

EuropaBio National Associations Council Summit 2022: modernised regulation and legislation will deliver the potential of European biotechnology

PRESS RELEASE

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Europe's countries are at the heart of its vision and development, and EuropaBio's creation 26 years ago was driven by National associations wishing to work together across Europe.

To celebrate the national momentum behind the European economy, EuropaBio organised its second National Associations Council Summit 'Biotechnology: Delivering Europe's industrial strategy across sectors' which took place during French Presidency of the Council of the EU and reflected its priorities in the field of biotechnology.

The Summit was co-hosted by EuropaBio members **France Biotech**, **MabDesign** and **Bioeconomy for Change** and brought more than 100 participants across industry and institutions to discuss key issues and deliver recommendations in **Healthcare** and **Industrial biotechnology** sectors.

Innovative therapeutics to patients in Europe and cross border healthcare

Healthcare is experiencing a major paradigm shift, from traditional one-size-fits-all medical care to personalized medicine tailored to the genomic, molecular, and lifestyle characteristics of individual patients. It will influence the development of science into therapies and the need to enable cross-border healthcare delivering benefit for European citizens.

Europe is a leader in Research and Development and Innovation and this has to translate rapidly into industrial performance. In his statement, **Kevin Alessandri, Tree Frog Therapeutics** stressed the importance of boosting Europe's competitiveness: 'When we go to the US, which dominates the regenerative medicine market, we witness a lot of talent and technology which actually comes from the



EU. As Europeans, we believe that we need to react to that and keep the pace with the international competition.'

National associations and the governments they support have a huge role to play; European legislative and regulatory reviews, such as the Pharma Strategy, will impact differently across Europe and countries need to bring aligned momentum for a genuine single European market.

'We need to make sure that the European legislation is going in the right direction. It is good to have this meeting today with the National Association Council and to discuss how we can work together on the European and country levels towards making Europe an attractive place to do research, manufacture, to launch new medicines.', said **Thomas Bols, PTC Therapeutics**.

There's huge potential in getting cross-border healthcare right; it delivers for patients and can assist in addressing issues around access to medicine. **Tomislav Sokol, MEP** delivered a statement on the cross border healthcare 'The legislation that regulates cross border healthcare is problematic as we have two set of tools that regulates the same thing in a different manner.' He also addressed the existing Transparency Directive which regulates what procedures member states have to undertake when they decide to reimburse new medicines 'The Transparency Directive has not been updated since its implementation 33 years ago, we need a new piece of legislation with clearer criteria. Without this, we will have issues with lack of transparency on reimbursement decisions.'

Stami Kritas, from national association HBio gave an overview on the biotechnology sector development in Greece. According to her, Covid-19 pandemic highlighted the importance of biotech sector and the country faces an increase number of start-ups in the healthcare sector. 'Greece has the skills and infrastructure to have specialised therapies, but we need more involvement of patient advocates and healthcare providers alongside a more streamlined process.'

Frédéric Druck, from national association Bio.be suggested that we should focus on the scale-up of young biotech companies in the next 10 years. 'If we want to have European products on the shelves, we need to consolidate our biotech sector. We need to anchor these new companies in the regions where they emerge so that they remain in Europe.'

'A core focus for EuropaBio, looking at the regulatory frameworks which apply to our members, is the need for simplification of the business environment in Europe for complex medicines development. We need a regulatory system that is accessible for SMEs, given a lot of innovative medicines originate from SME biotechnology companies'. **Seán Byrne, EuropaBio** pointed out that the EU regulation of medicines needs to become more streamlined, with expedited pathways to accelerate approval of innovative treatment. 'Agile regulatory environment will bring the EU in line with other regions in the world and allow patients to access medicines earlier.'



Industrial biotechnology and bioeconomy: Growth and innovation to market; novel foods

The second part of the summit was devoted to Industrial biotechnology. The sector plays two critical roles for Europe; transforming manufacturing processes as part of a global shift, and contributing to achieving the Green Deal objectives, with the reduced energy, water and waste in biological production.

EuropaBio calls for the need for a science-based, proportionate and predictable regulatory approach to current and future biotechnology innovation. One concrete example is the current discussions around the EU GM regulatory framework, which is not fit for purpose for new genomic techniques and their products, as also recognized by the European Commission last year. 'We see a clear need for a modernised EU GMO Legislation, and to keep up with the fast pace of innovation in this sector and be future proof, it should move from a process-centric to a product centric approach', said **Agnes Borg, EuropaBio**.

Elke Duwenig, BASF gave a perspective of the topic from the industry side. 'Europe needs to balance innovation and regulation in a new way. And must invest in renewable feedstocks, modern biotechnology and bio-energy as well as in fermentation capacities.'

Mathieu Brandibat, France 2030 continued on the need to invest in the new kind of feedstocks 'We need to promote biotechnology from R&D to maturation, in different ways including promoting new kinds of feedstock, developing new processes and addressing bottlenecks, and supporting investment.'

The discussion was followed by the intervention of **Denis Chereau from ITERG & PIVERT & IMPROVE** on the scale up challenges for companies in France. 'World transition, to sustainable production needs strong R&D to develop innovation in the bioeconomy. Developing synergies between R&D centres will contribute to strengthen the industry innovation and help to reduce time to market.' He added 'We need to bridge the valley of death between innovation and industrialization.'

CBE JU is the €2 billion partnership between the European Union and the Bio-based Industries Consortium (BIC) that funds projects advancing competitive circular bio-based industries in Europe. The representative of this partnership, **Virginia Puzzolo** on scaling up and de-risking investment 'Firstly, we need to work together. Public investment has a role to play in helping small companies attract further private investments. Secondly, it is important to bring together different actors to facilitate scale-up and transfer of technology.'

The final discussion included novel foods and their role in Europe's future sustainability and competitiveness, with the critical policy and regulatory framework that enables investment.



In the past 5 years we have seen a very strong acceleration for biobased products, linked also to local sourcing and sustainability concerns. **Nicolas Sordet from AFYREN** raised the question 'The market is changing and consumers' behaviour is changing. How can we consume better instead of bigger?'

Liam Sharon, of the SME Remilk stressed the importance on cutting age new technologies which secure the long term food reserves with a minimal impact on animals and environment. 'As a new producer, we are happy to share innovative products. Our aim is to bring more safety to the food world.'

His statement was supported by **Wieteke Wouters, HollandBio** who stressed the importance to innovate and find ways to produce more sustainably, and more animal friendly. She added 'We need a paradigm shift in the way we approach biotechnology innovation. We should not discriminate products based on the technology used to develop them.'

And while the Industrial biotechnology is booming and every day it seems like a new company is formed. 'We need in parallel to expand on pilot plant capacities to support scale up and testing', said **Hendrik Waegeman, Bio Base Europe Pilot Plant**.

The summit was moderated by **Tineke van hooland**, Chair of EuropaBio National Associations Council and chairs of the sessions **Ana Sofia Antunes**, mabdesign, **Chloé Evans**, France Biotech, **Christophe Luguel**, Bioeconomy for Change and **Agnes Borg**, EuropaBio.

The EuropaBio National Associations Council Summit now looks ahead to future presidencies, with the next Summit planned with Member **AseBio** for the Spanish Presidency in 2023.

The conclusions from the Summit will be summarised in the report, with a [recording](#) of the event immediately available here.

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About EuropaBio

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. 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 biobased and zero-waste economy. EuropaBio represents corporate and associate members, plus national biotechnology associations and bioregions.

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