BIA submission to the EFRA committee inquiry into Animal and Plant Health

About BIA

The BioIndustry Association (BIA) is the voice of the UK's innovative life science and biotech industry, and our mission is to enable and connect the UK ecosystem so that businesses can start, grow, and deliver world changing innovation. The BIA has a diverse membership, counting over 600 members including start-ups, scale-ups and established global companies, as well as universities, research centres, and investors. BIA is also connected to the European ecosystem through our membership of EuropaBio, the European trade association for biotechnology and the European Biosolutions Coalition a coalition of industry associations aiming to advance biosolutions in Europe.

Summary

We are responding to this call for evidence because the EU/UK SPS agreement has direct implications for the biotech sector. The Precision Breeding Act 2023 is a landmark piece of legislation that exemplifies the UK's ability to take a science-led, proportionate approach to regulation. It has created a globally competitive framework that supports innovation, investment, and sustainability in agricultural biotechnology. Pioneering UK companies are developing precision bred organisms (PBOs) to address challenges in food security, climate resilience, and sustainable farming, among other societal benefits. The pro-innovation regulatory pathway provided by the Precision Breeding Act is essential to their success, to delivering societal benefits from our world-leading science base, and to growing the economy based on high-value jobs and exports.

It is currently unclear what the impact of an SPS agreement may be on the Precision Breeding Act 2023. Government has stated that it is seeking to protect the legislation from being rolled back as part of the negotiations, but has been so far unable to guarantee its protection. Reversing on the UK's PBO framework in order to enter dynamic alignment with EU, would undermine the progress made and threaten the UK's leadership in biotech innovation. We therefore urge Government to safeguard the Precision Breeding Act and ensure that future SPS arrangements reflect the UK's commitment to enabling responsible innovation. Maintaining regulatory divergence in this area is

not only justified, but essential to the continued growth of the UK's biotech sector and its contribution to society, the environment, and the economy. However, in the long term, it is clear that the UK and Europe benefit from harmonised regulatory frameworks to allow business and trade to flow freely across the continent. The optimal scenario would be for the EU to adopt a more pro-innovation approach to its gene editing legislation, effectively aligning with our regulatory framework. The UK has the opportunity to showcase a modern approach to regulating new technologies to the EU and should support our European peers to embrace a regulatory framework that uplifts innovation.

Responses to questions

1. **What is a realistic timeline for the negotiation and implementation of an SPS agreement?**

It is difficult to give a precise estimation of the overall length of the process, which will depend on many factors, including the complexity of the scope of the agreement and the manner in which negotiations unfold. Based on precedence from EU SPS negotiations with similar countries (New Zealand and Switzerland), the process could take several years to complete.

Businesses need certainty regarding their regulatory requirements. Most biotech startups must go through an intensive R&D phase before they can place a product on the market and begin generating revenue. During this phase, companies are generally venture capital (VC) funded. In order to keep attracting VC investment, these businesses need regulatory stability and predictability, and a clear route to market for their products. It is crucial that those companies who have made plans to go to market in the UK, and who have secured investment on that basis, are able to see a clear runway to market. For example, we are aware of several businesses already preparing to make a submission under the new PBO regulatory framework once it opens in November. If there are to be changes to the regulatory regime, these businesses would need ample time to adjust their plans. In order to fully understand the impact of the SPS negotiations on the innovative biotech sector, we urge Government to closely consult with innovative companies throughout the entire negotiation and implementation process.

2. **What opportunities and risks are posed by the introduction of dynamic regulatory alignment with the EU?**

For the life sciences and biotech industry at large, the prospect of an agreement on SPS is welcomed. Regulatory alignment means that goods can flow more easily to and from the UK and the EU. Some of our members have reported challenges with importing animal-derived products under the Border Target Operating Model (BTOM) which set out the UK's approach to security

controls on imports of SPS goods, animal and plant products imported from the EU post Brexit. Entering alignment with the EU would facilitate the import of key reagents which are essential to the running of many biotechnology companies.

However, for some companies working in agricultural biotechnology, the prospect of dynamic alignment with the EU poses a risk, as this may jeopardise the UK's progressive regulatory framework for PBOs. The UK's current PBO regulations are more advanced than the EU's, which do not currently distinguish between genetically modified organisms (GMOs) and PBOs[1].

As we negotiate the SPS agreement, the UK must ensure that precision breeding is carved out as an exception to any dynamic alignment. Maintaining this regulatory framework will deliver clear benefits to the UK, such as:

- Economic benefits of home-grown companies scaling up in the UK.
- Signalling to international players that the UK is a place to do business and bring innovative products to market.
- Maintaining a pro-innovation regulatory framework gives investors the confidence to invest in UK businesses.
- The UK will have access to novel crop varieties which are resistant to pests and disease, resilient to climate change and more beneficial to the environment.
- Giving UK consumers access to new crop varieties with beneficial traits, such as tomatoes biofortified with vitamin D.

If the UK's precision breeding regulatory framework is not preserved, companies will need to go abroad to find a suitable place to bring their products to market, which would have a knock-on effect on both economic growth and our ability to adapt to a changing climate. Plant breeding currently contributes £1 billion in additional value each year to the UK economy and boosts yields by more than 1% per annum. To tackle increasing challenges in our food system and environment, further innovation is required, with precision breeding offering the potential for significant additional gains.

The EU is already following the path set by the UK with trilogue negotiations ongoing to create a new framework, carving out New Genomic Techniques (NGTs) from existing GMO legislation. While it is encouraging to see the EU making progress towards a modernised regulatory framework,

[1] Precision bred organisms (PBOs) are plants or animals where the genetic makeup of the organism has been altered using techniques of modern biotechnology (such as gene editing) in a precise way that could have been achieved through traditional breeding methods. Genetically modified organisms (GMOs) are organisms in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

these developments do not mean that the UK should put the progress made on precision breeding on pause while the EU catches up.

Long-term alignment

With trilogue negotiations still in progress in the EU, the finalised NGT text still needs to be voted on, and implementation could take years. Therefore, it would be untenable for the UK to wait for the EU NGT regulations to come into force.

In addition, there are differences between the EU NGT proposals and the UK PBO regulatory framework, which could further complicate future dynamic alignment. It is currently unclear what the finalised NGT rules will be, as there are several outstanding issues around patenting, traceability and labelling, and risk assessments, that are yet to be resolved. For example, the European Council's initial position included mandatory labelling requirements for certain NGTs. Mandatory labelling was ruled out when the UK PBO regulations were developed, as the UK Government concluded there was no justification for the provision of labelling on grounds of consumer safety.

Given these considerations, the optimal situation would be for the UK's PBO framework to be preserved as an exception to dynamic alignment, while the EU develops its approach to NGTs. Regulatory divergence is beneficial to the UK in the short term: the nascent precision breeding industry needs countries with dynamic regulatory frameworks in order to bring their first products to market. The UK is in a strategically advantageous position to capture the economic benefit of companies relocating to the UK to benefit from our advanced regulatory framework. However, in the long-term, regulatory divergence could place undue burden on companies operating in the UK. Once the EU system is fully operational, having two separate regulatory systems for the EU and the UK would be burdensome for UK companies as they would have to navigate two separate complex regulatory frameworks. Regulatory alignment would open up the European and UK markets, allowing for ease of trade and business in the long term. The UK's long-term aim should be to urge and support the EU to align its NGT regulations with the UK's Precision Breeding framework. The European Commission is currently undergoing preparations of its Biotech Act. The Biotech Act represents an opportunity for the EU to move towards a more favourable regulatory framework towards biotechnology and presents an opportunity to align with the UK. EuropaBio and the European Biosolutions Coalition, our European sister organisations, are in alignment with our position, demonstrating pan-European consensus from industry.

3. **How should traders, producers, businesses and policy makers prepare in sectors where regulatory divergence already exists or may emerge, such as in precision breeding, animal welfare and crop protection?**

It is critical that Government is clear on which areas of regulatory convergence or divergence add value to the UK's business environment. Proper assessment is needed to determine where we should be converging and diverging with EU legislation. This should be done in close consultation with innovators, startups and SMEs via trade associations.

It is clear that the Precision Breeding Act should be preserved. The academic community and the biotech industry welcomed the regulatory progress brought in by the Precision Breeding Act in 2023, and leading scientists are calling for it to be preserved. The UK's science-based, proportionate approach to precision breeding is a global model for enabling safe innovation, and it must not be compromised by the SPS negotiations.

The UK must ensure that any SPS agreement with the EU works for UK industry, not against it. That means safeguarding areas of strategic divergence like precision breeding, while identifying opportunities for convergence where it reduces unnecessary trade friction. Above all, businesses need regulatory clarity, business continuity, and confidence that the UK will be pro-innovation and continue to be led by science and pragmatism.

4. **How should the UK Government engage with industry stakeholders and devolved administrations to ensure the agreement aligns with wider agri-food and environmental goals?**

The Government has set out to support to the UK's burgeoning engineering biology sector, of which precision breeding is a cornerstone technology, due to its potential to deliver 2.32% real GDP growth by 2035. In the Digital and Technologies Sector Plan, the Government celebrates the new regulatory framework created by the Precision Breeding Act, which has positioned the UK at the forefront of the global plant breeding and CRISPR plants sector, which is projected to grow to nearly £11 billion by 2030.

The Sector Plan's goals for engineering biology include accelerating regulatory reform and taking the next step on international leadership by working with trusted partners to shape the global engineering biology research, innovation and business environment to ensure that the UK remains a priority destination for investment. It is clear that maintaining our competitive advantage of a pro-innovation regulatory framework on precision breeding is key to meeting those goals.

Government should therefore engage with innovative biotechnology businesses to understand how the SPS agreement will impact their ability to innovate. Working in partnership with industry is critical to ensuring that the SPS agreement has a positive impact on businesses, and trade associations are an effective way to do this. The BIA is a strong, established, and trusted partner of the UK government, with international links to European trade associations that provide another route for intel gathering and influence in the negotiations.

7. **What impact could the proposed SPS agreement have on upcoming agri-food and environmental strategies, such as the Land Use Framework, Food Strategy, Farming Roadmap, and efforts to improve farming profitability and sustainable growth?**

The proposed SPS agreement could have a significant influence on the UK's ability to harness agri-tech innovation, to deliver both economic and environmental outcomes. Agri-tech has been recognised as a frontier industry in the Modern Industrial Strategy, with precision breeding singled out in the Digital and Technologies Sector Plan as a leading example of engineering biology. Government investment reflects this priority, including up to £15 million over five years for Defra's Genetic Improvement Networks and £12.5 million from a recent Farming Innovation Programme competition focused on precision breeding, within a broader £200 million commitment to 2030. The precision breeding framework is emblematic of the UK's ambition to lead in pro-innovation regulation, as set out in the Regulation Action Plan, which calls for a system that supports growth, is proportionate and predictable, and keeps pace with technological advances. An SPS agreement that facilitates trade while safeguarding this framework would enhance the UK's competitive position. Conversely, if the agreement results in alignment with a more restrictive regime, it would undermine the regulatory agility that has been central to the UK's leadership ambitions in this area.

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