Regulated Products Reform Update

FSA 24-03-04 - This paper gives an update on the FSA's work on reforming the Regulated Products Service.

1. Introduction

1.1 In the December 2023 Board meeting we outlined plans to reform our Regulated Products Service (RPS) and briefed the Board on progress at the FSA Board retreat in January 2024. This paper presents:

- **our proposals for initial reforms** that will increase the speed and efficiency of the RPS;
- **the preliminary recommendations of the Board sub-group on regulated products delivery,** focusing on improvements within the current regulatory framework;
- **more information about how the FSA could make effective use of other regulators' opinions.**

1.2 The Board is asked to:

- **Comment** on our proposed initial reforms.
- **Discuss** the preliminary recommendations arising from the Board sub-group on regulated products delivery.
- **Note** the further work underway on the use of other regulators' opinions.

2. Background

2.1 Our approach to authorising regulated products is based on the EU model. This model protects food safety, is well-understood by applicants and trusted by consumers. However, aspects of this process are bureaucratic and resource intensive to operate for the regulator and for applicants and may appear disproportionate to the level of risk. A more efficient regulatory system will bring benefits to consumers through an enhanced choice of safe food whilst providing greater value for the taxpayer. The FSA Board has been clear that reform will be necessary to achieve a high-quality service: in the short-term, to make the current service work better, and in the longer-term to put in place an effective, proportionate and sustainable service that will be able to keep pace with innovation in the sector.

2.2 In December 2023, the Board agreed a set of reform principles to guide reform, with public health and consumer interests at the heart. These principles underpin the short- and longer-term reforms presented in this paper.

Principles for the Reform of the Regulated Products Service:

1. **We will protect public health.** There will be no reduction in food safety or standards as a result of our reforms.

2. **We will protect consumer interests.** Our new regulatory service will improve our ability to take consumer needs and preferences into account when making regulatory decisions.

3. **Decisions will be based on science and evidence.** We will continue to set high standards for evidence, working collaboratively with others on issues of mutual interest in order to maximise efficiency.

4. **We will be open and transparent.** We will continue to publish our risk assessments and the basis for our regulatory decisions; we will maintain our focus on excellent risk communication for consumers and we will improve communication with applicants at all stages of the process.

5. **We will streamline our regulatory process.** We will design an agile, responsive and future-proofed service that allows us to be flexible, proportionate and proactive in our regulatory approach. Market access for safe products, processes and food technologies will be efficient, easy to navigate for businesses, and work for a UK context.

6. **We will facilitate innovation and enterprise.** Our regulatory environment will be able to evolve with the developing food system, respond to emerging technologies, and will make the UK a preferred destination for approvals for safe, innovative products.

7. **We will strive for four-country working.** We will minimise divergence within the UK and aim to have a common approach to regulatory reform with a framework that operates across the four nations.

The Case For Change

2.3 The UK officially opened for applications at the end of the Transition Period, on 1 January 2021.The current caseload in the RPS is 450. We have completed 63 applications to date, taking on average around 2.5 years from the submission of an application to completion. Based on current inflows, resources, and processes, we expect the caseload to continue to grow from 450 in March 2024 to more than 570 by March 2026.

2.4 The inherited EU legislation was demonstrably not designed to operate in a Great Britain (GB) context and was transferred into GB legislation with only minor amendments for operability. The legislative requirements are prescriptive and, in some cases, not proportionate to the risk; this, along with resource limitations, prevents the FSA from being able to operate flexibly to address the growing number of applications efficiently.

2.5 Without urgent action, we will be unable to keep pace with this growing caseload. This will affect consumers' choice and access to new and potentially beneficial products. Putting the service on a sustainable footing, providing the high-quality service that consumers and applicants expect, will require both short- and longer-term reforms.

2.6 In the December Board paper on regulated products, we outlined two initial reform measures that, taken together would both reduce our caseload and future inflows, and shorten the time taken to authorise. These measures can be taken forward using powers under the Retained EU Law (Revocation and Reform) Act 2023: a proportionate, risk-based approach to the regulation of certain products currently requiring renewals; and a more efficient process for bringing authorisations into force following a Ministerial decision. Working closely with the

devolved administrations in Scotland and Wales, we are now preparing to bring forward legislation to make these changes, subject to a public consultation. Details about our proposals are in Section 3 below.

2.7 Our proposed legislative timeline requires ministerial support, public consultation and the laying of draft secondary legislation for debate in parliament. We know that this work is of high interest to applicants and industry sectors and will seek views from a wide range of stakeholders during consultation. Following analysis of consultation responses, FSA/Food Standards Scotland (FSS) officials will provide advice and recommendations to their respective Boards and relevant Ministers in England, Scotland and Wales (with Ministers in Northern Ireland kept informed) for decisions.

2.8 At the December Board meeting, the Board established a sub-group of the Board to scrutinise the current process and support the Executive to identify measures that could be put in place sooner, within current regulations. The sub-group presented preliminary recommendations to the Business Committee on 11 March, and these recommendations are in Section 4 below. Food Standards Scotland has undertaken similar analysis, and a representative of the FSS Board attended sub-group meetings. FSS will be presenting these recommendations to their Board in parallel.

3. Proposed Legislative Reforms

Renewals of Authorisations

3.1 For the majority of food and feed products we regulate, once a product is authorised, the company that makes that product does not need to apply again for their authorisation to be renewed. The FSA – through its risk analysis process and risk assessment – reviews any new information that emerges. If there is new evidence about safety, it will independently assess this evidence, and retains the ability to review existing authorisations and powers to take action to protect public health.

3.2 However, in line with EU legislation, authorisations for smoke flavourings, feed additives and genetically modified food and feed must be renewed every ten years. Since taking over the administration of approvals in 2021, the FSA has yet to reject any of the renewal applications received. At the same time, through its risk analysis process, when new evidence about the safety of a product emerges, the FSA can review existing authorisations. For example, such a review is underway for titanium dioxide as a food additive with the FSA considering updated evidence using its risk analysis process.

3.3 We estimate that currently 22% of the RPS caseload consists of applications solely for renewal of an existing authorisation (111 of 513 applications received up to end of February 2024). Processing large volumes of renewal applications significantly reduces the FSA's capacity to deal with new product authorisations to a reasonable timeline. The FSA anticipate a large number of feed additive renewal applications in the run-up to renewal deadlines in 2027, meaning that by 2027 over 50% of the applications the FSA is likely to have received into the service will have been renewal applications. Without reform this will put considerable strain on the FSA's resources, focused on products with many years of safe use where, in the majority of cases, we do not anticipate any change in risk.

3.4 Removing the renewals requirement essentially brings the regulation of these products in line with how we regulate other food and feed products. We retain the power to reconsider any product authorisation at any time. But the way in which we do it would be risk-based, not time-based, and informed by the FSA's independent assessment of any new scientific evidence about a particular product or its use. Freeing up resource creates future opportunities, for focusing on authorisations of new applications to the regulated product service.

3.5 The proposed reform would not negatively impact food and feed safety standards. Products subject to renewal requirements have already had their safety rigorously assessed during their initial authorisation. If new evidence emerges that requires a review of the decision, the FSA will assess the evidence and provide advice to Ministers to inform decisions regarding potentially modifying, suspending or revoking authorisations.

Removing the Need For a Statutory Instrument

3.6 After completion of a risk assessment, the FSA makes a recommendation to GB ministers, who then decide whether or not to approve a product. Under the current process, following ministerial approval from each of the GB nations, Statutory Instruments (SIs) must be laid, which confirms this decision in legislation, either via lists in the legislation concerning a regulated product regime or via individual SIs that authorise products. The use of statutory instruments to authorise approvals arises from the need to transpose EU legislation into assimilated law. There is a lack of direct equivalence between EU and UK national authorities which adds steps into the process not required when the UK was a Member State.

3.7 Officials draft policy instructions containing the terms of authorisation, which are sent to lawyers in each nation to draft SIs. These are laid in England, Wales, and Scotland to similar timelines, which can be heavily impacted by ministerial availability, parliamentary recess periods, and changing demands on legal and policy resources.

3.8 These factors add at least a three-month delay, and in the worst-case scenario, 6 months, between an application being formally approved and authorisation, as well as taking up considerable resource within the FSA, FSS and across the parliaments and assemblies of England, Wales and Scotland.

3.9 We propose that we remove the need for an SI, and instead create a publicly available official register, following ministerial approval. This simplifies the authorisation process, without compromising either ministerial decision-making and accountability, or our duty to protect consumers.

3.10 Under existing regulations, SIs are laid using the negative procedure, without automatic opportunity for parliamentary debate. To date 58 authorisations have been approved within six SIs since 2021 without issue.

3.11 With this reform, the role of Ministers as decision-makers will remain unchanged, and there are no changes to the technical and scientific scrutiny undertaken during the authorisation. Additionally, the FSA will explore options for non-legislative measures to ensure parliamentary oversight is achieved without the need to lay secondary legislation, for example by submitting an annual report to Parliament/Senedd.

Implementation

3.12 We want to make these reforms across GB and in consultation with Northern Ireland. We are working rapidly with the aim of achieving legislative change ahead of a general election which must take place on 28 January 2025 at the latest. Any changes to assimilated legislation are decisions for Ministers and ultimately for Parliament.

3.13 We have undertaken policy development and analysis to advise ministers to lay legislation using powers in the Retained EU Law (Revocation and Reform) Act 2023 as soon as possible this year. Our proposed legislative timeline is to enter parliamentary triage in April to lay the Statutory Instrument that will enable us to make these changes in July. This is subject both to Ministerial agreement, and the outcome of our formal consultation, which we plan to launch in early April.

Risks and mitigations

3.14 Completing policy development, legal drafting, consultation across the four nations and following parliamentary process to the above timeframe represents the most significant challenge to this work.

3.15 Removing renewals has a reputational risk as consumers may perceive this as reducing the level of FSA oversight. However, we currently have 12 regulated product regimes, nine of which do not have the requirement for renewals, so our proposed change brings the process for all regimes in line. We will engage extensively with consumer representative groups including through the formal consultation process to make sure we fully consider consumer interests in any changes we make.

3.16 Whilst these reforms are being recommended on a GB-wide basis, the Ministers in each GB nation will make their own decisions. Officials from all nations are working closely with the aim of achieving agreement between Ministers in different nations.

4. Preliminary Recommendations From Board Sub-Group

4.1 The sub-group on regulated products delivery was established to scrutinise the current performance of the RPS and make recommendations about further actions to improve performance. Given the growing caseload and the delivery challenges inherent in the service as laid out in assimilated law (formerly known as Retained EU law), the sub-group was specifically tasked with examining areas where the FSA and FSS can do more within the current regulatory framework and within existing limited resources, taking into account the respective risk appetites of the FSA and FSS Boards.

4.2 The preliminary recommendations (below) proposed by the sub-group were presented to the Business Committee on 11 March.

1. The FSA and FSS should actively manage the regulated products caseload so that resources are focused on achieving the best outcomes in the interests of consumers. Active management means making active choices about where to put resources so that the performance of the service as a whole is improved.
2. The FSA and FSS should review the approach to public consultation and engagement to ensure that it is proportionate and tailored to the needs of consumers and stakeholders.
3. At all stages of the process, firm deadlines must be set and adhered to when seeking information and input from stakeholders and applicants. Periods of time allowed for further information to be provided must be as short as is reasonable to meet the requirements.
4. Decisions at each stage of the process should be taken by a lead responsible official, limiting review and sign-off to the minimum required to meet quality standards and to achieve three- and four-country working.
5. The FSA and FSS must continue to make a strong case to Ministers that, without adequate resources and/or further changes to the process, performance of the current service will fail to deliver timely outcomes for the benefit of consumers and food businesses.

Implementation and next steps

4.3 Active caseload management is a key aspect of the proposed approach. The objective is to improve the performance of the service as a whole by ensuring resources are focused on achieving the best outcomes for consumers. An example of this could be an interim approach to renewals, pending the legislative changes outlined above. As products that have applied for renewal can lawfully remain on the market pending a decision and given that the FSA proposes to bring forward reforms to remove the requirement for renewal applications at set intervals, we will

consider pausing work on renewal applications currently in the service, for example the large number of routine animal feed additive renewals. We will also continue to receive new renewal applications so products can stay on the market but may consider pausing work on these applications. This would release resources to focus on new applications so they can be brought safely to market more quickly.

4.4 Following Board's steer, and before final decisions are taken about the approach to managing the growing caseload (such as pausing work on renewals), the FSA (and FSS) will undertake further work on implementation. In all cases, we will work within the agreed principles (see paragraph 2.2), ensuring that the management of our caseload is designed to protect public health. We will ensure the best outcomes in the interests of consumers, as well as supporting food businesses in facilitating innovation. We will engage with stakeholders and applicants before making any changes to the management of our caseload or administrative changes to the authorisation process and ensure that all changes in approach are considered carefully in the light of feedback and communicated clearly.

4.5 Because the regulated products authorisation process is highly integrated between England, Wales and Scotland, reaping the benefits of these proposed administrative reforms for consumers and for applicants will require a three-nation approach. Subject to the agreement of the recommendations by the FSA and FSS Boards, FSA and FSS officials will work on a three- and four-country basis to agree a delivery plan and timetable for implementation, including informing Ministers about the plans.

5. Use of Other Regulators' Opinions and Decisions

5.1 FSA/FSS are seeking opportunities to expand work with food and feed regulators internationally to ensure that the process of authorising regulated products is proportionate and efficient. We aim to identify opportunities to enable greater data-sharing and/or partnership approaches to risk assessment through formal agreements. This would enable knowledge and expertise to be shared and resource utilised effectively whilst still maintaining regulatory autonomy, to make decisions that are specific and appropriate in a GB context. We will return to the Board in June with more detailed plans on our proposals for international collaboration.

5.2 While we develop these longer-term approaches, we will continue to work proactively to ensure efficiencies are realised by expanding our use of other regulators' opinions. FSA and FSS already make some use of other regulators' risk assessments to inform our approach. In doing this, we ensure that the outputs from other regulators meet our standards and enable us to consider the needs of UK consumers. We will continue to implement this approach, ensuring reviews of other regulators' opinions are conducted wherever this is deemed appropriate and proportionate. For example, we have had a system in place for applications in our service where that application had been in the EU system prior to the UK's exit in January 2020. More recently, our scientists have been reviewing publicly available risk assessments from other regulators relating to renewals, reducing our timing for this stage in the process from months to weeks.

6. Conclusions

6.1 The Board is asked to:

- **Comment** on our proposed initial reforms;
- **Discuss** the preliminary recommendations arising from the Board sub-group on regulated products delivery;
- **Note** the further work underway on the use of other regulators' opinions.