SPS Agreement - Impact on Market Authorisation of Regulated Products

1 Purpose of the paper

1.1 This paper provides an update on delivery of the Market Authorisation of regulated products service and seeks decisions from the Board on two points relating to the likely impact of the Sanitary and Phytosanitary (SPS) Agreement.

1.2 While SPS negotiations remain underway, there remains a degree of uncertainty around the implications for the delivery of the service and what transition and implementation will look like ahead of an SPS Agreement coming into effect.

1.3 The Board is therefore asked to:

- **Discuss and provide a view** on early alignment and if the Board agrees with the recommendation to explore the principle of early access to EU market authorisations, if possible.
- **Discuss and provide a view** on the proposed approach to a review of application prioritisation within the Market Authorisation service once an SPS Agreement is reached.

2 Strategic priorities

2.1 This paper and the work of SPS and Market Authorisations supports delivery of all three strategic priorities with a focus on ensuring public health protection and evolving and reforming the regulatory landscape.

3 Background

3.1 In December 2025, the FSS and Food Standards Agency (FSA) Boards discussed and agreed prioritisation principles for the Market Authorisation of regulated products service, recognising the likely impacts of the SPS Agreement. Health Ministers in Scotland England and Wales agreed to the approach which continues to protect public health while continuing to work with the FSA on applications where ring-fenced funding from the UKG, via the FSA, has been provided to support sectors working on innovation and growth in the food sector.

3.2 While SPS negotiations remain underway, FSS and the FSA has continued to progress market authorisations in accordance with these prioritisation principles.

3.3 As part of UK Government led SPS stakeholder engagement events the FSA (with input where relevant from FSS) has contributed to Defra-led stakeholder engagement activity as well as continuing its own programme of stakeholder engagement since March, some of which have seen direct FSS involvement given

our joint responsibility to deliver Market Authorisations in Great Britain (GB). This has included:

- Issuing over 600 tailored letters to market authorisation applicants, GB authorisation holders, and trade associations to set out the potential implications of an SPS Agreement and to explain how the service intend to manage the caseload of applications for the market authorisation of regulated food and feed products prior to implementation of the Agreement, along with running a series of drop-in sessions for applicants;

- Publication of a special edition of the Market Authorisation newsletter in March 2026, distributed to over 1500 recipients and;

- Participating in a second series of roundtables held in May – meeting a total 71 stakeholders – focussed on market authorisations, food safety, hygiene and contaminants, and meat and products from animal origin. A tailored session was also provided for the cannabidiol (CBD) sector.

3.4 During the roundtables, we heard from industry stakeholders on the need for sufficient transition periods, phased implementation and sell-through arrangements. The strong message from many trade bodies and businesses has been that they will need at least a year between the summit and the entry into force of any agreement, to prepare for implementation. We have also been told that early alignment with the EU in some areas could support readiness and help facilitate preparations for future arrangements. In particular, we have heard that early access for GB business to products which have EU market authorisations could support business readiness. This idea is discussed in more detail below.

4 Discussion

4.1 Currently, businesses can only lawfully place regulated products (food additives, feed additives, food contact materials etc) on the GB market if they have a market authorisation from Ministers, following a safety assessment and advice from FSS or the FSA. In Northern Ireland, under the terms of the Windsor Framework, products can only be lawfully placed on the market if they have an authorisation from the EU.

4.2 In GB, a very similar authorisation process to the EU (set out in assimilated law) is applied and in practice, many products are already authorised in both jurisdictions. However, there has been divergence following independent science and evidence-based risk analysis. Some divergence has been EU-led, for example titanium dioxide is no longer authorised as a food additive in the EU, permitted levels of nitrites and nitrates have been reduced in EU authorisations, substances such as Bisphenol-A have been restricted and the EU recently introduced a new authorisation regime for recycled plastics in food contact materials. There has also been GB-led divergence, for example certain feed additives are permitted for use in a broader range of animal species in GB, certain novel foods have been approved to different conditions of use, and GB has removed the requirement for periodic renewals of market authorisations for three regulated product regimes in GB. We

may continue to diverge from the EU as further authorisation decisions are taken in GB; for example the CBD products discussed in [cross ref to CBD paper when published] are not authorised in the EU. Even where the same products are authorised in both jurisdictions, the terms of authorisation may differ.

4.3 The plans for dynamic alignment under the SPS Agreement mean that from the date the Agreement comes into force, all the GB authorisations cease to apply (subject to any exceptions that may be negotiated), and businesses would require an EU authorisation to place regulated products on the market in GB. This has significant implications for businesses who hold, or have applied for, GB authorisations, as well as for the wider food and feed sector. Until the final Agreement is reached and announced, we cannot know exactly the final detail of the Agreement, but in the meantime FSS and the FSA has written to every market authorisation holder and applicant as set out in para 3.3 to explain this position.

4.4 Against this background, this paper seeks views from the Board on two specific issues relating to transition and implementation for market authorisations; early alignment and prioritisation of the caseload. A similar paper is being presented to the FSA Board in tandem given the joint nature in which the GB market authorisation service is delivered.

Early alignment

4.5 As noted above, the case for early alignment with the EU on market authorisation was made strongly by some parts of the food industry. In particular, we have heard from food and feed manufacturers and trade bodies that early access for GB businesses to products which have EU market authorisations could support business readiness. It would enable them to begin reformulating products, switching packaging etc ahead of entry into force of the agreement.

4.6 In principle, FSS and the FSA do not foresee food safety issues with permitting use of EU-authorised products as well as GB-authorised products ahead of the date when the agreement enters into force. Products authorised by the EU have undergone a rigorous safety assessment very similar to that applied in GB, they are already permitted to be sold in Northern Ireland, and they would automatically become lawful in GB when the Agreement comes into force. However, FSS and the FSA does not have the power to permit businesses to use these products under the current law. Allowing early access to EU market authorisations would therefore require legislation.

4.7 The UK Government has said that following the SPS agreement, it will introduce legislation to give effect to the agreement, including taking swift action in these areas. Both FSS and the FSA see a case for recommending to Ministers that as part of the implementation process, we should explore the principle of early access to EU market authorisations if possible.

Prioritisation of the Market Authorisation service

4.8 There are around 390 applications currently in the GB Market Authorisations service, and on average it takes over two years for an application to reach authorisation. As noted in para 3.1 the FSS and FSA Boards agreed to a set of prioritisation principles for the service recognising the impact a likely SPS Agreement would have on delivering market authorisations. Whilst negotiations remain underway, the GB service has continued to make steady progress on applications in accordance with those agreed principles (which amount to just under a quarter of the caseload). Working within a constrained resource environment, particularly across FSS policy and legal capacity, the service has focussed its efforts on progressing priority applications to completion (authorisation, invalidation or withdrawal) according to our plans.

4.9 Since January 2026, we have completed 53 applications. Of these, the following have been publicly consulted on and authorised by Ministers:

- 5 full novel food applications (4 of which are Precision Fermentation (PF) applications)
- 1 novel food (traditional food notification)
- 1 food additive

4.10 The service has completed one Novel Food Status application (determination of novel food status), and following extensive engagement, concluded work on 15 CBD applications. An additional 30 applications have exited the service via invalidation and withdrawal routes, including 2 closed renewal applications (as of 31 July 2026). The service has also continued to work on safety assessments, with 19 published since January. Over the last quarter, progress has been made resolving complex policy issues that were necessary to unlock consultation and recommendation stages, while continuing to develop policy solutions in more challenging areas for innovative products.

4.11 The service has progressed 3 CBD applications to the final stages of risk management, and a further group of 10 CBD applications are also in the risk management stage. We are currently consulting on a Traditional Novel Food and are preparing to consult on our next batch of PF applications.

4.12 We recognise that the prioritisation of applications within the Service in the context of an SPS Agreement has been concerning to some applicants, particularly those who have applications that are unlikely to progress to the point of Ministerial decision before the Agreement is in place. We also recognise the impacts that the extended uncertainty may have had, following recent delays to the UK/EU Summit.

Negotiations with the EU are at an advanced stage and will conclude as soon as possible.

4.13 We recognise how significant any arrangements for early alignment would be for many applicants within the service, as we estimate nearly half of the applications relate to products already approved in the EU.

4.14 Both Boards agreed that the prioritisation principles should remain under active review as SPS negotiations progressed. There are several factors that may affect prioritisation, including:

- Clarity about the detail of the final agreement (including whether there are any exceptions to dynamic alignment in areas covered by the Market Authorisation service);
- Any change in the implementation timelines that would substantially alter assumptions about how many applications could be progressed through the service before the Agreement comes into force; and
- Any decisions about enabling access to EU authorisations through legislative change.

4.15 At this stage, there has not been a significant change in the assumptions under which the prioritisation was carried out. However, we should know more about all these factors during the course of the autumn. We recommend that, once an agreement is reached, officials across FSS and the FSA carry out a very rapid review of the prioritisation principles and return to our respective Boards with advice on whether any change in approach is warranted.

5 Identification of risks and issues

5.1 The Board's current risk appetite is already reflected in the prioritisation principles agreed in December 2025 and would be used to inform any rapid review in the future, should it be required.

5.2 With regards to the concept of early alignment, given FSS/Scottish Ministers have no powers to allow for the use of products authorised in the EU in advance of any SPS Agreement coming into force, it is clear that the Board's averse risk appetite when it comes to matters that fall short of legal requirements is relevant and will guide officials exploring this legislative option. Recognising the business benefit to any early alignment is also cognisant of the Board's desire to be open to policy approaches that are evidence-based, with the potential to produce the best outcomes in Scottish-specific circumstances.

5.3 Delivering authorisations on a GB basis alongside the FSA, within the refined scope covered by the prioritisation principles remains a challenge in FSS due to ongoing resource pressures, conflicting priorities, and staff capacity in both policy and legal. Given the current volume of work, the prospect of increased SPS activity

such as any legislative tasks associated with early alignment, will only add to that pressure. Due to the current pressure on the team, and without an injection of resource (and subsequent time to get up to speed) we have already had to pause policy support on business as usual activities however officials are also reviewing where we can adapt our approach and involvement in GB authorisations to mitigate any risks and delays when it comes to delivering the forward plan of authorisations.

5.4 As both FSS and FSA Boards are considering the joint advice of officials concurrently, there is a risk that both Boards have divergent views around recommendations made within respective papers. Should that occur, officials will work with FSA counterparts to understand those views and will return to the Board with any additional advice, as required.

5.5 There is a risk that continuing to resource the existing Market Authorisation caseload during the transition could displace other FSS priorities, particularly where some GB authorisations may subsequently cease to have effect following implementation of the SPS Agreement. This will require active prioritisation as negotiations progress and the future regulatory framework becomes clearer

6 Equality Impact Assessment and Fairer Scotland Duty

6.1 The need to complete an Equality Impact Assessment (EQIA) and consideration of the Fairer Scotland Duty is not applicable at this stage given the paper is seeking views from the Board.

7 Consumer Duty

7.1 Not applicable.

8 Conclusion/Recommendations

8.1 FSS recognise the potential benefits that early alignment for market authorisations could bring for business readiness. Subject to the outcome of negotiations and Ministerial decisions on potential legislative approaches, it is recommended that FSS officials continue to work with counterparts in the FSA to explore the principle of early alignment.

8.2 Given the evolving context and uncertainty around the final details, timing and implementation arrangements of the SPS Agreement, it is also recommended that FSS officials, working alongside the FSA as part of the GB Market Authorisation Service, should undertake a rapid review of the prioritisation approach once the final SPS Agreement is reached and details are known.

8.3 The Board is asked to:

- **Discuss and provide a view** on early alignment and if the Board agrees with the recommendation to explore the principle of early access to EU market authorisations, if possible.

- **Discuss and provide a view** on the proposed approach to a review of application prioritisation within the Market Authorisation service once an SPS Agreement is reached.

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Annex A

Current Prioritisation Principles

- 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 taken as part of the 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).

- We will continue to work with the FSA on applications where ring-fenced funding, from UKG via the FSA, has been provided to support sectors working on innovation and growth in the food sector. We assume these to be Cell Cultivated Products (CCP) and precision fermentation. FSA will also look to prioritise precision breeding applications, as this service was stood up in November, following legislation coming into effect in England.

- We will continue work on products very near the end of the process, particularly those on which we have already consulted on publicly. This means that, on current plans, we will continue work on three CBD frontrunners.