



# INNOVATIVE BIOTECHNOLOGY BENEFITTING PEOPLE AND PLANET



ANNUAL REPORT  
2018-2019

# FOREWORD

As we approach 2030, Europe and the wider world face a broad range of challenges on the journey towards delivering on the UN Sustainable Development Goals. With increasing demands on natural resources, an aging demographic with complex healthcare needs and the threat of climate change, new solutions are needed now more than ever.

The European biotech industry is uniquely positioned to deliver and, with the right support, it will create a new spectrum of biotech products and processes, to help meet current and future needs, benefitting people and planet.

The European biotech industry has already been central to the development of new therapies to treat unmet medical needs, producing more food on less land with less dependence on resources and significantly reducing GHG emissions across many industrial sectors.

But in order to fulfil the potential of EU Biotech and usher in a new age of "biologicalisation", alongside digitalisation, a collective EU commitment to a proportionate, fit-for-purpose, science-based policy approach, is essential.

In recent years, huge progress has been made in biotech with advances in genome editing and gene therapy offering up new hope in tackling some of our most devastating diseases and planetary challenges. These advances are potentially game-changing, but the science has evolved much faster than policy. Open and inclusive dialogue is now needed with civil



**Tjerk de Ruiter,**  
**EuropaBio Chair, CEO of Corbion.**




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society, industry, policy makers, interest groups and other thought leaders in order to create an innovation-based framework that enables safe and beneficial therapies and products to reach patients and consumers in a timely way.

The new European Parliament and Commission have the opportunity to capture the potential of innovative, value adding technologies such as biotech in Europe. Through bold political leadership, that defines and commits to the EU's ambitions for healthier people and planet, fostering Europe's strengths, rather than restricting them, they can rise to this challenge. EuropaBio and the growing European community of scientists, experts, innovators and students, working across the breadth of biotech, stand ready to support this ambition.

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CROSS-SECTOR

## HIGHLIGHTS

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- One technology - united in purpose
- Biotechnology Industry Manifesto 2019
- Our position on Genome Editing
- 6<sup>th</sup> European Biotech Week celebrated across the continent
- Promoting biotech innovation from European SMEs
- Excelling in social media

## CROSS-SECTOR



In addition to priorities in the healthcare, industrial and agricultural biotech sectors, EuropaBio, with the support of its National Associations, works on a number of industry-wide initiatives to strengthen biotechnology in Europe. These include intellectual property, SMEs, genome editing and outreach projects to raise the profile of European biotechnology among policymakers and the general public.

## Our Vision & Mission

### Our vision is of:

Innovative biotechnology benefitting people and planet

Our mission is for EuropaBio, the European Association for Bioindustries, to be the recognised voice of the European biotech community, championing world-class solutions for society's challenges.

EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life, to prevent, diagnose, treat and cure diseases, to improve the quality and quantity of food and feedstuffs and to move towards a bio-based and zero-waste economy.

## One technology - united in purpose

In addition to our healthcare, agricultural and industrial biotech goals, EuropaBio continues to work cross-sectorally in promoting **thought leadership** in three core areas:

1



Developing a new narrative on the benefits of biotech now and for the future

2



Establishing a science-based predictable approach to genome editing

3



Supporting the creation of a new EU Life Sciences and biotechnology strategy

# Biotechnology Industry Manifesto 2019

In 2019, EuropaBio developed its new manifesto with the aim of:

## Resetting the ambition for biotechnology in the EU

We promote five guiding principles for a competitive EU biotechnology industry:

1. Sound science-based policy making
2. Fast and equitable access to innovative biotechnology products and processes
3. Fair and sustainable Intellectual Property systems
4. A supportive and predictable funding framework
5. A highly-skilled workforce in all Member States

Our call to action asks policy makers and stakeholders to:

- Foster innovation-enabling supportive measures and regulation
- Build trust
- Protect intellectual property
- Establish a supportive and predictable funding framework
- Develop a strategy for biotechnology-focused industrial innovation



## Our position on Genome Editing

Following the EU Court of Justice ruling of 25 July 2018 on mutagenesis, EuropaBio calls upon European decision-makers to take policy action. The European Commission, should take an active role in bringing stakeholders together and should provide proportionate regulatory policies to enable innovation for developing products by genome editing methods. In April/ May 2019, an open letter on the court ruling was co-signed by 25 other leading EU industry associations and sent to the EU Member States.

To this end, EuropaBio calls for:

- science-based, predictable and proportionate rules that reflect technical progress and that seek to ensure that organisms developed with more sustainable, precise, modern mutagenesis techniques are not subject to disproportionate regulatory requirements.



- a fact-based platform for dialogue, information sharing and trust building to be set up by the European Commission that brings together policy makers, public researchers, civil society and industry.

## 6<sup>th</sup> European Biotech Week celebrated across the continent

The 2018 European Biotech Week, which took place between 24-30 September, gathered further momentum with over 135 events taking place in 18 different countries. The #BiotechWeek was celebrated by a great diversity of participants, from researchers and professionals to curious students, across all age groups.

EuropaBio hosted a week-long exhibition, highlighting the role of biotech in delivering on the UN Sustainable Development Goals, which took place in front of the European Parliament on Place Luxembourg, Brussels. The opening of the exhibition was hosted by MEP Christofer Fjellner and was attended by policymakers, scientists, industry peers and a large number of students.





## KEY FIGURES FOR THE WEEK INCLUDE

[www.biotechweek.org](http://www.biotechweek.org)



**135+**  
events



taking place in  
**18** countries



**330**  
media pick-ups



across  
**9** countries



**> 10.000**  
European citizens  
mobilised during the week



**> 2.300**  
@biotechweek  
followers

@

**> 1.000**  
#BiotechWeek tweets

#

**> 1.800**  
@Biotechweek visits

# Promoting biotech innovation from European SMEs

The 9<sup>th</sup> edition of the 'Most Innovative European Biotech SME Awards' recognised exceptional European small and medium sized biotech companies that developed novel and innovative ways of addressing societal, technical and environmental problems through the application of biotechnology. The 2018 award winners were Genoscience Pharma<sup>1</sup> (Healthcare Biotech), Lactips<sup>2</sup> (Industrial Biotech) and Phytowelt GreenTechnologies<sup>3</sup> (Agricultural Biotech).

## The 2018 award winners were:



From left to right: Dr. Peter Heinrich, EuropaBio SME Platform Chair; Dr. Peter Welters, CEO, Phytowelt GreenTechnologies; Philippe Halfon, President and Founder, Genoscience Pharma; Marie H  l  ne Gramatikoff, CEO, Lactips; Prof. Dr. Andrew Porter, University of Aberdeen; Cindy Khaldi, Manager Associate, Genoscience Pharma; Dr. Paul R  big, MEP; Joanna Dupont-Inglis, EuropaBio Secretary General.

### Agricultural Biotech category



### Healthcare Biotech category



### Industrial Biotech category



<sup>1</sup> Phytowelt GreenTechnologies is an SME focussing on plant-breeding projects that aim at enabling regional production of renewable resources. It is the first company able to produce a biotech raspberry fragrance in high quantity and quality without using energy inefficient petrochemical processes, which helps meet the big and unmet demand of the perfume, food and cosmetic markets for natural fragrances and flavours.

<sup>2</sup> Genoscience Pharma is an innovative SME located in Marseille, France that is in the product development phase with their therapy against cancer stem cells, which are considered to be responsible for treatment resistance and mutation. Genoscience's drug candidate has the potential to reduce the frequency of relapse when combined with chemotherapy.

<sup>3</sup> Lactips is specialised in the development of eco-friendly plastic raw material. Their material is the only bio-based, biodegradable, thermoplastic to be water soluble at room temperature and is made of milk proteins. These outstanding properties are brought by the industrial mastering of the transformation of milk protein into processable polymers.

The #BiotechSMEAwards were presented during a dinner ceremony in Brussels hosted by MEP Dr. Paul R  big where each of the finalists took part in a 'pitching session'.

During the event, Deputy Director-General Wolfgang Burtscher, DG Research, Science & Innovation of the European Commission emphasised biotech as a key enabling technology and encouraged biotech SMEs to keep playing a core role in delivering on the aspirations of Horizon Europe.



## Excelling in social media

This year, EuropaBio was listed among the Top 10 out of 600 EU industry associations for its profile and visibility on three key social media platforms by *Cambre Associates*:

 6<sup>th</sup>/600 with 13.596 followers

 10<sup>th</sup>/600 with 5.309 followers

 9<sup>th</sup>/600 with 181.926 views





HEALTHCARE  
BIOTECH

## HIGHLIGHTS

- Regular consultations with patient groups on EU health policy
- Meeting with European Medicines Agency (EMA) Executive Director, Prof. Guido Rasi
- New coalition of healthcare trade associations to work on public private partnerships with the European Commission
- Response to the European Ombudsman inquiry on how the EMA engages with medicines developers prior to marketing authorisation application
- Contribution to the European Commission's evaluation of the effects of the legislation on Orphan Medicinal Products (OMPs)

In the past year, EuropaBio has worked to strengthen the biotech ecosystem in order to enable healthcare biotechnology and medical innovation in Europe to flourish. Our key goal has been to harness Europe's scientific excellence to ensure the treatments of the future are developed here and that Europe remains at the forefront of global innovation.

In the coming year, we will continue to work on this by:

- Promoting a European Strategy for Life Sciences at EU level
- Building a stakeholder coalition to promote strengthening of the healthcare ecosystem in Europe
- Continuing to work with legislators, regulators, and healthcare systems, in order to ensure Europe maintains an innovative regulatory environment supporting medical innovations and breakthroughs
- Explaining the benefits of the biotech business model to a greater audience, showcasing the opportunities presented by upcoming technologies

## Regular consultations with patient groups on EU health policy



EuropaBio has hosted two discussion tables with external stakeholders, which included over 12 patient organisations and one payer, on important issues of common interest. The first of the two discussions focused on EU protections and incentives for innovative medicines, followed by a discussion on the EMA's draft strategy on regulatory science to

2025. As patients play an increasingly important role in the regulatory process, these discussions provided EuropaBio with valuable insights into the patients' vision for the future of developing scientific research into tangible treatments for patients.

## Meeting with European Medicines Agency (EMA) Executive Director, Prof. Guido Rasi



In October 2018, EuropaBio met with EMA Executive Director, Professor Guido Rasi, in order to hold an exchange of views on the current challenges and opportunities for the future of innovation in Europe. EuropaBio emphasised the need for a strong regulatory environment and a forward-thinking regulator in order to ensure we remain at the forefront of global innovation.

As a follow-up to the meeting, EuropaBio invited Professor Guido Rasi to participate at the BIO-EuropaBio EMA Roundtable meeting at the 2019 Bio International Convention in Philadelphia, 3-6 June.



## New coalition of healthcare trade associations to work on public private partnerships with the European Commission

EuropaBio worked with a number of EU trade associations in the healthcare field to develop a Strategic Research Agenda aimed at providing the outline for a potential future Public Private Partnership that would offer a unique value proposition by driving pre-competitive multi-sectorial collaboration.

The Strategic Research Agenda is based on five levers, ranging from the application of big data and artificial intelligence to enable new approaches to healthcare, to reinforcing value-based healthcare and allowing for outcomes-based reimbursement of integrated care.



## Response to the European Ombudsman inquiry on how the EMA engages with medicines developers prior to marketing authorisation application

## Contribution to the European Commission's evaluation of the effects of the legislation on Orphan Medicinal Products (OMP)

EuropaBio has been actively engaged and participated in the European Commission's ongoing evaluation of the OMP Regulation.

These activities included coordinating with members and National Associations to submit written responses, and participating in a telephone interview with the consultancy conducting the report. Furthermore, EuropaBio coordinated preparatory calls among members, including with other trade associations representing the innovative sector, in order to best prepare industry participation at a conference organised by the European Commission held to allow for an in-depth discussion with stakeholders on the functioning of the Regulation.

In October 2018, the European Ombudsman's office opened a public consultation into the arrangements the EMA has in place for engaging with individual medicine developers before an application for marketing authorisation is made.

EuropaBio submitted a detailed response to the consultation, emphasising the need for a sophisticated regulatory environment where medicine developers and regulatory authorities interact on a continuous basis in order to shape new regulatory standards in fields where science is moving fast.





AGRICULTURAL  
BIOTECH

## HIGHLIGHTS

- Securing Europe's access to GM crops
- Working for efficient and transparent risk assessment and improved risk communication
- Supporting science-based decision making in agriculture & plant breeding
- Communicating about GMOs

Genetically modified (GM) crops have been widely grown and consumed for over 20 years. EuropaBio has been working intensively to communicate their benefits and remove unnecessary barriers to GM grain and soybean imports into the EU, and to promote EU farmers' freedom of choice. Improved regulatory certainty and efficiency of the EU's GMO authorisation process are urgently needed. In reaction to the landmark EU Court of Justice ruling of 25 July 2018 on mutagenesis, we also call for science-based political decision making on genome edited products.

## Securing Europe's access to GM crops

2018-19 was a special year for European agricultural biotechnology, during which we have continued communicating on the importance of GMOs for the EU livestock sector. Amidst increasing political uncertainty, influenced by factors like on-going Brexit negotiations and European elections, we have continued to highlight our calls for science-based decision making. In 2018, seven GMO import approvals were granted, and timelines for approvals show slight signs of improvement. But uncertainty and underappreciation of GMOs remains in Europe. Through our **EU Protein Gap brochure**, now translated into German and Spanish, and related outreach, stakeholders have been informed about the benefits and need for agricultural biotechnology in Europe, including GM crops.



Beat Späth, EuropaBio's Agricultural Biotech Director, speaking at 'Crop Innovation & Business' 2019 Conference.



## Working for efficient and transparent risk assessment and improved risk communication

In the context of the EU's revision of the EU food risk assessment process adopted by the EU Parliament in April 2019, EuropaBio has led efforts to improve the efficiency and sustainability of EU risk assessment for GM crops. Whilst calling for the protection of confidential business information, we have demanded improved transparency of EFSA's internal procedures, presubmission meetings for GMO applicants, better risk communication, and improved respect for animal welfare in testing requirements, principles now enshrined to some extent in the updated legislation.

“

Science and fact must take precedence over fear and misinformation. We hope that the new rules will help to build much needed trust in our food chain, including in assessed products like GMOs.

EuropaBio (2019). Facts must trump fear: EuropaBio responds to EU Parliament vote on food chain risk assessment.



## Supporting science-based decision making in agriculture & plant breeding

EuropaBio formulated its position and reaction to the game-changing European Court of Justice ruling of 25 July 2018 on mutagenesis together with other affected sectors and prominently relayed the strong reactions from scientists and other stakeholders, in addition to ensuring the continuous alignment between the biotech sectors. As part of the Agri-Food Chain Coalition, representing 13 different food chain sectors across Europe, we helped to organise a conference on the agri-food chain's contributions to the UN's Sustainable Development Goals and communicated the importance of agricultural biotechnology.

“

The CJEU Ruling will bring European Agricultural innovation in plant breeding to a halt. EuropaBio (2018). Statement on court ruling that impacts genome-edited products.



“

Agricultural biotechnology, including GM crops, can help increase crop yields, lower food prices, and reduce energy consumption, water use and CO2 emissions. AFCC (2018). How innovation contributes to the Sustainable Development Goals.

#AgriFoodEU  
agrifoodcoalition.eu



# Communicating about GMOs

This year we boosted our communications platforms, including our new multi-lingual GMOinfo website and related social media accounts, which experienced a more than 3-fold increase of followership in just 12 months. We also published new and attractive factsheets outlining the need to **improve efficiency** in EU food risk assessment as well as the high **cost of approvals** associated with GMOs. Through a documentary **movie screening** co-organised with the International Plant Biotechnology Outreach cell of the VIB (Vlaams Instituut voor Biotechnologie) during our 2018 Biotech Week, we also reached out to a younger generation of biotech enthusiasts to discuss the need for and potential of agricultural biotechnology.



Jan Huitema (ALDE, MEP) discussing with students (left) and movie screening and debate of 'Well Fed' (right) during Biotech Week.

## INCREASING ENGAGEMENT @GMOinfoEU

> 5.600  
@GMOinfoEU  
followers



> 7.200  
tweets



Multiple languages  
including German,  
French and Italian





INDUSTRIAL  
BIOTECH

## HIGHLIGHTS

- EuropaBio materials illustrating ways how industrial biotech contributes to delivering the UN SDGs
- #EFIB2018
- European Bioeconomy Alliance
- An updated Bioeconomy Strategy for Europe
- The next R&I framework programme Horizon Europe and the BBI JU

Industrial biotech uses enzymes and micro-organisms to make bio-based products in a range of sectors. It has created a powerful toolkit of solutions that contribute to reducing our dependency on fossil carbon resources.

EuropaBio continues to raise awareness of the role of industrial biotech as central pillar of innovation and an enabler of the circular bioeconomy, also creating jobs, growth and competitiveness for Europe. Amongst other activities, we develop materials and messaging, contribute to high level events and panels and foster collaborations with other stakeholders with a view to obtain common objectives.

## EuropaBio materials illustrating ways how industrial biotech contributes to delivering the UN SDGs

The report and case studies set out the multiple roles of industrial biotech in enabling smarter, more efficient use of natural resources, developing renewable alternatives to traditional fossil-carbon products, helping to mitigate the impacts of climate change, reducing energy consumption and man-made emissions to soil, air and water. The report includes concrete policy recommendations and shows how industrial biotechnology already plays a valuable role in helping the EU to deliver on many of the UN Sustainable Development Goals, and that vast potential remains for the technology to offer even greater benefits.



## #EFIB2018 / 16-18 October 2018 Toulouse, France

Toulouse hosted the 11<sup>th</sup> edition of EuropaBio's annual congress on Industrial Biotechnology and the Bioeconomy under the theme *Industrial Biotech: Delivering new bio-based products and processes to meet the UN SDGs*.

#EFIB2018 gathered professionals from business, policy, academia and media to meet, discuss and raise awareness of advancements and innovations in industrial biotech and its role as an enabler of the circular bioeconomy. **EFIB 2019 will take place in Brussels between 30 September-2 October and we hope to see you there.**



For the first time, the EFIB exhibition featured a **Start-up Village** with the participation of 24 start-up companies from 11 countries.



Finland's MetGen Oy received the annual **John Sime Award** for the best innovation presentation.



Plantics BV from the Netherlands won the third edition of the **EFIB 'pitchfest'**.



Lise Kingo, CEO and Executive Director, United Nations Global Compact at EFIB 2018.



### OTHER FACTS & FIGURES ABOUT EFIB 2018



**500+**  
delegates



from **30**  
countries



**80+**  
high level speakers

including Lise Kingo, UN Global Compact, Jean Tirole, 2014 Nobel Laureate in Economic Sciences, Wolfgang Burtscher, European Commission, representatives from L'Oréal, Bioserie, Anellotech, Modern Meadow, Fashion for Good and many others.



**10**  
tracks

on topics including synthetic biology, new innovations in fields such as food, feed, nutrition and health, bio-based cosmetics, plastics and marine biotechnology.



## European Bioeconomy Alliance

EuropaBio is a founding and very active member of the European Bioeconomy Alliance, a cross-sectoral alliance of 12 leading European organisations representing sectors active in the bioeconomy. Over the past year the Alliance has produced several papers, and organised events on topics such as:

- **Benefits of the Bioeconomy:** How a strong EU bioeconomy can deliver on the UN SDGs
- **From research to reality:** How Europe's bioeconomy is leading the way to a truly circular economy (EBCD event)
- **Developing sustainable markets:** the role of the circular bioeconomy in the EU (high-level panel debate at the European Industry Days)



## An updated Bioeconomy Strategy for Europe

The Commission published its updated Bioeconomy Strategy in October 2018, and EuropaBio welcomed this renewed commitment to the EU bioeconomy. EuropaBio has been active in calling for an ambitious revision of the Strategy, and together with the European Bioeconomy Alliance actively promoted a set of joint policy asks for a strong European bioeconomy, prepared in light of the review and subsequent update of the Strategy. EuropaBio's Joanna Dupont-Inglis also chairs the European Bioeconomy Stakeholders' Panel.

## The next R&I framework programme Horizon Europe and the BBI JU

Over the coming years, investment in EU research and innovation will be essential to delivering solutions to a broad range of global challenges and EuropaBio promotes an appropriate level of funding for industrial biotechnology and the bioeconomy in this context.

The €3.7 billion Bio-Based Industries Joint Undertaking (BBI JU) has attracted investments, spurred innovation and created new value chains. In the framework of Horizon Europe it also will be critical to build on the innovation that has been enabled and ensure a continuation of the BBI JU, something that EuropaBio is actively supporting.



Juliette Jacques, Deputy Managing Director of Starch Europe, moderating at the EU Industry Days 2019.

Members of the European Bioeconomy Alliance:



# OUR TEAM



Since  
09/18

**Joanna Dupont-Inglis**  
Secretary General



Until  
08/18

**John Brennan**  
Secretary General



**Agnes Borg**  
Industrial Biotech  
Director



**Beat Späth**  
Agricultural Biotech  
Director



**Violeta Georgieva**  
Healthcare Biotech  
Legal Affairs Manager



**Darren Kinsella**  
Healthcare Biotech  
Manager



**Bernard Grimm**  
Healthcare Biotech  
Director

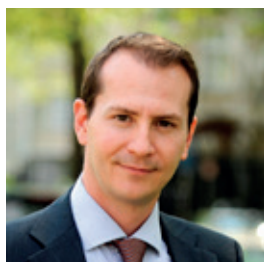


Until  
12/18

**Catherine De Feyter**  
Finance, HR & Office  
Administration Director



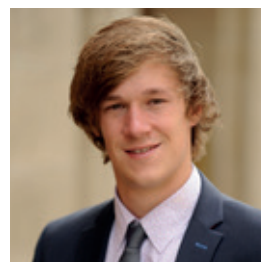
**Christine Devaux**  
PA to the Secretary General  
& IT and Office Manager



**Christopher Gallasch**  
Agricultural Biotech  
Communications Manager



**Clara Neven**  
Administration  
Assistant



**Clément Robijns**  
Communications & Events  
Manager



**Coen Frederiks**  
Agricultural Biotech  
Regulatory Affairs Officer



Until  
07/18

**Cosmin Popa**  
Communications, National  
Associations & SME Manager



Since  
01/19

**Erica Nevius**  
Finance & HR Manager



Since  
02/19

**Erica Poot**  
Industrial Biotech  
Manager



**Kai Künnecke**  
Communications  
Assistant



**Pedro Narro Sanchez**  
Agricultural Biotech  
Public Affairs Manager



**Petra Kostolaniova**  
Agricultural Biotech  
Regulatory Affairs Manager

# OUR MEMBERS

Our membership includes a wide range of corporate and associate members, as well as bio regions and industry associations involved in biotechnology throughout Europe. EuropaBio has 49 corporate and 27 associate members and bio regions and 15 national biotechnology associations – representing some 1.800 small and medium-sized enterprises across Europe.

## CORPORATE MEMBERS

AbbVie	Kedrion Biopharma
Ajinomoto Animal Nutrition Europe	Knowledge Transfer Network
ARD	Limagrain
Amgen	Merck
ActoBio Therapeutics	MolMed
BASF	MSD
Bayer	NatureWorks
Biomarin	Novamont
Bio-on	Novartis
Bluebird Bio	Novo Nordisk
Clariant	Novozymes
Corbion	Nestlé
CSL Behring	Pfizer
Clementia Pharmaceuticals	PTCBIO
Carbios	Recordati Rare Diseases
Dow AgroSciences	Royal DSM
DuPont	SOBI
Eli Lilly	Syngenta
Erytech	Sanofi Genzyme
Evonik Industries	Takeda Pharmaceutical
Gilead Sciences, Inc.	UniQure
IDEN Biotechnology	Vertex Pharmaceuticals
Johnson & Johnson	VectorLab
Keygene	ZeClinics
KWS SAAT SE	

## ASSOCIATE MEMBERS AND BIO REGIONS

Alkol Biotech	Nanobiotix
BIO NRW	NovaBiotics
Biosyntia	Nightingale Health
Cambridge Biomedical Consultants	Numaferm
CHAIN Biotechnology	Oryzon Genomics
DR. Regenold	OxyMem
EORTC	Perseus
Genoscience Pharma	Phytowelt GreenTechnologies
IAR	Redx Pharma
Intellia Therapeutics	SFL Pharma
Kaffe Bueno	Svanvid
Lactips	TiGenix
MetGen	Voisin Consulting Life Sciences
Medicortex Finland	

## NATIONAL ASSOCIATIONS

Italy	Assobiotec Federchimica
Spain	Asebio
Belgium	Bio.be
Germany	Bio Deutschland
Ireland	BioPharmaChem
UK	Bioindustry Association
Denmark	Dansk Biotek
Germany	DIB
Finland	Finnish Bioindustries
France	France Biotech
The Netherlands	HollandBio
Portugal	P-BIO
Switzerland	Scienceindustries
Sweden	Sweden Bio
Switzerland	Swiss Biotech Association



We keep working together for innovative  
biotechnology benefitting people and planet!

## EuropaBio aisbl

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