

Market Authorisations - Prioritisation

CLO 25/12/01 - Report by Rebecca Sudworth

1. Summary

1.1 This paper sets out a potential approach (subject to Ministerial agreement) for the FSA to make prioritisation decisions within the market authorisation service over the coming year, in the light of work on a Sanitary/Phytosanitary (SPS) agreement. We propose a set of prioritisation principles which will protect public health, support government growth priorities, and maximise the benefits of the separate funding currently in place from the Department of Science, Innovation and Technology (DSIT).

1.2 The rationale for this approach is twofold:

1) the value of avoiding nugatory work for applicants and for the FSA/Food Standards Scotland (FSS) as we anticipate dynamically aligning with EU decisions once the SPS agreement enters into force, and

2) the limited resource available, given staff are needed to work on preparations for the planned SPS agreement with the EU.

1.3 If this approach is agreed, we should communicate it publicly to give businesses more clarity about the status of their applications and enable them to plan for the likely changes in the operating context.

1.4 Because food and feed safety and standards are devolved matters, it would be necessary to seek the agreement of Ministers in Wales and Scotland who also have legal responsibilities for delivering this service.

2. Introduction

2.1 The Board is asked to **agree** to the prioritisation principles set out in paragraph 3.11.

3. Evidence and Discussion

3.1 Under dynamic alignment of SPS rules, EU market authorisations would apply in GB. This means that businesses would no longer apply to the FSA for authorisation and would apply to the EU instead. There will no longer be a need for the FSA's market authorisation service, unless any exceptions are agreed to dynamic alignment in areas covered by the service.

3.2 Until the legislation underpinning the SPS agreement is in place, we have ongoing legal obligations to receive and process applications in a timely manner, and the FSA continues to run a market authorisation service. However, a substantial number of applications in the service are unlikely to progress beyond the early stages before the agreement is in place, and even fewer are likely to progress to authorisation. We have therefore been thinking about what messages we

need to give to applicants and how best to prioritise the queue in these new circumstances.

3.3 While we have been engaging with trade associations to get a sense of their understanding of the potential agreement and its implications, we have not made any announcements about handling of existing applications already progressing through the service or given any guidance to those planning to apply. We have been clear in stakeholder briefings and in public discussion at our Board and at a recent EFRA committee hearing that, without additional resources for SPS work, our capacity to process market authorisations is severely limited and progress will slow substantially.

3.4 As of 30 October 2025, the current market authorisation caseload stands at 415 applications. To date, ten applications have been authorised in 2025/26, bringing the total authorised to 101 since we took on the service following EU Exit. The table below gives further information on the current caseload.

Phase	Average time taken (based on those completed to date)	Total number of applications in the service
Pre-Validation (including administrative checks and suitability)	6 months	157
Risk Assessment	8 months	146
Risk Management, Consultation and Authorisation	12 months	112
Total	2 years 2 months	415

3.5 The FSA already prioritises certain applications in the service, and plans workflow to ensure efficient delivery, for example, batching applications by regime. Work may be prioritised where there is new evidence about the safety of products already authorised, or where a more rapid authorisation is required on animal welfare grounds. Some of our work is currently separately funded by DSIT in line with wider Government priorities to support economic growth through safe innovation via a Sandbox and an Innovation Research Programme. These projects are already underway and, in line with the delivery agreements already in place, products in scope are progressing more quickly through the service – but potentially could go even faster, and more innovative products could make progress, if we chose to explicitly prioritise these applications.

3.6 On average, it takes over two years for an application to be processed through the service (excluding periods of time waiting for applicants to respond to requests for information). It is likely that only those applications well advanced in the final stages of the process would be able to be authorised before the introduction of legislation to align with the EU, based on the government's stated ambition to conclude the agreement in 2027.

3.7 As implementation of the SPS agreement approaches there will – unless negotiations collapse - be a diminishing benefit for both applicants and the FSA, both in progressing applications through the earlier stages of the process and authorising further products (unless there are cases where we agree that products on the market can remain in circulation in the long-term). Continuing to run a full service will require significant nugatory work for applicants (some of which are likely to gain greater benefit from focussing on gaining approval in the EU, particularly if they have only applied in GB) and for the FSA/FSS (where resource could be better focussed on planning and preparing for the SPS agreement).

3.8 However, there could be benefits to applicants in making progress through the service prior to any SPS agreement. For example, any authorisations made in 2026 could give some time on the market, depending on any transitional arrangements. For some products, a positive risk assessment from the FSA may also have some value in signalling to other regulators that a product is safe. Where a product is already authorised in the EU, an identical GB authorisation brings forward the opportunity to align across markets before an SPS agreement comes into effect.

3.9 Without action, the current situation will continue: resource pressures on the FSA/FSS will increase, progress on authorisations will continue to slow, nugatory work will increase, and businesses will continue to seek clarity.

3.10 We propose to change our approach to prioritisation of the queue in the light of the new context, with public communications to businesses that we will be doing this. We propose to set out principles to inform our prioritisation.

3.11 Our proposed principles are:

1) We will **continue to put consumer safety first**, prioritising work where there is a potential food or feed safety risk, which need to be addressed through decisions by the FSA as part of our authorisation process. Work may be prioritised where there is new evidence about the safety of products already authorised, or where a more rapid authorisation is required on animal welfare grounds. This includes cases in which we might need to withdraw authorisations due to food or feed safety risks. It could also include decisions where we are seeking to bring an existing market into compliance and provide safe options for consumers (such as for CBD, where we will provide further advice to the Board at a later date after considering the outcome of the consultation).

2) **We will prioritise work on applications which are within government priority sectors for innovation and growth.** We assume these three areas are Cell Cultivated Products (CCP), precision fermentation and precision breeding, given we have been given ring-fenced funding on the first two and government has just legislated on the third. The service for precision bred products opened on 13 November 2025, and there are currently no applications in the FSA's service.

3) **We will continue work on products very near the end of the process**, particularly those on which we have already consulted publicly. This means that, on current plans, we will continue work on the three CBD frontrunners (we have consulted on these in England and Wales, but a consultation has not yet been launched in Scotland so it will be some months before we are in a position to make recommendations to ministers across the three nations).

3.12 The resourcing situation and the anticipated short time before an SPS agreement mean that in practice applications which do not fall within these priorities are unlikely to progress through the queue.

3.13 This approach would need to be discussed and agreed with Ministers in DHSC and in the devolved nations (who are the appropriate authority responsible for deciding whether any particular product gets authorised), and Cabinet Office will need to clear the approach to communications and any lines to take, particularly given the interactions with negotiations.

3.14 If Board members are content with this proposed direction of travel, we will next prepare letters for the FSA Chair to send to Ministers in England and Wales seeking support for this approach and asking them to confirm priorities for innovation and growth. The FSA and FSS Chairs can discuss the matter with a view to FSS approaching Scottish Ministers in parallel. If Ministers also sign up to this approach, we will then engage with the Cabinet Office to discuss the prospect of public communication of the FSA's reprioritised caseload of market authorisations.

4. Conclusions

4.1 The Board is asked to AGREE to the prioritisation principles set out in paragraph 3.11.