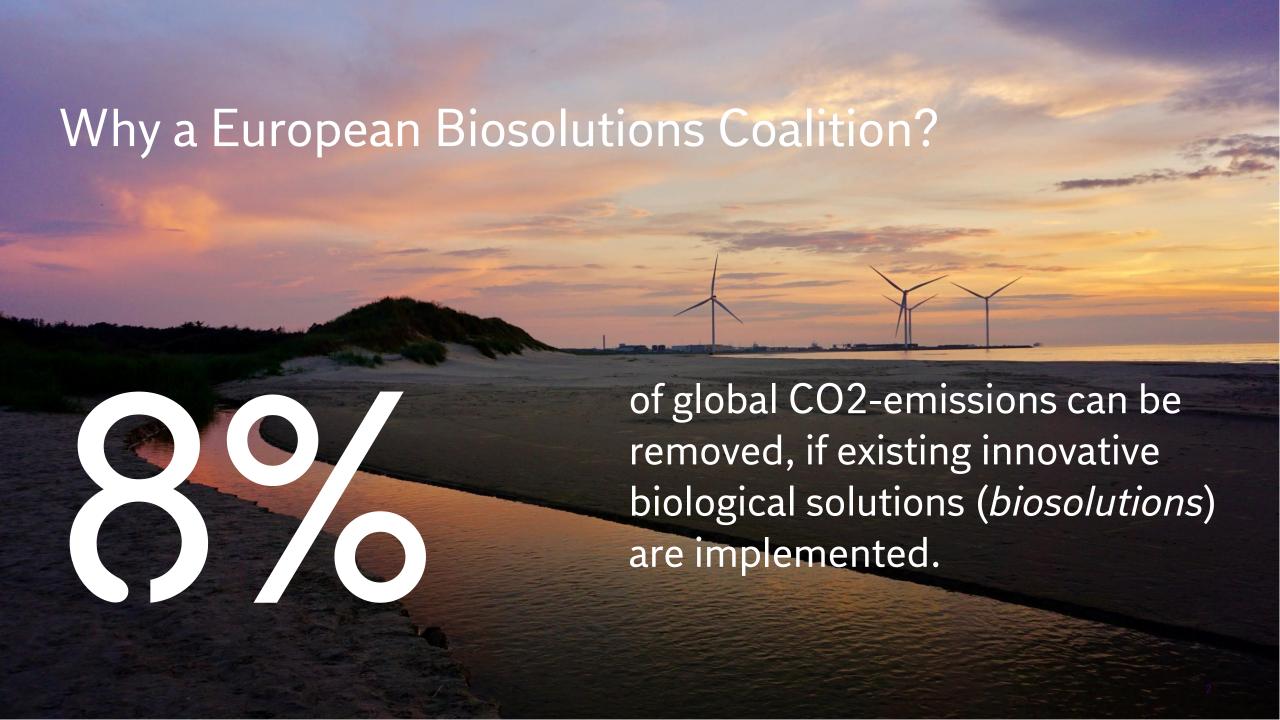


Mette Peetz-Schou, Leading Senior Advisor,
Danish Industry
(meps@di.dk)



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



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

















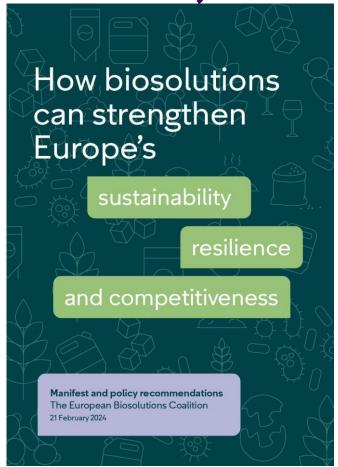






Coalition presented manifest and policy asks in

February 2024







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.

C2

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



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 biomanufacturing a key priority for 2024. This is a key assignment for the European Biosolutions Coalition to follow-up.

Photographer: Etienne Ansotte







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

- Check against delivery

Today, we present a communication on boosting biotechnology and biomanufacturing 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.

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 31 billion euros of EU GDP, and created over 210,000 direct jobs in healthcare, industry, and agriculture. Baine none of the fastest erromise inconsations. industries in Europe, these figures will rise furt

Last but not least, biotech also strengthens Euro instance, is already replacing fossil fuels in man-electricity.

So one thing comes clear: the potential of this se different players. Small rising start-ups, mid-size well-established worldwide leaders.

Whether big or small, those players are faced wi . A difficulty of getting from research to place

- European researchers,

 A limited access to finance, despite very his

specific sector. But in one way or another,

That's what we aim to do with this Communica We want to leverage Europe's clear scientific ed-solutions to the pressing problems that we are f Whether that means allowing small players to so We want to make Europe a world biotech leader

> Commission européenne European Commission



EUROPE'S CHOICE

POLITICAL GUIDELINES FOR THE NEXT EUROPEAN COMMISSION 2024-2029

Ursula von der Leyen

Candidate for the European Commission President





Ursula von der Leven

President of the European Commission

Stéphane Séjourné

Executive Vice-President-designate for Prosperity and Industrial Strategy

The Commission we will serve in together will be called upon to make choices that will

live up to that closely with the

ropean Parliament cuses on ensuring supporting people , green and digital

our democracy,

t. We will strive to

e way we interact

ssels, 17 September 2024



will work with our expectations that and businesses

Ursula von der Leyen President of the European Commission

Olivér Várhelyi

European Commission

Commissioner-designate for Health and Animal Welfare

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

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?



<u>European Biosolutions Coalition: For a Sustainable, Resilient and Competitive Europe - DI (eubiocoalition.eu)</u>

