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Interview

Head of the Swiss Biotech Association Michael Altorfer on why investments tripled in 2020 and the effects of COVID-19.

FREE EXCERPT

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EU earmarks billions for a future based on bioeconomy

Genome Editing

EC attempts to deregulate targeted mutation breeding

Euro BioFairs Compass

Your guide to the most attractive events in the second half of 2021

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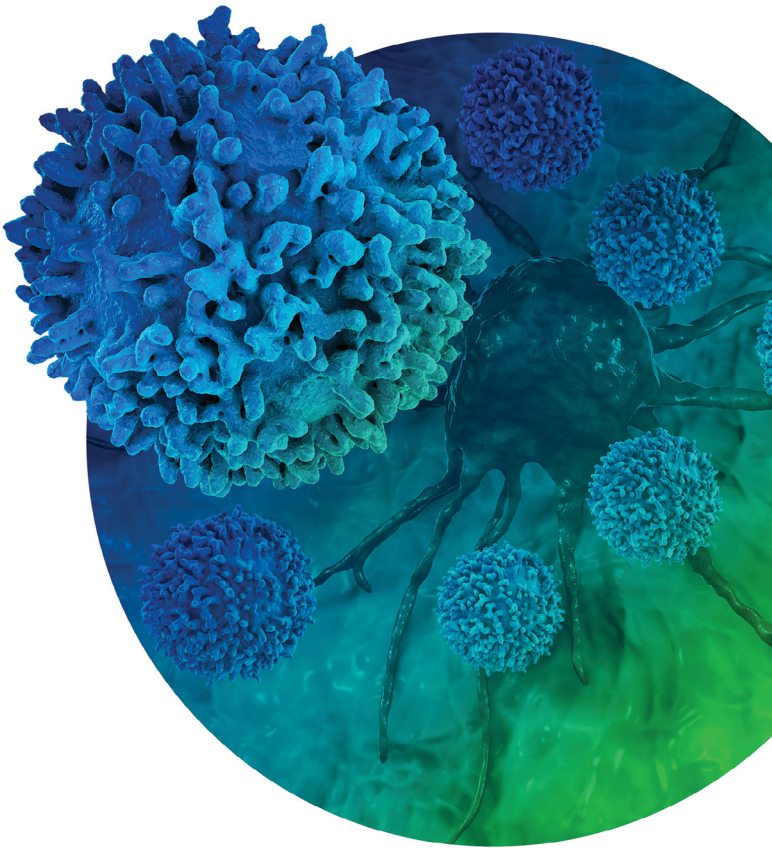

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Current EU GMO legislation is not fit for purpose

The Commission study on Novel Genomic Techniques (NGTs) underlines that plants resulting from NGTs have the potential to contribute to a more sustainable food system and support the objectives of the European Green Deal and the Farm to Fork Strategy. At the same time, the study finds that the current GMO legislation, adopted in 2001, is not fit for purpose for these innovative technologies.

The Commission study rightly concludes that NGTs constitute a diverse group of techniques, each of which can be used in various ways to achieve different results and products. Therefore, safety considerations depend on the technique, how it is used and the characteristics of the resulting product and cannot be made on all techniques as a whole.

PETRA JORASCH is a plant molecular biologist with more than 20 years of experience in the seed sector. In 2017 she became the spokesperson for Euroseeds on plant breeding innovation. Before she joined Euroseeds, Petra Jorasch was Vice Secretary General of the German Plant Breeders' Association (BDP) and German Federation for Plant Innovation (GFPi). Prior to that, the botanist has been working for more than 13 years as a patent officer for the Gesellschaft für Erwerb und Verwertung von Schutzrechten mbH (Society for the Acquisition and Exploitation of Industrial Property Rights).

The study also rightly acknowledges scientific consensus that mutations introduced by genome editing are of the same type as those obtained with conventional breeding techniques. This leads to the fundamental problem of lack of unique identification which – specifically in light of the different regulatory approach to NGTs in other countries – would constitute tremendous enforcement difficulties.

The international seed and breeding sector has always pointed to the importance of a global harmonized scope of regulatory oversight for plant breeding innovation to avoid trade limitations and disruptions. Now the Commission study confirms that any lack of such harmonisation will put EU operators at a competitive disadvantage, with further negative economic consequences. It may also qualify as a technical barrier to trade, potentially leading to numerous disputes between the EU and many of its main trade partners.

In addition, the study highlights that maintaining the current regulatory barriers would particularly affect small and medium-sized enterprises (SMEs) seeking to gain market access with novel genomic techniques. Given its unique structure, this is particularly relevant for the EU seed sector.

The findings of this Commission study clearly confirm that urgent action is needed to modernise its outdated GMO legislation to allow for a differentiated approach for products derived from innovative plant breeding methods.

Europe's plant breeding sector stands ready to support Commission, Member States and European Parliament in this process. A brand-new study from HFFA Research on "The socio-economic and environmental values of plant breeding in the EU" demonstrates the strategic importance of Plant Breeding Innovation to successfully achieve a sustainable and productive EU agriculture. Europe must act now and avoid undue lengthy processes if it truly wants to be a world leader in sustainability. ■

Picture: ESA

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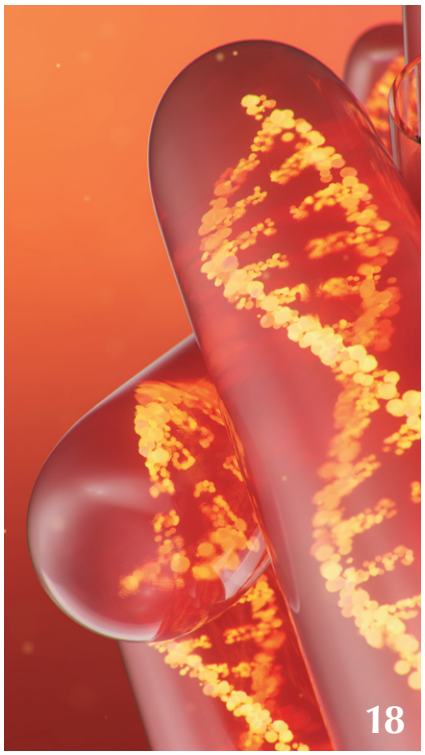
COVER STORY



The next revolution

The COVID-19 pandemic has dramatically boosted demand for GMP-compliantly manufactured plasmids and viral vectors for vaccine production, and CDMOs and other developers are racing to expand production capacities. In the post-pandemic era, an even more lucrative business than preventive vaccines beckons. The rapidly expanding market for gene and cell therapies is already worth billions, and could soon explode. Although many challenges in vector design and the manufacture of individually tailored therapies still have to be mastered, developers are optimistic.

INSIGHT EUROPE

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HORIZON EUROPE

Money in the pot

Defeating cancer, stopping global warming and halting infectious diseases – the newly approved €95.5bn Horizon Europe innovation programme has some ambitious goals. The means to these ends include new public-private partnerships. A €10bn EIB financing tool should help drive the biologisation of industry through the circular economy and bioeconomy.

NEW ASSOCIATION

Made in Austria

In April, Biotech Austria took off with more than 50 companies. EUROPEAN BIOTECHNOLOGY spoke with founding President Peter Llewellyn-Davies about goals, challenges for Austrian biotech companies and communication campaigns.

SPECIAL

EU Event Compass

EDITORIAL

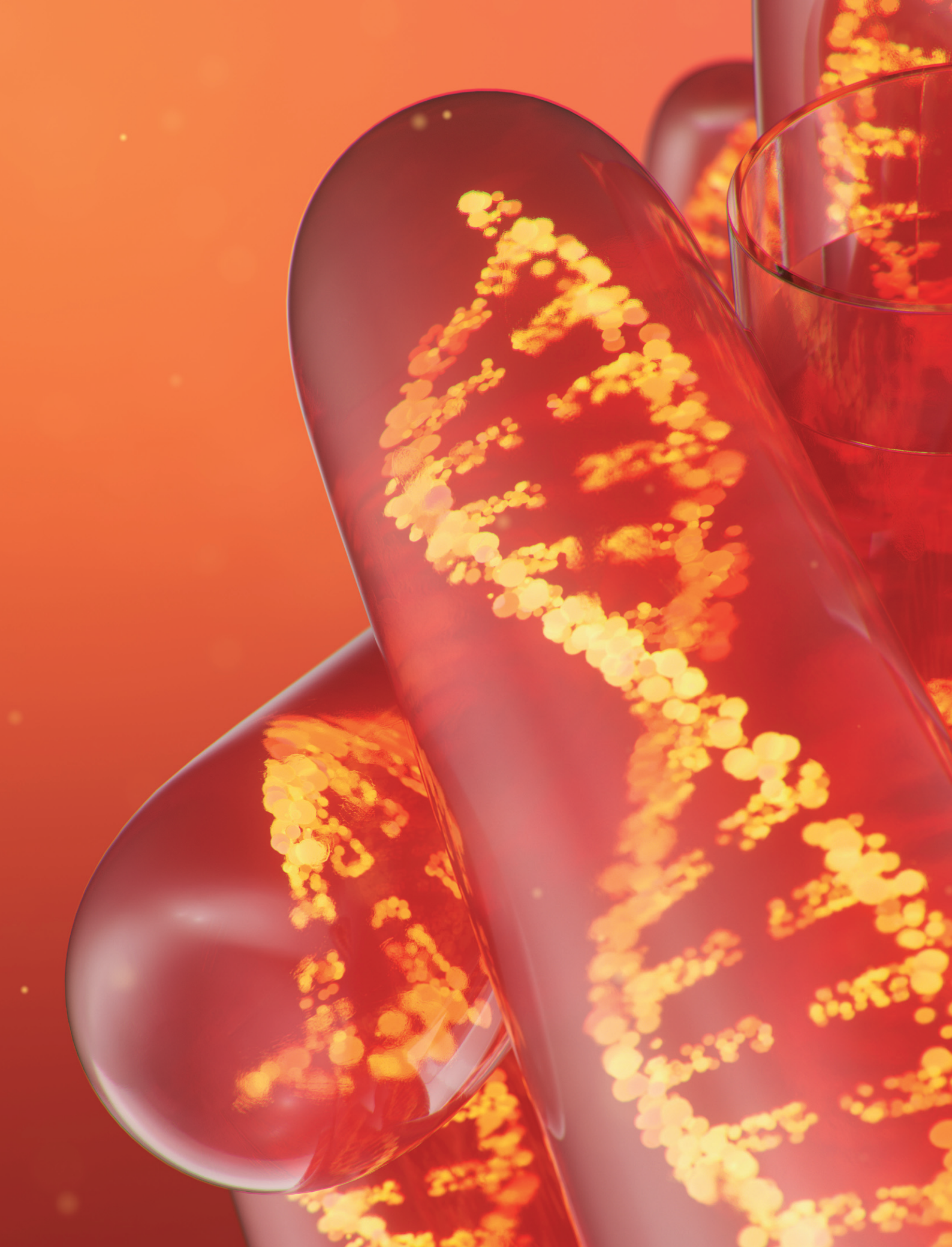
Who benefits?

This could be a hot summer in Brussels. A new study commissioned by the EC on the potential benefits of genome editing in plant breeding touches on the economic sensitivities of its fiercest opponents. It says that in order to achieve a 25% share of organic food as quickly as possible – and thus power more profit in the green industry – production must comply with UN sustainability goals. Organic farming, however, yields so little produce that much more land would be needed to achieve the same result as conventional farming. According to the Commission's logic, this means that genome editing must help raise yields to the same level as conventional produce (whose yield/unit area is only possible with help from pesticides and synthetic fertilisers). Since biological mutation breeding would be subject to strict EU GMO legislation, however, an exception would have to be made.

The issue is also certain to face stiff opposition from those who earn billions with organic food, and fear the loss of certification through such deregulation. Do national and EU decisionmakers really want to challenge seed and food giants so sustainability can win the day? Of course, responsibly applied biotechnology could help. The question is whether Brussels actually intends to enforce new rules – or just use sustainability arguments to continue with business as usual.

Thomas Gabrielczyk
Editor-in-Chief

Pictures: Biotech Austria (top): : Adobe Stock (left), BIOCOM AG (bottom left); Brazhyk - Freepik.com (Compass)



Business booms in gene and cell therapy

ATMPs The COVID-19 pandemic has dramatically boosted demand for GMP-compliantly manufactured plasmids and viral vectors for vaccine production. CDMOs and developers are racing to expand production capacities. In the post-pandemic era, an even more lucrative business than vaccines beckons. The rapidly expanding market for gene and cell therapies is already worth billions, and could soon soar much higher.

The pandemic has severely limited clinical testing and manufacturing of gene and cell therapies (GCT), but analysts expect demand to pick up quickly after it ends, mainly due to the rising incidence of cancer in industrialised nations. Experts from The Business Research Company (BRC) see huge market potential in the oncology segment – provided CAR-T, TCR-T therapies and mRNA cancer vaccines designed to boost the response rate to cancer immunotherapies can gain market approval for the treatment of solid tumours as well, which make up about 90% of all cases. "CAR-T therapies have been very effective for hematologic malignancies, with several products already on the market," confirms Karen Miller, SVP Clinical Pipeline at Adaptimmune plc (see interview p. 24). The ultimate goal at many companies, however, is to activate an immune response against the much larger group of solid tumours. While BRC expects the overall GCT market to grow from $4.39bn last year to $8.97bn by 2025, they predict the oncology segment alone will account for $6.73bn in sales during that period.

Tip of the iceberg

That analysis, however, is limited to the few large players that have either brought roughly a dozen gene and cell therapies to the market (see table, p. 22) or that are running pivotal trials. However, a number of technological challenges still have to be overcome – particularly in manufacturing autologous cell therapies. Another big question is whether the current GCT price range of between €0.2–€2.1m per patient will be reimbursed by health systems. But that hasn't stopped a huge number of innovative SMEs running hundreds of clinical trials in immuno-oncology and orphan gene therapies.

DR MARTIN SCHLEEF
CEO, Plasmid Factory GmbH, Bielefeld, Germany

? Is the demand for pandemic vaccines having a negative impact on the supply of vectors for gene and cell therapies?

! *In the higher quality levels – i.e. when production is GMP-compliant – it's generally true that there are limitations, but those are being countered in our company and in general by expanding production capacities. For the pharmaceutical industry, we'll continue expanding until the end of 2021.*

Pandemic – brake and accelerator

Lockdowns due to the COVID-19 pandemic have temporarily slammed the brakes on commercialisation dynamics though, since capacities for clinical testing and supplies of DNA plasmids have fallen short, with both urgently needed for vaccine production and GCT vector design. After a 50% rise in the number of pre-pandemic GCT trials initiated in 2020, trials that "were scheduled to start or be completed in 2020" have now been delayed. That's according to the GCT Catapult, Europe's largest translational centre for GCTs. It's based in Stevenage (UK), which is home to more than a quarter of Europe's GCT developers. According to the Catapult's 2020 Gene and Cell Therapy Trial Statistics, several trial centres and CROs had to put their work on hold due to closures this year. The full impact will only be seen in the 2022 statistics.

In addition, supply shortages of GMP-produced plasmids and starting materials needed for COVID-19 vaccine production are currently hampering the devel- […]

›› Read the full story in the printed issue.

Picture: Rost9 - Freepik.com (left); Plasmid Factory (right)

FREE EXCERPT

EU earmarks billions for bioeconomy

HORIZON EUROPE Defeating cancer, stopping global warming and halting infectious diseases – those are among the ambitious goals of the €95.5bn Horizon Europe innovation programme approved by the European Council in early May. The means to these ends include new public-private partnerships for life sciences and biotech companies. A €10bn EIB financing tool is additionally available to drive the biologisation of industry through the circular economy and bioeconomy.

It's the EU's cornerstone funding programme for research and innovation, and a sizeable chunk of Horizon Europe's budget of €95.5bn will be funnelled into achieving the Sustainable Development Goals (SDGs). After a lot of debate, the European Council has now adopted legislation aimed at complementing the legal framework around Horizon Europe (2021-2027). The EU Parliament approved the programme at the end of April, and it's good news for translational medicine. About €8.3bn are to be channelled into research and development in the "Health" cluster, which includes the fight against antimicrobial resistance, neglected diseases and cancer (see p. 62). Another €9bn is earmarked for "Food, Bioeconomy, Natural Resources, Agriculture & Environment", which will involve bio-based and industrial biotech solutions.

The Commission originally proposed €100bn to achieve the programme's politically ambitious goals, while the European Parliament wanted €120bn. Member states, however, wanted to pay much less. In the end, the EP managed to top-up the budget and agreed with the Commission and the Council on €95.5bn, to include €5.4bn from the Next Generation EU COVID-19 recovery fund. "The glass is half full and half empty," MEP and Horizon Europe rapporteur Christian Ehler said in April. "During this legislative term, we have to see how we're going to find more funds." Despite that worry, Ehler called Horizon Europe "the most important civilian research programme in the world."

However, criticism has arisen that associated countries like Switzerland and the UK won't initially have full access to Horizon Europe (see p. 38). "An overly protective 'EU-first' approach could hamper groundbreaking research and innovation, which is indispensable for improving the daily well-being of European citizens," according to Kurt Deketelaere, Secretary-General of the university network LERU. In a joint statement, the European network stressed its concerns "about proposals to restrict the UK, Switzerland and potentially other countries' access to certain parts of the programme."

A boost for the bioeconomy

Horizon Europe is meant to tackle climate change and help achieve the SDGs, but also to boost the EU's competitiveness and growth. That's a red rag for NGOs that have taken up the cause of environmental protection through zero growth. In the Commission's view, nine public-private partnerships (PPPs), which it has renamed 'European Partnerships', should provide the decisive impetus for the implementation of political goals. Initially, the Commission has reserved around €10bn for them.

Most of the new PPPs have predecessors in Horizon 2020. The cornerstone programme for the transformation to a more sustainable and competitive economy is the Circular Bio-based Europe partnership (CBE). "This partnership contributes significantly to the 2030 climate targets, paving the way for climate neutrality by 2050, and increases the sustainability and circularity of production and consumption systems in line with the European Green Deal," says the EC's draft. The biotech sector is well-placed to drive quite a few of the fundamental transformations envisaged in that Green Deal. The EC is funding CBE with about €1bn, which the partners "will match with at least an equivalent amount of investment." The proposal for regulation, the Single Basic Act (SBA), still needs to be adopted by the European Parliament and the European Council. Although the industry partners within the previous Bio-Based Industries Joint Undertaking (BBI JU) have praised the collaboration between the public sector and the private sector as a success story, at first glance they now seem to have reduced their own contributions from €2.7bn to €1bn.

To understand why, it's worth a look back at the last seven years. BBI JU was […]

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