

European
Biosolutions
Coalition

Making Europe's Biorevolution Happen

Case catalogue
2024



“I want Europe to make the most of the biotech revolution. Biotechnologies supported by AI and digital tools can help modernise entire parts of our economy, from farming and forestry to energy and health.”

Ursula von der Leyen, 2024

Political Guidelines 2024 – 2029

Making Europe's biorevolution happen

What does the mummified corpse of a man who lived in the 5th Century BCE have to do with the future of Europe? Quite a lot, as it would appear: To get around the obstacles of EU regulation, the small Danish craft brewery Herslev had to use findings from the 'Tollund Man' 's stomach contents to document that a beer based on straw and oil-rich seeds does not conflict with the EU 'Novel Food Act', since such ingredients were part of the man's diet more than two thousand years ago.

This is an example of the legislative obstacles that European biosolutions companies face in their efforts to bring biologically-based solutions to market. That needs to change. Europe has the ideas, the researchers, and the innovative companies, large and small, to apply nature's own tools such as fermentation, enzymes, and bacteria to solve many of the greatest challenges we face today.

Biosolutions is short for biological industrial green solutions. They are the key to enabling the transition from a fossil-based economy to a biologically-based economy. We can reduce the climate impact of food production and transportation. We can enhance Europe's geopolitical resilience and reduce dependency on fragile supply chains. We can create sustainable production of materials and feed a growing world population. And we can reduce land use, increase biodiversity, create new green jobs, and drive competitiveness. The McKinsey Global Institute estimates that up to 60% of the world's raw materials can be created biologically, significantly lowering the world's dependence on fossil oil¹.

But, as of now, Europe risks missing out on the opportunities of the biorevolution because of regulations that have been designed with fossil-based solutions in mind. Products and solutions that are based on natural materials and processes which are not harmful are stalled as they wait for approval. At the same time, the European system for regulatory renewal is the slowest in the world. This situation risks driving companies and researchers out of Europe, and with them the chance for Europe to lead the biorevolution. The European Biotech Act needs to deliver on regulations that reflect what we know today.

In this case collection, the European Biosolutions Coalition shares examples of what the European biosolutions sector has to offer the world. The cases also show the obstacles European innovators face in their efforts to create new solutions based on time-tested techniques from nature's own toolbox.

Over decades, we have been sowing the seeds for a European biorevolution. Now, we need to create the best possible conditions for biosolutions companies to ensure that the coming biorevolution will be European. We want to ensure that companies that were born in Europe grow here instead of elsewhere.

We have the knowledge. We have the companies. We have the techniques and we have the solutions.

Let's make Europe's biorevolution happen.

¹ 'The Bio Revolution – Innovations transforming economies, societies and our lives', Report, McKinsey Global Institute, 2020.

Content

What is a biosolution?	5
Barriers to a European biorevolution	8
To compete, Europe needs to scale up	10
Cases from across Europe	12
21st.BIO	14
AMSilk	16
Biosphere	18
Biotalys	20
BRAIN Biotech AG	22
dsm-firmenich	24
Epoch Biodesign	26
Koppert	28
Novonosis	30
PlantaRei® BIOTECH	32
Syngenta	34
Pili	36
Those Vegan Cowboys	38

*This case collection presents selected biosolutions from Europe, which contribute to a greener and more sustainable world.
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What is a biosolution?

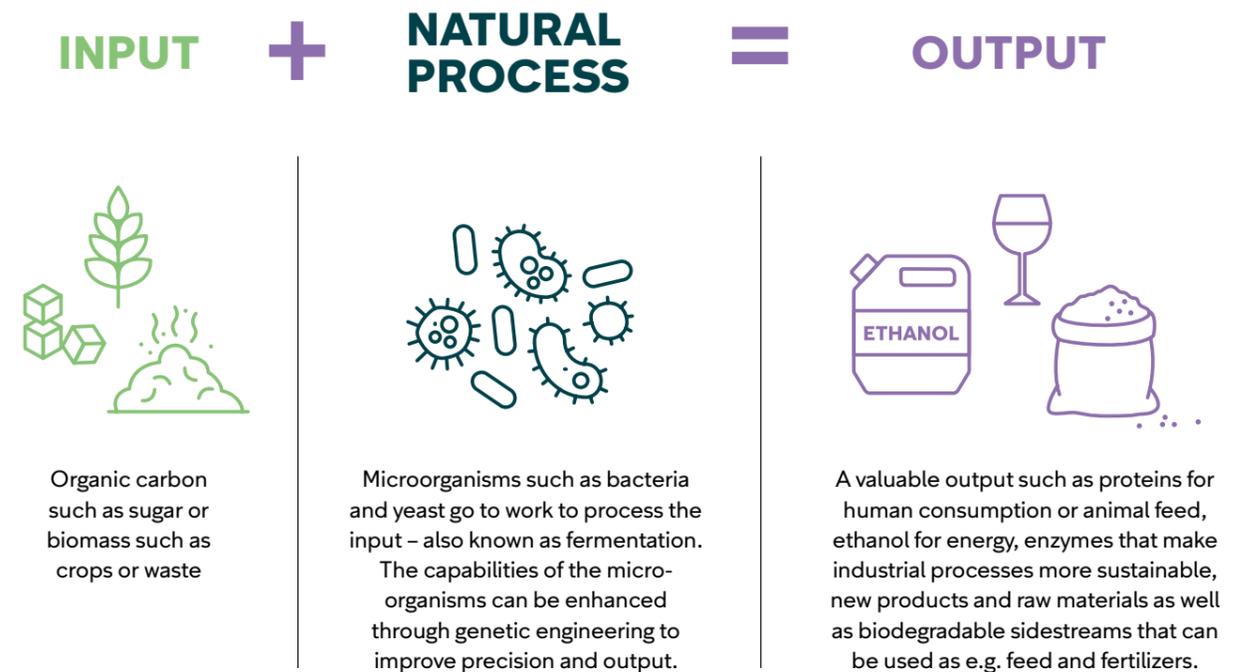
When we combine biology with technology, we enter the world of biosolutions. By using nature's own toolbox and applying it at scale, we can contribute significantly to combatting climate change, safeguarding biodiversity, protecting the environment, and securing food for a growing population.

The term Biosolutions refers to goods and services derived from combining biology and technology with the ambition of accelerating the Green Transition.

How does it work?

The industrial revolution was characterised by massive factories.

The bio-revolution is defined by 'micro-factories': Biosolutions are about using natural microorganisms and processes such as fermentation that have been used for centuries to create the products we need.



Key concepts within biosolutions



Bacteria

There are more bacteria on this planet than grains of sand – billions more. Bacteria are the most powerful life form on earth.

Bacteria and other microorganisms are essential for our survival (over 90 percent of the genes humans carry are contributed by the bacteria with which we live in close symbiosis). With bacteria we can boost plant health and keep food products fresh and safe for longer, simply because good bacteria help to naturally inhibit the development of pathogens and mould.



Enzymes

All living things have enzymes. Enzymes are biologically active proteins found everywhere in nature. When one substance needs to be transformed into another, nature uses enzymes to speed up and control the process.

Enzymes are small biological catalysts that increase the speed of various processes in living organisms. In the absence of enzymes, all chemical reactions would be so slow that the organism could not function.

Enzymes can be used on an industrial scale to optimize output, deliver better products, and accelerate processes, while saving water, energy, and raw materials.



Fermentation

Fermentation is the breakdown of carbohydrates like starch and sugar by microorganisms such as bacteria or yeast. Fermentation of food is an old technology used to safely preserve food for a longer period, for example in bread, cheese, wine, and fish. The technology is widely used in the current food system, from animal feed to yoghurt.

Fermentation has the potential to create a more sustainable food system with safer food by reducing spoilage and pathogens. Fermentation can also help produce healthier food and reduce food waste, for example by improving the nutritional composition of food and prolonging its shelf life. Microorganisms can be genetically engineered to produce high-value products such as nutrients, bio-pheromones, and biomaterials through precision fermentation.



Microorganisms

Microorganisms encompass different kinds of microscopic organisms that are found all around us in the millions.

There are many kinds of microorganisms, and specifically bacteria, yeasts, and algae are of interest. Their roles differ, yet they often use organic carbon as fuel for their natural processes, such as fermentation. Their output is essential for our environment and for human life.



Precision fermentation

Fermentation has been around for thousands of years in human societies. However, today we can use precision fermentation, which is a more calculated technology. Precision fermentation introduces organic carbon to microorganisms, especially bacteria and yeast, which then create outputs of different kinds of proteins.

These microorganisms have been carefully crafted and undergone specific bioengineering techniques. Here, they are given specific genetic codes that change the fermentation process by instructing them to produce the desired molecule or compound of interest, such as proteins or pigments. These genes are not new; in fact, they are identical to DNA sequences found in animals or plants. But no living beings need to be involved, as the DNA sequences can be kept and reproduced in digital databases.



Yeast

Yeast is another microorganism that has been present in the world for hundreds of millions of years. Yeast is actually a fungus, but it grows as single cells, rather than as a mushroom. Yeast consumes sugar and produces by-products such as alcohol, carbon dioxide that makes bread dough rise, and other biochemical compounds. Yeast enables fermentation, and thanks to advances in genetic engineering, yeast – just like bacteria – can be modified to produce high value products.

Barriers to a European biorevolution

This case collection presents a variety of innovative European biosolutions companies – and the many barriers they face in their efforts to bring new and more sustainable bio-based products and solutions to market, such as:

1

Regulation made for old paradigms

Today, biosolutions are regulated by various regulatory regimes in the EU. These sets of rules have one thing in common: they are not designed with biosolutions in mind. The current regulations are aimed at foods and fossil-based substances. This results in outdated regulatory requirements that do not support innovative biosolutions and the acceleration of the green transition.

2

Slow, slower, EU

The European system for regulatory renewal is the slowest in the world. Approval processes in the EU are three times as long as in the US and may take up to 8 years. The long timelines make it difficult to attract funding, making it hard to compete with similar players in the US and Asia.

One example: The Belgian company Those Vegan Cowboys produces milk proteins for cheese without the use of cows. The company already works together with large dairy players to make cheeses. But due to the European regulation timeline, Those Vegan Cowboys are not able to enter the European market for at least the next four years. This slows the speed of innovation, as they are ready to enter the market, but held back by regulation.

3

Biosolutions and bio-based industries are not recognised

No clear incentives for bio-based content in products are in place. Also, the current regulations do not always consider the role of sustainability properties, such as biodegradability and compostability, in a systemic way.

The consequence is this: European companies are now looking to other regions such as the United States, China, Brazil, Singapore, and the Middle East, when it comes to investment, production, and feasibly obtainable markets.

As a result, EU is falling behind its global peers, while preventing European consumers and industries from accessing innovative and sustainable solutions of European origin. These are solutions that could deliver on the EU's green ambitions.

To compete, Europe needs to scale up

Europe risks a scenario in which European researchers and companies sow the seeds of the biorevolution only to see others harvest the rewards. Investment in production and scale up-facilities for biomanufacturing is crucial if the European biorevolution is to happen.

1

The Opportunity

- Biosolutions have the potential to reduce the CO₂ equivalent emissions of food, materials, and energy dramatically and to replace fossil-based solutions.
- The market potential is enormous. For example, the market for biomanufactured ingredients within just three industries – speciality chemicals, foods, and chemical precursors – could reach EUR 180 billion by 2040, presuming the manufacturing capacity is there¹.
- Increasing the scale of biomanufacturing facilities increases the rewards significantly. Dairy is an example: with the current bio-based production facilities, the CO₂ equivalent emission can be reduced from 17.4 kg. per kilo of product in conventional production to 4.9 kg. per kilo. By scaling up biomanufacturing facilities we can reach 1.7 kg. per kilo – a 90% reduction of climate footprint².

¹ Market potential 200 billion USD, cf. 'Breaking the Cost Barrier on Biomanufacturing', Report, Boston Consulting Group, 2024.
² 'Breaking the Cost Barrier on Biomanufacturing', Report, Boston Consulting Group, 2024.

2

The Challenge

- While Europe offers strong support for science and R&D in biotechnology, scaling up commercialization to the industrial level poses significant challenges. This is especially true for SME's, which often face difficulties financing infrastructure to scale their biosolutions.
- Europe remains a hub for the biofabrication of established products, with large industrial fermenters for established products, such as enzyme production, controlled primarily by a few large players. However, these fermenters are not available to produce new, bio-based products.
- When it comes to scaling up to industrial production of thousands of tons in large fermenters, Europe faces serious challenges in competing with other regions. The US, in particular, has established strong federal and local government support for biofabrication, encouraging new investment in the biotech sector and providing a significant boost to the bioeconomy.

3

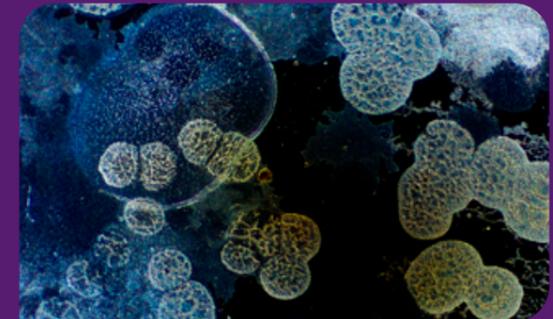
The Policy Recommendation

- Demonstrate clear policy and focused action to provide capital markets and industry support to scale up biotech companies with bankable business cases.
- Reduce bureaucratic hurdles for large-scale industrial investment and for the adaptation of existing biomanufacturing capacity to accommodate the production of innovative biomaterials.
- Improve incentives to invest in scaling and infrastructure capacity. Pilot facilities are needed to enable transition from R&D to market. And large-scale production facilities are needed if Europe is to become the world's biomanufacturer. For example, we call on member states to explore possibilities to utilise IPCEI funds for bioreactors and the development of a model where the EU could be a co-investor in public-private partnerships.

Cases from across Europe



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21st.BIO

Reinventing production with precision fermentation

Problem: We have the solutions, but not the facilities

As the world's population grows, the UN expects demand for proteins to double by 2050. This calls for a drastic increase in both food and material production while ensuring sustainability – a demand that animal production alone cannot meet.

Instead, we can look to nature for solutions. Biosolutions can produce up to 60% of the world's inputs sustainably¹.

A key technology for sustainable production of many biosolutions is precision fermentation, in which microorganisms are used to produce specific, high-quality products. This production method avoids synthetic chemicals, fossil fuels, and high-impact farming. And most importantly, it enables production on a very large scale, with the objective of reaching price parity with traditional unsustainable production methods.

However, few biotechnologies can effectively replace traditional production at industrial scale – yet.

Biosolution: Helping companies who change the world

The Danish company 21st.BIO was founded to make industrial-scale precision fermentation technology accessible for bulk protein production. This enables biosolutions companies across the globe to successfully bring proteins to market faster and at a competitive cost, while removing significant risk from their ventures in precision fermentation.

With a licence to use Novonesis technology, 21st.BIO leverages its precision fermentation technology platform to develop highly productive microbial strains and optimal fermentation processes, plus offer production upscaling guidance to its customers. 21st.BIO is active across the nutrition, food, biomaterials, agriculture and even mining sectors.

¹ *The biorevolution innovations transforming economies societies and our lives*



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In May 2024, the company inaugurated a pilot plant facility at its Søborg headquarters. Established as a mini factory, it is designed as a first step for 21st.BIO's customers to scale their production from the lab to industrial scale.

Impact: Sustainable bioproduction, at industrial scale

Precision fermentation is regarded as one of the most sustainable production methods in the world. Industrial scaling of precision fermentation is going to be crucial in securing global supply chains. As an example, several life cycle assessments (LCAs) have shown that, compared with traditional animal agriculture, dairy proteins produced by precision fermentation significantly reduce land use (90–92%), water use (95–99%), and greenhouse gas emissions (90–97%).²

Barriers: Regulations are unfriendly

While we need to speed up sustainable solutions for both planetary and human health, the approval process for many of these solutions is painfully slow, particularly in the EU's novel foods approval system. Current regulations are biosolutions-unfriendly, resulting in barriers to market access for sustainable products and solutions.

The same is true for financial and political support. Other regions in the world already strongly support biosolutions development. If the EU wants to remain competitive, it must support the biosolutions sector by fast-tracking approval processes and support the building of Europe's first industrial protein factories.

² *How Sustainable is Animal-Free Dairy? We Compare Precision Fermentation LCAs*

Website: 21st.bio

LinkedIn: [linkedin.com/company/21stbio](https://www.linkedin.com/company/21stbio)

AMSilk

Biotechnology is disrupting the material sector

Problem: Our textiles are good for style, but bad for nature

What you wear, the shoes you walk in, and the textiles and materials you put in your home matter. Not only for comfort and style, but more importantly for the wellbeing of our nature and climate. The materials sector is an enormous polluter, contributing to 23% of global CO₂ emissions.¹

This calls for new methods and a serious integration of strong and sustainable textiles into our daily lives. One is spider silk – one of the most fascinating materials on earth. It is two-and-a half times stronger than steel and extremely versatile. However, farming natural spider silk has not proven to be scalable.

Biosolution: Out with the spider, in with the microorganisms

The key to success is using biotechnology. The German company AMSilk is one of the prime movers in developing functional proteins that can be turned into strong and sustainable silk, replacing chemical products or products of animal origin. AMSilk's patented technology allows for the production of spider silk proteins on an industrial scale, using a genetically-engineered microorganism.

With biotechnology, AMSilk can produce a silk-like fibre that is vegan, demonstrably biodegradable, and solely produced with renewable resources. The material has a variety of applications, ranging from super-fine yarn for silk-like fabric to super-resistant yarns for advanced materials, such as composites or car seats. In medical use, the silk-like material is used to coat breast implants to prevent infection and reduce post-operative complications.

The material can be tailored to specific market or product requirements, while being biodegradable and producing significantly lower CO₂ emissions than traditional fabrics.

And variety is crucial. To be competitive, biomaterials need to offer other enhanced features that make them more appealing for certain markets or applications. AMSilk's materials are already available in commercial products on the market today, and the company's goal is to become a high-volume supplier of spider silk proteins for the textile industry and consumer goods. The ability to tailor-make materials and adapt their properties and performance to a specific need will be one of the core roles of biotech in the 21st century.

¹ [Industrial Biotech Impact Report 2023](#)



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Impact: Look to nature for better alternatives

It is estimated that 60% of global physical input could be made using biotechnology.² How? Just look towards nature for amazing tools like enzymes, microorganisms, and fermentation.

According to a recent Cradle-to-Gate Assessment, 1kg of AMSilk's Ultrafine Fibers demonstrate an 81% lower climate change impact (per kg CO₂) compared to natural silk. In addition, biofabrication as a production process requires only minimal use of land and water resources.

Barriers: Competition is hard, and patient investors few

For a company like AMSilk, financial and material support in Europe's bio-economy is crucial. But regional capital markets lack patient investors and risk-sharing mechanisms, leaving biotech firms with a need for support to compete with subsidised sectors.

While Europe offers strong support for science and research in biotechnology, scaling up commercialisation to the industrial level poses significant challenges. Europe remains a hub for the biofabrication of established products, with large industrial fermenters for established products such as enzyme production, controlled primarily by a few large players. However, these fermenters are not accessible to produce new products.

When it comes to scaling up to industrial production of thousands of tons in large fermenters, Europe faces serious challenges in competing with other regions. The US, in particular, has established strong federal and local government support for biofabrication, encouraging new investment in the biotech sector and providing a significant boost to the bioeconomy.

Website: amsilk.com

LinkedIn: [linkedin.com/company/amsilk-gmbh](https://www.linkedin.com/company/amsilk-gmbh)

² [The third wave of biomaterials: When innovation meets demand](#)

Biosphere

Taking sustainability to an industrial scale

Problem: The hurdles towards a biobased industry

Combining biology with technology holds tremendous potential in the battle against climate change and in our efforts to live more sustainably. But to fully release the potential of biosolutions, constant innovation is necessary to turn today's chemical industry into a biobased one – with green, sustainable, and environmentally friendly processes.

The key tools are already there. They are just too small to see: enzymes, microorganisms, and their derivatives. To put them into use – at scale – companies that develop biosolutions need a strong partner. A partner that delivers the research necessary to overcome technical and engineering hurdles. A partner that supports the process to implement biosolutions into industrial processes at full scale – and into our everyday lives.

Biosolutions: Sustainability and innovation go hand in hand

The Italian company Biosphere can be that partner. Biosphere is a key player in the Italian industrial biotechnology sector and works as a technology platform, delivering deep tech along with research-based scaling facilities in which other companies can improve and test their products. Biosphere provides research and development along with scale-up services in the field of fermentation and industrial biotechnology, supporting customers and partners in the industrialisation of their projects.

Biosphere is also known for its development of tailor-made enzymes and microorganisms for a variety of market sectors. For example, Biosphere develops optimised microbial strains that can improve a plant's nutrient uptake and protect against diseases. The company is also involved with the creation of cosmetic, nutraceutical and food ingredients that have enhanced properties thanks to the fermentation processes. Moreover, enzymatic processes are now under development

at Biosphere to solve end-of-life issues of plastic materials with new and sustainable degradation processes.

Impact: The power of enzymes

Turning today's chemical industry into a biobased one requires strong collaboration between scientists and the industry. Biosphere is a key facilitator in this collaboration, helping new and innovative biosolutions to go from idea to reality.

Biosphere customises enzymes, designing and optimising them for specific applications, so that they can perform a very selective action. Using enzymes avoids the production of by-products in chemical reactions while operating in mild reaction conditions. This means less energy consumption and fewer harsh chemical compounds. The result? A safer process for people and for the environment.

Barriers: High quality research calls for high funding

To unlock the great potential of biosolutions, actions are needed on multiple fronts. First and foremost, there is a big need for funding in high-quality research, ensuring high level training for graduates in a number of different fields. Funding is also crucial in supporting the development of existing scale-up facilities, to appropriately cover the gap between ideas and industrial applications.

Website: biospheresrl.com
LinkedIn: [linkedin.com/company/biosphere-spa](https://www.linkedin.com/company/biosphere-spa)



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Biotalys

Battling food waste with natural proteins for crop protection

Problem: What a waste!

Globally up to 30% of food produced for human consumption is wasted – even before it hits our plate¹. What a loss of resources and money, not to mention the massive impact it has on our climate: food waste is estimated by the Intergovernmental Panel on Climate Change to contribute 8–10% of total human-made greenhouse gas emissions².

This calls for numerous solutions – one being more innovative, biobased, and sustainable crop protection and food production. Still, chemical pesticides make up 90% of the market in today's agriculture with great risks for the environment.³

Biosolution: Battling fungi with proteins

Farmers cultivating high-value fruits like grapes and strawberries that are particularly vulnerable to destructive fungal diseases can turn to a promising solution being developed by the Belgian company Biotalys. This innovative bio-based approach effectively combats grey mould and powdery mildew, providing a safe, chemical-free defence for produce that is often consumed directly.

The first biobased crop protection product developed by Biotalys, a biofungicide named EVOCA™, is based on proteins – the core ingredient of nature. The proteins are produced through precision fermentation, a biological process that utilises mainly sustainable and natural resources. It is a production method with great potential to become a sustainable alternative to conventional chemical pesticides.

This is how the proteins work: They are mixed with water and then sprayed on the crop. Here they interfere with the cell wall of the fungus, which bursts, and the fungus dies off. The proteins themselves are fully biodegradable, turning into amino acids that could even be beneficial for soil life.

Impact: A greener tool for growers

With proteins from Biotalys, growers gain a revolutionary tool to safeguard their crops while maintaining yield and income. These proteins are engineered



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to replace chemical pesticides, ensuring crop protection and food consumption that is safer and more sustainable.

Extensive field trials around the globe have demonstrated that the product performs at par with existing crop protection products in spray rotation programmes. In grapes for example, the integration of a protein-based biocontrol in a spray rotation programme achieves fungal disease control comparable to or better than traditional methods, with effectiveness reaching up to 87% compared to untreated grapes.⁴

Barriers: We wait, and wait, and wait

At EU level the timelines to approve biobased solutions that can replace chemical pesticides is far too long. For example, Biotalys' first biofungicide, EVOCA, currently awaits registration by the European Commission. The file was submitted under Regulation 1107/2009 to the authorities in March 2021 and review has been going on for more than 3 years, with various regulatory steps still ahead. In the meantime, the product has already been produced in Italy and Austria, and Belgian and Danish distributors have been appointed. But European growers cannot start using the product if regulatory approval has not been obtained.

This threatens not only the viability of innovative small and medium-sized enterprises (SMEs), but more importantly the livelihood of farmers and the safety of produce for consumers.

To address these challenges, the sector is advocating for modifications to the current regulatory framework as a short- to mid-term solution. This can be achieved by establishing a green priority lane for biocontrol products, eliminating time-limited registration, reinstating provisional authorisations, and streamlining the process for label expansions. These changes would accelerate the authorisation process and bring biocontrol solutions to market more swiftly.

Website: biotalys.com

LinkedIn: [linkedin.com/company/biotalys-nv](https://www.linkedin.com/company/biotalys-nv)

¹ *The Boston Consulting Group, "Tackling the 1.6b ton food loss and waste crisis", 2018*

² *UN Sustainable Development Goals: the Sustainable Development Agenda*

³ *Biocontrol market now over worth 1.6 billion euro but EU policies a bottleneck to unlocking full potential*

⁴ *Biotalys announces results independent field trials US*

BRAIN Biotech AG

Upcycling CO₂ into a raw material

Problem: Our waste contains large amounts of carbon

Every day, industry and daily life produces significant quantities of waste streams such as household waste, sewage sludge, and industrial wastewater. An average of 740 grams of solid waste is produced by every person on Earth every day, amounting to 2.01 billion metric tons annually worldwide – equivalent to 502.5 million elephants.¹

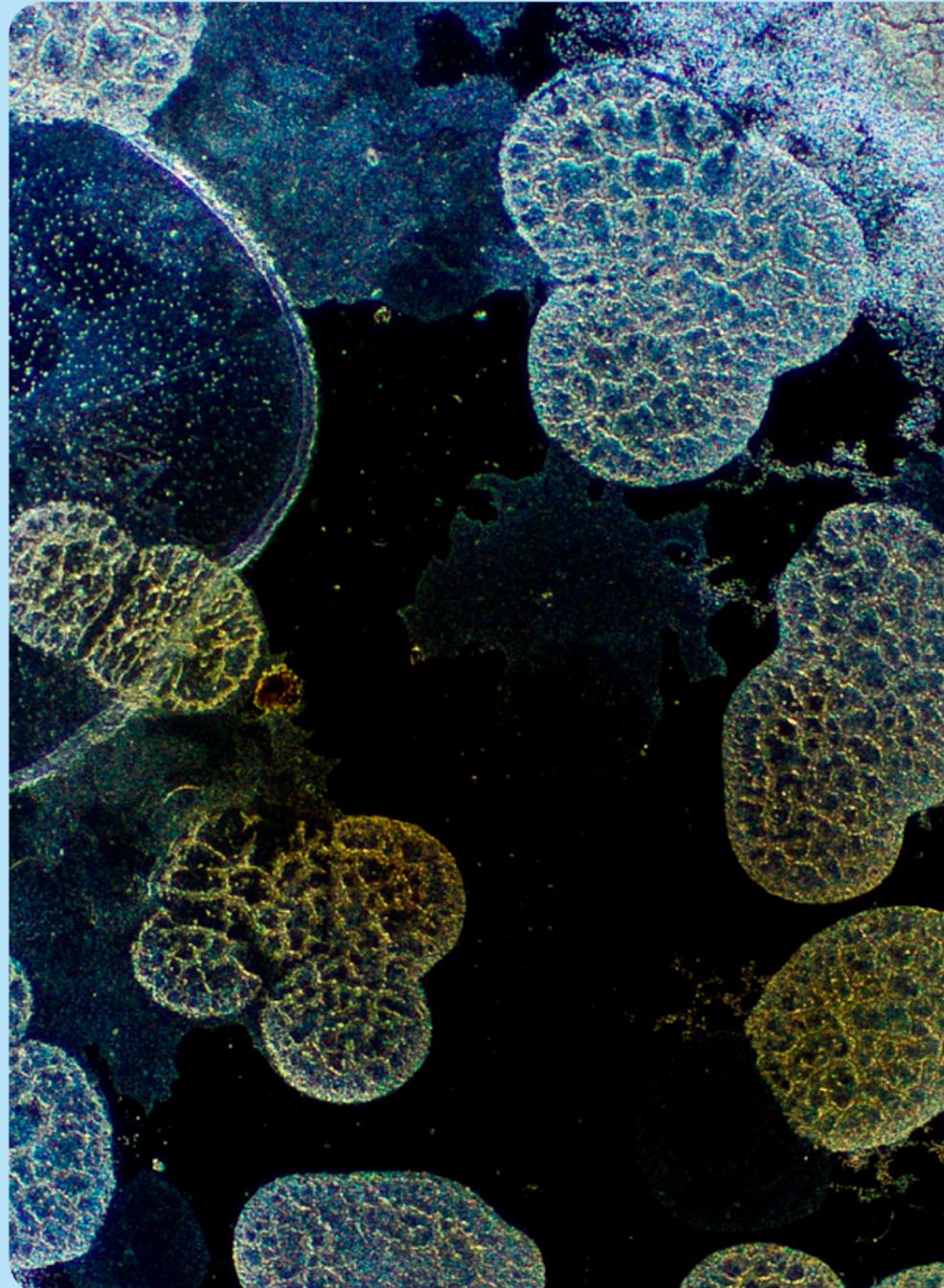
Hidden inside these streams are substantial quantities of carbon. When released into the air, this carbon poses a great threat to the environment. But what if we were able to convert the carbon from waste streams into valuable products – into a functional biomass?

Biosolution: From carbon-problem to carbon-potential

In Germany, a joint development program named ZeroCarbFP funded by the German government has been established to answer just that question. It uses biotechnology to identify enzymes and microorganisms that help utilise and transform waste streams into sources of raw materials. The best candidates are then optimised to prepare them for application in industrial production.

The German company BRAIN Biotech is in charge of developing a biotechnological process that utilises biogenic CO₂ from the production plants of Südzucker AG. The aim is to stabilise it for use as a raw material, convert it into valuable products, and eventually bring these processes to pilot scale.

BRAIN Biotech has now developed special microorganisms that use biogenic CO₂ as the carbon source to produce an intermediate raw material and to convert that to a platform chemical called monomer succinate. Due to its chemical structure, it can be easily converted into other chemical compounds and can also be used as a building block in polymer chemistry. Current uses include the production of clothing fibres, plastic,



¹ [Overview of municipal solid wastes-derived refuse-derived fuels for cement co-processing](#)



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solvents, paints, inks, food and feed additives, pharmaceuticals, and perfumes.

Impact: The future is CO₂ in products, not in the air

Converting carbon from waste streams into valuable CO₂-based products can help reduce greenhouse gas emissions from existing production facilities.

BRAIN Biotech's concept could also be licensed to other CO₂ suppliers, such as utility companies handling waste, coal, or lignite. It could be licensed to heavy industry like steel and concrete production, or even bioproduction facilities, to reduce their emissions as well.

Barriers: Let's help consumers make better choices

CO₂-based products have enormous potential, but the market is competitive. This calls for a different pricing policy to encourage the provision of CO₂-based products. If you ask BRAIN Biotech, it could be as simple as this: reward the material use of CO₂ while taxing fossil-based products. Another tool could be a labelling system that informs customers about the carbon footprint of individual products, giving them the information needed to make more sustainable choices. Such regulation needs to be put in place on all levels: international, EU, country- and state-wide.

Other regulatory hurdles include the use of "waste" material in certain markets, especially food or cosmetics or employing genetically optimised organisms (GMO) for production.

Website: brain-biotech.com

LinkedIn: linkedin.com/company/brainbiotech

dsm-firmenich

Improving infant health while taking better care of the planet

Challenge: Breast-fed or bottle-fed, babies need human milk oligosaccharides

Human milk represents the nutritional gold standard for the approximately 385,000 babies born each day across the globe. However, some mothers may choose not to breastfeed, may only partially breastfeed, or cannot breastfeed at all.

Infants who are not breast-fed miss out on the natural Human Milk Oligosaccharides (HMOs) that are crucial compounds in infant nutrition. With human milk being the only natural source of HMOs, one way to help these infants is to produce HMOs for infant formula at an industrial scale. This can be achieved by combining biology with technology.

Biosolution: Fermentation = more HMOs and less CO₂

The Swiss-Dutch company dsm-firmenich uses biotechnology to make the production of HMOs more efficient and sustainable.

Here is how it works: dsm-firmenich uses a dedicated micro-organism that has been subject to extensive research and checks to ensure its safety. Thanks to gene technology, the microorganism has been tailored to produce specific compounds: in this case, HMOs.

The production is achieved through precision fermentation, which is a process through which microorganisms, such as bacteria, are fed with carbon sources, such as sugars, to produce other molecules (in this case, HMOs). This happens within an isolated and controlled environment in which temperature, pH, feeding material, and other factors are strictly controlled. The customised microorganisms are separated from the final product, so that the final product does not contain any genetically modified microorganism (GMM).

This biotech-driven approach enables HMOs to be produced in ton quantities, ensuring these beneficial molecules are available and affordable for a much broader population. The production methods used at dsm-firmenich offer several other advantages too, particularly in terms of sustainability. The fermentation processes are operated with renewable resources and thereby contribute to



Website: dsm-firmenich.com/en/home.html
LinkedIn: [linkedin.com/company/dsm-firmenich](https://www.linkedin.com/company/dsm-firmenich)



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a circular economy. Biomass is recycled into biogas, while all electricity used is from renewable sources.

Impact: Better health, better planet

Breast milk is the gold standard for infant feeding and is the only natural source of HMOs. But when breast feeding is not possible, the best option is to improve infant formula with the addition of sustainably produced HMOs. Their intake has been associated with improvements in gastrointestinal microbiota and reduced infections and may assist with cognitive development.

It's a win-win situation, supporting the health and well-being of infants while also taking care of the planet that they will inherit.

Barriers: Regulation is hampering innovation

HMOs are registered as novel foods in the EU. At the same time, since they are produced with GMMs, their manufacturing process must comply with EU rules on the contained use of genetically modified micro-organisms (Directive 2009/41/EC). These regulations and their national implementation are becoming increasingly cumbersome. Result? The innovation and competitiveness of European industries are curtailed.

One example: some EU Member States, based on a questionable interpretation of EU legislation, require that the absence of recombinant DNA (rDNA) in such products is experimentally confirmed at the parts per billion level to demonstrate compliance of fermentation products with EU legislation on the contained use of GMMs. Achieving this level of purity is extremely demanding and not proportionate to the actual safety risks. And according to a significant body of scientific literature¹, the requirement for absence of rDNA is not per se of safety relevance but makes the production process more time-consuming and more costly than necessary.

¹ Lensch, A., Duwenig, E. and Dederer, H.-G. et al. (2022) Recombinant DNA in fermentation products is of no regulatory relevance. *Food Control* 141, 109170. <https://doi.org/10.1016/j.foodcont.2022.109170>.

Epoch Biodesign

Transforming plastic waste into a valuable resource

Problem: Life with plastic, not fantastic

Plastic is everywhere, from the bottom of the ocean to the cells of the food we consume. Most plastic is never recycled, so the Earth is now covered in over 10 billion tons of plastic waste¹.

Our mismanagement of plastic has made it one of the world's biggest environmental problems, and with no viable solution, it floods into our natural ecosystems. Alternatively, the plastic is incinerated, releasing polluting gases into the atmosphere, and with them, the value of their fossil carbon.

Biosolution: Machines of the biological kind

The UK company Epoch Biodesign has developed a technology that transforms plastic and textile waste into infinitely recyclable materials and everyday chemicals.

By combining generative AI, biology and chemistry, Epoch engineers “biological machines” known as enzymes. These enzymes catalyse rapid, low-energy chemical reactions to break down long plastic molecules into their chemical building blocks, which can be used to make virgin-quality recycled materials again and again. This significantly reduces carbon emissions and unlocks processes with game-changing unit economics.

With no compromise on cost or quality, Epoch Biodesign provides an end-of-life solution for complex pre-and post-consumer waste and is paving the way for a more sustainable, less polluted future in which production can be decoupled from fossil carbon extraction.

Impact: Solving two problems with one enzyme

The impact of this innovative technology is significant and multifaceted. Epoch Biodesign provides a solution for end-of-life plastic waste and produces sustainable recycled materials that reduce our reliance on fossil carbon.

This limits plastic pollution by providing an economic alternative to clogging landfills and oceans, harming wildlife, and littering ecosystems. It also lowers greenhouse gas emissions by decreasing our use of fossil carbon for the production of new chemicals and materials.

¹ [EIA study reveals a 10 billion tonne plastic pollution bomb ticking away in every corner of the planet](#)



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Transforming waste into a valuable resource supports a circular economy, promotes environmental sustainability, and helps mitigate climate change, benefiting both nature and human health.

Barriers: Let's design for recyclability

A number of developing and incoming EU regulations could remove barriers and support the adoption of this technology at scale, including the Waste Framework Directive, Ecodesign for Sustainable Products Regulations, and Extended Producer Responsibility (EPR).

For example, the requirement that textiles placed on the EU market have a certain percentage of closed-loop recycled content and be designed for recyclability will increase demand for the technology developed by Epoch Biodesign. Additionally, the potential for using EPR to finance end-of-life waste management facilities would ensure the collection and sorting of post-consumer waste scales to meet the demand, and therefore remove a significant barrier for the technology to access this feedstock.

A potential barrier to these regulations having the expected impact is the lack of harmonisation and clarity across different member states. In addition, it remains to be seen if manufacturers and brands will meet the requirements of the most demanding regulations or will find a way around them. Additionally, the use of the term “recycled” without truly defining what it means, and if it is from an open or closed-loop sources, provides additional challenges to promoting a truly circular solution within industries and for consumers.

Website: epochbiodesign.com

LinkedIn: [linkedin.com/company/epochbiodesign](https://www.linkedin.com/company/epochbiodesign)

Koppert

Look to nature to find safe and healthy ways of growing food

Problem: Food production is out of touch with nature

With a growing world population, we need to produce more food than ever before. But business as usual isn't working anymore. Not when our current agriculture and food system is responsible for a third of the world's greenhouse gas emissions and as much as 70% of land biodiversity loss.¹

Add to that pollution of our soil, air, and water along with considerable risks to human and animal health caused by chemical plant protection products. To make our food production healthier and more sustainable – and to pave the way for sustainable agriculture – we need to offer farmers and growers a selection of efficient and low-risk biological control solutions.

Biosolution: Protecting European crops with fungus

The Dutch company Koppert has more than 55 years of experience in the production of natural enemies and microorganisms. Found in nature, Koppert's products work as biological solutions for farmers and growers to protect their crops against pests and diseases.

One example is Mycotal – a fungus that can attack and kill pests. Mycotal works as a bio-insecticide that prevents whiteflies and several other pests in vegetables, ornamentals, nursery trees, and soft fruit in protected cultivation.

The bio-insecticide contains spores that germinate rapidly after spraying, penetrating the pest's body cavity and destroying its tissues. The fungus then grows through the insect cuticle and produces spores on the outside of the cadaver, which may spread the infection to other vulnerable pests.

Impact: Healthy plate, healthy farmer, healthy nature

Biocontrol allows farmers to operate in a sustainable manner and bring high-quality products to our tables.



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Bio-insecticides like Mycotal, which is already available on the market, originate from nature. They provide farmers and growers with tools to control pests and diseases in a sustainable and eco-friendly way. Koppert's biological solutions also reduce risks for human and animal health while supporting ecosystem services. They present no adverse effects on the environment while also being safe for beneficial insects.

Barriers: Same, but different

Measures are needed to speed-up the availability of biocontrol solutions so farmers and growers can have access to effective and safe alternatives. Unfortunately, the greatest barrier for the marketing of such products are the excessively lengthy and burdensome processes applicable to products like Mycotal under the EU Regulation 1107/2009.

The current European authorisation process is very slow, averaging 7 to 8 years, and in practice can take up to 10 years. In contrast, other major markets take only 1 to 3 years or less. As a result, Europe has become less attractive for new investment, forcing biocontrol companies, whose investors demand a timely return on investment, to deprioritise Europe.

Website: koppert.com

LinkedIn: linkedin.com/company/koppert-global

¹ Duurzaam voedsel | WWF | Voedselsysteem bedreigt natuur

Novonesis

Keeping food fresh for longer with fermentation

Problem: Yoghurts and other foods are wasted because they are past their use-by date

Food waste and food safety continue to be serious issues. In the EU alone, up to 17% of all yoghurt is wasted annually, equivalent to 1.5 million tons.¹

Up to 80% of yoghurt wastage occurs because the use-by date passes, sometimes without the product even being opened.² As consumers are becoming more conscious of what is in their foods, there is a need to address shelf-life issues without adding artificial ingredients.

Biosolution: Fighting bad bacteria with good bacteria.

Fermentation is an ancient way to keep food fresh for longer. It is a natural way to reduce spoilage and contamination with “bad” bacteria. The Danish company Novonesis produces beneficial bacterial cultures (food cultures) that optimise the fermentation process. This way, it is possible to enhance the quality, freshness, and shelf-life of the final product. The food cultures create an extra protective hurdle against “bad” bacteria in, for example, meat and dairy products, as well as in ready-to-eat foods, during processing, transportation, and storage, and even after the product has been opened.

Impact: 7 more days saves us tons of CO₂

The use of selected food cultures can play an important role in achieving the EU goals related to the reduction of food waste and CO₂ emissions. If food cultures are used to prolong shelf-life of yoghurt by 7 days, this could lead to a reduction of up to 30% of yoghurt waste in Europe alone. This reduction would result in estimated annual savings of 250 million euros and a decrease of 520,000 tons of CO₂ emissions.³ Similar reductions can be achieved for other food categories.

¹ Qbis Consulting 2016, *Reducing food waste and losses in the fresh dairy supply chain*, p. 31. The study was commissioned by Chr. Hansen
² *Ibid*, page 22
³ *Ibid*, page 31. See also Chr. Hansen's summary of the results, at: [Our fight against food waste \(chr-hansen.com\)](https://www.chr-hansen.com)



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Barrier: Fermentation is not an additive, it's a natural process

At the EU-level, a Commission proposal is being discussed to classify the use of food cultures outside of traditional fermentation as so-called “food additives” under the EU Food Additives Regulation. This proposal risks creating an unnecessary burden on the biosolutions industry and EU authorising bodies. It will also hinder the innovative potential that lies in fermentation technology, which is key in the transitioning towards more sustainable food systems.

In the EU, any substance that falls under the definition of a food additive must obtain a preapproval, go through an EFSA risk assessment, be authorised for use as a food additive in its specific product category, and be included in the ingredient declaration of that product with their name or ‘E’ number. Classifying food cultures as additives is unnecessary and disproportionate for food cultures, which are a normal part of the microflora of any food, our surroundings, and ourselves. Furthermore, food cultures have a long history of safe use as food ingredients in fermented foods.

Instead, a simple solution could be to inform consumers of the presence of food cultures in the food by labelling the food cultures in the ingredients list.

Website: novonesis.com/en

LinkedIn: linkedin.com/company/novonesis



PlantaRei® BIOTECH

Towards a greener cosmetics industry



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Problem: Beauty has an ugly side

Earth's resources are not infinite, and our planet is threatened by deforestation, loss of biodiversity, and climate change. This calls for action in many industries – including cosmetics production, which is estimated to be responsible for up to 1.5% of the world's greenhouse gas emissions.¹

Fortunately, consumers are ready: in 2023 the demand for natural and sustainable cosmetic products in Italy represented 63.9% of the total skincare products on the market.² The question is: is the cosmetic industry ready to go all the way?

Biosolution: Replacing hazardous chemicals with enzymes

Let's start with the main character of this biosolution: Glycerophosphoinositol (GPI). It's an active molecule naturally present in our organism, and it is widely used in dermo-cosmetics due to its proven soothing and anti-inflammatory properties. However, today's production of GPI involves chemical solvents and plants with a significant environmental impact, along with high operational costs.

The Italian company PlantaRei® has developed and patented a green alternative to GPI named GPI 4Planet™.

Unlike the traditional chemical process, it is based on a green production method that takes advantage of enzymes. Enzymatic reactions, in which specific proteins called enzymes interact with substrates to generate highly specific products, occur under mild conditions of temperature, pH, and pressure.

By putting enzymes to work, PlantaRei® avoids the use of any chemical solvents, lowering the carbon footprint of production and resulting in a green product of high quality. GPI 4Planet™ is now being produced in small initial batches for

use in dermatological preparations to treat atopic dermatitis and eczema, as well as in cosmetics formulations to counteract inflammation, and for sensitive skin.

Impact: Less land and waste

The new biobased production method relies on the highly precise activity of enzymes. This comes with several advantages: a reduction in resource consumption, fewer side products, and yields that are 2 to 3 times higher than the traditional chemical process. Moreover, it abolishes the use of solvents, avoiding the production of hazardous waste. Finally, the land footprint of PlantaRei®'s production plant is estimated to be three times smaller than a similar chemical synthesis plant. Altogether, the outcome is strikingly eco-friendly.

Barriers: We are bio-based, we are not a “chemical”

However, current regulation creates a problem. Today, REACH – the EU regulation of chemicals – limits production volumes and demands an overly stringent amount of data for approval. The result is significant cost burdens that heavily impact small and medium-sized biotech companies as well as broader and faster biosolutions adoption.

According to REACH, substances can be manufactured or imported without registration as long as the quantity remains below 1 ton per year. However, for biosolutions that adopt fewer or no chemicals in favour of greener substances, REACH inhibits the green transition. According to PlantaRei®, biosolutions generated with the use of green substances like enzymes rather than hazardous chemicals should be encouraged, and their production should face less stringent regulations due to the lower risks they present to human health and the environment.

Website: plantareibiotech.it/en



¹ [Quantis. \(2020\). Make Up the Future. Quantis.](#)

² [Cosmetica Italia. \(2024\). I dati del mercato a connotazione naturale e la percezione della sostenibilità da parte dei consumatori. Cosmetica Italia.](#)

Syngenta

Putting a sustainable toolbox into the hands of farmers

Problem: Farmers' toolboxes have a green gap

Faced with the challenges of climate change, biodiversity loss, and a food security crisis, the world is at a critical stage when it comes to transforming our food system. This calls for a new and more sustainable approach to agriculture, including providing farmers with a wider choice of plant protection tools. Farmers need tools to help them deliver agricultural productivity with stronger environmental performance whilst growing our food safely.

For more than a decade, the European Commission has been working to reduce farmers' dependency on synthetic pesticides. An important transition, but also one that has left European farmers with very few crop protection products available. The loss of conventional chemical pesticides far exceeds the introduction of new chemical or biological substances, limiting farmers' access to environmentally friendly technologies. This compromises the competitiveness of European farmers and jeopardises global food security.

Biosolution: One bacterium – three modes of action

Biocontrols have the potential to fill that gap in farmers' toolboxes. One of them is the bio-fungicide TAEGR0®, which has been developed by the Danish company Novonosis and distributed by the Swiss-based global company Syngenta.

The TAEGR0® solution is small – tiny even, but with multiple functions. Based on specific strain bacteria endospores that are activated when mixed with water, TAEGR0® can protect fruits and vegetables with multiple modes of action that complement each other. Once sprayed, it creates a physical barrier protecting the plant from pathogen colonisation. Then the bacteria release biologically active molecules that inhibit fungi and microbes. Finally, TAEGR0® helps activate the plant's natural defence system, making it ready to fight any pathogen attack.

Farmers – organic as well as conventional – can use the bio-fungicide TAEGR0® against broad spectrum diseases such as powdery mildews, botrytis, early blight, etc. This provides them with versatile and efficient protection for many crops cultivated throughout Europe, including grapes, berries, fruiting vegetables like tomato and cucurbits, as well as leafy and root vegetables.

Impact: More tools, more biodiversity

TAEGR0®'s modes of action present a remarkably low risk of resistance development, since they decrease the overall potential for the disease to spread. At



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the same time, increased weather variability will further challenge the ability of growers to predict disease outbreaks and plan spray programs, increasing the need for flexibility. When used as part of an integrated pest management strategy, TAEGR0® complements conventional products. Field tests showed that the integration of TAEGR0® within a standard spray program with reduced chemical input increases efficacy by 20% in most crops.

Due to its biological origin, various modes of action, low concentration needed, the ability for workers to re-enter the growing area quickly after application, and the short period between application and when the crop can be harvested, TAEGR0® achieves two goals simultaneously: it ensures a healthy yield while reducing chemical usage, thereby helping growers meet increasingly stringent residue level regulations and food chain standards. Because it is harmless to beneficial insects and pollinators, TAEGR0® ensures the preservation of vital ecosystem services, promoting biodiversity.

Barriers: The current biocontrol regulatory framework is a bottleneck

Taking new and sustainable biocontrol solutions to market is no easy task due to lengthy authorisation procedures and legal deadlines that are often not met. It takes in average 7 to 9 years for a biocontrol to enter the European market, and TAEGR0® was no exception with a lead-time of 8 years. In comparison, it takes 2 to 3 years to obtain registration in other key global markets, leaving the EU at a competitive disadvantage.

Furthermore, guidelines and data requirements do not match the specific characteristics of biocontrol products. This leads to excessive administrative burdens, costs, and delays for companies like Syngenta. Unfortunately, these obstacles cannot be adequately addressed under the current regulatory framework and fixing them would require substantial changes beyond the scope of the current Plant Protection Products Regulation (1107/2009).

Website: syngentabiologicals.com

LinkedIn: linkedin.com/company/syngenta-biologicals

Pili

Our favourite colour is carbon conscious

Problem: The production of colours is far from green

Today, 99% of colours used in products such as clothes, plastics, and automotive goods are produced using fossil fuels, leaving the colour industry dependent on the oil industry.¹ The global colour industry emits a total of 200 million tons of CO₂ and uses 20 million tons of hazardous chemicals every year to colour consumer goods, with significant climate and environmental impact.²

This calls for new, innovative, and decarbonised solutions.

Biosolutions: From biomass to bio-colour

The French bio-company Pili produces decarbonised colour alternatives based on renewable resources. And they do so by integrating biology with chemistry. The approach uses biomass in the form of renewable, traceable raw materials that are utilised to manufacture products without tapping into fossil resources.

Pili selects and optimises microorganisms and feeds them with biomass during fermentation to produce the building blocks of dyes and pigments. This fermentation process, widely used in industries such as pharmaceuticals and food, offers high reproducibility to meet diverse needs.

The biobased building block obtained is then converted into high-purity dyes, applying green chemistry principles such as low temperatures, water as a solvent, and catalytic methods to minimise waste. This process allows scalable, cost-effective dye manufacturing without compromising on quality.

Impact:

Pili's innovative technology enables the large-scale production of biobased dyes and pigments, offering a significant environmental advantage by drastically reducing CO₂ emissions compared to traditional fossil-based colourants. The company's primary goal is to cut emissions by up to 50% in the production of indigo blue, a key colour in the textile industry. With over 3 billion pairs of jeans sold annually, Pili strategically chose to focus on this pigment first to make a meaningful impact on one of the world's most polluting industries.

¹ To date, there are no studies about the global colour industry. The data mentioned are based on calculations made by Pili, which drew on several market studies such as Eurocolour Carbon Footprint Flyer and S&P Global Chemical Economics Handbook Pigment and Dyes

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In addition to pioneering sustainable indigo production at an industrial scale, Pili is developing blue, red, and yellow biobased pigments, further expanding its sustainable solutions for various industries. The company's commitment to sustainability extends beyond environmental benefits: its first production plant, set to launch in France, will create around 15 jobs in its first year of operation, contributing to local economic development while promoting cleaner, more sustainable industrial processes.

Barriers:

Innovative companies in the field of bio-based chemistry and biotechnology face unique regulatory challenges that hinder their development and growth. Unlike traditional industries, bio-based projects require longer development cycles, which demand extended and adapted economic support. However, the regulatory landscape within the EU presents significant barriers during the critical industrialisation phase.

One of the major regulatory obstacles is the lengthy process for obtaining operating permits from environmental authorities, which slows down the transition from research to industrial production, limiting the capacity of these companies to scale up and become commercially viable.

In addition, biobased products provide clear environmental and climate advantages over traditional alternatives. Yet, within the EU, they are not always adequately recognised in environmental regulations, including in Life Cycle Assessments (LCAs). If you ask Pili, a more favourable regulatory framework is needed to account for the environmental benefits of biobased products, giving them a competitive edge and encouraging broader adoption. This can stimulate investment and growth in the sector, supporting the EU's broader climate and sustainability goals.

Website: pili.bio

LinkedIn: [linkedin.com/company/pili](https://www.linkedin.com/company/pili)

Those Vegan Cowboys

Animal-free cheese made by a stainless steel cow

Problem: Dairy farming needs to up its game

Cheese is great. Cows are amazing. But dairy farming could do with an update. It's become notorious for its burden on land, water, biodiversity, and climate. Combine that with the expectation from the UN's Food and Agriculture Organisation (FAO) that global animal protein consumption will double by 2050, and it is clear that something's got to give.

Free the cow from cheese production, and the environmental impact becomes practically zero – a major leap forward for the entire industry.

Biosolution: Meet Margaret – the stainless steel cow

To make this happen, the Belgian company Those Vegan Cowboys has built a stainless-steel cow in their milk lab in Ghent, Belgium. You may call her Margaret, like that other Iron Lady who made European history.

By using the ancient art of fermentation, Margaret serves the world real classic grass-fed cheese with the help of microbes. The process is called precision fermentation: a technology 50 years in the making.

Margaret's microorganisms are trained to express the casein milk proteins. Caseins are then produced at large scale by grass-fed fermentation. It's a lot like brewing beer but instead of alcohol, you get the casein milk proteins.

Impact: Food for 5 times more people

Margaret is at least 5 times more efficient in energy conversion, land, and water use. She offers the dairy industry the key to grow past the cow's physical limitations in the healthiest way imaginable, and we can feed 5 times more people from the same amount of land. A recent comparison of company LCAs (life cycle assessments) show even greater benefits for non-animal fermented products.¹

Along these lines, an independent LCA at the University of Helsinki, focused on the different forms of energy used to produce all kinds of animal-free proteins from precision fermentation. Published in the journal ScienceDirect in 2021, it concluded that precision-fermented proteins had a 53 – 100% lower environmental impact than animal-based proteins.²

¹ Animal-Free Milk: What Precision Fermentation Dairy LCAs Tell Us (greenqueen.com.hk)

² An attributional life cycle assessment of microbial protein production: A case study on using hydrogen-oxidizing bacteria – ScienceDirect



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Margaret has already achieved the impossible: she produces real casein, the most difficult and essential ingredient for cheese. Now that different kinds of delicious regulatory cheeses are ripening in Those Vegan Cowboys' cheese caverns, the next steps are refining, upscaling and perhaps the biggest challenge of all: getting the paperwork sorted.

Barriers: The European Regulatory Approval process – so we look outside the EU

With EU's Novel Foods regulation and current timelines, European precision fermentation companies have no choice but to submit their applications in the USA & Asia. For example, the EU transparency regulation for food and the EU requirement for absence of host DNA in the product do not create an equal level playing field.

To be more specific: Those Vegan Cowboys can produce casein and are currently scaling. They work together with large dairy players to make the best cheeses. But due to the European regulation timeline, Those Vegan Cowboys are not able to enter the European market for at least the next four years. This disturbs the pace of innovation, as they are ready to enter the market, but held back by regulation. Due to the long timelines, it's hard for companies like Those Vegan Cowboys to attract funding, while similar players in the USA or Asia speed up. This creates an unequal playing field and puts Europe at a disadvantage in the progress towards a more sustainable food system.

That is why Those Vegan Cowboys together with other European precision fermentation companies formed the Food Fermentation Europe alliance to address EU legislation with one voice. As the old cowboy saying goes: if you want to go far, go together.

Website: thosevegancowboys.com

LinkedIn: linkedin.com/company/those-vegan-cowboys-grassroots-bandits

The European Biosolutions Coalition – who are we?

The European Biosolutions Coalition is an initiative established by European industry organisations, representing a substantial amount of the companies working with biosolutions in Europe, to elevate the prominence of biosolutions on the European agenda.

The Coalition is dedicated to advocating for the green transition, fostering more intelligent approaches within the industry, and creating enhanced prospects for companies working with biosolutions in the EU.

eubiocoalition.eu



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