Market Authorisation Service: Progress Report

FSA 24/12/06 - Report by Rebecca Sudworth, Director of Policy.

1 Introduction

1.1 In June 2024, we presented to the FSA Board our assessment of the market authorisation process and our early thinking on reforms and potential improvements.

1.2 This paper presents the following:

- The context underpinning our proposals
- A progress report on our reforms and improvements to the market authorisation process
- An update on the recently announced Regulatory Sandbox for Cell Cultivated Products (CCPs)
- Next steps for reform of market authorisations

1.3 We ask the Board to:

- **Note** the progress on our reform work and the Regulatory Sandbox
- **Agree** to our next steps

2 Context

2.1 The FSA has been running the process to make recommendations to ministers in England and Wales for granting market authorisations for certain food and feed products since January 2021. We have worked collaboratively with Food Standards Scotland (FSS), who have responsibility in Scotland.

2.2 Our priority is to protect public health and the interests of consumers by enabling timely access to safe new food and feed products. To do this, we must have a service in which consumers, businesses and investors have confidence, ensuring that food is safe, whilst supporting economic growth and innovation.

2.3 We have continued developing and implementing reforms and process improvements since the Board meeting in June. In the Chief Executive's Report to the September Board, we provided a brief progress update.

2.4 We believe that these reforms can help support the UK government mission to kickstart economic growth, making the UK an attractive place for investment, and on manifesto

commitments to facilitate innovation, update regulation and speed up approval timelines.

3 Progress on priority reforms and continuous improvements to the Market Authorisation Service

3.1 Delivery of the two proposals, previously identified as critical to making the authorisation process more efficient and fit for purpose, is underway:

- Replacing requirements that three regulated product regimes (feed additives, smoke flavourings and genetically modified organisms for food and feed) renew their authorisations every 10 years with a more proportionate and consistent approach, where action can be taken at any time if evidence suggests there is a safety concern;

- Allowing authorisations to come into effect following ministerial decision and then be published in an official public register or list, rather than by statutory instrument.

3.2 These proposals were agreed by the Board in early 2024, and we have since secured agreement from new ministers. The FSA and FSS's response to the public consultation on the proposals has been published.

3.3 The consultation informed the draft legislation, and we re-entered the parliamentary process in September. Pending the necessary consents, including from Welsh and Scottish ministers, we intend to introduce legislation on 29 January 2025. The legislation will then need to be debated and agreed in both Houses of the UK Parliament before it becomes law. If agreed, we intend that changes would be brought into force on 1 April 2025. This will enable the fourth tranche of authorisations scheduled for 2025 to benefit from the streamlined process.

3.4 We have also been preparing for implementation of these reforms. Online registers or lists of authorised products, and guidance, will be ready for each affected regime.

3.5 As well as these legislative reforms, we have continued to make improvements to the service this year. These include addressing the growing caseload and delivery challenges by actively managing the caseload, pausing around 30% of the total applications in the service. This is predominantly in anticipation of the legislative reform where products can safely and lawfully remain on the market or where we are waiting for further information from applicants in order to progress their application. This means we can focus our resources on active applications, achieving better outcomes in the public interest.

3.6 We have launched a new register on the FSA website which provides information about the progress of applications being considered by the service. Previously, the register was a basic spreadsheet on our website which was difficult to use; our upgraded approach enables applicants and other stakeholders to more easily check the status of applications and provides links to relevant published information such as safety assessments and any consultations. This will contribute to reducing queries to the service.

3.7 We have increased our stakeholder engagement and published the first market authorisation newsletter, which was circulated to almost 500 stakeholders. These regular communications provide increased transparency for the service, with updates on new entries to the register of regulated product applications, newly published safety assessments, consultations and authorisations. This will help applicants and stakeholders better understand the system and keep them informed of significant developments; again, this may reduce queries into the FSA and help less experienced applicants and sectors understand the requirements.

3.8 We have adopted a firmer approach when setting deadlines requesting further information from applicants. This ensures we manage applicant expectations and advise them of the consequences if deadlines are not met, particularly where there are lengthy delays in providing relevant information. This approach, alongside improved guidance, has resulted in 21 incomplete applications being removed from the service since April 2024, when we implemented these changes.

3.9 We have extended the use of other regulators' risk assessments to supplement our own opinions, within the legislative requirements for safety assessments. While previously used for renewal applications, new novel food and feed additive applications are now included. Since November 2023, we have assessed 17 routine applications through this route, and we have identified a further 15 to complete by end of March 2025. This saves significant time and resource, reducing safety assessment time from over 6 months (including progressing through the Scientific Advisory Committee assurance process) to around 6 weeks.

4 Cell-Cultivated Product (CCP) Regulatory Sandbox

4.1 Sandboxes are programmes that facilitate extensive dialogue between industry and a regulator to inform regulatory actions that strike the right balance between facilitating regulatory innovation and mitigating risk.

4.2 The FSA was awarded £1.6m from the Department of Science, Innovation and Technology's (DSIT) Engineering Biology Sandbox Fund to run a Regulatory Sandbox on CCPs. The FSA will run it in partnership with FSS between February 2025 and February 2027, operating across the four nations of the UK.

4.3 We ask the Board to note this funding and the planned start in February 2025.

What are CCPs?

4.4 CCPs are products produced by isolating cells from animals or plants, replicating them in a controlled environment, and then harvesting them to make a final food product. The FSA has received 4 CCP applications, all of which are in the validation stage. Based on discussions with potential applicants and market intelligence, we expect to receive up to 15 applications by late 2026.

4.5 CCPs are a completely new technology, and their potential safety risks are not yet well understood, meaning assessing them will take longer than more routine products. We require more knowledge on their production to make informed regulatory decisions, and there are complex regulatory questions that we must address before products can enter the market.

What will the sandbox do?

4.6 The programme team will work with a small number of CCP companies and academic participants to:

- **Test, create and run a new pre-application support service**: tailoring support for individual CCP companies to reduce delays, resolve key questions, and ensure high-quality dossiers.

- **Agree on food safety considerations**: working with sandbox participants to identify common safety hazards and tests that companies should conduct to generate data to prove hazard mitigation. We will also form a sub-committee of the Advisory Committee on Novel

Foods and Processes (ACNFP) with expertise on this technology.

- **Address essential policy questions across the four nations** that must be answered before CCPs go to market. Part of this will be to decide what information consumers will require about CCPs, including any labelling requirements.

4.7 The aim of the sandbox is to put in place the conditions so that CCP applications will be assessed within the same timeframes as routine applications. Without the additional resources, policy positions and new ways of working tested in the sandbox, we expect that CCP applications will take longer. The key outputs of the sandbox will be:

- **Published guidance for industry** outlining the safety hazards associated with CCP production and the minimum levels of tests companies should conduct to mitigate hazards. Topics will include nutritional detriment, chemical contamination, allergy, and microbiological hazards.

- **Published positions on key policy and regulatory questions,** including labelling and consumer information and requirements and responsibilities for regulation of CCP production, including cell biopsies and hygiene inspections.

- **At least two applications having undergone risk assessment** with opinions published by the ACNFP.

4.8 Lessons learned from the sandbox will also be applied to other market authorisation regimes as relevant.

5 Next steps for reform of Market Authorisations

5.1 We set out our vision for the future of the service in the June 2024 Board paper. Since then, the new UK Government has set out its priorities. We are conscious that any future SPS agreement with the EU, which was a manifesto commitment of this Government, will shape the operating context for longer term reform. At this stage, our focus is therefore on delivery of our priority reforms, with implementation planned for April 2025, and on setting up the sandbox programme, including onboarding industry and academic participants and recruiting policy and science staff, in preparation for programme start in February 2025.

5.2 Removing the need for renewals and SIs from the authorisation process will make a significant reduction in authorisation timelines, although there is more to be done. The development of the priority reforms has taken hundreds of hours of legal drafting time, plus additional policy resource, to make the required changes. For the next stage of reforms post April, we are narrowing the scope of the vision set out in our June 2024 Board paper to prioritise those changes that will speed up approval timelines significantly, without compromising safety, transparency and accountability. We will explore further changes to reduce delays to the authorisation process, for example by reviewing roles and responsibilities between the FSA and ministers, where (as a result of assimilated EU legislation) differences between EU and UK functions have resulted in additional inefficiencies and bureaucracy for the service.

5.3 The powers we are using to deliver our priority reforms expire in June 2026. These powers provide an opportunity to bring forward further legislative changes in the next 12 months. Bringing forward legislative change across more than 12 separate regulations is

complex and these powers provide the most efficient use of resource, ensuring timely delivery of future reforms. Presuming these powers are not extended, we will need to deliver the changes we have identified at pace during 2025, to bring them into force by May 2026. This means we would need to consult on our proposed changes in Summer 2025.

5.4 We will also continue to enhance our pre-application support offer. Improving pre-application support can make a significant difference for applicants. By developing our support for applicants to provide better quality information, the number of applications successfully validated will increase. This directly benefits applicants and allows the FSA to focus on the delivery of authorisations rather than resolving avoidable problems with dossiers. In Q4 2024/25, we will focus on reviewing public content on the FSA website to make it easier to use and more relevant, including updates to reflect ongoing improvements and reforms to the process.

6 Conclusion

6.1 We will provide a further update on progress in March 2025.

6.2 We ask the Board to:

- **Note** the progress on our reform work and the Regulatory Sandbox
- **Agree** to our next steps