US National Biotechnology and Biomanufacturing Initiative EBAC briefing



Globally, awareness of the value of the bioeconomy is growing. Spanning manufacturing, agriculture, and healthcare, the bioeconomy offers sustainable growth and employment whilst also contributing to our net zero targets and public health.

On 12 September, President Biden published an <u>Executive Order</u> setting out a National Biotechnology and Biomanufacturing Initiative (NBBI) which looks to accelerate the growth of the US bioeconomy. The Biden Administration estimates that engineering biology could be used extensively in manufacturing equivalent to <u>one third of global output</u>, or \$30 trillion, by the end of the decade.

This briefing will investigate the US initiative, comparing it to strategies in place in the UK and EU, and considering its impact on the UK bioeconomy. It is divided into two sections, the first providing the background to the NBBI and the second including policy detail and comparing the initiative to ongoing work in the UK.

Policy background

Defining the bioeconomy - where do life sciences fit in?

Definitions of the bioeconomy vary between countries, making it difficult to compare like for like.

The EO's own <u>lexicon</u> defines the bioeconomy as 'economic activity derived from the life sciences, particularly in the areas of biotechnology and biomanufacturing', where biomanufacturing is 'the use of biological systems to develop products, tools, and processes at commercial scale'. The emphasis on the life sciences here is noteworthy.

On the contrary, the <u>EU Bioeconomy Strategy</u> updated in 2018 explicitly excluded health and medicine. It defines the bioeconomy as 'all sectors and systems that rely on biological resources – animals, plants, microorganisms, and derived biomass... - as well as their functions and principles'.

The clearest definition of the UK bioeconomy came in the now-withdrawn <u>Bioeconomy Strategy</u>: 2018 to 2030: 'the economic potential of harnessing the power of bioscience, using renewable biological resources to replace fossil resources in innovative products, processes and services'. This is a broader bioeconomy than that proposed by the EU and one focused on sustainability and the challenge of net zero. However, the <u>UK Innovation Strategy</u> which superseded the strategy does not refer to the bioeconomy explicitly, increasing uncertainty over the UK's approach.

The US bioeconomy - regional regeneration and competition with China as drivers for action

The US bioeconomy was valued at \$950 billion in 2020, or ~5% of GDP. Benchmarking is a central part of the NBBI, so more precise figures will become available in 2023.

The EO has both a domestic and an international impetus. The NBBI aims to 'grow the economy across all of America'. This means regenerating regional economies beyond the existing clusters of Boston and the Bay Area, comparable to the levelling up agenda in the UK.

Biden's EO also comes at a time when US concern about the growth of the Chinese bioeconomy is at an all-time high. Previous US initiatives include the Obama administration's 2012 <u>National Bioeconomy Blueprint</u> and <u>a 2019 White House Summit</u> on the bioeconomy under President Trump, but the timing of this more substantive initiative coincides with growing competition with China.

The CHIPS (Creating Helpful Incentives to Produce Semiconductors) and <u>Science Act</u> of August 2022 took aim at the Chinese semiconductor industry which has overtaken the US as the world leader in this field during the twenty-first century. Valued at \$280 billion, the Act committed <u>billions of dollars to scientific</u> R&D, paving the way for the National Biotechnology and Biomanufacturing Initiative. Although the Chinese government does not employ the term 'bioeconomy', *Made in China 2025* and the thirteenth and fourteenth *Five Year Plans* all looked to <u>boost the bioeconomy</u>, with targets of \$1.2-1.6 trillion and 7% of GDP spend on R&D by 2025 in place. Alongside semiconductors, the bioeconomy could become another factor in ongoing trade competition between China and the US.

The executive order - what, who, and when?

Executive orders (EOs) are US presidential directives which coordinate a federal, 'whole-of-government' approach. Their rapidity made them key to the US COVID-19 response in March 2020, when President Trump <u>declared</u> a national emergency and reallocated medical resources. This executive order set out a timeline (see below) for a number of federal departments to develop new policies pertaining to different aspects of the bioeconomy. These policies are collectively referred to as the National Biotechnology and Biomanufacturing Initiative.

While ultimate responsibility lies with President Biden, much of the work of organising and collating and implementing reports lies with the Office for Science and Technology Policy (OSTP), directed by the <u>newly appointed</u> Dr. Arati Prabhakar, formerly of US Venture Partners and DARPA. Dr Prabhakar will play a crucial role in developing an implementation plan based on the suggestions made by the various departments' reports. The Assistant to the President for National Security Affairs, Jake Sullivan, and the Assistant to the President for Economic Policy, Brian Deese, will also play a role in coordination.

Another important player could be Dr Renee Wegrzyn, formerly of Gingko Bioworks and DARPA, appointed as the inaugural director of the Advanced Research Projects Agency for Health (ARPA-H) in March. With a \$1 billion budget, ARPA-H is modelled on the successful DARPA programme, seeking to emulate its success by backing high-risk research in the biomedical space.

As seen from the timeline below, directors from departments across federal government will contribute to the advancement of the NBBI.



une 2023

September 2023

Within 90 days, i.e by 11 December 2022:

The Director of the Office of Management and Budget will perform a budget crosscut to identify existing spending. The Secretary of Commerce will develop a 'lexicon for the bioeconomy' for benchmarking purposes.

Within 120 days, i.e. by 11 January 2023:

An Interagency Technical Working Group will be established. It will be chaired by the Chief Statistician and include representatives from Departments of Agriculture and Commerce, the Office for Science and Technology Policy (OSTP), and the National Science Federation (NSF).

Within 180 days, i.e. by 11 March 2023::

The Secretary of Health and Human Services, Xavier Becerra, is to provide a report on 'how to use biotechnology and biomanufacturing to achieve medical breakthroughs, reduce the overall burden of disease, and improve health outcomes'.

The Secretary of Energy, Jennifer Granholm, is to report on how biotech can 'adapt to and mitigate the impacts of climate change'.

The Secretary of Agriculture, Thomas Vilsack, is to provide a report on how biotech can improve agricultural sustainability by increasing yields, protecting against pests, and cultivating alternative foods etc.

The Secretary of Commerce, Gina Raimondo, will report on how biotech and biomanufacturing can strengthen the resilience of US supply chains.

The Director of the National Science Foundation, Sethuraman Panchanathan, will identify 'high-priority fundamental and use-inspired basic research goals' to advance the bioeconomy and 'address the societal goals identified'. A strategy will be developed for expanding domestic biomanufacturing capacity.

The Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and Department of Agriculture will identify 'areas of ambiguity, gaps, or uncertainties' in the regulatory environment.

Within 200 days, i.e. by 31 March 2023:

The Education Secretary, Miguel Cardona, will publish a plan for using Federal education and training programmes to boost the biotechnology workforce.

Within 240 days, i.e. by 9 May 2023:

The Director of National Intelligence will provide assessments of foreign threats to the US bioeconomy.

The Director of OSTP, in consultation with external stakeholders, shall issue a report supporting the **Data for the Bioeconomy Initiative** identifying key data types, planning on filling data gaps, and outlining the Federal resources required.

Within 180 + 100 days, i.e. by 19 June 2023:

Having received the reports due after 180 days, the Director of the OSTP, Arati Prabhakar, will work with other agencies to develop an implementation plan, bringing in external stakeholders.

The EPA, FDA, and Department of Agriculture will provide plain language information on relevant agencies' regulatory roles and will produce a **plan for regulatory reform**.

Within 1 year, i.e. by 11 September 2023:

The Secretary of Agriculture will submit a plan to support the resilience of the US biomass supply chain. Procuring agencies will establish a 'biobased procurement program' and feed back to the Director of the Office of Management and Budget on their biobased product procurement.

Within 2 years, i.e. by 11 September 2024:

The agencies given instructions will report back on measures taken and resources allocated.

All relevant staff will have completed training on 'biobased product purchasing'.

A report will be sent to the President on measures taken and resources allocated on bioeconomy skills and workforce development.

Policy detail

Comparing pillars of the US, UK, and EU bioeconomies

This section highlights the foci of the National Biotechnology and Biomanufacturing Initiative and compares the measures taken to those in the UK. The UK published a Bioeconomy Strategy in 2018 but this was withdrawn in 2021 and superseded by the Innovation Strategy, in addition to several pools of funding available across government. The table below includes a non-exhaustive overview of these policies.

With the 180 day timeline for government departments to report back (see above), we may not know policy specifics until 2023, although \$2 billion worth of measures have already been <u>announced</u> and are included below.

Area	US	UK
Investment	Federal investment is at the crux of the initiative and could be sizeable given the \$200bn committed to science R&D in the CHIPS Act, although only a fraction of this will cover the bioeconomy. Innovation will be fostered through a Regional Innovation Engines competition run by the National Science Foundation, \$200 million has been ringfenced for the bioeconomy through the Build Back Better Regional Challenge , and \$500 million in grants for fertiliser production.	In the UK, £39.8 billion has been budgeted for R&D between 2022 and 2025 in accordance with the Innovation Strategy, but again only a fraction of this will go towards bioeconomy R&D. As a percentage of GDP, this figure is comparable to the US's 3% mark, with the UK at >2.4%. This is supplemented by further pools of money, such as in the Net Zero Strategy, which supports R&D through the Net Zero Research and Innovation Framework.
Data and benchmarking	The NBBI sets out to foster a secure 'biological data ecosystem' through a Data for the Bioeconomy Initiative. The National Science Foundation has launched a \$20 million competition for a new biosciences data centre, with further funding announcements to follow. One of the strengths of the NBBI is that it covers the breadth of the bioeconomy and is engaging in benchmarking and definitional exercises to make it easier to oversee the national bioeconomy. Establishing new metrics will enable measurement of the rate of growth of the US bioeconomy.	The UK is further ahead than the US on this in the health space, with Secure Data Environments (SDEs) central to resources like the UK BioBank and strategies like <u>Data Saves Lives</u> embedding responsible data use in the NHS. The Department for Digital, Culture, Media and Sport (DCMS) has published a <u>National Data Strategy</u> , updated this year, which looks to build a 'world-leading data economy' while fostering growth and ensuring public trust. The UK, however, lacks a data initiative which considers the bioeconomy explicitly. There is also no cross-cutting benchmarking initiative comparable to that going in the US, making it more difficult to measure the growth of the UK bioeconomy.
Biomanufacturing and commercialisation	The NBBI looks to expand US domestic biomanufacturing, production capacity and processes, as well as increasing piloting and prototyping efforts to translate research into practice. The Department of Defense is investing \$1 billion in bioindustrial domestic manufacturing to establish a bioindustrial manufacturing base that will be accessible to U.S. investors. The Department is also launching a Tri-Service Biotechnology for a Resilient Supply Chain worth \$270 million to support the development of biobased materials for defence supply chains.	BIA's work with ABPI and Innovate UK on the Medicines Manufacturing Industry Partnership (MMIP) shows the benefits to be gained from collaboration between government and industry. The NBBI emphasises domestic manufacturing and onshoring, which is reflected in MMIP work in this area. KTN's Industrial Biotechnology Leadership Forum (IBLF) is another source of support. For example, new pools of funding have been made available by KTN to fund 'reimagining materials and manufacturing together'. They are worth £3 million together, with room to increase should the feasibility study be successful, and target projects focused on future economy materials, resource efficiency, and alternative bio-based chemical replacements. The Low Carbon Manufacturing Challenge Fund (£150k) and REforMM (£1m) also support UK biomanufacturing. One of the pillars of the UK Innovation Strategy is also focused on institutional change, such as the Tickell Review into UKRI organisation, mirroring US work on prompting a whole-of-government response. ARIA (the Advanced Research and Invention Agency) is a UK asset that looks to support highrisk, innovative research with its £800 million budget. Innovate UK's Biomedical Catalyst and Higher Education Innovation Funding provide some support, but there is more work to be done on university support for spin-outs and not much is bioeconomy specific.
Biomass production and biobased products	The NBBI will incentivise biomass production in a 'climate-smart' manner while expanding market opportunities for bioenergy and biobased products and increasing public procurement of these products across departments. US agencies will be assessed on their procurement processes' compatibility with sustainability objectives and their staff trained on sustainable procurement in the next two years. This is supported by the US's BioPreferred labelling programme, mirrored by the EU's Ecolabel. As a first step, the Department of Education is providing \$100 million for R&D into the conversion of biomass to fuels and chemicals.	The withdrawn Bioeconomy Strategy recommended using byproducts as feedstocks and developing 'new supply and value chains', but it is unclear who in government is now taking responsibility for this. Work and funding is ongoing in the agritech space, as exemplified by Defra's Farming Innovation Programme (£850k), Innovate UK's Better Food for All competition (£20m), and local projects like the BioYorkshire cluster. The Department for International Trade (DIT) has worked on expanding market opportunities through campaigns like Power of Biology.

Skills	The NBBI recognises the importance of a 'diverse, skilled workforce' to the growth of the bioeconomy, pledging to coordinate existing Federal education and training plans as well as 'recommending new efforts to promote multi-disciplinary education programmes' which span both graduate programmes and technical education. The I-Corps biotech entrepreneurship bootcamp will also be stepped up to deliver jobs in the bioeconomy 'across all of America'.	UK bioeconomy skills policy has often been linked by the UK government to the Levelling Up agenda in documents like the Life Sciences Vision, drawing parallels with Biden's promise to harness the benefits of the bioeconomy 'across all of America'. One of the pillars of the Innovation Strategy was to make 'the UK the most exciting place for innovation talent', referring to visas for innovators which contrast with the NBBI's emphasis on domestic workers.
Regulation	The NBBI looks to clarify and streamline regulation in order to produce a 'science and risk-based transparent system'. The FDA is '[spearheading] efforts to support advanced manufacturing through regulatory science, technical guidance and increased engagement with industry'. The Department of Agriculture is also updating its regulations to encourage innovation in agriculture.	MHRA is also undergoing a streamlining process post-Brexit, with its aspiration to become a more 'agile' regulator comparable to the NBBI's emphasis on creating a 'risk-based' system which allows innovation in the bioeconomy. Streamlining can also be seen in the sense that the Tickell Review and ARIA aim to reduce bureaucracy. The Innovation Strategy references 'consulting on how regulation can ensure that the UK is well-placed to extract the best value from innovation
Biosecurity	Biosecurity is a prominent part of the NBBI; the EO said that biological risk will be made 'a cornerstone of the life cycle of biotech and biomanufacturing R&D'. On biosecurity, the bioeconomy will be protected by 'adopting a forward-looking, proactive approach to assessing and anticipating threats' and by partnering with the private sector. A \$20 million bioassurane programme has been initiated.	The 2018 UK Biological Security Strategy was a joint undertaking between the Home Office, Department of Health and Social Care, and Department for Environment, Food and Rural Affairs (Defra). This set out the UK government's desire to understand, prevent, detect, and respond to biological risk for the first time. There was a call for further evidence in 2022, to which the BIA responded. The Defence Science and Technology Laboratory (Dstl) leads on the UK's application of science to defence. Dstl ran a competition to fund 'engineering biology for defence and security' in 2022, awarding companies approximately £100k each. The Defence and Security Industrial Strategy and the Innovation Strategy also touch upon biosecurity, but there is no crossgovernment approach on the same scale as that of the US.

Further comparisons can be made with the EU and Scottish bioeconomy strategies:

The EU does not include health within its bioeconomy, with most measures stemming from the EU <u>Green Deal</u> and <u>Bioeconomy Strategy</u>. Sizeable policies include:

- <u>€1 billion available</u> through Horizon Europe for R&I contributing to the aims of the Green Deal.
- The <u>EU Ecolabel</u> as an equivalent to the US BioPreferred programme to increase procurement of sustainable, biologically engineered products.
- Emphasis placed on the 'circular economy' as part of the EU's industrial push for net zero by 2050.
- EU Common Agricultural Policy and EU Biodiversity Strategy leading on the solutions to climate change offered by the bioeconomy.

Scotland provides another interesting case study, having <u>updated</u> its own bioeconomy strategy in 2022. Key policies include:

- Achieving a mature Scottish bioeconomy by 2025, with over 200 companies engaged in industrial biotechnology and turnover of £900 million.
- Emphasis on delivering a <u>circular economy</u> as part of Scotland's push for net zero by 2045. This runs in parallel with the work of <u>Zero Waste Scotland</u>, who are working on reusing the 27 million tonnes of Scottish bioresources available per annum.
- Updating the bioresource map of Scotland, developing a bioeconomy task force, and continuing to work with the Industrial Biotechnology Innovation Centre (IBioIC).
- Conducting a food system and bioeconomy skills gap analysis to develop green skills, training and development by 2025.

Conclusion

The policy detail of the NBBI will become clearer in 2023 as federal departments report back on their recommendations for advancing the US bioeconomy. The success of the initiative will depend on political factors, such as the ability to pass legislation following the weakening of the Biden Administration by the loss of the House of Representatives in the 2022 midterm elections. However, the EO clearly sets out the scale and ambition possible within a national bioeconomy strategy.

When analysed together with the EU and Scottish bioeconomy strategies, the US NBBI highlights the absence of an overarching approach in the UK since the withdrawal of the 2018 UK Bioeconomy Strategy. UK innovation and Net Zero strategies both contain effective policies, but alone they fail to address the cross-sector implications of the bioeconomy. This lack of a joined-up approach leaves the UK at risk of falling behind in novel areas such as biomass production, which the Scottish government is working on, and biosecurity, central to the US initiative.

The UK has all of the ingredients necessary for a world-leading bioeconomy: a large, and growing, number of disruptive SMEs working in the space, strong R&D capability at UK universities, and grant funding available from departments like Defra and the Department for Business and Trade. However, the cross-departmental breadth of the bioeconomy, spanning forestry, agriculture, and manufacturing, necessitates strong coordination by government. The UK can learn from the NBBI the value of government oversight and strategy in transforming these ingredients into a thriving bioeconomy. The creation of a Department for

Science, Innovation and Technology (DSIT) with cabinet-level representation in February 2023 could be key in driving this agenda forward.

As the global bioeconomy expands, there is a growing opportunity for the UK to become a global player in this field. Developing awareness of the bioeconomy across government, ensuring a welcoming ecosystem for investment, and educating the public about the benefits of the bioeconomy will all be important.

With OSTP recently <u>requesting input</u> on how to advance biotech development, and with departments' reports due by the end of March, BIA will continue to follow developments in this area.