

# BioIndustry Association response to the Government's consultation on the National Security and Investment Bill

## January 2021



### About the BIA

1. The BioIndustry Association (BIA) is the trade association for innovative life sciences in the UK. Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives.
2. Our members include:
  - Start-ups, biotechnology and innovative life science companies
  - Pharmaceutical and technological companies
  - Universities, research centres, tech transfer offices, incubators and accelerators
  - A wide range of life science service providers: investors, lawyers, IP consultants, and communications agencies
3. The BIA's members are at the forefront of innovative scientific developments targeting areas of unmet medical need. This innovation leads to better outcomes for patients, to the development of the knowledge-based economy and to economic growth. Many of our members are small, pre-revenue companies operating at the translation interface between academia and commercialisation.

### General comments on the National Security and Investment Bill and the life sciences sector

4. The BIA recognises the Government's motivations for implementing the National Security and Investment (NSI) Bill. We note that many other countries, including the US and major European economies, have similar regimes in place. However, the NSI regime as currently drafted in the Bill appears to be wider-ranging and more stringent compared to existing regimes in other countries. For example, unlike the NSI regime, similar regimes in other major economies typically do not cover domestic investors. It is important that the proposed NSI regime is viewed within a global context because of its potential impact on beneficial and welcome inward investment and innovation-led internationally mobile industries.
5. We would like to make the following general comments on the proposed regime, which we explain further in the following paragraphs:
  - The definitions on Engineering Biology and Artificial Intelligence will capture all companies within the UK life sciences sector, and the control thresholds will also capture most deals for scrutiny
  - As the vast majority of these companies and their technologies have no implications for national security, the NSI regime would place undue burden on hundreds of businesses in our sector and make the UK a less attractive place globally to start and build life sciences companies
  - The UK life sciences sector is heavily dependent on foreign investment, so implementation of the regime must not risk this capital source

- It is critical that BEIS is sufficiently staffed and has the level of expertise required to respond to notifications appropriately and quickly
  - The Government should provide further detail on technologies that it considers to be or not to be a national security concern, to provide more certainty to investors and companies
6. We expect the Bill and the proposed definitions will impact almost all businesses within the UK life sciences sector and require scrutiny of almost every deal, and as such risks harming investment and the attractiveness of the UK to global investment and business activity.
  7. The current definitions of the 17 sectors in the mandatory notification scheme cover a large proportion of the economy, and whilst we believe the definition of engineering biology and AI are attempting to be precise, they will in fact capture the entire life sciences sector as currently drafted. The vast majority of these companies are developing technologies that have no implications for national security. We are therefore concerned that the NSI regime would place undue burden on hundreds of businesses in our sector alone and make the UK a less attractive place globally to start and build life sciences companies.
  8. The UK has a globally recognised life sciences sector, which attracts, and is to a large extent reliant on, foreign investors. We have strong concerns about the impact the Bill could have on this investment and therefore the continued success of our sector. The pandemic has demonstrated the strength and importance of our industry, where it is working hand-in-hand with the Government to deliver tests, vaccines, and therapies at the scale needed to ease current lockdown restrictions and start economic recovery. The speed at which the Government Vaccine Taskforce, the NHS, and the Medicines and Healthcare products Regulatory Agency (MHRA) have worked with industry and academia has demonstrated the UK to be an even more attractive location to conduct life sciences R&D. As a result, the UK has a strategic opportunity to grow its innovation economy and deliver on the Government's ambition to make the UK the leading global hub for life sciences, as the Conservative Party committed to achieving in its 2019 Manifesto.
  9. We predict the Bill will require the notification of hundreds of deals each year from our sector alone. There have been 676 deals involving UK life science companies or companies that use AI in 2020, with a combined value of 16.5bn<sup>1</sup>. There were 870 deals in 2019 worth 12.4bn, and 870 in 2018 worth 8.3bn. It is not possible to determine how many of these would have involved an acquisition sufficient to trigger a notification, but the VC and IPO rounds common in these sectors typically involve the exchange of shares and control that would trigger a notification.
  10. Companies in the life sciences sector face long and expensive R&D timelines and, as SMEs generally focused on developing a specific new technology, they often do not have any other assets to generate revenue while the technology is developed. This means SMEs are dependent on successive fundraising rounds to maintain cash flow while carrying high levels of risk. A key challenge for the whole sector is to find enough investors willing to commit their capital to illiquid assets for five to fifteen years. This means that as a company develops and scales its technology, it will go through several funding rounds with different investors, each of which could take large equity stakes (5-15%).
  11. The sector would be significantly disrupted if companies must potentially wait for several months before a deal can proceed. As many early-stage biotech companies are pre-revenue, some companies would not be able to survive a prolonged waiting period. For investors, a waiting period of several

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<sup>1</sup> Pitchbook (accessed 10/12/20). Deals included: venture capital; private equity; IPO and follow-on public financing; and M&A.

months could also stop investments as generally the investment committees in venture capital firms do not allow a large time gap between deals being approved and investment. Moreover, it is also unclear how the regime would be implemented on public markets in practice, where trading happens almost instantaneously.

12. We have suggested how the sector definitions could be improved in our submission below. However, in practice, the identification of the risk posed by the use of AI and engineering biology that the NSI regime is seeking to protect against would be more helpful than developing ‘perfect’ definitions. In the Statement of Policy Intent,<sup>2</sup> the Government highlights that specific ‘core activities’ are of higher risk than others. We encourage the Government to specify what uses of technologies it considers to be core activities, or alternatively, to specify what technologies it does **not** consider to be such activities that would not require notification. In this way, companies and investors would have more certainty. We understand certain investors may be able to obtain pre-approval to confirm they do not pose a national security risk, which would be highly welcome.
13. Furthermore, even if the definitions of the sectors in the mandatory regime are amended, the BIA is concerned that the Government has underestimated the number of deals that will need to be reviewed due to voluntary notifications. Due to the wide scope of government powers under the regime, investors and companies are likely to notify the Department for Business, Energy and Industrial Strategy (BEIS) under the voluntary scheme to avoid after a potentially very damaging government call-in to deals that have been completed. The Government estimates to receive 1000-1800 notifications per year across all sectors, which does not appear realistic in light of the average of 807 annual deals over the past three years in the life sciences and AI industries alone, which we have quoted above. It is critical that BEIS is sufficiently staffed and has the level of expertise required to respond to notifications appropriately and quickly. If the review process takes long periods of time, then the life sciences sector is likely to be disrupted for the reasons outlined above, and the wider UK economy will suffer as a result.
14. The length of the BEIS review process could also have an undue effect on public markets and the Government must consider the NSI Bill in conjunction with its ambition to strengthen the UK’s position as a leading global financial centre. A well-functioning London public market is needed to ensure life sciences companies can access the capital they need to invest in R&D and scale in the UK. The BIA therefore welcomes the timely and ongoing UK Listing Review, chaired by Lord Hill.<sup>3</sup> The Review is set to make recommendations to the Government on how to encourage more high-quality UK equity listings and public offers. However, the Government must ensure that the objectives of the Review are not undermined by the NSI regime.
15. In summary, the Government should adjust its approach if it wishes to avoid negatively impacting investors, SMEs, and large companies that are active, or looking to become active, in the UK’s life sciences sector. The BIA represents a broad cross-section of the sector and we would welcome the opportunity to work with Ministers and government officials to ensure the regime is targeted to effectively achieve its policy goals whilst not harming the growth of the UK’s life sciences sector.

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<sup>2</sup> <https://www.gov.uk/government/publications/national-security-and-investment-bill-2020/statement-of-policy-intent>

<sup>3</sup> <https://www.gov.uk/government/publications/uk-listings-review>

## Consultation questions on Artificial Intelligence

### **Question 1: Are the sector definitions sufficiently clear to enable investors and businesses to self-assess whether they must notify and receive approval for relevant transactions? If not, how can the definitions be improved?**

16. AI is increasingly widespread across many different industries. To enable a meaningful and workable self-assessment regime, it needs to be much clearer what the Government means by the 'AI sector'. AI is in fact a platform technology used across many sectors and which can be put to many uses.
17. As explicitly recognised in the rationale for the definition, the proposed definition of AI is very wide. This purposely broad definition will most likely result in significant over-notification, resulting in an undue burden on investors, companies, and the Government. As the consultation document recognises that national security concerns will only arise in a "minority of cases", it is not clear why the definition needs to be so wide.
18. The Government should therefore consider in more detail what the minority of cases are that could threaten national security and provide clear case studies to guide any self-assessment process. The Government should also consider whether certain uses of AI can be ruled out upfront as highly unlikely to ever give rise to concerns. For example, the use of AI to augment and speed-up existing human processes, such as drug discovery, does not pose inherent national security challenges should the acquisition or control of ownership of that technology change.
19. In addition, there is no materiality threshold in the definition. In the current definition, **any** development of software or information that uses AI to perform a complex task is potentially in scope. Instead, the Government should focus more closely on the uses of AI where national security concerns are likely to raise, and tailor the definition to those identified uses.
20. The definition of AI could be improved by adopting other existing definitions of AI. Definitions already in use include those developed by the OECD and the European Commission's High-Level Expert Group on AI. However, adopting an existing definition does not address the underlying problem – that is, the lack of clarity of the uses of AI which the Government considers be inherently higher risk in terms of potential national security implications upon a sale of such technologies overseas. The use of AI to perform complex tasks does not inherently pose such concerns.

### **Question 2: To what extent are technical and scientific terms correct and sufficiently clear and commonly understood for the purposes of determining relevant activities?**

21. As set out above, there are currently too many different definitions of AI. Consistency is key to ensure investors and companies can understand and adhere to any new reporting regime. In practice, the identification of the risk posed by the used of AI that the new regime is seeking to protect against would be more helpful than developing a 'perfect' definition of AI.

### **Question 3: To what extent do these definitions include the areas of the economy where foreign investment has the greatest potential to cause national security risks?**

22. See previous answers. The AI definition is so wide as to potentially capture significant areas of the economy, many of which do not pose obvious national security risks.

### **Question 4: How else, aside from mandatory notification under the NSI regime, can the Government ensure relevant transactions receive appropriate screening while minimising the impact on business?**

23. As set out above, to minimise the impact of business, the Government should clearly set out the scope of the mandatory notification regime and ensure this scope is no wider than necessary. See paras 4-14 for our comments on how the mandatory regime will impact the life sciences sector as it is currently drafted. The Government estimates to receive 1000-1800 notifications per year across all sectors, which does not appear realistic in light of the average of 807 annual deals over the past three years in the life sciences and AI industries alone, which we have quoted above. It is critical that BEIS is sufficiently staffed and has the level of expertise required to respond to notifications appropriately and quickly. If the review process takes long periods of time, then the life sciences sector is likely to be disrupted for the reasons outlined above, and the wider UK economy will suffer as a result.
24. In addition, the Government should develop an online self-assessment tool that companies can use to ascertain whether they fall within the mandatory regime. If companies do not fall under the mandatory regime, the tool should state whether their future investments are likely to raise national security concerns. This way, companies could assess whether they should complete a voluntary notification. The Government should also consider whether companies could apply for and receive an exemption from the regime based on their technology before they start a new funding round. Such an exemption would ensure minimum impact on the negotiations and timings of a future investment.

**Question 5: Do these definitions strike the right balance between safeguarding national security and minimising the burdens placed on businesses and investors? Is it possible to narrow the scope of the definitions without compromising national security?**

25. No, we do not consider the current definition to strike the right balance between safeguarding national security and minimising the burdens placed on businesses and investors. It is possible to narrow the definition of AI, but as noted above, it is equally important to clarify the instances where the deployment of AI is likely to cause national security concerns. As noted in para 13, the Government should also ensure that the objectives of the UK Listing Review to strengthen the UK's public markets are not undermined by the NSI regime's broad sector definitions.

**Question 8: We have used a two-stage approach to define AI, referring to both cognitive functions and complex tasks. Does this approach work? Is this definition accurate in encompassing the breadth of AI technologies and summarising the complex tasks AI can be used to perform?**

26. See previous answers. The use of existing definitions rather than creating a new one would be preferred. In addition, the rationale for the two-stage approach is not clear. As explained above, regardless of the definition used for AI, the more important consideration for businesses is a clear articulation of the key areas of concern where material use of AI (rather than incidental or inconsequential use) might lead to national security concerns should the company deploying that technology be the subject of potential acquisition or control by another overseas entity.

**Question 9: This definition is intended to include companies that develop AI technologies but do not purchase AI products. Is that accurately reflected?**

27. If the rationale for making this distinction is to ensure that companies buying off-the-shelf products that incorporate some kind of AI technology (which is not subsequently modified in a meaningful way) are not caught, then we support that in principle. The use of the phrase 'purchase of AI products' suggests that the Government is looking to exclude some kind of passive consumption of AI products (whatever they are), or where AI is pre-baked into a piece of technology or a hardware or software system. However, we question whether such a distinction is workable in practice given the way in which AI works. It is inherently dynamic and fluid, and raises several questions: What if a company purchases

an 'AI product' but then integrates and deploys it within its own systems and operations? What is the difference between this and the 'development' of AI technology in the first place? Again, the ends to which the AI is deployed seem more pertinent to an assessment of national security risk rather than the point in time at which the AI is first developed. What happens where there are multiple parties in an ecosystem that 'develop AI'? What does it actually mean to 'develop AI' when the algorithms learn and change in a dynamic fashion?

## Consultation questions on Engineering Biology

### **Question 1: Are the sector definitions sufficiently clear to enable investors and businesses to self-assess whether they must notify and receive approval for relevant transactions? If not, how can the definitions be improved?**

28. Much like AI, engineering biology is a platform technology with a wide variety of uses. To enable a meaningful and workable self-assessment regime, it needs to be much clearer what the Government means by the 'engineering biology sector'. The current definition does not help with this and would capture large proportions of the UK's life sciences sector. If implemented, the definition would make it very difficult for investors and companies to conduct a self-assessment. As previously stated (see paras 4-14), this would lead to significant over-notification and consequently placing an undue burden on investors, companies, and the Government.

29. The main confusion in the definition stems from the Government attempt to differentiate synthetic biology from engineering biology. Broadly accepted definitions of synthetic/engineering biology do not use differentiated definitions and it is odd that the UK would diverge from the rest of the world on this. For example, the US National Institute for Standards and Technology defines engineering biology as:

Engineering biology (also known as synthetic biology) is the convergence of many disciplines to enable predictive engineering of living systems, the constituent components of living systems, and related biological processes for public benefit, such as curative advanced therapies, advanced material manufacturing, renewable energy sources, more resilient crops, and unprecedented data storage solutions.

As we noted in our answers on the definition of AI, consistency is key to ensure global investors and companies can understand and adhere to any new reporting regime. Developing a completely new definition of engineering biology does not provide assurance to investors and companies.

30. However, the same applies to the definition of engineering biology as we outlined in our answers on the definition of AI above; namely, in practice, the identification of the risk posed by the used of engineering biology that the new regime is seeking to protect against would be more helpful than developing a 'perfect' definition of engineering biology.

31. The Government should therefore consider in more detail what the minority of cases are that could threaten national security and provide clear case studies to guide any self-assessment process. The Government should also consider whether certain uses of engineering biology can be ruled out upfront as highly unlikely to ever give rise to concerns. For example, the use of engineering biology to engineer bio-based materials to capture target chemicals in wastewater does not pose inherent national security challenges should the acquisition or control of ownership of that technology change.

### **Question 2: To what extent are technical and scientific terms correct and sufficiently clear and commonly understood for the purposes of determining relevant activities?**

32. See answer above.

**Question 3: To what extent do these definitions include the areas of the economy where foreign investment has the greatest potential to cause national security risks?**

33. See previous answers. The definition of engineering biology is so wide as to potentially capture significant areas of the life sciences sector, many of which do not pose obvious national security risks.

**Question 4: How else, aside from mandatory notification under the NSI regime, can the Government ensure relevant transactions receive appropriate screening while minimising the impact on business?**

34. As set out above, to minimise the impact of business, the Government should clearly set out the scope of the mandatory notification regime and ensure this scope is no wider than necessary. See paras 4-13 for our comments on how the mandatory regime will impact the life sciences sector as it is currently drafted.

35. In addition, the Government should develop an online self-assessment tool that companies can use to ascertain whether they fall within the mandatory regime. If companies do not fall under the mandatory regime, the tool should state whether they are likely to be called in by the Secretary of State. This way, companies could assess whether they should complete a voluntary notification. The Government should also consider whether companies could apply for and receive an exemption from the regime based on their technology before they start a new funding round. We understand certain investors may be able to obtain pre-approval, which would be highly welcome. Such exemptions would ensure minimum impact on the negotiations and timings of a future investment.

**Question 5: Do these definitions strike the right balance between safeguarding national security and minimising the burdens placed on businesses and investors? Is it possible to narrow the scope of the definitions without compromising national security?**

36. No, we do not consider the current definition to strike the right balance between safeguarding national security and minimising the burdens placed on businesses and investors. It is possible to narrow the definition of engineering biology, but as noted above, it is equally important to clarify the circumstances in which the uses of engineering biology are likely to cause national security concerns. As noted in para 13, the Government should also ensure that the objectives of the UK Listing Review to strengthen the UK's public markets are not undermined by the NSI regime's broad sector definitions.

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