How biosolutions can strengthen Europe's

sustainability

resilience

and competitiveness

Manifest and policy recommendations

The European Biosolutions Coalition

21 February 2024

THE VISION:
The industrial bio revolution is a once in a lifetime opportunity for Europe

A tiny bio revolution with a huge impact is under way. During the last decade progress within research and innovation in biological sciences and technology has created an untapped potential for biosolutions to help Europe and the rest of the world meet some of the biggest challenges of our time.

When it comes to sustainable food systems, biodiversity, environment, and especially climate change, the world is at a crossroad; If Europe is to meet its green goals defined in strategies Fit for 55 and Farm to Fork, if the European Green Deal is to fulfil its promise and if Europe addresses globally relevant challenges, e.g., in the context of food and feed scarceness, biosolutions must be an integral part of Europe's strategy for a sustainable future.

The vision is to bring Europe back on track to a world where we have vastly reduced our need for fossil materials, water, and arable land. A clean environment and a world with enough nutritious food to feed a growing population in a sustainable way. A Europe of the future, where bio-based factories will be offering new jobs and contribute to the growth and resilience of our economy, and at the same time will allow to reduce greenhouse gas emission, achieving the emission goals that the world is setting up as well as derisking susceptible supply chains and reducing import dependencies.

If we start now, Europe can be a global lighthouse for biosolutions.

Biosolutions are based on nature's own tiny tools

Biological industrial green solutions – or in short, biosolutions – offer a powerful pathway to accelerate the transition towards a sustainable and greener future. Leveraging the potential of enzymes, microorganisms, bacterial cultures, and other biological tools, biosolutions can contribute to reducing environmental and climate impact.

Biosolutions combine biology and technology at scale. By applying nature's own tools, such as fermentation, enzymes, and bacteria, we can transition from a fossil-based to a more circular and bio-based economy.

'Inspired by nature' is the principal concept of biosolutions. Evolution has given nature a head start of millions of years to find solutions to the problems that humanity now faces. In the life science sector, the rule of thumb is that half of the world's medicine comes from nature. We face a similar potential in the biosolutions sector. McKinsey & Co. estimates that up to 60 % of the world's raw materials can be created biologically, which will significantly lower the world's dependence on fossil oil[1].

Biosolutions refer to the use of living microorganisms, enzymes, bacteria cultures, yeasts etc. which, through fermentation and bio-refinement, can address some of the most pressing global challenges, like food security, healthy nutrition, social and economic development, and resilience, in a sustainable way.

Biosolutions can contribute to reducing the environmental and climate impact in e.g. food production, industry, transport, and energy supply.

Biosolutions can also help to obtain proteins and other food ingredients without requiring agricultural production systems, e.g. by precision fermentation.

Biosolutions are therefore a great enabler of the green transition of both agriculture and the food sector, reducing waste and the use of land, and vastly improving food security, health, and biodiversity while creating new economic potential and green jobs at the same time.

Biosolutions are also a key tool to promote a sustainable and circular bioeconomy, where dryland crops and scraps from agro-industrial value chains can be used as input to produce bio-based products, able to solve environmental issues related to the protection of natural resources and to close the carbon cycles.

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

Biosolutions

Inspired by nature

Content

THE PROBLEM:
Biosolutions are regulated by 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.

For example, industrial biosolutions are subject to regulations aimed at regulating fossil-based substances and foods. This results in outdated regulatory requirements that do not support innovative biosolutions and the acceleration of the green transition.

Europe must speed up

The role of bio-based industries in promoting defossilisation and natural resources is not always recognized in the legislation.

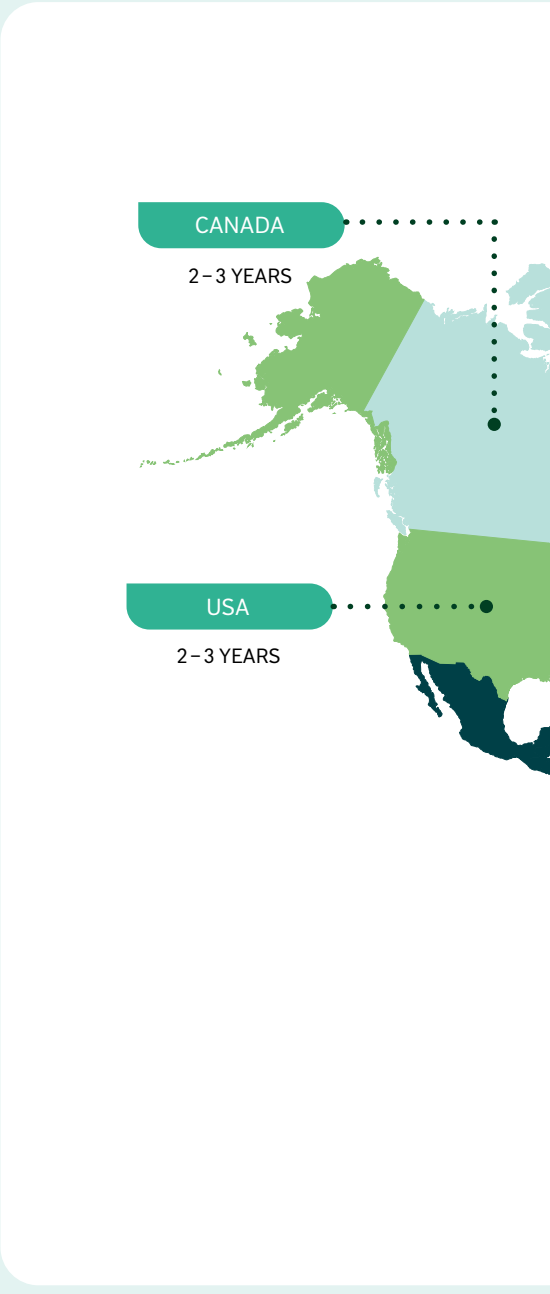
In terms of approval of new biological solutions, the European system for regulatory renewal is the slowest in the world, even though so much of the expertise and companies are founded in Europe.

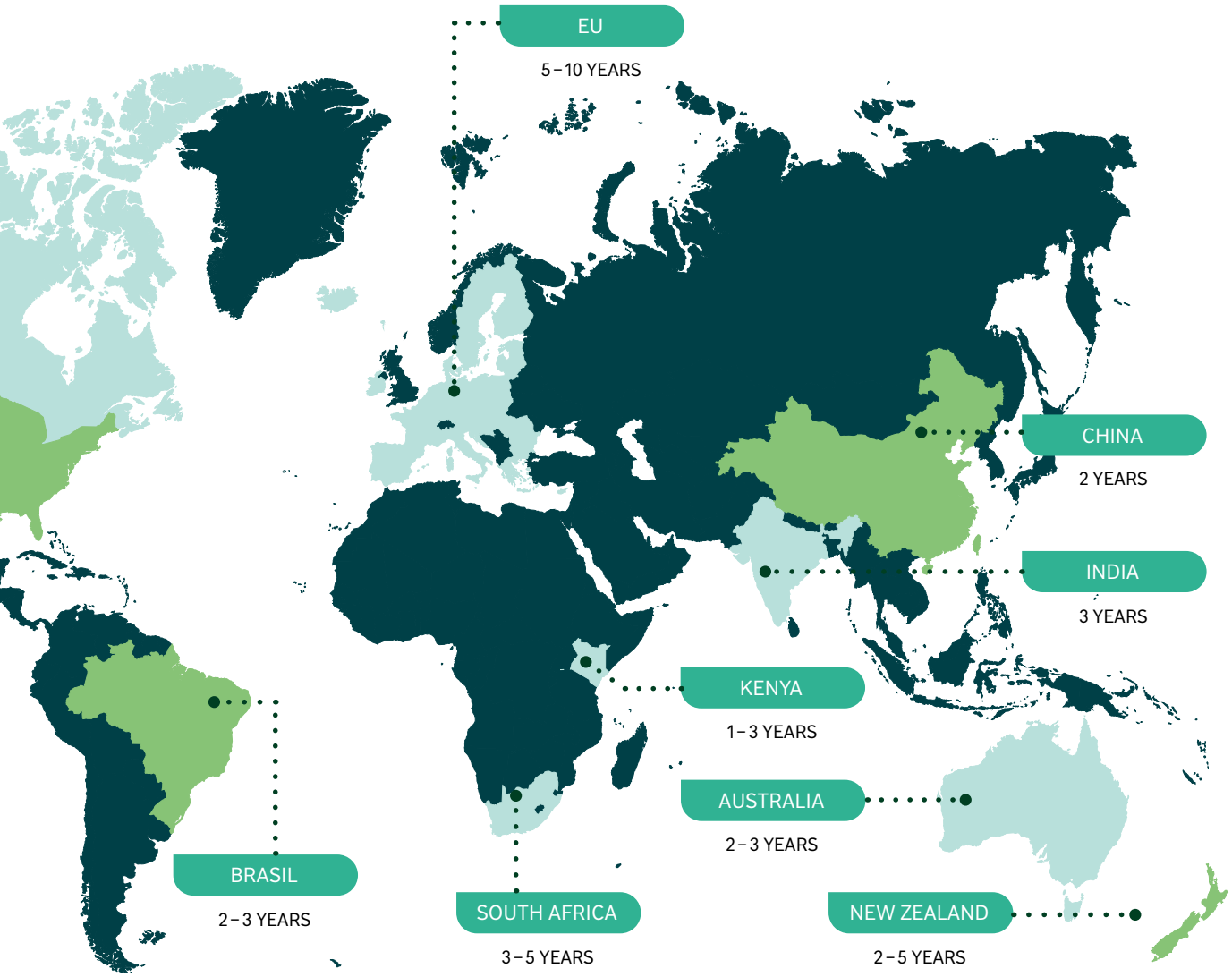
This is a serious problem, since it means that European companies are now looking to other regions such as United States, China, Brazil, Singapore, and the Middle East, both in terms of investments, production, and feasibly obtainable markets. The regulatory framework for biosolutions today simply does not support reaching the targets of the European Green Deal.

It takes up to three times as long to get approval for e.g., biological plant protection products in the EU than in the US, and there is a general lack of understanding of what biosolutions are and of the potential they hold.

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

As a result, EU is falling behind its global peers, losing tax revenue and both consumers and industry lack access to innovative products of European origin that could deliver on EU's green ambitions. If this trend continues, the EU will be remembered as the place where key enabling technologies were born but grown and scaled elsewhere.





Source: IBMA (the International Biocontrol Manufacturing Association)

THE SOLUTION:
Biosolutions can help us reach the green goals and create growth and jobs

Humans have used biosolutions for thousands of years. In fact, they have been used to an extent in which we do no longer consider them special. Fermentation is the key process in the making of beer, wine, cheese, and bread. Humans have used this process for thousands of years. Enzymes, making it possible to wash clothes at low temperatures, have been around for more than 60 years. And from cooking to upcycling of waste and side streams, we use good bacteria to work for us – not against us.

Advances in research have accelerated the development of tailored microorganisms producing for example specific food ingredients such as milk proteins, biological pesticides, and crops with resilience properties lost through thousands of years of targeted breeding solely focused on high yield.

The potential of biosolutions is so enormous that it is hard to grasp. At the same time, to reap the rewards of the solutions available authorities, companies, and researchers must work together more closely; to make the transition happen, to clear judicial obstacles, and to apply novel solutions at a scale and volume that matters. This is the only way to translate biosolutions into significant reductions of greenhouse gas emissions, green jobs, and sustainable growth.

Biosolutions are enablers to achieving net-zero in 2050. By applying the biosolutions we know today, we can reduce global CO_2-emissions by 8 %.[2] Even more if we add the solutions currently in the pipeline.

Biosolutions hold a vast potential for reducing food waste and for producing food for a growing global population, using a smaller land acreage than today and, in addition, creating the opportunity to turn the tide for biodiversity. If 10 % of the world's animal proteins were replaced with sustainable proteins from microbiological production, we will save 700 million tons of CO_2. Additionally, 900,000 km^2 of agricultural land will be free for other purposes – for example[3] restoration of nature and biodiversity.

Biosolutions hold the promise of a bio-based economy with safe, high-quality jobs and more efficient and resilient value chains, covering everything from construction to food production.

The biotechnology industry strengthens the labour market in Europe by directly creating what is currently calculated to approximately 225,000 jobs within the healthcare, industrial, and agricultural biotechnology sectors. Moreover, the bio-based industry supports more than 700,000 jobs in the overall European economy through indirect and induced effects. For each job within the biosolutions and biotechnology industry at large additionally 3.2 jobs are created in the overall economy.[4]

2 *Copenhagen Economics, 2022: The-potentials-of-biosolutions_final_20SEP2022.pdf (copenhageneconomics.com)*
3 *The Novozymes Report 2021*
4 *Measuring the economic footprint of the Biotechnology Industry in Europe (WifOR Study) - Europabio*

THE WINDOW FOR ACTION:
A new European Commission and European Elections

To quickly modernise or embrace innovation such as new biosolutions no mechanisms in EU legislation currently exists. Like several members have stated, the EU needs a proper overall strategy for biosolutions, just as a consistent implementation of the already agreed Innovation Principle from 2019 should be secured.[5]

The window for action is the European Elections in 2024 and a new European Commission with a new Work Program. The President of the European Commission, Mrs. Ursula von der Leyen in her State of the Union Address in September 2023 and accompanying Letter of Intent to the European Parliament set out an EU Biotech and Biomanufacturing Strategy as a key priority for the EU in 2024.

The window for action has been opened.

But what must be done? The European Biosolutions Coalition brings forward four principles for solutions, six recommendations and eight concrete proposals.

5 *Ensuring EU legislation supports innovation - European Commission (europa.eu)*

Four principles for solutions

We sum up our wishes in the four following principles:

Embrace Nature's Wisdom

Biosolutions capitalise on millions of years of natural evolution to address modern challenges. The EU should acknowledge this advantage and commit to harnessing nature's innovations for a sustainable future.

Improve the Regulatory Framework

Existing regulatory frameworks must evolve to support the unique attributes and potential of biosolutions. A shift from a fossil-based paradigm towards more sustainability and circularity, focusing on risk-benefit analysis and the unique characteristics of biological solutions is needed.

Move from a Process to a Product Centric Approval

We need to move away from a process centric approval system toward a product centric one. Rather than focusing on the methods used to tailor (micro-) organisms, the regulatory framework should focus on the traits and characteristics of the biosolutions to be approved.

Recognise Environmental and Climate Impact

The EU should acknowledge the significant positive impact of biosolutions on reducing greenhouse gas emissions, enhancing agricultural sustainability, making Europe more resilient and strategically autonomous, bringing down the use of undesired chemicals and fossil-based substances, improving circularity and biodiversity and thereby contributing to a healthier planet.

IMPACT:
Six Policy Recommendation to establish a green and bio-based paradigm

Following the four principles, the European Biosolutions Coalition proposes the following policy recommendations. Firstly, six recommendations for a more horizontal approach to biosolutions, enabling delivery on the EU Green Deal and, secondly, eight concrete and sector specific policy recommendations:

To establish a Green and Bio-based Paradigm the European Biosolution Coalition recommend to:

1

Invest in Research, Development, and Innovation

For the EU to keep up with other economies and continue to develop new solutions, substantial investments in developing new biosolutions are required. Europe has been ahead until now but is quickly losing ground as other regions and countries ramp up significantly.

Biosolutions should be part of the future Horizon program. In addition, biosolutions aimed directly at the agricultural sector should be integrated in the revision of the Common Agricultural Policy (CAP).

2

Improve incentives to invest in scaling and infrastructure capacity

To accelerate getting biosolutions to market, investment incentives must be improved. SME's have particular difficulties financing infrastructure to scale their biosolutions, especially through the early phase of the "valley of death".

Therefore, Pilot Facilities are needed to enable transition from R&D to market. We call on member states to explore possibilities to utilise IPCEI funds for bio-reactors. The development of a model where the EU could be co-investor in public-private partnerships, in infrastructure for scaling, could be a way forward for example through the European Investment Bank (EIB) and the European Innovation Council (EIC). Today there is a massive lack of investments in late stage-ventures for upscaling of biosolutions companies, also due to the regulatory barriers.

3

Ensure Fair EU Classification and revise the NACE codes

A new EU industrial policy is here to stay. It is therefore essential that biosolutions, biotechnology and biomanufacturing are placed at the heart and centre of the industrial policy, as well as reflected in the legislative proposals that follows from the new industrial policy paradigm.

To achieve this, biosolutions should be recognized in the EU classification of economic activity, the so-called NACE codes. Bio-based chemistry provides an important contribution to sustainability and defossilisation with raw materials leading to lower greenhouse gas emissions and the offer of bio-degradable or bio-compostable products.

We are fully aware, that biosolutions are not the only solutions to promote sustainability, and the use of bio-based raw materials is not necessarily the most sustainable solution every time. But to ensure that biosolutions investments are accurately classified as sustainable when appropriate, in addition to further increase access to sustainable finance for biosolutions companies, biosolutions should be included in the EU taxonomy and biosolutions should be integrated next time there is an update of the NACE codes.

Well ahead of time, the biosolutions sector hope to be involved in the discussion on exactly how this could be done.

4

Develop and use a Risk-Benefit Approach

Biosolutions suffer from a disproportionate focus on environmental and human health risks, compared to the environmental and human health benefits of the solutions. In addition, environmental externalities are not priced in most traditional products. Also, bio-based products do not receive proportionate benefits for doing relatively lesser harm to the environment and human health.

We suggest introducing and, to a much higher degree, use a risk-benefit analysis framework. This approach will guide regulatory decisions by considering and weighing both potential benefits and disadvantages. In this regard it will help if the EU Innovation Principle is fully implemented in all EU regulation and policy.[6]

6 ec_rtd_factsheet-innovation-principle.pdf (europa.eu)

5

Develop a European model of market access for biosolutions

The model could be a GRAS-inspired approach. GRAS is an American paradigm, which stands for Generally Recognised As Safe, where companies must apply due diligence in demonstrating and getting expert consensus on the safety of new biological solutions.[7]

This is a clear and straight forward process that secures the safety of products while avoiding the lengthy and administratively demanding approval processes currently in place in the EU. A similar model could be very helpful for example in the future revision of the REACH Directive.

7 Generally Recognized as Safe (GRAS) | FDA

6

Develop a framework for the fast approval of sustainable biosolutions

To accelerate the green transition, there is a need to allow for faster approval of sustainable biosolutions within several areas. These products are currently regulated under different regimes, which are cumbersome and time consuming. These regimes do not consider the risk profiles of products based on biosolutions and do not consider their ability to facilitate our green ambitions. A new horizontal framework, inspired by the EU's existing "New Legislative Framework" for products[8], could make up for that.

Approval procedures should move away from a process centric to a product centric approach. It should build on a risk-benefit approach and ensure regulatory sandboxes, allowing for the development, testing, and validation of innovative technologies in a controlled real-world environment, the full implementation of the Innovation Principle. Furthermore, it should provide better conditions for applicants to develop higher quality applications. Also, an approach to solve the challenges related to capacity shortages for assessment should be part of this framework.

To facilitate the shift towards a green and bio-based economy, a centralized approval process for biosolutions (i.e., living organisms: plants, animals, and microorganisms) could be established at a European level, including a mechanism ensuring coordination across units and member states. This new framework will allow to streamline and speed up the registration and approval process.

8 New legislative framework – European Commission (europa.eu)

The horizontal proposals 1 – 6 can of course be combined and, if achieved, would mean a new and much faster regime for the future of biosolutions in Europe. We do, however, realise that developing a new regime takes time. Therefore, we have also developed eight (8) concrete proposals for regulatory changes, which could be implemented fast, if the political will exists.

Eight proposals to improve the EU regulatory framework

1

Update Regulations for Microorganism-based Biosolutions

To enable or facilitate the use of all the new and innovative biosolutions, the regulatory framework for microorganisms needs to be modernized and simplified. Microorganisms with improved properties are already widely used for resource-efficient production of valuable substances and to fulfil specific functions. A variety of technologies are used for genetic adaptation and fine tuning. The current regulatory framework has not kept pace with the rapidly evolving science.[9]

For plants produced with New Genomic Techniques (NGT), a new regulatory proposal is currently under negotiation in the Council. A similar policy action for NGT microorganisms would be a first, although limited, step to facilitate the development of biosolutions. NGT represent only a subset of technologies used to improve strains. A future-proof legislation for microorganisms will have to cover all technologies, those already in use and those that will be developed in the future.

Therefore, regulation should take a product-oriented approach, instead of focusing on the process or technology like the existing regulatory framework. Focusing on the properties of the adapted microorganisms and their products would allow for a more graded and proportionate risk-based regulatory approach than current legislation. The nature and characteristics of the genetic change, considering the existing knowledge about possible safety risks, would determine the regulatory requirements and burden.

Microorganisms with improved properties have the potential to support important European political objectives, including a sustainable food system within the Commission's Green Deal and the Farm to Fork strategy adding a more resource-efficient, tailor-made bio-production, thus increasing European productivity and competitivity and lowering climate impacts. An enabling, flexible, and future-proof legislation for all fields of applications of microorganisms would support these goals.

9 *Over the past years, there have been concerning developments in the European Union, stipulating that absence of recombinant DNA might be interpreted as a regulatory requirement for fermentation products produced with GMMs. The EU should consider to align with the international consensus through the Joint Expert Committee on Food Additives (JECFA), administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), and its guidelines on food enzymes (2020). A proposal based on their work could be the following: (1) The legally binding criteria for regulation of fermentation products should be: (a) the method of production, i.e. on open fields vs. in closed, contained facilities; and (b) the absence of live cells of the production microorganism in contained-use products. (2) Absence vs. presence of recombinant DNA shall not be used as a regulatory criterion, but shall be an integral part of the safety assessment required under product-specific legislation.*

2

Modernise Novel Food Regulation

Collaborate with the European Commission to modernise the Novel Food Regulation which today is an extremely cumbersome and long-lasting process. The risk-profile of a food product should not be determined by whether or not it was consumed in the EU before or after the year 1997.

Instead, the assessment should consider benefits of new and innovative foods with the overarching goal of transitioning to a more circular and sustainable food system. There is a need to balance food safety, agility, and innovation within the legislative framework, and prioritise considerations of innovation and sustainability alongside food safety.

3

Faster approval of Biological Plant Protection Products

Ensure that sustainable alternatives to existing plant protection products are readily available. For this it is necessary to prepare a framework for faster approval of sustainable, low risk bio-pesticides. Establish a temporary short-term solution for bringing more biological solutions to the EU market by opening for regulatory sandboxing of sustainable bio-pesticides. The approval processes under this regime are far too cumbersome for biosolutions as the regime does not recognise and award those bio-based stimulants which impose a lesser burden on the environment.

Together these solutions play an important role in building a bigger, more robust toolbox for farmers through Integrated Pest Management (IPM) practices. An enabling regulatory environment and the adoption of incentives will be required to ensure that these innovative solutions can be fully developed and deployed to European farmers.

4

Faster Approval of Microbial Bio-Stimulants

To guarantee technological neutrality between conventional bio-stimulants and microbial bio-stimulants a framework for faster approval of microbial bio-stimulants needs to be prepared. Today, there does not seem to be technological neutrality guaranteed, making the approval of bio-stimulants extremely slow, the same way as with the biological plant protection products.

To create a more flexible and future proof framework, substitute the list of approved microorganisms in bio-stimulants under the fertilizer regulation with criteria for allowing new microorganisms. The criteria should consider the environmental benefits that bio-stimulants offer. Ensure transparency and accessibility of national rules. Shorter time to market for microbial bio-stimulants is crucial for the implementation of the Green Deal and Farm to Fork strategy, particularly when it comes to the reduction of use of fertilizers and to secure the 2030 reduction targets and environmental impact.

Microbial bio-stimulants are regulated under the fertilizer regulation and can be brought to the market either with the CE marking (that allows for free circulation within the EU) or through national approval systems (without the CE marking). Only 4 types of microorganisms are approved for CE marking and the planned attempts to expand the list is lengthy, requiring at least 6 years for other microorganisms to be marketed for free circulation, based on CE-marking. The situation leads innovative companies to move to other parts of the world, where the approval processes are easier and faster, jeopardizing EU job creation and environmental ambitions.

5

Modernise the Nutrition and Health Claims Legislation

The legislation on Nutrition and Health Claims needs to be updated to expedite the approval of the claims and to allow for more understandable and useful wording for consumers in the EU. The application process is complex, costly, and time-consuming.

The existing regulation has effectively prohibited most claims. It creates legal uncertainty for food business operators, who are unsure of what they can state on product packaging. Also, it creates confusion for consumers who may not fully comprehend the wording of the claim and therefore of the benefits they are purchasing. Its approval procedures and requirements for claims are outdated and disproportionate.

Given that the regulation is nearly two decades old, it is crucial to revise and modernise it to align with current capabilities. Furthermore, these restrictions not only undermine the EU's position on important markets, it also gives rise to fragmentation within the EU's market due to the inconsistent enforcement of the regulation across Member States, resulting in an uneven competitive landscape.

6

Modernise regulatory classification of food cultures

Food cultures used in dairy production (yoghurt, cheese, etc.) inherently have multiple effects. The bio-solutions industry is challenged by the risk of increased complexity and inconsistency of the application of the EU legislation, particularly in the context of protective cultures.

It should be ensured that the EU legislation supports the use of fermentation technologies and food cultures in the green transition of the food system and in the prevention of food waste, where the potentials are significant. For example, yoghurt waste in Europe alone could be reduced by 30 % if shelf life was extended by seven days, using existing bio protection solutions.

7

Ensure that the delegated acts under the Eco-design for Sustainable Products Regulation (ESPR) take biosolutions into account

The delegated acts extend the requirement far beyond energy efficiency labelling and call for the development of a digital product passport with extensive information obligations.

While the ESPR should not be used as a tool to regulate chemistry, the regulation still introduces a definition of “substances of concert”. It should be made explicit that the definition only relates to reuse and recycling – not the environment and human health, which belong in REACH. When setting the product specific requirements the definitions and methodologies regarding for example bio-based material are cruial.

8

Add transitional provisions to the Packaging and Packaging Waste Regulation (PPWR) that allow for market ramp up of new bio-based plastics

Bio-based plastics make an important contribution to reducing the CO_2-footprint of polymer materials and reduce dependence on fossil raw materials. The market penetration of new polymers is generally slow and initially only small production plants are set up.

If these small quantities must be recycled by type in the future, in accordance with the proposed EU regulation, this will immediately prevent the development and introduction of the polymers in question onto the market, as these quantities cannot be recycled economically. Research into, market-ramp-up and production (commercialisation) of new and marketable bio-polymers would only take place in third countries, making the EU dependent on external developments.

However, transitional provisions in the PPWR, that allow a market ramp-up to relevant production volumes (at least 10 years), must be added so that the recycling of new biopolymers can be carried out economically and in a scalable manner. Additionally, we recommend prescribing mandatory quota for the use of bio-based plastics in packaging. This might be realised by allowing to fulfil recycles usage quotas also with bio-based materials.

In addition, it should be noted, that it is also possible to use biosolutions (enzymes) to recycle fossil-based PET plastic to rPET, and this will also reduce the demand for new fossil-based plastic.

The biosolutions industry develops at a fast pace, constantly developing new solutions. Together with new solutions new recommendations for regulatory changes will probably follow in the future.

However, we have no time to waste. The European Biosolutions Coalition has been established to secure that the potential of the biosolutions industry is fulfilled in Europe to the benefit of all. We need to act and act fast, because the industrial bio revolution is a once in a lifetime opportunity for Europe.

The European Biosolutions Coalition – who are we?

The European Biosolutions Coalition is an initiative established by several 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

Danish Industry

iv

VNO NCW

BIO DEUTSCHLAND

economiesuisse

FEDERCHIMICA ASSOBIOTEC

With support from the Novo Nordisk Foundation