

Overcoming biological barriers

"A new solution should strive to be better, easier, cheaper or more reliable than the existing one."

BELINDA CLARKE

Efficacy, usability and regulatory constraints may have hindered more widespread adoption of biological products. *CPM* looks at how these barriers could be overcome, including innovative approaches to formulation.

By Janine Adamson and Rob Jones

Farmers are often told that biological products are the future, yet they remain little more than a niche part of the crop input world in the UK and Europe, according to data.

Analysis by global market research company DunhamTrimmer suggests biologicals make up just 0.5% of the crop input market value in the UK. France leads the way in Europe at just under 8%, with most other countries below 2% at best.

Those figures, to some extent, may mask the fact the market is growing in both the UK and Europe, fuelled by consumer demand for lower pesticide use.

At the same time, government regulation for the approval and re-approval of pesticides is becoming ever more challenging, with supermarkets responding to consumer concerns with their own standards and protocols. These can demand more draconian reductions in residue levels than regulatory standards, which with biocontrol products often

exempt from such, has driven adoption, particularly in the fresh produce sector.

But there remain barriers for the biological sector to overcome before products are truly mainstream, particularly in broadacre crops, acknowledges Dr Belinda Clarke, director of Agri-TechE. She says the organisation's membership is growing increasingly interested in biologicals, particularly given the regulatory pressure bearing down on some existing synthetic chemistry solutions.

"But a new solution should strive to be better, easier, cheaper or more reliable than the existing one," adds Belinda.

Unfortunately, biologicals have often struggled to fulfil even one of those criteria, let alone all four, which has led to farmer and agronomist confidence being dented, she believes.

A key part of repairing confidence will come through transparency around how these products work. "We're now

seeing more rigour and robustness around trials to understand how, where and when to use biologicals, aided by more forensic analysis and understanding of modes of action.

"The whole point of a biological product is you understand the environment in which you're applying it."

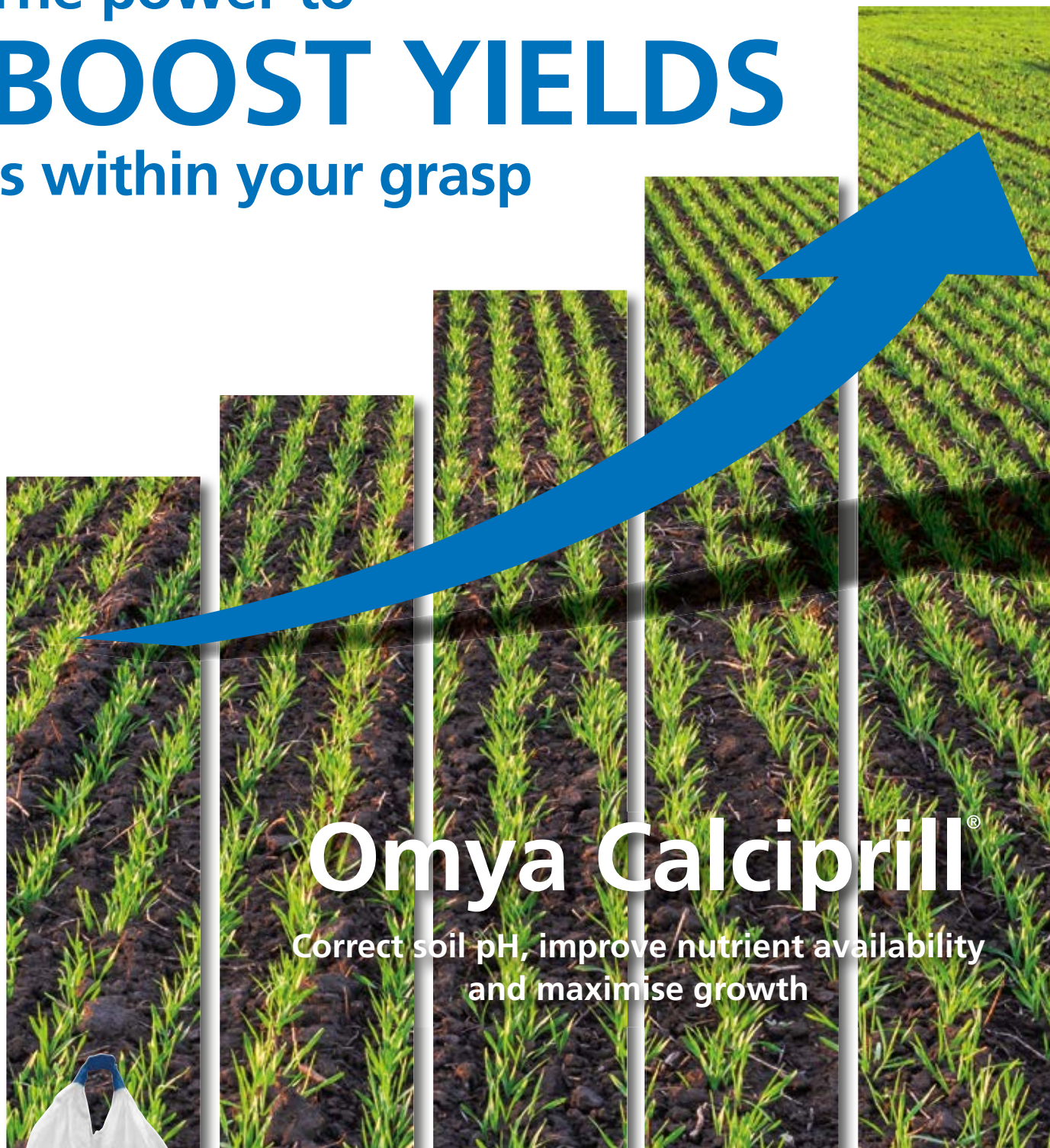
The downside is that it could mean trials are, by necessity, more expensive and complicated. "But as has been shown in protected crops, it's not



Artificial intelligence

AI is very good at modelling the behaviour of biological systems and organisms within it, says Agri-TechE's Dr Belinda Clarke. Photo: Agri-TechE

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THINKING OF TOMORROW





Current knowledge

There isn't necessarily the in-depth understanding of how biologicals actually work, states Agrii's Jodie Littleford.

► impossible to manufacture products that fulfil those criteria," she suggests.

Artificial intelligence tools could improve analysis, too. "AI is very good at modelling the behaviour of biological systems and organisms within it, and these models can take into account other parameters that we don't think about to help predict outcomes," comments Belinda.

Giving more exact recommendations about what problem a product solves and how it should be used could help to increase farmer confidence. This is rather than promising a biological will solve a wide range of problems or help with an abstract issue, believes Bayer's Richard Phillips.

He says it's about finding the best position for them and proving they work in that scenario. In fact, this has led to more research by Bayer to test products in set conditions, such as lack of water, low nitrogen or heat stress, says Richard.

"It's also about managing expectations – as an industry we've been guilty of over promising efficacy."

Some biological products can match the performance of conventional crop protection, believes Agrii technical manager, Don Pendergrast. "We're seeing ones that pass the bar when used as part of a programme, and they've become more refined, focusing on delivering specific quality traits or crop management."

Like Bayer, Agrii believes it's important that understanding of how and where to use biological products improves and becomes more focused, adds the firm's Jodie Littleford. "There isn't necessarily the in-depth understanding of how they actually work, which is part of the reason

we've made a significant investment in new glasshouse facilities at Throws Farm in Essex to help us to do that research."

One example is a sugar beet product that in the past has been used at four or five different timings, but Agrii has now identified that its strength is developing root systems, explains Don. "That's led to us applying it at either pre-emergence or early post-em, which helps the plant to progress through the early stress of beet herbicide applications."

EFFICACY CLAIMS

For biostimulants and biofertilisers, until relatively recently, a lack of regulation has played a role in allowing manufacturers and suppliers to launch this type of biological product without having to prove efficacy.

"The EU has just brought in overarching regulations for biostimulants where you have to undertake basic testing to show efficacy, although it's not to the same level as for crop protection. In the UK there's still very limited regulation though," says Richard.

In contrast, biopesticides follow many of the same rules and timelines as synthetic crop protection. The costs are slightly less because there are certain data you don't have to provide such as residues, but in this case, there's probably over-regulation that slows down innovation in the sector, notes Richard.

"We're yet to reach that perfect ground where one type is regulated enough, and the other is regulated correctly."

Another major challenge to be overcome for biological products to be used more widely is around scaling production, formulation, and the ease of use.

That's where a company many farmers may not have heard of brings its expertise. The Centre for Process Innovation (CPI) is a technology innovation centre and a founding member of the UK government's High Value Manufacturing Catapult.

Its aim is to ensure innovations have the best opportunity to be successfully marketed and works in areas as diverse as energy, health technology, pharmaceuticals and agrifood technology. "We have multiple sites for different technology teams," explains Dr Joanne Neary, fermentation manager for CPI's biotechnology centre, based on an old ICI site near Redcar.

"In biotech, we make raw materials for our clients – not commercially – but by designing processes from which either data or the material can be used to further

their journey towards commercialisation."

Facilities from lab-scale to pilot and demonstration plants up to 10,000 litre scale are used to help build a production process that's scalable, she explains. "Our clients can be anything from start-ups, established small and medium-sized enterprises, to global corporations. The start-ups tend to come with a live bacterial product, a nitrogen-fixing bacteria or biostimulant for example, that so far, they've only grown in a shake flask."

"We work with them to put that process in a fermenter – an industrially relevant environment to work up a production process."

A second centre concentrates on formulation. "If you're making a biological product with live microbes, formulation is everything," says Joanne.

"Often our agri-tech clients want to understand the formulation first because they know how to do fermentation, how to make microbes."

Liquid formulations are simpler to make, with sterility the main focus, explains Rosalind Hay, head of biomanufacturing at CPI. "The most important factor, if you're making a product that's a live microbe, is making sure no other microbes are introduced that spoil it."

But there are other significant disadvantages with liquid formulations, including having to keep them cold, and more expensive transport because of much greater bulk quantities than a solid formulation.

"So we work with customers to move away from that type of product, usually to a dried product. It's a complicated area



Formulation finesse

The Centre for Process Innovation's Joanne Neary believes when making a biological product with live microbes, formulation is everything.



Conflicting approaches

According to Cambridge Consultants' Niall Mottram, the moment a live biological organism is forced through a system designed for chemistry, it doesn't work out so well.

that we're still learning about along with our customers."

Drying techniques such as freeze, spray, or fluidised bed drying can increase shelf life and reduce volumes from litres of liquid product to single figure grammes, with the associated savings in packaging and transport costs, she highlights.

But the process also comes with major risks for viability, acknowledges Joanne. "You can't just put naked microbes into a freeze dryer and expect them to live through the process – you can lose around 99% of viability."

That's where CPI expertise in formulation comes to the fore, with the team using various excipients (non-active ingredients) to help retain greater viability, with 60-80% possible with gram-positive bacterial strains such as bacilli, she explains.

Gram-negative bacterial strains, such as *Pseudomonas* species, have weaker cell structures, making thermal stability even more challenging. "But these drying techniques are scalable and are most likely to be the immediate future for microbial products," says Joanne.

MICROENCAPSULATION

Further down the line, microencapsulation could be the formulation of choice. Used in the food industry for probiotics where it protects the bacteria from stomach acids, it's now being applied in agriculture, she adds.

"It's a tried and tested method for protecting cell viability. One potential use could be to make a product with both chemicals and microbes separated by the encapsulating polymer."

This could be used to create layers of functionality on a seed, for example. Another possibility with microencapsulation is to mix single encapsulated particles with different functions to create a bespoke mix, explains Joanne.

"A mix could have X% of micro particles to help with nitrogen fixation, and Y% to ward off a fungal disease, and could be tailored for different situations on farm."

Once on farm, there's still the question of how to apply them for maximum efficacy in an agricultural system designed to apply synthetic chemistry. This is because the moment you try to force a live biological organism through a system designed for chemistry, it doesn't work out so well, suggests Niall Mottram, head of agri-tech with Cambridge Consultants.

Academic research suggests only 10-20% of microbes survive when sprayed through industry-standard nozzles at high pressures. This led to research by Cambridge Consultants into how to redesign nozzles to make them compatible with biology as well as chemistry, says Niall.

Having analysed shear forces within four off-the-shelf options, which would turn microbes into 'mush', Niall made subtle changes to the geometry at the tip of the nozzle without compromising ►



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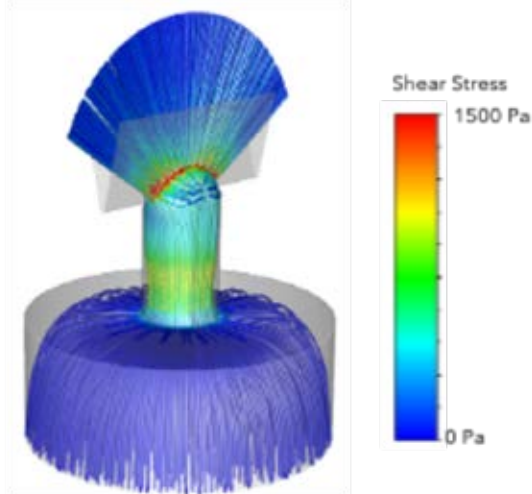
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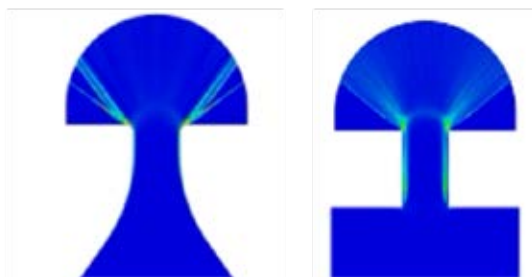


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New nozzle design

Cambridge Consultants has been undertaking work to design biocompatible nozzles.

spray performance.

“You go from a nozzle with quite a lot of sharp edges to something that’s gentler and more curved which removes the pinch points of shear, and improves survivability by up to 75%.” Increased survival should equate to better efficacy and / or allow the use of lower rates, reducing cost, he points out.

Both efficacy and cost were barriers to increased adoption Cambridge Consultants found while investigating the issue for an Agri-TechE report last year. Making an improved economic case for applying biologicals would also speed up adoption, he suggests.

According to Niall, the selective nature of biological products often necessitates multiple doses compared with conventional non-selective chemistry, adding to the cost of products that are usually at a premium to standard options.

“If we can find a way to make the commercials more

attractive, for example, through formulation improvements, nozzles that allow reduced rates, or multiple products applied in one pass, then the economics should become more attractive.”

Changes to legislation which allow greater concentrations of biological products – or indeed conventional chemistry – to be applied using precision application techniques and spot spraying, could also unlock adoption. “Legislation is holding this back – it hasn’t kept pace with technology innovation – but if you’re applying biologicals in very specific areas rather than across an entire field, you again improve the economics,” concludes Niall.

Joanne Neary from CPI will discuss how on-farm biological manufacture could be a future farm diversification opportunity in a webinar on 24 April hosted by Agri-TechE. To register to attend or find out more, visit www.agri-tech-e.co.uk