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Interview

Alessandro Toniolo, CEO at Resalis Tx, on the first obesity antisense trial and the Sanofi deal.

Deeptech

Bioeconomy

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FREE EXCERPT

The battle for green solutions

Pandemic Crossroads

Antimicrobial resistance, viruses and the next major health crisis

Molecular Breeding

What the compromise on New Genomic Techniques looks like

Oligos & Peptides European Biotechnology analyses the growing market





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Knowledge-based bioeonomy – reloaded



DR MARTIN LANGER, is an Executive VP of BRAIN Biotech AG, and since Jan 2023, he has held the position of Managing Director Bioscience **Operations Zwingenberg at BRAIN** Biotech. The biochemist has been working for BRAIN Biotech in various positions for 30 years. In 2013, he was appointed Executive Vice President. In 2015, he led the IPO team at BRAIN, ending successfully in February 2016. After growing the business within the BU Industrial BioSolutions for two years, he took over the position of Head of Business Development in 2020.

To meet the goals of the European Clean Industrial Deal, we must quickly transform our energy-intensive, fossil industries. Biotechnology provides the necessary toolbox, ranging from energy-saving biocatalysts for the chemical industry to climate-friendly production of animal feed and food proteins for more resilience, microbial recovery of rare critical materials, to the production of pharmaceutically active ingredients. Biotech applications ensure that we will meet the Sustainable Development Goals of the 2019 EU Bioeconomy Strategy – food security, sustainable use of natural resources, growing independence from fossil resources, and limiting climate change. At the same time, we will strengthen Europe's competitiveness and create new jobs.

However, why are we not really closer to the "biologisation" of industries? Well, from a global perspective, in the EU we are not the fastest region in the world when it comes to supporting industrial transformation but the USA, with its Inflation Reduction Act, China, with huge investements in fermentation capacity and biotech, Singapore, with its ultra-fast approval of novel foods, and Brazil, with a clear strategy on how to move forward in the bioeconomy.

What we can learn from them is that they significantly support innovators on their way to industrial-scale biomanufacturing. Why is this so important? It is about investment costs in demonstration or production plants (CAPEX). Many biological production processes today are price-competitive with their petrochemical counterparts. This price competitiveness ends at the point where investments in new production plants are needed. CAPEX costs have killed many sustainable business cases. Thus, forward thinking and time-limited strategic financing are needed. As Europe has not yet done so sufficiently, global players and start-ups are leaving Europe, taking advantage of funding oppor-

tunities abroad. An IPSEI (Important Project of Common European Interest) could be a tool for funding industrial transformation in the EU. However, we need more common financing tools to limit brain drain and keep value creation in Europe.

In addition, harmonisation of approval processes, such as for proteins from precision fermentation, is necessary in Europe. In Singapore and the USA, companies receive approval four times faster than in the EU, without compromising food safety.

The key is to recognise and implement the economic and sustainability potential that biotechnology offers to both industry and consumers. If we use biotechnology in a smart way, coupling it with new technologies such as AI and machine learning for process monitoring, development, and the prediction of molecular features, Europe will be at the forefront of the bioeconomy value creation. After all, it was in Europe, under the German EU Presidency in 2007, that bioeconomy was launched with the groundbreaking paper "En Route to the Knowledge-Based Bio-Economy." Let us make the bioeconomy a reality now and here – a Knowledge-Based Bio-Economy – reloaded for Europe and our economy! 4

COVER STORY



The Deeptech Bioeconomy battle

Faster, bolder, simpler – Ursula von der Leyen's cabinet is charting a course with January's Clean Industrial Deal. However, struggles between Commissioners over responsibilities and a lack of strategic investment in the EU bioeconomy to reduce CAPEX costs for green plants to produce fossil-free sustainable aviation fuels, chemicals, cultivated food, feed, ingredients and compostable materials that can replace plastics are currently jeopardising one of Europe's biggest economic opportunities for a recovery – and for growing less dependent on China and the US.

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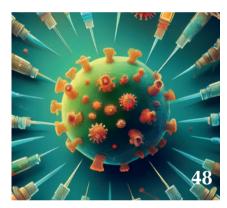
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ANTIBIOTIC RESISTANCE

The crossroads of the next pandemic

What do global pandemics and the growing crisis of antimicrobial resistance have in common? While EU member states prepare for the next viral pandemic and maintain vaccine production capacities, the 'silent pandemic' of AMR is mostly a fear only experts share. However, the current bird flu issues in the US demonstrate that the greatest risk of the next pandemic lies in animal farming – where 70% of all antibiotics are consumed.



NGT



Poland drives progress

The current Polish Presidency has tabled a draft modernising the EU's GMO rules by differentiating GMOs from NGTs – breeds produced by new genomic techniques. At attachee level, the draft that harmonises IP on NGTs with farmers' access to seeds was welcomed by roughly 80% of EU member states.



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EDITORIAL

No will to grow

Swiss fruit grower Marco Messerli uses poison sprays up to 48 times a year. Too much, he says, even though the insecticides and fungicides are authorised for organic farming. Instead, Messerli would prefer breeding more robust varieties: "If you really want to produce organic apples sustainably, you also have to allow new breeding methods." The Swiss Research Institute of Organic Agriculture is aware that breeders are working with CRISPR, but say "our customers don't want that." Because new genomic techniques (NGT), even to make old species high-yielding and therefore suitable for mass production, are not included in the definition of organic. Even if the techniques don't leave detectable traces in genomes. That's why out-of-the-box thinkers like Messerli have to give up or convert instead of realising market opportunities. The same applies to biotechnologists who see sustainability as an opportunity, and are trying to move beyond the EU definition of bio-based bioeconomy with precision fermentation, reprogramming microorganisms to produce cholesterol-free meat, milk for lactose intolerance, biofuel and plastics from atmospheric CO, and recombinant silk. But EU subsidisers don't seem interested, which is why the bloc's economy is going downhill. A ray of hope comes from Italy and Poland. In February, the Italian parliament approved €2.2bn for new biorefineries. Meanwhile Poland's draft to simplify NGT authorisation received 78% approval.

- fibralay



Thomas Gabrielczyk

Editor-in-Chief

Reprogrammed immortal and infinitely proliferating stem cells are an inexhaustible resource for both cell therapies and deeptech bioeconomy applications.

Fighting for the EU's crown jewels

DEEPTECH BIOECONOMY Faster, bolder, simpler: a course Ursula von der Leyen's cabinet is seeking to chart with January's Clean Industrial Deal. However, battles between Commissioners over responsibilities are jeopardising one of Europe's strongest cards when it comes to getting the economic engine running again. Courage is also lacking when it comes to investment in scaling up the AI-driven deeptech bioeconomy, which could strengthen resilience against China and the US.

lmost three guarters of CEOs from companies from eleven sectors with an annual turnover of more than €1.5bn are convinced the use of AI-supported synthetic biology will be crucial to achieving sustainability goals and better products. 1,100 of them surveyed believe the deeptech bioeconomy will turn crucial in the next 5-10 years (see Fig. 1, p. 16). Cap Gemini reported these figures long before the new EU Commission took up its work in December. Despite the clear industry statement, however, the terms 'biotechnology', 'bioeconomy' or 'synthetic biology' were barely mentioned in the first hundred days of Ursula von der Leyen's second term as EU Commission president. The silence on biotech was especially loud at the presentation of the Clean Industrial Deal - her cabinet's central industrial policy project. The 2paper combines the CO₂ reduction target of 90% by 2040 with a package of measures to revive stagnating economic growth and stop the outflow of investment from the EU.

However, one piece of good news remains: the Commission's binding work programme for 2025. It will update the 2020 EU strategy for the bioeconomy, which was never implemented through an action plan. The newly modernised bioeconomy strategy is slated to be presented in Copenhagen next December. However, the presentation of the EU Biotech Act, which was also originally planned for Q4/2025, has now been postponed until 2026. EUROPEAN BIOTECHNOLOGY learned why from circles close to the Commission: "Olivér Várhelyi, the Commissioner responsible for Health and Animal Protec-



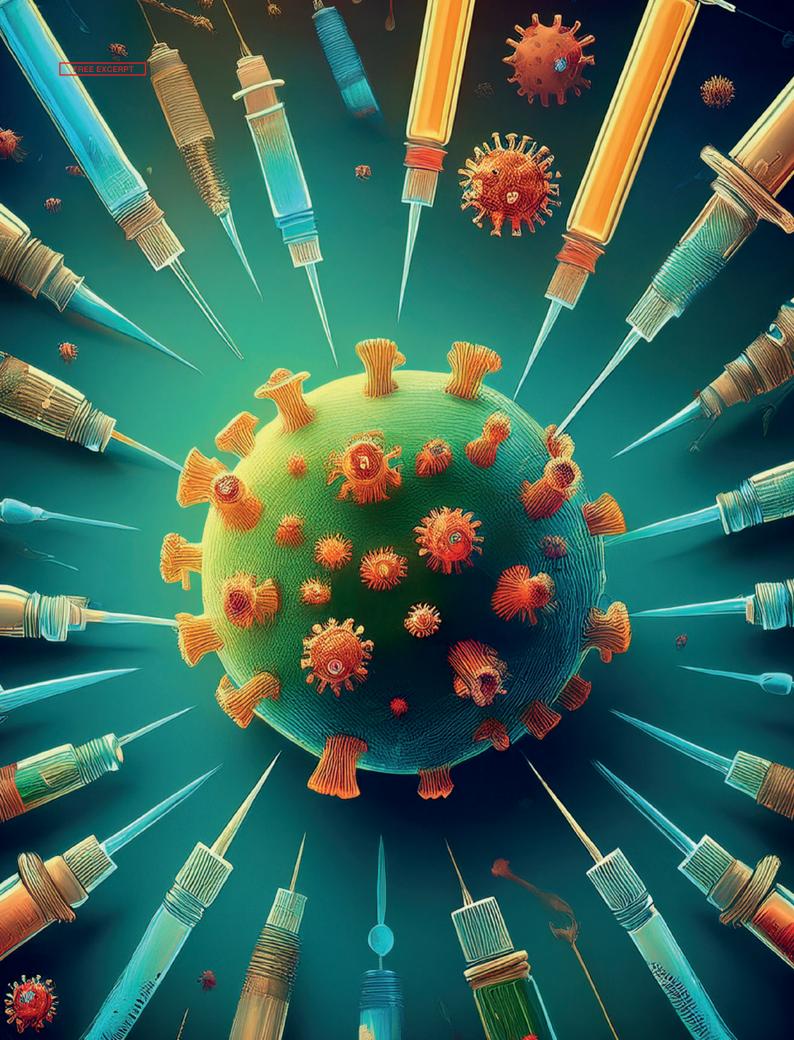
DR GUILLERMO NEVOT is Chair of the European Synthetic Biology Society

What does Europe need to foster the deeptech bioeconomy?

With AI we are moving from describing biological systems to actively designing new ones, from protein design to precision fermentation. Europe needs to keep up, scale up processes, take risks and support creative synthetic biology projects across all Europe if we want to have a seat in the global arena. tion, has strong reservations about crosssectional biotechnology applications in general." In contrast, Christophe Hansen – who leads Agriculture and Food – and Jessika Roswall, who is responsible for the competitive circular economy, are probiotech. They favour the production of feed proteins in fermenters in a climateand space-friendly manner, which would make Europe's agriculture more resilient to feed imports from the US and South America. "Várhelyi is also against the use of new genomic techniques (NGTs) for plant breeding," according to sources who did not wish to be named. "Instead of solving problems together, the Commission is preoccupied with itself. That's not good." Meanwhile, the Polish Council Presidency's latest proposals (see. p. 10) triggered a new, constructive discussion on simplifying NGT authorisation for health- and climate-optimised crops.

Silence aside, biotech will be key

The expansion of biotechnology as a key technology is inevitable though. That's because the former European Parliament gave majority support to the biotech action plan contained in 'Building the future with nature', a communication issued in April 2024 by former Competition Com-



At the crossroads of a new pandemic

PANDEMIC PREPARDENESS Europe received a slap-in-the-face wake-up call with COVID-19, and the EU's response to the infectious disease has impacted its relationships across the world. In the future, we may have to act swiftly, because the next challenge is beginning more silently – as an antibiotic crisis. It may end up affecting animal and human health in ways similar to a viral spillover event, but have an even bigger effect on our coexistence with other farmed species.

e are still far from conquering many infectious diseases, and even very old foes that seemed to be overcome still regularly pose new challenges. On the virus side, for instance, hundreds of measles cases have been reported in the border region between Texas and New Mexico in the US. Meanwhile polio has been detected in the German capital Berlin. Among other infectious microbes, the growing threat of antibiotic resistance looms ever larger. And battlefields in the Ukraine are giving rise to lethal pathogens that don't respond to our most effective treatments.

Preparedness in theory...

How are these headline-grabbing events in the world of infectious diseases connected? And post-COVID-19, is Europe better prepared for such challenges than it was before the most recent pandemic? Recurring local outbreaks of infectious diseases were common long before SARS-CoV-2 hit the world. Studies kicked off in the early 2000s examined Europe's preparations for potential pandemics. At the time, for historical reasons, influenza viruses were considered the most likely candidates for triggering the next 'big one'. However, most such studies received little attention, and when they did, they failed to establish a common understanding of the challenges involved or of appropriate measures for addressing them

Now largely forgotten, the so-called swine flu – a combination of pig, avian, and human viruses - became the first H1N1 pandemic in 2009. In the years that followed it, however, a rising number of studies began questioning whether we were really prepared for a much larger outbreak. Individual European countries developed a range of pandemic response initiatives (e.g.: UK Influenza Pandemic Preparedness Strategy 2011, Beredskapsplanering för pandemisk influensa, Sweden 2012; Swiss Influenza Pandemic Plan 2013, among others), but these plans were gradually buried deep in the archives of health authorities. Even right before the COVID-19 era arrived, a Scandinavian comparative study conducted from 2016-2018 ("Framing postpandemic preparedness: Comparing eight European plans", Martin Holmberg & Britta Lundgren in GLOBAL PUBLIC HEALTH) found that a fundamental problem was that officials did not seem to be speaking about the same issues – even when they were using the same terminology.

The shock and collective awakening were therefore all the greater when SARS-CoV-2 began spreading rapidly. It wasn't an influenza virus, true... but shouldn't recommendations for action have been transferable and applicable? Apparently not. Europe's scramble to address the disease resembled a henhouse raided by a fox. There was havoc in some areas, while others were left seemingly untouched. The initial reaction across Europe was not one of collective, cross-border action, but rather a desperate and ultimately futile attempt to isolate outbreaks, contain the virus within local and regional clusters, and shield those areas that had initially been spared from infiltration by infected individuals and carriers.

...did not work in emergency

Eventually, Europe's institutions converged on a more unified COVID strategy. While it may not have been perfect in every respect – nor entirely transparent and comprehensible – it nonetheless played a crucial role in bringing the virus under control through a coordinated vaccination approach. Efforts in therapeutics for treating COVID infections, on the other hand, remained scarce. Remdesivir, Paxlovid and Ibuprofen were and still are the treatments of choice when patients are hospitalised.

Numerous experts and committees

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