

BIA submission: FSA consultation on precision breeding regulatory framework

Overview

The BioIndustry Association (BIA) is the trade association for the innovative life sciences and biotech industry 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 and connecting the UK ecosystem so that businesses can start, grow and deliver world-changing innovation. BIA is also a member of EuropaBio, the European trade association for biotechnology.

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

We welcome this consultation on the regulatory framework for precision bred organisms. The UK's biotech sector includes emerging companies developing novel foods and feed through the power of biological innovation. The UK's burgeoning field of engineering biology can be empowered by an agile and forward-looking, pro-innovation regulatory ecosystem that enables safe and responsible innovation. It is vital to get the regulatory framework right, to ensure that the UK can remain an attractive place for innovative companies to start-up and grow, and to attract foreign investment and top global talent. Ultimately, this will safeguard the UK as a country in which science and technology can be developed to the benefit of society, the environment and the economy.

Many of our members are small, pre-revenue companies operating at the translation interface between academia and commercialisation. We will therefore only respond to section one of the consultation and include a note on the importance of also including gene edited microorganisms within this important regulatory review.

Note: This response does not need to be confidential.

Section 1

Question 8: To what extent you support the intentions of the precision breeding act, to remove certain products of modern biotechnology from the scope of GM regulations and regulate them in a more proportionate way?

Strongly support.

Question 9: Please explain your reasons for your answer to question 8.

The BIA [supports](#) the intentions of the precision breeding act. Gene editing can help society tackle environmental challenges, and enable the transition to a sustainable bioeconomy. In order to transform and sustainably grow its economy through scientific and technological progress, the UK needs an innovation-friendly regulatory framework that enables the biotechnology industry. Critical to this is having a framework that fosters commercialisation by regulating the product instead of the process of its creation, and the act and this consultation are welcome steps towards that objective.

We welcome the Government's efforts to regulate Precision Bred Organisms (PBOs) in a more proportionate way after the [Advisory Committee on Releases to the Environment \(ACRE\)](#) found that organisms produced by gene editing or another genetic technology would not pose a greater safety risk than a traditionally bred or naturally occurring version of that organism, as a result of how it was produced. The wider GM regulations on the UK's statute are burdensome, ineffective and outdated. By modernising this legislation, and the underlying regulatory framework, the UK will be able to reap the benefits of modern biotechnology, including in the following ways.

1. Economic benefits

Regulating PBOs for food and feed in a proportionate manner will support the UK biotechnology sector and the wide range of businesses that depend on it to succeed and remain competitive in a global economy. Consumers are increasingly demanding sustainable products. Countries with science-led gene editing and GM regulations have been capturing the economic benefits of this demand for many years. For example, the US engineering biology sector, which largely consists of companies working with and developing new gene editing technologies and GMOs, [raised](#) \$10.3 billion in 2022.

When developing a route to market for gene edited food and feed in England, and the UK, the regulatory costs associated with this need to be considered, as (global) companies may not deem the UK a favourable R&D location if regulatory costs are high, the route to market difficult, and export opportunities low. Providing a clear and effective route to market for gene edited products will help the UK attract inward investment from global companies and make the UK a go-to

destination for innovative plant and animal breeding technologies, much in the same way that the UK is a global destination for innovative medical technologies. With its strong science base and thriving biotech ecosystem, the UK is already well-positioned to benefit economically from gene editing technologies. A science-based regulatory approach also enables more engineering biology start-ups to be created, which would further attract investment from global companies and investors, create job opportunities, and support the Government's [National Vision for Engineering Biology](#).

2. Environmental benefits

As climate change escalates, developing new ways of reducing our environmental footprint for a more sustainable society is becoming more pressing. Gene edited crops, animals and novel foods are key to developing a more resilient and sustainable agri-food system. This technology can help us get closer to meeting the United Nations' Sustainable Development Goals (SDGs), and the commitments made at COP28. For example, PBOs can have a huge benefit to the environment by tackling the overuse of chemicals in food production, which has a huge impact on biodiversity. Gene editing allows us to create crops that are resistant to diseases like [blight](#), and [high performing](#) in the face of changing climate conditions. Gene editing can be used [to enhance food security](#) sustainably by improving farming productivity and yields without imposing too much of a burden on the environment. One example of a UK SME working in this space, is Norwich-based SME [Tropic Biosciences](#). They use cutting-edge genetic technologies to develop high-performing commercial varieties of tropical crops which promote cultivation efficiencies, enhance consumer health, and improve sustainable environmental practices.

Regulating the product, not the process

PBOs should be regulated in a way that is proportionate to the level of risk that they pose. It is the final characteristics of an organism which determine whether it presents any safety risks, regardless of the method used to produce that organism. The FSA should therefore take an innovation-friendly, technology agnostic approach when establishing a regulatory framework for PBOs. The UK is already at the forefront of responsible biological innovation, with the recent publication of the [UK Biological Security Strategy](#) and the efforts of the [Biosecurity Leadership Council](#), making us best placed to appropriately evaluate risks and safely place PBOs on the market.

The regulation should move us closer to regulating the product not the process; in other words, organisms should be evaluated based on their traits, and the genetic changes that are responsible for those traits, not the technology used to develop them. Only a proportionate, predictable, fit-for-purpose and science-based approach, providing equal regulatory treatment to equivalent products independent of their production method, will enable us to leverage the full potential of genetic technology to benefit citizens, the economy, and the environment. This approach allows

for more innovative products to reach the market and ensure that the regulation will remain relevant in the future as genetic engineering technologies continue to evolve rapidly.

Lastly, it is important that any regulation is designed with small companies in mind. These companies are leading innovation in the biotech sector, and regulation must not be too burdensome as it otherwise runs the risk of preventing safe, innovative and beneficial products from entering the market. It is also essential to keep in mind ongoing developments to the European regulatory framework. The impacts of regulatory divergence need to be assessed to ensure that the burden on SMEs operating in both the UK and European markets remains manageable. For these reasons it is crucial that SMEs are engaged in the development of the regulatory framework to ensure it is appropriate for them. This consultation is a welcome step, and we strongly encourage continued engagement and testing with the end users of any new regulatory framework.

The inclusion of microorganisms in the regulatory review

Microorganisms are not being considered as part of this consultation based on the recommendation of ACRE to treat them separately from plants and animals. However, we believe that for a cohesive approach to enabling PBOs across sectors, microorganisms should be taken into account in the ongoing regulatory review for plants, food and feed. New regulation for PBOs for food and feed may set the ground for future regulation of precision bred microorganisms. Therefore, advanced knowledge on microorganisms can and should contribute to the wider policy and regulatory developments on precision bred food and feed. This is recognised in the European Union: the [European Commission has mandated the European Food Safety Authority](#) to provide a scientific opinion on new developments in biotechnology applied to microorganisms (expected publication June 2024). The intermediate outcome of this exercise, a horizon scanning on microorganisms and their products obtained by new developments in biotechnology, was [recently published](#).

Genetically improved microorganisms are the key to innovation in industrial biotechnology. They serve as products or as production organisms for fermentation products and are widely used in the manufacturing of everyday products and pharmaceuticals; for instance, enzymes harvested from microorganisms are used in a wide range of applications in the food, feed, biofuel, and detergent industries. This is accomplished using scientific techniques, tools and methods that are constantly evolving. The optimisation of microorganisms used in industrial biotechnology results in both efficiency and sustainability benefits, such as higher yields of the intended molecules (e.g. amino acids, vitamins, or enzymes), elimination of genes that are of potential safety concern, improvements in the utilisation of nutrients and in reducing our ecological footprint.

We therefore urge the Government to take active steps to modernise the regulatory framework for microorganisms in order to enable industrial biotechnology's significant role in the Government's Net Zero agenda and 25 Year Environment Plan, and accommodate for the sector's fast pace of innovation. The regulation should be based on the characteristics of a microorganism rather than on the technologies used to develop it. A product-based, rather than process-based, approach should be the leading principle here as well. This would ensure a science-based, proportionate, and predictable regulatory system that is future-proof, especially in terms of scientific and technological developments, and support the UK industrial biotechnology sector to remain competitive.

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