Market Authorisation Modernisation

FSA 25/06/05 - Report by Rebecca Sudworth, Director of Policy

1 Introduction

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

1.2 The Board is invited to **discuss** and **agree** to the proposals outlined in section 3, and the delivery timetable set out in sections 5 and 6.

2 Context

2.1 The FSA is working with Food Standards Scotland (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 FSA/FSS risk assessment advice and subsequent publication in an official register/list.

2.2 Following our update in the Chief Executive's report to the Board in March 2025, we have developed further proposals to streamline the market authorisation service, without compromising the safety of food and animal feed.

2.3 Streamlining the regulatory system is a key part of the UK Government's growth mission, to facilitate investment and innovation to drive economic growth. The Government's Regulatory Action Plan, published in March 2025, sets out that a new approach to regulation is needed to support growth and reduce the administrative costs of regulation. Our proposals support this agenda. Growth and investment in the food sector relies on trust in food. Our proposals will keep food safe whilst supporting timely access to safe new food and feed products for consumers. The proposals will support economic growth by removing unnecessary bureaucracy from the approvals process, making it swifter and reducing the regulatory burden on businesses.

2.4 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.

2.5 The uncertainty introduced by the SPS negotiations may affect the delivery timetable for these reforms, as set out in more detail in sections 4 and 5.

2.6 Ultimately, decisions on both the content and timing of reforms will be for ministers in England, Wales and Scotland. As Northern Ireland (NI) Ministers do not directly decide on applications, legislation is unlikely to be required in NI for these reforms, however we will continue to engage with NI ministers throughout the process under the provisional Food and Feed Hygiene and Safety common framework.

3 Proposals

3.1 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.

Reviewing the decision-making process

3.2 Each authorisation decision is currently taken by three sets of Ministers (in the UK Government, Scottish Government and Welsh Government) based on FSA/FSS advice. Many of these decisions are routine and technical in nature, and Ministers, to date, have agreed with all FSA and FSS recommendations on whether to authorise products since the service has been running. It also carries a cost, since the need to co-ordinate provision of formal advice to three sets of Ministers can extend approval timescales for businesses, as well as taking up valuable ministerial time.

3.3 The FSA/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.

3.4 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), which have powers to make decisions themselves on most authorisations. We propose that ministers empower the FSA/FSS to take market authorisation decisions. Granting

similar regulatory powers to the FSA/FSS will align it with the responsibilities of other safety regulators. 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.

3.5 This will enable ministers to focus on authorisation decisions by exception, for example, where there is considerable public interest or impact. The option for Ministers to retain a “call-in” power would ensure ministers retain overall control of the authorisation of food and feed.

3.6 There are well established Common Framework governance arrangements in place which will continue to underpin ministerial oversight. Determination of the authorisation status of applications will be subject to four-nation working, as provided for by the provisional Food and Feed Safety and Hygiene Common Framework. Where ministers are no longer making decisions, any necessary amendments to the framework will be considered as part of this work.

Clarifying administrative roles and responsibilities in legislation

3.7 We are proposing to clarify specific administrative roles and responsibilities between ministers and the FSA/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.

3.8 This will reduce administrative burdens and lead-in times for applications to progress through the system. Currently, ministerial consent across the nations must be sought by the FSA/FSS at various stages throughout the risk assessment process(NB this paper is focused on FSA, but similar considerations apply to FSS).For example, the FSA cannot reject applications that do not meet the required standard at the risk assessment stage without seeking ministerial approval, and the FSA must notify ministers every time it publishes a risk opinion/assessment on the safety of a product. 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

3.9 We propose to legislate to clarify the process by which the FSA 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. The FSA in some circumstances can use other regulators’ risk assessments which meet our standards to inform FSA 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.

3.10 Amending legislation will allow the FSA 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 deliver on the recommendations made by the FSA’s Chief Scientific Adviser to 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 the FSA 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)

3.11 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, the FSA can use European Union Reference Laboratory (EURL) reports to inform authorisation decisions where applications have already received a EURL report.

3.12 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

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

3.14 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.

3.15 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 the Government 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.

3.16 This proposal also requires the creation of online public registers for PARNUTs and extraction solvents, to align these regimes with other regulated products.

4 SPS considerations

4.1 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 to how it operates now. If any exceptions are agreed, we will need to consider the process for these items separately.

4.2 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.

4.3 As discussions on an SPS agreement develop, we will consider likely market authorisation pathways and how these reforms would align – this may shape future thinking on the timetable for reforms.

5 Delivery considerations

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

5.2 If the Board agrees to the reform proposals set out above, the logical next step is to launch a consultation to test the ideas. We propose doing so at the most appropriate time, based on which legislative vehicle is most suitable to enact the changes (see section 6).

5.3 These reforms would normally need to be introduced through multiple pieces of secondary legislation in all three countries within Great Britain. While optimum powers can be provided by the Retained EU Law Act 2023 (REUL Act), there is limited time to do this because the key powers required are due to expire on 23 June 2026.Time is extremely tight, as use of these powers requires ministerial agreement in England, Wales and Scotland, and we would then need to launch a public consultation by early July to meet this deadline. It would however provide the fastest route to deliver these reforms, which have so far been a priority for the FSA and a part of the UK Government's regulation for growth agenda.

5.4 If we are unable to use REUL Act powers, the delivery of the legislation via multiple pieces of secondary legislation would be more complex and would likely take longer to implement, bringing us closer to (or even beyond) the likely conclusion of any SPS agreement. While we do not have certainty yet on the scope of any post-SPS agreement legislative vehicles, there would certainly need to be legislation to implement any SPS agreement, which may provide another vehicle for reform. If an SPS agreement is negotiated quickly, there may be limited value in making reforms which could be superseded by whatever is agreed, and this would also take up policy capacity that could otherwise be deployed in support of SPS work. 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.

5.5 It will ultimately be for ministers to decide what reforms to adopt, and which legislative vehicle to use.

6 Next steps

6.1 Given the challenge of delivering these reforms within the extremely tight timeframe required for use of REUL Act powers, coupled with the uncertainty of the SPS negotiations, if the Board agrees, we propose that we should keep working up these proposals and take the most suitable route for delivery as the context develops and as we get views from ministers.

6.2 If this Board, the FSS Board and ministers agree to the proposals, we will seek to launch a consultation, the timing of which would be dependent on the chosen delivery route. This could either be by early July if ministers agree to use of the REUL Act, or potentially in the autumn of 2025 when the progress of SPS negotiations may be clearer.

6.3 Following the outcome of the public consultation, we will work to develop legislation. There would need to be continued engagement across the four-nations as work continues to develop the proposed reforms post-consultation, including the relevant consents where required.