



**Global Overview of Enabling Policies**  
**Perspectives of**  
**the European Biosolutions Coalition**

**Mette Peetz-Schou, Leading Senior Advisor,**  
**Danish Industry**  
**([meps@di.dk](mailto:meps@di.dk))**

# Why a European Biosolutions Coalition?

8%

of global CO<sub>2</sub>-emissions can be removed, if existing innovative biological solutions (*biosolutions*) are implemented.

# Need to reduce regulatory complexity and time to market

Area	Steps	Process
Pesticides (EC)1107/2009	Two-step approach Active substance Plant Protection Product (Low-Risk procedure)	Rapporteur MS-EFSA-EC-ScoPAFF adoption Zonal Rapporteur MS – Mutual recognition
Microstimulants (EU)2019/1009	Two parallel processes CE-marking (4 streams only) National approval	Certification by Notified Body Mutual recognition
Novel Foods (EU)2015/2283	One process	EFSA-EC-ScoPAFF adoption
Additives (EC)1333/2008	One process	EC-EFSA-EC-ScoPAFF adoption
Enzymes (EC)1332/2008	One process National rules still apply	EC-EFSA-EC-ScoPAFF adoption (process stuck) Chemicals that are not SVHC can be marketed if they comply with REACH

Requirements in the legislation – Guidance by EC/EFSA – Implementation by EFSA

# European Biosolutions Coalition

- A Coalition of like-minded and ambitious national industry organisations
- Danish Industry was one of the 5 founding members
- Our purpose is to highlight the importance of streamlining the regulatory framework for biosolutions in the EU and member states
- Our goal is to have strong ambitions on biosolutions, biotechnology and biomanufacturing included in the next European Commission work programme



Danish Industry



# Coalition presented manifest and policy asks in February 2024

## How biosolutions can strengthen Europe's

sustainability

resilience

and competitiveness

Manifest and policy recommendations  
The European Biosolutions Coalition  
21 February 2024

### Four principles for solutions

We sum up our wishes in the four following principles:

- Embrace Nature's Wisdom**  
Biosolutions capitalize 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 make (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 Biosolutions Coalition recommend:

- 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 rapidly being overtaken as other regions and countries ramp up significantly. Biosolutions should be part of the Horizon Europe 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. SMEs 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 utilize IPCEI funds for bio-research. 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 major lack of investments in late stage venture for scaling of biosolutions companies, also due to the regulatory barriers.

### to improve the network

#### 1 Bio-based Biosolutions

Biosolutions, the regulatory and simplified. Microorganisms with efficient production of valuable molecules are used for genetic ad. Has not kept pace with the rapidly changing market.

A new regulatory proposal is needed for NBT microorganisms. NBT is a future proof legislation for products and those that will be developed.

#### 2 Modernise Novel Food Regulation

Collaborate with the European Commission to modernise the Novel Food Regulation which today is an obstacle for a food product should not be determined by whether or not it was consumed in the EU before or after the year 1997.

#### 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 framework for faster approval of sustainable bio-pesticides. The approval process under this regime are far too cumbersome and slow. These bio-based alternatives which improve a better location 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. The existing regulatory environment and the sufficient incentives will be required to ensure that these novel solutions can be fully developed and deployed to European farmers.

small production plants are...  
When small quantities must be recycled by time 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, make-up quantities and production (commercialisation) of new and marketable bio-polymers will only take place in those 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 stable manner. Additionally, we recommend providing mandatory quotas for the use of bio-based plastics in packaging. This might be realized by allowing to fulfil recycle 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 least partly, 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 ensure that the potential of the biosolutions industry is fulfilled 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.

# Three approaches to improving the legislative framework for biosolutions

Improving the implementation of the current regulatory framework

Specific files (in agri-food sector)

Novel Foods

Pesticides

Fertilizers (Biostimulants)

Additives

Enzymes

etc.

# 01

Proposals for revision of existing framework through revision of individual regulations

Specific files (in agri-food sector)

Novel Foods

Pesticides

Fertilizers (Biostimulants)

Additives

Enzymes

etc.

# 02

Development of a new regulatory framework for Emerging Biosolutions

Long term solution

Inspired by the New Legislative Framework for CE-marked Goods

Vision:

What to do if we had no legislation and started from scratch

# 03

Biotechnology Act

## Letter of intent

In September 2023, in her State of The Union and the following Letter of Intent to the European Parliament, the European Commission President, Mrs Ursula von der Leyen made biotech and biomufacturing a key priority for 2024. This is a key assignment for the European Biosolutions Coalition to follow-up.

Photographer: Elienne Ansotte



# EUROPE'S CHOICE

## POLITICAL GUIDELINES FOR THE NEXT EUROPEAN COMMISSION 2024–2029

**Ursula von der Leyen**  
*Candidate for the European Commission President*

### European Commission - Statement



#### Statement by EVP Margrethe Vestager on the European Commission's communication "Building the future with nature: Boosting Biotechnology and Biomufacturing in the EU"

Brussels, 20 March 2024

- Check against delivery -

Today, we present a communication on boosting biotechnology and biomufacturing in the EU.

Everywhere across Europe, we are faced with the same problems. Climate change affects us all. Resource scarcity affects us all. Inequality in health treatments affects us all - with rare diseases that still can't find any cure.

To many of these problems, biotechnology provides solutions. These days, we are witnessing nothing less than a small revolution in the area of biotechnologies.

Let me give you a few examples.

- In health, biotechnology is what could bring treatments to diseases we thought incurable. Recently, I had the pleasure to visit a company in Ghent called Argens. It is using antibody-cells from llamas to treat autoimmune diseases, that had no solution so far.
- Top innovators are working on new materials that look and work like plastic, except they're made of organic by-products. And fully biodegradable. Imagine what a full-scale deployment of such technology could mean - potentially solve the crisis we have with plastic pollution.
- Across Europe, biotech businesses are also using natural processes to produce colour pigments, to replace chemical colouring agents. It would help to decrease the colossal use of water from the textile sector. And avoid that toxic residues end-up in our waterways.

But that's not all.

With this potential to solve some of our most pressing problems, biotechnology also largely supports Europe's economy, and high-quality jobs. Already in 2018, it contributed directly 11 billion euros of EU GDP, and created over 210,000 direct jobs in healthcare, industry, and agriculture. Moreover, one of our fastest growing innovative industries in Europe, these figures will rise further.

Last but not least, biotech also strengthens Europe's resilience. It is already replacing fossil fuels in many electricity.

So one thing comes clear: the potential of this sector is huge. It is a sector that can play a key role in our different players. Small rising start-ups, mid-size well-established worldwide leaders.

Whether big or small, those players are faced with:

- A difficulty of getting from research to place European researchers,
- A limited access to finance, despite very high growth potential,
- Too much complexity in regulation, and too slow.

European biotech businesses may be affected by these specific sector. But in one way or another, they are all affected.

That's what we aim to do with this Communication. We want to leverage Europe's clear scientific edge to find solutions to the pressing problems that we are facing.

Whether that means allowing small players to scale up, or supporting established players.

We want to make Europe a world biotech leader.



## MISSION LETTER

Brussels, 17 September 2024

**Ursula von der Leyen**  
President of the European Commission

**Stéphane Séjourné**

**Executive Vice-President-designate for Prosperity and Industrial Strategy**

Dear Stéphane,

The Commission we will serve in together will be called upon to make choices that will shape our continent and our Union for years and decades to come. In a time of great global instability and great expectations of Europeans, we must live up to that responsibility. We must deliver and lead from the front, working closely with the people and regions of Europe and the parliaments, governments and institutions that serve them.

European Parliament focuses on ensuring supporting people, green and digital transition. We will work with our partners and better assert our interests around the world.

Expectations that we and businesses have for the way we interact.

## MISSION LETTER

Brussels, 17 September 2024

**Ursula von der Leyen**  
President of the European Commission



**Olivér Várhelyi**

**Commissioner-designate for Health and Animal Welfare**

Dear Olivér,

The Commission we will serve in together will be called upon to make choices that will shape our continent and our Union for years and decades to come. In a time of great global instability and great expectations of Europeans, we must live up to that responsibility. We must deliver and lead from the front, working closely with the people and regions of Europe and the parliaments, governments and institutions that serve them.

This was the spirit of the Political Guidelines which I presented to the European Parliament in July 2024 - our common plan for European strength and unity. It focuses on ensuring our security in every sense in a more dangerous and turbulent world, on supporting people and citizens by strengthening our prosperity, our social market economy, green and digital transitions and sustaining our unique quality of life. We will strengthen our democracy, rally around our values and ensure that we are stronger at home. We will work with our partners and better assert our interests around the world.

Together, we will respond to the real and legitimate concerns and expectations that Europeans expressed at the last elections. We will be closer to people and businesses where it really matters with practical support and sustained investment. We will strive to make Europe faster and simpler in the way that we act - and in the way we interact.

# Questions?



[European Biosolutions Coalition: For a Sustainable, Resilient and Competitive Europe - DI \(eubiocoalition.eu\)](https://eubiocoalition.eu)