Market Authorisations Modernisation

1 Purpose of the paper

1.1 This paper is for discussion and decision.

1.2 This paper sets out FSS' proposals for further reforms to the market authorisation service for regulated food and feed products.

1.3 The Board is asked to:

- **discuss and provisionally agree** to the proposals outlined in section 4.1 – 4.14 (**noting** that further changes may be needed), and the recommended delivery timetable set out in section 5.1.

2 Strategic aims

2.1 This work supports FSS Strategic Outcome 1 – Food is Safe and Authentic and 5 – FSS is trusted and influential.

3 Background

3.1 FSS is working with the Food Standards Agency (FSS) to modernise the market authorisation process. Our initial set of legislative reforms to the service came into force on 1 April 2025 through a GB wide statutory instrument (SI), the Food and Feed (Regulated Products) (Amendment, Revocation, Consequential and Transitional Provision) Regulations 2025. This SI removed requirements for the periodic renewal of authorisations that existed for feed additives, smoke flavourings and food or feed containing, consisting of or produced from genetically modified organisms (GMOs); and removed the requirement for authorisations to be prescribed by statutory instruments, enabling authorisations to come into effect following a ministerial decision based on FSS/FSA risk assessment advice and subsequent publication in an official register/list.

3.2 Following our update to the Board in December 2024, we have further developed proposals to streamline the market authorisation service, without compromising the safety of food and animal feed.

3.3 These reform proposals were developed with awareness that the UK Government had set out its ambition to negotiate a Sanitary and Phytosanitary (SPS) agreement with the EU, and with the intention to be as future proofed as possible. However, following the UK-EU Leaders' Summit on 19 May, the UK and EU have published a document which sets out their common understanding of work towards a common SPS area. This document confirmed that future negotiations on an SPS agreement will follow a model of dynamic alignment with EU law in SPS policy areas, with a short list of limited exceptions to be agreed based on specified criteria. The outcome of these negotiations will clearly have a bearing on the future of the

market authorisation service and the scope for reform, and we may need to flex these proposals when that outcome is clear. However, at this stage, we seek the Board's agreement in principle to the reforms set out in this paper, on the understanding that further changes may be needed as a result of SPS negotiations.

4 Discussion

Proposals

4.1 These proposals will reduce administrative burdens within the current authorisation process and strengthen our legal framework where existing regulations are unclear or unworkable. This will be achieved without compromising consumer safety. There are five reforms proposed:

- Reviewing the decision-making process
- Clarifying roles and responsibilities in legislation
- Use of other regulators' risk assessments
- Use of European Union Reference Laboratory (EURL) reports
- If practicable, streamlining certain common authorisation provisions and creating a common process for authorisation of feed for particular nutritional purposes (known as PARNUTs) and extraction solvents.

<u>Reviewing the decision-making process</u>

4.2 Each authorisation decision is currently taken by Scottish Ministers based on FSS advice. Many of these decisions are routine and technical in nature, and Ministers, to date, have agreed with all FSS recommendations on whether to authorise products since the service has been running.

4.3 FSS provide thorough technical and scientific scrutiny through skilled and experienced risk assessors and expert independent advisory committees to risk assess individual authorisations and provide safety opinions, from which risk management advice and decision-making recommendations are formed. This proposal will not change this process.

4.4 Our market authorisation service is out of step with the approach taken in other safety regulators' authorisation regimes; regulators such as the Medicines and Healthcare products Regulatory Agency, Veterinary Medicine Directorate, and the Health and Safety Executive (for pesticides), have powers to make decisions themselves on most authorisations. We propose that ministers empower FSS to take market authorisation decisions which will align it with the responsibilities of other safety regulators.

4.5 The proposal includes the option to maintain ministerial oversight of decision-making mechanisms across the nations via the implementation of a "call-in" procedure, so that ministers would retain the power to make decisions on applications.

Clarifying administrative roles and responsibilities in legislation

4.6 We are proposing to clarify specific administrative roles and responsibilities between ministers and FSS within the legislation, including those that add additional burdens to the process. This will provide sound legal basis for applications to be processed swiftly and efficiently.

4.7 This will reduce administrative burdens and lead-in times for applications to progress through the system. For example, it is FSS who understand what is required for a valid novel food application yet this must be referred to Scottish Ministers to decide whether that application is valid. There are around 500 applications at various stages within the market authorisation service and without reforming the roles and responsibilities set out in legislation, this will continue to impact the lead times for an authorisation decision.

Use of other regulators' risk assessments

4.8 We propose to legislate to clarify the process by which FSS can make use of risk assessments from regulators from other countries for all applications where the scientific assessment meets our high standards and internationally recognised risk analysis principles. FSS in some circumstances can use other regulators' risk assessments which meet our standards to inform FSS opinions and enable us to consider the needs of UK consumers. This can reduce the average time for an application to progress through the system from around 6 months to 6 weeks.

4.9 Amending legislation will allow FSS to be able to directly use or review risk assessments from other regulators for all relevant applications, without necessarily needing to repeat detailed aspects of the risk assessment. This will expand the use of other regulators' risk assessments and enable applications to be assessed more quickly, reducing timelines and the resource commitment at the risk assessment stage. It will also mean that FSS can focus valuable scientific resources on assessing new and innovative applications, rather than performing in-depth reviews where risks are well understood.

Continued use of the European Union Reference Laboratory reports (GMO and feed additives)

4.10 Assimilated law requires a 'reference laboratory' to evaluate analytical/detection methods. Since EU Exit, the UK has contracted a National Reference Laboratory (NRL) that can verify analytical/detection methods used as part of the approvals process for GMO and feed additive applications. We are proposing to clarify the definition of 'reference laboratory' used in legislation to ensure that beyond doubt, where appropriate, FSS can use European Union Reference Laboratory (EURL) reports to inform authorisation decisions where applications have already received a EURL report.

4.11 This will reduce duplication of work, time and bottlenecks in the system caused by limited laboratory capacity as well as providing significant cost savings to the applicant (up to £126,000 per application). In cases where NRL reports are still

required, we propose to clarify charging requirements for applicants to increase transparency of what charges cover.

New authorisation processes

4.12 We are proposing to rationalise market authorisation legislation to consolidate certain provisions for all regulated product authorisations.

4.13 The current application process is set out across separate complex regulations that cover several regulated product regimes. Consolidating certain provisions would streamline the legislation to support operation of the generic risk analysis process. It would allow the administrative application process to be separated from the technical and regime specific requirements, making the legislation simpler, more transparent, and easier to update in the future.

4.14 There are currently gaps in the legislation which means there is no set process to authorise PARNUTs and extraction solvents. There are legislative powers for Scottish Ministers to set out a process for authorising PARNUTs. There are general powers but no set process for authorising extraction solvents. The proposed consolidation process for authorisation provisions would address this current gap in legislation by also applying to these regimes.

SPS considerations

4.15 At this stage it is not clear what form dynamic alignment would take, and the details of any agreement are subject to further negotiation. It could be that the UK aligns with all EU market authorisation decisions, which would mean that the market authorisation process within GB would look quite different.

4.16 Some of the changes set out above, such as the use of EURL reports or other regulators' opinions, could take us closer to alignment in the intervening period, but all might ultimately be superseded by whatever regime is put in place to deliver dynamic alignment.

4.17 As discussions on an SPS agreement develop we will consider likely market authorisation pathways and how these reforms would align.

Legislative Vehicle

4.18 These proposals have been jointly developed in collaboration across the four nations, working closely with FSA, who are taking these proposals to their Board in parallel.

4.19 The reform proposals set out above would normally need to be introduced through multiple pieces of secondary legislation in all three countries within Great Britain. However, subject to ministerial agreement in Scotland, England and Wales, the optimum powers to make further legislative reforms to relevant market authorisation legislation can be provided by the Retained EU Law Act 2023 (REUL Act).

4.20 There is limited time to implement these proposals via the REUL Act, because the key powers required are due to expire on 23 June 2026. Working backwards from this date and taking into account elections in Scotland and Wales, we would need to launch a public consultation on the proposed reforms almost immediately. If REUL Act powers are not used, this deadline would not apply, however the delivery of the legislation would be more complex and would likely take longer to implement, bringing us closer to (or even beyond) the potential conclusion of any SPS agreement.

4.21 The Board has so far supported the case for improving the market authorisation process and the REUL Act provides a vehicle to do so relatively quickly. However, if an SPS agreement is also negotiated quickly, there may be limited value in making reforms which could be superseded by whatever is agreed. An alternative approach would be to seek to build these reforms into a wider piece of policy work to design how market authorisations will be implemented in GB following an SPS agreement. There would certainly need to be legislation to implement any SPS agreement, which may provide another vehicle for reform.

Resource

4.22 The Board will need to be mindful of, and consider, the priority they wish to give to regulated products reform and the risk associated with resourcing FSS involvement alongside FSA and our ability to meaningfully engage.

4.23 This programme of work would draw on the same regulatory policy resource currently delivering our core statutory responsibilities in Scotland and is already operating with a resource deficit.

4.24 We anticipate significant policy and legal resource will be required to fully engage and progress any legislative and implementation work related to the food safety and standards elements of an SPS Agreement in Scotland.

4.25 Additionally, we anticipate policy support will be required by other FSS priorities over the timeframe of this work, and the impact here will need consideration too.

5 Options

5.1 We would welcome the Board's views on whether we should:

a) Press ahead quickly with a consultation on these reforms, aiming to take the opportunity of legislation under the REUL Act, or

b) Seek, if possible, to incorporate these reforms in any wider work to design a post-SPS market authorisation regime and consult on the remaining changes required once the whole package is clear.

5.2. We strongly recommend option b).

5.3. Option a delivers the proposed reforms in the shortest timescale. If any SPS agreement is delayed, then this option gives the most benefit in terms of streamlining the service and delivering efficiencies. However, option a does risk being nugatory work if the SPS agreement moves quickly and will take up significant policy and legal resource that could otherwise be deployed in support of the SPS work and other priorities such as SAFER and the delivery of our current legal obligations with regard to business-as-usual market authorisations. It will also mean taking up valuable Ministerial and Parliamentary time with limited short-term benefit. The timetable for option a is considerably pressured with a GB instrument likely to be needed to be laid at Westminster in February 2026. This is of course subject to the agreement of the Scottish Ministers and the Scottish Parliament.

5.4. Option b would involve delaying reforms which have so far been a priority for FSS, however the announcement on SPS means that we need to reconsider our priorities. This option would allow our limited and valuable resource to be deployed on the forthcoming SPS and other priority work whilst considering which reforms need to and can be encompassed within any future post-SPS regulatory framework, instead of making changes which may need to be reversed.

6 Equality Impact Assessment and Fairer Scotland Duty

6.1 Equality Impact and Fairer Scotland Duty assessments are not considered necessary for this paper. These will be considered at a more appropriate stage.

7 Consumer Duty

7.1 The reforms discussed in this paper concern improvements to the market authorisation of regulated products rather than changes which would affect the safety of food and feed products. The proposals and recommendations therefore will not impact directly on consumers and the safety of food and feed products which are available to them.

8 Recommendations

8.1 The Board is asked to:

8.2 **discuss and provisionally agree** to the proposals outlined in section 4.1 – 4.14 (**noting** that further changes may be needed), and the recommended delivery timetable set out in section 5.1.

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