Written evidence from Food Standards Agency (ENB0015)

Introduction

The Food Standards Agency (FSA) was established by the Food Standards Act 1999, in the wake of the BSE crisis, as a non-ministerial government department and a regulator; created to be at arm's length from Government and independent of sectoral interests. Our primary objective in carrying out our functions, set out in statute, is to protect public health from risks which may arise in connection with the consumption of food (including risks caused by the way in which it is produced or supplied) and otherwise protect the interests of consumers in relation to food and feed[1]. Our statutory functions include developing, or assisting in the development of, policies connected with food safety or other interests of consumers in relation to food, providing advice, information or assistance in respect of such matters to any public authority, carrying out and commissioning research, setting the standards for and monitoring performance of enforcement authorities in enforcing relevant legislation, and providing advice and information to the public. We have many functions across a range of sector-specific and general legislation. So, as well as being a regulator, we act as a policymaker, evidence-generator and watchdog for the food system. The FSA's statutory purpose means that we are focused on ensuring that food and feed is safe and that it is what it says it is.

Food and feed policy is a devolved matter. The FSA is accountable to ministers in England, Wales and Northern Ireland, and we work closely with Food Standards Scotland (FSS). We are governed by an independent Board appointed by ministers in the countries we serve.

Growth and innovation in the food industry is intrinsically linked to food being safe, and consumers having confidence that new foods entering the market have undergone thorough safety assessments. As well as posing risk to consumers, unsafe food would damage trust in UK food and the reputation of technologies associated with it. The FSA's role in conducting independent safety assessments of engineering biology-derived foods is essential to maintain trust in UK food. A fair, robust, and consistent regulatory process ensures consumer and investor confidence in the safety of novel products, and it is in businesses' interests that we maintain the highest food standards.

[1] References to food in this document should generally be taken to cover both food and animal feed.

The FSA's Board's aim is to deliver regulation in a transparent, consistent way that is easily understood by the public, industry, and other key stakeholders to build confidence in the system. It is committed to ensuring that we deliver better and more efficient regulatory services to the benefit of consumers and business.

Given the breadth of food and food-related products that can be included within engineering biology, including innovative biobased food contact materials like packaging, precision fermentation, pre/probiotics found in foods like yoghurt, and cell-cultivated products (a type of food produced by culturing animal cells in a lab rather than raising and slaughtering animals), we believe that engineering biology can play a large role in meeting the increasing demand from government and consumers to foster a food system that is more sustainable and that promotes animal welfare.

We have contributed to the DSIT-led coordinated government department response, including information on the UK's strength in engineering biology, its applications, risks, and economic potential as it relates to food and feed. As an independent regulator, we wanted to highlight the specific regulatory opportunities and challenges that engineering biology presents in the food and feed sector and therefore have confined our individual response to Questions 6 and 7.

6. How should engineering biology be regulated?

Current regulatory approach

The FSA, working jointly with Food Standards Scotland, assesses and authorises all new food and animal feed products entering the GB market. The rules on regulated products, which cover novel foods (including those produced through engineering biology) ensure that any new products undergo a rigorous safety assessment as part of a risk analysis process, before they can be authorised as safe and be sold.

When any new food is brought to market, including those produced through engineering biology, there are always potential risks associated with it. Risk analysis is the process of assessing, managing and communicating food and animal feed safety risks. The risk assessment and product authorisation process is fundamentally the same for foods produced through engineering biology as for any other novel food, with the same core risk areas. However, not all foods produced through engineering biology are the same and will require different levels of work before we are confident in assessing their risk. We must understand the

production methods, ingredients, and hazards involved in food produced through engineering biology to enable us to conduct robust risk analysis and ensure that food remains safe and is what it says it is.

The potential hazards associated with cell-cultivated products (CCPs) provide a good example of the types of hazards or issues relating to consumer interests that engineering-biology derived foods might pose and the steps the FSA and industry should take to mitigate them:

- **Nutritional imbalance**: The assumption often is that cell-cultivated products will offer comparable nutritional quality to traditional meat. If consumers rely solely on this assumption, they may unintentionally adopt diets lacking in vital nutrients. Producers will have to ensure that lab-grown meat products are nutritionally balanced or that they clearly communicate the actual nutritional profile to consumers.

- **Chemical contamination**: The process of growing CCPs in a lab involves the addition of growth promoters or hormones to facilitate cell growth. While efforts may be made to minimise residues, traces of these chemicals could remain in the final product. A better understanding of the level of this exposure and the potential consequences will be vital to consumer safety.

- **Allergy concerns**: CCP production involves growing animal cells in an artificial environment, which may result in differences in allergen profiles compared to traditional meat. For instance, the use of scaffolds for cell growth could introduce unexpected allergens. Producers must conduct thorough allergen testing and there will need to be effective mitigation such as labelling to protect consumer.

- **Microbiological hazards**: CCPs, lacking the natural immune defences of animals, are susceptible to contamination by microorganisms. We will need to assess the hygiene practices and quality control measures in place for preventing microbial contamination for confidence in the safety of the final product. This includes monitoring for traditional foodborne pathogens as well emerging threats from the production process such as mycoplasma and foodborne viruses.

- **Traceability and cross-contamination**: The unique nature of CCP production poses challenges for traceability and verification of product authenticity. Establishing robust traceability systems and implementing effective measures to prevent cross-contamination are critical for ensuring consumer confidence and regulatory compliance. We will have to assess the steps put in place in supply

chain management and verification processes to address these concerns.

The FSA's plans for regulatory reform

Our risk analysis and authorisation procedures ensure high standards and safety for consumers. We have identified potential to streamline our regulatory process further and are in the process of reforming our regulated products service so that safe, innovative products can come to market more quickly. This includes products created through engineering biology and those with the potential to bring health and environmental benefits.

The regulatory framework for novel foods in Great Britain today is based on the EU system that became part of UK law in 2020. It was designed so that all EU member states - with their collective resources and expertise - agreed to regulatory authorisations together, without a focus on the future UK food system.

We now have the opportunity to develop and tailor the framework for the UK. The legislative requirements that we inherited from the EU are highly prescriptive and, in some cases, not proportionate to the risk. For example, the EU regulations mandate that certain products that have received regulatory approval must undergo a separate 'reauthorisation' every ten years. We believe that this step is not proportionate to the potential risks and wish to remove this as part of our intention to overhaul the regulated products process. Our system for pre-market authorisation is complex, and not sufficiently flexible or future-proofed to respond to a changing food system. The system, and the legislation underpinning it, was designed to regulate a food landscape that has since evolved substantially.

Novel technologies are challenging conventional understanding about food and food regulation. Many of the technologies are being pioneered by smaller 'start-up' companies that do not have the resources to thoroughly assess legislation and have little experience in engaging with regulators. Without reform, the system risks hindering innovation, limiting consumer choice, and pushing UK businesses abroad. The new food technologies produced by engineering biology highlight the need for a reformed regulatory system that is more efficient and proportionate in regulating foods of the future – such as those derived from engineering biology - whilst maintaining our current high levels of food safety.

We recognise the challenges with the current system, with the journey to authorisation taking an average of two and a half years, depending on the complexity and quality of the application. There can be uncertainty for applicants and delays, particularly when it is not clear how existing regulations and guidance applies to their products. The more novel the production techniques and ingredients, the more time assessing and devising ways of mitigating risks will take. We want to improve upon this and are therefore planning to overhaul our regulated products process, to deliver significant improvements on the current model, giving us a regulatory framework (including for products created using novel foods and biobased food contact materials) that will encourage innovation and help make the UK a more attractive place to develop and market novel foods.

We have already started consultation on two initial reforms: removing the requirement to reauthorise certain regulated products every ten years and removing the requirement to lay legislation to authorise regulated products. The FSA Board will consider other proposals at its meeting in June, the proceedings of which will be publicly available. Through these reforms, the FSA will provide greater clarity to companies that are producing engineering biology products about how their products will be regulated, allowing them to foster confidence among their investors. We will work across government and with all relevant regulatory bodies to ensure that the UK's regulatory landscape will help engineering biology-derived products to reach the market.

7. What are the possible barriers and limitations to good and effective use of engineering biology?

We have focused our answer to this question on addressing the specific regulatory challenges that could impede the good and effective use of engineering biology, conscious that DSIT are addressing other challenges in the cross-government response they are coordinating.

A lack of regulatory knowledge around food companies that make use of engineering biology in their products means they can face uncertainty about how the FSA regulates the safety of their products, leading to delays, increased costs, and difficulty in attracting investment. If the FSA does not have a clear understanding of the production methods, ingredients and processes used to produce these products, it affects our ability to make efficient regulatory decisions including the expertise needed to make a robust risk assessment. There are also significant policy issues that must be addressed before products can be placed on

the market, including which regulatory regimes they should be assessed under and how they should be labelled. We also will need to hire staff with suitable expertise to assess novel technologies, including toxicologists and cell biologists. To help work on these issues for CCP in particular, the FSA has applied for sandbox funding from DSIT to work with the industry and academia to agree on how the FSA can ensure consumer safety, provide extensive support to companies to navigate the regulatory system, and solve the policy questions that would enable CCP food to enter the GB market.

We are also very concerned about the resourcing pressures that local authorities are currently facing and their capacity and capability to deliver official controls[2], which include the enforcement of regulated products on the market. In 'Our Food 2022', the FSA and FSS independent review of food standards across the UK, we highlight a 14% decrease in Environmental Health Officers (EHO) 2010/11 and a 45% decrease in Trading Standards Officers (TSO) since 2011/12.[3] Without enough people with the right skills to deliver essential food controls, it will be more difficult to identify, monitor and respond to risks to food safety, leaving consumers and businesses vulnerable. Considering the scientific expertise that may be required to enforce controls about engineering biology-derived foods, the FSA will need to consider whether the existing enforcement model will be fit for purpose for these products.

07 May 2024

[2] Local Authority and Capacity and Capability research (food.gov.uk)
[3] Our Food 2022: Keeping it clean | Food Standards Agency