Sphaeroteca fuliginea*, *Leveillula taurica*, and *Uncinula necator*) on crops including cucurbits, onions and grapes.
- Jun 26, 2024 Rovensa Next launched the biofungicide Row-Vispo (*Bacillus subtilis* strain IAB/BS03) in Brazil. The product is targeted at the control of diseases including Asian rust (*Phakopsora pachyrhizi*) and brown spot (*Septoria glycines*) in soybeans.
- Oct 31, 2024 Syngenta Biologicals launched the biofungicide Reverb (*Bacillus subtilis / Bacillus pumilus / Bacillus velezensis*) in Brazil for use on soybean to control key foliar diseases. The product can also be used on other crops, such as maize, cotton, sugarcane, wheat, coffee and F&V.
- Jan 24, 2025 FMC received approval from the EU for two of its proprietary microbial strains under the low risk substance classification. The low risk status of these substances is expected to help to minimise registration timelines for products containing these active ingredients, such as the biofungicides Ataplan (*Bacillus velezensis* CEPA RTI301 / *Bacillus subtilis* CEPA RTI477), Provilar (*Bacillus velezensis* strain RTI301 / *Bacillus subtilis* strain RTI477), and Forenia (*Bacillus velezensis* strain RTI301 / *Bacillus subtilis* strain RTI477).

- Jan 30, 2025 Amvac entered into a regional distribution agreement with the agricultural biologicals company DPH Biologicals. Under the long-term agreement, Amvac will resell DPH Biologicals' key products in the US, including the biocontrol product BellaTrove Companion Maxx (*Bacillus amyloliquefaciens* strain ENV503)
- Feb 21, 2025 The European Commission approved the microorganism Bacillus subtilis strain RTI477 as a low risk active substance for use as a pesticide, with the approval valid until 12th February 2040. Bacillus subtilis strain RTI477 is a naturally occurring, non-modified bacterium originally isolated from the root of the plant species Moringa oleifera growing in North Carolina, USA, in 2013. The microorganism, submitted for approval by FMC, can be used as a biofungicide for the control of soil-borne diseases such as Rhizoctonia sclerotiorum, Phoma solani, Pythium spp., Phytophthora capsici, Sclerotinia lingam, Plasmodiophora brassicae and Fusarium spp. in field and greenhouse (permanent) and walk-in tunnels crops.

Sales of *B. subtilis* reached an estimated \$29 million in 2023, representing average growth of 20.1% per annum between 2018 and 2023.

Trichoderma spp.

Trichoderma is a fungal genus containing several species that have been used as biopesticides against other fungi. These work through multiple mechanisms, including antibiotic activity, parasitism, host plant resistance induction, and direct fungal competition. Most of the available products from this genus are based on *T. harzianum*, *T. asperellum* and/or *T. viride*, which have applications in foliar and seed treatment or soil application. These organisms readily colonise the root zone and form symbiotic relationships with plants.

Sales of fungicides based on *Trichoderma* species were estimated at \$91 million in 2023, with average annual growth of 26.5% over the period 2018-2023. The major markets are Brazil, China, Italy, and Chile, mostly for the important soybean and fruit and vegetable markets where this AI finds its primary applications.

- In 2020, the Canadian Pest Management Regulatory Agency granted registration for the sale and use of the active fungicidal ingredient *Trichoderma asperellum* strain T34 and the products T34 Biocontrol Technical and Asperello T34 Biocontrol, which contain the active ingredient. This approval covers the control of certain fungal diseases on greenhouse ornamentals, cannabis produced commercially indoors, and greenhouse vegetables.
- Feb 25, 2021 Lusosem launched the biofungicide Blindar (*Trichoderma gamsii / Trichoderma asperellum*) in Portugal for the control of fungi causing disease such as Esca in grapevines and for control of soil fungi affecting horticultural, fruit and ornamental crops. The product was initially developed by Isagro, in partnership with researchers from the University of Florence.
- Apr 23, 2021 Koppert Biological Systems launched the biological industrial seed treatment BioTSI Koppert in Brazil. The product, which combines the microbial fungicide and nematicide Trianum DS (*Trichoderma harzianum*, strain T22) and the nematicide Veraneio (*Bacillus amyloliquefaciens*, strain UMAF6614), is intended to protect crops against fungi and root nematodes and reportedly results in improved plant health and vigour due to increased root volume.
- May 5, 2021 Andermatt Biocontrol's Tunisian distribution partner, Aloha Agriculture, gained Tunisian registration for the biological fungicide T-77 (*Trichoderma atroviride*), which provides protection against *Botrytis* in fruit and vegetable crops; and the biological insecticide Bb-Protec (*Beauveria bassiana*), which is targeted at the control of sucking pests in fruit and vegetable crops.

- May 10, 2021 Helm Argentina and Terragene entered a development and distribution agreement for biological products in Argentina. The first product to be distributed under this partnership will be Innobio Protergium, a soybean seed treatment comprising *Bacillus velezensis, Trichoderma harzianum* and *Bradyrhizobium japonicum*. Innobio Protergium was made available in 2021 and is targeted at the control of soil microorganisms that affect the seed and whilst also improving the solubilisation of nutrients and biological fixation of nitrogen.
- Dec 1, 2021 The Argentinian microbiological product development company Rizobacter, a subsidiary of Bioceres Crop Solutions, gained approval in Brazil for its biofungicide Rizoderma. Based on *Trichoderma harzianum* strain TH2, the product was developed by Rizobacter alongside the Argentinian National Technology Institute (INTA). Rizoderma is intended to control a range of soil and seed borne pathogens, including *Sclerotinia sclerotiorum*, *Macrophomina*, *Fusarium*, *Rhizoctonia*, *Drechslera*, *Bipolaris*, *Cercospora* and *Phomopsis*.
- Mar 1, 2022 The Indian Institute of Technology (IIT) Kanpur, in collaboration with ICAR-Indian Institute of Rice Research and University of Hyderabad, developed a novel nanoparticle-based biodegradable-carbonoid-metabolite (BioDCM) that can protect agricultural crops from fungal and bacterial infections. The nano-bio-pesticide is developed to produce a biodegradable nanoparticle system from the secondary metabolites of the fungus *Trichoderma asperellum* strain TAIK1 and has reportedly been shown to be effective against *Xanthomonas oryzae*, a bacterium most commonly found on rice.
- De Sangosse Brasil (DSB), a subsidiary of France's De Sangosse Group, entered the Brazilian biologicals market through the launch of its Bio Solutions portfolio. The company's Bio Solutions portfolio currently encompasses 7 products including: Gladiador (*Trichoderma asperellum* – CBMAI 1622) – biological fungicide
- Oct 28, 2022 Health Canada's Pest Management Regulatory Agency (PMRA) granted registration for the sale and use of the microbial pest control agents contained in *Trichoderma asperellum* ICC 012 technical, *Trichoderma gamsii* ICC 080 Technical and Foretryx, containing the technical grade active ingredients *Trichoderma asperellum* strain ICC 012 and *Trichoderma gamsii* strain ICC 080, for the suppression of certain fungal diseases on field and greenhouse fruiting vegetables, squash, lettuce, field and greenhouse strawberries, greenhouse ornamentals and cannabis produced commercially indoors.
- Nov 9, 2022 The biocontrol and pollination company Biobest gained approval for the biofungicide Asperello (*Trichoderma asperellum* strain T34) in Denmark and Morocco. In Denmark, the product has been approved for use against *Pythium* and *Fusarium* in ornamental, bulb and cut flower crops, as well as greenhouse vegetable, salad and berry crops, cucumber, squash, melon, courgette, lettuce, leafy vegetables, herbs, berries and seed production. Asperello has also been approved for use against *Pythium* in tomatoes and peppers and *Didymella* in cucumber crops. In Morocco, the product has been approved for use against *Pythium* in tomatoes and peppers and *Didymella* in cucumber crops.
- Nov 18, 2022 Koppert Argentina announced the launch of a bioinput pack that combines an inoculant with a fungicide, based on *Trichoderma harzianum*, that can be applied up to 25 days before planting. The product has previously been introduced in Brazil.
- Dec 8, 2022 Brazil granted approval for TZ Biotec's Trichoningyd FR 25 (*Trichoderma koningiopsis* strain CCT 2142), is a biofungicide registered for the control of *Fusarium oxysporum*.
- Feb 2, 2023 The European Commission approved the microorganism *Trichoderma atroviride* strain AT10, with the approval valid until 20th February 2038. *Trichoderma atroviride* strain AT10 is a filamentous fungus isolated from the soil in Tarragona, Spain, and can be used as a biofungicide to control various fungal pathogens, including *Sclerotinia spp*.

- Feb 7, 2023 The European Commission approved the microorganism *Trichoderma atroviride* strain AGR2 until 21st February 2038. *Trichoderma atroviride* strain AGR2 is a wild-type strain, a filamentous fungus isolated from plant fragments in a cultivated soil in France. The strain can be used as a biofungicide to control various fungal pathogens, including *Sclerotinia sclerotiorum* on oilseed rape.
- Feb 23, 2023 Certis Biologicals launched the biofungicide SoilGard (*Trichoderma virens*) in the USA. The microbial fungicide is targeted at the control of *Pythium, Rhizoctonia* and *Fusarium*, and has a variety of label uses, including in greenhouses and nurseries, agricultural food crops and ornamentals. SoilGard will be available for purchase across 50 states.
- Mar 17, 2023 Koppert do Brasil entered into a partnership with the application technology company Orion Tecnologia e Sistemas regarding the in-furrow application of biological products for grain crops. Through the partnership, Koppert customers will gain access to Orion's equipment, which has been developed specifically for in-furrow applications of biologicals, with the aim of improving and maintaining the quality and effectiveness of biological products. Koppert's portfolio of products that can be applied in-furrow include the fungicide / nematicide Trichodermil (*Trichoderma harzianum*)
- Apr 14, 2023 Andermatt received approval in Brazil for the biofungicide T-77 (*Trichoderma atroviride* strain 77B), also trademarked as ATROVERDE 77, with *Trichoderma atroviride* representing a new active ingredient in the country. The product has been registered for use on all crops to control white mould (*Sclerotinia sclerotiorum*).
- Apr 28, 2023 Koppert's biological fungicide Trianum-P (*Trichoderma harzianum* strain T22) received approval in the Netherlands and Belgium for use on pears to treat Brown spot (*Stemphylium versicarium*). The product, which was already approved for use on several outdoor crops, is intended to be sprayed full field on the ground to reduce the growth of the soil-borne Stemphylium, resulting in a lower number of infective ascospores.
- May 25, 2023 Dhanuka Agritech entered the agricultural biologicals market through the launch of its new BiologiQ portfolio in India. The company's BiologiQ portfolio currently encompasses 3 products:
 - Spornil (*Trichoderma harzianum*) biofungicide targeted at the control of wilt, rot, and damping.
 - Downil (based on an aerobic, gram-positive, motile, and adaptive soil bacterium) biofungicide for the control of downy mildew.
 - Whiteaxe (*Metarhizium anisopliae*) bioinsecticide for the control of white grub, termites, and borers.

Dhanuka's BiologiQ portfolio of products will expand to include additional crop protection, soil health, and plant nutrition products, all of which can be used alone or in combination with conventional chemical products as part of an integrated pest management strategy.

- May 26, 2023 Andermatt launched the biofungicide Atroverde 77 (*Trichoderma atroviride* strain 77B) in Brazil. The product, which was approved for use in the country earlier in 2023, is intended for the control of white mould (*Sclerotinia sclerotiorum*).
- Jun 7, 2023 AMVAC GreenSolutions, AMVAC's US-based biologicals segment, launched the biological fungicide Vintec (*Trichoderma atroviride* strain SC1) for use on almonds. The product, originally developed and registered in the US by the biological crop protection company Bi-PA (2019), is targeted at the control of fungal pathogens, including *Phaeomoniella chlamydospora* and *Phaeoacremonium aleophilum*, which are the cause of trunk diseases. Vintec is also registered for use on grapes and has been used in Europe in grape production to manage grapevine trunk diseases.

- Jul 26, 2023 Locus Agriculture, a provider of biological inputs and advisory services, expanded the availability of its Rhizolizer biological product line to include products suited for the fruit and vegetable crop sector. The new Rhizolizer Duo products contain proprietary *Trichoderma* and *Bacillus* strains and are designed to colonise roots, promote early root development and improve crop productivity. The Rhizolizer line of products is also available for various row crops.
- Feb 22, 2024 Amvac and Biotor Labs, a Nicaragua-based developer of biological control solutions, introduced the biofungicide Trichomax (*Trichoderma asperellum*) in Mexico for the control of soilborne diseases. The product, which is already available in Nicaragua, Honduras, Dominican Republic, Costa Rica, and Panama, is expected to receive Mexican approval by the beginning of 2025. Amvac and Biotor Labs expanded their Global Product Evaluation and Exclusive Option contract through to July 2024.
- Mar 1, 2024 The crop inputs company Alltec launched the seed treatment biofungicide TrichoSmart Mega (*Bacillus megaterium* Ara6 / *Trichoderma harzianum* TH10) in Argentina. In addition to control of diseases, the product reportedly improves plant growth and tolerance to biotic and abiotic stressors.
- Apr 10, 2024 Agrobiológica Sustentabilidade, the biologicals-focused subsidiary of the agribusiness Crop Care Holding, launched the biofungicide Powerfung (*Trichoderma asperellum* strain CCT 2165) in Brazil. The product is intended for the control of fusarium wilt (*Fusarium oxysporum* f. sp. *Lycopersici*), root rot (*Rhizoctonia solani*), and white mold (*Sclerotinia sclerotiorum*).
- Jun 7, 2024 IPL Biologicals launched the biofungicide Agenor (*Trichoderma asperellum* strain IPL/ThN) in India for use on rice. The product has reportedly demonstrated strong efficacy against Bakanae (*Gibberella fujikuroi*), a seedborne fungal disease also known as foot rot.
- Aug 23, 2024 The US EPA received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products:
 - MBFi LLC, *Trichoderma asperellum* DSM 33649 at 100% proposed for manufacturing use only to formulate fungicide and nematicide end-use products.
 - MBFi LLC, Trillum DS (*Trichoderma asperellum* DSM33649) at 1% proposed for control of soil-borne fungal pathogens and nematodes on outdoor agricultural and greenhouse crops, ornamental plants, and turf.
 - MBFi LLC, Trillum WP (*Trichoderma asperellum* DSM33649) at 1% proposed for control of soil-borne fungal pathogens and nematodes on outdoor agricultural and greenhouse crops, ornamental plants, and turf.
- Oct 9, 2024 Koppert and Orion entered into a strategic partnership to advance in-furrow applications of biological crop protection products. Following European field trials on row crops, the companies will now offer in-furrow applications for products including Capirel (*Steinernema feltiae*), Casea (*Steinernema carpocapsae*) and the biofungicide Trianum (*Trichoderma harzianum* strain T22). The collaboration builds on an existing agreement between the companies in Brazil
- Jan 28, 2025 The European Commission extended the approval periods to 30th November 2026 for *Trichoderma atroviride* (formerly *T. harzianum*) strain T11; *Trichoderma harzianum* Rifai strains T-22 and ITEM 908; *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T-25, and TV-1; and *Trichoderma gamsii* (formerly *T. viride*) strain ICC080.

Bacillus pumilus

B. pumilus strain QST2808 was developed by AgraQuest, which was acquired by Bayer Crop Science in 2013. This product is sold as Sonata and is used to control fungi such as mildews, blights, and moulds in a range of crops, including maize, soybean, and cereals. Sales are led by the US market, where the product is sold by Bayer, and France, where Corteva distributes the product as Ballad for use on cruciferous vegetables. Sales were \$28 million in 2023, with average annual growth of 36.9% over the period 2018-2023.

- In 2019, Bayer received registration approval for Sonata (*Bacillus pumilus* QST 2808) in Italy, with the product registered for the control of fungal diseases in vine and horticultural crops.
- Dec 14, 2021 The Brazilian biologicals company Biotrop Soluções Biológicas launched its biological fungicide Bombardeiro in Brazil. The product, based on *Bacillus subtilis* strain CNPSo 2720, *Bacillus velezensis* strain CNPSo 3602 and *Bacillus pumilus* strain CNPSo 3203, is targeted at the control of brown spot (*Septoria glycines*) on a range of crops, including soybean.
- Oct 31, 2024 Syngenta Biologicals launched the biofungicide Reverb (*Bacillus subtilis / Bacillus pumilus / Bacillus velezensis*) in Brazil for use on soybean to control key foliar diseases. The product can also be used on other crops, such as maize, cotton, sugarcane, wheat, coffee and F&V.
- Jan 30, 2025 Amvac entered into a regional distribution agreement with the agricultural biologicals company DPH Biologicals. Under the long-term agreement, Amvac will resell DPH Biologicals' key products in the US, including the biocontrol product BellaTrove Companion Maxx (*Bacillus amyloliquefaciens* strain ENV503), and the biofertilisers TerraTrove SP-1 Classic (Humus extract / algae / *Bacillus amyloliquefaciens* / *Bacillus licheniformis* / *Bacillus megaterium* / *Bacillus pumilus* / *Bacillus subtilis*) and TerraTrove AmplAphex (*Bacillus amyloliquefaciens* / *Bacillus licheniformis* / *Bacillus subtilis*). The agreement is expected to help expand Amvac's GreenSolutions portfolio while also expanding DPH Biologicals' footprint into specialty crop markets.
- Apr 14, 2025 Koppert received a label extension in Brazil for the biofungicide Caravan (*Bacillus pumilus* strain CNPSo 3203), with the product now also approved for use on sugarcane in addition to soybean, maize and cotton. For sugarcane, Caravan has been registered for the control of foliar diseases, including red rot (*Colletotrichum falcatum*), brown leaf spot (*Cercospora longipes*), orange rust (*Puccinia kuehnii*) and sugarcane rust (*Puccinia melanocephala*).

Regulatory Situation

The regulatory situation for biological pesticides is generally more favourable in most country markets than it is for conventional chemical products, with the natural origin commonly being seen as safer. However, the number of biological active ingredients reaching the market in the EU, where microbial biofungicides are regulated through the same mechanisms as conventional chemicals, is relatively low. A crucial factor is the high cost of registering a new active ingredient for use, which limits the ability of the (often small) companies that have developed these new technologies to pursue registration. Interest from larger companies has led to acquisitions and licensing agreements with smaller biological product developers, which will likely increase the number of biological fungicide AIs reaching the market in the coming years.

The table below shows the microbial fungicides approved for use in the EU and USA.

EU	USA	Activity	Туре
ABE-IT 56		Fungicide	Bacteria
	Agrobacterium radiobacter (strain K84)	Fungicide	Bacteria
	Agrobacterium radiobacter strain K1026	Fungicide	Bacteria
	Ampelomyces quisqualis isolate M-10	Fungicide	Fungus
Ampelomyces quisqualis strain AQ10		Fungicide	Bacteria
	Aspergillus flavus NRRL 21882	Fungicide	Fungus
Aspergillus flavus strain MUCL 54911		Fungicide	Bacteria
Aureobasidium pullulans (strains DSM 14940 and DSM 14941)		Fungicide	Bacteria
Bacillus amyloliquefaciens (formerly subtilis) str. QST 713		Fungicide	Bacteria
Bacillus amyloliquefaciens AH2		Fungicide	Bacteria
Bacillus amyloliquefaciens AT-332		Fungicide	Bacteria
Bacillus amyloliquefaciens IT-45		Fungicide	Bacteria
Bacillus amyloliquefaciens strain FZB24	Bacillus amyloliquefaciens strain FZB24	Fungicide	Bacteria
Bacillus amyloliquefaciens strain FZB42		Fungicide	Bacteria
Bacillus amyloliquefaciens strain MBI 600	Bacillus amyloliquefaciens strain MBI 600	Fungicide / nematicide	Bacteria
Bacillus amyloliquefaciens subsp. plantarum D747		Fungicide	Bacteria
Bacillus licheniformis strain FMCH001		Fungicide / nematicide	Yeast
	Bacillus licheniformis strain SB3086	Fungicide	Bacteria
Bacillus nakamurai F727		Fungicide	Fungus
	Bacillus pumilus strain GB34	Fungicide	Bacteria
Bacillus pumilus strain QST 2808	Bacillus pumilus strain QST 2808	Fungicide	Fungus
	Bacillus subtilis GB03	Fungicide	Bacteria
Bacillus subtilis strain FMCH002		Fungicide / nematicide	Microbia
Bacillus subtilis strain IAB/BS03		Fungicide	Yeast
	Bacillus subtilis strain QST 713	Fungicide	Bacteria
Bacillus subtilis strain RTI477		Fungicide	Fungi
Bacillus velezensis strain RTI301		Insecticide / fungicide	Fungi
	Burkholderia (pseudomonas) cepacia type Wisconsin isolate/strain J82	Fungicide / nematicide	Bacteria
	Burkholderia (Pseudomonas) cepacia type Wisconsin isolate/strain M54	Fungicide / nematicide	Bacteria
	Candida oleophila isolate I-182	Fungicide (post harvest)	Yeast
Candida oleophila strain O		Fungicide (post harvest)	Fungi
Clonostachys rosea strain J1446 (Gliocladium catenulatum strain J1446)		Fungicide	Bacteria
Coniothyrium minitans Strain CON/M/91-08 (DSM 9660)	Coniothyrium minitans strain CON/M/91- 08	Fungicide	Bacteria
	Dried fermentation solids and solubles resulting from fermentation of <i>Trichoderma harzianum</i> isolate T-39, containing T-39 fungus propagules, as either conidia or mycelia	Fungicide	Fungus
	Gliocladium virens GL-21	Fungicide	Fungus
Lysate of Willaertia magna C2c Maky		Fungicide	Fungus
Metschnikowia fructicola strain NRRL Y-27328		Fungicide	Fung

	Pantoea agglomerans strain C9-1	Fungicide	Bacteria
Phlebiopsis gigantea strain FOC PG 410.3		fungicide (non crop)	Fungi
Phlebiopsis gigantea strain VRA 1835		fungicide (non crop)	Bacteria
Phlebiopsis gigantea strain VRA 1984		fungicide (non crop)	Bacteria
	Pseudomonas aureofaciens strain Tx-1	Fungicide	Bacteria
	Pseudomonas chlororaphis strain 63-28	Fungicide	Bacteria
Pseudomonas chlororaphis strain MA342		Fungicide	Fungus
	Pseudomonas fluorescens	Fungicide	Bacteria
	Pseudomonas fluorescens 1629RS	Fungicide	Bacteria
	Pseudomonas fluorescens A506	Fungicide	Bacteria
Pseudomonas sp. Strain DSMZ 13134		Fungicide	Fungus
	Pseudomonas Syringae 742RS	Fungicide	Bacteria
	Pseudomonas syringae, strain ESC 10	Fungicide	Bacteria
	Pseudomonas syringae, strain ESC-11	Fungicide	Bacteria
	Pseudozyma flocculosa	Fungicide	Fungus
Pythium oligandrum strain B301		Fungicide	Fungus
Pythium oligandrum strain M1		Fungicide	Fungus
Saccharomyces cerevisiae strain LAS02		Fungicide	Fungus
Streptomyces lydicus strain WYEC 108	Streptomyces lydicus strain WYEC 108	Fungicide	Fungus
Streptomyces strain K61 (formerly S. griseoviridis)	Streptomyces strain K61 (formerly S. griseoviridis)	Fungicide	Fungus
Tribasic copper sulphate		Fungicide	Fungus
Trichoderma afroharzianum (formerly T. harzianum) <u>strain</u> T-22	Trichoderma afroharzianum (formerly T. harzianum) strain T-22	Fungicide	Fungus
Trichoderma afroharzianum (formerly T. harzianum) strain T-22 and atrobrunneum (formerly T. harzianum) strain ITEM 908		Fungicide	Fungus
Trichoderma afroharzianum Th2RI99		Fungicide	Fungus
Trichoderma asperellum (formerly T. harzianum) strain ICC012		Fungicide	Fungus
Trichoderma asperellum (formerly T. harzianum) strains ICC012, Trichoderma asperellum (formerly T. viride) T25 and Trichoderma asperellum (formerly T. viride) TV1		Fungicide	Fungus
Trichoderma asperellum (formerly T. viride) strain T-25		Fungicide	Fungus
Trichoderma asperellum (formerly T. viride) strain TV-1		Fungicide	Fungus
Trichoderma asperellum strain T34		Fungicide	Fungus
Trichoderma atrobrunneum (formerly T. harzianum) strain ITEM 908		Fungicide	Fungus
Trichoderma atroviride (formerly T. harzianum) strain T11		Fungicide	Fungus
Trichoderma atroviride 77B		Fungicide	Fungus
Trichoderma atroviride AGR2		Fungicide	Fungi
Trichoderma atroviride AT10		Fungicide	Bacteria
Trichoderma atroviride strain I-1237		Fungicide	Bacteria
Trichoderma atroviride strain SC1		Fungicide	Bacteria
<i>Trichoderma gamsii</i> (formerly <i>T. viride</i>) strain CC080		Fungicide	Bacteria
	Trichoderma hamatum TH382	Fungicide	Fungus
Trichoderma harzianum T78		Fungicide	Bacteria
	Trichoderma polysporum (ATCC 20475)	Fungicide	Fungus
	Trichoderma viride (ATCC 20476)	Fungicide	Fungus

Note: Green = approved (EU) registered (USA), orange = pending approval, purple = registration review. Information is correct as of May 2025

Company Involvement

Several microbial fungicides have reached the market through research by dedicated biological crop protection companies. For example, Koppert has developed the botryticide *Metschnikowia fructicola* while Biopreparáty has launched Polyversum (*Pythium oligandrum*). On the other hand, multinational involvement has generally come from acquisitions, such as Bayer's acquisitions of AgraQuest (which included *Bacillus pumilus*) and Prophyta (which developed *Coniothyrium minitans*). Smaller companies have generally gained access to technologies through licensing agreements, with Gowan and De Sangosse gaining licenses to *Pythium oligandrum* from Biopreparáty, Certis USA gaining licenses to Kumiai's *Bacillus amyloliquefaciens* and the University of Szeged's *Bacillus mojavensis* strain R3B, and Arysta gaining access to Bion Tech's *B. subtilis* in Japan.

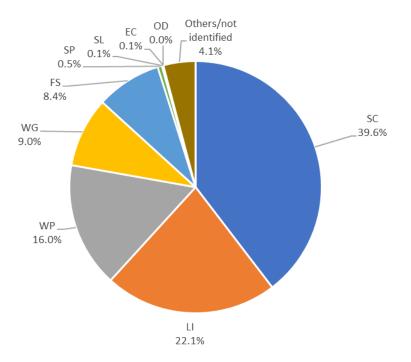
In 2023 Syngenta merged its in-house biologicals business with Valagro, the biostimulants and specialty nutrients company the company acquired in 2020, under the brand name Syngenta Biologicals. The new business is expected to benefit from Syngenta's existing R&D pipeline, commercial network and production capabilities, and will be enhanced by the incorporation of Valagro's proprietary technology platform and staff. The Syngenta Biologicals portfolio includes the biofungicide Taegro (*Bacillus amyloliquefaciens* strain FZB24). The company intends to pursue collaborations aimed at expanding its product portfolio across a range of applications, including foliar, seed treatments, combinations with fertilisers, and non-agricultural uses.

The below table(s) on key active ingredients and key companies is derived directly from AgBioInvestor's exclusive primary market research study that surveyed biological- and biostimulantgrowers, which were conducted for the first time in 2023 and profiled the 2022 agricultural market. The market research surveyed many key agricultural markets for biologicals, including: USA, Mexico, Chile, Brazil, Argentina, France, Italy, Spain and Turkey. The Ais have been ranked by farm-gate value (\$m.). Quantification of these data and much more biological market research can be found in the separate subscription product AgbioInsight.

Biofungicides: Microbials Key Companies		
Strain	Key Companies	
Bacillus amyloliquefaciens Strain QST713	Bayer	
Chenopodium quinoa saponins	Heads Up Plant Protectants	
Trichoderma harzianum strain TH2	Rizobacter	
Trichoderma harzianum strain CCT 7589	Simbiose	
	Bioma	
Bacillus amyloliquefaciens isolate CBMAI 1301	Dillon Biotecnologia	
	Simbiose	
Bacillus amyloliquefaciens Strain MBI600	BASF	
Bacillus amyloliquefaciens	Mitsui & Co. (Certis)	
	BASF	
Trichoderma harzianum subsp. Rifai strain ESALQ-1306	Koppert	
Trichoderma harzianum strain CCC 176-2001	Fitoquimica	
Bacillus amyloliquefaciens Strain Mbi600 / Bacillus pumilus strain BU F-33	BASF	
	Corteva	
Trichoderma harzianum isolate IBLF 006	Ballagro	
Bacillus amyloliquefaciens strain MBI 600	BASF	
Trichoderma harzianum	Tecnologias Naturales Internacional	
	Biokrone	
	Tropfen	
	Plant Health Care	
	UPL	

Formulation Types – Value Share

The below chart(s) are derived from the biological focussed market research that AgbioInvestor conducted and illustrates the value share attributed to various formulation type codes.



Biofungicides: Microbials

Code	Description	Code	Description
AE	Aerosol dispenser	LI	Liquid
AL	Other liquids to be applied undiluted	LS	Solution for seed treatment
СВ	Bait concentrate	ME	Micro emulsion
CS	Capsule suspension	OD	Oil dispersion
DC	Dispersible concentrate	SC	Suspension concentrate
DF	Dry flowable	SL	Soluble concentrate
DP	Dustable powder	SP	Water soluble powder
EC	Emulsifiable concentrate	VP	Vapour releasing product
EW	Emulsion, water in oil	WG	Water dispersible granule
FS	Flowable concentrate for seed treatment	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment
LC	Liquid concentrate		

Research and Development

Research and development for new microbial fungicides concerns three primary areas: discovering new fungi, bacteria, and other microbes that have fungicidal activity; developing new strains of existing organisms with improved efficacy; and improving formulations to increase efficacy in the field and usability for growers.

- Apr 28, 2022 Bee Vectoring Technologies (BVT) submitted its proprietary biofungicide product Clonostachys rosea CR-7 for registration in Mexico. The application was submitted to COFEPRIS (The Federal Commission for Protection from Sanitary Risks) on April 19th and included CR-7 trial data, with the trial conducted in Mexico. The application was part of a 2022 programme to submit the product in up to four new jurisdictions, with registration already secured in the US in 2019.
- Jun 16, 2022 The Brazilian company Leaf Agrociência entered into an agreement with the state universities of Northern Paraná (UENP) and Londrina (UEL). Through the partnership, the company will aim to commercialise a novel microbial biofungicide for the control of Asian soybean rust, that has been developed at UENP. The agreement includes a TRL (Technology Readiness Level / Level of Technological Maturity) for the microbiological product. Researchers at UEL will work on the development of first and second-generation biological products, following on from the work carried out at UENP, with the aim of producing a second-generation product in which the active ingredient of the final product will be a metabolite produced by microorganisms and not the microorganisms themselves.
- Jun 24, 2022 Certis Biologicals and Novozymes announced a collaboration to develop solutions for the control of fungal diseases. Through this agreement, the companies will jointly develop their respective technologies, with combinations of Certis Biologicals' biofungicide active ingredient and Novozymes' LCO Promoter technologies currently being tested in field trials in the Midwestern USA. Certis Biologicals' biofungicide provides broad-spectrum preventative control or suppression of many fungal and bacterial plant diseases. Novozymes technology utilises Lipo-chitooligosaccharide (LCO) Promoter technology, which has been developed to maximise plant health and crop performance.

- Aug 18, 2022 Bee Vectoring Technologies (BVT) was granted a patent (Patent Number BR112016005139-4) in Brazil for its *Clonostachys rosea* CR-7 microbial strain (CR-7) covering its use as a biological control agent in agriculture in any application method, in any formulation (solid or liquid), for yield improvement and for disease control. The strain has previously received a patent regarding its validation as a plant treatment in several other countries: Belgium, Germany, Spain, France, UK, Greece, Italy, Poland, Portugal, Romania, Serbia, Switzerland, the Netherlands and Turkey
- Oct 12, 2022 Lavie Bio, the ag-biologicals subsidiary of Evogene, submitted its biofungicide product LAV.311 to the US EPA for approval. The product is a water dispersible granule (WDG) based on the bacterium *Pseudomonas coleopterorum*, possessing multiple modes of action and targeted at the control of fruit rots and powdery mildews. The company intends to commercialise the product for the 2024 growing season, subject to approval. Lavie Bio progressed its leading biofungicide candidates, LAV.311 and LAV.312, to the precommercialisation development stage in December 2021, with LAV.311 prioritised as the lead candidate for final development and regulatory dossier submission.
- Dec 8, 2022 Bee Vectoring Technologies (BVT) submitted its proprietary biofungicide product *Clonostachys rosea* CR-7 (CR-7) for regulatory review and approval in Canada. The submission is focused on crops that require pollination by commercially reared and managed bees, including strawberries, tomatoes, canola, blueberries, sunflowers, cherries and plums. BVT has been granted an experimental use permit for CR-7, which will allow the company to conduct demonstration trials in multiple crops in Canada starting in 2023 prior to regulatory approval being obtained. This latest application comes as part of the company's plan to significantly increase its geographic footprint and follows a similar regulatory submission in Mexico made earlier this year.
- Jan 19, 2023 the State University of Londrina (UEL) obtained a patent in Brazil for a biological agent developed to control fungal diseases in plants. The agent was created based on the bacterium *Bacillus velezensis*, a microorganism found in the soil that promotes plant growth. The biofungicide can be used on soybeans to protect against White Mould (*Sclerotinia sclerotiorum*) and Asian Soybean Rust (*Phakopsora pachyrhizi*).
- Jul 17, 2023 Lavie Bio, a subsidiary of Evogene, entered into a licensing agreement with Corteva, through which Corteva has obtained exclusive rights to further develop and commercialise biofungicide product candidates targeting fruit rots and powdery mildew from Lavie Bio. The agreement follows two years of independent field validation conducted by both companies and represents part of Lavie Bio's strategy to expand its market reach by leveraging Corteva's existing commercial network and expertise.
- Jul 27, 2023 Solvay established a partnership with the University of São Paulo (ESALQ-USP Escola Superior de Agricultura Luiz de Queiroz) aimed at developing bioinsecticides, biofungicides, bionematicides and inoculants for use in different crops. The partnership will leverage ESALQ-USP's expertise in biopesticides, bioprocesses and agronomic applications, and Solvay's knowledge in formulations for the agricultural sector.
- Nov 10, 2023 Lavie Bio, the ag-biologicals subsidiary of Evogene, announced positive trial
 results for its biofungicide candidate LAV321. The product, which was tested for the control
 of downy mildew and late blight diseases in field trials on vine crops in Europe, has been
 developed using the company's Biology Driven Design (BDD) platform. The company planned
 to advance product development in 2024, with multinational partners conducting field trials,
 in some cases representing a second year of validation, before planning to start regulatory
 processes by the end of 2024.

- Jan 23, 2024 Vitales, a Brazilian agricultural biopesticides company headquartered in Uberaba, Minas Gerais, invested R\$ 1.3 million (\$260,000) in partnership with Embrapii-Esalq unit to develop four new biological products. In the initial phase of the partnership, the companies intend to develop a bioinsecticide, a biofungicide, a bionematicide, and a bioinoculant based on fungi and bacteria, with application and main focus on soybean, maize, sugarcane, cotton, coffee and pasture. The company intends to continue investing in this partnership model, anticipating investments of approximately R\$ 20 million (\$4 million) for research over the next three years.
- Mar 19, 2024 Bayer and Lavie Bio, the ag-biologicals subsidiary of Evogene, announced they
 were to extend their joint validation trials for biofungicides after successful first-year
 laboratory and greenhouse testing. The tests reportedly demonstrated the efficacy of Lavie
 Bio's biofungicides in addressing fruit and vegetable diseases, and the companies will progress
 to a second year of validation trials in field experiments.
- May 10, 2024 Aphea.Bio, a provider of microbial solutions for agriculture, submitted applications for regulatory approval from the US EPA for its *Streptomyces*-based biofungicides Valoria and Virtuosa. Both products have been developed using Aphea.Bio's high-throughput R&D platform APEXbio, with Valoria designed to control diseases such as head blight, yellow rust, leaf blotch, and powdery mildew, in wheat, and Virtuosa intended to control diseases such as grey mould and powdery mildew in fruit and vegetables. The company is currently proceeding with registration activities and intends to submit further applications in the European Union and California.
- May 16, 2024 Bee Vectoring Technologies (BVT) has announced research and development advancements for its proprietary biofungicide *Clonostachys rosea* strain CR-7 for use as a soybean seed treatment. The product is reported to have demonstrated a long shelf life once applied to soybean seeds, and is compatible with other seed treatment products, including biologicals and chemical pesticides. In addition, tests have shown that CR-7 does not harm soybean plant germination or growth. A commercial formulation of the seed treatment product is currently in development.
- Aug 6, 2024 The ISO Technical Committee for common names of pesticides and other agrochemicals has approved the name of Silvateam S.p.A.'s fungicidal and nematicidal plant extract as galquin. The material is a mixture of esters extracted from pods of the legume *Tara spinosa*, comprising esters of quinic acids with gallic acid.
- Aug 21, 2024 Nihon Nohyaku acquired a novel microbial biofungicide as part of its plans to expand its biologicals business. The company intends to develop the biofungicide globally, with initial commercialisation expected in the US, where the product has recently been approved by the EPA.
- Aug 28, 2024 CXC AG, a Canada-based company specialising in commercialising universitydeveloped technologies for agriculture, received a patent from the US Patent and Trademark Office for a product containing *Bacillus pumilus* and *Bacillus subtilis* bacteria strains to control *Streptomyces scabies*, a causal agent of common scab in potatoes. The product has been developed in partnership with McGill University.

- Aug 29, 2024 Ginkgo Bioworks has entered a partnership with Vitales, a subsidiary of the Brazilian agribusiness holding company Uby Agro, to accelerate the development and commercialisation of two biofungicides. The products are targeted at the control of key soybean diseases in Brazil, including Soybean Sudden Death Syndrome (*Fusarium virguliforme*) and target sport (*Corynespora cassiicola*). Specific microbial strains were selected for Vitales, leveraging Ginkgo's collection of pre-validated strain assets, with the partnership also to utilise Ginkgo's expertise in formulation to enable the development of various prototype formulations specifically for use in Brazilian agriculture, including seed treatments and foliar applications. Vitales was established in 2023, with the set-up of the company including a R\$100 million manufacturing facility in the state of Minas Gerais
- Nov 20, 2024 Lavie Bio, the ag-biologicals subsidiary of Evogene, announced progress in the development of its LAV321 bio-fungicide, targeting downy mildew. Over three years of field trials across Europe, evaluating the efficacy of LAV321 in protecting crops from fungal diseases, LAV321 demonstrated an average efficacy rate of 70% against downy mildew in grapes. Following these results, Lavie Bio will advance LAV321 to the last stage of product development toward commercialisation.

The company announced its intention last year to advance product development in 2024, with multinational partners conducting field trials, in some cases representing a second year of validation, before planning to start regulatory processes by the end of 2024.

- Dec 13, 2024 Koppert entered a partnership with Amoéba, an industrial greentech company specialising in the development of natural microbiological solutions based on the patented use of amoebae, through which the companies intend to launch a biofungicide. The companies will exclusively explore opportunities for cooperation in areas such as distribution, production, registration, financing, and product development of Axpera (lysate of *Willaertia magna* C2c Maky) and new biocontrol products. Amoéba recently announced its intention to commercially launch its biofungicide products Axpera Green and Axpera Noa, part of its Axpera Product Line, in the US with approval expected by 2025
- Dec 19, 2024 Amoéba received recognition from the European Food Safety Authority (EFSA) of the fungicidal efficacy and low-risk profile of Axpera (lysate of *Willaertia magna* C2c Maky). The assessment has determined that the product satisfies the criteria for exemption from maximum residue levels.

Market Outlook

The microbial biofungicide sector remains relatively small in relation to the larger conventional fungicides market, and is around half the size of the microbial bioinsecticides market. Market growth is, however, strong, driven by a favourable regulatory environment in many key regional markets that perceive the group as displaying a low toxicity profile. Markets such as the EU, China and Japan, are increasingly favouring such technology through the implementation of strong regulatory shifts that encourage biological uptake and discourage conventional chemistry use; a notable example of this is the EU's Farm to Fork strategy, as well as Japan's Green Food System Strategy and China's zero-growth strategy.

In support of the European Union's Farm to Fork strategy, in 2022 EU member states endorsed four legal acts aimed at simplifying the approval and authorisation process for biological plant protection products which contain microorganisms. Prior to these legal acts, the regulatory requirements for microorganisms were based on principles very similar to those for chemical active substances. The four new legal acts follow a different approach and are based on the biology and ecology of each microorganism, taking into account the most recent scientific knowledge. This approach is aimed at making the regulatory requirements for microorganisms more fit-for-purpose and flexible, leading to streamlined application dossiers, more straight forward risk assessment, and shorter timelines to get access to the EU market.

Similar to other segments, there is likely to be competition from newer conventional chemistries, including newer generation SDHIs (e.g. fluindapyr, isoflucypram, inpyrfluxam) and triazoles (e.g. mefentrifluconazole) as well as new modes of action such as fluoxapiprolin, oxathiapiprolin, and florylpicoxamid. However, there is also an opportunity to have some degree of complementarity with these products in mixtures and spray applications for the biofungicide products that demonstrate the greatest compatibility.

Due to the strong future growth potential within the sector, there has been a significant level of companies taking a position through acquisitions, licensing agreements and research agreements. Although many biological products are developed by relatively small companies with niche market positions, the increasing focus on utilising biological crop protection solutions in conjunction with conventional chemicals has resulted in larger companies looking to partner with, or acquire, these companies in order to utilise a wider distribution network and increase the market penetration for these products.

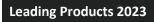
Biofungicides are generally active through alternative modes of action from conventional chemistry, and as a result are significantly less likely to encounter resistance development, which has led to a wide number of products occupying a position in resistance management programmes.

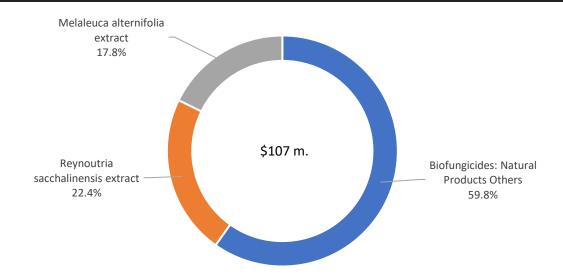
As such, biological treatments hold considerable prospects in areas where resistance development in key diseases continues to be a major issue; a problem that is present across a wide number of country and crop sectors. Exacerbating this situation is a continued decline in the number of new synthetic chemistries that are progressing through development pipelines to commercial status.

Taking the above into account, we forecast that the microbial biofungicide market will increase at a rate of 12.4% p.a. between 2023 and 2028 (in real terms – constant currency and pricing). This rate is somewhat lower than the forecasted rate of +13.4% p.a. over the same period for plant based biofungicides.

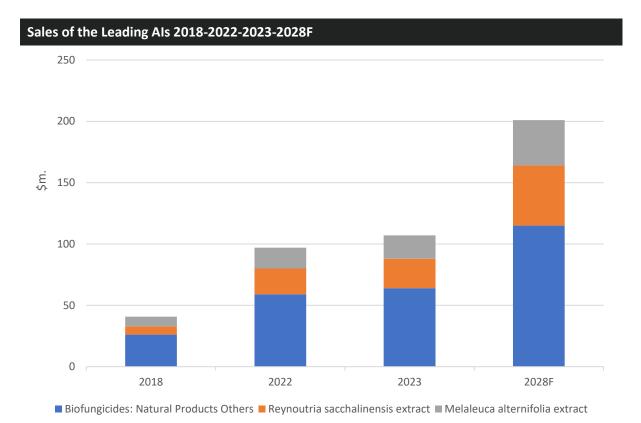
Biofungicides: Natural Products

Sales Performance of Natural-Product Biofungicides					
Year	Natural Product Biofungicide Sales (\$ m.)	Total Fungicide Sales (\$ m.)	Natural Product Biofungicide Share of Biofungicides (%)	Natural Product Biofungicide Share All of Total Fungicides (%)	
2018	41	15,927	25.15	0.26	
2022	97	19,453	26.58	0.50	
2023	107	19,878	26.82	0.54	
2028F	201	21,992	27.69	0.91	
1-yr Change (%)	10.3	2.2			
5-yr CAGR (% p.a.)	21.3	4.5			
5-yr CAGR F (% p.a.)	13.4	2.0			





Leading Biopesticides: Natural Product Biofungicides				
AI	Timing	Main Crops	Sales 2023 (\$ m.)	Sales 2028F (\$ m.)
Reynoutria sacchalinensis extract	Foliar	F&V, Cereals	24	49
Melaleuca alternifolia extract	Foliar	F&V, Vine	19	37



Introduction

This segment includes plant extracts from a range of species, with the most significant being *Chenopodium quinoa* (quinoa) saponins, orange oil and other citrus oils, tea tree oil (*Melaleuca alternifolia* extract), and giant knotweed extract (*Reynoutria sacchalinensis*). Similar to microbial biofungicides, this segment is smaller than the corresponding natural product based bioinsecticide segment but is also growing at a fast rate growing by an average of 21.3 % p.a. over the last 5 years.

The complex nature of plant extracts means that by nature they often contain a diverse range of phytocompounds such as terpenoids, alkaloids, saponins, essential oils (volatile compounds, esters, terpenes, phenols) glycosides, peptides, proteins, sugars, lectins and others. This diversity can create potential issues around ensuring consistency of product composition year-on-year and may also create challenges with consistency of formulation stability, field performance and regulatory issues.

Example compounds

- Terpenoids thymol, carvacrol, citral, eugenol, limonene, pinene
- Alkaloids berberine, vincristine, vinblastine, coptisine, cryptolepine, cinchona alkaloids, capsaicin
- **Saponins** quillaja saponins, soapnuts saponins (*sapindus spp*.), ginsenosides, hederagenin saponins, bitter gourd saponins, yucca saponins
- Essential oils neem oil, tea tree oil, oregano oil, thyme oil, cinnamon oil, clove oil, peppermint oil
- Peptides defensins, thionins, cecropins, cyclotides
- **Proteins** chitinases, glucanases, lytic proteins, ribosome-inactivating proteins (rips), lectins, antifungal peptides
- Saccharides chitosan, mannitol, trehalose, sucrose, xylitol
- Lectins wheat germ agglutinin (WGA), concanavalin a (Con A), allium lectins.

A number of modes of action may be at work when plant extracts are used as fungicides, either solo modes of action, or where there are multiple modalities, either independently where their effects are additive alone or they may be synergistic.

Plant extracts may be composed of compounds that inhibit certain enzymes involved in fungal growth and metabolism. For example, protease inhibitors may interfere with fungal proteases, which are essential for protein digestion and fungal growth. Another example is the inhibition of chitin synthesis, an important process for fungal cell wall formation and development of hyphae which are the filamentous structures containing digestive enzymes that spread outwards in search of nutrients. Inhibition of hyphae development can ultimately limit the further development of the pathogen colony. Examples of compounds that inhibit cell wall production include certain phenols, terpenoids, and alkaloids. Additionally, some plant extracts can induce the production of reactive oxygen species (ROS) within fungal cells, leading to oxidative stress and damage to cellular components.

Whilst the above mentioned modalities broadly interfere with the structural elements of the pathogen cells, another modality is the interference of cellular processes such as the interference of fungal signal transduction pathways. This can lead to the disrupting of essential cellular processes and inhibit fungal growth and development. For example, the modulation of calcium ion signalling, cyclic AMP (cAMP), or mitogen-activated protein kinases (MAPKs) involved in fungal responses to environmental cues.

Certain plant extracts can trigger programmed cell death (apoptosis) in fungal cells, leading to controlled cell death and inhibition of fungal growth. Apoptosis-inducing compounds in plant extracts may activate specific signalling pathways or trigger the release of apoptotic factors within fungal cells, ultimately leading to cell death.

Similar to other classes of biopesticide, the induction of systemic resistance (ISR) may activate plant signalling pathways and stimulate the production of defence-related compounds, such as phytoalexins, pathogenesis-related proteins, and antimicrobial peptides, which can inhibit fungal growth and further colonisation.

Products

Reynoutria sacchalinensis extract

Profarm (formerly Marrone Bio Innovations - MBI) markets an extract of giant knotweed (*Reynoutria sacchalinensis*) as Regalia and Reysana. This product, which activates the natural defence systems of the plant, is used on a wide range of fruit and vegetable crops to control fungal diseases such as grey mould and powdery mildew; it is also active on some bacterial diseases. In addition, these products have also been introduced on row crops such as wheat and soybean, while recent registrations have expanded use of this extract into a number of additional niche sectors, such as cannabis.

Since its introduction, the company has expanded use of this product into more crop and country markets and has also established relationships with third-party companies to increase market penetration. The most significant of these agreements are outlined below:

- A distribution agreement with Great Harvest Agri Chemicals Corporation (GHAC), whereby GHAC will register and commercialise MBI's biofungicide Regalia in the Philippines. Regalia is being targeted at controlling black sigatoka disease in bananas, a prominent disease of this crop.
- An agreement with the Israeli crop-protection product distributor Lidorr Chemicals, under which Lidorr will develop and market MBI's Reysana in Israel.

- An agreement with the crop input product supplier TerraLink Horticulture for TerraLink to distribute Regalia Maxx in western Canada. This distribution agreement coincided with Regalia Maxx gaining a label expansion in Canada to cover use on cannabis crops.
- The development of the product by FMC in Chile through a 2011 agreement with Marrone, under which FMC gained an exclusive license to develop and distribute the product throughout Latin America. Crop uses in Chile include blueberries, vines, and walnuts. FMC subsequently received approval in Brazil for use on lettuce, carrot, papaya, mango, watermelon, melon, peppers, and grapes, expanding on registrations for tomato, beans, and potato.
- An agreement whereby Plant Products acts as the distributor for Regalia Maxx in eastern and central Canada.
- An agreement for Hop Tri Investment Corporation to distribute Regalia in Vietnam and Cambodia on an exclusive basis for use on a range of fruits and vegetables.
- A distribution agreement with UPL under which UPL will distribute Regalia Maxx in the Republic of South Africa.
- A product development collaboration with Vive Crop Protection to provide a suite of crop protection solutions to the US market, combining *Reynoutria* extract with conventional chemistry utilising Vive's Allosperse Delivery System. The first product to be offered from this collaboration is the fungicide AZterknot FC (*Reynoutria* extract/azoxystrobin), which received US EPA approval in mid-2021.
- May 15, 2020 Marrone Bio Innovations (MBI) announced that its biofungicide Regalia Maxx (*Reynoutria sachalinensis* extract) had received approval in Canada for indoor and outdoor use on cannabis and hemp, with the product already approved for use on several other crops in the country. The product is targeted at the control of diseases, such as Botrytis and powdery mildew.
- Feb 9, 2021 Marrone Bio Innovations (MBI) introduced the biological plant health product Pacesetter (*Reynoutria sachalinensis*) in the USA for use on a range of row crops, including maize, soybeans, cereal grains and cotton. The product, which is designed to be applied as a foliar treatment together with conventional fungicides, reportedly increases leaf chlorophyll content, improving plant health. The usage on row crops expands MBI's offerings from the company's current focus on specialty crops for its foliar plant health products.
- May 11, 2021 Vive Crop Protection received approval from the US EPA for the fungicide AZterknot (*Reynoutria* extract / azoxystrobin), developed through a collaboration with Marrone Bio Innovations (see AgbioNews Aug 7, 2020). The product, which is registered for use on a broad range of crops for soil and foliar applications, combines plant health and disease control benefits with Vive's patented Allosperse nanotechnology delivery system, which reportedly provides superior handling characteristics including compatibility with infurrow, pop-up and foliar liquid fertilisers.
- Apr 13, 2022 Prime Source, a division of Albaugh, launched the fungicide AzoxyBio (azoxystrobin / *Reynoutria sachalinensis* extract) in the USA. The product is targeted at broad-spectrum, preventive control of key turf and ornamental diseases, whilst the mode of action of the *Reynoutria sachalinensisas* component boosts the plant's immune systems, mitigating against resistance development. The product has received EPA registration and was to be made available for purchase in spring 2022.

• Jul 3, 2023 Rizobacter has introduced the biofungicide product Regalia Maxx (*Reynoutria sachalinensis* extract), targeted at controlling various fungal and bacterial diseases, including Botrytis and powdery mildew, to its product portfolio. Regalia Maxx is designed to strengthen the natural defences of the plant, by stimulating the production of phytoalexins and phenolic compounds to increase the activity of defence proteins. The product is also intended to stimulate lignin production, for improved plant vigour and standability, as well as stimulate the production of chlorophyll and phytohormones, for increased photosynthetic activity.

Sales in 2023 reached \$24 million, representing average growth of 28.7% p.a. between 2018 and 2023.

Melaleuca alternifolia extract

An oil extract of tea tree (*Melaleuca alternifolia*) is the active constituent of STK Bio-Ag's Timorex Gold and Timorex Act fungicides. In addition, the company has also introduced the hybrid conventional/biological fungicide Regev (difenoconazole/*Melaleuca alternifolia* extract) in several markets. This product provides control of a broad range of diseases including black/yellow sigatoka, powdery mildew, *Rhizopus*, *Botrytis*, early blight, and *Cladosporium*.

Like many other biological companies, STK has established commercial relationships with third parties to maximise market penetration for products based on *Melaleuca alternifolia* extract. These relationships are listed below:

- A collaboration with BASF for the distribution of Timorex Gold in Brazil. BASF holds exclusive rights to market and sell the product in Brazil for use on a wide range of crops, including grapes, bananas, coffee, and tomatoes. This represents BASF's first biological fungicide for use on speciality crops in Brazil.
- An agreement with Summit Agro USA whereby Summit Agro will act as the sole distributor of STK's products in the US.
- An agreement with STK Agricenter, a subsidiary of Amvac Netherlands, through which Agricenter is the sole distributor of STK's products in Central America.
- An agreement with Adama to distribute Timorex Gold and Regev in Colombia, where Timorex Gold has been approved for use on bananas, rice, ornamentals, tomatoes, avocados, onions, coffee, corn, tobacco, potatoes, passionfruit, and pitahaya in the country. Regev has been approved for rice, with label extensions planned for bananas, ornamentals, coffee, and tomatoes.
- An agreement with Sipcam-Oxon for the distribution of the biofungicide Timorex Gold in Spain. Sipcam markets and sells the product in Spain for use on cucumber and courgettes, with applications for label extensions to several other crops. Spain is the first country in Western Europe to approve the use of Timorex Gold, and plans are in place for the product to enter the rest of the region within the next few years.
- An agreement with Adama to distribute Timorex Gold and Regev in Ecuador, where Timorex Gold is approved for use on banana, rice, tomatoes, avocados, onions, coffee, tobacco, passion fruit, and broccoli, among other. Regev has been approved for bananas, with label extension plans to include rice and ornamentals.
- An agreement with Ascenza to be the exclusive distributor of Regev in Mexico. This product has been approved for the control of Black Sigatoka in bananas, Anthracnose in Strawberries, Early Blight in tomatoes, and Powdery Mildew in a large range of fruits and vegetables, including peppers, apples, and tomatoes.

Key Melaleuca alternifolia Product Launches

- Apr 2, 2020 Summit Agro USA announced the introduction of two products to the US market: the insecticide Verdepryn 100SL (cyclaniliprole) and the biological fungicide Timorex Act (*Melaleuca alternifolia* extract). Verdepryn provides broad spectrum insect control in a range of crops including pome fruit, stone fruit, grapes, berries, tree nuts and citrus. Timorex Act controls a broad spectrum of fungal and bacterial plant diseases, including powdery mildew, early blight and botrytis in a variety of fruit and vegetable crops.
- May 12, 2020 Summit Agro USA announced the launch of STK Bio-Ag's hybrid fungicide Regev in the US. The product, which combines the conventional active ingredient difenoconazole with tea tree (*Melaleuca alternifolia*) oil, will be available to use on a variety of crops including soybeans, rice and potatoes and also on speciality crops such as cucurbits, fruiting vegetables, bulb vegetables, brassica leafy vegetables, legume vegetables, grapes, tree nuts and citrus for the control of a board spectrum of diseases. In April 2019 the Israel-based company STK Bio-Ag Technologies formed a distribution agreement with Summit Agro USA for Summit Agro to act as the exclusive distributor of STK products in the US.
- May 18, 2020 STK Bio-Ag Technologies announced that its hybrid conventional and biological fungicide Regev had received registration in Chile. The product has been approved for the control of powdery mildew in tomatoes and apple scab in pome fruits, with a label expansion pending covering control of grey mould and powdery mildew in grapes, brown rot and sour rot in stone fruits and *Alternaria* in cherries. The product combines the conventional active ingredient difenoconazole with the key component of the company's Timorex Gold product, tea tree (*Melaleuca alternifolia*) oil.
- Sep 8, 2020 STK Bio-ag Technologies and Ascenza entered into an agreement under which Ascenza was to become the exclusive distributor of STK's hybrid conventional and biological fungicide Regev in Mexico. Regev combines the active ingredient difenoconazole with *Melaleuca alternifolia* extract and has been approved for the control of Black Sigatoka in bananas, Anthracnose in strawberries, Early Blight in tomatoes and Powdery Mildew in a large range of fruits and vegetables including peppers, apples and tomatoes. The product is expected to receive registration approval in Mexico in the coming months.
- Feb 5, 2021 STK bio-ag technologies gained registration for its biofungicide Timorex Act (*Melaleuca alternifolia*) in Mexico. The product, which will be distributed exclusively by Syngenta, controls a broad spectrum of fungal and bacterial plant diseases, including powdery mildew, early blight and Botrytis in a variety of fruit and vegetable crops. During 2020 the product was launched in the US with Summit Agro as the distributor.
- May 17, 2022 Summit Agro USA announced the introduction of the hybrid fungicide Regev HBX in the USA. The product, which combines the conventional active ingredient difenoconazole with tea tree (*Melaleuca alternifolia*) oil, is targeted at the control of frogeye leaf spot and Asian soybean rust on soybean, rice blast, and pecan scab as well as a broad spectrum of bacterial and fungal diseases across soybean, rice, and pecan crops.
- Dec 1, 2022 STK bio-ag technologies launched the hybrid fungicide Yarden in Turkey for use on citrus and tomatoes, with label expansions planned for grapes, cherries, peaches and nectarines, eggplants and peppers. The product, which combines the conventional active ingredient fludioxonil with tea tree (*Melaleuca alternifolia*) oil, is intended for the control of post-harvest diseases, including rots, grey mould, and damping off. Yarden will be distributed in Turkey by Nufarm. STK also announced plans for the product to be launched into additional country markets, including Colombia and the rest of Latin America.

- Jul 20, 2023 Avgust received approval in Russia for the hybrid fungicide Shrilank for use on fruit and vegetable crops. The product, which combines the conventional active ingredient difenoconazole with tea tree oil (*Melaleuca alternifolia*), is targeted at the control of bacterial and fungal diseases, including scab, powdery mildew and *Alternaria*. Shrilank reportedly represents the first hybrid fungicide for use in the Russian F&V market.
- Sep 9, 2024 Adama received a label extension in Chile for the hybrid conventional and biological fungicide Regev (difenoconazole / tea tree extract (*Melaleuca alternifolia*)).
- Apr 17, 2025 STK Bio-ag Technologies and UPL signed an exclusive strategic agreement to introduce the biofungicide Timorex Pro to the Mexican market. Timorex Pro, based on tea tree oil (*Melaleuca alternifolia*), is targeted at the control of ascomycete and bacterial plant diseases such as powdery mildew, early blight, and *Botrytis*, in a range of fruit and vegetable crops.

Sales of these products reached \$19 million in 2023, benefiting from increased market penetration in recent years boosted by the above agreements and country expansions, a rate of 19.6% p.a. between 2018 and 2023.

Regulatory Situation

As with microbial products, the regulatory situation is generally favourable for fungicides in the natural products class. The table below summarises the natural-product insecticides approved for crop protection in the EU and USA.

In the USA the EPA classifies biopesticides as 'reduced-risk pesticides' and as such they qualify for fast-track registration.

In the EU a plant extract pesticide is defined as a 'botanical active substance' which consists of:

"...one or more components found in plants and obtained by subjecting plants or parts of plants of the same species to a process such as pressing, milling, crushing, distillation and/or extractions. The process may include further concentration, purification and/or blending, provided that the chemical nature of the components is not intentionally modified/altered by chemical and/or microbial processes."

Botanical active substances have to be approved under Regulation (EC) No 1107/2009 and a dossier has to be compiled according to the data requirements as laid down in Regulation (EU) No 283/2013 (active substance) and Regulation (EU) No 284/2013 (plant protection product). Therefore unlike microbial pesticides where there are some reduced requirements/provisions, plant extracts are subject to the same process as that of the conventional pesticides.

EU	USA	Activity	Туре
	2-phenylethyl propanoate	Fungicide	Natural Product
Allium cepa L. bulb extract		Insect repellent / Fungicide	Natural Product
	Allyl isothiocyanate	Fungicide	Plant Extract
Antoferine	,,.	Fungicide	Natural product
Aqueous extract from the			
erminated seeds of sweet upinus albus		Fungicide	Natural product
-	Azadirachtin	Acaricide / Fungicide / Insecticide	Plant Extract
azadirachtin (<i>Margosa</i> extract)		Acaricide / Fungicide / Insecticide	Plant Extract
	Capsaicin	Fungicide	Plant Extract
Carvone		Fungicide	Natural product
	Cedarwood oil	Repellents / Feeding depressants / Fungicide	Plant Extract
Cerevisane		Fungicide	Natural product
	Chitin	Fungicide	Animal Extract
Tinnamaldehyde	Cinnamaldehyde	Attractant / Fungicide / Repellent	Plant Extract
	Clarified hydrophobic neem oil	Acaricide / Fungicide / Insecticide	Plant Extract
COS-OGA		Fungicide	Natural product
	Diallyl disulfide	Fungicide / Nematicide	Plant Extract
quisetum arvense L.		Fungicide	Natural product
ugenol		Insecticide / Fungicide	Natural product
xtract from tea tree		Fungicide	Natural product
	Garlic oil	Fungicide / Bactericide	Plant Extract
Geraniol		Fungicide / Bactericide	Plant Extract
	Harpin protein	Fungicide	Natural product
	Jojoba oil	Fungicide / Insecticide	Plant Extract
aminarin	-	Fungicide	Natural product
-Carvone		Fungicide / PGR	Natural product
ecithins (basic substance)		Fungicide	Natural product
, , , , , , , , , , , , , , , , , , , ,	L-Glutamic acid	Fungicide / PGR	Natural Product
Mustard seeds powder		Fungicide	Natural product
pondo.	Neem oil	Acaricide / Fungicide / Insecticide	Plant Extract
	Oils, tea-tree	Fungicide	Plant Extract
Onion oil		Insect repellent / Fungicide	Natural Product
OptiCHOS		Fungicide	Natural Product
	Oriental mustard seed (Brassica juncea)	Nematicide/Fungicide	Plant Extract
	Plant extract (Derived from Quercus falcata, Opuntia lindheimer, Rhus aromatica, and Rhizophoria mangle tissues)	Fungicide	Natural product
Plant oils / Clove oil		Fungicide/ Herbicide / Insecticide/ Nematicide	Natural product
Plant oils / Spear mint oil		Fungicide / PGR	Natural product
<i>Reynoutria sachalinensis</i> extract	Reynoutria sachalinensis	Fungicide	Plant extract
Sunflower oil		Insecticide / Fungicide	Natural product
Swinglea glutinosa, ext.		Fungicide	Natural product
Whey		Fungicide	Natural Product
Willow bark and stem extract		Fungicide	Natural Product
Yucca Schidigera extract		Biostimulant / Fungicide / Bactericide	Natural product

Note: Green = approved (EU) registered (USA), orange = pending approval, purple = registration review, blue = pending registration. Information is correct as of May 2025.

Biofungicides: Natural Product Target Pests			
Strain	Pests Controlled		
Chenopodium quinoa saponins	Damping Off (<i>Rhizoctonia solani</i>); White Mold (<i>Sclerotinia sclerotiorum</i>) and Sudden Death Syndrome (<i>Fusarium virguliforme</i>)		
Orange Oil	Mites, Whiteflies, Leafhopper, Psyllids, Scales, Thrips, Leafhopper, Froghopper, Plant disease		
Melaleuca alternifolia extract	Powdery mildew (<i>Erysiphe necator</i>), Botrytis (<i>Botrytis cinerea</i>)		
Reynoutria Sacchalinensis Extract	Powdery mildew and Gray mold (Botrytis)		
Chitosan	Rust, Septoria, Alternaria, powdery mildew		
Laminarin	Scab, powdery mildew, fruit rot and fire blight		
Clove Oil / Vegetable Oil	Gloeosporium spp,; Penicillium spp.		
Eugenol / Geraniol / Thymol	Botrytis		
Citrus x paradisi extract	Powdery mildew (<i>Podosphaera xanthii</i>), broad spectrum range of plant diseases, viruses and bacteria		
Chestnut extracts	Verticillium dahlia, Trichoderma harzianum, Cladosporium cucumerinum, Penicillium citrinum, Fusarium solani, Sclerotinia sclerotiorum, Rhizoctonia solani, Botrytis cinerea, Alternaria solani, Cryphonectria parasitica		
Equisetum arvense extract	Powdery mildew; Peach leaf curl; Scab; Root rot, Seedling blight		

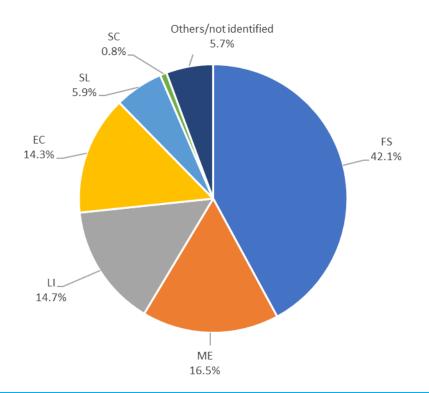
The below table(s) on key active ingredients and key companies is derived directly from AgBioInvestor's exclusive primary market research study that surveyed biological- and biostimulantgrowers, which were conducted for the first time in 2023 and profiled the 2022 agricultural market. The market research surveyed many key agricultural markets for biologicals, including: USA, Mexico, Chile, Brazil, Argentina, France, Italy, Spain and Turkey. The Ais have been ranked by farm-gate value (\$m.). Quantification of these data and much more biological market research can be found in the separate subscription product AgbioInsight.

blight

Key Companies with Involvement in Biofungicide: Natural Product			
Al	Key Companies		
Chenopodium quinoa saponins	Heads Up Plant Protectants		
Orange Oil	Vivagro		
Melaleuca alternifolia extract	STK bio-ag Technologies		
	Syngenta		
	Biomor		
Reynoutria Sacchalinensis Extract	Profram (formerly MBI)		
Chitosan	Bioactive Products Group		
	Comercial Mida		
Laminarin	UPL (Goemar)		
Clove Oil / Vegetable Oil	Xeda International		
Eugenol / Geraniol / Thymol	Sipcam-Oxon		
Citrus x paradisi extract	Quimetal Industrial / New Tech Agro		
	Chemie / New Tech Agro		
Chestnut extracts	Vithal Bio		
Citrus sinensis extract	Agrospec		
Equisetum arvense extract	Seipasa		

Formulation Types – Value Share

The below chart(s) are derived from the biological focussed market research that AgbioInvestor conducted and illustrates the value share attributed to various formulation type codes.



Code	Description	Code	Description
AE	Aerosol dispenser	LI	Liquid
AL	Other liquids to be applied undiluted	LS	Solution for seed treatment
СВ	Bait concentrate	ME	Micro emulsion
CS	Capsule suspension	OD	Oil dispersion
DC	Dispersible concentrate	SC	Suspension concentrate
DF	Dry flowable	SL	Soluble concentrate
DP	Dustable powder	SP	Water soluble powder
EC	Emulsifiable concentrate	VP	Vapour releasing product
EW	Emulsion, water in oil	WG	Water dispersible granule
FS	Flowable concentrate for seed treatment	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment
LC	Liquid concentrate		

Research and Development

In the field of plant extracts, much of the research centres around selecting and optimising extracts with both the right components and blend of constituents in order to provide suitable disease control when applied to crops. A significant share of the R&D effort is targeted towards identifying plant species and the associated synergisms of the multiple components therein, or from blending with other plant extracts. Formulation development and integration into spraying equipment is also an important means of fostering greater product efficacy and uptake.

• Jan 17, 2022 Botanical Solution Inc (BSI), a start-up company focused on the discovery and manufacture of plant-based active ingredients and products from advanced botanicals, announced the close of a \$6.1 million Series A financing round, led by Otter Capital. The funding will be used to support the production and sales growth of the company's BotriStop biofungicide, globally branded as Quillibrium, which is based on the extract of a plant native to Chile, *Quillaja saponaria*. The new funding will also accelerate market readiness of new botanical biopesticide products currently in later development stages and enable the expansion of BSI's R&D pipeline.

Quillibrium was launched in Peru in 2021 and is expected to be commercialised soon in Mexico by Syngenta through an expanded distribution agreement in 2021; the product is also currently progressing through the US regulatory process. This latest round of funding follows the \$3.3 million seed funding that the company secured in 2020.

- Oct 24, 2022 Biotalys and Novozymes announced that they had successfully completed a feasibility study for Biotalys' protein-based biofungicide product Evoca. Through the study, Novozymes obtained proof of concept for a new manufacturing process that offers possible cost of goods and scaling advantages, which may expand the commercial potential of Evoca. Biotalys and Novozymes entered a partnership earlier in 2022 to explore additional routes for the upscaling and production of Evoca. Evoca is intended to control fungal diseases such as *Botrytis* and powdery mildew in fruits and vegetables and is expected to obtain approval from the EPA for use in the USA in early 2023.
- Sep 4, 2023 Agrobiológica Sustentabilidade, the biologicals-focused subsidiary of the agribusiness Crop Care Holding, opened a new R&D facility in Itápolis, São Paulo. The facility, announced in 2022, will focus on the research and development of biological products, including bionematicides, bioherbicides, biofungicides and bioinsecticides, for the Brazilian and wider Latin American market.
- Sep 25, 2023 Plant Health Care (PHC) submitted applications to the regulatory agency in Mexico for the commercialisation of two peptide products, PHC25279 for use on major crops, with the product derived from PHC's PREtec (Plant Response Elicitor) technology platform. PHC25279 is a biofungicide intended for use in an integrated disease control programme to control a broad spectrum of plant diseases. In Mexico, the product is expected to find immediate application for the control of Grey Mould (*Botrytis cinerea*) in berries, Downy Mildew (*Pseudoperonospora cubensis*) in cucurbits such as cucumbers, and Late Blight (*Phytothphora infestans*) in tomatoes and other *Solanaceae* crops. Additional PHC25279 product label claims against various other plant pathogens are planned.

- May 2, 2024 Biotalys, a Belgium-based developer of protein-based biological crop protection solutions, initiated field trials for BioFun-6, a biofungicide programme developed on the company's Agrobody technology platform. BioFun-6 will target botrytis, powdery mildew and anthracnose in fruit and vegetables. Biotalys has developed several candidate bioactive ingredients for BioFun-6, and the company will test one of the lead molecules in field trials starting in May 2024. The company will collaborate with selected third parties such as contract research organisations to perform these trials. The first round of field trials will focus on grapes and tomatoes in Europe, with initial results expected by the end of this year.
- Sep 2, 2024 Biotalys, a developer of protein-based agricultural inputs, received approval from the Dutch regulator CTGB (College voor de Toelating van Gewasbeschermingsmiddelen en Biociden) for large-scale demonstration trials in greenhouses of its biofungicide candidate, Evoca. The product has been approved for testing against powdery mildew in 40 hectares of tomatoes, 20 hectares of cucumbers and 10 hectares of strawberries, with the produce from the trial permitted for sale for human consumption. The decision to approve downstream sales of the produce from the trial remains subject to appeal.
- Sep 17, 2024 The biotechnology and enzyme solution company Elemental Enzymes entered into a three-year agreement with Agldea to advance screening of Elemental Enzymes' technologies in the US, focusing on row crops. Elemental Enzymes' products are intended to help address challenges such as drought, heat stress, disease mitigation, and fertiliser use efficiency. The company has partnered with multinational crop protection companies, including Adama and Corteva.
- Sep 17, 2024 the Belgian developer of protein-based biological crop protection products Biotalys received patents for its Evoca biofungicide from both the European Patent Office (EPO) and the United States Patent and Trademark Office (USPTO). The company has also requested patent protection for the product's active ingredient in additional countries, including Argentina, Brazil, and South Africa. Evoca is a protein-based biofungicide targeted at controlling fungal diseases in fruits and vegetables, and is classified by the Fungicide Resistance Action Committee (FRAC) as having a novel mode of action. The milestones achieved for Evoca are intended to help set the stage for Evoca NG, which is expected to be Biotalys' first commercial fungicide and features the same active ingredient but with optimised production prices and formulation.
- Oct 1, 2024 Biotalys, a developer of protein-based biological crop protection products, introduced a new biofungicide programme, BioFun-8, into its R&D pipeline. This initiative aims to create a fungicide to combat Alternaria, a significant fungal disease affecting fruits, vegetables, and speciality crops, to minimise crop damage and yield loss. The company will utilise its proprietary Agrobody 2.0 technology platform to accelerate product development. The move constitutes part of the company's strategy to capitalise on what it anticipates will be increased demand for alternatives to conventional chemical controls in the sector due to increased resistance and future regulatory challenges.
- Mar 10, 2025 Ascribe announced positive results from its 2024 field trials in India for its nontoxic crop protection solution for Bacterial Leaf Blight (BLB) in rice, Phytalix. The trials, conducted across 17 sites, reportedly showed an 83% reduction in BLB severity and a yield increase of up to 30% in high BLB pressure areas. Phytalix is based on a natural molecule from the soil microbiome and can be applied as a foliar spray at low application rates, offering a sustainable alternative to synthetic pesticides and antibiotics. Regulatory procedures are underway in Brazil, USA, and key Asian rice-producing countries.

Mar 11, 2025 Biotalys has successfully completed initial field trials of its biofungicide candidate BioFun-6, the company's second biocontrol programme against grey mould and powdery mildew in fruits and vegetables. The trials were commissioned by Biotalys and conducted in Europe and the US by external contract research organisations (CRO's). The BioFun-6 candidate was tested at different dose rates in grapes against grey mould, and in cucumbers and tomatoes against powdery mildew. The results showed that the BioFun-6 biocontrol can reportedly achieve the same level of performance as Biotalys' other biofungicide product, Evoca, at lower dosage rates.

Market Outlook

The natural product biofungicide segment, is smaller than the corresponding natural product segment within bioinsecticides, largely down to being a relatively new and emerging segment, at least from the perspective product availability and efficacy. Similar to the natural product insecticide segment, there may be challenges around consistency of product composition. Plant extracts often contain multiple phytocompounds, with additive or synergistic modes of action in the field. Many of these mechanisms are often poorly understood, further compounding the issues of consistency and also providing agronomic advice to growers. Only the largest companies will be able to invest in the R&D and field trials necessary to optimise field use, or those smaller companies that can achieve partnerships with larger companies.

The sustainability of the raw material supply for production of plant extracts may also be a consideration from both an environmental and supply chain perspective. The latter of which could create issues surrounding scalability of product supply.

Whilst more efficacious product is coming to market, there still remains a degree of uncertainty within growers surrounding the correct utilisation of products in the field, particularly around field stability, timing of application, cost and efficacy. Biofungicides are generally subject to lower levels of resistance development due to their often multiple modes of action. However, it should be noted that biopesticides are not immune from resistance development, therefore it may be necessary for the products to be targeted within integrated pest management strategies, and for product stewardship to be undertaken in conjunction with agronomic advisors.

Taking all of this into account, it can be expected that the natural product biofungicide segment will increase at a rate of +13.4% p.a. on average between 2023 and 2028 in real terms (constant currency and pricing).

Biological Others

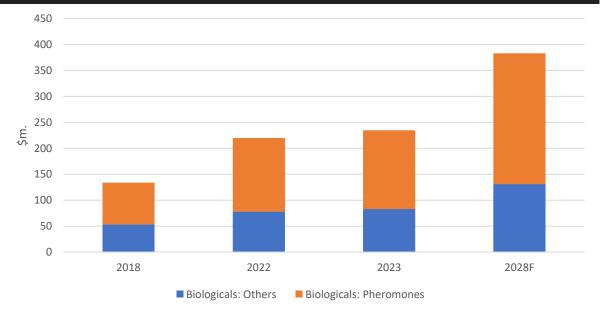
Sales Performance of Biological Others				
Year	Bio-others Sales (\$ m.)	Total Other Sales (\$ m.)	Share of Bio-others to Total Others (%)	Share of Total Others to Total Crop Protection (%)
2018	134	1,796	12.01	3.09
2022	220	2,189	12.05	2.93
2023	235	2,174	11.93	2.91
2028F	383	2,438	11.61	3.00
1-yr Change (%)	6.7	-0.7		
5-yr CAGR (% p.a.)	11.9	3.9		
5-yr CAGR Forecast (% p.a.)	10.3	2.3		

CCP = Conventional crop protection

Segment Split 2023



Sales of the Leading Classes, 2018-2022-2023-2028F



Introduction

This section covers two main segments, that of pheromones and others (mostly biofumigants). The pheromone segment specifically covers active ingredients used for mating disruption and excludes pheromones used in trapping and monitoring systems. It also covers only the value of the active ingredient used in the product and not the value of any packaging (such as dispensers, clips, coils and diffusers, etc).

The value of the pheromone segment has increased at a rate of 13.5% p.a. on average between 2018 and 2023 driven by increasing usage in integrated pest management strategies as well as demand for high value fruit and vegetable crops and organic agriculture.

Likewise, the biofumigant segment has increased at a robust pace, rising by an average of 9.2% p.a. between 2018 and 2023, driven by usage of biofumigants in F&V cultivation as well as the loss of older chemical fumigants products to regulatory action.

Sales Performance of Pheromones				
Year	Pheromones Sales (\$ m.)	Total Others Sales (\$ m.)	Pheromones Share of Biological Others (%)	Pheromones Share of Total Others (%)
2018	80	1,796	60.14	4.48
2022	142	2,189	64.55	6.49
2023	152	2,174	64.68	6.98
2028F	252	2,438	65.80	10.34
1-yr Change (%)	6.9	-0.7		
5-yr CAGR (% p.a.)	13.5	3.9		
5-yr CAGR F (% p.a.)	10.7	2.3		

Biological Others: Pheromones

Introduction

Mating disruption works by releasing synthetically produced pheromones (also known as semiochemicals) that prevent male insects finding females and mating, by causing confusion in the male seeking a partner to reproduce. This leads to lower population numbers over time, but the main drawback is that the efficacy is not immediate and if not applied at the correct time, the pheromones may have insufficient efficacy. This creates challenges for managing grower expectations and future product uptake, however the products are generally used in speciality crops where growers use robust integrated pest management practices.

Pheromones are typically secreted externally by an organism to send information to members of the same species, and are part of the chemical signalling and communication pathways of insects and other species. Dispensers in the crop might mimic a calling female, attracting the male to false sources, or dispensers might release such high levels of pheromone that the background concentration masks or disrupts normal communication.

The mode of action typically falls under five main categories:

Adaptation and habituation to exogenous pheromone application

Long-term exposure to a stimulus can affect the sensory organs (olfactory glands) or nervous system of the pest species modulating regular function. There are two main types of sensory response that may occur:

- Adaptation occurs when olfactory glands are exposed constantly to high and uniform levels of pheromone in the field, inhibiting their ability to detect the pheromone. Recovery from this occurs rapidly, in 2 to 3 seconds, when they are no longer exposed to the pheromone.
- Habituation occurs when high concentrations of a pheromone inhibit the insect's ability to
 respond over longer periods from several minutes to hours. When exposed to a normal amount
 of pheromone, the nerve does respond in a normal way. This modality may provide longer lasting
 disruption but may come with the downside of requiring higher volumes of pheromone for a
 consistent period to achieve the desired effect.

False trail generation

Under this modality the male moth can still sense and respond to the pheromone, but due to a number of dispensers distributed throughout the field, the insect will spend more time and energy following pheromone trails to false sources rather than to a female, reducing the chance of population proliferation.

Masking

Under this scenario, the olfactory glands are still able to respond to pheromone levels which are not as high as under the habituation scenario, but are high enough to mask the trail from a calling female impacting finding a mating female. Unlike the false trail generation above, this relies less on the placement of a distributed number of dispensers and more about the absolute levels in the field. Clearly, there will be overlap between both masking and false trail generation in the field, since they are both sub habituation modalities.

Imbalanced sensory input

The composition of the pheromones released can also have a distinct fingerprint for certain species and processes. The pheromone composition released by most species may have multiple components and at different ratios. The ratio applied in the field may lead to similar sexual confusion and difficulties for males to find a female.

Antipheromones

Antipheromones are chemicals that are analogues to the wild-type pheromones expressed by the female insect or may have completely different chemical structures. So anti-pheromones are distinct from true pheromone for a given species in that they cause the target disrupting effects whilst differing in structure in some way from the chemically identical version of the pheromone that may be used above. Some antipheromones may compete with the true pheromone for the same receptor sites on the insects' sensory organs. However, some antipheromones that do not chemically resemble the true pheromones, may also block mate location.

Key advantages of pheromones in crop protection

The key strengths of pheromone usage in crop protection are myriad. Chief among these are their strong compatibility in integrated pest management (IPM) strategies. Pheromones do not interact with other components of IPM strategies due to their high specificity to target species and unique modality.

Due to overreliance on conventional crop protection chemistries, pheromones are ideally suited to preventing and reducing insect resistance development by providing a highly specific and additional mode of action. However, it should be noted that pheromones are not immune to resistance development themselves.

The high selectivity of action due to the species-specific nature of the pheromones means they are often safe to beneficial insects such as pollinators and natural enemies.

From an environmental fate and ecotox perspective, pheromones have the benefit of low volumes of application and the fast breakdown in the environment. Additionally, pheromones are not subject to maximum residue limits (MRLs) as is the case with conventional insecticides. This makes them especially attractive for fruit and nut producers that export to the EU where MRLs have been tightening in recent years.

From the perspective of growers, pheromones also feature favourable handling characteristics such as low- mammalian toxicity, zero or low re-entry interval and zero pre-harvest interval (PHI). Pheromone dispensers are also convenient for the grower as they are often programmed to automatically dispense the correct level of pheromones at set intervals.

Key disadvantages of pheromones in crop protection

A key drawback of mating disruption pheromones is that due to the modality of mating disruption, the effect on insect populations is not immediate and if not applied at the correct timing may have insufficient efficacy. The use of pheromones in attractant/monitoring traps (outside the scope of this segment definition) may be more useful in the short term as they may permit spray decisions to be made for other insecticide classes with more immediate activity.

Another key drawback is that the costs to produce synthetic pheromones are generally high, and application costs can be high on a per hectare basis limiting uptake in row crops and favouring speciality crop growers of high value produce.

Due to the high pest specificity pheromones multiple pheromones or other control methods may need to be employed, however it is unlikely that growers would utilise pheromones on its own, since growers using them are more likely to be using IPM strategies.

Pheromone application methods typically require powered dispensers, or plastic clips that need to be physically attached to trees or plants, with these needing to be placed at regular intervals which can be labour intensive. Automated dispensers can be more expensive than more basic pheromone dispensers, and less precise. Field conditions such as temperature, wind direction, humidity can also complicate the application process and field efficacy.

Although resistance issues are significantly less of a risk, it is still possible for insects to develop resistance to pheromones, since subsequent generations that are present may have been selected for lower olfactory response to the pheromones.

Products

Lavandulyl Senecioate

Is an arthropod mating disruptor that is structurally similar to a pheromone produced by the female vine mealybug (*Planococcus ficus*). *Lavandulyl senecioate* is frequently used in polymer dispensers to disrupt the normal mating cycle of the pest in vine crops.

• Oct 17, 2024 The European Commission amended the maximum residue levels (MRLs) on food and feed of plant and animal origin. *Lavandulyl senecioate* was renewed as a low-risk active substance. The conditions of use of these substances is not expected to lead to the presence of residues in food or feed commodities that may pose a risk to the consumer and, therefore, no MRLs are required. For the active substances flonicamid, clopyralid and difenoconazole, MRLs have been reviewed.

(E,Z)-7,9-Dodecadienyl acetate

Originally isolated from the European grapevine moth (*Lobesia botrana*) pheromone gland the pheromone functions as a mating disruptor for various Lepidopteran insects including the European grapevine moth.

• September 26, 2024 Syngenta launched the pheromone-based product Exployo Vit ([E,Z]-7,9-Dodecadien-1-yl acetate) in Argentina for use on vine. The product, developed by the French company M2i, is a natural sprayable solution which is targeted at the control of European grapevine moth (*Lobesia botrana*).

(E,E)-8,10-Dodecadien-1-ol

Is a mating disrupting pheromone that is expressed by the codling moth (*Laspeyresia pomonella*). The AI is used in a range of speciality crops such as nuts as well as a range of pome and stone fruits.

(Z,Z)-11,13-Hexadecadienal

Is one of the principal components of navel orangeworm (*Pamyelois transitella*) and is used for mating disruption in crops such as tree nuts.

(Z)-11-Hexadecen-1-yl acetate

Is a natural product found in cabbage moth (*Mamestra brassicae*) and variegated cutworm (*Peridroma saucia*) that is used as a mating disruptor in a range of horticultural crops. Key pests including control of diamondback moth (*Plutella xylostella*) and other insect pests.

Regulatory Situation

In the USA, the EPA considers pheromones and identical or substantially similar compounds labelled for use only in pheromone traps and pheromone traps in which those chemicals are the sole active ingredients, as not falling subject to regulation under FIFRA. The use of pheromones in traps in conjunction with conventional pesticides, or in other application methods (such as dispensers for mating disruption), is subject to regulation under FIFRA.

In the EU Pheromones are generally considered to be low-risk active substances pursuant to Article 22 of Regulation (EC) No 1107/2009. Low-risk substances are approved for 15 years instead of 10 years, and data protection on the studies submitted for the approval and subsequent authorisation is extended from 10 to 13 years. Similar to the microbials segment a fast-track authorisation procedure with reduced timelines (120 days) is in place. Low risk description can also be used on product marketing.

EU	USA	Target	Туре
	(E)-(3,3- Dimethylcyclohexylidene)acetaldehyde	Pheromone	Attractant
	(E)-11-Tetradecen-1-ol acetate	Pheromone	Attractant
E)-11-Tetradecen-1-yl acetate		Pheromone	Attractant
	(E)-4-Tridecen-I-yl acetate	Pheromone	Attractant
E)-5-Decen-1-ol	(E)-5-Decen-1-ol	Pheromone	Attractant
E)-5-Decen-1-yl acetate (SCLP Acetates)		Pheromone	Attractant
E)-8-Dodecen-1-yl acetate	(E)-8-Dodecen-1-yl acetate	Pheromone	Attractant
	(E)-9-Dodecen-1-ol acetate	Pheromone	Attractant
	(E)-9-Tricosene	Pheromone	Mating Disruption
E,E)-7,9-Dodecadien-1-yl acetate		Pheromone	Mating Disruption
E,E)-8,10-Dodecadien-1-ol		Pheromone	Mating Disruption
E,E)-8,10-Dodecadien-1-yl acetate		Pheromone	Mating Disruption
E,Z)-2,13-Octadecadien-1-yl acetate		Pheromone	Attractant
E,Z)-3,13-Octadecadien-1-yl acetate		Pheromone	Attractant
E,Z)-3,8-Tetradecadien-1-yl acetate		Pheromone	Mating Disruption
E,Z)-7,9-Dodecadien-1-yl acetate		Pheromone	Mating Disruption
E,Z,Z)-3,8,11-Tetradecatrien-1-yl acetate		Pheromone	Attractant
	(R,Z)-5-(1-Decenyl)dihydro-2(3H)- furanone	Pheromone	Mating Disruption
	(Z)-(3,3- Dimethylcyclohexylidene)acetaldehyde	Pheromone	Attractant
Z)-11-Hexadecen-1-ol		Pheromone	Attractant
Z)-11-Hexadecen-1-yl acetate		Pheromone	Attractant
Z)-11-Hexadecenal	(Z)-11-Hexadecenal	Pheromone	Mating Disruption
	(Z)-11-Hexadecenyl acetate	Pheromone	Mating Disruption
Z)-11-Tetradecen-1-yl acetate	(Z)-11-Tetradecenyl acetate	Pheromone	Attractant
Z)-13-Octadecenal (SCLP Aldehydes)		Pheromone	Attractant
	(Z)-2-(3,3- Dimethylcyclohexylidene)ethanol	Pheromone	Attractant
	(Z)-4-Tridecen-1-yl acetate	Pheromone	Attractant
	(Z)-6-Heneicosen-11-one	Pheromone	Attractant
Z)-7-dodecen-1-yl acetate		Pheromone	Attractant
Z)-7-Tetradecenal		Pheromone	Mating Disruption
Z)-8-Dodecen-1-ol		Pheromone	Attractant
Z)-8-Dodecen-1-yl acetate	(Z)-8-Dodecen-1-yl acetate	Pheromone	Attractant
Z)-8-Tetradecen-1-ol		Pheromone	Attractant
Z)-8-Tetradecen-1-yl acetate		Pheromone	Mating Disruption
Z)-9-Dodecen-1-yl acetate		Pheromone	Mating Disruption
Z)-9-Hexadecenal		Pheromone	Attractant
Z)-9-Tetradecen-1-ol	(Z)-9-Tetradecen-1-ol	Pheromone	Mating Disruption
Z)-9-Tetradecen-1-yl acetate		Pheromone	Mating Disruption
	(Z)-Dodecen-1-ol	Pheromone	Mating Disruption
Z,E)-7,11-Hexadecadien-1-yl acetate		Pheromone	Attractant
Z,E)-9,11-tetradecadien-1-yl-acetate		Pheromone	Attractant
	(Z,E)-9,12-Tetradecadien-1-ol acetate	Pheromone	Mating Disruption
Z,E)-9,12-Tetradecadien-1-yl acetate SCLP - Acetates)		Pheromone	Attractant
	(Z,Z)-11,13-Hexadecadienal	Pheromone	Mating Disruption
Z,Z)-3,13-Octadecadien-1-yl acetate SCLP Acetates)		Pheromone	Attractant

Z,Z)-7,11-Hexadecadien-1-yl acetate SCLP Acetates)		Pheromone	Attractant
	[(3 <i>S</i> ,6 <i>R</i>)-3-methyl-6-prop-1-en-2-yldec-9- enyl] acetate	Pheromone	Insecticide
	[(3S,6S)-3-methyl-6-prop-1-en-2-yldec-9- enyl] acetate	Pheromone	Insecticide
	[(7E,11E)-hexadeca-7,11-dienyl] acetate	Pheromone	Mating Disruption
	[(7Z,11E)-hexadeca-7,11-dienyl] acetate	Pheromone	Mating Disruption
	[(7Z,11Z)-hexadeca-7,11-dienyl] acetate	Pheromone	Mating Disruption
	[(Z)-dodec-9-enyl] acetate	Pheromone	Attractant
1,4-Dimethylnaphthalene	1,4-dimethylnaphthalene	Pheromone	Attractant
1-Decanol		Pheromone	Mating Disruption
	1-Octen-3-ol	Pheromone	Attractant
	2-[(1R,2S)-1-methyl-2-prop-1-en-2- ylcyclobutyl]ethanol	Pheromone	Attractant
	2-Hydroxy-3-methylcyclopent-2-enone	Pheromone	Attractant
	3-Ketopetromyzonol sulfate	Pheromone	Mating Disruption
	3-Methyl-2-cyclohexen-1-one	Pheromone	Mating Disruption
	4-(3-Oxobutyl)phenyl acetate	Pheromone	Attractant
	CheckMate Technical Pheromone	Pheromone	Mating Disruption
	cis-7,8-Epoxy-2-methyloctadecane	Pheromone	Mating Disruption
	cis-9-Tricosene	Pheromone	Mating Disruption
	Citral	Pheromone	Attractant
Fatty acids C8-C10 methyl esters (CAS 85566-26-3) (Methyl octanoate (CAS 111- 11-5); Methyl decanoate (CAS 110-42-9))		Pheromone	Attractant
	Fish oil	Pheromone	Repellent
	German cockroach pheromone	Pheromone	Attractant
Hexadecyl acetate (SCLP Acetates)		Pheromone	Mating Disruption
	Lauryl alcohol	Pheromone	Mating Disruption
Methyl decanoate (CAS 110-42-9)		Pheromone	Attractant
Methyl octanoate (CAS 111-11-5)		Pheromone	Attractant
	Nerolidol	Pheromone	Mite mating disruption
n-Tetradecylacetate (SCLP Acetates)		Pheromone	Attractant
	Oxypurinol	Pheromone	Attractant
	Periplanone B	Pheromone	Attractant
	tert-butyl 4-chloro-2-methylcyclohexane- 1-carboxylate	Pheromone	Attractant
Tetradecan-1-ol (SCLP Alcohols)		Pheromone	Attractant
	Verbenone	Pheromone	Repellent

Note: Green = approved (EU) registered (USA), orange = pending approval, red = not registered purple = registration review, light blue = reregistration blue = pending registration. Information is correct as of April 2024.

Company Involvement

The below table(s) on key active ingredients and key companies is derived directly from AgBioInvestor's exclusive primary market research study that surveyed biological- and biostimulantgrowers, which were conducted for the first time in 2023 and profiled the 2022 agricultural market. The market research surveyed many key agricultural markets for biologicals, including: USA, Mexico, Chile, Brazil, Argentina, France, Italy, Spain and Turkey. The AIs have been ranked by farm-gate value (\$m.). Quantification of these data and much more biological market research can be found in the separate subscription product AgbioInsight.

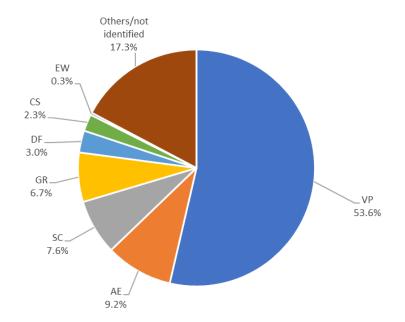
Jun 30, 2022 FMC entered into a definitive agreement to acquire BioPhero, a pheromone research and production company based in Denmark, for a purchase price of \$200 million. BioPhero produces its products at its new facility utilising a yeast fermentation process, which allows the mass-production of bio-based pheromones at relatively low cost. Due to the production process and associated lower costs, BioPhero is targeting pheromone-based insect control in row crops, where traditionally this method would normally be utilised in fruit crops, such as vineyards and orchards. BioPhero received \$17 million in Series A funding in 2021 with participation from FMC Ventures.

The acquisition adds BioPhero's pheromone insect control technology to FMC's portfolio and R&D pipeline. FMC's purchase of BioPhero comes after the launch of its new Plant Health business, Biologicals by FMC in 2022. Following the acquisition, FMC intends to launch five new pheromone products over the next three to five years. In addition, the company cites the opportunity to expand the use of fermentation technologies across a broad range of crops targeting a variety of pests, including fungi and weeds.

Key Companies with Involvement in Pheromones	
Al	Key Companies
Lavandulyl senecioate	Suterra
(E, Z)-7,9-Dodecadien-1-Yl Acetate	Shin-Etsu
(E,Z)-7,9-Dodecadienyl acetate	Shin-Etsu
	CSR
	Trece
(E,E)-8,10-Dodecadien-1-Ol	Suterra
	Shin-Etsu
	BASF
	M2i Biocontrol
	Gowan
	Mitsui & Co.
	Tosvar
	(Z,Z)-11,13-Hexadecadienal
(Z,Z)-11,13-Hexadecadienal (E)-8-Dodecen-1-Yl Acetate / (E,E)-8,10- Dodecadien-1-Ol / (Z)-8-Dodecen-1-Ol / (Z)-8-	Suterra Pacific Biocontrol
Dodecen-1-Yl Acetate / Dodecanol / Tetradecan-1- Ol	
(E,Z)-2,13-Octadecadienyl Acetate + (E,Z)-3,13- Octadecadienyl Acetate	Shin-Etsu
(E, Z)-7,9-Dodecadien-1-Yl Acetate / Dodecan-1-yl acetate	BASF
(Z)-11-Hexadecen-1-YI Acetate	Suterra
(E,Z)-7,9-dodecadien-1-yl acetate	Shin-etsu Chemical M2i Biocontrol ISCA
	Exosect
(E)-8-Dodecen-1-Yl Acetate / (Z)-8-Dodecen-1-Ol / (Z)-8-Dodecen-1-Yl Acetate	Shin-Etsu
	Suterra
(E,E)-8,10-Dodecadien-1-Ol / 1-Tetradecanol / Dodecan-1-Ol	Shin-Etsu
(E,E)-8,10-Dodecadien-1-Ol / 1-Dodecanol / 1- Tetradecanol	Shin-Etsu
(E)-8-Dodecen-1-Yl Acetate / (E,E)-8,10- Dodecadien-1-Ol / (Z)-8-Dodecen-1-Ol / (Z)-8- Dodecen-1-Yl Acetate	Suterra
	Pacific Biocontrol
(E/Z)-8-Dodecen-1-Yl Acetate	BASF
(E,E)-8,10-Dodecadien-1-OI / Dodecyl-acetate	Suterra BASF

Formulation Types – Value Share

The below chart(s) are derived from the biological focussed market research that AgbioInvestor conducted, and illustrates the value share attributed to various formulation type codes.



Code	Description	Code	Description
AE	Aerosol dispenser	LI	Liquid
AL	Other liquids to be applied undiluted	LS	Solution for seed treatment
СВ	Bait concentrate	ME	Micro emulsion
CS	Capsule suspension	OD	Oil dispersion
DC	Dispersible concentrate	SC	Suspension concentrate
DF	Dry flowable	SL	Soluble concentrate
DP	Dustable powder	SP	Water soluble powder
EC	Emulsifiable concentrate	VP	Vapour releasing product
EW	Emulsion, water in oil	WG	Water dispersible granule
FS	Flowable concentrate for seed treatment	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment
LC	Liquid concentrate		

Research and Development

Similar to macrobials, the pheromone segment is of a relatively small size compared to other biopesticide segments, and often serves niche end markets, largely in speciality crops fruit, veg and tree nuts. The pheromones on the market are well established and the number of new molecules entering the market is low, largely down to the challenges of identifying new natural source species. Instead, the majority of R&D in pheromones surrounds formulation and delivery technologies. Active component selection, particularly research around the optimum blends and ratios of various pheromone species, is also important.

 May 19, 2020 Corteva and the France-based biological crop protection company M2i Life Sciences entered into multi-year global agreements for the research, development, and commercialisation of pheromone-based insect control solutions. Both companies will collaborate to bring to market M2i's portfolio of semiochemicals, which include pheromonebased products, for specialty and row crops, whilst also combining their respective technologies to develop novel solutions to help farmers control crop pests and extend the life of plant-based insect-control traits.

The multi-year agreements represent the first collaboration agreements for Corteva's newly created global Biologicals portfolio, which is focused on developing resources for farmers using foliar and soil applied biological controls, nutrition use efficiency and bio-stimulants, soil health and bio-fertilisers.

- Sep 24, 2021 The US EPA received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products including Bedoukian Research's- Bedoukian Delta-Dodelactone Technical (Insect pheromone, repellent—Delta-Dodecalactone (2H-pyran-2-one, 6-heptyltetrahydro-) at 98.7%) proposed for manufacturing of insect repellents for indoor, non-food use.
- Apr 1, 2022 BASF announced the launch of a new feature for its Xarvio Scouting mobile app which utilises instant image recognition to identify and count codling moths, grape moths, and oriental fruit moths caught in pheromone traps. Users take an image of the trap with their smartphone and submit the image for analysis, with the app returning information detailing the insect pest type and number. The feature has been developed for grape, pome fruit and stone fruit growers in France, Germany, Greece, Italy, Poland, Spain and the UK.
- Sep 19, 2023 Embrapa, Brazil's agricultural research organisation, obtained a patent for a process to obtain a nanocomposite particle, which is capable of slow and controlled release of agricultural inputs. The process can isolate calcium carbonate nanocomposite and lignin kraft from gaseous emissions, which can be used to facilitate the slow and controlled release of several compounds for agricultural use such as pesticides, pheromones, fertilisers or combinations of them. The technology reportedly has the potential to reduce the volume of input applications, whilst the process of isolating the particle can capture carbon dioxide, contributing to emission reductions.
- Sep 5, 2024 Syngenta Biologicals and Provivi established a collaboration to develop and commercialise two pheromone-based products for the control of Yellow Stem Borer (YSB) in India and Indonesia, and Fall Armyworm (FAW) in Thailand. The products, YSB Eco-Dispenser and FAW Eco-Granules, will be made available to farmers in 2026. Syngenta and Provivi have previously collaborated to commercialise the pheromone product Nelvium in Indonesia for the control of rice stem borer insects

Market Outlook

The pheromone market will likely continue to represent a small market share of the overall biopesticide segment, largely due to the niche nature of the technology. The main outlets for pheromones will continue to be within speciality crop situations, however there may be greater uptake of mating disruption pheromones within row crop situations to tackle specific resistance issues as part of integrated pest management strategies. However, the prohibitively high costs associated with pheromone technologies will limit this to the most challenging situations and likely where grower incomes are the highest, or where government support through subsidies and sustainability programs are greatest.

In addition to the increase in the adoption of integrated pest management practices, pheromones will also benefit from increasing demand for high quality fruit and vegetables in developing nations, particularly within Asia. For example, in India, the government has been actively promoting biopesticides, including pheromones, providing subsidies and financial assistance for farmers adopting IPM practices. Public outreach is also very important in promoting grower awareness and education around their use. High smartphone adoption in countries such as India and other parts of Southeast Asia coupled with basic agronomy advice services and digital ag apps can be used to foster favourable integrated pest management practices, including pheromones in conjunction with financial assistance. For example, in India, the National Centre for Integrated Pest Management (NCIPM) conducts research and provides guidance on the use of pheromones in agriculture. Likewise in China the government has been encouraging the use of pheromones in agriculture through support for research institutions as well as government subsidies.

The limiting factors with pheromone market growth will mostly come from the cost of application coupled with challenges surrounding correct use of these products, such as timing, field distribution, pheromone selection due to pest specificity, over reliance on a single technology as well as climatic pressure on orchard regions, where abandonment may increase in coming years due to severe droughts.

Taking this into consideration, we anticipate that the market will grow at a rate of +10.7% p.a. between 2023 and 2028 (constant currency and pricing) to reach \$252 million.

Biological Others: Others

Sales Performance of Biological Others: Others									
Year	Biological Others: Others Sales (\$ m.)	Total Others Sales (\$ m.)	Biological Others: Others Share of Biological Others (%)	Biological Others: Others Share of Total Others (%)					
2018	53	1,796	39.86	2.97					
2022	78	2,189	35.45	3.56					
2023	83	2,174	35.32	3.81					
2028F	131	2,438	34.20	5.37					
1-yr Change (%)	6.2	-0.7							
5-yr CAGR (% p.a.)	9.2	3.9							
5-yr CAGR F (% p.a.)	9.6	2.3							

Overview

This segment primarily includes biofumigants, which are products derived from natural sources that contain a volatile component that is effective in suppressing soil borne disease, insects, nematodes, mites and/or weeds. This segment specifically covers products that are traded, rather than cover crop seeds such as Brassicas like mustard and radish that are grown before being macerated and incorporated into the soil when preparing the field for subsequent cultivation of the main crop.

Allyl isothiocyanate (AITC)

An example of a traded biofumigant is allyl isothiocyanate (AITC) which is sold by Isagro as Dominus, and is a broad-spectrum product that controls soil-borne fungi, nematodes, weeds and insects in tomato, strawberry, cucumber, pepper and lettuce. The product may be delivered to the soil via drip irrigation under sealed covers. Soil coverage is for around 10-14 days followed by 1 day of aeration versus around 21-28 days total pre-transplant interval for legacy methods.

AITC reacts in a non-selective and irreversible manner with proteins and amino acids to create stable compounds containing sulfhydryl groups, disulfide bonds, and amines. These covalent bonds alter the structure of proteins or amino acids, disrupting normal cell functions, including enzymatic reactions and metabolic processes. AITC is effective due to its ability to travel as a gas through soil pore spaces, whilst its low hydrophobicity prevents extensive partitioning to the solid phase of the soil.

AITC is a naturally occurring compound Brassicas, particularly mustard, radish, cabbage, and broccoli. AITC may also be synthesised artificially however in the USA it is not approved as a synthetic approved for use in organic agriculture by the National Organic Standards Board (NOSB). It is however, registered as a biochemical and a conventional chemical in the US by the EPA, where it was first registered by the in 1962 for use in pesticides and rodent control products.

• Oct 2, 2013 Isagro received approval for US regulators for its Dominus bio-fumigant product. Dominus is based on Isagro's patented technology and contains the active ingredient allyl isothiocyanate. The product is for use as a pre-plant soil treatment in the control of soil-borne fungi, nematodes, weeds and insect pests in a wide range of crops.

- Mar 4, 2021 The Canadian agricultural biotechnology company MustGrow Biologics announced it had isolated and concentrated a thiocyanate product from mustard seed. MustGrow is developing thiocyanate extracts as an organic non-selective bioherbicide that is soil active with systemic translocated properties. Greenhouse testing of MustGrow's new thiocyanate bioherbicide extract has commenced, including in combination with MustGrow's mustard-based biopesticide TerraMG (active ingredient Allyl isothiocyanate)
- Apr 30, 2021 MustGrow Biologics and Univar Canada subsidiary NexusBioAg announced a collaborative field trial program in Canada. NexusBioAg was to conduct the field trials of MustGrow's mustard derived biopesticide TerraMG (allyl isothiocyanate) for treatment of Clubroot and *Aphanomyces* diseases in canola and pulse crops respectively. The aim was for NexusBioAg's technical and commercial expertise to accelerate the development and potential commercialisation of TerraMG for use in Canada on canola and pulse crops.
- Jul 20, 2022 NexusBioAg, a division of Univar Solutions, and MustGrow Biologics entered into an exclusive marketing and distribution agreement for TerraMG (allyl isothiocyanate) in the Canadian canola and pulse markets.
- Sep 12, 2023 NexusBioAg, a Univar Canada subsidiary, announced that it was to add MustGrow Biologic's mustard derived pre-plant soil fumigant TerraMG (allyl isothiocyanate) to its BioAdvantage Trials Program in 2024, following successful research trials in 2023.

Research and Development

Currently most of the R&D centres around identifying novel extracts to be used as biofumigants, however due to the more limited addressable market for this niche segment, this is currently a smaller area of active research compared to other plant extract segments within insecticides, fungicides and herbicides. Examples include MustGrow's mustard-based biopesticide TerraMG (active ingredient Allyl isothiocyanate) being developed for use in combination with MustGrow's thiocyanate bioherbicide extract.

Other research and development in this area is centred around formulation technology to optimise irrigation strategies as well as the associated systems such as the polymer films used to create the soil fumigation treatment tunnels and precision agriculture control systems.

Within the non-traded adjacent market of cultivating cover crops, the main areas of R&D are in optimising cultivation practices such as cultivar breeding and selection of varieties with high levels of glucosinolates and other bioactive compounds for effective biofumigation.

Market Outlook

The outlook for biofumigants is likely to be boosted by the broad spectrum of activity across a number of pest categories including insects, nematodes, mites, and weeds. Given the gaps in the market from older chemical fumigants such as methyl bromide, the outlook for biofumigants is favourable, but it is likely that they will remain focussed on use in protected agriculture due to the nature of application through drip irrigation, which in itself requires specialist equipment for application.

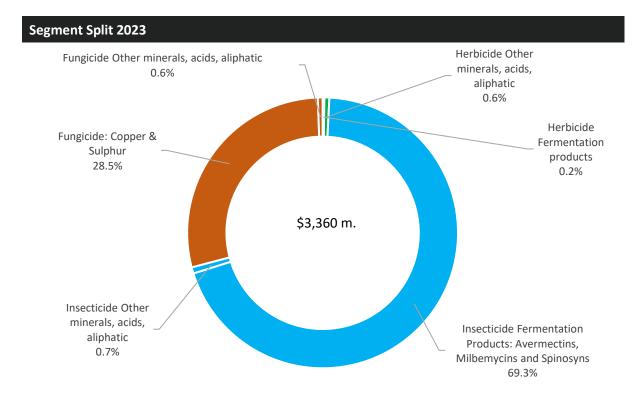
Traded biofumigants such as allyl isothiocyanate will also face competition from the practice of cultivating cover crops of brassicas, which are incorporated into the soil in the subsequent season. However, the overlap between the two is limited, given that the latter is more applicable in open field settings.

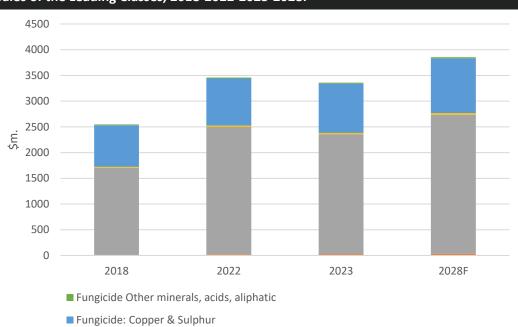
The uptake of biofumigants will be supported by a greater push towards sustainable practices in develop ag economies, particularly high-value fruit and veg, as older chemistries are lost, as well as a greater demand for organic agriculture in developed ag economies and major fruit and veg exporters. Given the push towards more stringent residue limits in markets such as Europe, then the broad spectrum of activity coupled with zero residues, is a clear benefit to fruit and veg exporters.

Taking this into account we anticipate that the biopesticide others: others segment will increase by an average of 9.6% per annum between 2023 and 2028 to reach \$131 million.

Bio-aligned Crop Protection

Bio-aligned Crop Protection Market and Forecast										
					US\$m.					
Туре	2018	2022	2023	2028F	2023/2022 (%)	2023/2018 (% p.a.)	2028F/2023 (% p.a.)			
Fermentation products: bioherbicide	3	6	7	9	16.7	18.5	5.2			
Other minerals, acids, aliphatic	9	18	20	24	11.1	17.3	3.7			
Bio-aligned herbicides	12	24	27	33	12.5	17.6	4.1			
Fermentation Products: Avermectins, Milbemycins and Spinosyns	1692	2477	2330	2705	-5.9	6.6	3.0			
Other minerals, acids, aliphatic	19	24	25	31	4.2	5.6	4.4			
Bio-aligned insecticides	1711	2501	2355	2736	-5.8	6.6	3.0			
Copper & Sulphur	810	916	959	1063	4.7	3.4	2.1			
Other minerals, acids, aliphatic	13	18	19	23	5.6	7.9	3.9			
Bio-aligned Fungicides	823	934	978	1086	4.7	3.5	2.1			
Total	2546	3459	3360	3855	-2.9	5.7	2.8			





Sales of the Leading Classes, 2018-2022-2023-2028F

- Insecticide Other minerals, acids, aliphatic
- Insecticide Fermentation Products: Avermectins, Milbemycins and Spinosyns
- Herbicide Other minerals, acids, aliphatic
- Herbicide Fermentation products

Introduction

This section profiles those products which fall under what AgbioInvestor classifies as bio-aligned.

ABI'S DEFINITION OF BIO-ALIGNED PRODUCTS

'Products with efficacy in controlling pests for use in growing harvestable produce derived from a natural or biological source and that have since undergone subsequent modification or are atypical from biological processes'.

The term 'bio-aligned' has been chosen to reflect the subtle distinction necessary to differentiate product classes, such as copper and sulphur fungicides, which have traditionally been used in organic agriculture but have unique regulatory and environmental profiles compared to biopesticide products. Although they have a natural source, fermentation products and bacterial extracts such as avermectins, milbemycins, and spinosyns often undergo subsequent modification and are often positioned as biochemical alternatives to chemical CP. The term 'bio-aligned' also includes additional herbicidal, insecticidal, and fungicidal fermentation products and minerals, like:

- Copper and sulphur fungicides.
- Fermentation products.
- Mineral products and other basic substances that could potentially be found within living organisms (e.g. potassium bicarbonate).

The sector as a whole is broken down into the 6 segments below. If we take the total of the segment, this increased at a rate of +5.7% p.a. between 2018 and 2023. Within this, the most significant segments are that of the fermentation product insecticides which increased at a rate of 6.6% p.a. over the same period to reach \$2,330 million, and the copper and sulfur fungicide segment which increased by 3.4% between 2018 and 2023 to reach \$959 million. Fermentation product insecticides have benefitted from their broad spectrum of activity as well as generally lower levels of regulatory concern compared to some of the older classes of chemistry they have helped replace. Copper and sulfur fungicides are effectively commoditised fungicides, with industry dynamics partly influenced by recent regulatory restrictions on copper, but also from weather patterns in key vine and horticulture regions. Copper and sulfur fungicide market maturity in markets such as Europe and North America is balanced against increased demand for F&V crops in developing ag economies such as India and Southeast Asia, where they are an attractive low-cost multi-site mode of action for disease control.

- Herbicide Fermentation products
- Herbicide Other minerals, acids, aliphatic
- Insecticide Fermentation Products: Avermectins, Milbemycins and Spinosyns
- Insecticide Other minerals, acids, aliphatic
- Fungicide: Copper & Sulphur
- Fungicide Other minerals, acids, aliphatic

Sales Performance of Herbicides: Fermentation Products							
Year	Herbicides: Fermentation Products Sales (\$ m.)	Total Herbicide Sales (\$ m.)	Herbicides: Fermentation Products Share of Bio-aligned Herbicides (%)	Herbicides: Fermentation Products Share of Total Herbicides (%)			
2018	3	23,646	25.00	0.01			
2022	6	31,547	25.00	0.02			
2023	7	31,017	25.93	0.02			
2028F	9	32,390	27.27	0.03			
1-yr Change (%)	16.7	-1.7					
5-yr CAGR (% p.a.)	18.5	5.6					
5-yr CAGR F (% p.a.)	5.2	0.9					

Herbicides: Fermentation Products

Introduction

The development of the bioherbicide segment as a whole has been limited up until this point with the focus mostly being on microbial based species as well as natural products. As a result of this relative infancy, there remains a need to further develop other production methods such as fermentation technology. The commercial fermentation of fungi for use in agriculture, such as the bioconversion of fermentation product insecticides is well established, however the production of fermentation product bioherbicides is still an emerging segment with limited market size.

Key challenges include a complex manufacturing process, where a high biomass yield is essential for commercialisation and cost purposes. Some microorganisms produce low amounts of their secondary metabolites, making it difficult for viable industrial production to take place. Development and optimisation of the specific culture medium and reaction conditions may lead to the greater production of these secondary metabolites. For example, the production of secondary metabolites may be negatively impacted by the sugar concentration in a mechanism known as catabolite repression, which allows microorganisms to adapt quickly to a rapidly metabolisable carbon and energy source first.

The produced biomass must also display good shelf life and formulation stability as well as being compatible with the farmers tank-mix and spray equipment. Field stability under a myriad of different conditions as well as grower safety, efficacy and cost of application will also determine the future uptake of fermentation product herbicide usage. The use of adjuvants and advanced formulation technology as a whole is essential for the success of bioherbicide products.

Many of the fermentation product herbicides researched in the literature have relied upon the use of submerged fermentation, which are generally more cost effective than other production methods such as solid state fermentation.

• Submerged fermentation is a method of cultivating microorganisms in closed flask (bioreactors) and with liquid nutrient media (broths). Conditions can be closely monitored and controlled including the supply of oxygen in aerobic conditions, as well as other parameters such as pH, temperature, viscosity, dissolved oxygen, foam formation, biomass formation, substrate utilization and desired product formation

• Solid-state fermentation consists of the selected microorganisms (bacteria, fungi and yeasts) being cultivated on a moist, solid, non-soluble organic material that acts as a support and nutrient source for the growth of the microorganisms, in the absence or near absence of free-flowing water. This more closely mimics the natural habitat of many microorganisms.

Active Ingredients

Fermented strains have been identified below in the literature. It is unclear how much penetration of these specific products into the commercial market there is. However, there is expected to be a small market value for traded fermentation product herbicides.

Diaporthe sp.

The bioherbicide active of this species is produced from the solid-state fermentation (SSF) of *Diaporthe sp.* and was studied for phytotoxicity to cucumber (*Cucumis sativus*). Before the fermentation, the solid substrate was supplemented with corn steep liquor and/or soybean bran. The mixture is then inoculated with the feedstock strain and fermentations carried out for 7 days at 28 degrees Celsius.

Fermentation of fungus Phoma sp.

This AI demonstrated activity in pre-emergence and post-emergence, assays for phytotoxicity to cucumber and sorghum. Other references in the literature mention control of field thistle (*Cirsium arvense*)

Tirchoderma koningiopsis – fermentation product extracts of cellulase, amylase, peroxidase and lipase

These fermentation products have been demonstrated to provide control of milkweed (Euphorbia *heterophylla*). Other studies have indicated control of Mexican fire plant (*Euphorbia heterophylla*), causing up to 60% of foliar damage, without presenting phytotoxicity against corn crops.

Fusarium oxysporum / Fusarium ploriferatum - fermentation product extracts of cellulase, amylase, peroxidase and lipase

This active ingredient combination of fermentation product extracts has also been shown to possess activity against Mexican fire plant (*Euphorbia heterophylla*).

Fusarium fujikuroi - exopolysaccharides

Exopolysaccharides are secondary metabolites produced by microorganisms. These may be produced at different concentrations depending on the fermentation methodology used. In the literature, bioassays screen for activity in cucumber and sorghum.

Gloeocercospora sorghi

Conidia also known as spores, are the asexual reproductive structures of fungi usually produced at the tip or side of hyphae or on special spore-producing structures called conidiophores. This bioherbicide based on conidia from *Gloeocercospora sorghi* was shown to have activity against johnsongrass (*Sorghum halepense (L.) Pers.*)

Regulatory Situation

Fermentation products in the EU are subject to the same regulatory processes as for other conventional pesticides with the relevant regulation for placing of products on the EU market being Regulation (EC) No 1107/2009. This regulation applies to all pesticides, including those derived from fermentation processes, therefore it is necessary to prepare the same regulatory dossier, including studies to certify satisfactory ecotox, toxicology, residue levels and efficacy. As such, the registration process can take a similar length of time compared to conventional pesticides.

In the USA, all Als must be registered by the Environmental Protection Agency (EPA) through the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This also includes biological products, with the Biopesticides and Pollution Prevention Division (BPPD) section of the EPA responsible for all biopesticide regulatory activities. Fermentation products are generally considered to be the product of microbial species, and different data sets must be submitted to register biochemical and microbial biological products. They are generally regarded as reduced-risk pesticides, while genetically modified microbial pesticides may be subject to additional data or information requirements on a case-by-case basis. This depends on the particular microorganism, the parent microorganism, the proposed use pattern, and the manner and extent of the modification.

Some specific requirements for regulatory submissions for fermentation products in the USA include:

- Microbial Identification to provide detailed characterisation of the producing strain
- Pathogenicity and infectivity studies are required to ensure that the end product does not pose risks of infection to humans or animals
- Production process characterisation must include information on the nature of the fermentation process and what quality control procedures are in place to ensure product consistency and absence of harmful contaminants.

Research and Development

As an emerging segment the research and development of new products is likely to be a key driver of the future size of the market, as there are currently very few products, and certainly none of any significant commercial scale. As mentioned above, the research and development to date has focussed on *Diaporthe sp., Phoma sp., Tirchoderma koningiopsis, Fusarium oxysporum, Fusarium ploriferatum, Fusarium fujikuroi* and *Gloeocercospora sorghi*. Key Barriers that need to be overcome in research clearly centre around efficacy as well as managing the cost of production, shelf life and field stability.

Market Outlook

The outlook for the fermentation product herbicide segment is currently more limited compared to the true biologicals market, which we forecast to grow at a rate of 5.2% p.a. between 2023 and 2028 to reach \$9m. Clearly there is a greater degree of uncertainty in the development of this segment, due to the limited range of products that are currently on the market as well as the high cost of production and challenges with shelf life.

Similar to the microbial bioherbicide segment, managing grower awareness through a conducive marketing strategy, likely in partnership with agronomists, distributors, representatives and cooperatives will be key to fostering product uptake and correct usage. The development of the sector will also rely on efficacious products coming to market, such that grower perception will not adversely be impacted.

Sales Performance of Herbicides: Other minerals, acids, aliphatic						
Year	Herbicides: Other minerals, acids, aliphatic Sales (\$ m.)	Total Herbicide Sales (\$ m.)	Herbicides: Other minerals, acids, aliphatic Share of Bio-aligned Herbicide Sales (%)	Herbicides: Other minerals, acids, aliphatic Share of Total Herbicides (%)		
2018	9	23,646	75.00	0.04		
2022	18	31,547	75.00	0.06		
2023	20	31,017	74.07	0.06		
2028F	24	32,390	72.73	0.07		
1-yr Change (%)	11.1	-1.7				
5-yr CAGR (% p.a.)	17.3	5.6				
5-yr CAGR F (% p.a.)	3.7	0.9				

Herbicides: Other minerals, acids, aliphatic

Introduction

In this profile we include the bio-aligned herbicide products, those that are sometimes considered to be true biological products due to their basic substance character or because they are based on minerals products. Whilst they can play an important role alongside what AgBioinvestor considers to be 'true biological' products such as plant extracts or microbial based bioherbicides, **due to their mineral or basic substance nature they are placed in the bio-aligned definition and not considered as part of the biologicals definition.**

The greatest portion of bioherbicide sales have likely occurred in the non-crop market in recent years. For example, restrictions on glyphosate use in home, garden, and city landscapes have increased market demand for alternatives, with "Glyphosate-Free Roundup" based on acetic acid (vinegar) being marketed instead.

Important non-crop products include the moss herbicide iron sulphate, which is included in mixtures with conventional products like 2,4-D and dicamba (broadleaf weed control), and the non-selective contact herbicide pelargonic acid, touted as an attractive glyphosate alternative that potentially replaces some of glyphosate's lost crop protection uses. The market for bio-aligned herbicides for crop applications was small in 2022, at around \$18 million.

Products

The below table highlights the key bio-aligned herbicide active ingredients that are based on minerals/salts and organic acids.

Bio-aligned herbicides: Key Information							
Active Ingredient (AI)	Туре	Source	Spectrum	Timing	Rate (Kg _{Al} / Ha)	Usage	Companies
Acetic acid	Natural Product	Yeast Fermentat ion	Annual & Perennial BLW and GRA	Foliar: Contact		Non-Crop (Home & Garden, Railroads, Golf Courses)	Ecoval Technologies, Various
Iron sulphate	Natural Product	Naturally Occurring	Selective (Mosses)	Foliar: Contact		Non-Crop (Home & Garden, Turf)	Neudorff, Various
Pelargonic acid	Natural Product	Sunflower Oil, Beef Tallow	Non- Selective	Foliar: Contact, Dessica nt		Non-Crop (Home & Garden, Railroads, Golf Courses), Crop (F&V, Field Crops)	Agro Green / Novag, Belchim, Biosafe, De Sangosse
Sodium chloride	Natural Product	Naturally Occurring	Selective (Baccharis Halimfolia)	Soil <i>,</i> Spot (stump)	10- 1000	Non-crop (Salt marshes)	Institut Technique de l'Agriculture Biologique
lron HEDTA (FeHEDTA)	Natural Product	Naturally Occurring	Selective (Mosses)	Foliar: Contact		Non-Crop (Home & Garden, Turf)	Neudorff

Natural Products

Acetic acid

Acetic acid, also known as vinegar, is a contact herbicide that burns foliage upon application. While this product has long been known by gardeners to have utility in weed control, acetic acid has significant disadvantages in large scale commercial settings compared to synthetic herbicides. Notably, it requires multiple applications and carries a relatively high cost, particularly when used at the higher concentrations required to reach effective levels of control. The table below outlines the costs of various bioherbicides available in the USA for non-crop applications and shows the cost disparities between biological products and glyphosate. Acetic acid at 5% concentration has the lowest cost per unit area; however, in study tests, it has shown poor efficacy. In contrast, the 20% concentration formulation was four times more costly because it required three applications to achieve good weed control. These cost disadvantages have limited acetic acid's commercial success in crop protection, with some evidence that organic production of fruits and vegetables is the key use case.

Cost for Various Bioherbicides in Non-Crop Application	ns.	
Product Name	Retail Price (\$/L)	Cost (\$/1,000 sq.ft.)
Nature's Glory Weed and Grass Killer (acetic acid)	6.27	38.87
Scythe (pelargonic acid)	9.95	19.9
17.4 M acetic acid (used at 5% concentration)	10.28	10.28
17.4 M acetic acid (used at 20% concentration)	10.28	41.12
RoundUp (glyphosate)	51.85	12.34
Source: Cornell		

Iron Salts

Iron salts such as iron sulphate and Iron HEDTA are often classed as bioherbicides, with the US EPA regulating Iron HEDTA as a biopesticide. However due to the mineral/basic substance nature of the AI we include this in the bio-aligned definition. Iron salts are used as fertilisers for micronutrient deficiencies and are also used for moss control on lawns. Multiple companies are active in selling iron salts as herbicides, including Neudorff, with the vast majority of sales going to the turf and landscape sector and only very minor sales being for crop protection applications.

Pelargonic Acid

Pelargonic acid (also known as nonanoic acid because it is a nine-carbon saturated fatty acid) is a naturally occurring non-selective plant- or animal-derived soap that exerts contact activity when applied to plant leaves. It is derived from oils, notably through ozonolysis of beef tallow, and is named for its presence in oils from *Geranium* species (*Pelargonium*). Unlike many of the bioherbicides on the market, pelargonic acid has many and growing uses in crop protection.

This has been stimulated in part by regulatory actions against glyphosate, the fast burn-down action of pelargonic acid, and the requirement of some producers for effective 'natural' weed control solutions.

Pelargonic acid was brought to market as a bioherbicide by Mycogen in 1995, with the company initially advertising the product as 'Scythe' for non-crop applications. It is thought to exert its activity through desiccation of vegetation by destroying the waxy cuticle, although Mycogen also notes its potential to lower the internal pH in the plant leaf, leading to a loss of cellular ATP and Glucose-6-phosphate; this generates membrane dysfunction, eventually leading to cell leakage and collapse and tissue desiccation.

Although introduced in 1995, pelargonic acid's potential was severely limited by its costs compared to other burndown products such as glyphosate and paraquat; indeed, this remains a limitation of the product (see table on previous page). Furthermore, because it only fully controls small weeds and only injures larger weeds' leaves, it often requires multiple applications after leaves have grown back. In contrast, glyphosate is fully systemic, killing plant roots even when applied to leaf surfaces. Consequently, sales have remained minor, primarily for use in orchards and vineyards.

The Belgian company Belchim, now majority-owned by Mitsui & Co., has made several introductions of pelargonic acid under the Belhouka brand—for example, in the USA for burndown of annual and perennial broadleaf and grass weeds in turf, landscape, hardscape, and ornamental areas, and in Canada for burndown, spot, and inter-row weed control in fruit, vegetable, and field crops. Belchim has also released pelargonic acid products for desiccant and pre-harvest weed management in potato and cereal crops, sucker control in grapes and tree fruits, and control of unwanted weeds and mosses in non-crop areas.

Belchim's position with pelargonic acid came from the acquisition of Jade SARL, a French biologicals company headquartered in Mérigna. At the time of its acquisition, the company held several registrations for pelargonic acid under the brand names Beloukha, Katoun, Katoun Gold, and Enclean

Even as Belchim has made major moves in the crop protection space with pelargonic acid, other companies – notably Monsanto (now Bayer), Albaugh, Ragan and Massey, and The Scotts Company – have been active with the product in the non-crop arena, often in mixtures with glyphosate. In addition, Novag SAS and Agro Green USA launched the product as Emerion 7700 in Colombia in 2019.

In 2013, De Sangosse acquired a stake in the UK company Alpha Pesticides, which has a portfolio of biological products, including herbicides based on pelargonic acid and insecticides based on potassium salts of fatty acids and long-chain fatty acids.

Mar 5, 2025 Health Canada's Pest Management Regulatory Agency opened a consultation on the proposed registration of pelargonic acid technical and Beloukha Herbicide which contains the active ingredient, submitted by Belchim Crop Protection Canada. The herbicide is intended for weed control in greenhouse-grown cucumbers, tomatoes, peppers, lettuce, and various ornamentals in both greenhouse and outdoor settings.

Potassium salts of fatty acids

(capric and caprylic acid, lauric acid, oleic acid, methyl decanoate, and methyl octanoate)

In addition to pelargonic acid, a diverse range of other herbicidal soaps have relatively minor usage. These include caprylic acid and methyl decanoate and octanoate, which generally have similar properties to pelargonic acid.

• Sep 5, 2023 Certis Belchim received approval in the Netherlands for the bioinsecticide Neudosan (based on fatty acids and potassium salts) to control sucking pests in ornamental crops, as well as open fields and protected food crops. Certis previously entered a cooperative agreement with the German company Progema for the product's development and distribution

Sodium chloride

Sodium chloride, or table salt, is a basic substance that has been registered as an herbicide in the EU for a very specific use case: control of the invasive *Baccharis halimfolia* in salt marshes. However, it also has utility as a fungicide and insecticide for control of powdery mildew (*Erysiphe necator*) and grapevine moth (*Lobesia botrana*). In addition, there have been further product developments using this active ingredient, notably including EcoMight (peppermint oil/potassium sorbate/sodium chloride) for use in non-crop settings. EcoMight is a post-emergent, systemic herbicide that exerts action via translocation into plant roots and reportedly offers effective control of common and invasive weeds. Interestingly, this is a systemic product, while pelargonic acid and others are only contact-active.

Regulatory Situation

The regulatory situation for herbicides based on minerals, organic acids and aliphatic molecules are generally favourable since in most countries they are considered to be "low-risk" or "basic substance" active ingredients.

An active substance can be approved as a low-risk substance if it meets the regular approval criteria and in addition meets the low-risk criteria as specified in Annex II, point 5 of Regulation (EC) 1107/2009. Low-risk substances are approved for 15 years instead of 10 years and data protection on the studies submitted for the approval and subsequent authorisation is extended from 10 to 13 years. Similar to the microbials segment, a fast-track authorisation procedure with reduced timelines (120 days) is in place. In contrast to conventional pesticide AIs, low-risk substances may be granted approval based partly on literature, data, and scientifically reasoned opinions. Low risk description can also be used on product marketing.

Basic substances are substances that are not predominantly used for plant protection purposes but may be useful in plant protection. They are substances of no concern and can be approved for plant protection use as far as their risks are acceptable. Their approval by the European Commission allows the use for purposes of plant protection, but they cannot be sold specifically as a plant protection product. Their approval is based on existing evaluations carried out following other EU legislations. Authorisation is issued for the entire EU for an indefinite period.

Seven bio-aligned active ingredients with herbicidal properties were registered in the EU in 2025, with the majority being herbicidal soaps such as capric acid and caprylic acid. Some of these are used primarily as insecticides or fungicides but also exhibit herbicidal properties. In addition, acetic acid, and sodium chloride have also been registered.

Six bio-aligned herbicides have been registered in the USA. Acetic acid is no longer registered as of 2025. Pelargonic acid is a natural product that is also registered in the EU and mainly used in non-crop settings such as turf.

Bioherbicides Approved for Use in the EU and USA						
EU	USA	Class				
Acetic acid	Acetic acid	Organic acid				
Calcium carbonate	Calcium carbonate	Basic substance				
Capric acid	Capric acid	Organic acid				
Caprylic acid	Caprylic acid	Organic acid				
Lauric acid	Lauric acid	Organic acid				
Oleic acid	Oleic acid	Organic acid				
Pelargonic acid	Pelargonic acid	Organic acid				
Sodium chloride	Sodium chloride	Basic substance				
Vinegar	Vinegar	Organic Acid/ Basic substance				

Note: Green = approved (EU) registered (USA), orange = pending approval, purple = registration review, Red = not approved. Information is correct as of May 2025.

Research and Development

Due to the basic substance nature of many of the active ingredients in this classification, the majority of R&D to date is currently centred around optimisation and development of formulations. For example, optimisation of the concentration and pH for balancing crop safety against efficacy. The use of adjuvants and surfactants to improve the wetting and spreading properties of compounds can be used to ensure optimum coverage and spreading, as well as improving shelf life and stability. Development of granular formulations can increase the convenience of application of basic herbicide substances such as acetic acid and other minerals, whilst tank-mix compatibility ensures that the products will have a greater range of operator benefits.

Market Outlook

The key benefits that the mineral, acids and aliphatic herbicide segments possess is that many of the products are generally low-cost solutions that offer moderate levels of control across a broad range of weed species. The 'basic substance' character often means that registration processes are typically expedited with significantly lower costs and timescales even compared to that of the 'true' biopesticide segments. Some of the downsides are that many of the products offer only moderate suppression of weeds rather than control, and multiple applications may be required across the season, increasing grower labour and costs. Where these actives excel is in their usage in organic agriculture where few alternatives exist.

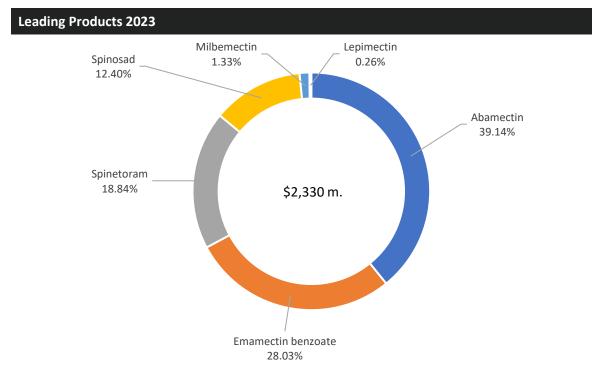
The increase in demand for organic produce is also likely to benefit the demand for such products, however this will likely be tempered by the usage of other strategies compatible with integrated pest management, such as cover cropping, crop rotation, grazing by livestock, tillage, manual weeding and a range of novel robotic/laser weeding technologies. Clearly, all of these strategies are outside of the mainstream of weed control within agriculture, and the dynamics of bio-aligned herbicide uptake will very much depend on local factors influencing the structure of production systems in those markets, and the unique weed spectra that is locally present. For example, high-value crop growers in California may be more likely to use expensive robotic/laser weeding technologies.

For bio-aligned herbicides and bioherbicides, perhaps more than any other biopesticide segment will require a robust go-to-market strategy, both from the perspective of tailored regional solutions, but also from the perspective of uptake and education surrounding the correct usage by growers.

Mineral herbicides are likely to be complementary to 'true bioherbicides', allowing for a broader control spectrum and efficacy, whilst maintaining compatibility with integrated pest management (IPM) and organic agriculture practices. Taking all of this into account we forecast that the bio-aligned herbicide market will increase by an average of 3.7% p.a. over 2023 to 2028 to reach \$24 million.

Insecticides: Fermentation Products

Sales Performance o Spinosyns)	f Insecticides: Fe	rmentation Products	(Avermectins, Milbe	mycins, and
Year	Insecticides: Fermentation Products Sales (\$ m.)	Total Insecticide Sales (\$ m.)	Insecticides: Fermentation Products Share of Bio-aligned Insecticides (%)	Insecticides: Fermentation Products Share of Total Insecticides (%)
2018	1,692	16,796	98.89	10.07
2022	2,477	21,566	99.04	11.49
2023	2,330	21,737	98.94	10.72
2028F	2,705	24,446	98.87	11.07
1-yr Change (%)	-5.9	0.8		
5-yr CAGR (% p.a.)	6.6	5.3		
5-yr CAGR F (% p.a.)	3.0	2.4		

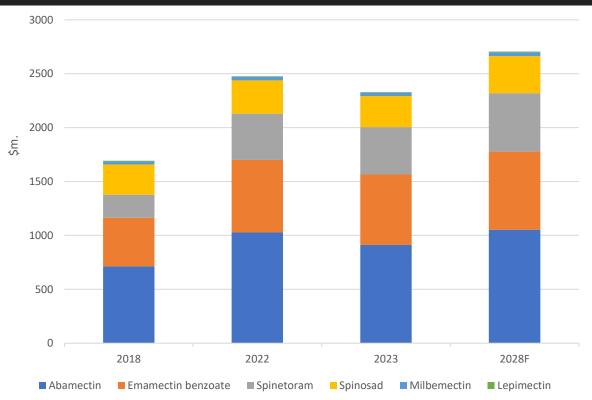


Leading Fermentation Products: Avermectins, Milbemycins, and Spinosyns							
АІ	ΜΟΑ	YOI	Timing	Main Crops	Rate (kg/Ha)	Sales 2023 (\$ m.)	Sales 2028F (\$ m.)
Abamectin	Glutamate-Gated Chloride Channel (Glucl) Allosteric Modulators	1985	Foliar	Cereals, Maize, Rice, Soybean, Cotton, Vine, Pome fruit, F&V	0.005 - 0.45	912	1053
Emamectin Benzoate	Glutamate-Gated Chloride Channel (Glucl) Allosteric Modulators	1998	Foliar	Maize, Rice, Soybean, Cotton, F&V	0.008 - 0.011	653	725

Bio-aligned Insecticides: Fermentation Products

Spinetoram	Nicotinic Acetylcholine Receptor (Nachr) Allosteric Modulators	2007	Foliar	Rice, Pome fruit, F&V, Nuts, Tea	0.2 - 0.4	439	541
Spinosad	Nicotinic Acetylcholine Receptor (Nachr) Allosteric Modulators	1995	Foliar	Maize, Soybean, Cotton, Potato, Vine, F&V	0.05 - 0.1	289	345
Milbemectin	Glutamate-Gated Chloride Channel (Glucl) Allosteric Modulators	1991	Foliar	Pome fruit, F&V, Plantations	0.01	31	34
Lepimectin	Glutamate-Gated Chloride Channel (Glucl) Allosteric Modulators	2010	Foliar	Vine, F&V, Tea, Ornamentals	0.01 - 0.03	6	7

Sales of Avermectins, Milbemycins, and Spinosyns, 2018-2022-2023-2028F



Introduction

As with the inorganic fungicides, AgbioInvestor does not consider fermentation products as a group to be biologicals, although certain active ingredients from this group are widely considered to be of natural origin, with spinosad (a mix of spinosyns) being derived directly from bacterial fermentation and being approved for organic agriculture in some cases. Although the fermentation products (avermectins, milbemycins, and spinosyns) are produced via bacterial fermentation, key members of the group are subsequently modified by chemical synthesis.

Avermectins (e.g. abamectin, emamectin benzoate): These naturally occurring compounds are generated as fermentation products of the soil actinomycete *Streptomyces avermitilis*. Emamectin benzoate is prepared from a mixture of 90% emamectin B1a and 10% emamectin B1b with methylamine, with the benzoate salt prepared via reaction with methyl benzoate.

Milbemycins (e.g. milbemectin, lepimectin): Milbemycins are generated through fermentation by *Streptomyces hygroscopicus*. They have a similar mechanism of action, but a longer half-life, than the avermectins.

Spinosyns (e.g. spinosad, spinetoram): Spinosyns are derived from fermentation by the soil bacteria *Saccharopolyspora spinosa* and *Saccharopolyspora pogona*. Spinosad is entirely derived from fermentation, whereas spinetoram is created by making two synthetic modifications to fermentation-derived spinosyn starting materials. The spinosyns exert their effects through a novel mode of action, primarily targeting binding sites on the nicotinic acetylcholine receptors (nAChRs) of insect nervous systems; these sites are distinct from those at which other insecticides have their activity. As a result, these insecticides show improved selectivity towards target insect pests, with lesser activity towards beneficial insects.

Products

Abamectin

The avermectin abamectin was developed and first introduced by Merck in 1985. Novartis subsequently acquired the product, and it is now part of Syngenta's portfolio. Although the product is widely used in crop protection, the main uses are in animal health, primarily as an anthelmintic (control of parasitic worms). The product is amongst the leading insecticides on the global market, benefiting from its selectivity and efficacy against a wide range of insect pests on several important crops, with the main crop uses being fruit & vegetables, rice, soybean, cotton and maize.

The product is sold in a wide range of country markets, with the most significant in 2023 in terms of sales being China, accounting for more than half of the total sales, although Brazil, the USA, Vietnam, Argentina and Mexico are also important.

Syngenta's sales of the product have come under increasing pressure from generic competition originating from a variety of off-patent manufacturers. Vive Crop Protection and SipcamRotam have collaborated on an abamectin-based nematicide from Vive's portfolio for the turf and ornamental market in the US, while the California-based Amvac, who specialise in post-patent innovation, acquired Adama's abamectin portfolio in the US. Nufarm Americas has also taken a position in the product with several registrations for the use of Abamex in the US for the control of psyllids, mites, leafminers and other pests.

Abamectin has come under regulatory scrutiny in more recent years, with a Brazilian federal judge suspending abamectin registrations in the country during 2018. This action stemmed from a request

by the Brazilian Public Ministry, which acts as a consumer protection agency in the country, to reevaluate the toxicology studies being undertaken by the Brazilian health agency, ANVISA, for the product. In 2023 the product's EU approval was successfully renewed until 31 March 2038, although only uses that allow the controlled exchange of material and energy with the surroundings and prevent the release of plant protection products into the environment may be authorised, in particular uses in permanent greenhouses.

Recent product introductions include:

- May 31, 2021 Syngenta launched the insecticide Instivo (chlorantraniliprole / abamectin) in Brazil for use on a range of crops including soybeans, maize, cotton and beans. The product is targeted at the control of all species of *Spodoptera* as well as *Helicoverpa, Anticarsia* and mites. The product features the company's OPT formulation technology and is also waterbased and solvent-free. Additionally, Instivo allows for complete coverage of the bottom and pointer leaves enhancing distribution.
- Mar 25, 2022 Vive Crop Protection announced the launch of its new cotton nematicide/insecticide/miticide Averland FC (abamectin). The product has been designed for in-furrow application and is reportedly compatible with liquid fertilisers.
- Jun 7, 2022 Syngenta launched the nematicide Tervigo (abamectin) in Spain, with the product registered for use on the most greenhouse horticultural crops. Tervigo protects the root system against nematodes and reportedly offers a biostimulant effect, improving production and quality.
- Oct 11, 2022 YC Agro Perú, a subsidiary of Shenzhen Yancheng Chemicals, launched the insecticide Sudux (abamectin) in Peru. The product is targeted at the control of *Diptera*, *Homoptera*, *Coleoptera* and *Lepidoptera* pests and mites in vines.
- Mar 10, 2023, The European Commission renewed the approval for abamectin until 31st March 2038. The Commission has, however, specified that only uses that allow the controlled exchange of material and energy with the surroundings and prevent the release of plant protection products into the environment may be authorised, in particular uses in permanent greenhouses. Member states are to pay particular attention to the protection of operators and workers and the effect of photolysis on the levels of pesticide residues.
- Jun 21, 2023 Dharmaj Crop Group has introduced the insecticide Oleppo (abamectin) in India. Oleppo is a broad-spectrum systemic insecticide and acaricide that also possesses strong translaminar, contact and stomach activity.
- Sep 19, 2024 Syngenta launched the insecticide Vermitec (abamectin) in Russia. The product is intended to suppress all feeding stages of mites and thrips in soybean crops.
- Nov 8, 2024 Best Agrolife received approval in India for the insecticide Bestman (fipronil / abamectin / tolfenpyrad). The product is targeted at the control of a range of pests including aphids, thrips, mites, and fruit borers in chilli, cotton, and vegetable crops.
- Nov 26, 2024 Best Agrolife received a patent for the insecticide Bestman (abamectin / fipronil / tolfenpyrad), representing the sixth patent the company has received that year. The product is an SC formulation targeted at the control of a range of pests including aphids, thrips, mites, and fruit borers in chilli, cotton, and vegetable crops. Bestman is expected to be launched in early 2025.
- Dec 18, 2024 The Indian agrochemical company Best Agrolife received a patent for a novel insecticide formulation containing spiromesifen, hexythiazox and abamectin. The product is designed for the control of mites at all stages, as well as sucking pests such as whiteflies, in high-value crops including cotton, chilli and tea.

- Jan 9, 2025 The European Chemicals Agency (ECHA) added 40 hazardous substances to its Prior Informed Consent (PIC) Regulation, of which 35 are pesticides and the remaining five are industrial chemicals. From 1st March 2025, under the PIC regulation, EU Exporters will be required to notify their intention to export the added substances, which includes abamectin.
- February 28, 2025 Vive Crop Protection is seeking a label expansion from the US EPA for its nematicide Averland FC (abamectin) to expand the product's use into soybeans, targeting soybean cyst nematode. The product first gained US registration in 2019, and has since received expansions for use in potatoes in 2021 and cotton in 2022.

Sales of the product declined by 11.5% to \$912 million in 2023, as weaker sales in China impacted overall performance. Between 2018 and 2023, sales have increased by an average of 5.0% annually.

Emamectin benzoate

As with abamectin, emamectin benzoate is an avermectin analogue from Syngenta which provides control of a range of Lepidopteran pests. The product was first introduced in 1998, initially in Japan, South Korea and the USA for use on fruit & vegetables. Usage subsequently expanded to cotton, where the product is effective at controlling bollworm.

China now accounts for the overwhelming majority for use of the product, particularly fruit and vegetable crops, although rice is also significant. Brazil, India and Japan are also significant markets, although to a smaller degree, with use focused on fruit and vegetable crops, although cotton is also significant.

Recent developments involving the product include the launch of Syngenta's broad-spectrum mixture product Influx (emamectin benzoate / lufenuron) in Brazil for the control of Lepidopteran pests on a range of crops in 2021. The product finds use on soybeans, maize, cotton and beans. In China, Sinochem International Crop Care launched the insecticide Lingyi (tetrachlorantraniliprole / emamectin benzoate) in China for the control of Lepidopteran pests, such as rice leaf folder.

Several other Chinese companies have also taken a position in the product: Hailir Pesticides and Chemicals Group began construction of a new ¥2 billion (approximately \$291 million) production plant in 2019, focusing primarily on the production of technical and formulated emamectin benzoate, as well as other active ingredients.

- May 6, 2022 Syngenta received a new approval from the US EPA for the insecticide Denim (emamectin benzoate) for foliar use on soybeans to protect against lepidopteran pests such as soybean loopers, green cloverworms, velvetbean caterpillars and bollworms. The product has previously been approved by the EPA for use on cotton and tobacco.
- May 17, 2022 Parijat Industries launched the insecticide Velektin (emamectin benzoate / profenophos) for the control of lepidopteran pests in cotton, maize and chillies. The product offers increased duration of control of target pests such as fall armyworm (*Spodoptera frugiperda*) in maize and fruit borers (*Helicoverpa armigera*) in chillies due to its improved ovilarvicidal effect. The product is reportedly the first insecticide in India to receive a permanent registration from the Central Insecticide Board for control of fall armyworm with the product also submitted for registration in Tanzania, Ivory Coast, Mali and Ethiopia. It has also received a provisional registration for use on maize in Myanmar.

- Aug 16, 2022 Syngenta received approval in the Netherlands for the insecticide Proclaim (emamectin benzoate). The product has been approved for the control of Lepidopteran pests in floristry (pot plants and cut flowers), tree nurseries, perennials and seed and breeding cultivation. Proclaim can also be used in several other covered cultivations, such as aubergines, strawberries, melons, pumpkins and cucumbers.
- In 2022 Willowood Chemicals obtained a 20-year patent in South Africa for a combination of insecticide active ingredients emamectin benzoate, deltamethrin and lambda-cyhalothrin. The mixture is designed for foliar control of a wide range of sucking and chewing pests in cotton and maize, including aphids, thrips, bollworms and fall armyworms.
- Jun 6, 2023 The Brazilian Health Regulatory Agency (Anvisa) approved the toxicological evaluations of 13 Syngenta products containing the new insecticide active ingredient isocycloseram, branded as Plinazolin:
 - Konik (emamectin benzoate / isocycloseram) for use on potato and tomato crops.
 - Longgor (emamectin benzoate / isocycloseram) for use on potato and tomato crops.
 - Vulter (emamectin benzoate / isocycloseram) for use on cotton, garlic, peanuts, oats, sugarcane, rye, barley, peas, beans, chickpeas, lentils, millet, maize, soybean, sorghum, wheat, and triticale.
- Jun 20, 2024 Best Agrolife announced the launch of the insecticide Nemagen (chlorantraniliprole / novaluron / emamectin benzoate) in India after recently gaining regulatory approval. The product is intended for the control of Lepidopteran, Coleopteran and Dipteran pests in vegetables, grains, fruits, and pulses.
- Jul 30, 2024 Best Agrolife received a patent for the insecticide Nemagen (chlorantraniliprole / novaluron / emamectin benzoate), representing the fourth patent the company has received that year. The product is intended for broad spectrum pest control, including Lepidopteran, Coleopteran and Dipteran pests, in field crops, pulses and fruit and vegetables.
- Sep 30, 2024 The European Commission extended the approval period of emamectin to 15 November 2026.
- Mar 17, 2025 JU Agri Sciences, an Indian provider of crop protection and crop nutrition solutions, launched Ayaka (emamectin benzoate / lambda-cyhalothrin / bifenthrin), its first inhouse developed patented insecticide, for use in Rabi rice in India. Ayaka offers a triplecombination solution for managing stem borer and leaf folder, and has been introduced across key rice growing regions in West Bengal, Odisha, Chhattisgarh, Telangana, Andhra Pradesh, Karnataka, and Tamil Nadu.

Sales of emamectin benzoate decreased by 2.8% in 2023 to \$653 million, primarily due to declines in the leading market of China. Between 2018 and 2023, sales increased by an average of 7.7% per annum.

Spinetoram

Spinetoram, first introduced by Dow (now Corteva) in 2007, is a spinosad analogue that provides a broad spectrum of insect control, including some Coleopteran pests. The key brand names are Delegate for fruit and nut trees and Radiant for vegetables. In 2021 Corteva announced the new global brand name for spinetoram as Jemvelva.

First introductions took place in the USA and Canada, although usage has subsequently spread to a wide range of country markets. The primary country market is Brazil, followed by the US, China and India, with usage concentrated on fruit and vegetable crops, soybean, cotton and maize. The product is also included in several mixture products, notably Corteva's Intrepid Edge, which also contains methoxyfenozide, for use on soybeans and certain nut crops in the USA.

In 2018, Corteva commenced construction of a new packaging facility at its production site in Cernay, France. The facility is intended to focus on products derived from natural origins, including spinetoram. It is understood that the facility became fully operational in September 2019. It was also announced in 2019 that Corteva planned to expand its Midland, Michigan manufacturing facility to increase the company's global production capacity for its spinosyns in response to high demand. The project was completed in August 2022, and coupled with the recent expansion of the company's Harbor Beach facility, has increased Corteva's total spinosyn manufacturing capacity by approximately 50%.

In 2020, Corteva launched the insecticide Revolux (spinetoram / methoxyfenozide) in Brazil for use on coffee crops, targeted at the control of coffee leaf miner. The product is also labelled for use on cotton, sugarcane, and soybean to control various Lepidopteran pests and southern armyworm. Additionally, Exalt (spinetoram) was launched in Spain for the control of various insect pests in horticultural crops such as tomato, pepper, eggplant and cucurbits. In China, Corteva launched Aiduole in 2021, representing the company's seventh spinetoram-based product launched in the country. The product is intended for the control of rice stem borer and rice leaf roller. In 2022, Corteva introduced Radiant in Ukraine, for use on a range of crops, including maize, sunflower and soybean. More recently, the company launched the insecticide/fungicide product Beam Paratus (spinetoram / tricyclazole / triflumezopyrim) in Japan for use on rice to control planthoppers, leafhoppers and rice leaf folder, as well as rice blast.

May 6, 2022 Corteva introduced the insecticide Radiant (spinetoram) in Ukraine. The product is targeted at the control of various lepidopteran and coleopteran pests on a range of crops including maize, sunflower, soybean, cabbage, apple, tomato, onion and grapevine.

Aug 12, 2022 Corteva announced the completion of its \$242 million capital investment project at its manufacturing facility in Midland, Michigan. The project, which included plans for expanded spinosyn production capacity, was announced in 2019 in response to increased global demand for Corteva's spinosyn products, including spinosad and spinetoram. Coupled with the recent expansion of the company's Harbor Beach facility, Corteva's total spinosyn manufacturing capacity has been increased by approximately 50%.

Apr 20, 2023 Corteva launched the insecticide/fungicide product Beam Paratus (spinetoram / tricyclazole / triflumezopyrim) in Japan for use on rice. The product is targeted at the control of planthoppers, leafhoppers and rice leaf folder (*Cnaphalocrocis medinalis*), as well as rice blast (*Magnaporthe grisea*).

Nov 17, 2023 Corteva gained additional registrations for the insecticide Intrepid Edge (spinetoram / methoxyfenozide) in Brazil. The product, launched in the country in 2019 for the control of select

Lepidopteran pests in soybeans and cotton, is now also labelled for the control of thrips and sunflower looper (*Rachiplusia nu*) in soybeans, and thrips in peanut crops.

Sales of spinetoram increased by 2.6% in 2023 to \$439 million, with sales between 2018 and 2023 rising by an average of 15.3% per annum, largely driven by the development of the market in Brazil, and, to a lesser extent, China and India.

Spinosad

The broad-spectrum insecticide spinosad was also introduced by Dow (now Corteva) in 1995, with the product initially targeted at the control of a range of Lepidopteran pests on fruit & vegetables. Syngenta also has a position in the product with its Regard SC seed treatment, targeted at the control of seedcorn and onion maggots. In addition, Nissan Chemical has introduced Shario, a mixture which also includes isotianil, imidacloprid and thifluzamide, for use in rice in Japan. Crop usage is mostly focused on fruit and vegetable crops, although maize and cotton crops also generate sales. As with spinetoram, Corteva has introduced a new global brand name for spinosad: Qalcova. Resistance issues have been reported in China for spinosad.

In support of spinetoram's development Corteva initiated the construction of a new packaging facility at its production site in Cernay, France which will focus on several products of natural origin, including spinetoram, which is produced on-site. The company has also completed a \$242 million capital investment project at its manufacturing facility in Midland, Michigan, which included plans for expanded spinosyn production capacity. Coupled with the recent expansion of the company's Harbor Beach facility, Corteva's total spinosyn manufacturing capacity has been increased by approximately 50%.

Recent product activity includes the registration and launch of Corteva's Entrust Organic in Australia for use on over 80 crops to several damaging Lepidopteran species including Diamondback moth, Heliothis, Cluster caterpillar, Light brown apple moth and loopers, as well as other insect pests such as Western flower thrip, leaf miner and Cherry slugs. Corteva has since also launched Spintor GR in Germany to control wireworms in potatoes.

Mar 29, 2023 Corteva launched the insecticide Spintor GR (spinosad) in Germany to control wireworms in potatoes, with the insect pest estimated to impact more than 50,000 hectares of crops in the country. The product, which can also be used on maize and sweetcorn, has been registered for organic production.

Jan 28, 2025 The European Commission extended the approval periods for 23 active ingredients due to ongoing delays in the procedure for evaluating the approvals. This includes the approval period being extended to 31st October 2026 for spinosad.

Sales of spinosad declined by 6.2% in 2023 to \$289 million, despite apparent growth in the leading market of India, which has been offset by declines in several countries, including the USA, Spain and Japan. Between 2018 and 2023, sales increased by an average of 0.6% per annum.

Milbemectin

The milbemycin milbemectin was developed by Sankyo and first introduced in 1991, with the key brand name being Milbeknock. The product, which is generated through the fermentation of *Streptomyces hygroscopicus*, is mainly used in Japan as a miticide, with fruit & vegetables being the key crops. In addition to this use as a miticide, the product is also widely used in animal health.

The product is now available in a range of other countries outside Japan, with the Netherlands being the first EU introduction in 2002 where it is used on greenhouse ornamentals. Belchim hold the distribution rights to the product in the European market. Sales are focused on Japan and Spain, particularly fruit and vegetable crops.

• Jan 28, 2025 The European Commission extended the approval periods for 40 active ingredients due to ongoing delays in the procedure for evaluating the approvals. The approval period has been extended to 31st May 2026 for milbemectin.

Sales declined by 6.1% in 2023 to \$31 million, although sales between 2018 and 2023 increased by an average of 2.1% per annum.

Lepimectin

Lepimectin from Mitsui Chemicals Agro represents the most recent introduction from this class of insecticides, being first launched in Japan in 2010. The product provides control of a range of insects on fruit & vegetables and tea.

The product is of limited commercial significance, with sales of around \$6 million in 2023.

Regulatory Situation

This class of products benefits from a generally favourable environmental profile, including high selectivity against target organisms and minimal detrimental effects to mammals. This is reflected in their broad acceptance in the EU regulatory framework, where four of the products have received approval, although emamectin has been identified as a target for substitution. However, regulatory pressure on the product class appears to be increasing, with spinetoram's EU approval not renewed in 2024. The current approvals for milbemectin and spinosad are set to expire in 2025.

Regarding spinosad, the Netherlands is acting as the Rapporteur Member State (RMS) for its renewal and assessed the substance, finding that it did not meet the criteria to be classified as an endocrine disruptor and proposed the maintenance of the Reproductive Toxicity Category 2 classification. Subsequently, the assessment was opened for public comment, which closed in the latter part of 2023, with generally positive comments supporting the renewal of the substance. A decision on the renewal is expected in the near future.

However, despite a generally favourable profile, fermentation products in the EU are subject to the same regulatory processes as for other conventional pesticides with the relevant regulation for placing of products on the EU market being Regulation (EC) No 1107/2009. This regulation applies to all pesticides, including those derived from fermentation processes, therefore it is necessary to prepare the same regulatory dossier, including studies to certify satisfactory ecotox, toxicology, residue levels and efficacy. As such the registration process can take a similar length of time compared to conventional pesticides.

In the USA, all AIs must be registered by the Environmental Protection Agency (EPA) through the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This also includes biological products, with the Biopesticides and Pollution Prevention Division (BPPD) section of the EPA responsible for all biopesticide regulatory activities. Fermentation products are generally considered to be the product of microbial species, and different data sets must be submitted to register biochemical and microbial biological products. They are generally regarded as reduced-risk pesticides, while genetically modified microbial pesticides may be subject to additional data or information requirements on a case-by-case basis. This depends on the particular microorganism, the parent microorganism, the proposed use pattern, and the manner and extent of the modification.

Some specific requirements for regulatory submissions for fermentation products in the USA include:

- Microbial Identification to provide detailed characterisation of the producing strain
- Pathogenicity and infectivity studies are required to ensure that the end product does not pose risks of infection to humans or animals
- Production process characterisation must include information on the nature of the fermentation process and what quality control procedures are in place to ensure product consistency and absence of harmful contaminants.

Of those products to have been approved in the US, abamectin, emamectin benzoate, and spinosad are currently undergoing regulatory review.

Regulatory Approval Status of Avermectins, Milbemycins, Spinosyns						
AI	EU Approval Status	US EPA Approval Status	EU Candidate for Substitution			
Abamectin	Y	Y				
Emamectin benzoate	Y	Y	Y			
Lepimectin	х	-				
Milbemectin	Y	х				
Spinetoram	х	Y				
Spinosad	Y	Y				

The table below summarises the regulatory status of these insecticides in the EU and USA:

Note: 'D'= approved, 'x' = not approved, '-' = no information. Purple = Registration review. Information correct as of May 2025.

Company Involvement

The key companies involved in the development of this class were Merck (now Syngenta) and Dow (now Corteva), with both companies now the key suppliers of the leading four products in terms of sales. In addition, Japanese companies have also been involved in the class, although this is generally through the less commercially significant products lepimectin and milbemectin.

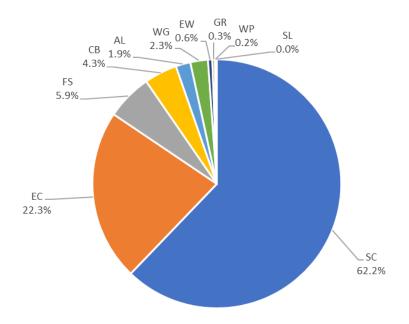
Generic competition was relatively limited, partly due to the costs and complexities associated with the manufacture of these products, although Chinese production of abamectin and emamectin has been increasing. Spinosad is now off-patent, and generic manufacture is increasing, with Indian companies in particular having an early interest in the AI.

The following table highlights the developer, current owner of the original brand and key marketing companies of the avermectin, milbemycin and spinosyn fermentation product insecticides.

Key Companies with Involvement in Avermectins, Milbemycins & Spinosyns					
AI	Developer	Current Owner	Key Marketing Companies		
abamectin	Merck	Syngenta	Syngenta, FMC, Nortox, Vive Crop Protection		
emamectin benzoate	Merck	Syngenta	Syngenta, Rallis, Crystal Phosphate		
lepimectin	Mitsui Chemicals	Mitsui Chemicals	Mitsui Chemicals Agro		
milbemectin	Sankyo	Sankyo, Belchim	Mitsui Chemicals Agro, Sumitomo Chemical, Gowan		
spinetoram	Dow	Corteva	Corteva, Sumitomo Chemical, FarmHannong		
spinosad	Eli Lily	Corteva	Corteva, Aimco Pesticides, Nagarjuna		

Formulation Types – Value Share

The below chart(s) are derived from the biological focussed market research that AgbioInvestor conducted, and illustrates the value share attributed to various formulation type codes.



Bio-aligned Insecticides: Fermentation Products

Code	Description	Code	Description
AE	Aerosol dispenser	LI	Liquid
AL	Other liquids to be applied undiluted	LS	Solution for seed treatment
СВ	Bait concentrate	ME	Micro emulsion
CS	Capsule suspension	OD	Oil dispersion
DC	Dispersible concentrate	SC	Suspension concentrate
DF	Dry flowable	SL	Soluble concentrate
DP	Dustable powder	SP	Water soluble powder
EC	Emulsifiable concentrate	VP	Vapour releasing product
EW	Emulsion, water in oil	WG	Water dispersible granule
FS	Flowable concentrate for seed treatment	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment
10	Liquid concontrato		

LC Liquid concentrate

Research and Development

Research and development on this class is now limited to finding new uses and formulations of the existing products in the class, with no products in the R&D pipeline at the major R&D-driven companies in the industry.

The most recent product to be introduced was lepimectin, being first launched in 2010 from the development pipeline of Mitsui Chemicals Agro.

Recent developments include the integration of the avermectins into seed treatments, in combination with a range of other insecticides and often fungicides, in efforts to broaden the spectrum of control.

Market Outlook

Fermentation products have been amongst the fastest-growing classes of insecticides over the last few years, with the class benefitting from a high level of efficacy in a range of insect control situations, as well as novel modes of action that provide a good fit in resistance-avoidance strategies. This growth has been driven primarily by the avermectin, milbemycin and spinosyn group of products, rather than the older nereistoxin analogue products.

Product use remains heavily focussed on fruit & vegetables, although in more recent years, companies have begun to place an increasing focus on seed-treatment use, together with mixture partners, allowing for a greater spectrum of control and use in sectors where the products did not previously have a high profile. As a result, products within this category have started to expand beyond the traditional fruit & vegetable crop sectors in which they were present into a number of new markets, notably soybean, cotton, rice and maize. Abamectin used as a seed treatment provides control of nematodes, a key growth driver for the product in recent years.

As product use continues to increase, there remain several key areas where future development is likely to lie; in the short term, the favourable environmental profile of these products – particularly in markets such as the EU – has inclined regulatory bodies to look favourably on products viewed as suitable alternatives to conventional crop protection products.

An increasing focus on insect control utilising products derived from biological sources should also be attractive, notably in the EU, where these products could act as the cornerstone of integrated pest management (IPM) programmes. In addition, as the EU seeks to reduce volume applications of conventional chemical pesticides and boost organic crop production, these products are well positioned to provide a suitable option for insect control.

A potential negative factor is the increasing levels of generic competition that exists, with the first entrants in the class now off-patent. This has resulted in some pricing deflation and, subsequently, a depressing effect on growth in the value of the sector, although the costs and complexities associated with the manufacture of these products have so far held back generic company involvement somewhat.

Avermectins, milbemycins and spinosyns are used on a wide range of pests and crop groups. The favourable environmental profile for most of these AIs is expected to benefit sales in the future. However, the removal of spinetoram from the EU market is expected to impact market development somewhat. Abamectin is expected to continue to benefit from use as a nematicidal seed treatment in high-value GM markets. Overall, the strongest growth is expected from the spinosyns, significantly ahead of the overall conventional insecticide market, with the spinosyns expected to be key drivers.

As a result of the above factors, we expect the market value of the fermentation products: avermectins, milbemycins and spinosyns class to increase at an average annual rate of 3.0% between 2023 and 2028 in real terms (constant pricing and currency), ahead of the expected average growth for the total insecticide market of 2.4% per annum.

Sales Performance of Insecticides: Other minerals, acids, aliphatic							
Year	Insecticides: Other minerals, acids, aliphatic Sales (\$ m.)	Total Insecticide Sales (\$ m.)	Insecticides: Other minerals, acids, aliphatic Share of Bio-aligned Insecticide Sales (%)	Insecticides: Other minerals, acids, aliphatic Share of Total Insecticides (%)			
2018	19	16,796	1.11	0.11			
2022	24	21,566	0.96	0.11			
2023	25	21,737	1.06	0.12			
2028F	31	24,446	1.13	0.13			
1-yr Change (%)	4.2	0.8					
5-yr CAGR (% p.a.)	5.6	5.3					
5-yr CAGR F (% p.a.)	4.4	2.4					

Insecticides: Other minerals, acids, aliphatic

Introduction

This market segment includes bio-aligned products that have an identified insecticidal activity. Many of these active ingredients are basic substances such as sodium chloride, sodium ferric and potassium silicate, as well as organic acids and minerals such as kaolin.

It should be noted that often these actives have multiple activities across sectors, including herbicidal and fungicidal activity. Whilst this is a positive from the perspective of controlling multiple pathogens, the nature of these compounds may mean that crop selectivity, dosage and timing needs to be considered if herbicidal activity is present. Efficacy and resistance issues may also be a concern compared to established crop protection actives on the chemical side, and newer generation bioinsecticide may offer stronger efficacy as well as offering a range of other plant health benefits.

Products

Capric acid / Caprylic acid

Capric acid and caprylic acid are short-chain (C10/C8 respectively), saturated acids occurring naturally in palm and coconut oils, as well as certain types of milk. They may also be produced from ethylene using the Ziegler process. In addition to having insecticidal action, the molecule may be used for its, acaricidal, herbicidal, plant growth regulating, and antimicrobial activity.

On contact, the acids can disrupt the cell membranes of insects as well as potentially interfering with the function of key insect enzymes. The molecule may also act as a feeding deterrent and generally repellent.

Oleic acid

Oleic acid is a monounsaturated omega-9 fatty acid that occurs naturally in various animal and vegetable fats and oils. Pest targets include aphids, whiteflies, mites, thrips, and certain Lepidopteran species. The active works by disrupting cell membranes in the insect bodies, leading to dehydration, suffocation, and eventually death.

Sorbitol octanoate / Sucrose octanoate

Sucrose octanoate esters and sorbitol octanoate are structurally similar and exert similar actions on biological systems. Both substances are intended to control mites and certain soft-bodied insect pests

(e.g., aphids, caterpillars, glassy-winged sharpshooters) on food and non-food crops. Both decompose in the environment to similar harmless substances, and both act by disrupting the waxy outer layer (cuticle) of mites and various soft-bodied insects, causing the insect or mite to dry out and die.

Carbon dioxide

Carbon dioxide may be used as a post-harvest fumigant in enclosed spaces such as silos, storage facilities and shipping containers. The molecule may also be used as a fumigant in greenhouse cultivation and other enclosed cultivation. It is reported that exposure to a CO_2 concentration of 1% for one hour is an effective fumigation technique against pests such as whitefly. However it is important to consider operator exposure since for humans, the short-term exposure limit in many countries is 3% by volume (i.e. 30,000 ppm) and the long term 8-hour time-weighted average exposure limit is 0.5% by volume (i.e. 5000 ppm).

Iron Phosphate

Iron phosphate is a molluscicide used in controlling snails and slugs on food crops and ornamentals at outdoor and indoor sites. Example species include *Deroceras reticulatum*, *Derceras laeve* and *Arion subfuscus*. The active works by interfering with calcium metabolism in the digestive system causing a cessation of feeding, however this may take several days to take effect. The active is environmentally benign since it has a low mammalian toxicity and is readily used by plants as nutrients for growth.

Kaolin

Kaolin, also known as aluminium silicate hydrate; hydrated aluminium silicate, is a mineral substance that has no direct pesticidal activity but is used to generate a barrier that prevents pests from coming into contact with the plant, including insects, mites, fungi, bacteria as well as preventing sunburn from intense UV radiation. It is insoluble in water and is therefore sprayed as a powdered suspension on crops, where it forms a barrier film that repels and prevents target pests from penetrating leaves or other parts of the plant. To be effective, the suspension must coat all parts of the plant.

Jun 28, 2022 The Australian Pesticides and Veterinary Medicines Authority (APVMA) approved the new active constituent calcined kaolin. The agency has also approved Tessenderlo Kerley's Surround WP Crop Protectant, which contains the active ingredient, for use as a repellent of citrus gall wasp in citrus.

Jul 4, 2022 The Canadian Pest Management Regulatory Agency completed its re-evaluation of the naturally occurring clay mineral kaolin as an insecticide, finding that continued registration of the product is acceptable for most uses. As part of the continued registration, the agency has imposed label updates as mitigation measures for human and environmental health, including:

- Update to standard label statements (wording related to personal protective equipment and health precautions).
- Updates to standard label statements (environmental precautions, directions for use, disposal and storage).

Potassium Silicate

Potassium silicate is the potassium salt of silicic acid. The substance from the perspective of crop protection forms a barrier that reduces feeding by insect species as well as potentially making them less attractive/tasting. Mites and fungi may also be controlled by the active. In formulation, potassium silicate is readily absorbed by the plant where it can stimulate a plants natural defences including the production of allelochemicals (defence compounds).

Sodium chloride

Is a basic salt that may be used in a range of antimicrobial, bactericide, fungicide; insecticide; molluscicidal, herbicide, desiccant and defoliant scenarios. Slugs, snails, soft-bodied insects, such as aphids and mealybugs and some caterpillar species, may be susceptible to the dehydrating effects of sodium chloride when applied directly to them or their feeding areas.

Cockroaches and ants, while not directly controlled by the active ingredient may have their movements disrupted when applied in entry/exit points of buildings.

Sodium Ferric EDTA

Sodium Ferric ethylenediaminetetraacetate (Sodium Ferric EDTA) is used to make slug and snail control products such as baits intended for use as a molluscicide in agricultural, nursery, greenhouse, and home and garden applications. When Sodium Ferric EDTA is ingested by slugs or snails, the iron in the compound interacts with the hemocyanin common to the blood of crustaceans, and eventually causes death.

Regulatory Situation

The regulatory situation for insecticides based on minerals, organic acids and aliphatic molecules are generally favourable since in most countries they are considered to be "low-risk" or "basic substance" active ingredients.

An active substance can be approved as a low-risk substance if it meets the regular approval criteria and in addition meets the low-risk criteria as specified in Annex II, point 5 of Regulation (EC) 1107/2009. Low-risk substances are approved for 15 years instead of 10 years and data protection on the studies submitted for the approval and subsequent authorisation is extended from 10 to 13 years. Similar to the microbials segment, a fast-track authorisation procedure with reduced timelines (120 days) is in place. In contrast to conventional pesticide Als, low-risk substances may be granted approval based partly on literature, data, and scientifically reasoned opinions. Low risk description can also be used on product marketing.

Basic substances are substances that are not predominantly used for plant protection purposes but may be useful in plant protection. They are substances of no concern and can be approved for plant protection use as far as their risks are acceptable. Their approval by the European Commission allows the use for purposes of plant protection, but they cannot be sold specifically as a plant protection product. Their approval is based on existing evaluations carried out following other EU legislations. Authorisation is issued for the entire EU for an indefinite period.

Regulatory Status of Insecticides - Other minerals, acids, aliphatic in the EU and USA			
EU	USA		
	Alcohols, C6-12		
Benzoic acid	Benzoic acid		
Capric acid (CAS 334-48-5)	Capric acid (CAS 334-48-5)		
Caprylic acid (CAS 124-07-2)	Caprylic acid (CAS 124-07-2)		
Carbon Dioxide	Carbon Dioxide		
diatomaceous earth	Silicon dioxide (SiO ₂)		
	ethyl (2 <i>E</i> ,4 <i>E</i> ,7 <i>S</i>)-3,7,11-trimethyldodeca-2,4-dienoate		
Fatty acids C7-C18 and C18 unsaturated potassium salts (CAS 67701-09-1) (Capric acid (CAS 334-48-5); Caprylic acid (CAS 124-07-2); Lauric acid (CAS 143-07-7); Oleic acid (CAS 112-80-1))	Potassium laurate		
	Octanoic acid, ester with 1,2-propanediol		
Oleic acid (CAS 112-80-1)	Oleic acid (CAS 112-80-1)		
Paraffin oil/(CAS 64742-46-7)	Paraffin oil/(CAS 64742-46-7)		
Paraffin oil/(CAS 72623-86-0)	Paraffin oil/(CAS 72623-86-0)		
Paraffin oil/(CAS 8042-47-5)	Paraffin oil/(CAS 8042-47-5)		
Paraffin oil/(CAS 97862-82-3)	Paraffin oil/(CAS 97862-82-3)		
	Potassium laurate		
Sodium chloride	Sodium chloride		
	Sodium ferric ethylenediaminetetraacetate		
	Sodium lauryl sulfate		
	Sorbitol octanoate		

Note: Green = approved (EU) registered (USA), orange = pending approval, purple = registration review, light blue = reregistration blue = pending registration, red = not registered. Information is correct as of May 2025.

Company Involvement

Many of the more basic substances listed below are often supplied by small companies with relatively limited marketing capacity and reach. However, Gowan and Bayer are examples of larger companies involved in this class, with Gowan supplying products based on fatty acids. Bayer also distributes fatty acids (marketed as Flipper) to control sucking pests in Europe, with the company having gained the license from the UK biological crop protection company Alpha Biocontrol.

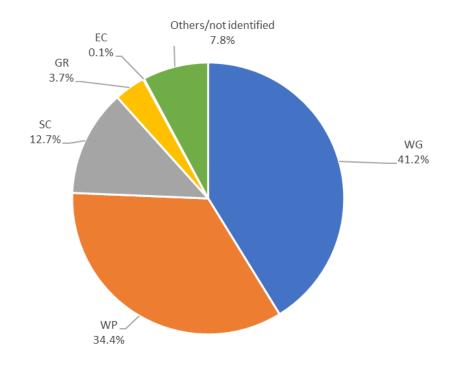
Key Companies with Involvement in Microbial Insecticides

Al	Key Companies
Capric acid	Ecolab
Caprylic acid	Ecolab
Fatty acids*	Gowan, Bayer, Alpha Biocontrol
Iron Phosphate	Multiple
Kaolin	Novasource
Oleic acid	Neudorff
Potassium Silicate	PQ Corporation
Sodium chloride	ITAB
Sodium Ferric EDTA	Neudorff
Sorbitol octanoate	Ava Chemical

* Multiple analogous products.

Formulation Types – Value Share

The below chart(s) are derived from the biological focussed market research that AgbioInvestor conducted, and illustrates the value share attributed to various formulation type codes.



Code	Description	Code	Description
AE	Aerosol dispenser	LI	Liquid
AL	Other liquids to be applied undiluted	LS	Solution for seed treatment
СВ	Bait concentrate	ME	Micro emulsion
CS	Capsule suspension	OD	Oil dispersion
DC	Dispersible concentrate	SC	Suspension concentrate
DF	Dry flowable	SL	Soluble concentrate
DP	Dustable powder	SP	Water soluble powder
EC	Emulsifiable concentrate	VP	Vapour releasing product
EW	Emulsion, water in oil	WG	Water dispersible granule
FS	Flowable concentrate for seed treatment	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment
LC	Liquid concentrate		

Research and Development

Due to the basic substance nature of many of the active ingredients in this classification, the majority of R&D to date is currently centred around optimisation of formulation development. For example, optimisation of the particle size and concentration to enhance efficacy and the use of adjuvants and surfactants to improve coverage and spreading can greatly improve field performance as well as improving shelf life and stability.

Development of granular formulations can increase the convenience of application of basic insecticide substances, whilst optimisation of particle size can improve the performance of products such as wettable powders. Optimising tank-mix compatibility also ensures that the products will have a greater range of operator benefits and convenience.

Market Outlook

In a similar trend to that of other bio-aligned pesticide segments within herbicides and fungicides, the mineral and organic acid nature of the ais often means that the products are relatively low cost, and subject to more conducive regulatory pathways. Despite the products having a low cost, they may not provide full control, only suppression and require multiple applications. Unlike the bio-aligned herbicide segment, which we believe will not face significant competition from the development of the microbial bioherbicide segment, which may be mutually complementary, the bio-aligned insecticide segment is likely to face technology competition from a range of 'true' bioinsecticides. The rationale behind this view, is that there are far more options for insect control within bioinsecticides, such as microbials and plant extracts, as well as fermentation products within bio-aligned insecticides. More efficacious products on the biologicals side will also temper growth.

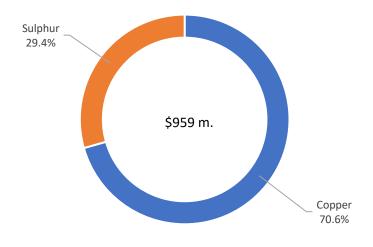
There are also new chemical insecticides from R&D that in conjunction with bioinsecticides (either used in hybrids or spray programs), may mean that basic substances such as these are of less importance in integrated pest management strategies. These may include diamides, and new modes of active entering the market from company pipelines.

The forecast for the next 5 years is for growth of 4.4% p.a. on average between 2023 and 2028 on a constant currency and pricing level to reach \$31 million.

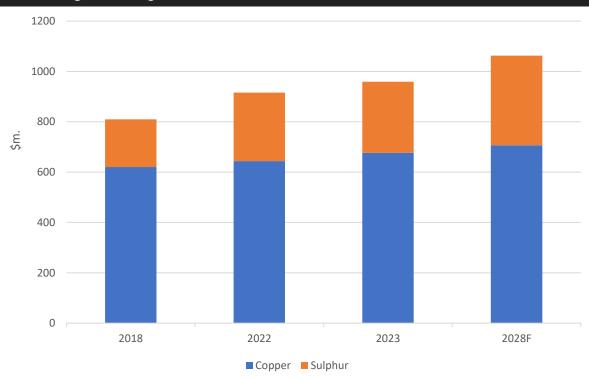
Fungicides: Contact - Inorganics

Sales Performance of Contact Fungicides: Inorganics				
Year	Contact Fungicides: Inorganics Sales (\$ m.)	Total Fungicide Sales (\$ m.)	Contact Fungicides: Inorganics Share of Bio- aligned Fungicide Sales (%)	Contact Fungicides: Inorganics Share of Total Fungicides (%)
2018	810	15,927	98.42	5.09
2022	916	19,453	98.07	4.71
2023	959	19,878	98.06	4.82
2028F	1,063	21,992	97.88	4.83
1-yr Change (%)	4.7	2.2		
5-yr CAGR (% p.a.)	3.4	4.5		
5-yr CAGR F (% p.a.)	2.1	2.0		

Leading Products 2023



Leading Contact Fungicides: Inorganics						
AI	ΥΟΙ	Timing	Main Crops	Rate (kg/Ha)	Sales 2023 (\$ m.)	Sales 2028F (\$ m.)
Copper Fungicides 1700s Foliar		Foliar	Rice, Potato, Vine, Pome fruit, F&V, Plantations	0.6 - 4.5	677	707
Sulphur	1880	Foliar	Vine, Pome fruit, F&V	2.4 - 10	282	356



Contact Fungicides: Inorganics Sales 2018-2022-2023-2028F

Introduction

Although AgbioInvestor does not consider copper and sulphur to be truly biological pesticides, they are often considered as such and approved for use in organic agriculture. However, similar to other segments where the actives are based on basic substances or minerals, AgbioInvestor considers inorganic fungicides such as copper and sulfur as bio-aligned fungicides. This is in part due to regulatory challenges, such as was witnessed for copper fungicides in Europe where volume application restrictions were applied. Inorganic contact fungicides are amongst the oldest forms of disease control for use on crops, with recorded usage dating as far back as the 18th century.

Products

Copper Fungicides

The usage of copper as a means of controlling crop disease can be traced back to the 18th century, with copper sulphate being used as a seed treatment on cereals. The 1800s saw the introduction of copper sulphate pentahydrate and since then, a number of different copper salts have been introduced, including copper oxychloride (early 1900s); copper hydroxide (1968); copper octanoate (1990s); and Bordeaux mixture, a combination of copper sulphate and slaked lime (1885). Copper oxychloride, copper oxide, Bordeaux mixture, copper hydroxide and tribasic copper sulphate are still widely used in crop protection.

Copper fungicides have a very wide spectrum of control of bacterial and fungal diseases, and coupled with their relatively low price, this has led to them becoming widely used around the world in a range of crops, with foliar application on fruit & vegetables such as vine, tomato, potato and tree fruits being the most significant.

The commodity nature of copper as a feedstock, and its provision of a broad spectrum of disease control at relatively low cost, has led to a number of companies becoming involved in the manufacture or sale of copper-based fungicides. The most notable of these are Albaugh, UPL, Oxiquimica, Nufarm, IQV, Nordox, Mitsui & Co and Isagro (now Gowan).

The key country markets are Spain, Brazil, Italy, France and China, although a large number of further country markets are also relatively high value. Crop use is dominated by fruit & vegetables, mainly vines, where copper is effective in controlling powdery mildew, with other notable crop uses being soybean, rice and sugar beet.

In 2020, Isagro (now part of Gowan) acquired Phoenix-Del Srl, an Italian company focused on the registration and sale of copper-based agropharmaceuticals, for a total of €3.6 million (\$4.2 million).

Recent product introductions and registrations include Rotam's Kypros (copper), launched in Brazil in 2021; Ascenza's Cuprital 700 (copper oxychloride), also launched in Brazil in 2021, intended for the control of Asian rust; and Kocide 3000 (copper-hydroxide), launched in India in 2022 by Mitsui & Co.'s group company Bharat Certis AgriScience.

- In 2023 Corteva transferred its interest in the handling of all Kocide (copper-hydroxide) fungicide products in Japan to Mitsui & Co., with these operations transferred to Mitsui & Co. by October 10, 2023.
- Feb 3, 2023 Certis Biologicals launched the fungicide Kocide 50DF (copper hydroxide) in the US. The product is intended for use in citrus and speciality crops, providing protection against various fungal plant diseases, including blight, anthracnose, crown, canker, phytophthora and rot. Kocide 50DF comprises a new formulation designed to reduce clogging issues during mixing.
- Apr 4, 2023 Nissan Chemical and Amoéba entered into a collaboration to evaluate the performance of a mixture of Nissan's Leimay (amisulbrom) and Amoéba's AXP12 (*Willaertia magna* C2c Maky) in controlling grapevine downy mildew. The mixture has been tested in two trials in Italy in conditions of high disease pressure, and preliminary results show the enhanced performance of the mixture compared to both products individually and the reference product copper hydroxide.
- Mar 21, 2024 The US EPA approved expanded crop uses of Sym-Agro's Instill (copper sulfate pentahydrate) bactericide / fungicide. As a result, the product is now registered for use on coffee, potato, hazelnut, and sugar beet for the management of diseases.
- Jul 3, 2024 FMC launched the fungicide Cosuit (copper hydroxide) in India for use on a range of crops, including vines, rice, tomato, chilli and tea.
- Jul 18, 2024 Ningxia Gerui Fine Chemical, a subsidiary of Rainbow Chemical, announced it was to invest RMB32 million (approximately \$4.4 million) to expand its fungicide production capacity. The project includes production lines for prochloraz (500 t/a), thifluzamide (50 t/a), procymidone (100 t/a), and copper hydroxide (200 t/a).
- Nov 5, 2024 Albaugh launched the fungicide Reconil RFT (copper) in Brazil. Previously approved for use in soybean, cotton, onion and beans for control of *Cercospora*, the product has been relaunched with the addition of adjuvants that are intended to increase the quality of the formulation and provide rain fastness. Reconil RFT is recommended for resistance management in soybeans and various other crops and offers broad spectrum of disease control. The product is also labelled for use on avocado, cotton, peanut, potato, cocoa, sugarcane, onion, bean, fig, guava, papaya, mango, quince, loquat, soybean, tomato, wheat, and grape.

- Jan 22, 2025 Nantong Shizhuang Chemical announced it was to conduct a major expansion project at its facility in Yangkou Chemical Industrial Park, Rudong County, Nantong City. The project represents a total investment of 510 million yuan (approximately \$70.1 million), and involves increased annual production capacities for key pesticide active ingredients, including indoxacarb (1,000 tonnes), oxine copper (1,000 tonnes), metaflumizone (500 tonnes), and acequinocyl (500 tonnes).
- Feb 7, 2025 Certis Belchim introduced the fungicide Valis Plus (copper) in Ghana. The product is targeted at providing preventative and curative control of cocoa black pod, caused by Phytophthora pathogens.

Sales of copper fungicides increased by 5.1% in 2023 to reach \$677 million, supported by stronger sales in several key markets, including Brazil and France. Sales have also been positive in the longer-term, rising by an average of 1.8% per annum between 2018 and 2023.

Sulphur

The usage of elemental sulphur in crop protection can be traced back to the 1880s. In addition to its disease control properties, particularly for powdery mildew on vines and scab on pome fruit, sulphur is also used as a miticide in certain situations, primarily on citrus. As well as being applied in basic powder form, sulphur is also available in more advanced formulations. EU approval has been extended to 15 April 2025 due to ongoing delays in the procedure for evaluating approvals.

Ceradis Crop Protection obtained a registration in Italy for its biofungicide CeraSulfur (sulphur) during early 2021, with the product to be distributed in the country by De Sangosse Italia. Its use is targeted at the control of diseases such as powdery mildew in a range of crops, including wine grapes and pome fruits. A further registration was obtained by the company in Turkey during the same year, for vine and tomato. In addition, a distribution was formed between Ceradis Crop Protection and Certis Europe during the year, under which Certis Europe will distribute CeraSulfur in Hungary, Czech Republic, and Slovakia.

The sulphur in Cerasulfur is derived from bacteria that turn hydrogen sulfide, a by-product of biogas production, into elemental sulphur. This sulfur is reported to have a smaller particle size in comparison to conventional sulphur, and its hydrophilic profile enables easier handling and combining with other products.

More recent activity regarding sulphur-based crop protection products includes registration of Syngenta's fungicide Aquicine Duo (sulphur / potassium phosphonates) in France, with the product intended for use on wheat and other cereals for the control of *Septoria*.

In addition, the Indian agrochemical company Best Agrolife launched Tricolor (difenoconazole / sulphur / trifloxystrobin) in India for use on wheat, rice, tomato and apple to control powdery mildew, scab and rice sheath blight.

- May 21, 2024 the European Commission extended the approval period for lime sulphur to 31 January 2027.
- Jan 28, 2025 the European Commission extended the approval period for sulphur to 31st July 2026.

Key country markets include the EU countries of France, Italy, and Spain, with the USA and China also of importance. Sales of sulphur increased by 3.7% in 2023 to reach \$282 million, boosted by gains in the US and Europe. Between 2018 and 2023, sales increased by an average of 8.2% per annum.

Regulatory Situation

The European Commission has further extended the approval period of sulphur due to ongoing delays in the procedure for evaluating approvals; as a result, the product's approval expiration date is now 15 April 2025.

Concerns over heavy metal accumulation has led to significant debate over the safety and use of copper-based products, particularly in organic cultivation where relatively few disease control options exist. As such, copper has attracted regulatory concerns primarily due to its tendency to accumulate in soils. As copper salts are generally perceived as natural products, they are often approved for use in organic production systems, where they are used in significant volumes.

Although copper fungicides are significant products in Europe, particularly in viticulture, and hold EU registrations, they have been marked as candidates for substitution in the region, meaning that if any product with a similar spectrum of action and efficacy can be demonstrated to be effective in the same crops, then the product registration should be denied. Given the low cost, broad spectrum and multi-site nature of copper fungicides, it seems unlikely that a suitable substitution is available at this time. As with sulphur, the EU approval for copper has been extended due to delays in the approval process and is now set to expire on 31 December 2025.

Regulatory Status of Contact Fungicides: Inorganics in the EU and USA						
AI	EU Approval Status	US EPA Approval Status	EU Candidate for Substitution			
Bordeaux mixture	\checkmark	\checkmark	x			
Copper fungicides	\checkmark	\checkmark	x			
Sulfur	\checkmark	\checkmark	-			

The table below summarises the regulatory status of these fungicides in the EU and USA.

Note: $\sqrt{'}$ = approved, x' = not approved, - = no information. Purple = registration review. Information correct as of May 2025.

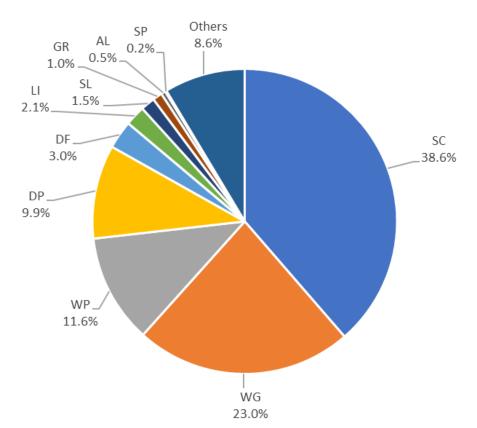
Company Involvement

The inorganic contact fungicides were amongst the first products to be used for disease control in crop protection, as a result the products have been off-patent for a number of years, and are now manufactured and sold by a range of companies worldwide. Copper and sulphur are primarily extracted from mines, with the key companies involved in these products often also being heavily involved in these mining operations, such as Mitsui Agriscience, UPL and Sulphur Mills. The following table highlights the developer, current owner of the original brand and key marketing companies of inorganic contact fungicides.

Key Companies with Involvement in Contact Fungicides - Inorganics					
AI	Developer	Current Owner	Key Marketing Companies		
Copper Fungicides	-	-	Albaugh, UPL, Oxiquimica, Nufarm, Mitsui & Co		
Fentin	Hoescht, Philips-Duphar	Bayer, UPL	Syngenta, UPL, Nufarm		
Sulphur	-	-	UPL, BASF, Syngenta, Sulphur Mills		

Formulation Types – Value Share

The below chart(s) are derived from the biological focussed market research that AgbioInvestor conducted, and illustrates the value share attributed to various formulation type codes.



Code	Description	Code	Description
AE	Aerosol dispenser	LI	Liquid
AL	Other liquids to be applied undiluted	LS	Solution for seed treatment
СВ	Bait concentrate	ME	Micro emulsion
CS	Capsule suspension	OD	Oil dispersion
DC	Dispersible concentrate	SC	Suspension concentrate
DF	Dry flowable	SL	Soluble concentrate
DP	Dustable powder	SP	Water soluble powder
EC	Emulsifiable concentrate	VP	Vapour releasing product
EW	Emulsion, water in oil	WG	Water dispersible granule
FS	Flowable concentrate for seed treatment	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment
LC	Liquid concentrate		

Research and Development

Research and development in this category of fungicides focuses on the development of new formulations which are determined to offer improved environmental and handler safety, with contamination of water supplies of these compounds being a prime concern. Formulations which can maintain efficacy whilst allowing for lower application rates or educe number of applications required are currently in development.

A key example of the current R&D taking place in this sector comes from the Italian company Isagro, which is currently developing new copper-based formulations that are active at lower dose rates and have a broader spectrum of activity than currently available products. Isagro recently acquired Phoenix-Del Srl, an Italian company that registers and sells copper-based agropharmaceuticals, for a total of €3.6 million (\$4.2 million). This acquisition should support Isagro's plans to grow its copper-based products and biosolutions segment.

Market Outlook

Copper and sulphur continue to play important roles in disease control, particularly for fruits and vegetables, due to their multi-site activity, which lowers the likelihood of resistance development. This constitutes a key benefit of this product group. An important disadvantage of these products is their contact activity, meaning that they only provide preventative control, with no curative properties. Sales values for these products are influenced largely by the prices of their raw elemental materials: for example, in times of lower copper or sulphur prices, sales values can be deflated. In addition, future sales may potentially be hampered by regulatory concerns, with copper in particular facing current restrictions in several key markets, notably the EU.

However, the development of new formulations may assuage some of these concerns due to their potential for lower application rates, increased spectrum of action, and improved rain-fastness (which can potentially limit the number of applications required). While the higher costs of these advanced formulations may boost the overall market value, this would likely be offset by the required reduction in the volume of applications.

A key benefit of inorganic products is their designation in the EU as 'organic pesticides'; organic production is expected to expand in the coming years, driven by the EU's goal of boosting organic crop production by 25% while reducing the applied volumes of conventional organic chemicals by half. However, we have seen many of these sustainability goals thrown into question due to recent announcements by the EU commission, which may place that 25% target in question, at least from the perspective of which year this would be targeted to.

The age of these products means that they are off-patent and offered by a wide range of companies globally; however, because many of these patents expired years or even decades ago, the greatest effects of this have long since passed.

Greater demand may come from emerging ag economies, where they may be used for their low-cost and broad spectrum of control, which can support the increase of quality in F&V crops. Developing nations are likely to see a greater demand for F&V and therefore fungicide usage to boost quality.

Due to these factors, we expect the market value of copper and sulfur fungicides is forecast to increase at a marginal rate of 2.1% in real terms between 2023 and 2028 to reach \$1,063 million.

Year	Fungicides: Other minerals, acids, aliphatic Sales (\$ m.)	Total Fungicide Sales (\$ m.)	Fungicides: Other minerals, acids, aliphatic Share of Bio-aligned Fungicide Sales (%)	Fungicides: Other minerals, acids, aliphatic Share of Total Fungicides (%)
2018	13	15,927	1.58	0.08
2022	18	19,453	1.93	0.09
2023	19	19,878	1.94	0.10
2028F	23	21,992	2.12	0.10
1-yr Change (%)	5.6	2.2		
5-yr CAGR (% p.a.)	7.9	4.5		
5-yr CAGR F (% p.a.)	3.9	2.0		

Fungicides: Other minerals, acids, aliphatic

Introduction

This market segment includes bio-aligned products that have an identified fungicidal activity. Many of these active ingredients are basic substances such as potassium bicarbonate or acids such as phosphorous acid. It should also be noted that often these active have multiple activities across sectors, including herbicidal and insecticidal activity. Whilst this is a positive from the perspective of controlling multiple pathogens, the nature of these compounds may mean that crop selectivity, dosage and timing needs to be considered if herbicidal activity is present. Efficacy and resistance issues may also be a concern compared to established crop protection actives on the chemical side, and newer generation biofungicides may offer stronger efficacy as well as offering a range of other plant health benefits.

Products

Potassium Bicarbonate

Potassium bicarbonate acts primarily by altering the pH on the surface of the plant and hindering cell wall stability, such that conditions are no longer optimal for the growth of fungi. The AI is effective against a broad range of fungal pathogens, including powdery mildew, downy mildew, black spot, and rust diseases. Similar to other basic substances the mammalian toxicity is low, whilst ecotox considerations are minimal. Potassium bicarbonate is typically applied as a foliar spray both for preventive and curative control and is typically approved for use in organic farming systems by many organic certifying agencies and regulatory authorities.

Jan 7, 2022 Certis Europe renewed its distribution agreement for Armicarb (potassium bicarbonate), also sold under the brand names Kumar and Karma. The agreement with De Sangosse follows its acquisition of Agronaturalis in 2021 (see AgbioNews Sep 23, 2021) and secures the exclusive distribution of Amicarb in Certis Europe's original operating area.

Phosphorous Acid

Phosphorous acids mode of action is through the modulation of the fungal pathogen's metabolic processes. Additionally, phosphorous acid has been shown to stimulate the plant's natural defence mechanisms. The ai is effective against a broad-spectrum of fungal diseases both in a preventative and curative fashion including downy mildew, *Phytophthora* root rot, *Pythium* blight, and other pathogens. Additionally, the AI has been shown to have both systemic and translaminar activity, ensuring activity from within plant foliage. Similar to other basic substances, the mammalian and

ecotoxicity is low, however due to the acidic (albeit weak acid) nature of the product, operator handling considerations are still important.

Phosphonates

Potassium phosphonate acts by inducing systemic acquired resistance (SAR) in plants, and therefore the plant's natural defence mechanisms for disease resistance. In addition to this, the AI has direct fungicidal properties, through the disruption of fungal cell membranes thereby limiting current populations and future replication. Potassium phosphonate may be applied as a foliar treatment or soil drench, and is effective against a broad range of pathogens, both preventive and curative settings, including downy mildew, *Phytophthora* root rot, *Pythium blight*, and other pathogens. The AI features systemic activity as well as translaminar activity when used as a primary control method, but the systemic acquired activity may trigger overall plant response. This class of active also benefits from low mammalian and ecotoxicity.

- May 3, 2023 Syngenta received approval in France for the biofungicide Aquicine Duo (sulphur / potassium phosphonates). The product was expected to be commercialised in the country in 2024, and is intended for use on wheat and other cereals for the control of Septoria.
- Nov 20, 2023 BASF launched the fungicide Privest (ametoctradin / potassium phosphonates) in the UK for use in potato. The product is intended for early season control of late blight in all potato varieties, including seed crops.
- Nov 27, 2023 Adama launched the fungicide Folpan Energy (folpet / potassium phosphonate) in Italy, with the product to be made available for sale from January 2024. Folpan Energy is intended for use on vines to control several diseases, including downy mildew and *Botrytis*.
- Nov 5, 2024 BASF received registration in Italy for the fungicide Enervin System (ametoctradin / potassium phosphonate). The product is intended for the systemic control of downy mildew on vines and vegetables.
- Feb 18, 2025 Syngenta launched the biological fungicide Aquicine (potassium phosphonate) in Italy for use on wine and table grapes. The product, which can also be used on a variety of other fruit and vegetable crops, is intended for the control of a range of diseases including downy mildew.

Potassium Hydrogen Carbonate

Potassium hydrogen carbonate, also known as potassium bicarbonate, acts primarily by altering the pH on the surface of plant tissues, creating an environment that is less favourable for the growth and reproduction of fungal pathogens, through the disruption of fungal cell walls. Potassium hydrogen carbonate is typically applied as a foliar spray, and like other bio-aligned fungicides generally has a low toxicity to animals and the environment. It is available in various formulations, including wettable powders, liquid concentrates, and ready-to-use sprays.

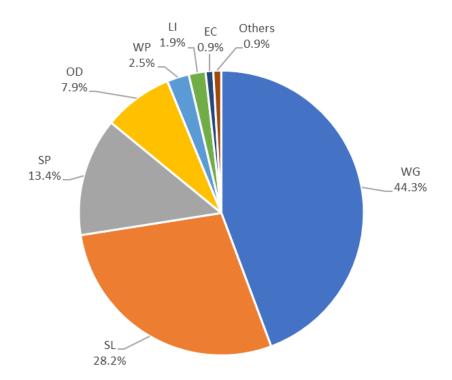
Company Involvement

The below table(s) on key active ingredients and key companies is derived directly from AgBioInvestor's exclusive primary market research study that surveyed biological- and biostimulantgrowers, which were conducted for the first time in 2023 and profiled the 2022 agricultural market. The market research surveyed many key agricultural markets for biologicals, including: USA, Mexico, Chile, Brazil, Argentina, France, Italy, Spain and Turkey. The Ais have been ranked by farm-gate value (\$m.). Quantification of these data and much more biological market research can be found in the separate subscription product AgbioInsight.

Biofungicides: Microbials Key Companies				
Strain	Key Companies			
Potassium Bicarbonate	OAT Agrio Biofa Agronaturalis Bioworks UPL			
Phosphorous Acid	Loveland Plant Food Systems			
Potassium Phosphonate	De Sangosse Saga			
Potassium Hydrogen Carbonate	OAT Agrio Biofa Agronaturalis SCAM Mitsui & Co. SBM			
Disodium phosphonate	Syngenta			

Formulation Types – Value Share

The below chart(s) are derived from the biological focussed market research that AgbioInvestor conducted, and illustrates the value share attributed to various formulation type codes.



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CS	Capsule suspension	OD	Oil dispersion
DC	Dispersible concentrate	SC	Suspension concentrate
DF	Dry flowable	SL	Soluble concentrate
DP	Dustable powder	SP	Water soluble powder
EC	Emulsifiable concentrate	VP	Vapour releasing product
EW	Emulsion, water in oil	WG	Water dispersible granule
FS	Flowable concentrate for seed treatment	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment
LC	Liquid concentrate		

Regulatory Situation

The regulatory situation for fungicides based on minerals, organic acids and aliphatic molecules are generally favourable since in most countries they are considered to be "low-risk" or "basic substance" active ingredients.

An active substance can be approved as a low-risk substance if it meets the regular approval criteria and in addition meets the low-risk criteria as specified in Annex II, point 5 of Regulation (EC) 1107/2009. Low-risk substances are approved for 15 years instead of 10 years and data protection on the studies submitted for the approval and subsequent authorisation is extended from 10 to 13 years. Similar to the microbials segment, a fast-track authorisation procedure with reduced timelines (120 days) is in place. In contrast to conventional pesticide Als, low-risk substances may be granted approval based partly on literature, data, and scientifically reasoned opinions. Low risk description can also be used on product marketing.

Basic substances are substances that are not predominantly used for plant protection purposes but may be useful in plant protection. They are substances of no concern and can be approved for plant protection use as far as their risks are acceptable. Their approval by the European Commission allows the use for purposes of plant protection, but they cannot be sold specifically as a plant protection product. Their approval is based on existing evaluations carried out following other EU legislations. Authorisation is issued for the entire EU for an indefinite period.

Regulatory Status of Fun	gicides - Other minerals, ac	ids, aliphatic in the EU and	USA
EU Approval Status	USA Approval Status	Class	Туре
Benzoic acid	Benzoic acid	Insecticide / fungicide	Organic acid
Calcium carbonate	Calcium carbonate	Herbicide / fungicide	Mineral
	Citric acid	Fungicide	Organic acid
Clayed charcoal		Fungicide	Mineral
	Ethaneperoxoic acid	Fungicide	Organic acid
	Ethanol	Fungicide	Aliphatic alcohol
	Farnesol	Fungicide	Aliphatic alcohol
	Gamma-aminobutyric acid	Fungicide / PGR	Organic acid
	Isopropyl alcohol	Fungicide	Organic alcohol
L-Ascorbic acid		Fungicide	Organic acid
Lauric acid (CAS 143-07-7)		Fungicide	Organic acid
	Phosphorous acid	Fertiliser / fungicide	Mineral
Potassium hydrogen carbonate		Fungicide	Mineral
	Potassium laurate	Fungicide / insecticide / bactericide	Aliphatic
Potassium phosphonates (formerly potassium phosphite)		Fungicide	Mineral
	Sodium bicarbonate	Fungicide	Basic substance
Sodium hydrogen carbonate (basic substance)	Sodium hydrogen carbonate	Fungicide	Basic substance
	Sodium hydrogen sulfate	Fungicide	Basic substance
Vinegar	Vinegar	Herbicide/Fungicide	Organic Acid

Note: Green = approved (EU) registered (USA), orange = pending approval, purple = registration review, blue = reregistration. Information is correct as of May 2025

Research and Development

Due to the basic substance nature of many of the active ingredients in this classification, the majority of R&D to date is currently centred around optimisation of formulation development. For example, optimisation of the particle size and concentration to enhance efficacy and the use of adjuvants and surfactants to improve coverage and spreading can greatly improve field performance as well as improving shelf life and stability.

Development of granular formulations can increase the convenience of application of basic fungicide substances, whilst optimisation of particle size can improve the performance of products such as wettable granules. Surfactants and other adjuvants are also important in this class due to the prevalence of soluble liquid (SL) formulations, further underscoring the importance of optimising products for tank-mix compatibility to ensures that the products will have a greater range of operator benefits and convenience.

Market Outlook

In a similar trend to that of other bio-aligned pesticide segments within herbicides and insecticide, the mineral and organic acid nature of the ais often means that the products are relatively low cost, and subject to more conducive regulatory pathways. Despite the products having a low cost, they may not provide full control, only suppression and require multiple applications. Unlike the bio-aligned herbicide segment, which we believe will not face significant competition from the development of the microbial bioherbicide segment (which may be mutually complementary), the bio-aligned fungicide segment is likely to face technology competition from a range of 'true' biofungicides. The rationale behind this view, is that there are far more options for disease control within biofungicides, such as microbials and plant extracts. More efficacious products on the biologicals side will also temper growth.

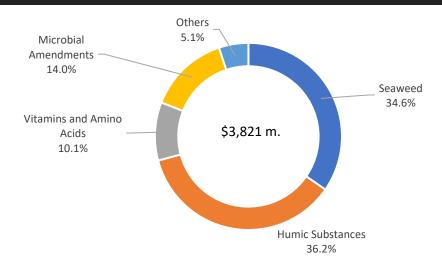
There are also new chemical fungicides from R&D that in conjunction with biofungicides, may mean that basic substances such as these are of less importance in integrated pest management strategies. These include newer generation SDHIs and new modes of action.

The forecast for the next 5 years is for growth of 3.9% p.a. on average between 2023 and 2028 on a constant currency and pricing level to reach \$23 million.

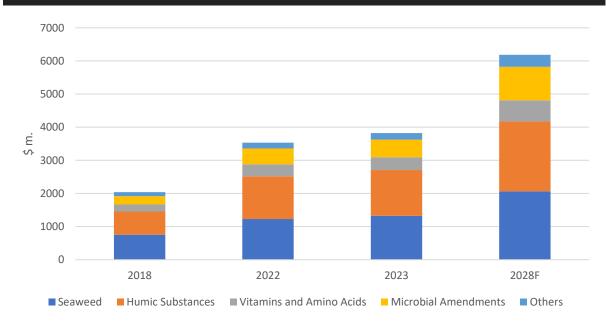
Biostimulants

Biostimulant Market and Forecast							
		US	\$m.				
Туре					2023/2022	2023/2018	2028/2023
	2018	2022	2023	2028F	%	CAGR (%)	CAGR (%)
Seaweed	754	1227	1323	2062	7.9	11.9	9.3
Humic Substances	699	1293	1384	2111	7.0	14.6	8.8
Vitamins and Amino Acids	212	360	385	642	6.9	12.6	10.8
Microbial Amendments	255	477	534	1010	11.9	16.0	13.6
Others	122	177	195	359	10.0	9.8	13.0
Total	2042	3534	3821	6184	8.1	13.3	10.1

Segment Split 2023



Sales of the Leading Classes, 2018-2022-2023-2028F



Plants can modify their surroundings through root exudation into the rhizosphere of various compounds that alter soil's physical and chemical properties and mediate interactions between plants and rhizospheric microorganisms. There are two classes of root exudates:

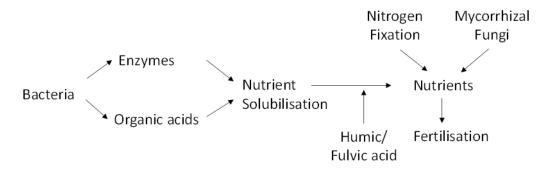
- Low-molecular-weight compounds, such as amino acids, organic acids, sugars, and phenolics.
- High-molecular-weight compounds, such as polysaccharides and proteins.

Many biostimulants mimic or enhance these root exudates and produce (or stimulate the production of) the substrates necessary for natural processes within a plant.

In broad terms, biostimulants can be categorised into four categories based on composition:

- 1. Seaweed extracts
- 2. Humic substances
- 3. Vitamins and Amino Acids
- 4. Microbial Amendments
- 5. Others (Plant extracts, hormones)

The complexity of biostimulation



Many biostimulating attributes ascribed to bacteria are a function of the nutrients they liberate. Bacteria can secrete enzymes and organic acids responsible for nutrient solubilisation/mobilisation in the soil, which plants then utilise to enhance growth. In addition, humic and fulvic acids aid in nutrient transport and plant absorption. Nutrients can also be supplied via nitrogen fixation or via the actions of mycorrhizal fungi, meaning that many quite different 'biostimulant' actions can lead to comparable outcomes.

Similarly, many biostimulants stimulate the production of plant hormones and phytoalexins, so the product does not exert a direct biostimulatory effect; instead, it has secondary activity by inducing a natural biochemical response within the plant, enhancing growth or resistance to stress or pathogens.

This distinction is essential because the AgbioInvestor definition of a 'biostimulant' covers only the AI with the plant health or nutrient uptake efficacy. Micronutrients and 'bio-source' macronutrients (NPK) are specifically excluded and are part of the 'bio-aligned' sector for biostimulants, covering micronutrients such as boron, manganese, and nickel.

ABI'S DEFINITION OF BIOSTIMULANT PRODUCTS

'Products that enhance natural plant processes in several areas such as nutrient solubilisation, nutrient uptake, abiotic stress and/or quality enhancement, but without having a direct activity against pests or plant stress'.

Components that do not directly modulate one or more of these areas are not considered biostimulants under ABI's definition, even if they are constituents in the same branded product containing components that meet this definition.

ABI defines biostimulants in this way to treat all products identically, regardless of how the selling company or other industry stakeholders advertise them. For example, in a biostimulant product containing seaweed extract, boron (B), and molybdenum (Mo), the seaweed extract (organic acids) would be considered the component with biostimulating activity because it enhances the solubilisation of the boron and molybdenum micronutrients. All micronutrient components and products containing only micronutrients are considered bio-aligned plant nutrition products.

ABI'S DEFINITION OF BIO-ALIGNED PLANT NUTRITION (BPN) PRODUCTS

Products and product components that consist of micronutrients such as boron (B), sulphur (S), manganese (Mn), iron (Fe), nickel (Ni), copper (Cu), zinc (Zn), molybdenum (Mo), calcium (Ca), sodium (Na), magnesium (Mg), cobalt (Co), aluminium (Al), and silicon (Si)

This definition specifically excludes nitrogen, phosphorus, and potassium (NPK) fertilisers, regardless of their source.

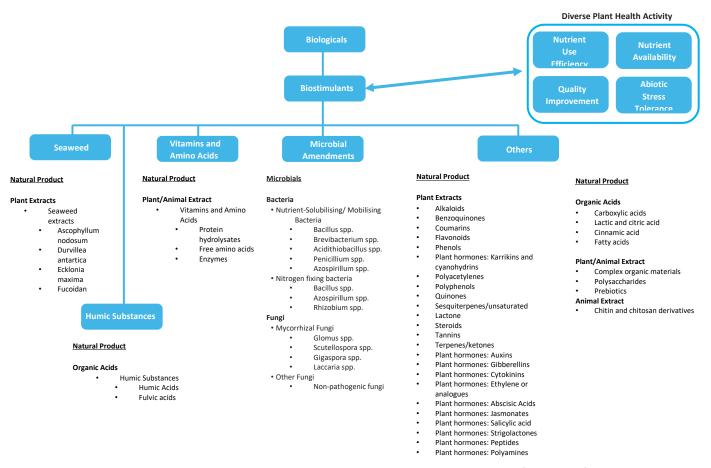
Products described as bio-fertilisers are not within the scope of this report because they are even more loosely defined than biostimulants. Indeed, products with similar compositions could be marketed as biostimulants by one company and as biofertilisers by another. ABI would categorise such products as biostimulants if they contain components within the scope of our biostimulants definition.

Biofertilisers that contain general organic matter, such as composts, green waste, and soil amendments, are not considered biostimulant products. 'Bio-source NPK fertilisers' and similar products are also not part of the definition. In this report, the term 'biofertiliser' refers to such materials, not biostimulant products.

The taxonomy shown below focuses on the activity classifications within the biostimulants market. It can be broadly split into five main categories: seaweed extracts, humic substances, vitamins and amino acids, microbial amendments, and other. As discussed above, there are two main classifications below these: natural products and microbials. Natural products can be divided into plant extracts, animal extracts, and organic acids. Several product categories within the 'other' category consist of organic acids. Other organic acids are found within the humic substances category, including fulvic acid and humic acids, which are complex organic acids; these include various aliphatic organic acids, lactic acid, and citric acid.

The various products belonging to the animal extract classification, such as free amino acids, protein hydrolysates, prebiotics, complex organic materials, and chitin and chitosan derivatives, are notable because their status as a 'non-plant source' brings additional considerations. Although the regulatory landscape for biostimulants is becoming increasingly harmonised and streamlined across many markets, animal-sourced biostimulants may create a further layer of regulation that must be considered during the launch of these products. The sustainability of animal-based products may also impact the market development of these products through considerations about product registration, how they fit into national sustainability agendas, and, to a lesser extent, consumer preferences. The sustainability of other natural source materials, such as seaweed, may also become a significant constraint in the future.

The 'other' category encompasses diverse plant extracts, including several plant hormones that modulate the natural processes within the target crops, such as abscisic acids, auxins, cytokinins, ethylene or analogues, gibberellins, jasmonates, karrikins and cyanohydrins, peptides, polyamines, salicylic acid, steroids, and strigolactones.



In the chart above, the product categories broadly relate to the activity classifications of nutrient use efficiency, nutrient availability, quality improvement, and abiotic stress tolerance. For many products sold as biostimulants, there is not necessarily a direct correlation between the constituent profile (i.e., which AIs are present) and the end activity of the product. Often, products with similar profiles may be positioned in different end-use scenarios. Furthermore, the same product may elicit different responses in different crops. Even excluding the company's market positioning of the product, the activity of biostimulants is not necessarily correlated to the constituent profile; many products' activity is spread across a spectrum of activity characteristics, leading to the activation of multiple, interdependent, and often synergistic biological processes. Therefore, it is vital to consider the end use of biologicals as a comprehensive 'plant health' management tool. This approach differs from the conventional CP section of the industry, where identification of a given AI leads to a succinct definition of end activity and an initial understanding of AI synergy.

These factors can create significant challenges for the biostimulants industry in communicating the benefits and correct use of products, as well as by addressing the challenges facing regulators around product quality assurance and transparency.

Function of Nutrients

Because biostimulants can increase nutrient bioavailability or absorption by plants, it is important to understand how key nutrients effect plants. The following table reviews these nutrients and their respective effects.

Macronutrients			
Element	Symbol	Use	Absorption
Nitrogen	N	Essential for plant growth and for chlorophyll synthesis.	Taken up as ammonium (NH4+) or the nitrate (NO3-) ion, or from materials such as water-soluble amino acids
Phosphorus	Ρ	A vital component of adenosine triphosphate (ATP), formed by photosynthesis. Stimulates root development, stem length, and flower formation	Absorbed from the soil as primary and secondary orthophosphates
Potassium	К	Essential for plant growth and reproduction, activates at least 80 enzymes. Influences water-use efficiency by regulating stomata.	Absorbed from the soil in ionic form (K+)
Secondary Nutrients			
Magnesium	Mg	Important in root formation and an essential component of chlorophyll. Also active as a Phosphorus carrier.	Absorbed from limestone
Sulphur	S	Required for amino acid and protein biosynthesis. Important in chlorophyll formation, photosynthesis, and winter crop hardiness. Aids seed production and nitrogen fixation.	Absorbed from organic matter and minerals
Calcium	Ca	Enables nitrogen-fixing bacteria to capture atmospheric nitrogen and improves nutrient absorption by roots. Assists in cell wall formation and normal cell division and enhances disease resistance.	Absorbed as the Ca2+ cation
Non-fertiliser elemen	ts		
Hydrogen	Н	Necessary for the production of glucose. Hydrogen from water is important in photosynthesis and plant respiration.	Absorbed from the atmosphere and soil
Carbon	С	Building block for photosynthesis and important in the production of starches, carbohydrates, cellulose, lignin, and protein.	Absorbed from the atmosphere and soil, particularly from crop residues, green manure, and animal waste
Oxygen	0	Only small amounts required for respiration. Important in changing the oxidative state of other elements, affecting their usage/expulsion from the plant.	Absorbed from the soil and produced via photosynthesis from carbon dioxide

Biostimulants

Micronutrients			
Element	Symbol	Use	Absorption
Boron	В	Essential for cell wall formation and rapidly growing points within the plant; improves seed set in plants under stress.	Absorbed from the soil as boric acid from organic matter
Chlorine	CI	Reduces the impact of fungal disease, plays a role in stomatal regulation and water breakdown, and activates several enzymes. It supports the absorption of Ca, Mg, and K into the plant.	Absorbed as the chloride (Cl-) anion from salt in other materials
Manganese	Mn	Activates several important metabolic reactions and has a direct role in photosynthesis and chlorophyll synthesis. It accelerates germination and maturity while increasing the availability of phosphorus (P) and calcium (Ca).	Taken up by plants as the divalent cation Mn2+
Iron	Fe	Iron is a component of many enzymes associated with energy transfer, lignin formation, and nitrogen reduction and fixation. It serves as a catalyst in chlorophyll formation and acts as a carrier of oxygen in root nodules.	Foliar absorption as the ferrous (Fe2+) cation. Only poor absorption by roots
Nickel	Ni	Nickel is a component of urease, responsible for converting urea to ammonia, and is important in nitrogen metabolism.	Absorbed as the divalent cation Ni2+
Copper	Cu	Copper activates enzymes and catalyses reactions in chlorophyll formation, lignin synthesis, and carbohydrate and nitrogen metabolism.	Uptake decreases as soil pH increases. Competes with other metals for absorption by roots and has low mobility within plants
Zinc	Zn	Involved in enzyme systems that regulate early growth stages. Vital for fruit, seed, and root system development, photosynthesis, formation of plant growth regulators, and crop stress protection.	Absorbed by plants as the divalent Zn2+ cation; uptake decreases as soil pH increases
Molybdenum	Мо	Required for the synthesis and activity of nitrate reductase, vital for the process of symbiotic nitrogen fixation by Rhizobia. Needed to convert inorganic phosphorus to organic forms in the plant.	Absorbed by plants as the MoO4 2- anion; availability increases as pH rises

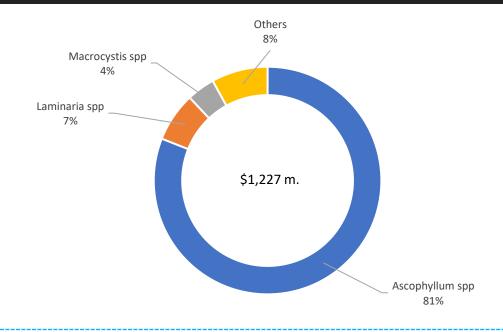
Silicon is not classed as a micronutrient, although its deposition in the epidermis provides a physical barrier to pathogens and insects and increases mechanical stability in the plant, thereby reducing the incidence of lodging and reducing transpiration rates.

To be effective biostimulants, nutrients must be available to plants. In many cases, they can interreact or be bound by the soil, which affects their bioavailability. Therefore, nutrients are often applied in chelated form to prevent cross-reactivity; this is achieved with a chelating agent or buffer, such as EDTA (Ethylene diamine tetra acetic acid), EDDHA (Ethylenediamine diamine di-o-hydroxyphenyl acetic acid), EGTA (Ethylene glycol bis [2-aminoethyl ether] tetra-acetic acid), or citric acid. When nutrients become bound into the soil, they can be released by solubilising or mobilising bacteria.

Biostimulants: Seaweed

Sales Performance of Biostimulants: Seaweed Biostimulants						
Year	Seaweed Biostimulant Sales (\$ m.)	Share of Biostimulants Segment %				
2018	754	36.9				
2022	1227	34.7				
2023	1323	34.6				
2028F	2062	33.3				
1-yr Change (%)	7.9					
5-yr CAGR (% p.a.)	11.9					
5-yr CAGR F (% p.a.)	9.3					

Leading Products, 2022



2022 market research data have been included in this report for context and will be updated in future iterations of this report once we have sufficient uptake of proposed future syndicated Bio MR studies. AgbioInvestor analyses multiple sources in addition to this to produce the current market year (2023) data.

Sales of the Leading Als 2022			
	Al	2022 \$m.	
	Ascophyllum spp	994	
	Laminaria spp	86	
	Macrocystis spp	49	
	Others	98	
Seaweed Total		1227	

Introduction

Seaweed extracts have applications in numerous fields: soil health through microbe enhancement; plant establishment through enhancing root growth; nutrient uptake through micronutrient solubilisation; stress management by offsetting the impact of drought, heat, cold, and salinity; crop quality by improving fruit set, size, colour, firmness, fruit uniformity, reducing fruit drop and in post-harvest longevity by reducing oxidation.

Seaweed extracts may contain arrange of phytocompounds including:

- Micro-nutrients/trace elements
- Phytohormones, and precursors/stimulators of endogenous production of phytohormones (e.g. Auxins, cytokinins, betaines, and gibberellins)
- Amino acids
- Saccharides
- Anti-stress substances such as osmo-protectors
- Natural chelating agents (e.g. Mannitol and alginic acid)
- Polysaccharides that can induce resistance to adversity and environmental stress (e.g. Laminarin and oligosaccharides)
- Vitamins
- Antioxidants

Along with humic substances the seaweed segment represents the two most significant product segments in the biostimulants industry. Key considerations that the seaweed industry needs to manage are the sustainability of supply, transportation costs and impact, supply chain efficiencies, product composition, addressing grower hesitancy for product usage as well as maintaining a strident focus on product efficacy and consistency of product composition.

Products

Seaweed extracts

In terms of seaweed species the most commonly used are brown algae (*Phaeophyta*), particularly *Ascophyllum nodosum*, as well as others including *Fucus spp., Laminaria spp., Sargassum spp., Ecklonia spp., Durvillaea spp.,* and *Turbinaria spp.*, this is typically because they are fast growing, achieving high levels of biomass and are widespread in the environment. Despite this the conservation of the marine environment through sustainable harvesting needs to be considered, especially as the demand for seaweed derived biostimulants increases.

From the perspective of mode of action, the positive effects of seaweed extracts on plant growth is still an area of active research. The activity is often at least partly independent of the pure fertilisation value alone, and of their micronutrient and phytohormone contents. The end activity is also the result of a delicate interplay of various plants processes that may be altered upon treatment, as well as supported by the nutritional contents of the extract such as micronutrients and macronutrients.

The pathways triggered by the bioactive compounds present in the seaweed extracts are often unknown and synergistic activities are proposed due to the often-low concentrations of components in the mixture. Bioactive compounds that have been identified in *Ascophyllum nodosum* extracts include poly- and oligosaccharides absent in plants, including laminaran, fucan, and alginate; betaines; sterols; vitamins; amino acids; macro- and micronutrients; phytohormones, such as abscisic acid, cytokinins, and auxins; and other compounds with hormone-like activities. The hormone concentration in seaweed extracts is typically low and only relatively small amounts of extracts are applied to plants. It is thought that seaweed extracts work by altering the endogenous balance of plant hormones by modulating the hormonal homeostasis, a self-regulating process by which plants can maintain internal stability while adjusting to varying field conditions. They may also regulate the transcription of a certain transporters (molecules, such as proteins, specialised for translocating water, food, wastes and other materials within plants) to alter nutrient uptake and assimilation, stimulate and protect photosynthesis, and dampen stress-induced responses.

Some key commercial issues that may arise from the use of seaweed extracts include:

- Changes in the extraction conditions may give rise to different profiles of the phytochemicals present in the end product. This can lead to products produced from the same feedstock having significantly different plant response when applied.
- Natural variations in phytocompound ratios may alter the profile of such compounds in the end product, therefore there may be issues from season-to-season around maintaining a consistent composition. This may also be an issue from a regulatory perspective.

Ascophyllum nodosum extract

Ascophyllum nodosum is a large and common brown algae species that is found in intertidal areas (where the ocean meets the land between high and low tides) around the periphery of the North Atlantic Ocean. It is particularly common on the north-western coast of Europe Iceland and the northeast coast of North America.

This species finds use in many different product types beyond agricultural use such as direct food production, animal feed, skin and hair care products, cleaners, de-greasers, equestrian products and nutritional supplements. Therefore, the biostimulant industry need also consider the growing demand for this resource from other competing industries.

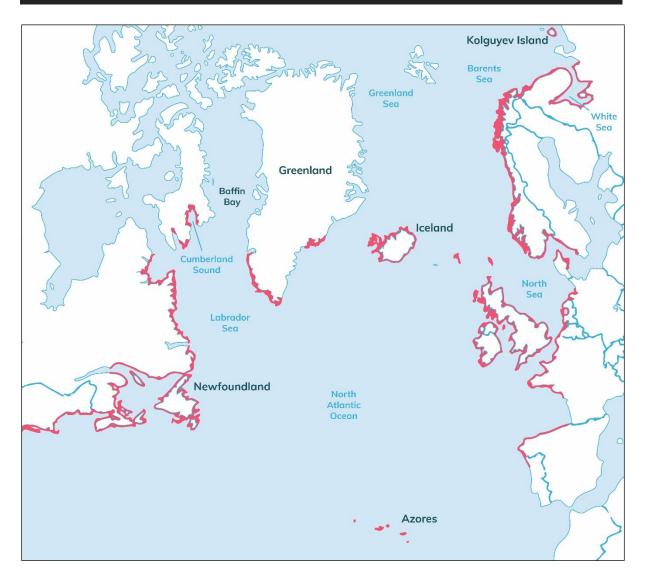
Ascophyllum nodosum is typically long-lived and very effective at accumulating nutrients and minerals from the surrounding seawater. Fronds (plants) can live to 15 years old before breakage. The holdfasts, from which new fronds regenerate, are observed to exist for much longer so whole plants may live to be several decades old. Studies have found that a typical Ascophyllum nodosum frond needed five years to develop into a fertile plant.

Ascophyllum nodosum is dioecious (where each specimen has either male or female reproductive parts) and like all other species of fucoids has only a sexual generation. Receptacles (stems to which the floral organs are attached) are initiated in spring and may take one year to become fertile. Therefore, receptacles are present on the plant for 12-14 months and ripen in April to June of the following year. Gametes (reproductive cells) are released from April onwards and the release of gametes is triggered by the exposure of ripe receptacles to air overnight. Fertilisation takes place externally and zygotes (a sperm cell fertilised egg) settle and form a rhizoid (small proto plant) within ten days. The receptacles are then shed during June.

Recruitment (colony building) in *Ascophyllum nodosum* is very poor with few germlings found on the shore. The reason for this poor recruitment is poorly understood, because the species invests the same high level of energy in reproduction as other fucoids and is extremely fertile every year. However, the reproductive period lasts about two months, much shorter than for other fucoids. Some research indicates that it may be due to a special combination of climatic or environmental conditions that is needed for an effective recolonization of *Ascophyllum nodosum*. The slow growth rate of germlings, may increase the chance of predation and being obscured by diatoms (unicellular marine organisms). Therefore, the biostimulants industry needs to carefully consider the sustainability of the harvesting of seaweed colonies, as the population dynamics are not fully understood.

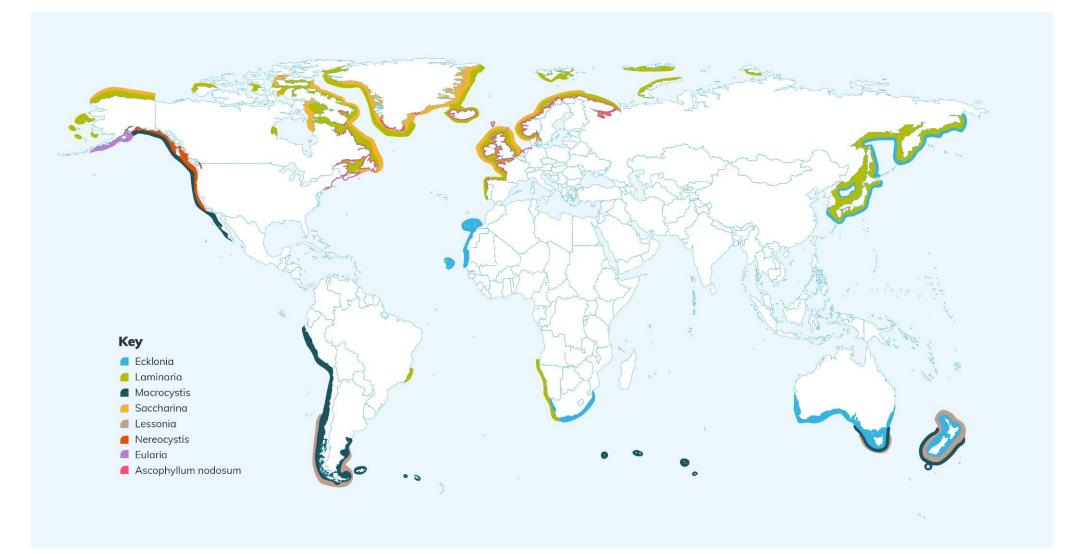
Seaweed may exist in separate ecological ecads (forms) in addition to distinct species, therefore being analogous to cultivars in agriculture. In Europe, direct reproduction of the ecad "mackaii" of *Ascophyllum nodosum* is vegetative, and the sexual reproduction gives rise to attached *Ascophyllum nodosum*. The frond in this form has extensive dichotomous branching and bears few air bladders, therefore the plants drift in large, spherical masses in sheltered waters and may thus be more difficult to harvest than for the attached ecads.

Ascophyllum Nodosum Natural Distribution



Component	Representative %	Component	Representative %
Major Components		Minerals	
Alginic acid	15 to 30	Na	4.6
Laminarin	0 to 10	К	3.8
		Са	1.0
Fucoidan	4 to 10	Mg	0.9
Carbohydrates (e.g. mannitol)	10	Fe	0.013
Protein	5 to 10	Mn	0.002
Fats	2 to 7		
Tannins	2 to 10	Total	10.2
Essential Amino Acids		Non-Essential Amino Acids	
Leucine	0.5	Glutamic acid	1.7
Lysine	0.4	Asparagine	0.8
Threonine	0.4	Alanine	0.7
Valine	0.4	Glycine	0.4
Phenylalanine	0.3	Proline	0.4
Arginine	0.3	Serine	0.4
Isoleucine	0.3	Tyrosine	0.2
Methionine	0.1	Cysteine	0.0
Histidine	0.1		
Total EAA	2.9	Total NEAA	4.6

Natural Distribution of Other Commercially Relevant Seaweed Species



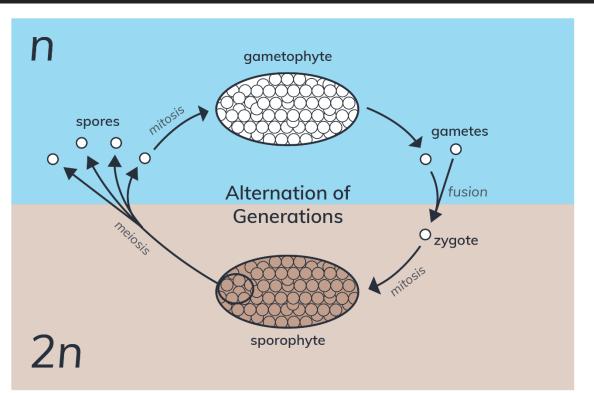
Laminaria spp.

Laminaria, commonly known as kelps, represents a diverse genus of brown alga and is considered as one of the most important seaweed genera because of its high number of species, biomass, dominance, and economic significance. There are 33 species of *Laminaria* currently accepted taxonomically.

Laminaria is typically found in colder ocean waters, such as arctic regions. The genus prefers to form colonies in regions where there are rocky shores, which affords *Laminaria* a suitable substrate to attach to. Due to the height of the *Laminaria*, they provide protection for creatures that the open ocean does not normally afford, therefore they are an important part of the marine ecosystem, and sustainability of harvesting needs to be carefully considered.

Laminaria is generally farmed using the floating raft method, in which young *Laminaria* sporophytes are attached to submerged ropes, that are subsequently attached to floating rafts. *Laminaria* along with *Macrocytis* have the highest primary productivity rates with an annual net production in the range of 1-2 kg/m of carbon.

Laminaria is commonly found in temperate regions but may grow vegetatively in tropical or semitropical conditions. Although the genus is a perennial, which can survive for more than 15 years, its blades in most of the species last for only 1 year. Laminaria hyperborean and Laminaria digitata are found in the northern Atlantic while Laminaria solidungula produces dense growths in the Alaskan Beaufort Sea. Laminaria exhibits a diplohaplontic life cycle (see below), with macroscopic sporophytes followed by a microscopic gametophyte with an oogamous (fusion of large immotile female gametes) mode of sexual reproduction:



Laminaria Lifecyle

Laminaria expresses a haplo-diplophasic life cycle, in which it alternates from a macroscopic thallic sporophyte structure, consisting of the holdfast, a stipe, and the blades, to a filamentous, microscopic gametophyte. The sporophyte structure of *Laminaria* can grow to around 7 metres (23 ft), which is

large in comparison to other algae, but still smaller than the giant kelps such as *Macrocystis* and *Nereocystis*, which can grow up to 40–50 metres (130–160 ft).

The gametophyte structure is of the order of millimeters in length, with this phase consisting of one type of tissue. The more complex sporophyte phase is made up of different types of tissue. One of these tissues includes a sieve-like element which translocates photoassimilates – the phytocompounds formed using light-dependent reactions, allowing the seaweed to harvest useful energy for biosynthesis of biostimulant relevant compounds.

Macrocystis integrifolia extract

Macrocystis spp. is a genus of kelp widely distributed in subtropical, temperate, and sub-Antarctic oceans of the southern hemisphere (e.g. Chile, Argentina, New Zealand, Australia, South Africa and the western USA/Canada).

Macrocystis has pneumatocysts (air bladders) at the base of its blades. The sporophytes are perennial and the individual plant may live for up to three years. The stipes/fronds within a whole individual undergo senescence (ageing), where each frond may persist for approximately 100 days.

Macrocystis integrifolia, one of the leading commercial species within the genus, grows to approximately 6 m (20 ft) long and is found on intertidal rocks or shallow subtidal rocks along the west coast of North America and in South America. Similar to other seaweed species, it forms extensive forests and serves as an important marine habitat.

Chlorophyta sp. Extract

Members of the *Chlorophyta*, or "grass-green algae" form the largest of the eight divisions of algae. It includes about 7,000 species of mostly aquatic photosynthetic eukaryotic organisms with around 90% of all known species living in freshwater. Most of the grass-green algae are fresh-water forms with only a limited number of marine types. Due to their inherent small size and high growth rate, *Chlorophyta* are ideally suited to cultivation in bioreactors, therefore compared to naturally harvested seaweed species, the sustainability element swings more towards overall energy and water consumption.

Some examples include:

- *Chlamydomonas reinhardti* Under optimal growth conditions, cells may undergo two or three rounds of mitosis before the daughter cells are released from the old cell wall into the medium. Therefore, a single growth step may result in 4 or 8 daughter cells per mother cell, leading to exponential growth.
- Chlamydomonas reinhardtii and Chlorella sorokiniana cells have been shown to promote the development of maize root systems. *C. sorokiniana* specifically increased the number of secondary roots. *C. reinhardtii* treated plants have been shown to improve micro-nutrient accumulation on roots and shoots.

Ecklonia maxima extract

Ecklonia maxima, commonly known as sea bamboo, is a type of kelp indigenous to the southern oceans, predominantly being distributed along the southern Atlantic coastline of Africa. Within these regions, it thrives in shallow, temperate waters and forms extensive underwater forests, with depths ranging up to 8 meters (26 feet). *Ecklonia spp* are also found in northwest African/Canary Islands waters, Australia, New Zealand, Japan and eastern Russia.

Plant growth regulators such as auxins, cytokinins, polyamines, gibberellins, abscisic acid, and brassinosteroids have been identified from *E. maxima*. Major components include phloroglucinol and eckol. Eckol has been shown to stimulate maize shoot and root elongation and the number of seminal (main, early) roots. In mung bean assays eckol demonstrated auxin-like activity with an increased number of roots, shoot elongation, and seedling weight.

South African company Kelp Products International's Kelpak is a major product based on *E. maxima*. Kelpak makes use of the company's cold Cellburst process, which extracts phytocompounds in a more benign way reportedly ensuring a more efficacious and consistent product. Most other seaweed extracts make use of chemical extraction or a combination of heat, mincing or freezing to extract the active elements, which of course may lead to some degradation.

Regulatory Situation

Europe

Regulation has been poorly defined for biostimulants. However, under the new European fertiliser regulation (EU fertiliser Regulation 2019/1009), PBSs (plant biostimulants) are classified as fertilisers, except those that are also pesticides, whereas PGRs (plant growth regulators) are classified as pesticides. In the US, PBSs are likely to be classified separately from fertilisers; however, this issue is still in discussion.

The EU enforced the Fertilising Products Regulation (EU n°2019/1009) in July 2022, which defines and establishes processes for biostimulant approvals, including requiring efficacy testing to show that the product has biostimulant effects and is not just a fertiliser. This highlights a critical development in defining plant biostimulants by their function, not their ingredients.

Biostimulants are regulated for the whole EU market alongside national regulations with two routes for placing PBSs on the market:

- National: Gain national registration, then seek mutual recognition with other member states.
- **EU:** Gain EU-wide registration and 'CE' mark for sale across the whole of the EU.

By including biostimulant products and explicitly excluding them from EU plant protection products, Regulation 1107/2009 closes a regulatory gap by bringing biostimulants under harmonised rules from June 2022. However, it simultaneously opens another gap, mainly because the official definition of biostimulants (i.e. those eligible for registration under the EU framework in the future) is mainly legal and regulatory, not scientific.

Many plant processes are active in abiotic and biotic defence mechanisms, meaning that dual-use products may now fall under the sole claim of biotic functionality. This could lead, for example, to requirements to register products previously marketed under the national fertiliser laws as 'biostimulants' under the plant protection product framework. If a product is effective only against abiotic stress, it does not fulfil the criteria of the plant protection regulation. This is exemplified by products containing the *Trichoderma* species, which, in many cases, have been marketed as a biostimulant, plant, or soil amendments but may now have to be authorised as a plant protection product due to their fungicidal action.

Dual-action products against abiotic and biotic stress may be eligible for registration under the plant protection framework because respective substance/product categories, such as 'elicitor' or 'plant activator', are already included in and covered by Regulation 1107/2009.

The current impact on timescales is unknown due to the relatively recent introduction of this new regulation. Still, limited capacity due to the process of establishing assessment standards within Conformity Assessment Bodies (CAB), also known as Notified Bodies (NBs), has taken longer than expected. Therefore, to date, only a handful of accredited CABs are ready to act in reviewing and approving new product dossiers. Registration fees are currently around €100,00 to €500,000.

USA

Historically, the registration of biostimulants has been far less advanced. However, in 2022 the US introduced the Plant Biostimulant Act, which defines biostimulants as:

'a substance, microorganism, or mixture thereof, that, when applied to seeds, plants, the rhizosphere, soil, or other growth media, act to support a plant's natural processes independently of the biostimulant's nutrient content, including by improving nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality, or yield.'

The act aims to harmonise the US and EU definitions, set a national framework for registering biostimulants, and more accurately describe benefits on product labels. The regulation also aims to:

- Develop a model bill for use across states to streamline the registration process.
- Educate growers on the benefits of biostimulants for soil health, sustainability, and climatesmart agriculture opportunities.
- Achieve regulatory clarity from the EPA regarding existing regulations, including defining plant growth regulators within FIFRA.

The EPA intends to distinguish plant biostimulants from PGRs, with PBS defined by the exclusion method as a substance or microorganism that does not conform to the definition of a PGR under FIFRA, aiming to remove previous ambiguity of where products fall. In the US, fertilisers are regulated by the US Department of Agriculture (USDA), whereas pesticides, including PGRs under FIFRA, are regulated by the EPA. For example, an algae extract is considered a PGR and is regulated under FIFRA by the EPA; therefore, the registration requirements for algae extract are similar to those for pesticides.

In November 2024, the EPA released draft guidance for plant regulator products and claims, including plant biostimulants. The aim of this draft guidance is to more clearly define which components are considered plant regulators and, therefore, subject to regulation as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136–136y.

Although FIFRA does not define the term plant biostimulants, some products being sold as plant biostimulants may trigger regulation under FIFRA as plant regulators. Other plant biostimulant products will not require registration as a pesticide under the plant regulator definition outlined in FIFRA section 2(v), or because they do not fit within the specific functionality definitions provided under FIFRA regarding plant regulator function.

Products which are not considered to be plant growth regulators and are therefore excluded from registration under FIFRA:

- **Plant nutrients and trace elements**: Plant nutrients and trace elements, which can be considered as falling under the umbrella term "fertilizers," are described in EPA's FIFRA regulations as "plant nutrient product[s] consisting of one or more macronutrients, or micronutrient trace elements necessary to normal growth of plants and in a form readily useable by plants" [40 CFR 152.6(g)(1)].
- **Plant inoculants**: Plant inoculants are "...product[s] consisting of microorganisms to be applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system" [40 CFR 152.6(g)(2)].
- **Soil amendments**: Soil amendments (which include soil additives and soil conditioners) are "...product[s] containing a substance or substances intended for the purpose of improving soil characteristics favorable for plant growth" [40 CFR 152.6(g)(3)].
- Vitamin-hormone products: Under FIFRA section 2(v), "the term 'plant regulator' shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, non-poisonous in the undiluted packaged concentration." Per 40 CFR 152.6(f), "vitamin hormone products" are further described as follows:
 - "A product consisting of a mixture of plant hormones, plant nutrients, inoculants, or soil amendments is not a "plant regulator" under Section 2(v) of FIFRA, provided it meets the following criteria:
 - The product, in the undiluted package concentration at which it is distributed or sold, meets the criteria... for Toxicity Category III or IV; and
 - The product is not intended for use on food crop sites, and is labelled accordingly.

During registration of both plant growth regulators and biostimulants, the claims made by the registrant, and on the product label are also considered by the EPA as part of its evaluation of the appropriate regulatory pathway. However, it should be noted that the EPA does not solely look at the claims made. Products that contain an active ingredient consistent with pesticidal/plant growth regulator usage will be registered as such regardless of how the registrant makes claims for its use. Similarly, if a biostimulant product claims pest-control properties, it will be considered as a pesticide under FIFRA.

The EPA outlined in this draft guidance documentexample claims that may exclude a product from registration as a pesticide under FIFRA. These are not exhaustive, and as mentioned previously, if the active ingredient is consistent with a pesticidal active then it will be registered as such. The examples provided relate specifically to **plant nutrition-based claims**, **plant inoculant-based claims** and **soil amendment-based claims**. These can generally be summarised as modalities that *indirectly* support crop health, such as correcting nutrient deficiencies in the soil, optimising conditions for abiotic stress tolerance, soil structure/biodiversity, and increases to nutrient availability/uptake (e.g. through promoting root growth, nutrient solubilisation etc). The claims made by vitamin-hormone products need to be considered more carefully given that they are considered by the agency to contain components that can be considered as regulating plant physiological processes.

Plant regulator claims may be made for vitamin-hormone products when they meet both criteria for exclusion from the plant regulator definition, as specified under 40 CFR 152.6(f)(1) & (2).

This means that the product is considered 'non-toxic' but crucially also not for use on food crops, which means this exclusion has no relevance for agriculture beyond non-crop uses such as turf and ornamentals.

The guidance document goes on to discuss the definition of a plant growth regulator.

A naturally occurring substance would be considered a "plant regulator," and a product label claim would be considered a "plant regulator claim" if:

The substance or mixture of substances, through physiological action:

- 1. Accelerates or retards the rate of plant growth;
- 2. Accelerates or retards the rate of plant maturation;
- 3. Or otherwise alters the behaviour of plants or the produce thereof;

<u>and</u>

if the substance or mixture of substances does not fall under one of the exclusion categories listed in 40 CFR 152.6(f) & (g) as vitamin-hormone products, plant nutrients, plant inoculants or soil amendments; or under 40 CFR 152.8(a) as a fertilizer.

Plant regulator claims may be made for vitamin-hormone products when they meet both criteria for exclusion from the plant regulator definition, as specified under 40 CFR 152.6(f)(1) & (2). When claims for increased or decreased growth, yield, germination, maturation, etc. are consequent to intended uses of products or substances as plant nutrients (fertilizers), plant inoculants, soil amendments, and/or as other non-pesticidal uses, such products and substances may be excluded from regulation under FIFRA in the absence of any plant regulator claims.

This would imply that plant nutrients, plant inoculants or soil amendments that <u>do</u> have plant growth regulating capabilities and/or claims would be excluded from FIFRA registration, provided that they meet the requirements of the above exclusions, and have at least some 'non-plant growth regulating claims'. The exception here is that this doesn't apply for vitamin-hormone products used in food crops.

Examples of active ingredients that are considered to have no other usage other than as plant growth regulators and therefore pesticides under FIFRA include (but not limited to):

- Auxins
- Cytokinins
- Gibberellins
- Ethylene
- Abscisic acid

Other substances that may be included in this category include:

- Corn glutens
- L-Glutamic Acid (LGA) and gamma-Aminobutyric Acid (GABA)
- Homobrassinolide and other brassinosteroids
- Lysophosphatidylethanolamine (LPE)
- 1-Octanol
- Sodium o-nitrophenolate, sodium p-nitrophenolate, and sodium guaiacolate

There are numerous substances that may have plant regulator activity, as well as additional modes of action, not considered to be plant regulator modes of action that may include, but are not limited to:

- Abiotic stress tolerance
- Water and nutrient use efficiency/uptake;
- Nutrient availability increased availability of inorganic nutrients in the soil to plant roots and seeds; improving biotic and abiotic characteristics of soils

Examples of these include:

- Seaweed extracts (SWE)
- Complex Polymeric Polyhydroxy Acids (CPPAs) and Humic Acids (HAs)

Both of these categories of active ingredients are generally understood to have direct physiological effects on growth, yield, maturation, and produce quality.

The Agency also recognizes that not all uses of PBS may be intended for plant regulator or other pest control purposes. If it can be demonstrated that a particular product has the activity claimed on the product label (and any other informational media) and does not make any plant regulator or pest control claims on the product label (and any other informational media) it may be excluded from FIFRA regulation.

Therefore, a natural product such as seaweed extracts and humic substances will be excluded from registration as a pesticide, provided that the product does not claim plant regulator activity, and claims activity under the plant health examples cited in the guidance document (Tables 1a-c and 2), or those analogous to those non-exhaustive examples.

Finally, the document also outlines how other 'conventional' components in the mixture should be considered, as well as components generated as a result of the extraction process.

If a conventional chemical plant regulator is contained within a PBS product, the product likely would be considered a conventional chemical pesticide by the Agency and would be subject to registration under FIFRA.

Novel substances may be present in plant biostimulant products that were not present in the original plant source material, but were formed as a result of the extraction methods and/or post-extraction processing but will require further scrutiny under FIFRA by the Agency to determine if they have the potential for pest control and/or plant regulator activity.

In summary, the guidance document outlines the importance of understanding the mode of action of the components in the product and associated claims, including the ability to produce performance data supporting such claims. Plant growth activity alone will not permit registration as a biostimulant, and companies must have an awareness of the physiological responses of the product and make sure that label claims, and those made in the process of regulation align with this.

Brazil

Under the first Fertilizer Law of 1980 (6.894/1980) and subsequent decree number 4.954/2004, fertilisers were defined as "mineral or organic substances, natural or synthetic, that provide one or more plant nutrients". For biofertilisers, Brazilian legislation previously utilised two definitions:

- (i) Inoculants: products containing micro-organisms that have a favourable impact on plant growth
- (ii) Biofertilizers: products containing an active ingredient or organic agent, free from agrochemical substances, capable of acting directly or indirectly on all or part of cultivated plants, enhancing their productivity, regardless of their hormonal or stimulant value

The generally vague definitions and regulation of biostimulants has in the past generated uncertainties for companies wishing to enter the market and represented a challenge surrounding grower confidence in product efficacy, composition, and quality assurance. However, few barriers have existed to introducing a biostimulant product into the market. There have been steps in 2024 to update and clarify the legislation under the 'Bioinputs Law'.

On December 23, 2024, Law No. 15,070/2024 ('Bioinputs Law'), which regulates the production, use, and commercialisation of bioinputs in the agricultural sector, was published in the Official Gazette. The new law regulates the production, use, and commercialisation of bioinputs for agricultural,

The Bioinputs Law defines a bioinput as: product, process or technology of plant, animal or microbial, including that originating from a biotechnological process, or structurally similar and functionally identical to that of natural origin, intended for use in production, protection, storage and processing of agricultural products or in production systems or planted forests, which interferes with the growth, development and response mechanism of animals, plants, microorganisms, soil and derived substances and that interact with the products and physical-chemical and biological processes.

Bioinputs include those "used in agricultural activity, including biostimulators or growth or performance inhibitors, semiochemicals, biochemicals, phytochemicals, metabolites, organic macromolecules, agents biological control products, soil conditioners, biofertilizers and inoculants."

However, the updated pesticide law stops short of defining each of these categories in detail.

livestock, aquaculture, and forestry use in Brazil, whilst also promoting the production and adoption of such products.

Argentina

Biostimulants and organic-chemical fertilisers must also be registered through SENASA. The general fees required for registration are relatively low compared to other markets, such as North America and Europe. However, this is more than offset by the level of complexity, the current lack of a fast-track registration process, and the generally lower levels of capacity and regulatory expertise required for a more expedited future process.

In November 2024, the government announced that all phytosanitary and bioinput procedures were centralised through an online platform known as SIGTrámites. On this platform users can register their products, facilitate self-management, gain insights on process traceability, reduce processing times, gain support, boost communication and make online payments. The platform may be used for newly formulated phytosanitary products, registration requests for prioritised items and registration requests for bio-inputs for plant nutrition.

China

In China, biostimulants are currently regulated through NY/T 3831-2021 Organic Water-Soluble Fertilizers-General Regulations; biostimulants are regulated alongside fertilisers and treated as microbial fertilisers or organic water-soluble fertilisers. This is overseen by the Chinese Ministry of Agriculture and Rural Affairs. The current regulation provides improved definitions that resolve biostimulant products' previously ambiguous legal status. Additionally, the regulation offers a premarketing procedure, product classifications, general rules on raw materials, nutrient contents, and labelling requirements.

The key product classes, such as inoculants and rhizobia, are registered under microbial fertilisers. Other biostimulants, such as chitosan, are listed under 'Water-soluble fertilisers':

- WSF containing amino acid.
- WSF containing humic acid.
- Organic WSF containing alginic acid.
- Organic WSF containing chitosan.
- Organic WSF containing polyglutamic acid.
- Organic WSF containing polyaspartic acid.
- Other WSF containing molasses, low-value fish and its fermented products, as well as other organic materials.

Overseas applicants must follow several requirements, including using a Chinese agent for application. This involves supplying critical information on product properties. Depending on raw materials, manufacturing processes, and end uses, toxicity tests and efficacy trials are sometimes required. These generally have lower requirements than urea, ammonium nitrate, and other fundamental nutrition products; therefore, they do not require technical review for registration. Following these tests, a technical permit is granted for commercialisation.

Japan

Japan does not legally define biostimulants, which are registered under the Fertiliser Control Law or Soil Fertility Enhancement Act. MAFF's 'Green Food System Strategy' targets a reduction in the use of chemical fertilisers. However, several products considered biostimulants are broadly used with registration under the Fertiliser Control Law or Soil Fertility Enhancement Act.

In response to the amendment of the Fertiliser Regulation in the EU, an industry group in Japan has been established to actively promote communication with the competent authorities to facilitate the standardisation of biostimulants.

With its new 'Green Food System Strategy', MAFF targets reducing chemical fertiliser use by recognising biostimulants as a valuable tool to lower fertiliser inputs and reduce environmental impacts. The Japanese Crop Protection Association has announced that the industry will proceed with developing biostimulants to support this strategic goal.

India

India's biostimulant definition is broadly aligned with that of the EU. Biostimulants are currently regulated through Fertiliser Control Order (FCO), which defines biostimulants as:

...a substance or micro-organism or a combination of both whose primary function when applied to plants, seeds or rhizosphere is to stimulate physiological processes in plants and to enhance its nutrient uptake, growth, yield, nutrition efficiency, crop quality and tolerance to stress, regardless of its nutrient content, but does not include pesticides or plant growth regulators which are regulated under the Insecticide Act, 1968.

India's Fertilizer (Inorganic, Organic or Mixed) (Control) Amendment Order was introduced in 2021. These new regulations require manufacturers to register products with the relevant authority providing a set of information on chemistry (composition, analytical methods, shelf-life), bio-efficacy trials conducted by the Indian Council of Agricultural Research (ICAR), state agricultural universities (SAUs) (preferably in agro-ecological zones), and toxicity data and heavy metal analysis.

The regulations also establish a regulatory body to monitor the end-to-end movements within the industry. The committee controls the quality and specifications of all biostimulants and ensures the use of safe substances and organic compounds in product manufacturing.

Farming-related services and speciality products dominate the Indian agrochemical landscape. The Federation of Indian Chambers of Commerce & Industry (FICCI) categorises biostimulants under the latter category alongside micronutrients, biopesticides, and biofertilisers that have recently begun to permeate the markets.

In May 2024 the Indian Union Ministry of Agriculture and Farmers Welfare issued a new amendment to the Fertilizer (Inorganic, Organic or Mixed) (Control) Order, 1985. Titled the 'Fertilizer (Inorganic, Organic or Mixed) (Control) (Third) Amendment Order, 2024,', the issue is intended to regulate the specifications and approval process for biostimulants in the agricultural sector. Key provisions of the amendment include:

- Increased specifications for biostimulant products, including their name, active ingredient or tracer molecule, chemical composition (in cases where active ingredients or tracer molecules cannot be indicated), and the name of the crop to which they are applied.
- The introduction of a new category for live microorganisms, excluding biofertilisers and biopesticides, within the specifications for biostimulants.

- Alterations to the application for new biostimulants, including the submission of data regarding categories, such as chemistry, bio-efficacy trials, toxicity, heavy metal analysis, and a product sample accompanied by an affidavit affirming compliance with pesticide limits.
- Toxicology data exemptions for certain biostimulants, such as protein hydrolysates, seaweed extracts, amino acids, vitamins, humic and fulvic acid.
- Alterations to pesticide limits within biostimulant products, set at 1 part per million (ppm), replacing the previous limit of 0.01 ppm.

The amendment aims to provide a framework for regulating and approving biostimulants in agriculture to ensure their safety, efficacy, and adherence to specified standards.

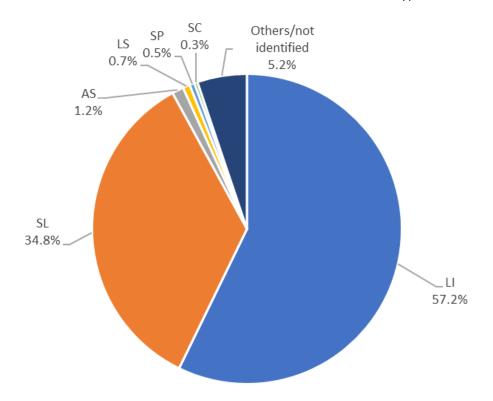
Company Involvement

The below table(s) on key active ingredients and key companies is derived directly from AgBioInvestor's exclusive primary market research study that surveyed biological- and biostimulantgrowers, which were conducted for the first time in 2023 and profiled the 2022 agricultural market. The market research surveyed many key agricultural markets for biologicals, including: the USA, Mexico, Chile, Brazil, Argentina, France, Italy, Spain and Turkey. The AIs have been ranked by farmgate value (\$m.). Quantification of these data and much more biological market research can be found in the separate subscription product AgbioInsight.

Key Companies with Involvement in Biostimulants: Seaweed				
Al	Key Companies			
Seaweed extracts	UPL			
	Сотро			
	Sumitomo Chemical			
	Acadian Seaplants			
	Biobizz			
	UPL (Goemar)			
	Timac Agro			
	Sipcam-Oxon			
	SCAM			
	Aspe Agro			
	Green Agricoltura			
	Advancing Eco Agriculture			
	Biofermex			
	Bio3G			
	Indigrow			
	Cifo			
	Sustainable Agro Solutions			
	Agronutrition			
	Omex			
	Acadian			
Ascophyllum nodosum extract	Intergal			
	Yara			
	UPL			
	Sarabia			
	Syngenta (Valagro)			
	CBC (Biogard)			
	Fertenia			
	Olmix			
	Kimitec			
	K-Adriatica			
	Vithal Bio			
	Acadian			
	Rovensa (Ascenza)			
	Neudorff			
	BioTechnica			
	Acadian Plant Health			
	Valagro			
	Adama			
	BMS Micro-nutrients			
	Rigrantec			
Ecklonia maxima extract	Alzchem Trotsberg			
	Kelp Products			
	Kelpak			
	Сотро			
	Agrial			
	Compo Expert			

Formulation Types – Value Share

The below chart(s) are derived from the biological focussed market research that AgbioInvestor conducted, and illustrates the value share attributed to various formulation type codes.



Code	Description	Code	Description
AE	Aerosol dispenser	LI	Liquid
AL	Other liquids to be applied undiluted	LS	Solution for seed treatment
СВ	Bait concentrate	ME	Micro emulsion
CS	Capsule suspension	OD	Oil dispersion
DC	Dispersible concentrate	SC	Suspension concentrate
DF	Dry flowable	SL	Soluble concentrate
DP	Dustable powder	SP	Water soluble powder
EC	Emulsifiable concentrate	VP	Vapour releasing product
EW	Emulsion, water in oil	WG	Water dispersible granule
FS	Flowable concentrate for seed treatment	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment
LC	Liquid concentrate		

Research and Development

Although the seaweed segment is dominated by established species such as *Ascophyllum spp*, *Laminaria spp* and *Macrocystis spp*, there is both the continued development of novel formulations of established species, research into modes of action, consistency of manufacturing processes to minimise variability in composition year-on-year as much as possible, and research on integrating the products into agronomic prescription services within digital ag.

In addition to the research and development in existing strains, a number of new species are actively being studied for their relevance to agriculture:

Elkhorn sea moss (*Kappaphycus alvarezii*) and *Chondrus crispus* (Irish moss) are species of red algae with high levels of carrageenan which has been shown to have potential for enhancing plant growth by stimulating cell division and elongation, and also improving soil health, root structure and increasing resistance to abiotic stress by triggering systemic acquired resistance (SAR). Extracts of this species are also rich in other polysaccharides and growth-promoting substances, which can enhance overall plant health and resilience to stress.

Kappaphycus alvarezii is commonly found in warm tropical and subtropical waters:

- o Southeast Asia: Philippines, Indonesia, Malaysia, Thailand, Vietnam
- o South Asia: India, Sri Lanka
- East Asia: China, Japan
- o Pacific Islands: Fiji, Papua New Guinea, Solomon Islands, Vanuatu
- Africa: Madagascar, Tanzania
- o Central America: Mexico, Belize, Panama
- o Caribbean: Jamaica, Dominican Republic
- o South America: Ecuador, Brazil

Chondrus crispus is primarily found in the North Atlantic Ocean

- o North America: Canada (Atlantic provinces), United States (New England region)
- Europe: Ireland, United Kingdom, Iceland, Norway, France, Portugal
- Asia: Russia (Far East)
- Oceania: New Zealand

Sea lettuce (*Ulva* spp.) have been researched for their high protein content as well as associated minerals, and vitamins. *Ulva* extracts also contain a range of phytohormones (e.g., auxins, cytokinins, and gibberellins). Together these components boost root development, and overall plant growth. Betaines and polyphenols contained in the extracts can also improve abiotic stress tolerance.

Ulva spp. is commonly found in numerous regions (cosmopolitan distribution)

- North America: Canada, United States (coastal areas of both the Atlantic and Pacific Oceans)
- Europe: United Kingdom, Ireland, France, Spain, Portugal, Norway, Denmark, Netherlands, Belgium, Germany, Sweden, Finland, Iceland, Russia (Baltic Sea and Arctic Ocean coasts)
- \circ $\;$ Asia: China, Japan, South Korea, India, Vietnam, Thailand $\;$
- o Oceania: Australia, New Zealand
- Africa: South Africa, Egypt, Morocco
- o South America: Chile, Argentina
- Central America and the Caribbean: Mexico, Panama, Costa Rica, Cuba, Dominican Republic, Bahamas

Irish moss (*Gracilaria* spp.) is a red seaweed that is rich in agar and other polysaccharides. Recent research is exploring its potential as a biostimulant, particularly due to its hormone content, such as auxins, gibberellins, and cytokinins that can enhance seed germination, root development, and overall plant vigour. Like other seaweed species, betaines and polyphenol antioxidants can assist with improving the abiotic stress tolerance of the plant.

Gracilaria spp. are widely distributed in temperate to tropical regions around the world in areas with warm water temperatures and moderate salinity levels.

- North America: United States (California, Florida, Texas), Mexico, Canada
- Central America and the Caribbean: Panama, Costa Rica, Jamaica, Dominican Republic, Bahamas, Puerto Rico, Cuba
- o South America: Brazil, Chile, Peru, Colombia, Ecuador, Venezuela, Argentina
- Europe: Spain, Portugal, France, Italy, United Kingdom
- Africa: South Africa, Mauritius, Madagascar, Tanzania, Senegal
- Asia: China, Japan, South Korea, Vietnam, Philippines, Indonesia, Malaysia, Thailand, India
- o Oceania: Australia, New Zealand, Fiji, Papua New Guinea
- Middle East: United Arab Emirates, Saudi Arabia, Oman, Iran

Porphyra spp. (known as nori) is another species of red seaweed rich in proteins and vitamins. Unlike elkhorn sea moss (*Kappaphycus alvarezii*) and *Chondrus crispus* (Irish moss), *Porphyra spp*. does not contain high levels of carrageenan. These species are however rich in compounds that are common to other seaweed species such as phytohormones (auxins, cytokinins, and gibberellins), and therefore are able to boost plant health. Betaines and polyphenols also boost plant abiotic stress tolerance.

Porphyra species are primarily found in temperate to cold coastal waters around the world, with significant concentrations in the North Pacific and North Atlantic Oceans.

- North America: United States (Pacific Northwest, Atlantic Northeast), Canada (Atlantic provinces)
- o Europe: United Kingdom, Ireland, France, Norway, Iceland
- Asia: Japan, China, South Korea, Taiwan
- Oceania: New Zealand, Australia
- Africa: South Africa
- o South America: Chile
- o Pacific Islands: Fiji, Papua New Guinea, Solomon Islands
- North Asia: Russia (Far East)

Market Outlook

The outlook for seaweed based biostimulants is highly positive, driven by their use to boost a number of crop outcomes, from overall yield and quality through to abiotic stress tolerance. As one of the more established segments within biostimulants, this class has achieved greater market penetration through established sourcing and manufacturing procedures. Although the precise mechanisms by which seaweed extracts operate is still not well understood, due to the considerable commercial activity in this area, the market has moved towards a more consistent product with a clearer activity and value proposition for growers. As seaweed biostimulants can increase nutrient use efficiency as well as nutrient bioavailability in the soil, they have attracted considerable interest in recent years in light of volatile fertiliser prices. Although fertiliser prices have lowered into 2024 and 2025, they remain high compared to the pre-2022 pricing spikes. Farmers are increasingly looking to find means of reducing the volume of chemical fertilisers that need to be applied.

Crucial to the future success of the seaweed segment will be the sustainability of the natural feedstock, as well as the energy used in production and transportation. Although there is an abundance of seaweed in many northern and southern latitudes, that grows at a fast pace, there are considerations around protection of the marine environment as well as recovery of seaweed regions.

We are forecasting that the seaweed segment will increase at a rate of 9.3% p.a. between 2023 and 2028 to reach \$2,062 million. A rate which is slightly lower than that of the humic substances segment (+8.8% p.a.), and further below that of the vitamins and amino acid segment (+10.8% p.a.), microbial amendments (+13.6% p.a.) and the others segment (including a range of other plant extracts +13.0% p.a.). The main rationale for this is that there is likely to be some modest competition from other segments, particularly microbial amendments for nitrogen fixation, as well as fast growth within the others segment which includes plant extracts, an area of increasing company activity and research.

Biostimulants: Humic Substances

Sales Performance of Biostimulants: Humic Substances			
Year	Humic Substances Sales (\$ m.)	Share of Biostimulants Segment %	
2018	699	34.2	
2022	1293	36.6	
2023	1384	36.2	
2028F	2111	34.1	
1-yr Change (%)	7.0		
5-yr CAGR (% p.a.)	14.6		
5-yr CAGR F (% p.a.)	8.8		

Leading Products, 2022



Sales of the Leading Sub-segments 2022		
Sub-segment	2022 \$m.	
Humic Substances / Humic acids	739	
Fulvic Acid	554	
Humic Substances Total	1293	

Introduction

Humic substances, humic acids and fulvic acids are an umbrella terms for a diverse range of naturally derived substances found in decayed materials such as soil and peat strata or fossilised materials in natural mineral deposits. Both humic and fulvic acids contribute to the overall health of the soil biome by enhancing key parameters such as water retention, nutrient availability and overall soil structure. These factors can support overall plant health and critical properties such as root propagation. Similar to other categories of plant biostimulants this can lead to a mosaic of synergistic end effects on the plant ranging from tolerance to abiotic stress, quality and yield enhancement.

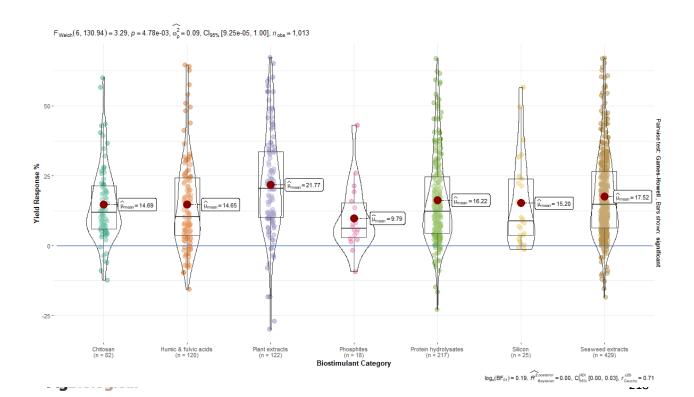
The extracts also frequently contain essential minerals for plant health, the result of decay of the original living matter that produced them. The chemical properties of the acids components depends on the molecular weight of the finished product, and like seaweed extracts, due to the broad distribution of components in the natural source material, consistency of product supply is a critical factor in ensuring the expected effects of the end product when used by growers. Despite significant soil research activity, the distinct chemical structure of humic substances remains only partially understood, potentially creating further issues surrounding product consistency and also marketing of product to growers.

Leading Products

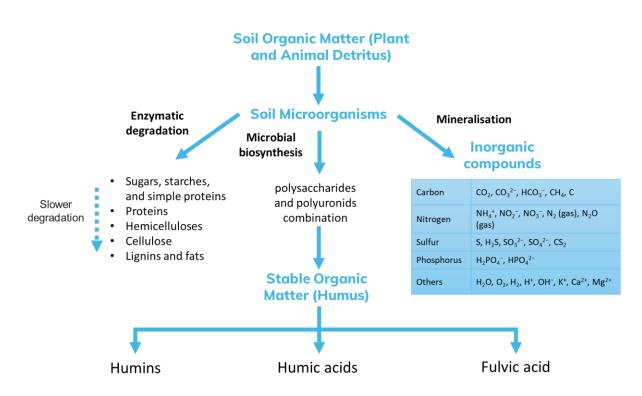
A typical humic substance is a mixture of many molecules, some of which are based on a repeating motif of aromatic nuclei with phenolic and carboxylic substituents. Soils which contain adequate humin, humic adds (HAs), and fulvic adds (FAs) typically are conducive to plants that are less subject to stress, overall healthier, produce higher yields, and the nutritional quality of the crop and feeds are superior.

However, it should be noted that a meta-analysis of numerous literature articles (see below chart) on the yield benefits of biostimulants indicated that in a not insignificant number of cases the product actually led to a reduction in yield:

Field Trials for Yield Benefits



Simplified Soil Structure Schematic



Humic substance is an umbrella term covering humic acid, fulvic acid, humin and hymatomelanic acid. Humic matter in an agricultural context typically represents the components that are chemically extracted from the soil organic matter. Age and origin of the source material determine the chemical structure of humic substances. In general, humic substances derived from soil and peat (which takes hundreds to thousands of years to form) have higher molecular weight, a higher number of functional groups, more carbohydrate units and less polyaromatic units than humic substances derived from leonardite/brown coal (which takes millions of years to form). It is this diversity of the molecular components, and indeed their complexity within the soil humeome that confers to humic matter its bioactivity in soil and its role as a plant growth promoter.

Contemporary studies typically perceive humic substances not as large macropolymers but as diverse, relatively small molecular constituents of soil organic matter. The view also speculates that components self-assemble into supramolecular associations and consist of a range of compounds derived from biological processes, as well as those formed through abiotic and biotic reactions in soil.

Key Biochemical Parameters of Humic Substances

The below table highlights the key interplay of the biochemical characteristics of humic substance, particularly molecular weight and how this influences the fertilising properties of the substances.

	0		0.	•	
Humin		Humic Acid		Fulvic Acid	
Molecular weight		1		L.	
decreasing	(^	γ	~	
10,000,000	100,000		10,000		1000
Carbon content (g/kg) decreasing					
550	620	560	520		430
330	020	500	520		450
					\rightarrow
Nitrogen content (g/kg)					
decreasing					
46	55		43		7
					\rightarrow
Cation exchange capacity (c					
mol/kg)					
and acidity increasing					
100	300		500		1000
Oxygen content (g/kg)					
increasing					
340	290	360	440		510
0.0	230	000			
Hydrogen content (g/kg)					
variable					
55	29	67	33		50
			-		
Fertilizer properties - plant					
response increasing					
Slow response		Mid-response		Rapid Response	

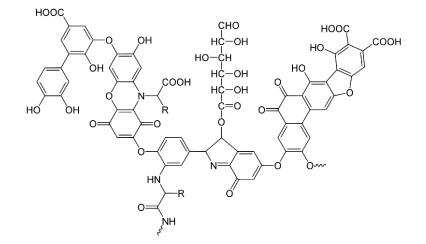
Modified from Dixon, J. B. and S. B. Weed, 1989. Page 95 In "Minerals in Soil Environments" Soil Science Society of America, Madison, Wisconsin

Humins

Humins constitute a portion of humic substances that remain insoluble in both alkaline (high pH) and acidic (low pH) conditions, as well as in water regardless of pH. Characterized by their large molecular weights, ranging from approximately 100,000 to 10,000,000 AMU, humins contrast with carbohydrates, which typically have molecular weights ranging from about 500 to 100,000 AMU. Despite ongoing research, the chemical and physical properties of humins are only partially understood. Within soil environments, humins exhibit significant resistance to decomposition, making them the most durable among the humic substances. Their presence plays crucial roles in enhancing soil properties such as water retention, structural integrity, stability, cation exchange capacity, and overall fertility. As a result, humins emerge as important constituents for sustaining fertile soils.

Humic Acids

Example humic acid



Humic acids (HAs) comprise a mixture of weak aliphatic (carbon chains) and aromatic (carbon rings) organic acids which are not soluble in water under acid conditions but are soluble in water under alkaline conditions. Humic acids consist of that fraction of humic substances that are precipitated from aqueous solution when the pH is decreased below 2. Humic acids are termed polydisperse because of their spectrum of chemical features. They tend to be considered flexible linear polymers that exist as random coils with cross linked bonds. Typically, 35% of the humic acid molecules are aromatic, while the remaining structures are in the form of aliphatic moieties. The molecular size of humic acids range from approximately 10,000 to 100,000 AMU. Humic acid polymers readily bind clay minerals to form stable organic clay complexes. Peripheral pores in the polymer are capable of accommodating (binding) natural and synthetic organic chemicals in a lattice (clathrate) type arrangement.

Humic acids readily form salts with inorganic trace mineral elements. Literature studies of extracts of naturally occurring humic acids have identified the presence of over 60 different mineral elements. These trace elements are bound to humic add molecules in a form that can be readily utilized by various living organisms. As a result, humic acids function as important ion exchange and metal complexing (chelating) systems.

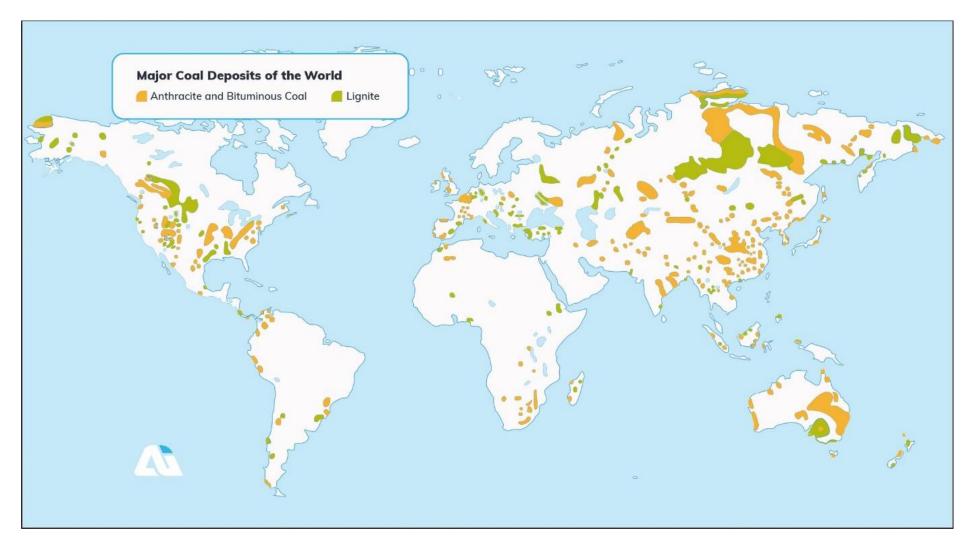
Fulvic Acids

Fulvic acids (FAs) are a mixture of weak aliphatic and aromatic organic acids which are soluble in water at all pH conditions (acidic, neutral and alkaline). Their composition and molecular structure is often varied. The size of fulvic acids are smaller than humic acids, with molecular weights which range from approximately 1,000 to 10,000 AMU. Fulvic acids have an oxygen content around twice that of humic acids, and they typically have many carboxyl (COOH) and hydroxyl (COH) groups, therefore fulvic acids (FAs) are much more chemically reactive. The ionic exchange capacity of fulvic acids is more than double that of humic acids. This high exchange capacity is due to the total number of carboxyl (COOH) groups present. The number of carboxyl groups present in fulvic acids ranges from 520 to 1120 cmol (H⁺)/kg. Analysis of fulvic acids collected from a range of sources indicated no evidence of methoxy groups (OCH3) groups, they are low in phenols, and are less aromatic compared to humic acids from the same sources.

Because of the relatively small size of fulvic acid molecules they can readily enter plant roots, stems, and leaves. As they enter these plant parts they carry trace minerals from plant surfaces into plant tissues. Fulvic acids are therefore key ingredients of foliar fertilizers. Foliar spray applications containing fulvic acid mineral chelates, at specific plant growth stages, can be used as a means to boost a range of plant health outcomes including yield, quality and overall resistance to abiotic and biotic stress. Fulvic acids are the amongst the most effective carbon containing chelating compounds known and due to their plant compatibility, they have seen considerable interest from the biostimulants industry.

Lignite Deposits of the World

Lignite (brown coal) is a key source of fulvic acids. The below map indicates the proven reserves in the world.



Lignite (brown coal) Production 2022		
Country	Million tons	
China	325.0	
Indonesia	140.0	
Germany	130.8	
Russia*	89.0	
Turkey	80.9	
Poland	54.6	
India	44.8	
USA	43.1	
Australia	39.1	
Bulgaria	35.5	

* Soft brown coal also includes sub-bituminous coal.

China remained the world's largest coal and lignite producer in 2022, accounting more than for half of supply (51% in 2022) and its share is growing (+4% points since 2019), followed by India (11%) and Indonesia (8%).

When looking at the proven reserve data above, China produced around 325 million tonnes of lignite in 2022 from a proven reserve of 7,968 million tonnes. This equates to approximately 4% of the current proven reserves. If this rate of production continues then the country would have used all of its proven reserve estimate by around 2050.

Proven Coal Reserves			
	Subbituminous & Lignite		
Country	Proven Reserve (mT)	%	
Russia	90,730	28.40%	
Australia	76,508	23.90%	
Germany	36,100	11.30%	
United States	30,052	9.40%	
Turkey	10,975	3.40%	
Indonesia	10,878	3.40%	
China	7,968	2.50%	
Serbia	7,112	2.20%	
New Zealand	6,750	2.10%	
Poland	5,937	1.90%	
Brazil	5,049	1.60%	
India	4,895	1.50%	
Greece	2,876	0.90%	
Pakistan	2,857	0.90%	
Hungary	2,633	0.80%	
Czech Republic	2,547	0.80%	
Ukraine	2,336	0.70%	

Biostimulants: Humic Substances

Canada	2,236	0.70%
Bulgaria	2,174	0.70%
Mongolia	1,350	0.40%
Thailand	1,063	0.30%
Spain	319	0.10%
Vietnam	244	0.10%
Mexico	51	0.02%
World	319,879	100.0%

Source German Federal Institute for Geosciences and Natural Resources (BGR)

British Petroleum (BP) defines "total proved reserves of coal" as "generally taken to be those quantities that geological and engineering information indicates with reasonable certainty can be recovered in the future from known reservoirs under existing economic and operating conditions" Therefore, like oil reserves, coal reserves can vary with coal and carbon prices defining ultimately what is economically extractable, and leading to various definitions of what constitutes a "reserve".

In contrast to internationally traded commodities, like hard or soft coal, lignite is typically not transported over long distances from its mining location due to its relatively low value compared to transportation expenses. As a result, lignite does not have a standardised national price. For instance, the costs of lignite within India exhibit significant variation.

Production Methodology

Humic and fulvic acids are extracted from soil and other solid phase sources into a strongly basic aqueous solution of sodium hydroxide or potassium hydroxide.

- Humic acids are precipitated from this solution by adjusting the pH to 1 with hydrochloric acid.
- The alcohol-soluble portion of humic fraction is typically identified as ulmic acid.
 - \circ $\;$ So-called "grey humic acids" (GHA) are soluble in low-ionic-strength alkaline media.
 - "Brown humic acids" (BHA) are soluble in alkaline conditions independent of ionic strength
- Fulvic acids is left in solution at pH 1. They remain soluble independent of pH and ionic strength.
- Humin is insoluble in dilute alkali.

Regulatory Situation

Europe

Regulation has been poorly defined for biostimulants. However, under the new European fertiliser regulation (EU fertiliser Regulation 2019/1009), PBSs (plant biostimulants) are classified as fertilisers, except those that are also pesticides, whereas PGRs (plant growth regulators) are classified as pesticides. In the US, PBSs are likely to be classified separately from fertilisers; however, this issue is still in discussion.

The EU enforced the Fertilising Products Regulation (EU n°2019/1009) in July 2022, which defines and establishes processes for biostimulant approvals, including requiring efficacy testing to show that the product has biostimulant effects and is not just a fertiliser. This highlights a critical development in defining plant biostimulants by their function, not their ingredients.

Biostimulants are regulated for the whole EU market alongside national regulations with two routes for placing PBSs on the market:

- National: Gain national registration, then seek mutual recognition with other member states.
- **EU:** Gain EU-wide registration and 'CE' mark for sale across the whole of the EU.

By including biostimulant products and explicitly excluding them from EU plant protection products, Regulation 1107/2009 closes a regulatory gap by bringing biostimulants under harmonised rules from June 2022. However, it simultaneously opens another gap, mainly because the official definition of biostimulants (i.e. those eligible for registration under the EU framework in the future) is mainly legal and regulatory, not scientific.

Many plant processes are active in abiotic and biotic defence mechanisms, meaning that dual-use products may now fall under the sole claim of biotic functionality. This could lead, for example, to requirements to register products previously marketed under the national fertiliser laws as 'biostimulants' under the plant protection product framework. If a product is effective only against abiotic stress, it does not fulfil the criteria of the plant protection regulation. This is exemplified by products containing the *Trichoderma* species, which, in many cases, have been marketed as a biostimulant, plant, or soil amendments but may now have to be authorised as a plant protection product due to their fungicidal action.

Dual-action products against abiotic and biotic stress may be eligible for registration under the plant protection framework because respective substance/product categories, such as 'elicitor' or 'plant activator', are already included in and covered by Regulation 1107/2009.

The current impact on timescales is unknown due to the relatively recent introduction of this new regulation. Still, limited capacity due to the process of establishing assessment standards within Conformity Assessment Bodies (CAB), also known as Notified Bodies (NBs), has taken longer than expected. Therefore, to date, only a handful of accredited CABs are ready to act in reviewing and approving new product dossiers. Registration fees are currently around €100,00 to €500,000.

USA

Historically, the registration of biostimulants has been far less advanced. However, in 2022 the US introduced the Plant Biostimulant Act, which defines biostimulants as:

a substance, microorganism, or mixture thereof, that, when applied to seeds, plants, the rhizosphere, soil, or other growth media, act to support a plant's natural processes independently of the biostimulant's nutrient content, including by improving nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality, or yield.

The act aims to harmonise the US and EU definitions, set a national framework for registering biostimulants, and more accurately describe benefits on product labels. The regulation also aims to:

- Develop a model bill for use across states to streamline the registration process.
- Educate growers on the benefits of biostimulants for soil health, sustainability, and climatesmart agriculture opportunities.
- Achieve regulatory clarity from the EPA regarding existing regulations, including defining plant growth regulators within FIFRA.

The EPA intends to distinguish plant biostimulants from PGRs, with PBS defined by the exclusion method as a substance or microorganism that does not conform to the definition of a PGR under FIFRA, aiming to remove previous ambiguity of where products fall. In the US, fertilisers are regulated by the US Department of Agriculture (USDA), whereas pesticides, including PGRs under FIFRA, are regulated by the EPA. For example, an algae extract is considered a PGR and is regulated under FIFRA by the EPA; therefore, the registration requirements for algae extract are similar to those for pesticides.

In November 2024, the EPA released draft guidance for plant regulator products and claims, including plant biostimulants. The aim of this draft guidance is to more clearly define which components are considered plant regulators and, therefore, subject to regulation as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136–136y.

Although FIFRA does not define the term plant biostimulants, some products being sold as plant biostimulants may trigger regulation under FIFRA as plant regulators. Other plant biostimulant products will not require registration as a pesticide under the plant regulator definition outlined in FIFRA section 2(v), or because they do not fit within the specific functionality definitions provided under FIFRA regarding plant regulator function.

Products which are not considered to be plant growth regulators and are therefore excluded from registration under FIFRA:

- Plant nutrients and trace elements: Plant nutrients and trace elements, which can be considered as falling under the umbrella term "fertilizers," are described in EPA's FIFRA regulations as "plant nutrient product[s] consisting of one or more macronutrients, or micronutrient trace elements necessary to normal growth of plants and in a form readily useable by plants" [40 CFR 152.6(g)(1)].
- **Plant inoculants**: Plant inoculants are "...product[s] consisting of microorganisms to be applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system" [40 CFR 152.6(g)(2)].
- **Soil amendments**: Soil amendments (which include soil additives and soil conditioners) are "...product[s] containing a substance or substances intended for the purpose of improving soil characteristics favorable for plant growth" [40 CFR 152.6(g)(3)].
- Vitamin-hormone products: Under FIFRA section 2(v), "the term 'plant regulator' shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, non-poisonous in the undiluted packaged concentration." Per 40 CFR 152.6(f), "vitamin hormone products" are further described as follows:
 - "A product consisting of a mixture of plant hormones, plant nutrients, inoculants, or soil amendments is not a "plant regulator" under Section 2(v) of FIFRA, provided it meets the following criteria:
 - The product, in the undiluted package concentration at which it is distributed or sold, meets the criteria... for Toxicity Category III or IV; and
 - The product is not intended for use on food crop sites, and is labelled accordingly.

During registration of both plant growth regulators and biostimulants, the claims made by the registrant, and on the product label are also considered by the EPA as part of its evaluation of the appropriate regulatory pathway. However, it should be noted that the EPA does not solely look at the claims made. Products that contain an active ingredient consistent with pesticidal/plant growth regulator usage will be registered as such regardless of how the registrant makes claims for its use. Similarly, if a biostimulant product claims pest-control properties, it will be considered as a pesticide under FIFRA.

The EPA outlined in this draft guidance document, example claims that may exclude a product from registration as a pesticide under FIFRA. These are not exhaustive, and as mentioned previously, if the active ingredient is consistent with a pesticidal active then it will be registered as such. The examples provided relate specifically to **plant nutrition-based claims**, **plant inoculant-based claims** and **soil amendment-based claims**. These can generally be summarised as modalities that *indirectly* support crop health, such as correcting nutrient deficiencies in the soil, optimising conditions for abiotic stress tolerance, soil structure/biodiversity, and increases to nutrient availability/uptake (e.g. through promoting root growth, nutrient solubilisation etc). The claims made by vitamin-hormone products need to be considered more carefully given that they are considered by the agency to contain components that can be considered as regulating plant physiological processes.

Plant regulator claims may be made for vitamin-hormone products when they meet both criteria for exclusion from the plant regulator definition, as specified under 40 CFR 152.6(f)(1) & (2).

This means that the product is considered 'non-toxic' but crucially also not for use on food crops, which means this exclusion has no relevance for agriculture beyond non-crop uses such as turf and ornamentals.

The guidance document goes on to discuss the definition of a plant growth regulator.

A naturally occurring substance would be considered a "plant regulator," and a product label claim would be considered a "plant regulator claim" if:

The substance or mixture of substances, through physiological action:

- 1. Accelerates or retards the rate of plant growth;
- 2. Accelerates or retards the rate of plant maturation;
- 3. Or otherwise alters the behaviour of plants or the produce thereof;

<u>and</u>

if the substance or mixture of substances does not fall under one of the exclusion categories listed in 40 CFR 152.6(f) & (g) as vitamin-hormone products, plant nutrients, plant inoculants or soil amendments; or under 40 CFR 152.8(a) as a fertilizer.

Plant regulator claims may be made for vitamin-hormone products when they meet both criteria for exclusion from the plant regulator definition, as specified under 40 CFR 152.6(f)(1) & (2). When claims for increased or decreased growth, yield, germination, maturation, etc. are consequent to intended uses of products or substances as plant nutrients (fertilizers), plant inoculants, soil amendments, and/or as other non-pesticidal uses, such products and substances may be excluded from regulation under FIFRA in the absence of any plant regulator claims.

This would imply that plant nutrients, plant inoculants or soil amendments that <u>do</u> have plant growth regulating capabilities and/or claims would be excluded from FIFRA registration, provided that they meet the requirements of the above exclusions, and have at least some 'non-plant growth regulating claims'. The exception here is that this doesn't apply for vitamin-hormone products used in food crops.

Examples of active ingredients that are considered to have no other usage other than as plant growth regulators and therefore pesticides under FIFRA include (but not limited to):

- Auxins
- Cytokinins
- Gibberellins
- Ethylene
- Abscisic acid

Other substances that may be included in this category include:

- Corn glutens
- L-Glutamic Acid (LGA) and gamma-Aminobutyric Acid (GABA)
- Homobrassinolide and other brassinosteroids
- Lysophosphatidylethanolamine (LPE)
- 1-Octanol
- Sodium o-nitrophenolate, sodium p-nitrophenolate, and sodium guaiacolate

There are numerous substances that may have plant regulator activity, as well as additional modes of action, not considered to be plant regulator modes of action that may include, but are not limited to:

- Abiotic stress tolerance
- Water and nutrient use efficiency/uptake;

• Nutrient availability - increased availability of inorganic nutrients in the soil to plant roots and seeds; improving biotic and abiotic characteristics of soils

Examples of these include:

- Seaweed extracts (SWE)
- Complex Polymeric Polyhydroxy Acids (CPPAs) and Humic Acids (HAs)

Both of these categories of active ingredients are generally understood to have direct physiological effects on growth, yield, maturation, and produce quality.

The Agency also recognizes that not all uses of PBS may be intended for plant regulator or other pest control purposes. If it can be demonstrated that a particular product has the activity claimed on the product label (and any other informational media) and does not make any plant regulator or pest control claims on the product label (and any other informational media) it may be excluded from FIFRA regulation.

Therefore, a natural product such as seaweed extracts and humic substances will be excluded from registration as a pesticide, provided that the product does not claim plant regulator activity, and claims activity under the plant health examples cited in the guidance document (Tables 1a-c and 2), or those analogous to those non-exhaustive examples.

Finally, the document also outlines how other 'conventional' components in the mixture should be considered, as well as components generated as a result of the extraction process.

If a conventional chemical plant regulator is contained within a PBS product, the product likely would be considered a conventional chemical pesticide by the Agency and would be subject to registration under FIFRA.

Novel substances may be present in plant biostimulant products that were not present in the original plant source material, but were formed as a result of the extraction methods and/or post-extraction processing but will require further scrutiny under FIFRA by the Agency to determine if they have the potential for pest control and/or plant regulator activity.

In summary, the guidance document outlines the importance of understanding the mode of action of the components in the product and associated claims, including the ability to produce performance data supporting such claims. Plant growth activity alone will not permit registration as a biostimulant, and companies must have an awareness of the physiological responses of the product and make sure that label claims, and those made in the process of regulation align with this.

Brazil

Under the first Fertilizer Law of 1980 (6.894/1980) and subsequent decree number 4.954/2004, fertilizers were defined as "mineral or organic substances, natural or synthetic, that provide one or more plant nutrients". For biofertilizers, Brazilian legislation previously utilised two definitions:

- (i) Inoculants: products containing micro-organisms that have a favourable impact on plant growth
- (ii) Biofertilizers: products containing an active ingredient or organic agent, free from agrochemical substances, capable of acting directly or indirectly on all or part of cultivated plants, enhancing their productivity, regardless of their hormonal or stimulant value

The generally vague definitions and regulation of biostimulants has in the past generated uncertainties for companies wishing to enter the market and represented a challenge surrounding grower confidence in product efficacy, composition, and quality assurance. However, few barriers have existed to introducing a biostimulant product into the market. There have been steps in 2024 to update and clarify the legislation under the 'Bioinputs Law'.

On December 23, 2024, Law No. 15,070/2024 ('Bioinputs Law'), which regulates the production, use, and commercialisation of bioinputs in the agricultural sector, was published in the Official Gazette. The new law regulates the production, use, and commercialisation of bioinputs for agricultural,

The Bioinputs Law defines a bioinput as: product, process or technology of plant, animal or microbial, including that originating from a biotechnological process, or structurally similar and functionally identical to that of natural origin, intended for use in production, protection, storage and processing of agricultural products or in production systems or planted forests, which interferes with the growth, development and response mechanism of animals, plants, microorganisms, soil and derived substances and that interact with the products and physical-chemical and biological processes.

Bioinputs include those "used in agricultural activity, including biostimulators or growth or performance inhibitors, semiochemicals, biochemicals, phytochemicals, metabolites, organic macromolecules, agents biological control products, soil conditioners, biofertilizers and inoculants."

However, the updated pesticide law stops short of defining each of these categories in detail.

livestock, aquaculture, and forestry use in Brazil, whilst also promoting the production and adoption of such products.

Argentina

Biostimulants and organic-chemical fertilisers must also be registered through SENASA. The general fees required for registration are relatively low compared to other markets, such as North America and Europe. However, this is more than offset by the level of complexity, the current lack of a fast-track registration process, and the generally lower levels of capacity and regulatory expertise required for a more expedited future process.

In November 2024, the government announced that all phytosanitary and bioinput procedures were centralised through an online platform known as SIGTrámites. On this platform users can register their products, facilitate self-management, gain insights on process traceability, reduce processing times, gain support, boost communication and make online payments. The platform may be used for newly formulated phytosanitary products, registration requests for prioritised items and registration requests for bio-inputs for plant nutrition.

China

In China, biostimulants are currently regulated through NY/T 3831-2021 Organic Water-Soluble Fertilizers-General Regulations; biostimulants are regulated alongside fertilisers and treated as microbial fertilisers or organic water-soluble fertilisers. This is overseen by the Chinese Ministry of Agriculture and Rural Affairs. The current regulation provides improved definitions that resolve biostimulant products' previously ambiguous legal status. Additionally, the regulation offers a premarketing procedure, product classifications, general rules on raw materials, nutrient contents, and labelling requirements.

The key product classes, such as inoculants and rhizobia, are registered under microbial fertilisers. Other biostimulants, such as chitosan, are listed under 'Water-soluble fertilisers':

- WSF containing amino acid.
- WSF containing humic acid.
- Organic WSF containing alginic acid.
- Organic WSF containing chitosan.
- Organic WSF containing polyglutamic acid.
- Organic WSF containing polyaspartic acid.
- Other WSF containing molasses, low-value fish and its fermented products, as well as other organic materials.

Overseas applicants must follow several requirements, including using a Chinese agent for application. This involves supplying critical information on product properties. Depending on raw materials, manufacturing processes, and end uses, toxicity tests and efficacy trials are sometimes required. These generally have lower requirements than urea, ammonium nitrate, and other fundamental nutrition products; therefore, they do not require technical review for registration. Following these tests, a technical permit is granted for commercialisation.

Japan

Japan does not legally define biostimulants, which are registered under the Fertiliser Control Law or Soil Fertility Enhancement Act. MAFF's 'Green Food System Strategy' targets a reduction in the use of chemical fertilisers. However, several products considered biostimulants are broadly used with registration under the Fertiliser Control Law or Soil Fertility Enhancement Act.

In response to the amendment of the Fertiliser Regulation in the EU, an industry group in Japan has been established to actively promote communication with the competent authorities to facilitate the standardisation of biostimulants. With its new 'Green Food System Strategy', MAFF targets reducing chemical fertiliser use by recognising biostimulants as a valuable tool to lower fertiliser inputs and reduce environmental impacts. The Japanese Crop Protection Association has announced that the industry will proceed with developing biostimulants to support this strategic goal.

India

India's biostimulant definition is broadly aligned with that of the EU. Biostimulants are currently regulated through Fertiliser Control Order (FCO), which defines biostimulants as:

...a substance or micro-organism or a combination of both whose primary function when applied to plants, seeds or rhizosphere is to stimulate physiological processes in plants and to enhance its nutrient uptake, growth, yield, nutrition efficiency, crop quality and tolerance to stress, regardless of its nutrient content, but does not include pesticides or plant growth regulators which are regulated under the Insecticide Act, 1968.

India's Fertilizer (Inorganic, Organic or Mixed) (Control) Amendment Order was introduced in 2021. These new regulations require manufacturers to register products with the relevant authority providing a set of information on chemistry (composition, analytical methods, shelf-life), bio-efficacy trials conducted by the Indian Council of Agricultural Research (ICAR), state agricultural universities (SAUs) (preferably in agro-ecological zones), and toxicity data and heavy metal analysis.

The regulations also establish a regulatory body to monitor the end-to-end movements within the industry. The committee controls the quality and specifications of all biostimulants, and ensures the use of safe substances and organic compounds in product manufacturing.

Farming-related services and speciality products dominate the Indian agrochemical landscape. The Federation of Indian Chambers of Commerce & Industry (FICCI) categorises biostimulants under the latter category alongside micronutrients, biopesticides, and biofertilisers that have recently begun to permeate the markets.

In May 2024 the Indian Union Ministry of Agriculture and Farmers Welfare issued a new amendment to the Fertilizer (Inorganic, Organic or Mixed) (Control) Order, 1985. Titled the 'Fertilizer (Inorganic, Organic or Mixed) (Control) (Third) Amendment Order, 2024,', the issue is intended to regulate the specifications and approval process for biostimulants in the agricultural sector. Key provisions of the amendment include:

- Increased specifications for biostimulant products, including their name, active ingredient or tracer molecule, chemical composition (in cases where active ingredients or tracer molecules cannot be indicated), and the name of the crop to which they are applied.
- The introduction of a new category for live microorganisms, excluding biofertilisers and biopesticides, within the specifications for biostimulants.
- Alterations to the application for new biostimulants, including the submission of data regarding categories, such as chemistry, bio-efficacy trials, toxicity, heavy metal analysis, and a product sample accompanied by an affidavit affirming compliance with pesticide limits.
- Toxicology data exemptions for certain biostimulants, such as protein hydrolysates, seaweed extracts, amino acids, vitamins, humic and fulvic acid.
- Alterations to pesticide limits within biostimulant products, set at 1 part per million (ppm), replacing the previous limit of 0.01 ppm.

The amendment aims to provide a framework for regulating and approving biostimulants in agriculture to ensure their safety, efficacy, and adherence to specified standards.

Company Involvement

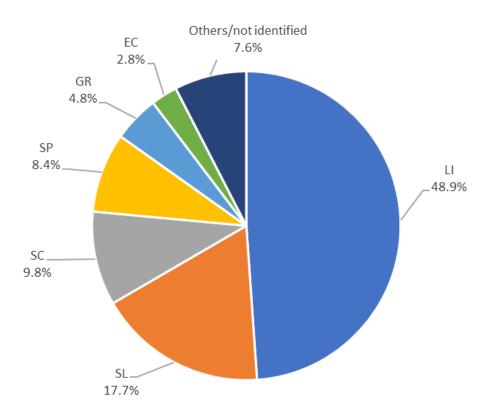
The below table(s) on key active ingredients and key companies is derived directly from AgBioInvestor's exclusive primary market research study that surveyed biological- and biostimulantgrowers, which were conducted for the first time in 2023 and profiled the 2022 agricultural market. The market research surveyed many key agricultural markets for biologicals, including: USA, Mexico, Chile, Brazil, Argentina, France, Italy, Spain and Turkey. The Ais have been ranked by farm-gate value (\$m.). Quantification of these data and much more biological market research can be found in the separate subscription product AgbioInsight.

AI	Key Companies
Humic acid	Sipcam-Oxon
	Timac Agro
	Fagro
	Delta
	Cengiz Tarim
	Grupo Bioquimico Mexicano
	Rigrantec
	Actagro
	UPL
	JH Biotech
	Afepasa
	Biobizz
	Dunya
	Advancing Eco Agriculture
	Biofermex
	Atlantica Agricola
	AgriFarm
	Ag Logic
	Arvensis
Humic substances	Agrochimica
	Agrivalle
	Timac Agro
	Nutrelic
	Rovensa (Tradecorp)
	Loveland
	SuperBAC Bio Technology Solutions
	Agronutrition
	Kimitec
Fulvic acids	Timac Agro
	Fagro
	Aminochem
	UPL
	Bayer
	Cengiz Tarim
	Diagro
	Adama

Afepasa
Biobizz
Atlantica Agricola
Ag Logic
Bures
Arvensis
Iberfol
Agrylap
Rovensa (Tradecorp)
Coda
Nutrelic
Biosustenta

Formulation Types – Value Share

The below chart(s) are derived from the biological focussed market research that AgbioInvestor conducted, and illustrates the value share attributed to various formulation type codes.



Code	Description	Code	Description
AE	Aerosol dispenser	LI	Liquid
AL	Other liquids to be applied undiluted	LS	Solution for seed treatment
СВ	Bait concentrate	ME	Micro emulsion
CS	Capsule suspension	OD	Oil dispersion
DC	Dispersible concentrate	SC	Suspension concentrate
DF	Dry flowable	SL	Soluble concentrate
DP	Dustable powder	SP	Water soluble powder
EC	Emulsifiable concentrate	VP	Vapour releasing product
EW	Emulsion, water in oil	WG	Water dispersible granule
FS	Flowable concentrate for seed treatment	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment
LC	Liquid concentrate		

Research and Development

Due to the character of humic and fulvic acids, the rate of innovation is perhaps lower than for microbial amendments where a large number of new strains can be discovered and optimised through gene editing and other genomic techniques. Likewise in seaweeds, there are some new species that can be utilised. Humic acids and fulvic acid research and development has mostly centred around the optimisation of extraction and production methods, such as solvents, temperatures and processes. As these products are more commoditised than other biostimulants due to their production from commodity feedstocks such as brown coal and composts, any efficiencies that can be realised in the production process can only benefit the innovating company's bottom line.

Formulation enhancements to boost storage and shelf life through optimisation of parameters such as pH, particle size solvents and the use of adjuvants are another area of active research. Particle size is also crucial in influencing the end activity of the product, particularly down to the diverse range of molecular masses of the humic and fulvic acids present. Consistency of product supply also boosts the confidence growers will have in a given company's products.

Further research is also need around the optimum timing and usage parameters of humic substances, since incorrect usage can actually lead to yield penalties. This includes exploring different application techniques such as foliar spraying, fertigation, and soil drenching, as well as synergies with other biostimulants and plant nutrients.

Market Outlook

The humic substance segment is likely to grow at a broadly similar rate compared to that of the seaweed segment due to comparable use case scenarios. However, due to the significant deposits of brown coal (lignite) in countries such as China, and the strong domestic push towards food security in that market, humic substances growth is likely to be at a slightly faster rate compared to seaweed extracts.

Also like the seaweed extract segment, humic acids will benefit from usage to improve soil structure, soil microbiomes, root structure and reduction in fertiliser applications. Due to the high-volume, low-margin nature of brown coal deposits, it is most likely that product will find the best market fit closer to end-markets, another reason why the Chinese market for fulvic and humic acids is so strong and expected to drive future growth.

Some of the downsides to use of humic acids includes the fact that humic acid based biostimulants can vary significantly in quality and both acid and mineral composition, depending on their source and processing methods. This inconsistency can lead to unpredictable results in agricultural applications, which could harm the uptake of products in the longer term. The use of humic and fulvic acids and their effectiveness is also influenced by soil type, weather conditions, and also the crop and cultivation practices. This further underlines the need for a robust partnership with agronomists and also further research on optimal usage, to prevent a yield penalty being realised.

The quality of the source material also needs to be carefully considered to ensure that it does not contain heavy metals or other contaminants. The cost of humic acid products may also be prohibitive for some growers, particularly in markets that are farther from the feedstock leonardite deposits. The environmental impact of mining also needs to be addressed, such that the downstream benefits of humic substances are not being offset by the upstream mining impacts. There are of course other sources of humic acids such as green wastes that utilise a different source of material.

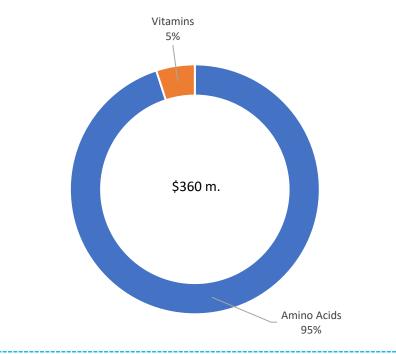
There are also a vast number of companies active in China producing humic substances such as humic acids and fulvic acids, perhaps unsurprisingly given that the country has one of the most significant leonardite deposits. There is the potential for oversupply to enter the market, leading to both consolidation of the Chinese biostimulants suppliers, but also for some companies to leave the market due to profitability issues in what is potentially the most commoditised biostimulant segment.

Taking this into account the humic substances segment is forecast to grow at a rate of +14.6% p.a. to \$2,111 million between 2023 and 2028.

Biostimulants: Vitamins and Amino Acids

Sales Performance of Biostimulants: Vitamins and Amino Acids		
Year	Vitamins and Amino Acids Biostimulant Sales (\$ m.)	Share of Biostimulants Segment %
2017	212	10.4
2021	360	10.2
2022	385	10.1
2027F	642	10.4
1-yr Change (%)	6.9	
5-yr CAGR (% p.a.)	12.6	
5-yr CAGR F (% p.a.)	10.8	

Leading Products, 2022



2022 market research data have been included in this report for context and will be updated in future iterations of this report once we have sufficient uptake of proposed future syndicated Bio MR studies. AgbioInvestor analyses multiple sources in addition to this to produce the current market year (2023) data.

Sales of the Leading Sub-Segments 2022		
	Sub-Segment	2022 \$m.
	Amino Acids	342
	Vitamins	18
Vitamins and Amino Acids Total		360

Introduction

Amino acid biostimulants play important roles in photosynthesis, enhancing nutrient uptake, stress defence, pollination, and fruit formation. They also serve as precursors to hormones and growth factors. Protein hydrolysates derived from both plant and animal sources are important sources of amino acids.

This segment definition also includes vitamins which although not essential for plant growth are highly useful in protecting plants against a wide range of biotic and abiotic stresses, including water stress, ozone, UV light, salinity and disease resistance.

A major source of protein hydrolysates is the leather tanning industry which produces significant amounts of collagen as a waste product. However, this can be utilised as a protein that can be hydrolyzed into valuable amino acids, peptides and compounds for agricultural use.

Products

Amino acids can be applied as foliar sprays, soil amendments, or fertigation supplements boost the plant's access to nitrogen and other essential nutrients. In turn they can be used to stimulate plant growth, root development, and nutrient uptake efficiency (such as calcium, magnesium, iron, and zinc), within plants, as well as improving abiotic stress tolerance.

Another key benefit of amino acids in agriculture is that they can contribute to favourable soil health by promoting microbial activity, organic matter decomposition, and nutrient cycling in the rhizosphere. They can also serve as energy sources for beneficial soil microbes, leading to greater microbial biodiversity and better soil structure, as well as stimulating the release of plant-available nutrients from organic matter.

Amino acids are also of utility in seed treatments where they can be used to improve seed germination rates, uniformity, and seedling vigour through the activation metabolic processes and the mobilisation of energy and nutrient reserves. This then fosters early seedling growth, quicker emergence, establishment, and improved crop stand.

Amino acids can be combined with conventional fertilisers to enhance their efficiency and reduce nutrient losses through leaching, volatilisation, or fixation. Couple this with the nitrogen fixing potential of many microbial amendment biostimulants and other classes that boost nutrient availability and uptake, this can then lead to a creation of novel classes of biostimulant product mixtures that can address the need to lower exogenous chemical fertiliser applications.

Amino acids are useful in some post-harvest settings where they can extend the shelf life and improve the post-harvest quality of fruits, vegetables, and ornamental crops through the regulation of ethylene production, delayed senescence and ripening processes.

Amino Acids	
Element	Activity
Glutamine	Stimulates plant growth and increases tolerance to adverse climate conditions. It is also an important precursor in the production of new amino acids. It plays a role in enhancing nutrient-uptake and nitrogen-assimilation pathways.
Serine and Valine	Improve plant resistance mechanisms to adverse conditions; improve fruit and grain quality.
Lysine	Active and essential in the stimulation of photosynthesis; important in the response to abiotic and biotic stresses through the sacharopine pathway. Enhances germination.
Arginine	A precursor to cytokinin production involved in cell growth, auxiliary bud growth, and leaf senescence.
Aspartate	Plays a role in many metabolic processes.
Methionine	Increases crop yield and quality; active in metabolic responses that assist plants in adapting to diverse environmental conditions; serves as a precursor in ethylene production to induce ripening. Enhances germination.
Tryptophan	Precursor in the synthesis of auxins.
Tyrosine	Required for the synthesis of proteins and metabolites with diverse physiological functions, such as antioxidants, pollinator attractants (betalain), and inducers of secondary metabolism-defence compounds (rosmarinic acid, dhurrin, and benzylisoquinoline alkaloids).
Proline	Increases pollen fertility.
Leucine and Alanine	Improve fruit and grain quality.
Cysteine	Plays a role in plant tolerance to heavy metals through chelation and binding.
Glycine	Results in higher leaf concentrations of nitrogen, potassium, magnesium, and zinc, resulting in higher chlorophyll levels.

Vitamins	
Element	Activity
Vitamin C	Helps protect the plant against water stress, ozone and UV radiation. It is used in the photosynthetic process; it can regulate cell growth (Smirnoff and Weelet, 2000) and serves as a redox buffer. However, excess Vitamin C can have a negative impact in plant growth (Quian et al. 2014).
Vitamin B1	Is an antioxidant that helps protect plants from different environmental stresses like salinity (Sayed and Gadallah 2002). It can improve plant resistance against bacterial, fungal and viral infections (Ahn et al, 2005). It plays an important role in tissue culture media. There is a myth that Vitamin B1 stimulates root growth or reduces transplant shock, but there is no scientific evidence to prove that.
Vitamin B2	Is used for plant protection against diseases. It acts as an antioxidant and it promotes plant growth.
Vitamin B3	Niacin and niacinamide are water-soluble B vitamins of the B group that reduces the oxidative stress of the plant and increases the CO ₂ biosynthesis capacity
Vitamin B6	Creates resistance against plant diseases (Zhang et al, 2015) and it acts as an antioxidant.
Vitamin E	Researchers from the University of Toronto and Michigan State University found that Vitamin E helps with water and nutrient transport under cold conditions.
Vitamin K	Is an antioxidant that plays an important role in photosynthesis.

Regulatory Situation

Europe

Regulation has been poorly defined for biostimulants. However, under the new European fertiliser regulation (EU fertiliser Regulation 2019/1009), PBSs (plant biostimulants) are classified as fertilisers, except those that are also pesticides, whereas PGRs (plant growth regulators) are classified as pesticides. In the US, PBSs are likely to be classified separately from fertilisers; however, this issue is still in discussion.

The EU enforced the Fertilising Products Regulation (EU n°2019/1009) in July 2022, which defines and establishes processes for biostimulant approvals, including requiring efficacy testing to show that the product has biostimulant effects and is not just a fertiliser. This highlights a critical development in defining plant biostimulants by their function, not their ingredients.

Biostimulants are regulated for the whole EU market alongside national regulations with two routes for placing PBSs on the market:

- National: Gain national registration, then seek mutual recognition with other member states.
- **EU:** Gain EU-wide registration and 'CE' mark for sale across the whole of the EU.

By including biostimulant products and explicitly excluding them from EU plant protection products, Regulation 1107/2009 closes a regulatory gap by bringing biostimulants under harmonised rules from June 2022. However, it simultaneously opens another gap, mainly because the official definition of biostimulants (i.e. those eligible for registration under the EU framework in the future) is mainly legal and regulatory, not scientific.

Many plant processes are active in abiotic and biotic defence mechanisms, meaning that dual-use products may now fall under the sole claim of biotic functionality. This could lead, for example, to requirements to register products previously marketed under the national fertiliser laws as 'biostimulants' under the plant protection product framework. If a product is effective only against abiotic stress, it does not fulfil the criteria of the plant protection regulation. This is exemplified by products containing the *Trichoderma* species, which, in many cases, have been marketed as a biostimulant, plant, or soil amendments but may now have to be authorised as a plant protection product due to their fungicidal action.

Dual-action products against abiotic and biotic stress may be eligible for registration under the plant protection framework because respective substance/product categories, such as 'elicitor' or 'plant activator', are already included in and covered by Regulation 1107/2009.

The current impact on timescales is unknown due to the relatively recent introduction of this new regulation. Still, limited capacity due to the process of establishing assessment standards within Conformity Assessment Bodies (CAB), also known as Notified Bodies (NBs), has taken longer than expected. Therefore, to date, only a handful of accredited CABs are ready to act in reviewing and approving new product dossiers. Registration fees are currently around €100,00 to €500,000.

USA

Historically, the registration of biostimulants has been far less advanced. However, in 2022 the US introduced the Plant Biostimulant Act, which defines biostimulants as:

a substance, microorganism, or mixture thereof, that, when applied to seeds, plants, the rhizosphere, soil, or other growth media, act to support a plant's natural processes independently of the biostimulant's nutrient content, including by improving nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality, or yield.

The act aims to harmonise the US and EU definitions, set a national framework for registering biostimulants, and more accurately describe benefits on product labels. The regulation also aims to:

- Develop a model bill for use across states to streamline the registration process.
- Educate growers on the benefits of biostimulants for soil health, sustainability, and climatesmart agriculture opportunities.
- Achieve regulatory clarity from the EPA regarding existing regulations, including defining plant growth regulators within FIFRA.

The EPA intends to distinguish plant biostimulants from PGRs, with PBS defined by the exclusion method as a substance or microorganism that does not conform to the definition of a PGR under FIFRA, aiming to remove previous ambiguity of where products fall. In the US, fertilisers are regulated by the US Department of Agriculture (USDA), whereas pesticides, including PGRs under FIFRA, are regulated by the EPA. For example, an algae extract is considered a PGR and is regulated under FIFRA by the EPA; therefore, the registration requirements for algae extract are similar to those for pesticides.

In November 2024, the EPA released draft guidance for plant regulator products and claims, including plant biostimulants. The aim of this draft guidance is to more clearly define which components are considered plant regulators and, therefore, subject to regulation as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136–136y.

Although FIFRA does not define the term plant biostimulants, some products being sold as plant biostimulants may trigger regulation under FIFRA as plant regulators. Other plant biostimulant products will not require registration as a pesticide under the plant regulator definition outlined in FIFRA section 2(v), or because they do not fit within the specific functionality definitions provided under FIFRA regarding plant regulator function.

Products which are not considered to be plant growth regulators and are therefore excluded from registration under FIFRA:

- Plant nutrients and trace elements: Plant nutrients and trace elements, which can be considered as falling under the umbrella term "fertilizers," are described in EPA's FIFRA regulations as "plant nutrient product[s] consisting of one or more macronutrients, or micronutrient trace elements necessary to normal growth of plants and in a form readily useable by plants" [40 CFR 152.6(g)(1)].
- **Plant inoculants**: Plant inoculants are "...product[s] consisting of microorganisms to be applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system" [40 CFR 152.6(g)(2)].
- **Soil amendments**: Soil amendments (which include soil additives and soil conditioners) are "...product[s] containing a substance or substances intended for the purpose of improving soil characteristics favorable for plant growth" [40 CFR 152.6(g)(3)].
- Vitamin-hormone products: Under FIFRA section 2(v), "the term 'plant regulator' shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, non-poisonous in the undiluted packaged concentration." Per 40 CFR 152.6(f), "vitamin hormone products" are further described as follows:
 - "A product consisting of a mixture of plant hormones, plant nutrients, inoculants, or soil amendments is not a "plant regulator" under Section 2(v) of FIFRA, provided it meets the following criteria:
 - The product, in the undiluted package concentration at which it is distributed or sold, meets the criteria... for Toxicity Category III or IV; and
 - The product is not intended for use on food crop sites, and is labelled accordingly.

During registration of both plant growth regulators and biostimulants, the claims made by the registrant, and on the product label are also considered by the EPA as part of its evaluation of the appropriate regulatory pathway. However, it should be noted that the EPA does not solely look at the claims made. Products that contain an active ingredient consistent with pesticidal/plant growth regulator usage will be registered as such regardless of how the registrant makes claims for its use. Similarly, if a biostimulant product claims pest-control properties, it will be considered as a pesticide under FIFRA.

The EPA outlined in this draft guidance document, example claims that may exclude a product from registration as a pesticide under FIFRA. These are not exhaustive, and as mentioned previously, if the active ingredient is consistent with a pesticidal active then it will be registered as such. The examples provided relate specifically to **plant nutrition-based claims**, **plant inoculant-based claims** and **soil amendment-based claims**. These can generally be summarised as modalities that *indirectly* support crop health, such as correcting nutrient deficiencies in the soil, optimising conditions for abiotic stress tolerance, soil structure/biodiversity, and increases to nutrient availability/uptake (e.g. through promoting root growth, nutrient solubilisation etc). The claims made by vitamin-hormone products need to be considered more carefully given that they are considered by the agency to contain components that can be considered as regulating plant physiological processes.

Plant regulator claims may be made for vitamin-hormone products when they meet both criteria for exclusion from the plant regulator definition, as specified under 40 CFR 152.6(f)(1) & (2).

This means that the product is considered 'non-toxic' but crucially also not for use on food crops, which means this exclusion has no relevance for agriculture beyond non-crop uses such as turf and ornamentals.

The guidance document goes on to discuss the definition of a plant growth regulator.

A naturally occurring substance would be considered a "plant regulator," and a product label claim would be considered a "plant regulator claim" if:

The substance or mixture of substances, through physiological action:

- 1. Accelerates or retards the rate of plant growth;
- 2. Accelerates or retards the rate of plant maturation;
- 3. Or otherwise alters the behaviour of plants or the produce thereof;

and

if the substance or mixture of substances does not fall under one of the exclusion categories listed in 40 CFR 152.6(f) & (g) as vitamin-hormone products, plant nutrients, plant inoculants or soil amendments; or under 40 CFR 152.8(a) as a fertilizer.

Plant regulator claims may be made for vitamin-hormone products when they meet both criteria for exclusion from the plant regulator definition, as specified under 40 CFR 152.6(f)(1) & (2). When claims for increased or decreased growth, yield, germination, maturation, etc. are consequent to intended uses of products or substances as plant nutrients (fertilizers), plant inoculants, soil amendments, and/or as other non-pesticidal uses, such products and substances may be excluded from regulation under FIFRA in the absence of any plant regulator claims.

This would imply that plant nutrients, plant inoculants or soil amendments that <u>do</u> have plant growth regulating capabilities and/or claims would be excluded from FIFRA registration, provided that they meet the requirements of the above exclusions, and have at least some 'non-plant growth regulating claims'. The exception here is that this doesn't apply for vitamin-hormone products used in food crops.

Examples of active ingredients that are considered to have no other usage other than as plant growth regulators and therefore pesticides under FIFRA include (but not limited to):

- Auxins
- Cytokinins
- Gibberellins
- Ethylene
- Abscisic acid

Other substances that may be included in this category include:

- Corn glutens
- L-Glutamic Acid (LGA) and gamma-Aminobutyric Acid (GABA)
- Homobrassinolide and other brassinosteroids
- Lysophosphatidylethanolamine (LPE)
- 1-Octanol
- Sodium o-nitrophenolate, sodium p-nitrophenolate, and sodium guaiacolate

There are numerous substances that may have plant regulator activity, as well as additional modes of action, not considered to be plant regulator modes of action that may include, but are not limited to:

- Abiotic stress tolerance
- Water and nutrient use efficiency/uptake;

• Nutrient availability - increased availability of inorganic nutrients in the soil to plant roots and seeds; improving biotic and abiotic characteristics of soils

Examples of these include:

- Seaweed extracts (SWE)
- Complex Polymeric Polyhydroxy Acids (CPPAs) and Humic Acids (HAs)

Both of these categories of active ingredients are generally understood to have direct physiological effects on growth, yield, maturation, and produce quality.

The Agency also recognizes that not all uses of PBS may be intended for plant regulator or other pest control purposes. If it can be demonstrated that a particular product has the activity claimed on the product label (and any other informational media) and does not make any plant regulator or pest control claims on the product label (and any other informational media) it may be excluded from FIFRA regulation.

Therefore, a natural product such as seaweed extracts and humic substances will be excluded from registration as a pesticide, provided that the product does not claim plant regulator activity, and claims activity under the plant health examples cited in the guidance document (Tables 1a-c and 2), or those analogous to those non-exhaustive examples.

Finally, the document also outlines how other 'conventional' components in the mixture should be considered, as well as components generated as a result of the extraction process.

If a conventional chemical plant regulator is contained within a PBS product, the product likely would be considered a conventional chemical pesticide by the Agency and would be subject to registration under FIFRA.

Novel substances may be present in plant biostimulant products that were not present in the original plant source material, but were formed as a result of the extraction methods and/or post-extraction processing but will require further scrutiny under FIFRA by the Agency to determine if they have the potential for pest control and/or plant regulator activity.

In summary, the guidance document outlines the importance of understanding the mode of action of the components in the product and associated claims, including the ability to produce performance data supporting such claims. Plant growth activity alone will not permit registration as a biostimulant, and companies must have an awareness of the physiological responses of the product and make sure that label claims, and those made in the process of regulation align with this.

Brazil

Under the first Fertilizer Law of 1980 (6.894/1980) and subsequent decree number 4.954/2004, fertilizers were defined as "mineral or organic substances, natural or synthetic, that provide one or more plant nutrients". For biofertilizers, Brazilian legislation previously utilised two definitions:

- (i) Inoculants: products containing micro-organisms that have a favourable impact on plant growth
- (ii) Biofertilizers: products containing an active ingredient or organic agent, free from agrochemical substances, capable of acting directly or indirectly on all or part of cultivated plants, enhancing their productivity, regardless of their hormonal or stimulant value

The generally vague definitions and regulation of biostimulants has in the past generated uncertainties for companies wishing to enter the market and represented a challenge surrounding grower confidence in product efficacy, composition, and quality assurance. However, few barriers have existed to introducing a biostimulant product into the market. There have been steps in 2024 to update and clarify the legislation under the 'Bioinputs Law'.

On December 23, 2024, Law No. 15,070/2024 ('Bioinputs Law'), which regulates the production, use, and commercialisation of bioinputs in the agricultural sector, was published in the Official Gazette. The new law regulates the production, use, and commercialisation of bioinputs for agricultural,

The Bioinputs Law defines a bioinput as: product, process or technology of plant, animal or microbial, including that originating from a biotechnological process, or structurally similar and functionally identical to that of natural origin, intended for use in production, protection, storage and processing of agricultural products or in production systems or planted forests, which interferes with the growth, development and response mechanism of animals, plants, microorganisms, soil and derived substances and that interact with the products and physical-chemical and biological processes.

Bioinputs include those "used in agricultural activity, including biostimulators or growth or performance inhibitors, semiochemicals, biochemicals, phytochemicals, metabolites, organic macromolecules, agents biological control products, soil conditioners, biofertilizers and inoculants."

However, the updated pesticide law stops short of defining each of these categories in detail.

livestock, aquaculture, and forestry use in Brazil, whilst also promoting the production and adoption of such products.

Argentina

Biostimulants and organic-chemical fertilisers must also be registered through SENASA. The general fees required for registration are relatively low compared to other markets, such as North America and Europe. However, this is more than offset by the level of complexity, the current lack of a fast-track registration process, and the generally lower levels of capacity and regulatory expertise required for a more expedited future process.

In November 2024, the government announced that all phytosanitary and bioinput procedures were centralised through an online platform known as SIGTrámites. On this platform users can register their products, facilitate self-management, gain insights on process traceability, reduce processing times, gain support, boost communication and make online payments. The platform may be used for newly formulated phytosanitary products, registration requests for prioritised items and registration requests for bio-inputs for plant nutrition.

China

In China, biostimulants are currently regulated through NY/T 3831-2021 Organic Water-Soluble Fertilizers-General Regulations; biostimulants are regulated alongside fertilisers and treated as microbial fertilisers or organic water-soluble fertilisers. This is overseen by the Chinese Ministry of Agriculture and Rural Affairs. The current regulation provides improved definitions that resolve biostimulant products' previously ambiguous legal status. Additionally, the regulation offers a premarketing procedure, product classifications, general rules on raw materials, nutrient contents, and labelling requirements.

The key product classes, such as inoculants and rhizobia, are registered under microbial fertilisers. Other biostimulants, such as chitosan, are listed under 'Water-soluble fertilisers':

- WSF containing amino acid.
- WSF containing humic acid.
- Organic WSF containing alginic acid.
- Organic WSF containing chitosan.
- Organic WSF containing polyglutamic acid.
- Organic WSF containing polyaspartic acid.
- Other WSF containing molasses, low-value fish and its fermented products, as well as other organic materials.

Overseas applicants must follow several requirements, including using a Chinese agent for application. This involves supplying critical information on product properties. Depending on raw materials, manufacturing processes, and end uses, toxicity tests and efficacy trials are sometimes required. These generally have lower requirements than urea, ammonium nitrate, and other fundamental nutrition products; therefore, they do not require technical review for registration. Following these tests, a technical permit is granted for commercialisation.

Japan

Japan does not legally define biostimulants, which are registered under the Fertiliser Control Law or Soil Fertility Enhancement Act. MAFF's 'Green Food System Strategy' targets a reduction in the use of chemical fertilisers. However, several products considered biostimulants are broadly used with registration under the Fertiliser Control Law or Soil Fertility Enhancement Act.

In response to the amendment of the Fertiliser Regulation in the EU, an industry group in Japan has been established to actively promote communication with the competent authorities to facilitate the standardisation of biostimulants.

With its new 'Green Food System Strategy', MAFF targets reducing chemical fertiliser use by recognising biostimulants as a valuable tool to lower fertiliser inputs and reduce environmental impacts. The Japanese Crop Protection Association has announced that the industry will proceed with developing biostimulants to support this strategic goal.

India

India's biostimulant definition is broadly aligned with that of the EU. Biostimulants are currently regulated through Fertiliser Control Order (FCO), which defines biostimulants as:

...a substance or micro-organism or a combination of both whose primary function when applied to plants, seeds or rhizosphere is to stimulate physiological processes in plants and to enhance its nutrient uptake, growth, yield, nutrition efficiency, crop quality and tolerance to stress, regardless of its nutrient content, but does not include pesticides or plant growth regulators which are regulated under the Insecticide Act, 1968.

India's Fertilizer (Inorganic, Organic or Mixed) (Control) Amendment Order was introduced in 2021. These new regulations require manufacturers to register products with the relevant authority providing a set of information on chemistry (composition, analytical methods, shelf-life), bio-efficacy trials conducted by the Indian Council of Agricultural Research (ICAR), state agricultural universities (SAUs) (preferably in agro-ecological zones), and toxicity data and heavy metal analysis.

The regulations also establish a regulatory body to monitor the end-to-end movements within the industry. The committee controls the quality and specifications of all biostimulants and ensures the use of safe substances and organic compounds in product manufacturing.

Farming-related services and speciality products dominate the Indian agrochemical landscape. The Federation of Indian Chambers of Commerce & Industry (FICCI) categorises biostimulants under the latter category alongside micronutrients, biopesticides, and biofertilisers that have recently begun to permeate the markets.

In May 2024 the Indian Union Ministry of Agriculture and Farmers Welfare issued a new amendment to the Fertilizer (Inorganic, Organic or Mixed) (Control) Order, 1985. Titled the 'Fertilizer (Inorganic, Organic or Mixed) (Control) (Third) Amendment Order, 2024,', the issue is intended to regulate the specifications and approval process for biostimulants in the agricultural sector. Key provisions of the amendment include:

- Increased specifications for biostimulant products, including their name, active ingredient or tracer molecule, chemical composition (in cases where active ingredients or tracer molecules cannot be indicated), and the name of the crop to which they are applied.
- The introduction of a new category for live microorganisms, excluding biofertilisers and biopesticides, within the specifications for biostimulants.

- Alterations to the application for new biostimulants, including the submission of data regarding categories, such as chemistry, bio-efficacy trials, toxicity, heavy metal analysis, and a product sample accompanied by an affidavit affirming compliance with pesticide limits.
- Toxicology data exemptions for certain biostimulants, such as **protein hydrolysates**, seaweed extracts, **amino acids**, vitamins, humic and fulvic acid.
- Alterations to pesticide limits within biostimulant products, set at 1 part per million (ppm), replacing the previous limit of 0.01 ppm.

The amendment aims to provide a framework for regulating and approving biostimulants in agriculture to ensure their safety, efficacy, and adherence to specified standards.

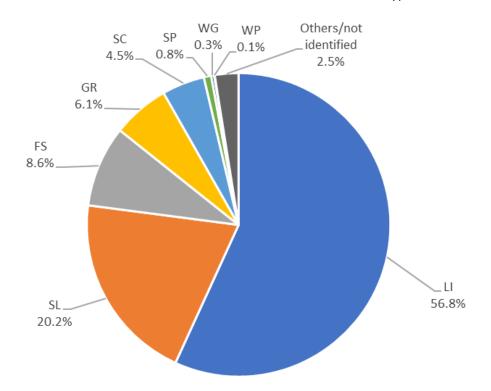
Company Involvement

The below table(s) on key active ingredients and key companies is derived directly from AgBioInvestor's exclusive primary market research study that surveyed biological- and biostimulantgrowers, which were conducted for the first time in 2023 and profiled the 2022 agricultural market. The market research surveyed many key agricultural markets for biologicals, including: the USA, Mexico, Chile, Brazil, Argentina, France, Italy, Spain and Turkey. The Ais have been ranked by farmgate value (\$m.). Quantification of these data and much more biological market research can be found in the separate subscription product AgbioInsight.

Key Companies with Involvement in Biostimulants: Vitamins and Amino Acids		
AI	Key Companies	
Amino acids	Syngenta	
	Albaugh	
	Timac Agro	
	CBC (Biogard)	
	Bioiberica	
	Seipasa	
	Sicit Group	
	Gowan	
	Compo Expert	
	Bayer	
	Biolchim	
	Forplant	
	Aminochem	
	Pevesa Biotech	
	Merschman Seeds	
	UPL	
	ILSA	
	Sustainable Agro Solutions	
	Kimitec	
	Sumitomo Chemical	

Formulation Types – Value Share

The below chart(s) are derived from the biological focussed market research that AgbioInvestor conducted, and illustrates the value share attributed to various formulation type codes.



Code	Description	Code	Description
AE	Aerosol dispenser	LI	Liquid
AL	Other liquids to be applied undiluted	LS	Solution for seed treatment
СВ	Bait concentrate	ME	Micro emulsion
CS	Capsule suspension	OD	Oil dispersion
DC	Dispersible concentrate	SC	Suspension concentrate
DF	Dry flowable	SL	Soluble concentrate
DP	Dustable powder	SP	Water soluble powder
EC	Emulsifiable concentrate	VP	Vapour releasing product
EW	Emulsion, water in oil	WG	Water dispersible granule
FS	Flowable concentrate for seed treatment	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment
LC	Liquid concentrate		

Research and Development

Due to the complex biochemical nature of protein hydrolysates as a diverse mixture of peptides, amino acids, and other organic compounds derived from the enzymatic or chemical hydrolysis of proteins, the main areas of research surround the optimisation of manufacturing processes, and producing product with a consistent profile of constituents. Optimisation of formulation technology is also important to include foliar treatments, irrigation, soil drench and seed treatments.

Further to this, other areas of active research surround cultivation practices such as the identification and quality control of the source animal and plant material, optimisation of application timing, dosage, amino acid profile selection.

Literature studies that have reviewed the efficiency of different manufacturing processes, such as the CO₂ emissions, energy consumption and water use showed that the production process of the animalderived protein hydrolysate was characterized by around 25% higher energy use and almost 60% higher CO₂ emissions, in comparison with some of the newer enzymatic production processes such as legume-derived protein.

A number of techniques are currently employed to assess the effectiveness of amino acids as well as peptides in plants, including quantitative PCR (qPCR) which measures the expression levels of genes associated with growth, nutrient uptake, and stress responses in plants treated with peptides. RNA Sequencing (RNA-Seq) may also be used to provide a detailed overview of gene expression changes induced by the exogenous peptide application. Computational techniques within the diverse umbrella of 'bioinformatics' may also be employed to help select and optimise amino acids for treatment. This may include molecular docking studies aimed at predicting the interaction between peptides and plant receptors or enzymes, and machine learning to analyse large datasets derived from field and glasshouse trials to assist with the identification of components with the greatest impact in crops.

A range of companies are actively using computational techniques to assist with the optimisation of enzymes, peptides and amino acids:

- Novozymes
- BASF
- Agrinos
- Biolchim
- Valagro
- Isagro
- Koppert Biological Systems
- PlantResponse Biotech
- Biotalys
- Andermatt Biocontrol

Market Outlook

The vitamin and amino acid segment is expected to benefit from the increasing usage in markets such as Brazil where they are used in soybeans and sugarcane as well as soybeans in Argentina. Brazil and other countries within south America are likely to see a considerable increase in climate volatility in the coming years. Amino acids can assist with boosting tolerance to abiotic stress. A key benefit of many amino acid products is that they are a low-cost byproduct of the meat processing industry through protein hydrolysis.

Amino acids are also used extensively in speciality crops, tree fruit, vine and orchard crops in Europe. Although these markets are relatively mature from the perspective of biologicals usage, the issues with fertiliser price and supply volatility were particularly acutely felt in the regions following the initiation of the Russia-Ukraine conflict, therefore a greater uptake of such products for boosting overall plant health will likely continue. Europe is also seeing a greater level of climatic volatility, therefore further enhancing the proposition of improving abiotic stress tolerance through the use of amino acids and vitamin products.

Amino acids are a particular driver of quality in crops, therefore we can expect their usage to grow in developing ag economies within southeast Asia and China in particular. However, the downside here is that the cost may be prohibitive with regards to small holder farmers, and the potential for inconsistencies in product composition may also impact the field performance and future uptake of these products.

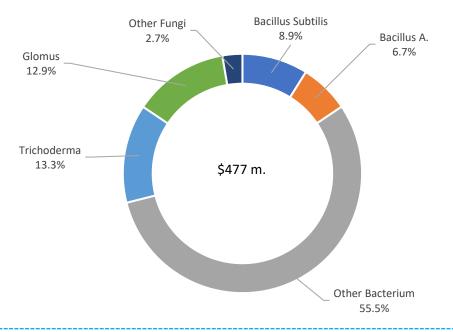
Some potential downsides to the use of amino acids in agriculture beyond challenges with consistency of composition and cost include the potential for overuse to create nutrient imbalances in soil, whilst over application can also negatively impact the soil microbiome. Run-off of amino acid overapplication can also lead to eutrophication of water bodies, the process of nutrient accumulation which causes an over-growth of microbes and depletion of dissolved oxygen levels. In order to mitigate these effects, it is essential for products to be used in conjunction with sound agronomic advice to manage the correct timing, dosages as well a field specific prescription. Precision ag applications can potentially help with achieving these goals.

Taking the above factors into account we can expect the market to grow at a rate of 10.8% p.a. between 2023 and 2028 to reach \$642 million.

Biostimulants:

Sales Performance of Biostimulants: Microbial Amendments			
Year	Microbial Amendments Biostimulant Sales (\$ m.)	Share of Biostimulants Segment %	
2018	255	12.5	
2022	477	13.5	
2023	534	14.0	
2028F	1010	16.3	
1-yr Change (%)	11.9		
5-yr CAGR (% p.a.)	16.0		
5-yr CAGR F (% p.a.)	13.6		

Introduction



2022 market research data have been included in this report for context and will be updated in future iterations of this report once we have sufficient uptake of proposed future syndicated Bio MR studies. AgbioInvestor analyses multiple sources in addition to this to produce the current market year (2023) data.

Sales of the Leading Als 2022		
Class	AI	2022 \$m.
Bacteria		339
	Bacillus subtilis	42
	Bacillus amyloliquefaciens	32
	Other Bacterium	265
Fungi		138
	Trichoderma spp.	64
	Glomus spp.	62
	Other Fungi	13
Total		477

Introduction

There are several ways that microbial species both fungal and bacterial can act as biostimulants, sometimes termed 'microbial amendments', 'soil inoculants' or 'biofertilisers'. For the purpose of our analysis, we include all products with these modalities under the term microbial amendment, and consider them to be biostimulants. Microbial amendments may refer to any bacterial or fungal species that has an effect on one or more processes or parameters beneficial to plants, such as nutrient availability (the levels of bioavailable nutrients), nutrient uptake efficiency (the ability of the plant to absorb those bioavailable nutrients), plant quality and resistance to abiotic stress.

It is estimated that around half of all exogenous nitrogen applied to crops is lost and not available to the crop. There are three main mechanisms causing this: leaching, denitrification, and surface volatilisation.

- Nitrogen leaching occurs when nitrogen, typically in the form of nitrate (NO3-), traverses downward through the soil dissolved in water, and eventually reaching and potentially contaminating groundwater or surface water bodies.
- Denitrification is a microbial process that converts nitrate (NO₃-) and nitrite (NO₂-) into gaseous nitrogen compounds, such as nitrogen gas (N₂) or nitrous oxide (N₂O), under anaerobic (low oxygen) conditions such as water-logged fields. This can lead to significant nutrient loss but also produce potent greenhouse gases such as NO₂.
- Surface volatilisation is where gaseous ammonia (NH₃) is evolved following biochemical conversion of fertiliser under optimal conditions such as warm soil temperatures, high soil pH, and favourable moisture.

It is essential to minimise these routes of loss, since they can lead to a number of environmental pollution modes including ammonium aerosol formation and leaching into bodies of water where eutrophication (e.g. algal blooms) can occur harming ecosystems.

Within this class of biostimulant there are a few main classes of microbes:

- **Plant Growth-Promoting Rhizobacteria (PGPR)**: colonize the rhizosphere (root zone) of plants and promote growth through various mechanisms such as nitrogen fixation, phosphate solubilisation, and production of plant hormones like auxins.
- Arbuscular Mycorrhizal Fungi (AMF): form symbiotic associations in the root zone of crops, improving factors such as plant vigour by enhancing the root system's ability to efficiently absorb water and nutrients under variable environmental conditions throughout the entire crop cycle.
- **Endophytes:** unlike AMFs which exist in the root zone, endophytes are beneficial microbes that live within plant tissues. They can also enhance plant growth by producing growth-promoting substances, improving nutrient uptake, and providing protection against pathogens.

Products

Nutrient-Solubilising/Mobilising Bacteria

Nutrient-Solubilising/Mobilising Bacteria		
Class	Nutrient	
Brevibacterium	Calcite (Calcium carbonate)	
Acidithiobacillus ferooxidans (Thiobacillus ferooxidans)	Iron, Sulphur, Zinc	
Penicillium citrinum	Manganese	
Azospirillum brasilense	Phosphorus	
Bacillus megaterium	Phosphorus	
Bacillus polymixa	Phosphorus	
Bacillus subtilis	Phosphorus	
Bacillus velezensis	Phosphorus	
Penicillium bilaiae	Phosphorus	
Pseudomonas striata	Phosphorus	
Fracturia aurantia	Potassium	
Bacillus mycoides	Silica	

Phosphorus is commonly deficient in most natural soils because it is fixed as insoluble iron or aluminium phosphates in acidic soils or as calcium phosphates in alkaline soils. Bacterial genera such as *Aspergillus, Bacillus, Pseudomonas,* and *Penicillium* secrete organic acids (mimicking root exudates) that lower soil pH, resulting in the dissolution of fixed phosphates in soil. Several rhizosphere-colonising bacteria (*Pseudomonas* spp. and *Bacillus* spp.) solubilise insoluble inorganic phosphates, such as tri-calcium phosphate, di-calcium phosphate, hydroxyapatite, and rock phosphate.

Rhizobacteria also improve zinc availability in the root zone. *Brevibacterium* produces siderophores and extracellular polysaccharides that enhance calcite (calcium) dissolution.

Another method for enhancing nutrient availability to a crop is using nitrogen-fixing bacteria and Mycorrhizal fungi.

Nitrogen fixing bacteria	
Class	Activity
Azospirillum	Fixing nitrogen within the rhizosphere of host plants, mostly grasses.
Rhizobium, Bradyrhizobium	Colonising the host plant's root system through the root hairs, resulting in the formation of nodules, a plant-derived membrane where the bacteria act to fix nitrogen.
Azotobacter, Bacillus, Clostridium, Klebsiella, Gluconacetobacter	Heterotrophic bacteria that live in the soil and fix nitrogen from the atmosphere and soil without direct interaction with other organisms.
Azolla, Frankia	Forming a symbiotic relationship with the host plant, utilising sugars from the host to provide the energy needed for nitrogen fixation.
Methylobacterium spp.	Forms a symbiotic relationship with host plant that can grow using compounds containing only one carbon (C1), such as methanol or methylamine. Also expresses nitrogenases.

Nitrogen-fixing bacteria

Mycorrhizal Fungi

Mycorrhizal Fungi	
Class	Activity
Glomeromycota (Glomus intraradices, Glomus mosseae, Glomus coronatum, Scutellospora calospora, Gigaspora margarita, and Laccaria bicolor)	Arbuscular mycorrhizae form a symbiotic relationship with the host plant, providing water and nutrients in exchange for carbon/sugars. The fungi form a hyphal network in the soil adjacent to the roots of the host and penetrate plant cells to form vesicles (arbuscules) where nutrient exchange occurs.
Ericoid mycorrhiza (Ascomycetes)	Forming coils of hyphae around the outermost layer of root cells; responsible for breaking down waste matter into nutrients for absorption by plants.
Myco hetrotrophic mycorrhiza (Basidiomycetes)	In this situation, the host plant receives nutrients from the fungus rather than photosynthesis
Monotropoid mycorrhiza (Boletus)	In this situation, the host plant is parasitic on the fungus as a source of carbon.

Glomus aggregatum / Glomus etunicatum / Glomus intraradices / Glomus mosseoe

These strains are sold by Sumitomo / Valent USA as EndoPrime with four arbuscular mycorrhizal fungi (AMF) strains that improves plant vigour by enhancing the root system's ability to efficiently absorb water and nutrients. In addition, the hyphae produce enzymes that release nutrients within the soil and create vesicles to store resources until they are required by the plant.

The product is a concentrated suspendable powder (SP) formulation and is optimised for use as an infurrow spray, seed treatment, soil drench, transplant treatment, bare root treatment, and potato seed piece treatment for improvement of plant vigour. Labelled crop uses include leafy vegetables, cucurbits, fruiting veg, onions, potato, sweet potato, soft fruit, soybean, corn, cereals, cotton and trees/vines.

- Feb 14, 2018 Valent USA, a subsidiary of Sumitomo Chemical, launched MycoApply EndoPrime, for use on maize in the USA. The product improves nutrient use efficiency, drought tolerance and yield potential.
- Feb 7, 2019 Valent USA announced the launch of a liquid formulation of MycoApply EndoPrime SC. The product, which is applied in-furrow and improves nutrient use efficiency, drought tolerance and yield potential.
- Sep 6, 2019 The Canadian Food Inspection Agency (CFIA) approved the commercial use of Groundwork BioAgs Rootella F, Rootella G, Rootella S and Rootella WP mycorrhizal inoculants, based on the endomycorrhiza Glomus intraradices. This follows similar approvals in other countries, including the US, Brazil, Ukraine and Belgium. These inoculants are intended to increase the number of microorganisms at the root level of plants, promoting root growth and improving nutrient uptake.
- Dec 20, 2023 Groundwork BioAg, a company specialising in mycorrhizal inoculants, received approval for its mycorrhizal inoculant Rootella (based on the endomycorrhiza *Glomus intraradices*), in China, Argentina and South Africa. Led by its representative office in Hainan province, China, the company is completing local trials in maize, soybean, wheat, cotton and select specialty crops, and expects to offer Rootella to farmers before China's 2024 planting season. The company plans to distribute through the local distributor Agrivested in South Africa and expects to have a distribution agreement in place covering Argentina in 2024.

• Jan 7, 2025 Groundwork BioAg, a producer of mycorrhizal inoculants, entered into an exclusive commercial agreement with Adama to offer Rootella (based on the endomycorrhiza *Glomus intraradices*) mycorrhizal inoculants to Chinese farmers, building on Groundwork BioAg's successful introduction of Rootella to local distributors in the country following the product's approval for commercialization in 2023. Rootella has also received registration approval in Argentina and South Africa. Adama will offer Rootella for use on maize, soybean, wheat, cotton and select speciality crops starting in the 2025 planting season.

Trichoderma harzianum

Unlike the above strains, *Trichoderma harzianum* is not an arbuscular mycorrhizal fungus (AMF). *Trichoderma* species, generate biostimulating effects through various mechanisms such as hormone production and nutrient solubilization. For example, Symborg's Tricho Sym Bio associates with the plant root and increases lateral root formation, while optimizing microbiological interactions in the rhizosphere. In this way, it manages to increase tolerance to stress and promote seed germination, vegetative growth and production.

- May 10, 2021 Helm Argentina and Terragene entered a development and distribution agreement for biological products in Argentina. The first product to be distributed under this partnership was to be Innobio Protergium, a soybean seed treatment comprising *Bacillus velezensis, Trichoderma harzianum* and *Bradyrhizobium japonicum*. Innobio Protergium is targeted at the control of soil microorganisms that affect the seed, whilst also improving the solubilisation of nutrients and biological fixation of nitrogen.
- Nov 18, 2022 Koppert Argentina announced the launch of a bioinput pack that combines an inoculant with a fungicide, based on *Trichoderma harzianum*, that can be applied up to 25 days before planting. The product has previously been introduced in Brazil.
- Mar 8, 2023 The agricultural biotechnology company LIDA Plant Research, part of the Japanese company OAT Agrio, launched its Bioforce biostimulant product range. The company's Bioforce products, including Rental Bioforce, a special formulation based on humic acids from leonardite and seaweed enriched with selected strains of *Trichoderma harzianum* and *Bacillus spp*.
- Mar 1, 2024 The crop inputs company Alltec launched the seed treatment biofungicide TrichoSmart Mega (*Bacillus megaterium* Ara6 / *Trichoderma harzianum* TH10) in Argentina. In addition to control of diseases, the product reportedly improves plant growth and tolerance to biotic and abiotic stressors.

Other Trichoderma spp.

- Jul 23, 2024 The Orion Group, a specialist in in-furrow applied biological products, launched its new Lynx brand of biological products in Brazil, based on three main products designed to enhance crop productivity and nitrogen fixation.
 - BioPartners *Brazilian azospirillum* (strain Ab-V5 and Ab-V6)
 - BioPartners *Bradyrhizobium japonicum* (SEMIA 5079 & 5080)
 - **BioPartners Trichoderma asperelloides (CEPA MMBF 94/17)**
- Aug 23, 2024 The US EPA received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products:
 - MBFi LLC, *Trichoderma asperellum* DSM 33649 at 100% proposed for manufacturing use only to formulate fungicide and nematicide end-use products.
 - MBFi LLC, Trillum DS (*Trichoderma asperellum* DSM33649) at 1% proposed for control of soil-borne fungal pathogens and nematodes on outdoor agricultural and greenhouse crops, ornamental plants, and turf.

 MBFi LLC, Trillum WP (*Trichoderma asperellum* DSM33649) at 1% proposed for control of soil-borne fungal pathogens and nematodes on outdoor agricultural and greenhouse crops, ornamental plants, and turf.

Calothrix castelli

Calothrix castelli, a filamentous cyanobacterium that is capable of a number of agriculturally relevant traits including plant growth promotion through the expression of phytohormones and enhancing nitrogen fixation by converting atmospheric nitrogen to bioavailable ammonia. *Calothrix castelli* is also capable of producing exopolysaccharides (EPS) that have been shown to boost the retention of soil moisture.

Bacillus subtilis

This parent species is used across a number of biocontrol segments including bioinsecticides, biofungicides and bionematicides. In the biostimulant segment, the species has a number of key activities including nutrient solubilisation (both phosphorus and potassium), increasing tolerance to drought and heat stress and the induction of systemic resistance (ISR). Due to the ability of the strain to produce a number of phytohormones such as gibberellins, auxins and cytokinins, *Bacillus subtilis* is also able to promote plant vigour and yield through stimulation of a number of plant processes including root and shoot development.

- May 26, 2020 The Spanish biological crop protection company Seipasa received registration in Spain for its root biostimulant product Radisei for use on various crops including almond, vine, olive, blueberry, banana, citrus and kiwi. The product, which is based on *Bacillus subtilis* strain SEIBS23, activates different biological processes in the soil, unlocks essential micro and macronutrients and promotes the development of a plant's root system.
- Oct 14, 2020 BASF introduced Vault IP Plus to its US soybean seed treatment portfolio based on Vault IP Plus (*Bacillus subtilis* strain BU1814 / *Bacillus amyloliquefaciens* strain MBI 600 / *Bradyrhizobium japonicum*) for the suppression of soil-borne diseases, including the fungal pathogens *Fusarium* and *Rhizoctonia*, which are the cause of root rot. In addition to two biofungicide active ingredients, the product contains an on-seed inoculant product (*Bradyrhizobium japonicum*) that is designed to fix nitrogen.
- Apr 21, 2021 FMC and Syngenta entered into a commercial agreement whereby Syngenta
 was to distribute FMC's new biological seed treatment for use on maize and soybean in
 Canada. The seed treatment, which Syngenta was to commercialise under the brand name
 Draco (*Bacillus licheniformis / Bacillus subtilis*), offers control of pests such as *Rhizoctonia*and nematodes. The product also reportedly provides biostimulant activity which
 improves water utilisation by the roots and enhances plant performance.
- Jun 25, 2021 Seipasa received a label extension for its root biostimulant Radisei (*Bacillus subtilis* strain SEIBS23) in Spain. The product is registered for use on horticultural soil crops, both outdoors and in the greenhouse, having already been approved for use on various crops including almond, vine, olive, blueberry, banana, citrus, and kiwi.
- Sep 28, 2022 BASF added Nodulator IP Plus to its Canadian crop establishment portfolio based on *Bacillus subtilis* strain BU1814 / *Bacillus amyloliquefaciens* strain MBI 600 / *Bradyrhizobium japonicum* strain 532C. Nodulator IP Plus is a soybean biofungicide / inoculant seed treatment for the suppression of diseases including *Fusarium*, *Rhizoctonia*, and *Pythium*. The on-seed inoculant product (*Bradyrhizobium japonicum* strain 532C) provides enhanced nodulation and early-season vigour to promote a stronger root system.

- Sep 25, 2023 Janssen PMP, a subdivision of Janssen Pharmaceutica, entered into a commercial partnership with the Switzerland-based company Eléphant Vert. Through the partnership, Janssen PMP became the exclusive distributor for two of Elephant Vert's biostimulant products including Novastim (*Bacillus subtilis*), in Australia, New Zealand, the US (excluding the Midwest), Peru, Chile, Mexico, Colombia, South Africa, Belgium, and the Netherlands.
- Oct 2, 2023 Nihon Nohyaku announced the launch of its biostimulant Cross Value (*Bacillus licheniformis* DSM5749 / *Bacillus subtilis* DSM5750) in Japan. The strains of bacteria are targeted at enhancing the plant response to abiotic stresses to increase crop production. The company reported that field trial results showed yield improvements in strawberry and cucumbers, as well as root development enhancement in asparagus.
- Jul 11, 2024 Rovensa Next launched the biofertiliser Wiibio. The product, which is based on a *Bacillus subtilis* F1 bacterial strain and combined with organic matter and rhizogenic substances enriched with calcium, is intended to improve the microbial diversity of soil and enhance plant development. Wiibio can be used in a wide range of crops and is specifically formulated for soil application during the early to mid-vegetative cycle, as well as post-harvest in perennial crops.

Penicillium bilaiae

The species is a fungi that is capable of enhancing the levels of bioavailable phosphates in the soil through the expression of various enzymes and organic acids, boosting root growth and shoot development, stress tolerance and early season vigour. A key product is Bayer's JumpStart WT which is a liquid seed treatment labelled for use in a broad range of crops including cereals, soybean, maize, canola/rape, legumes and others.

- Sep 27, 2021 Novozymes announced the launch of 3 new biological products for the US market containing *Penicillium bilaiae*:
 - BioniQ (*Penicillium bilaiae* / *Bacillus amyloliquefaciens* / *Trichoderma virens*), an inoculant for row crops that strengthens roots, enhances nutrient availability and improves yield
 - TagTeam BioniQ Pro (*Penicillium bilaiae / Rhizobium leguminosarum / Bacillus amyloliquefaciens / Trichoderma virens*)
 - TagTram BioniQ Chickpea (*Penicillium bilaiae / Rhizobium leguminosarum / Bacillus amyloliquefaciens / Trichoderma virens*), inoculants that improve stress tolerance, nutritional availability and efficiency, and enhance yield in pulse and chickpea crops

Methylobacterium symbioticum strain Sb23

This species forms a symbiotic relationship with host plant, and the bacterium can grow using compounds containing only one carbon (C1), such as methanol or methylamine. The species is also capable of expressing nitrogenase enzymes, which catalyse the reduction of N_2 gas to ammonia (NH₃) or ammonium (NH₄⁺), thereby making the nitrogen gas bioavailable.

Nitrogenase enzymes are highly specialised and energy-intensive, requiring specific conditions to function optimally. Key products include Corteva/Symborg's UtrishaN and BlueN which are both wettable powders based on *Methylobacterium symbioticum* strain Sb23 which is applied to foliage and is absorbed through leaf stomata. UtrishaN and BlueN are labelled for use in key crops such as cereals, oilseed rape, maize, legumes, potato, sugarbeet grass and a wide range of fruits and vegetables.

- Apr 22, 2021 Corteva Agriscience and Symborg announced a multi-year agreement around a nitrogen-based fixation product in the US, Canada, Brazil and Argentina. Through the agreement, Symborg was to provide an exclusive distribution license to Corteva for the endophytic bacterium *Methylobacterium sybioticum*, which works with the plant to secure nitrogen from the atmosphere. Corteva was to leverage its distribution network, market reach and research and development capabilities. The Corteva product, to be branded Utrisha N nutrient efficiency optimiser, is designed to maximise crop yield and is available for field and row crops, sugar cane, turf & ornamental and for range and pasture. The agreement also enables Corteva and Symborg to co-distribute the product in specialties crops on an exclusive basis.
- Jul 23, 2021 Corteva and Symborg expanded on the above distribution agreement covering endophytic bacterium *Methylobacterium symbioticum* products in the US, Canada, Brazil and Argentina. Through the expanded agreement, Corteva was granted an exclusive licence that now also covers distribution in most European countries (except the Nordic Countries, the Netherlands and Israel). Corteva offers two brands, Utrisha N and BlueN, which are both nutrient efficiency optimisers to improve crop yield potential, which are available for key food crops.
- Apr 9, 2024 Corteva launched the biostimulant Utrisha N (*Methylobacterium sybioticum*) in Australia. Following the 2023 acquisition of Symborg, Corteva, holds the international patent for this bacterium for extraction, formulation and multiplication process, as well as purification and formulation.
- May 29, 2024 Corteva launched Utrisha N in Japan for use on a range of crops including rice, maize, and F&V.
- Jun 20, 2024 Corteva launched Utrisha N in Brazil for foliar use on maize.

Bradyrhizobium japonicum

Similar to *Methylobacterium symbioticum* as seen above, *Bradyrhizobium japonicum* is a nitrogen fixing soil dwelling bacterium that is mainly used in soybeans and legumes. The species colonises root nodules, where the bacteria interact with root hairs and express 'nod factors' (lipochitooligosaccharides). This expression leads to root hair modification and allows *B. japonicum* to enter root hairs where they multiply rapidly. In the nodules *Bradyrhizobium spp.* expresses nitrogenases that catalyse the conversion of atmospheric N to ammonia (NH₃) and ammonium (NH₄+). Soil factors influencing *B. japonicum* survival include pH, temperature, texture, water content, and soil-available nitrogen.

- Aug 19, 2019 Lallemand Plant Care launched two new spherical granular inoculants in Canada: Lalfix Duo FS Soybean and Lalfix FS Pea and Lentil. The products, which are reportedly the first spherical inoculant formulations in the Canadian market, have been shown to enhance the placement and survival of the two active strains of *Rhizobium leguminosarum* for pea and lentil and *Bradyrhizobium japonicum* for soybeans, improving nodulation and nitrogen fixation in both crops.
- Oct 14, 2020 BASF introduced to its US soybean seed treatment portfolio Vault IP Plus a biofungicide / inoculant seed treatment for the suppression of soil-borne diseases, including the fungal pathogens *Fusarium* and *Rhizoctonia*, which are the cause of root rot. In addition to two biofungicide active ingredients, the product contains an on-seed inoculant product (*Bradyrhizobium japonicum*) that is designed to deliver a high concentration of beneficial rhizobia bacteria to the soybean plant, maximising yield potential by reducing the risk of the plant not having enough nitrogen.
- Dec 9, 2020 XiteBio received approval in Canada for the liquid inoculants SoyRhizo (*Bradyrhizobium japonicum*) and PulseRhizo (*Rhizobium leguminosarum*) for use in organic agriculture. The two inoculants utilise XiteBio's advanced growth promoting technology which reportedly helps crops to fix atmospheric nitrogen.
- Jan 18, 2021 the Argentinian microbiological product development company Rizobacter launched the biological soybean inoculant Signum (*Bradyrhizobium japonicum*) in Brazil. The product, which contains the company's Bio-Inducer technology, is intended to promote more rapid biological fixation of nitrogen and improve nodulation, even under abiotic stress situations such as drought and floods. Rizobacter's Bio-Inducer technology accelerates initial, early communication between rhizobial bacteria and plant roots and triggers earlier nodulation for maximum nitrogen fixation.
- Jan 19, 2021 Heliae Agriculture entered into a strategic collaboration with the Argentinian microbiological product development company Rizobacter to provide farmers throughout the US and Eastern Canada with new solutions to add value to their farming operations. Through the agreement, Heliae was to integrate Rizobacter's biological solutions into its product and technology offerings, starting from January 2021. Rizobacter products to be integrated into the Heliae portfolio include the soybean inoculant Rizoliq TOP HC, which contains the nitrogen-fixing bacteria *Bradyrhizobium japonicum*.

• Apr 16, 2021 the Argentinian microbiological product development company Rizobacter announced it had partnered with the University of Illinois' Feed the Future Soybean Innovation Lab (SIL) to bring soybean technology to 26 African countries. The partnership will provide the SIL Pan-African Soybean Variety Trial (PAT) network with access to Rizobacter's Rizoliq TOP inoculant product whilst also providing Rizobacter access to new African markets through the PAT network, which includes seed companies, nucleus growers, processors, national agricultural research stations, universities, and commercial farmers.

Rizoliq TOP is formulated with Osmo Protection Technology, which reportedly provides the inoculant with a higher concentration, a more robust physiological state, and greater tolerance to stresses to improve the survival of microorganisms on the seed. The higher concentration of *Bradyrhizobium japonicum* ensures that the radicle of the germinated seed is quickly infected, accelerating and maximizing the process of biological fixation of nitrogen.

- May 10, 2021 Helm Argentina and Terragene entered a development and distribution
 agreement for biological products in Argentina. The first product to be distributed under this
 partnership was Innobio Protergium, a soybean seed treatment comprising *Bacillus velezensis*, *Trichoderma harzianum* and *Bradyrhizobium japonicum*. Innobio Protergium is targeted at the
 control of soil microorganisms that affect the seed and whilst also improving the solubilisation
 of nutrients and biological fixation of nitrogen.
- Sep 27, 2021 Novozymes announced the launch of Optimize FXC (*Bradyrhizobium japonicum*) for soybeans in the USA, which increases biological nitrogen fixation, accessibility to soil nutrients and water absorption.
- Sep 28, 2022 BASF added to its Canadian crop establishment portfolio Nodulator IP Plus, which is a soybean biofungicide / inoculant seed treatment for the suppression of diseases including *Fusarium, Rhizoctonia,* and *Pythium.* In addition to two biofungicide active ingredients, the product contains an on-seed inoculant product (*Bradyrhizobium japonicum* strain 532C), which is reported to provide enhanced nodulation and early-season vigour to promote a stronger root system.
- Mar 17, 2023 Koppert do Brasil entered into a partnership with the application technology company Orion Tecnologia e Sistemas regarding the in-furrow application of biological products for grain crops. Through the partnership, Koppert customers gained access to Orion's equipment, which has been developed specifically for in-furrow applications of biologicals, with the aim of improving and maintaining the quality and effectiveness of biological products.
 - Koppert's portfolio of products that can be applied in-furrow include the inoculants Azokop (Azospirillum brasilense) and Rizokop (Bradyrhizobium japonicum), the fungicide / nematicide Trichodermil (Trichoderma harzianum), the nematicide Veraneio (Bacillus amyloliquefaciens), and the bioactivator Stingray (Ascophyllum nodosum).
- Aug 21, 2023 The UK-based biologicals company Bionema launched a range of biofertiliser products in the UK for use in agriculture, horticulture, forestry, sport turf and amenities including *Bradyrhizobium japonicum* BNL1061. The products utilise Bionema's IncapsuleX microencapsulation formulation technology, which is reported to improve product delivery and efficacy.
- Jul 16, 2024 Biosphera, a bioinput manufacturing company headquartered in Paraná, Brazil, luanched the biological inoculant Nitrosphera Fusion (*Bradyrhizobium elkanii / Bradyrhizobium japonicum*) in Brazil. The product is targeted for use on soybean crops, and is intended to promote nitrogen fixation, increasing the biological availability of the nutrient for soybean plants.

- Jul 19, 2024 Novonesis launched the biological inoculant LeguMax Plus (*Bradyrhizobium japonicum*) in Brazil. The product is targeted at use on soybean to promote biological nitrogen fixation, increasing the biological availability of the nutrient for soybean plants. LeguMax Plus can also be used for in-furrow inoculation, which reportedly enables the inoculant to act as a protective layer for the seed.
- Jul 23, 2024 The Orion Group, a specialist in in-furrow applied biological products, launched its new Lynx brand of biological products in Brazil, based on three main products designed to enhance crop productivity and nitrogen fixation.
 - o BioPartners Brazilian azospirillum (strain Ab-V5 and Ab-V6)
 - BioPartners Bradyrhizobium japonicum (SEMIA 5079 & 5080)
 - o BioPartners Trichoderma asperelloides (CEPA MMBF 94/17)
- Dec 12, 2024 Koppert Argentina entered into a distribution agreement with the Bolivian company Greenfield. Through the agreement, Greenfield has incorporated a number of Koppert products into its portfolio for the Bolivian market, including Rizokop (*Bradyrhizobium japonicum*), Koprotect, Azokop (*Azospirillum brasilense*) and Nitrobac (*Gluconacetobacter diazotrophicus*).

Kosakonia sacchari and Klebsiella variicola

These strains from Pivot Bio are gene-edited soil inoculants are able to more efficiently fix atmospheric nitrogen in the form of ammonia under field conditions for cereal, corn and sorghum. The company is currently positioning these products as the first ever "on-seed nitrogen", however there are other such inoculants on the market.

Derived from a wild nitrogen-fixing microbe isolated from agricultural soils, *Klebsiella variicola* 137-1036 ("Kv137-1036") retains the ability of the parent strain to colonise corn roots whilst increasing nitrogen fixation activity 122-fold in nitrogen-rich environments. The strain is used in-furrow and as a seed treatment for corn

The company identified and characterised another agricultural soil-derived wild-type diazotroph (*Klebsiella variicola* strain 137; Kv137) through the use of computational and synthetic biology tools. This strain was then gene edited to produce *K. variicola* strain 137-1036 (Kv137-1036). The product is used in-furrow and as a seed treatment in barley, millet, oats, sorghum, sunflower and spring wheat.

- In 2019 the company launched the in-furrow product Proven for use in corn in select states within the USA offering a reduction of 20 pounds of nitrogen per acre.
- In 2021 the company replaced the in-furrow product Proven with Proven 40 in corn, offering a 40 pounds per acre reduction in nitrogen applications.
- In 2021 the company launched Pivot Bio Return for use in small grain crops such as barley, millet, oats, sorghum, sunflower and spring wheat, and was reported to offer a 25 pounds per acre reduction in sorghum. The product was made available in the following states that year: Idaho, Kansas, Missouri, Nebraska, North Dakota, Oklahoma, Oregon, South Dakota, Texas and Washington.
- Aug 31, 2022 Pivot Bio launched a novel class of microbial nitrogen technology in the US. The products, Proven 40 On-Seed and Return On-Seed, deliver nitrogen-producing microbes directly to the seed and can be integrated during the planting of crops such as maize, sorghum, and wheat.
- Mar 3, 2025 Pivot Bio introduced the biological cotton seed treatment product CERT-N (containing *Klebsiella variicola* and *Kosakonia sacchari*) in the US. The product provides a source of nitrogen to cotton plants from emergence to harvest, providing weatherproof nitrogen and supporting crop yield. The product will be available through Pivot Bio's

distribution partners for a select group of growers this season, with a full commercial launch for the 2026 planting season.

March 17, 2025 Pivot Bio launched Proven G3, a new product in its line of nitrogen-fixing ag
solutions in the US. The product will be commercially available in 2026, pending state
registrations, and represents the company's third-generation nitrogen solution for maize and
is the its first Proven product with multiple modes of action. Proven G3 enhances Pivot Bio's
proprietary gene-edited nitrogen-fixing technology offering and adds an exclusive microbe
blend that increases nutrient uptake and nitrogen-use efficiency.

Regulatory Situation

Europe

Regulation has been poorly defined for biostimulants. However, under the new European fertiliser regulation (EU fertiliser Regulation 2019/1009), PBSs (plant biostimulants) are classified as fertilisers, except those that are also pesticides, whereas PGRs (plant growth regulators) are classified as pesticides. In the US, PBSs are likely to be classified separately from fertilisers; however, this issue is still in discussion.

The EU enforced the Fertilising Products Regulation (EU n°2019/1009) in July 2022, which defines and establishes processes for biostimulant approvals, including requiring efficacy testing to show that the product has biostimulant effects and is not just a fertiliser. This highlights a critical development in defining plant biostimulants by their function, not their ingredients.

Biostimulants are regulated for the whole EU market alongside national regulations with two routes for placing PBSs on the market:

- National: Gain national registration, then seek mutual recognition with other member states.
- **EU:** Gain EU-wide registration and 'CE' mark for sale across the whole of the EU.

By including biostimulant products and explicitly excluding them from EU plant protection products, Regulation 1107/2009 closes a regulatory gap by bringing biostimulants under harmonised rules from June 2022. However, it simultaneously opens another gap, mainly because the official definition of biostimulants (i.e. those eligible for registration under the EU framework in the future) is mainly legal and regulatory, not scientific.

Many plant processes are active in abiotic and biotic defence mechanisms, meaning that dual-use products may now fall under the sole claim of biotic functionality. This could lead, for example, to requirements to register products previously marketed under the national fertiliser laws as 'biostimulants' under the plant protection product framework. If a product is effective only against abiotic stress, it does not fulfil the criteria of the plant protection regulation. This is exemplified by products containing the *Trichoderma* species, which, in many cases, have been marketed as a biostimulant, plant, or soil amendments but may now have to be authorised as a plant protection product due to their fungicidal action.

Dual-action products against abiotic and biotic stress may be eligible for registration under the plant protection framework because respective substance/product categories, such as 'elicitor' or 'plant activator', are already included in and covered by Regulation 1107/2009.

The current impact on timescales is unknown due to the relatively recent introduction of this new regulation. Still, limited capacity due to the process of establishing assessment standards within Conformity Assessment Bodies (CAB), also known as Notified Bodies (NBs), has taken longer than expected. Therefore, to date, only a handful of accredited CABs are ready to act in reviewing and approving new product dossiers. Registration fees are currently around $\leq 100,00$ to $\leq 500,000$.

USA

Historically, the registration of biostimulants has been far less advanced. However, in 2022 the US introduced the Plant Biostimulant Act, which defines biostimulants as:

a substance, *microorganism*, or mixture thereof, that, when applied to seeds, plants, the rhizosphere, soil, or other growth media, act to support a plant's natural processes independently of the biostimulant's nutrient content, including by improving nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality, or yield.

The act aims to harmonise the US and EU definitions, set a national framework for registering biostimulants, and more accurately describe benefits on product labels. The regulation also aims to:

- Develop a model bill for use across states to streamline the registration process.
- Educate growers on the benefits of biostimulants for soil health, sustainability, and climatesmart agriculture opportunities.
- Achieve regulatory clarity from the EPA regarding existing regulations, including defining plant growth regulators within FIFRA.

The EPA intends to distinguish plant biostimulants from PGRs, with PBS defined by the exclusion method as a substance or **microorganism** that does not conform to the definition of a PGR under FIFRA, aiming to remove previous ambiguity of where products fall. In the US, fertilisers are regulated by the US Department of Agriculture (USDA), whereas pesticides, including PGRs under FIFRA, are regulated by the EPA. For example, an algae extract is considered a PGR and is regulated under FIFRA by the EPA; therefore, the registration requirements for algae extract are similar to those for pesticides.

In November 2024, the EPA released draft guidance for plant regulator products and claims, including plant biostimulants. The aim of this draft guidance is to more clearly define which components are considered plant regulators and, therefore, subject to regulation as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136–136y.

Although FIFRA does not define the term plant biostimulants, some products being sold as plant biostimulants may trigger regulation under FIFRA as plant regulators. Other plant biostimulant products will not require registration as a pesticide under the plant regulator definition outlined in FIFRA section 2(v), or because they do not fit within the specific functionality definitions provided under FIFRA regarding plant regulator function.

Products which are not considered to be plant growth regulators and are therefore excluded from registration under FIFRA:

- Plant nutrients and trace elements: Plant nutrients and trace elements, which can be considered as falling under the umbrella term "fertilizers," are described in EPA's FIFRA regulations as "plant nutrient product[s] consisting of one or more macronutrients, or micronutrient trace elements necessary to normal growth of plants and in a form readily useable by plants" [40 CFR 152.6(g)(1)].
- **Plant inoculants**: Plant inoculants are "...product[s] consisting of microorganisms to be applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system" [40 CFR 152.6(g)(2)].
- **Soil amendments**: Soil amendments (which include soil additives and soil conditioners) are "...product[s] containing a substance or substances intended for the purpose of improving soil characteristics favorable for plant growth" [40 CFR 152.6(g)(3)].
- Vitamin-hormone products: Under FIFRA section 2(v), "the term 'plant regulator' shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, non-poisonous in the undiluted packaged concentration." Per 40 CFR 152.6(f), "vitamin hormone products" are further described as follows:
 - "A product consisting of a mixture of plant hormones, plant nutrients, inoculants, or soil amendments is not a "plant regulator" under Section 2(v) of FIFRA, provided it meets the following criteria:
 - The product, in the undiluted package concentration at which it is distributed or sold, meets the criteria... for Toxicity Category III or IV; and
 - The product is not intended for use on food crop sites, and is labelled accordingly.

During registration of both plant growth regulators and biostimulants, the claims made by the registrant, and on the product label are also considered by the EPA as part of its evaluation of the appropriate regulatory pathway. However, it should be noted that the EPA does not solely look at the claims made. Products that contain an active ingredient consistent with pesticidal/plant growth regulator usage will be registered as such regardless of how the registrant makes claims for its use. Similarly, if a biostimulant product claims pest-control properties, it will be considered as a pesticide under FIFRA.

The EPA outlined in this draft guidance document, example claims that may exclude a product from registration as a pesticide under FIFRA. These are not exhaustive, and as mentioned previously, if the active ingredient is consistent with a pesticidal active then it will be registered as such. The examples provided relate specifically to **plant nutrition-based claims**, **plant inoculant-based claims** and **soil amendment-based claims**. These can generally be summarised as modalities that *indirectly* support crop health, such as correcting nutrient deficiencies in the soil, optimising conditions for abiotic stress tolerance, soil structure/biodiversity, and increases to nutrient availability/uptake (e.g. through promoting root growth, nutrient solubilisation etc). The claims made by vitamin-hormone products need to be considered more carefully given that they are considered by the agency to contain components that can be considered as regulating plant physiological processes.

Plant regulator claims may be made for vitamin-hormone products when they meet both criteria for exclusion from the plant regulator definition, as specified under 40 CFR 152.6(f)(1) & (2).

This means that the product is considered 'non-toxic' but crucially also not for use on food crops, which means this exclusion has no relevance for agriculture beyond non-crop uses such as turf and ornamentals.

The guidance document goes on to discuss the definition of a plant growth regulator.

A naturally occurring substance would be considered a "plant regulator," and a product label claim would be considered a "plant regulator claim" if:

The substance or mixture of substances, through physiological action:

- 1. Accelerates or retards the rate of plant growth;
- 2. Accelerates or retards the rate of plant maturation;
- 3. Or otherwise alters the behaviour of plants or the produce thereof;

<u>and</u>

if the substance or mixture of substances does not fall under one of the exclusion categories listed in 40 CFR 152.6(f) & (g) as vitamin-hormone products, plant nutrients, plant inoculants or soil amendments; or under 40 CFR 152.8(a) as a fertilizer.

Plant regulator claims may be made for vitamin-hormone products when they meet both criteria for exclusion from the plant regulator definition, as specified under 40 CFR 152.6(f)(1) & (2). When claims for increased or decreased growth, yield, germination, maturation, etc. are consequent to intended uses of products or substances as plant nutrients (fertilizers), plant inoculants, soil amendments, and/or as other non-pesticidal uses, such products and substances may be excluded from regulation under FIFRA in the absence of any plant regulator claims.

This would imply that plant nutrients, plant inoculants or soil amendments that <u>do</u> have plant growth regulating capabilities and/or claims would be excluded from FIFRA registration, provided that they meet the requirements of the above exclusions, and have at least some 'non-plant growth regulating claims'. The exception here is that this doesn't apply for vitamin-hormone products used in food crops.

Examples of active ingredients that are considered to have no other usage other than as plant growth regulators and therefore pesticides under FIFRA include (but not limited to):

- Auxins
- Cytokinins
- Gibberellins
- Ethylene
- Abscisic acid

Other substances that may be included in this category include:

- Corn glutens
- L-Glutamic Acid (LGA) and gamma-Aminobutyric Acid (GABA)
- Homobrassinolide and other brassinosteroids
- Lysophosphatidylethanolamine (LPE)
- 1-Octanol
- Sodium o-nitrophenolate, sodium p-nitrophenolate, and sodium guaiacolate

There are numerous substances that may have plant regulator activity, as well as additional modes of action, not considered to be plant regulator modes of action that may include, but are not limited to:

- Abiotic stress tolerance
- Water and nutrient use efficiency/uptake;

• Nutrient availability - increased availability of inorganic nutrients in the soil to plant roots and seeds; improving biotic and abiotic characteristics of soils

Examples of these include:

- Seaweed extracts (SWE)
- Complex Polymeric Polyhydroxy Acids (CPPAs) and Humic Acids (HAs)

Both of these categories of active ingredients are generally understood to have direct physiological effects on growth, yield, maturation, and produce quality.

The Agency also recognizes that not all uses of PBS may be intended for plant regulator or other pest control purposes. If it can be demonstrated that a particular product has the activity claimed on the product label (and any other informational media) and does not make any plant regulator or pest control claims on the product label (and any other informational media) it may be excluded from FIFRA regulation.

Therefore, a natural product such as seaweed extracts and humic substances will be excluded from registration as a pesticide, provided that the product does not claim plant regulator activity, and claims activity under the plant health examples cited in the guidance document (Tables 1a-c and 2), or those analogous to those non-exhaustive examples.

Finally, the document also outlines how other 'conventional' components in the mixture should be considered, as well as components generated as a result of the extraction process.

If a conventional chemical plant regulator is contained within a PBS product, the product likely would be considered a conventional chemical pesticide by the Agency and would be subject to registration under FIFRA.

Novel substances may be present in plant biostimulant products that were not present in the original plant source material, but were formed as a result of the extraction methods and/or post-extraction processing but will require further scrutiny under FIFRA by the Agency to determine if they have the potential for pest control and/or plant regulator activity.

In summary, the guidance document outlines the importance of understanding the mode of action of the components in the product and associated claims, including the ability to produce performance data supporting such claims. Plant growth activity alone will not permit registration as a biostimulant, and companies must have an awareness of the physiological responses of the product and make sure that label claims, and those made in the process of regulation align with this.

Brazil

Under the first Fertilizer Law of 1980 (6.894/1980) and subsequent decree number 4.954/2004, fertilizers were defined as "mineral or organic substances, natural or synthetic, that provide one or more plant nutrients". For biofertilizers, Brazilian legislation previously utilised two definitions:

- (i) Inoculants: products containing micro-organisms that have a favourable impact on plant growth
- (ii) Biofertilizers: products containing an active ingredient or organic agent, free from agrochemical substances, capable of acting directly or indirectly on all or part of cultivated plants, enhancing their productivity, regardless of their hormonal or stimulant value

The generally vague definitions and regulation of biostimulants has in the past generated uncertainties for companies wishing to enter the market and represented a challenge surrounding grower confidence in product efficacy, composition, and quality assurance. However, few barriers have existed to introducing a biostimulant product into the market. There have been steps in 2024 to update and clarify the legislation under the 'Bioinputs Law'.

On December 23, 2024, Law No. 15,070/2024 ('Bioinputs Law'), which regulates the production, use, and commercialisation of bioinputs in the agricultural sector, was published in the Official Gazette. The new law regulates the production, use, and commercialisation of bioinputs for agricultural,

The Bioinputs Law defines a bioinput as: product, process or technology of plant, animal or microbial, including that originating from a biotechnological process, or structurally similar and functionally identical to that of natural origin, intended for use in production, protection, storage and processing of agricultural products or in production systems or planted forests, which interferes with the growth, development and response mechanism of animals, plants, microorganisms, soil and derived substances and that interact with the products and physical-chemical and biological processes.

Bioinputs include those "used in agricultural activity, including biostimulators or growth or performance inhibitors, semiochemicals, biochemicals, phytochemicals, metabolites, organic macromolecules, agents biological control products, soil conditioners, biofertilizers and inoculants."

However, the updated pesticide law stops short of defining each of these categories in detail.

livestock, aquaculture, and forestry use in Brazil, whilst also promoting the production and adoption of such products.

Argentina

Biostimulants and organic-chemical fertilisers must also be registered through SENASA. The general fees required for registration are relatively low compared to other markets, such as North America and Europe. However, this is more than offset by the level of complexity, the current lack of a fast-track registration process, and the generally lower levels of capacity and regulatory expertise required for a more expedited future process.

In November 2024, the government announced that all phytosanitary and bioinput procedures were centralised through an online platform known as SIGTrámites. On this platform users can register their products, facilitate self-management, gain insights on process traceability, reduce processing times, gain support, boost communication and make online payments. The platform may be used for newly formulated phytosanitary products, registration requests for prioritised items and registration requests for bio-inputs for plant nutrition.

China

In China, biostimulants are currently regulated through NY/T 3831-2021 Organic Water-Soluble Fertilizers-General Regulations; biostimulants are regulated alongside fertilisers and treated as **microbial fertilisers** or organic water-soluble fertilisers. This is overseen by the Chinese Ministry of Agriculture and Rural Affairs. The current regulation provides improved definitions that resolve biostimulant products' previously ambiguous legal status. Additionally, the regulation offers a pre-marketing procedure, product classifications, general rules on raw materials, nutrient contents, and labelling requirements.

The key product classes, such as inoculants and rhizobia, are registered under microbial fertilisers. Other biostimulants, such as chitosan, are listed under 'Water-soluble fertilisers':

- WSF containing amino acid.
- WSF containing humic acid.
- Organic WSF containing alginic acid.
- Organic WSF containing chitosan.
- Organic WSF containing polyglutamic acid.
- Organic WSF containing polyaspartic acid.
- Other WSF containing molasses, low-value fish and its fermented products, as well as other organic materials.

Overseas applicants must follow several requirements, including using a Chinese agent for application. This involves supplying critical information on product properties. Depending on raw materials, manufacturing processes, and end uses, toxicity tests and efficacy trials are sometimes required. These generally have lower requirements than urea, ammonium nitrate, and other fundamental nutrition products; therefore, they do not require technical review for registration. Following these tests, a technical permit is granted for commercialisation.

Japan

Japan does not legally define biostimulants, which are registered under the Fertiliser Control Law or Soil Fertility Enhancement Act. MAFF's 'Green Food System Strategy' targets a reduction in the use of chemical fertilisers. However, several products considered biostimulants are broadly used with registration under the Fertiliser Control Law or Soil Fertility Enhancement Act.

In response to the amendment of the Fertiliser Regulation in the EU, an industry group in Japan has been established to actively promote communication with the competent authorities to facilitate the standardisation of biostimulants.

With its new 'Green Food System Strategy', MAFF targets reducing chemical fertiliser use by recognising biostimulants as a valuable tool to lower fertiliser inputs and reduce environmental impacts. The Japanese Crop Protection Association has announced that the industry will proceed with developing biostimulants to support this strategic goal.

India

India's biostimulant definition is broadly aligned with that of the EU. Biostimulants are currently regulated through Fertiliser Control Order (FCO), which defines biostimulants as:

...a substance or micro-organism or a combination of both whose primary function when applied to plants, seeds or rhizosphere is to stimulate physiological processes in plants and to enhance its nutrient uptake, growth, yield, nutrition efficiency, crop quality and tolerance to stress, regardless of its nutrient content, but does not include pesticides or plant growth regulators which are regulated under the Insecticide Act, 1968.

India's Fertilizer (Inorganic, Organic or Mixed) (Control) Amendment Order was introduced in 2021. These new regulations require manufacturers to register products with the relevant authority providing a set of information on chemistry (composition, analytical methods, shelf-life), bio-efficacy trials conducted by the Indian Council of Agricultural Research (ICAR), state agricultural universities (SAUs) (preferably in agro-ecological zones), and toxicity data and heavy metal analysis.

The regulations also establish a regulatory body to monitor the end-to-end movements within the industry. The committee controls the quality and specifications of all biostimulants and ensures the use of safe substances and organic compounds in product manufacturing.

Farming-related services and speciality products dominate the Indian agrochemical landscape. The Federation of Indian Chambers of Commerce & Industry (FICCI) categorises biostimulants under the latter category alongside micronutrients, biopesticides, and biofertilisers that have recently begun to permeate the markets.

In May 2024 the Indian Union Ministry of Agriculture and Farmers Welfare issued a new amendment to the Fertilizer (Inorganic, Organic or Mixed) (Control) Order, 1985. Titled the 'Fertilizer (Inorganic, Organic or Mixed) (Control) (Third) Amendment Order, 2024,', the issue is intended to regulate the specifications and approval process for biostimulants in the agricultural sector. Key provisions of the amendment include:

- Increased specifications for biostimulant products, including their name, active ingredient or tracer molecule, chemical composition (in cases where active ingredients or tracer molecules cannot be indicated), and the name of the crop to which they are applied.
- The introduction of a new category for live microorganisms, excluding biofertilisers and biopesticides, within the specifications for biostimulants.

- Alterations to the application for new biostimulants, including the submission of data regarding categories, such as chemistry, bio-efficacy trials, toxicity, heavy metal analysis, and a product sample accompanied by an affidavit affirming compliance with pesticide limits.
- Toxicology data exemptions for certain biostimulants, such as protein hydrolysates, seaweed extracts, amino acids, vitamins, humic and fulvic acid.
- Alterations to pesticide limits within biostimulant products, set at 1 part per million (ppm), replacing the previous limit of 0.01 ppm.

The amendment aims to provide a framework for regulating and approving biostimulants in agriculture to ensure their safety, efficacy, and adherence to specified standards

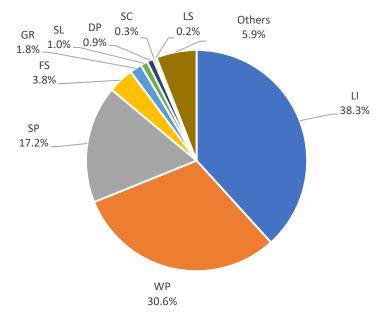
Company Involvement

The below table(s) on key active ingredients and key companies is derived directly from AgBioInvestor's exclusive primary market research study that surveyed biological- and biostimulantgrowers, which were conducted for the first time in 2023 and profiled the 2022 agricultural market. The market research surveyed many key agricultural markets for biologicals, including: USA, Mexico, Chile, Brazil, Argentina, France, Italy, Spain and Turkey. The Ais have been ranked by farm-gate value (\$m.). Quantification of these data and much more biological market research can be found in the separate subscription product AgbioInsight.

Key Companies with Involvement in Biostimulants: Microbial Amendments		
AI	Key Companies	
Glomus aggregatum / Glomus etunicatum / Glomus intraradices / Glomus mosseoe	Sumitomo Chemical	
Trichoderma Harzianum	Ballagro / Nooa	
	Biokrone	
	Direct Biologicals	
	Locus Agricultural Solutions	
	Simbiose	
Calothrix castelli	Univex	
Bacillus Subtilis	Indigo Ag	
	BMF Tec Bio	
Penicillium bilaiae	Bayer	
Methylobacterium symbioticum strain Sb23	Corteva (Symborg)	
Bradyrhizobium japonicum	Bayer	

Formulation Types – Value Share

The below chart(s) are derived from the biological focussed market research that AgbioInvestor conducted, and illustrates the value share attributed to various formulation type codes.



*Excludes unidentified formulations. Above identified formulations represents 63.2% of survey responses, unidentified represents 36.8% of responses.

Code	Description	Code	Description
AE	Aerosol dispenser	LI	Liquid
AL	Other liquids to be applied undiluted	LS	Solution for seed treatment
СВ	Bait concentrate	ME	Micro emulsion
CS	Capsule suspension	OD	Oil dispersion
DC	Dispersible concentrate	SC	Suspension concentrate
DF	Dry flowable	SL	Soluble concentrate
DP	Dustable powder	SP	Water soluble powder
EC	Emulsifiable concentrate	VP	Vapour releasing product
EW	Emulsion, water in oil	WG	Water dispersible granule
FS	Flowable concentrate for seed treatment	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment
LC	Liquid concentrate		

Research and Development

In the field of microbial amendments, much of the research centres around selecting and optimising strains for their ability to facilitate a greater bioavailability of soil nutrients (nutrient availability) and/or to enhance nutrient use efficiency (e.g. enhancement of root structures). This can involve screening wild-type strains from a range of sources such as soil, roots, plant tissue, compost and animals. These can then be assembled into strain libraries, and subject to genomics analysis to understand the field potential of the strains.

Further work is then conducted to optimise the manufacturing conditions for culturing economically viable levels of the strains. Formulation development is essential to produce a product that is not only stable in storage, but is compatible with application equipment, able to penetrate the plant tissue, roots or remain stable in the soil, and also remain viable for long enough in the field to produce the desired effect.

Another key area of R&D we are increasingly seeing is the gene editing of soil inoculants, such as those marketed by Pivot Bio (*Kosakonia sacchari* and *Klebsiella variicola*). One of the key reasons for further optimisation of strains is not only to ensure greater efficacy, but also to ensure the survival of the microbes under field concentrations of synthetic fertilisers. This trend of optimisation is also undertaken through other techniques such as mutagenesis and screening of wild types.

 Apr 16, 2021 The Argentinian microbiological product development company Rizobacter partnered with the University of Illinois' Feed the Future Soybean Innovation Lab (SIL) to bring soybean technology to 26 African countries. The partnership will provide the SIL Pan-African Soybean Variety Trial (PAT) network with access to Rizobacter's Rizoliq TOP inoculant product whilst also providing Rizobacter access to new African markets through the PAT network, which includes seed companies, nucleus growers, processors, national agricultural research stations, universities, and commercial farmers.

Rizoliq TOP is formulated with Osmo Protection Technology, which reportedly provides the inoculant with a higher concentration, a more robust physiological state, and greater tolerance to stresses to improve the survival of microorganisms on the seed. The higher concentration of Bradyrhizobium japonicum ensures that the radicle of the germinated seed is quickly infected, accelerating and maximizing the process of biological fixation of nitrogen.

- Sep 28, 2021 Valent BioSciences and Kansas State University entered into a long-term soil health and carbon smart farming research agreement. The project aims to investigate the interactions controlling soil carbon stability and carbon and nitrogen dynamics. The project will evaluate how soil inoculants containing arbuscular mycorrhizal fungi and soil conservation management practices influence soil health. Soil cores from Kansas State University studies will be evaluated using imaging technologies at the Donald Danforth Plant Science centre in St. Louis, Missouri.
- Feb 23, 2022 Legume Technology, a British inoculant and biostimulant company, and Green Universe Agriculture, a Spanish biotech company, entered into a sustainable inputs partnership. Under the partnership, the companies will share knowledge and strategic vision in an attempt to increase agricultural productivity and improve resource-use efficiency. The alliance is intended to allow both parties to develop microbial products to cover a broader range of crops and streamline the development of novel products.

• Mar 30, 2022 Amvac and BASF entered into an agreement under which the companies will develop the granular soybean inoculant Rhizo-Flo for use in the SIMPAS systems. The product is intended to increase the nitrogen fixing capacity of soybean crops, through stimulating *Bradyrhizobium spp.*, which penetrate the soybean plant root system and form nodules that can fix nitrogen.

Amvac's SIMPAS system allows for variable and precisely applications of up to three, in-furrow crop inputs while planting, including nematicides, fungicides, micronutrients, insecticides, inoculants, and biologicals.

- Jul 27, 2023 Solvay established a partnership with the University of São Paulo (ESALQ-USP Escola Superior de Agricultura Luiz de Queiroz) aimed at developing bioinsecticides, biofungicides, bionematicides and inoculants for use in different crops. The partnership will leverage ESALQ-USP's expertise in biopesticides, bioprocesses and agronomic applications, and Solvay's knowledge in formulations for the agricultural sector.
- Jan 23, 2024 Vitales, a Brazilian agricultural biopesticides company headquartered in Uberaba, Minas Gerais, invested R\$ 1.3 million (\$260,000) in partnership with Embrapii-Esalq unit to develop four new biological products. In the initial phase of the partnership, the companies intend to develop a bioinsecticide, a biofungicide, a bionematicide, and a bioinoculant based on fungi and bacteria, with application and main focus on soybean, maize, sugarcane, cotton, coffee and pasture. The company intends to continue investing in this partnership model, anticipating investments of approximately R\$ 20 million (\$4 million) for research over the next three years.
- Jul 18, 2024 The speciality minerals and chemicals company ICL and Lavie Bio, an ag-biologicals company and subsidiary of Evogene, announced a milestone in their biostimulant development collaboration. The companies have identified multiple microbial candidates with potential commercial viability as biostimulants solutions for key row crops facing various abiotic stresses by utilising Lavie Bio's proprietary artificial intelligence platform, Biology Driven Design (BDD), to accelerate the screening process. More than a dozen novel candidates, which met the product requirements for efficacy, stability, shelf life and fertiliser compatibility, were computationally identified and verified in multiple greenhouse trials. The companies will now progress with field trials in both the US and Brazil in the second half of 2024 with plans to initiate the regulatory procedures by 2026. Lavie Bio will continue to be responsible for product development whilst ICL will be responsible for product stewardship through to commercialisation.
- Nov 4, 2024 Aphea.Bio, a provider of microbial solutions for agriculture, received €1.9 million (approximately \$2.5 million) in funding from VLAIO to support the continued development of its seed treatment biostimulant Initia. The product, initially aimed at maize, is designed to enhance germination, early vigour, root biomass and nutrient use efficiency (nitrogen and phosphorus). Aphea.Bio intends to utilise the funding from VLAIO to help expand the market reach of Initia to key markets in the US and Brazil following positive field trials in the EU, with the company also to explore the product's potential for use in the fruit and vegetables sector.

Market Outlook

The outlook for the microbial amendment segment is the most positive of all the major biostimulant segments. This is largely down to the potential for offsetting some of the need to apply synthetic nitrogen fertiliser, but also other exogenous nutrients through the ability of many strains to enhance the nutrient availability of other key macro and micro nutrients in the soil. The key factor here is that microbial amendments in isolation can only ever maximise the usage of what is already there in the soil zone, therefore nutrient deficient soils such as those present in countries like Brazil will not respond as well to certain microbial amendments. This is often tackled by microbes being used alongside other natural source material rich in nutrients such as seaweed extracts, humic substances and micronutrients themselves. Clearly one exception to this are microbial amendments that fix nitrogen from the atmosphere, and we anticipate that this sub-class of microbial amendment will have both the greatest level of R&D, investment, and new product introductions.

Recent periods of fertiliser price volatility have accelerated the trend of greater adoption by growers. This coupled with greater product availability and product consistency has also driven the market. In the past, microbial amendments (typically referred to as inoculants) had a perception of being costly, poorly efficacious and not delivering a significant return on investment.

Other potential downsides to microbial amendment usage include sensitivity to exogenous nitrogen levels in the soil from fertiliser applications which can reduce the viability of the applied microbes. Variations in field conditions such as soil temperatures, soil pH, moisture/nutrient levels and also the application of pesticides (particularly fungicides) can also impact performance of the microbes.

However, we are increasingly seeing more gene editing of soil inoculants, such as those marketed by Pivot Bio (*Kosakonia sacchari* and *Klebsiella variicola*). This trend of optimisation through gene editing and other techniques such as mutagenesis and screening of wild types is likely to accelerate as the segment gains more traction with farmers. Further formulation development will also be required to ensure that products have the best possible shelf life, stability and field performance.

Taking all these factors into consideration we anticipate that the microbial amendment segment will be the fastest growing major segment of biostimulants rising by a forecasted 16.0% p.a. (constant currency and pricing) between 2023 and 2028 to reach \$1,010 million.

Biostimulants: Others

Sales Performance of Biostimulants: Other			
Year	Biostimulant: Others Sales (\$ m.)	Share of Biostimulants Segment %	
2018	122	6.0	
2022	177	5.0	
2023	195	5.1	
2028F	359	5.8	
1-yr Change (%)	10.0		
5-yr CAGR (% p.a.)	9.8		
5-yr CAGR F (% p.a.)	13.0		

Introduction

This section covers the remaining components that are typically found in plant extracts and therefore consists of a broad range of plant hormones, allelochemicals, plant nutrients and plant growth factors.

Plant growth factors, also known as plant growth regulators or phytohormones, are chemical substances that regulate various aspects of plant growth and development, and control processes such as cell division, elongation, differentiation, and responses to environmental stimuli. The major classes of plant growth factors include auxins, cytokinins, polyamines, strigolactones, gibberellins, abscisic acid (ABA), ethylene, brassinosteroids and jasmonates.

An allelochemical is a chemical compound produced by one organism that affects the growth, development, behaviour, or survival of another organism, typically within the same ecosystem. In the context of biostimulation they can be employed to generate a biological response in the relevant crop, boosting one or more plant outcomes.

Due to the natural source of many of these compounds, they often do not exist in isolation, and lead to complex end products. They are also often present in extracts of other classes such as seaweed biostimulants, or intentionally mixed with other classes such as microbial amendments. Some of the biostimulants in the others class may also be synthesised in the laboratory due to their simpler biochemical nature, such as some of the more basic aliphatic and aromatic acids. For the purpose of this analysis, the market sizing for 'Biostimulants: Others' is on the basis of the assigned value of these components in traded products and excludes the value of the same compounds if naturally found in a seaweed product. However, if the components are found in *another* plant extract then they are included here in this segmental definition.

Biostimulants: Others

Key Components			
Class	Туре	Potential Source	Potential Synthesis
Plant hormones			
Auxins	Plant hormone	Plant Extract	Naturally occurring/ synthetic
Cytokinins	Plant hormone	Plant Extract	Naturally occurring
Ethylene or analogues	Plant hormone	Plant Extract	Naturally occurring/ synthetic
Gibberellins	Plant hormone	Plant Extract	Naturally occurring
Karrikins and cyanohydrins	Plant hormone/ Allelochemicals	Plant Extract	Naturally occurring
Organic Acids	Plant hormone	Plant Extract	Naturally occurring/ synthetic
Polyamines	Plant hormone	Plant Extract	Naturally occurring/ synthetic
Steroids	Plant hormone/ Allelochemicals	Plant Extract	Naturally occurring/ synthetic
Strigolactones	Plant hormone	Plant Extract	Naturally occurring
Non-hormonal biostimulants			
Benzoquinones	Allelochemicals	Plant Extract	Naturally occurring/ synthetic
Chitin and chitosan derivatives		Animal Extract	Naturally occurring/ synthetic
Complex organic materials		Plant/Animal Extract	Naturally occurring
Coumarins	Allelochemicals	Plant Extract	Naturally occurring/ synthetic
Flavonoids	Allelochemicals	Plant Extract	Naturally occurring/ synthetic
Phenols	Allelochemicals	Plant Extract	Naturally occurring/ synthetic
Polyacetylenes	Allelochemicals	Plant Extract	Naturally occurring/ synthetic
Polyphenols	Allelochemicals	Plant Extract	Naturally occurring
Polysaccharides		Plant/Animal Extract	Naturally occurring
Quinones	Allelochemicals	Plant Extract	Naturally occurring/ synthetic
Sesquiterpenes/unsaturated lactone	Allelochemicals	Plant Extract	Naturally occurring
Tannins	Allelochemicals	Plant Extract	Naturally occurring/ synthetic
Terpenes/ketones	Allelochemicals	Plant Extract	Naturally occurring/ synthetic

Plant Homones

Auxins

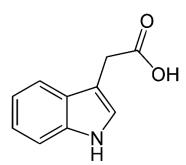
Auxins represent a broad group of plant hormones that are responsible for cell growth, cell division and cell expansion in the actively growing parts of the plant. They regulate a broad spectrum of processes, including reactions to light and gravity, overall root and shoot structure, organ arrangement, vascular system formation, and tissue culture growth.

Auxins can be found in all parts of plants in varying concentrations, with this concentration having an influencing factor on plant development. Additionally, regulation of auxin metabolism and transport, is also a significant influencing factor on plant development. When exposed to exogenous auxins, plant cells can undergo significant changes in gene expression, either up- or down-regulated.

The auxin perception pathway refers to the series of molecular events through which plant cells detect and respond to the presence of auxin. It begins with the binding of auxin molecules to specific receptors known as Transport Inhibitor Response 1/Auxin Signalling F-Box (TIR1/AFB) proteins in the cytoplasm or associated with the cell membrane. Upon auxin binding, the TIR1/AFB proteins undergo a conformational change, allowing them to interact with Auxin/Indole-3-Acetic Acid (Aux/IAA) proteins which triggers the ubiquitination of Aux/IAA proteins by an E3 ubiquitin ligase complex, marking them for degradation by the proteasome. The degradation of these Aux/IAA proteins then de-inhibits transcription factors known as Auxin Response Factors (ARFs), which regulate the expression of auxin-responsive genes. ARFs are then free to translocate to the nucleus where they may bind to specific DNA sequences called Auxin Response Elements (AREs) located in the promoters of target genes. This binding either up or down regulates the transcription of these genes. It is this gene modulation that leads to various cellular responses to exogenous auxin application such as cell elongation, division, differentiation, tropic responses, and organ development.

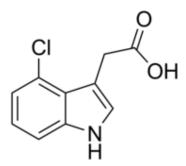
Key examples

Indole-3-acetic acid (IAA)



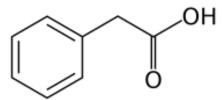
Indole-3-acetic acid (IAA) is synthesized primarily in the apical meristems, young leaves, and developing seeds of plants and influences processes such as: cell elongation (particularly in stems and coleoptiles) as well as increased cell wall plasticity and expansion. IAA may inhibit the growth of lateral buds, conversely promoting the influence of the apical bud in controlling shoot growth. IAA regulates root growth and development, including elongation, branching, and gravitropism (growth in response to gravity). IAA also influences phototropism (growth towards light) and reproductive development.

4-Chloroindole-3-acetic acid (4-CI-IAA)



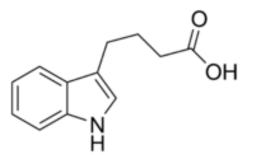
4-Chloroindole-3-acetic acid (4-CI-IAA) is a synthetic analogue of indole-3-acetic acid (IAA), derived from IAA by substituting a chlorine atom at the fourth position of the indole ring. 4-CI-IAA functions also promote cell elongation, contributing to stem elongation and other growth processes, as well as root elongation, branching, and gravitropism. 4-CI-IAA may play a role in flower and fruit development, including the initiation of floral primordia and fruit growth. Compared to IAA, 4-CI-IAA may exhibit different strength of plant responses, particularly a stronger cell elongation response.

2-phenylacetic acid (PAA)



2-phenylacetic acid (PAA) is an aromatic compound with a phenyl group attached to the second carbon atom of the acetic acid molecule. PAA can act as a growth regulator, including root elongation and lateral root formation. The auxin can stimulate seed germination by breaking seed dormancy or promoting embryo growth. PAA may influence flowering time, flower development in some plants, depending on species and field conditions although its specific effects can vary depending on the species and environmental conditions. PAA has been implicated in the regulation of fruit ripening processes, including fruit coloration, softening, and aroma development. As well as biotic tress response.

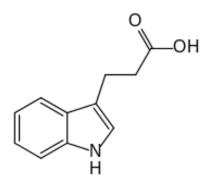
Indole-3-butyric acid (IBA)



Indole-3-butyric acid (IBA) is structurally similar to indole-3-acetic acid (IAA) but differs in the length of the carbon chain attached to the indole ring. IBA is able to promote shoot elongation, leaf expansion, and fruit development. IBA also influences root development and stimulates the formation of adventitious roots, which are roots that form from non-root tissues, such as stems or leaves. IBA can also enhance seed germination by breaking seed dormancy and promoting uniform and vigorous seedling emergence.

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Indole-3-propionic acid (IPA)



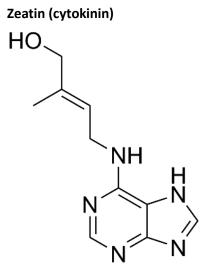
Indole-3-propionic acid (IPA) is structurally similar to other auxins, such as indole-3-acetic acid (IAA), but with a propionic acid side chain attached to the indole ring. Similar to other auxins, IPA may promote root growth and stimulate the formation of adventitious roots. The auxin has also been implicated in triggering plant defence responses through induction of the expression of defence-related genes. IPA is also produced by certain microorganisms, where it can serve as a metabolic intermediate or signalling molecule. Its presence in the rhizosphere may play a role in soil microbial health and nutrient cycling processes.

Cytokinins

Cytokinins are *N*6 substituted adenine derivatives that affect many aspects of plant growth and development, including cell division, shoot initiation and growth, leaf senescence, apical dominance, nutrient uptake, phyllotaxis (the arrangement of leaves on a plant stem), and vascular, gametophyte, and embryonic development, as well as the response to biotic and abiotic factors.

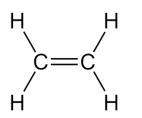
Naturally occurring cytokinins are adenine derivatives with distinct substitutions attached to the *N*6 position of the adenine ring. The most common class of cytokinins have isoprenoid side chains. Cytokinin equilibrates with auxins within plants, with the balance between cytokinins and auxins affecting growth characteristics, however this is still not fully understood underlining the importance of biostimulant research and consistency of composition to ensure expected efficacy. Where auxins typically signal vertical growth, cytokinins may signal for lateral growth.

Cytokinins can also delay senescence (ageing) within the plant by increasing the production of new proteins while limiting the destruction of older proteins. This can also be beneficial to mitigate abiotic stress that can be caused by drought, excessive moisture and extreme temperatures. Implicated in this effect is many cytokinins' ability to delay senescence triggered by the release of ethylene, another hormone.



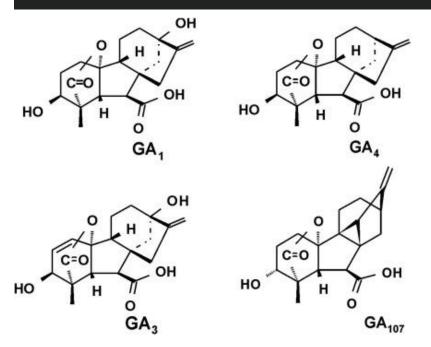
Zeatin is a naturally occurring cytokinin first isolated from corn (*Zea mays*) that has activity across a number of areas including cell division and differentiation in meristematic tissues such as shoot and root apices and the stimulation of lateral root development. This may stimulate the growth of lateral shoots and the formation of new leaves. Zeatin has also been shown to delay leaf senescence, the aging process in plants by inhibiting the breakdown of chlorophyll and other cellular components, maintaining leaf greenness and photosynthetic activity. Zeatin may influence the transition from vegetative to reproductive growth and promoting the initiation of flower primordia and the development of floral organs. Fruit development such as fruit set, size, shape, and quality may also be influenced by the auxin.

Ethylene and analogues



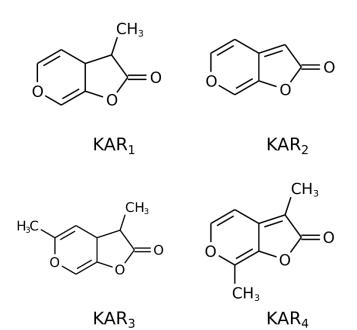
Ethylene and its associated analogues are phytohormones that have been shown to increase plant growth and yield. It is particularly implicated in senescence (ageing) of plants and depending on its concentration, timing of application and target species, it may either promote or inhibit growth and senescence processes. Ethylene influences the development of leaves such as abscission (shedding), flowers development/opening, and fruits ripening. Ethylene is also implicated in plant abiotic stress response, stimulating senescence prematurely ripening. Therefore, analogues of ethylene that can inhibit ethylene receptors or ethylene production in the plant may delay this process or facilitate abiotic stress tolerance.

Gibberellins



Gibberellins (GAs) are plant hormones that regulate various developmental processes. Gibberellins can promote stem and leaf elongation by stimulating cell division and expansion in the stem's internodes and leaf cells respectively. Gibberellins also influence the transition from vegetative to reproductive growth and promote flowering as well as fruit development and growth, particularly in seedless fruits like grapes and oranges. They can stimulate cell division and enlargement in the fruit tissues, leading to increased fruit size. Gibberellins can also enhance/initiate seed germination as well as breaking dormancy in certain perennial plants.

Karrikins and Cyanohydrins



Karrikins constitute a group of closely related small organic molecules generated during the combustion of plant matter. They facilitate seed germination and plant growth by mimicking signalling hormones called strigolactones. Karrikins are produced through the heating or burning of carbohydrates, such as sugars and polysaccharides, notably cellulose. While there is no direct evidence of karrikins naturally occurring in plants, it is theorised that molecules similar to karrikins may exist.

They are reported to cause more vigorous growth of some seedlings, including maize and tomato, and in Arabidopsis thaliana karrikins have been shown to influence seedling photomorphogenesis (the process by which plants regulate their growth and development in response to light signals), causing smaller stature seedlings with larger cotyledons.

Karrikins have the potential to promote plant resilience against temperature, drought, heavy metals, salinity, and other abiotic stressors. Drawbacks may be the high cost of karrikins and lack of reliable field application protocols around timing and concentration may be significant barriers to their commercial potential.

Karrikins may also have potential applications in biological control by stimulating the germination of weed seeds, allowing for targeted weed management strategies, however this would fall under the bioherbicide segment.

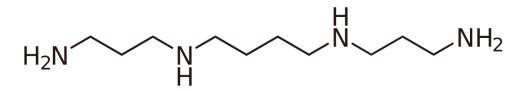
Polyamines

Polyamines (PAs) are low molecular weight aliphatic nitrogenous bases containing two or more amino groups, that have potent biological activity. Putrescine (Put), spermidine (Spd), and spermine (Spm) are the main PAs in plants and are found in all plants. They are involved in the regulation of diverse physiological processes, such as flower development, embryogenesis, organogenesis, senescence, and fruit maturation and development.

Exogenous application of polyamines, such as spermidine or putrescine, can enhance seed germination rates and improve seedling vigour. Polyamines are also involved in root growth and development, including root elongation, branching, and lateral root formation boosting the absorption of water and nutrients. Polyamines can also help plants tolerate various abiotic stresses, including drought, salinity, temperature, and heavy metals. They act as osmoprotectants, scavengers of reactive oxygen species (ROS), and regulators of stress-responsive gene expression, thereby enhancing plant resilience. Exogenous application of polyamines during flowering can improve fruit set, reduce flower and fruit abortion, and enhance fruit quality attributes such as size, colour, and shelf life, and they can also be applied post-harvest to prolong quality and delay ripening.

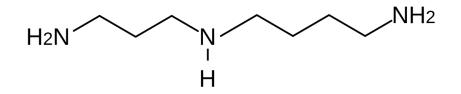
Spermine

Spermine is a polyamine involved in cellular metabolism that is found in all eukaryotic cells. The precursor for synthesis of spermine is the amino acid ornithine.



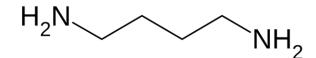
Spermidine

Spermidine is an aliphatic polyamine. Spermidine synthase (SPDS) catalyzes its formation from putrescine. It is a precursor to other polyamines, such as spermine and its structural isomer thermospermine.



Putrescine

Putrescine is widely found in plant tissues and is implicated in stress responses in plants, both to biotic and abiotic. The absence of putrescine in plants is associated with an increase in both parasite and fungal population in plants.



Organic acids

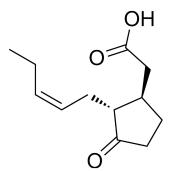
Abscisic acid

Abscisic acid (ABA) is a plant growth regulator that has a range of functions including regulating seed maturation, seed dormancy, biotic and abiotic stress response, and leaf and bud abscission.

In terms of regulating seed dormancy high levels of exogenous ABA can inhibit germination. In abiotic stress scenarios ABA mitigates water scarcity by promoting stomatal closure to reduce water loss through transpiration and by signalling for the production of protective compounds like osmoprotectants. ABA has also been shown to plays a role in regulating root growth and development, particularly under water stress conditions where it can inhibit primary root growth while promoting the formation of lateral roots, which may be useful in encouraging plants to utilise a larger soil volume for water uptake.

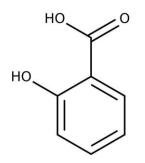
ProTone from Valent BioSciences contains S-ABA (Abscisic Acid) and stimulates anthocyanin biosynthesis and accumulation. S-ABA mediates a number of responses in grapes (Vitis spp.) including switching on the anthocyanin genes which can be used to improve colour development and uniformity in grapes, increasing yield, supporting earlier harvest, and increasing shipping and storage longevity. It can also be used for accelerating defoliation in fruit, nuts, and vines in the Autumn season, as well as promoting fruit thinning in pears and apples when applied at post bloom.

Jasmonic acid



Jasmonic acid (JA) is an endogenous growth-regulating hormone, initially identified as a stress-related hormone. JA does not play an independent regulatory role, but rather works in a complex signal network with other phytohormone signalling pathways. Jasmonic acid regulates processes such as growth inhibition, senescence, tendril coiling, flower development and leaf abscission. In the agricultural context JA can been used in seed treatments, where it stimulates the natural defences in seedlings that germinate from the treated seeds. ABA is also of utility in boosting abiotic stress tolerance to salt, drought, temperature, and heavy metal stress.

Salicylic acid



Salicylic acid (SA, o-hydroxybenzic acid). Application of low-concentration salicylic acid can enhance anabolism (synthesis of complex molecules from simpler ones), increases grain weight, the number of grains, yield, and improves quality. Salicylic acid can also be used to promote seed germination by breaking seed dormancy and enhancing seedling vigour.

Salicylic acid has been shown to induce systemic acquired resistance (SAR), a plant immune response that triggers the accumulation of salicylic acid in various parts of the plant, priming them for rapid and effective defence responses upon subsequent pathogen attack. Salicylic acid may also be used for regulating plant responses to various abiotic stresses, including drought, salinity, temperature extremes, and heavy metal toxicity through the activation of stress-responsive genes, and scavenging reactive oxygen species (ROS).

Steroids

Brassinosteroids

Brassinosteroids (BRs) are a group of polyhydroxylated steroidal phytohormones that are required for the development, growth, and productivity of plants. These hormones are involved in regulating the division, elongation, and differentiation of numerous cell types throughout the entire plant life cycle. BRs can participate in physiological processes in response to stress by modulating plant growth, and improving plant performance by interacting with plant growth regulators or other plant hormones. As with other classes of plant hormone, the concentration, either too high or too low can have radically different outcomes in the plant underscoring the importance of correct dosage under field conditions.

Brassinosteroids regulate the expression of genes involved in cell wall biosynthesis, leading to increased cell elongation and plant growth. They also influence stem elongation and root growth and play a role in the formation of vascular tissues such as xylem and phloem, influencing the transport of water, nutrients, and signalling molecules throughout the plant. Brassinosteroids can be used to promote seed germination, breaking dormancy and promoting uniform germination, boosting seedling establishment. BRs have been shown to promote photomorphogenic responses such as hypocotyl (the part of the stem of an embryo plant beneath the stalks of the seed leaves or cotyledons and directly above the root), elongation, leaf expansion, and chloroplast development, allowing crops to optimise light capture and energy production.

As with other classes of hormone, BRs can boost abiotic stress tolerance, including drought, salinity, and temperature, as well as biotic responses to pathogen infestation. This is achieved through regulating the expression of stress-responsive genes, scavenging reactive oxygen species (ROS), and modulating stress signalling pathways.

BRs can also be used to boost fruit and vegetable production by influencing flower development, pollen viability, and fruit set, by regulating the expression of genes involved in flower initiation, pollen tube growth, and ovule development, contributing to successful reproduction and seed production.

Strigolactones

Strigolactones are signalling compounds that have two main functions: first, as endogenous hormones to control plant development, and second as components of root exudates to promote symbiotic interactions between plants and soil microbes. These compounds were first identified in root exudates for their capability to trigger the germination of seeds belonging to parasitic plants like Striga, commonly known as 'witchweed' (see bioherbicide section). Strigolactones may be used to stimulate the catastrophic germination of such weeds, including by applying certain arbuscular mycorrhizal fungi (AMF) that produce these compounds, however this is not included in the biostimulant definition, rather falling under the bioherbicide definition.

From the perspective of biostimulants strigolactones can promote lateral root formation and root hair development, enhancing the ability of plants to make efficient use of the soil zone for seeking water and nutrients. This can be particularly beneficial in nutrient-poor soils or under conditions of drought stress. Strigolactones have also been shown to influence shoot architecture by inhibiting shoot branching. This can be advantageous in crops where controlling branching patterns is desirable for optimal yield or harvesting practices such as corn and wheat (e.g. reducing tillers), tomatoes and tobacco (suckers), sunflower for producing a larger single head, as well as cotton where reducing branching can benefit light penetration in the canopy.

Strigolactones are also involved in establishing symbiotic relationships between plants and beneficial soil microorganisms, such as mycorrhizal fungi which can help to foster a healthy soil microbiome and improve nutrient uptake, particularly phosphorus.

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Non-hormonal biostimulants

Chitin and chitosan derivatives

Chitosan is a co-polymer of N-acetyl-d-glucosamine and d-glucosamine. Chitin is the most abundant aminopolysaccharide polymer occurring in nature, and is the building block that gives strength to the exoskeletons of crustaceans, insects, and the cell walls of fungi. Through enzymatic or chemical deacetylation, chitin can be converted to the agriculturally relevant derivative, chitosan, which may be applied through foliar spraying, direct incorporation in soil or coating of seeds. The main natural sources of chitin are shrimp and crab shells, which are an abundant byproduct of the food-processing industry, that provides large quantities of this biopolymer to be used in agriculture but also in biomedical applications, cosmetics, food, paper, pharmacy and textile industries. Key benefits of using chitosan primarily concern its biodegradability, low-toxicity, and natural origin from food processing, although the animal source may create some issues around sustainability and consumer preferences.

Use of Chitosan can induce several defensive genes in plants and enzymes in the reactive oxygen species scavenging system of plants. Chitosan also finds utility as a biostimulant for promoting plant growth, abiotic stress tolerance, and pathogen resistance. Chitosan also promotes plant growth by stimulating root development and architecture, enhancing nutrient uptake, and increasing plant vigour.

Disease Resistance: Chitosan has antimicrobial properties and can induce plant defence mechanisms against pathogens. It activates the plant's innate immune system, triggering the production of defence-related compounds such as phytoalexins, pathogenesis-related proteins, and reactive oxygen species, thereby enhancing resistance to diseases caused by fungi, bacteria, and viruses.

Chitosan has been shown to enhances nutrient use efficiency in plants by improving uptake, translocation, and assimilation, by chelating metal ions in the soil, increasing bioavailability. Chitosanbased formulations can also be used as seed treatments to improve seed germination, seedling vigour, and establishment.

Coumarins

Coumarin and its derivatives are an important group of natural compounds that can be found in seeds, fruits, flowers, roots, leaves, and stems, although the largest concentration is generally in fruits and flowers. There are different classifications for plant derived coumarins including simple hydroxycoumarins, furocoumarins and isofurocoumarins, pyranocoumarins, biscoumarins, and dihydroisocoumarins.

Key activities include the stimulation of root growth and development, particularly root elongation and branching which can lead to improved nutrient and water uptake from the soil. Coumarins can also modulate plant growth and development by influencing hormone signalling, such as auxin and cytokinin pathways. Coumarins may also facilitate nutrient uptake and assimilation in plants by enhancing the activity of nutrient transporters and enzymes involved in nutrient metabolism. In the root zone they may act as signalling molecules to attract beneficial microorganisms, such as nitrogenfixing bacteria and mycorrhizal fungi, which can enhance nutrient availability and plant growth.

Some coumarin derivatives have been reported to improve seed germination rates and seedling establishment, including promoting uniform germination, acceleration of seedling emergence, and vigour. Coumarins also exhibit antimicrobial properties and can enhance plant defence mechanisms against disease pathogens through the stimulation in production of compounds such as phytoalexins and pathogenesis-related proteins. Coumarins have also been shown to enhance plant tolerance to various abiotic stresses, including drought, salinity, and heavy metal toxicity.

Coumarins are commonly found in a wide range of plants such as sweet woodruff (*Galium odoratum*), sweet clover (*Melilotus spp.*), tonka bean (*Dipteryx odorata*), cassia cinnamon (*Cinnamomum aromaticum*), common lavender (*Lavandula angustifolia*), mullein (*Verbascum spp.*), angelica (*Angelica archangelica*), licorice (*Glycyrrhiza glabra*), Mulberry (*Morus spp.*), sweet grass (*Hierochloe odorata*)

Flavonoids

Flavonoids are secondary metabolites found in plants that play diverse roles encompassing plant growth, pigmentation, UV protection, and various defence and signalling functions. Key examples of sub-classifications of flavonoids include chalcones, flavones, flavanols, anthocyanins, and proanthocyanins.

Flavonoids can play an important role in biostimulants for seed germination, seedling growth, and development as well as serving as protective agents against various biotic and abiotic stresses including acting as UV filters, signalling molecules, allelopathic compounds, phytoalexins, detoxifiers, and antimicrobial defences. They also contribute to drought resistance, and are postulated to be involved in plant heat acclimation and freezing tolerance.

Polyphenols/Phenolics

Phenolic compounds are arguably the most abundant secondary metabolites in plants and are often found in the cell walls and vacuoles of epidermal and subepidermal cells with most of these derived from I-phenylalanine through the phenylpropanoid pathway. These phenolics can be constitutive or induced in plants.

The roles of endogenous phenolic compounds in plants are very diverse, including the scavenging of reactive oxygen species; the reduction of UV radiation damage; they defend plants against herbivores, pathogens and weeds; the enhancement of nutrient availability and uptake; seed germination and dormancy breaking. An example of a useful phytoalexin is resveratrol which plays a crucial role in plant response to biotic and abiotic stresses, such as UV light, pathogen attacks, boron toxicity, ozone, and salt stress.

Polyacetylenes

Naturally occurring polyacetylenes include all compounds containing two or more conjugated carboncarbon triple bonds. Polyacetylenes are widely distributed, occurring in plants, fungi, lichens, moss, marine algae, and invertebrates. Polyacetylenes are considered to be phytoalexins - low molecular weight antimicrobial compounds that are produced by plants as a response to biotic and abiotic stresses - which play an important ecological role in response to biotic stress as well as abiotic stresses such as heavy metals, salinity and UV light.

Polysaccharides

Polysaccharides are long-chain polymeric carbohydrates composed of monosaccharide units bound together by glycosidic linkages. Polysaccharides typically contain more than ten monosaccharide units, whereas oligosaccharides contain three to ten monosaccharide units.

Microalgal polysaccharides have been shown to be effective elicitor agents that can protect plants against biotic stresses, as well as having biostimulant activity promoting plant growth, nutrient uptake and abiotic stresses tolerance. Recently studies, have also demonstrated the biostimulant effect of microalgal extracts on promoting seed germination, seedling growth and yields of lettuce and tomato plants.

Quinones

There are three main sub-classes of quinones relevant to biostimulantion:

Benzoquinones - plastoquinone and ubiquinone, are the principal benzoquinones that serve crucial functions in plants. Both plastoquinone and ubiquinone are involved in the electron transport chain in photosynthesis. Benzoquinones, particularly plastoquinone, act as antioxidants in plants, helping to neutralize harmful reactive oxygen species (ROS) generated during photosynthesis and other metabolic processes. By scavenging ROS, benzoquinones protect plant cells from oxidative damage, maintaining cellular integrity and function. Abiotic stress functions include factors such as drought, salinity, temperature and heavy metals.

Benzoquinones are commonly found in walnuts, onions, tea and eucalyptus amongst other plants. They influence processes such as seed germination, root and shoot growth, flowering, and fruit ripening, as well as regulating defence mechanisms by contributing to the synthesis of phytoalexins, which are secondary metabolites produced by plants in response to stress or attack, which have antimicrobial and antifungal properties. Additionally, benzoquinones may participate in signalling pathways that activate plant defence responses, including the production of defence-related proteins and compounds.

<u>Naphthoquinones</u> are the products of bacterial and fungal metabolism, as well as secondary metabolism in higher plants, where they are produced and used as natural defence biomolecules particularly by scavenging reactive oxygen species (ROS) produced during stress conditions such as drought, high temperatures, or pathogen infestation. They can also boost nutrient availability by fostering healthy soil microbiomes and also through influencing ion transport across cell membranes. They are commonly found in sundews (*Drosera spp.*), bugloss (*Arnebia spp.*), madder (*Rubia tinctorum*), leadworts (*Plumbago spp.*), false black pepper (*Embelia ribes*) and west indian woodnettle (*Laportea aestuans*)

<u>Anthraquinones</u>, have similar activity to the above classes, and are based on anthracene which has a moiety of three benzene rings bonded together. They are found in a range of plants including: *aloe vera*, rhubarb (*Rheum rhabarbarum*), senna (*Senna alexandrina*), Cascara sagrada (*Rhamnus purshiana*) and buckthorn (*Rhamnus spp*.).

Some studies have indicated that crops produced elevated antioxidant following application of certain humic substances due to the presence of specific molecules in the humic extract. These molecules, such as quinones and flavonoids, can act as both antioxidants and pro-oxidants that can trigger the plant's defensive system leading to a rapid and effective response to nutrient deficiency, boosting plant health and productivity.

Sesquiterpenes/unsaturated lactone

Sesquiterpenes are a class of terpenes that consist of three isoprene units and often have the molecular formula C₁₅H₂₄. Sesquiterpenes are naturally occurring compounds that have shown potential as biostimulants in agriculture including by enhancing root development, shoot elongation, and overall plant vigour leading to increased biomass and improved crop yields. Additionally, certain sesquiterpenes serve as floral attractants for pollinators, promoting pollination and seed set, thereby contributing to increased crop yields and fruit quality.

Sesquiterpenes have been reported to enhance plant tolerance to various abiotic stresses, such as drought, salinity, heat, and cold. This includes regulating osmotic balance, scavenging reactive oxygen species (ROS), and activating stress-responsive pathways. Some sesquiterpenes can enhance plant biotic defence mechanisms, including stimulating production of antimicrobial compounds, phytoalexins and defence-related proteins.

Exogenous sesquiterpenes when applied to the soil can benefit the soil microbiome and nutrient cycling processes in the rhizosphere, attracting beneficial microorganisms, such as mycorrhizal fungi and nitrogen-fixing bacteria, which can enhance nutrient uptake and promote plant growth and overall plant health.

Tannins

Plant tannins are water-soluble polyphenols that can promote plant growth by enhancing root development, shoot elongation, and overall plant vigour. Tannins can also improve nutrient uptake by enhancing the activity of nutrient transporters and enzymes involved in nutrient metabolism, as well as chelating metal ions in the soil increasing their bioavailability. Tannins can contribute to soil health by enhancing soil structure, increasing water retention, and promoting beneficial microbial activity in the rhizosphere.

Tannins enhance abiotic stress tolerance, including drought, salinity, heat, and heavy metal toxicity. They can scavenge reactive oxygen species (ROS), regulate osmotic balance, and modulate stress-responsive gene expression. Some tannins possess antimicrobial and antifungal properties and can enhance production of defence-related compounds, such as phytoalexins and pathogenesis-related proteins.

Regulatory Situation

Europe

Regulation has been poorly defined for biostimulants. However, under the new European fertiliser regulation (EU fertiliser Regulation 2019/1009), PBSs (plant biostimulants) are classified as fertilisers, except those that are also pesticides, whereas PGRs (plant growth regulators) are classified as pesticides. In the US, PBSs are likely to be classified separately from fertilisers; however, this issue is still in discussion.

The EU enforced the Fertilising Products Regulation (EU n°2019/1009) in July 2022, which defines and establishes processes for biostimulant approvals, including requiring efficacy testing to show that the product has biostimulant effects and is not just a fertiliser. This highlights a critical development in defining plant biostimulants by their function, not their ingredients.

Biostimulants are regulated for the whole EU market alongside national regulations with two routes for placing PBSs on the market:

- National: Gain national registration, then seek mutual recognition with other member states.
- **EU:** Gain EU-wide registration and 'CE' mark for sale across the whole of the EU.

By including biostimulant products and explicitly excluding them from EU plant protection products, Regulation 1107/2009 closes a regulatory gap by bringing biostimulants under harmonised rules from June 2022. However, it simultaneously opens another gap, mainly because the official definition of biostimulants (i.e. those eligible for registration under the EU framework in the future) is mainly legal and regulatory, not scientific.

Many plant processes are active in abiotic and biotic defence mechanisms, meaning that dual-use products may now fall under the sole claim of biotic functionality. This could lead, for example, to requirements to register products previously marketed under the national fertiliser laws as 'biostimulants' under the plant protection product framework. If a product is effective only against abiotic stress, it does not fulfil the criteria of the plant protection regulation. This is exemplified by products containing the *Trichoderma* species, which, in many cases, have been marketed as a biostimulant, plant, or soil amendments but may now have to be authorised as a plant protection product due to their fungicidal action.

Dual-action products against abiotic and biotic stress may be eligible for registration under the plant protection framework because respective substance/product categories, such as 'elicitor' or 'plant activator', are already included in and covered by Regulation 1107/2009.

The current impact on timescales is unknown due to the relatively recent introduction of this new regulation. Still, limited capacity due to the process of establishing assessment standards within Conformity Assessment Bodies (CAB), also known as Notified Bodies (NBs), has taken longer than expected. Therefore, to date, only a handful of accredited CABs are ready to act in reviewing and approving new product dossiers. Registration fees are currently around $\leq 100,00$ to $\leq 500,000$.

USA

Historically, the registration of biostimulants has been far less advanced. However, in 2022 the US introduced the Plant Biostimulant Act, which defines biostimulants as:

a substance, microorganism, or mixture thereof, that, when applied to seeds, plants, the rhizosphere, soil, or other growth media, act to support a plant's natural processes independently of the biostimulant's nutrient content, including by improving nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality, or yield.

The act aims to harmonise the US and EU definitions, set a national framework for registering biostimulants, and more accurately describe benefits on product labels. The regulation also aims to:

- Develop a model bill for use across states to streamline the registration process.
- Educate growers on the benefits of biostimulants for soil health, sustainability, and climatesmart agriculture opportunities.
- Achieve regulatory clarity from the EPA regarding existing regulations, including defining plant growth regulators within FIFRA.

The EPA intends to distinguish plant biostimulants from PGRs, with PBS defined by the exclusion method as a substance or microorganism that does not conform to the definition of a PGR under FIFRA, aiming to remove previous ambiguity of where products fall. In the US, fertilisers are regulated by the US Department of Agriculture (USDA), whereas pesticides, including PGRs under FIFRA, are regulated by the EPA. For example, an algae extract is considered a PGR and is regulated under FIFRA by the EPA; therefore, the registration requirements for algae extract are similar to those for pesticides.

In November 2024, the EPA released draft guidance for plant regulator products and claims, including plant biostimulants. The aim of this draft guidance is to more clearly define which components are considered plant regulators and, therefore, subject to regulation as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136–136y.

Although FIFRA does not define the term plant biostimulants, some products being sold as plant biostimulants may trigger regulation under FIFRA as plant regulators. Other plant biostimulant products will not require registration as a pesticide under the plant regulator definition outlined in FIFRA section 2(v), or because they do not fit within the specific functionality definitions provided under FIFRA regarding plant regulator function.

Products which are not considered to be plant growth regulators and are therefore excluded from registration under FIFRA:

- Plant nutrients and trace elements: Plant nutrients and trace elements, which can be considered as falling under the umbrella term "fertilizers," are described in EPA's FIFRA regulations as "plant nutrient product[s] consisting of one or more macronutrients, or micronutrient trace elements necessary to normal growth of plants and in a form readily useable by plants" [40 CFR 152.6(g)(1)].
- **Plant inoculants**: Plant inoculants are "...product[s] consisting of microorganisms to be applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system" [40 CFR 152.6(g)(2)].
- **Soil amendments**: Soil amendments (which include soil additives and soil conditioners) are "...product[s] containing a substance or substances intended for the purpose of improving soil characteristics favorable for plant growth" [40 CFR 152.6(g)(3)].
- Vitamin-hormone products: Under FIFRA section 2(v), "the term 'plant regulator' shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, non-poisonous in the undiluted packaged concentration." Per 40 CFR 152.6(f), "vitamin hormone products" are further described as follows:
 - "A product consisting of a mixture of plant hormones, plant nutrients, inoculants, or soil amendments is not a "plant regulator" under Section 2(v) of FIFRA, provided it meets the following criteria:
 - The product, in the undiluted package concentration at which it is distributed or sold, meets the criteria... for Toxicity Category III or IV; and
 - The product is not intended for use on food crop sites, and is labelled accordingly.

During registration of both plant growth regulators and biostimulants, the claims made by the registrant, and on the product label are also considered by the EPA as part of its evaluation of the appropriate regulatory pathway. However, it should be noted that the EPA does not solely look at the claims made. Products that contain an active ingredient consistent with pesticidal/plant growth regulator usage will be registered as such regardless of how the registrant makes claims for its use. Similarly, if a biostimulant product claims pest-control properties, it will be considered as a pesticide under FIFRA.

The EPA outlined in this draft guidance document, example claims that may exclude a product from registration as a pesticide under FIFRA. These are not exhaustive, and as mentioned previously, if the active ingredient is consistent with a pesticidal active then it will be registered as such. The examples provided relate specifically to **plant nutrition-based claims**, **plant inoculant-based claims** and **soil amendment-based claims**. These can generally be summarised as modalities that *indirectly* support crop health, such as correcting nutrient deficiencies in the soil, optimising conditions for abiotic stress tolerance, soil structure/biodiversity, and increases to nutrient availability/uptake (e.g. through promoting root growth, nutrient solubilisation etc). The claims made by vitamin-hormone products need to be considered more carefully given that they are considered by the agency to contain components that can be considered as regulating plant physiological processes.

Plant regulator claims may be made for vitamin-hormone products when they meet both criteria for exclusion from the plant regulator definition, as specified under 40 CFR 152.6(f)(1) & (2).

This means that the product is considered 'non-toxic' but crucially also not for use on food crops, which means this exclusion has no relevance for agriculture beyond non-crop uses such as turf and ornamentals.

The guidance document goes on to discuss the definition of a plant growth regulator.

A naturally occurring substance would be considered a "plant regulator," and a product label claim would be considered a "plant regulator claim" if:

The substance or mixture of substances, through physiological action:

- 1. Accelerates or retards the rate of plant growth;
- 2. Accelerates or retards the rate of plant maturation;
- 3. Or otherwise alters the behaviour of plants or the produce thereof;

<u>and</u>

if the substance or mixture of substances does not fall under one of the exclusion categories listed in 40 CFR 152.6(f) & (g) as vitamin-hormone products, plant nutrients, plant inoculants or soil amendments; or under 40 CFR 152.8(a) as a fertilizer.

Plant regulator claims may be made for vitamin-hormone products when they meet both criteria for exclusion from the plant regulator definition, as specified under 40 CFR 152.6(f)(1) & (2). When claims for increased or decreased growth, yield, germination, maturation, etc. are consequent to intended uses of products or substances as plant nutrients (fertilizers), plant inoculants, soil amendments, and/or as other non-pesticidal uses, such products and substances may be excluded from regulation under FIFRA in the absence of any plant regulator claims.

This would imply that plant nutrients, plant inoculants or soil amendments that <u>do</u> have plant growth regulating capabilities and/or claims would be excluded from FIFRA registration, provided that they meet the requirements of the above exclusions, and have at least some 'non-plant growth regulating claims'. <u>The exception here is that this doesn't apply for vitamin-hormone products used in food crops.</u>

Examples of active ingredients that are considered to have no other usage other than as plant growth regulators and therefore pesticides under FIFRA include (but not limited to):

- Auxins
- Cytokinins
- Gibberellins
- Ethylene
- Abscisic acid

Other substances that may be included in this category include:

- Corn glutens
- L-Glutamic Acid (LGA) and gamma-Aminobutyric Acid (GABA)
- Homobrassinolide and other brassinosteroids
- Lysophosphatidylethanolamine (LPE)
- 1-Octanol
- Sodium o-nitrophenolate, sodium p-nitrophenolate, and sodium guaiacolate

There are numerous substances that may have plant regulator activity, as well as additional modes of action, not considered to be plant regulator modes of action that may include, but are not limited to:

- Abiotic stress tolerance
- Water and nutrient use efficiency/uptake;

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• Nutrient availability - increased availability of inorganic nutrients in the soil to plant roots and seeds; improving biotic and abiotic characteristics of soils

Examples of these include:

- Seaweed extracts (SWE)
- Complex Polymeric Polyhydroxy Acids (CPPAs) and Humic Acids (HAs)

Both of these categories of active ingredients are generally understood to have direct physiological effects on growth, yield, maturation, and produce quality.

The Agency also recognizes that not all uses of PBS may be intended for plant regulator or other pest control purposes. If it can be demonstrated that a particular product has the activity claimed on the product label (and any other informational media) and does not make any plant regulator or pest control claims on the product label (and any other informational media) it may be excluded from FIFRA regulation.

Therefore, a natural product such as seaweed extracts and humic substances will be excluded from registration as a pesticide, provided that the product does not claim plant regulator activity, and claims activity under the plant health examples cited in the guidance document (Tables 1a-c and 2), or those analogous to those non-exhaustive examples.

Finally, the document also outlines how other 'conventional' components in the mixture should be considered, as well as components generated as a result of the extraction process.

If a conventional chemical plant regulator is contained within a PBS product, the product likely would be considered a conventional chemical pesticide by the Agency and would be subject to registration under FIFRA.

Novel substances may be present in plant biostimulant products that were not present in the original plant source material, but were formed as a result of the extraction methods and/or post-extraction processing but will require further scrutiny under FIFRA by the Agency to determine if they have the potential for pest control and/or plant regulator activity.

In summary, the guidance document outlines the importance of understanding the mode of action of the components in the product and associated claims, including the ability to produce performance data supporting such claims. Plant growth activity alone will not permit registration as a biostimulant, and companies must have an awareness of the physiological responses of the product and make sure that label claims, and those made in the process of regulation align with this.

Brazil

Under the first Fertilizer Law of 1980 (6.894/1980) and subsequent decree number 4.954/2004, fertilizers were defined as "mineral or organic substances, natural or synthetic, that provide one or more plant nutrients". For biofertilizers, Brazilian legislation previously utilised two definitions:

- (i) Inoculants: products containing micro-organisms that have a favourable impact on plant growth
- (ii) Biofertilizers: products containing an active ingredient or organic agent, free from agrochemical substances, capable of acting directly or indirectly on all or part of cultivated plants, enhancing their productivity, regardless of their hormonal or stimulant value

The generally vague definitions and regulation of biostimulants has in the past generated uncertainties for companies wishing to enter the market and represented a challenge surrounding grower confidence in product efficacy, composition, and quality assurance. However, few barriers have existed to introducing a biostimulant product into the market. There have been steps in 2024 to update and clarify the legislation under the 'Bioinputs Law'.

On December 23, 2024, Law No. 15,070/2024 ('Bioinputs Law'), which regulates the production, use, and commercialisation of bioinputs in the agricultural sector, was published in the Official Gazette. The new law regulates the production, use, and commercialisation of bioinputs for agricultural,

The Bioinputs Law defines a bioinput as: product, process or technology of plant, animal or microbial, including that originating from a biotechnological process, or structurally similar and functionally identical to that of natural origin, intended for use in production, protection, storage and processing of agricultural products or in production systems or planted forests, which interferes with the growth, development and response mechanism of animals, plants, microorganisms, soil and derived substances and that interact with the products and physical-chemical and biological processes.

Bioinputs include those "used in agricultural activity, including biostimulators or growth or performance inhibitors, semiochemicals, biochemicals, **phytochemicals**, **metabolites**, **organic macromolecules**, agents biological control products, soil conditioners, biofertilizers and inoculants."

However, the updated pesticide law stops short of defining each of these categories in detail.

livestock, aquaculture, and forestry use in Brazil, whilst also promoting the production and adoption of such products.

Argentina

Biostimulants and organic-chemical fertilisers must also be registered through SENASA. The general fees required for registration are relatively low compared to other markets, such as North America and Europe. However, this is more than offset by the level of complexity, the current lack of a fast-track registration process, and the generally lower levels of capacity and regulatory expertise required for a more expedited future process.

In November 2024, the government announced that all phytosanitary and bioinput procedures were centralised through an online platform known as SIGTrámites. On this platform users can register their products, facilitate self-management, gain insights on process traceability, reduce processing times, gain support, boost communication and make online payments. The platform may be used for newly formulated phytosanitary products, registration requests for prioritised items and registration requests for bio-inputs for plant nutrition.

China

In China, biostimulants are currently regulated through NY/T 3831-2021 Organic Water-Soluble Fertilizers-General Regulations; biostimulants are regulated alongside fertilisers and treated as microbial fertilisers or organic water-soluble fertilisers. This is overseen by the Chinese Ministry of Agriculture and Rural Affairs. The current regulation provides improved definitions that resolve biostimulant products' previously ambiguous legal status. Additionally, the regulation offers a pre-marketing procedure, product classifications, general rules on raw materials, nutrient contents, and labelling requirements.

The key product classes, such as inoculants and rhizobia, are registered under microbial fertilisers. Other biostimulants, such as chitosan, are listed under 'Water-soluble fertilisers':

- WSF containing amino acid.
- WSF containing humic acid.
- Organic WSF containing alginic acid.
- Organic WSF containing chitosan.
- Organic WSF containing polyglutamic acid.
- Organic WSF containing polyaspartic acid.
- Other WSF containing molasses, low-value fish and its fermented products, as well as other organic materials.

Overseas applicants must follow several requirements, including using a Chinese agent for application. This involves supplying critical information on product properties. Depending on raw materials, manufacturing processes, and end uses, toxicity tests and efficacy trials are sometimes required. These generally have lower requirements than urea, ammonium nitrate, and other fundamental nutrition products; therefore, they do not require technical review for registration. Following these tests, a technical permit is granted for commercialisation.

Japan

Japan does not legally define biostimulants, which are registered under the Fertiliser Control Law or Soil Fertility Enhancement Act. MAFF's 'Green Food System Strategy' targets a reduction in the use of chemical fertilisers. However, several products considered biostimulants are broadly used with registration under the Fertiliser Control Law or Soil Fertility Enhancement Act.

In response to the amendment of the Fertiliser Regulation in the EU, an industry group in Japan has been established to actively promote communication with the competent authorities to facilitate the standardisation of biostimulants.

With its new 'Green Food System Strategy', MAFF targets reducing chemical fertiliser use by recognising biostimulants as a valuable tool to lower fertiliser inputs and reduce environmental impacts. The Japanese Crop Protection Association has announced that the industry will proceed with developing biostimulants to support this strategic goal.

India

India's biostimulant definition is broadly aligned with that of the EU. Biostimulants are currently regulated through Fertiliser Control Order (FCO), which defines biostimulants as:

...a substance or micro-organism or a combination of both whose primary function when applied to plants, seeds or rhizosphere is to stimulate physiological processes in plants and to enhance its nutrient uptake, growth, yield, nutrition efficiency, crop quality and tolerance to stress, regardless of its nutrient content, but does not include pesticides or plant growth regulators which are regulated under the Insecticide Act, 1968.

India's Fertilizer (Inorganic, Organic or Mixed) (Control) Amendment Order was introduced in 2021. These new regulations require manufacturers to register products with the relevant authority providing a set of information on chemistry (composition, analytical methods, shelf-life), bio-efficacy trials conducted by the Indian Council of Agricultural Research (ICAR), state agricultural universities (SAUs) (preferably in agro-ecological zones), and toxicity data and heavy metal analysis.

The regulations also establish a regulatory body to monitor the end-to-end movements within the industry. The committee controls the quality and specifications of all biostimulants and ensures the use of safe substances and organic compounds in product manufacturing.

Farming-related services and speciality products dominate the Indian agrochemical landscape. The Federation of Indian Chambers of Commerce & Industry (FICCI) categorises biostimulants under the latter category alongside micronutrients, biopesticides, and biofertilisers that have recently begun to permeate the markets.

In May 2024 the Indian Union Ministry of Agriculture and Farmers Welfare issued a new amendment to the Fertilizer (Inorganic, Organic or Mixed) (Control) Order, 1985. Titled the 'Fertilizer (Inorganic, Organic or Mixed) (Control) (Third) Amendment Order, 2024,', the issue is intended to regulate the specifications and approval process for biostimulants in the agricultural sector. Key provisions of the amendment include:

- Increased specifications for biostimulant products, including their name, active ingredient or tracer molecule, chemical composition (in cases where active ingredients or tracer molecules cannot be indicated), and the name of the crop to which they are applied.
- The introduction of a new category for live microorganisms, excluding biofertilisers and biopesticides, within the specifications for biostimulants.
- Alterations to the application for new biostimulants, including the submission of data regarding categories, such as chemistry, bio-efficacy trials, toxicity, heavy metal analysis, and a product sample accompanied by an affidavit affirming compliance with pesticide limits.
- Toxicology data exemptions for certain biostimulants, such as protein hydrolysates, seaweed extracts, amino acids, vitamins, humic and fulvic acid.
- Alterations to pesticide limits within biostimulant products, set at 1 part per million (ppm), replacing the previous limit of 0.01 ppm.

The amendment aims to provide a framework for regulating and approving biostimulants in agriculture to ensure their safety, efficacy, and adherence to specified standards.

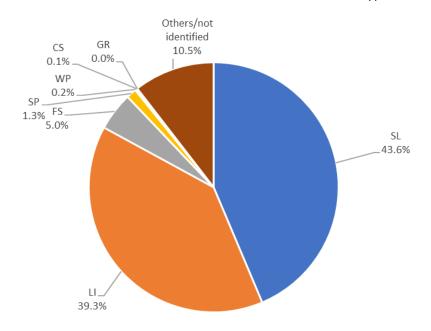
Company Involvement

The below table(s) on key active ingredients and key companies is derived directly from AgBioInvestor's exclusive primary market research study that surveyed biological- and biostimulantgrowers, which were conducted for the first time in 2023 and profiled the 2022 agricultural market. The market research surveyed many key agricultural markets for biologicals, including: the USA, Mexico, Chile, Brazil, Argentina, France, Italy, Spain and Turkey. The Ais have been ranked by farmgate value (\$m.). Quantification of these data and much more biological market research can be found in the separate subscription product AgbioInsight.

AI	Key Companies
Plant Extracts	Corteva (Stoller)
	Grupo Bioquimico Mexicano
	Grozyme
	UPL
	Amaltis
	Hello Nature
	Biolchim
	Bayer
	Meristem
	Merschman Seeds
	Lida
	Valagro
	Winfield
	Fagro
	Lemdax
	Biojal
	CBC (Biogard)
	BioDea
	Futureco Bioscience
Animal Extracts	Serbios
	Syngenta (Valagro)
	Bio3G
	Timac Agro
	Aminochem
	SICIT 2000
	Albaugh (Rotam)
	Bloemen
	Neem Italia
	NutriPlant

Formulation Types – Value Share

The below chart(s) are derived from the biological focussed market research that AgbioInvestor conducted, and illustrates the value share attributed to various formulation type codes.



Code	Description	Code	Description
AE	Aerosol dispenser	LI	Liquid
AL	Other liquids to be applied undiluted	LS	Solution for seed treatment
СВ	Bait concentrate	ME	Micro emulsion
CS	Capsule suspension	OD	Oil dispersion
DC	Dispersible concentrate	SC	Suspension concentrate
DF	Dry flowable	SL	Soluble concentrate
DP	Dustable powder	SP	Water soluble powder
EC	Emulsifiable concentrate	VP	Vapour releasing product
EW	Emulsion, water in oil	WG	Water dispersible granule
FS	Flowable concentrate for seed treatment	WP	Wettable powder
GR	Granule	WS	Water dispersible powder for slurry treatment
10	Liquid concentrate		

LC Liquid concentrate

Research and Development

In the field of plant extracts, much of the research centres around selecting and optimising extracts with both the right components and blend of constituents in order to foster the desired effect when applied to crops. Therefore, in that regard there is some degree of commonality with that of the strategy for R&D within microbial amendments, given the similarly diverse range of source material and associated synergisms of multiple components.

Some key areas include:

- Development of extraction techniques such as solvent specifications, supercritical fluid extraction, ultrasound- and microwave-assisted extraction
- Characterisation of the phytocompounds present and monitoring/quality assurance of feed stocks and derived plant extracts to maintain consistency of composition
- Plant genomics tools can be used to better elucidate the complex biochemical pathways that are up- or down-regulated on application of exogenous plant extracts, and foster a greater understanding of plant extract modalities.
- Gene editing of feedstock plants can be used to alter the balance of specific phytocompounds for extraction (subject to regulation)
- In-vivo, glasshouse and field trials to obtain the optimal application conditions and activity including effects on germination rate, seedling growth rates, chlorophyll content, amino acid content, hormonal content, metabolite profiling, stress response, and ultimately the yield response and produce quality.

Some recent events have included:

- Dec 22, 2021 Koppert Biological Systems entered into an agreement with Royal HaskoningDHV and ChainCraft to use Kaumera, a biological material extracted from wastewater, as a biostimulant for use in agriculture and horticulture. This natural biopolymer can be extracted from wastewater using the Nereda purification process. The removal of this product reduces remaining sludge in treatment water by up to 30%, reducing wastewater treatment costs.
- Jun 12, 2023 Adama Chile entered a partnership with the Argentinian company Agrocube regarding the development of biological solutions for agriculture. Agrocube is involved in the development of polyphenols, naturally-occurring compounds derived from plants. The use of polyphenols can be used to support a plant's natural defences against various stresses, including pest and disease pressure. Polyphenols are also reported to improve soil health and nutrient absorption. Under the partnership, the two companies will work together to develop bionematicides, biofungicides and bioinsecticides.
- Nov 29, 2023 Yara announced that it will launch YaraAmplix, a new range of biostimulants formulated with mostly natural ingredients such as seaweed and plant extracts, intended to support tolerance to abiotic stress, and improve nutrient use efficiency, crop yield and quality. YaraAmplix is expected to be commercially available in China, Brazil, and France by the end of 2023, and will gradually be rolled out to the rest of the world in 2024.
- Dec 4, 2023 Syngenta announced it was to launch the biostimulant AbioThree in Japan from December 12th, with introduction limited to Hokkaido prefecture. The product, which contains fermented plant extracts, as well as copper and zinc, is intended to support nutrient absorption and improve soil health.

- Oct 3, 2024 Corteva introduced the biostimulant Stimulate Yield Enhancer in Ukraine, with the
 product recommended for use on a range of crops including soybean, maize, cereals, oilseed
 rape, sugar beet, fruit and vegetables. Stimulate Yield Enhancer is based on three plant
 phytohormones, cytokinin (as kinetin), gibberellic acid, and indole-3-butyric acid, and is
 intended to enhance plant growth and development by stimulating cell division, cell
 differentiation and enlargement, nutrient uptake and nutrient utilisation. The product will be
 made available in Ukraine during the 2024/25 season.
- Oct 23, 2024 BASF and Elicit Plant entered into a partnership to introduce EliSun-a, for sunflower, and EliGrain-a, for cereals, during the 2024-2025 campaign in France. Under the terms of the agreement, BASF will make available the products developed by Elicit Plant across its existing distribution network. Based on phytosterol technology, the biostimulants are intended to improve crop resilience to climate stress by enhancing water use efficiency and reducing drought impact.
- Nov 6, 2024 Syngenta introduced the liquid foliar biostimulant YieldON in Canada for use on maize, wheat and other row crops. The product is based on a combination of plant- and seaweed-derived biomolecules, with trace elements of micronutrients manganese, zinc, and molybdenum. YieldON will be made available to row crop growers in Canada in time for the 2025 growing season.
- January 9, 2025 Syngenta Crop Protection and TraitSeq entered into a collaboration agreement aimed at developing biostimulant solutions. Through the agreement, the companies will leverage Syngenta's expertise in crop biology and TraitSeq's proprietary artificial intelligence to identify predictive biomarkers to track a plant's cellular response to biostimulant applications. The identification of specific biomarkers is expected to enable accelerated efficacy assessments of a new biostimulant candidates, with the development of such biostimulants also supporting Syngenta's sustainability strategy.

TraitSeq, a company which uses artificial intelligence (AI) to train predictive models for complex traits in agriculture, was spun out from the Earlham Institute in 2024.

- Apr 1, 2025 MustGrow Biologics has announced the addition of three new biological solutions to its existing Canadian product lines through its recently acquired Canadian sales and distribution division, NexusBioAg:
 - EZ-Gro Max (kinetin, IBA, and gibberellic acid and biostimulants such as salicylic acid and vitamin C): biostimulant designed to enhance foliar nutrition, improve plant growth, and increase yield potential while mitigating environmental stress. Labelled for use on alfalfa, barley, canola, maize, oats, potatoes, rye, soybeans, and wheat.
 - EZ-Gro Cyto (cytokinin, as kinetin, salicylic acid, thiamine hydrochloride, ascorbic acid): biostimulant designed to support crops in drought, heat, cold, and salinity stress conditions. Labelled for use on alfalfa, barley, canola, chickpeas, maize, lentils, oats, peas, rye, soybeans, sunflower, and wheat.
 - $\circ\;$ Rootella: mycorrhizal inoculant designed to improve plant fertility, resilience, and sustainability.
- Apr 29, 2025 Cultiva received registration in the EU for its crop cuticle supplement Parka. The product leverages Parka's proprietary SureSeal technology, a phospholipid formulation aimed at improving a plant's tolerance to abiotic stress, such as heat, moisture, and wind, to improve crop health and yield. It is targeted at use on woody perennial crops, including apples, cherries, citrus, grapes, nut crops, and stone fruits.

Market Outlook

As discussed above the others segment contains a plethora of plant extracts, and biochemicals (some of which can be synthesised commercially) that are not covered by the other main segments. It is this diversity that gives rise to the possibility of R&D in new classes of product and innovation at the mixture product level through synergistic interactions. Some key challenges that need to be overcome in this segment include issues with consistency of product composition (largely down to the variability of the plant source). In many cases it is not clear how the delicate interplay of components, their ratios and character lead to the end activity in the field. This can often be influenced by synergisms of these components as well as formulation types, timing and also external factors such as the field conditions and soil structure.

Despite these challenges plant extract based biostimulants will be amongst the fastest growing segments in the coming years, albeit from a small base, driven by the potential for producing products tailored to niche segments, both by crop type but also addressing region specific climatic challenges, soil health and demands of consumers for higher fruit and veg quality. Their inclusion as part of mixture products with other classes will also drive wider uptake.

Taking the above factors into account we expect that the other biostimulant segment will increase at a rate of 13.0% p.a. between 2023 and 2028 (constant currency and pricing).