Risk Analysis and Regulated Products Service Update

1 Purpose of the paper

1.1 This paper provides the Board with a routine quarterly performance update on the Food Standards Scotland (FSS) and Food Standards Agency (FSA) joint Risk Analysis process and GB Regulated Products service. In addition, and following on from previous Board discussions, proposals for priority reforms to the regulated products authorisation process are presented. This paper also reports the preliminary recommendations for improvements within the current regulatory framework.

1.2 The Board is asked to:

- **Note** the update on the performance of the risk analysis process and regulated products service (Sections 4 & 5);
- **Note and comment** on our proposed priority reforms to the regulated products authorisation process, which are subject to agreement from Ministers(Section 6);
- **Discuss and endorse** in principle, the preliminary recommendations arising from the FSA Board sub-group, subject to further work to develop a detailed implementation plan (Section 7);
- **Agree** the recommendation that future business as usual performance reporting on risk analysis and the regulated products service will go to the Finance and Business Committee (Section 8).

2 Strategic aims

2.1 The work of Risk Analysis and the Regulated Products service supports FSS Strategic Outcomes 1 – Food is Safe and Authentic; 3 – Responsible Food Businesses are enabled to thrive and 5 – FSS is trusted and influential. It also links to Goal 1 of the Corporate Plan: to have a food safety and standards assurance system that commands international respect and consumer confidence, supporting the Scottish economy beyond EU Exit.

3 Background

3.1 This paper provides the Board with an update on the joint FSS/FSA Risk Analysis (RA) process since the December Board update paper. This includes applications progressing through the Regulated Products (RP) service and issues that FSS and FSA has chosen to proactively consider.

3.2 The GB approach to authorising RP is based on the EU model. This model protects food safety and is well-understood by applicants. However, aspects of this process are bureaucratic and resource intensive to operate for the regulator and for applicants, and disproportionate to the level of risk. The FSS Board has been clear that reform will be necessary to achieve an acceptable level of performance: 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 fit for the future. At the December Board meeting, plans were outlined for reform of the RP service and the Board was briefed on progress at the FSS Board seminar in February 2024. Now the proposals for these initial reforms, which will increase the speed, efficiency and resilience of the RP Service, are presented in Section 6.

3.3 In addition, a FSA Board sub-group on regulated products delivery was established to scrutinise the current performance of the RP Service and make recommendations about further actions to improve performance. Due to the GB nature of the service, it was agreed by both Chairs that the FSS Deputy Chair should join the sub-group to ensure FSS views were considered in the development of any recommendations. The preliminary recommendations made by this sub-group focus on improvements within the current regulatory framework and are presented in Section 7.

4 Risk Analysis

4.1 Issues that are being considered by the FSS and FSA through our joint food and animal feed RA process are published to an online register. Issues are published following initial consideration, once it is confirmed that risk assessment or other evidence is required, and the risk assessment phase of the process commences.

4.2 As of 29 December 2023, there were 33 items recorded on the public risk analysis register, including issues completed. Of these, 21 issues were actively progressing. Changes in the register since the last update include 4 new items at the stage of 'Development and Consideration of Risk Management Options', these were:

- current Salmonella risk profile of UK-produced hen shell eggs
- assessment of the Codex Expert Committee reports on establishing threshold levels for allergens of global and regional importance
- risk to consumers from Campylobacter in small broiler slaughterhouses
- review of high risk food and feed import controls under retained Regulation 2019/1793 (third review)

4.3 There are currently seven 'non-routine' issues on the register, these are listed at Annex A and are unchanged from the December 2023 Board update.

4.4 Ten issues are now marked complete on the public register; 4 more since the December 2023 Board update. A summary of the risk management advice is provided on the online register for each of the four issues, which are:

- risk assessment on Avian Influenza infection via food chain
- microbiological risk assessment to support development of advice and guidance to manage outbreaks of norovirus associated with consumption of raw oysters
- risk profile - Live Bivalve Molluscs (LBMs): Oysters
- assessment of the risk of allergic reaction from fortification of non-wholemeal wheat flour with folic acid

5. Regulated Products Service

5.1 As of 29 December 2023, the caseload in the RP service has slightly reduced and is now at 447 (in line with expectations). We have received 45 new contacts in this reporting period, 35 (78%) of which have sufficient information to progress. There were 13 authorisations scheduled for this quarter which were completed, increasing the number of completed applications to 63.

5.2 The Scottish Statutory Instrument (SSI) authorising 13 feed additives from Tranche 2 came into force on 22 December 2023, with equivalent legislation coming into force in England and Wales simultaneously.

5.3 Work has started on Tranche 3 with a consultation launched on 2 February for 4 novel foods, 3 food additives, removal of 22 flavouring authorisations and setting a limit for ethylene oxide. A consultation for 26 feed additives will be launching in the coming weeks. Estimated dates for completion for applications at the risk management stage are provided in the table below.

33 applications	**Expected timeframe for consultation**	**Expected timeframe for coming into force (pending ministerial and legislative clearances)**
4 Novel Foods	Q4 23/24 (launched Feb 2024)	Q2/3 24/25
3 Food Additives	Q4 23/24 (launched Feb 2024)	Q2/3 24/25
26 Feed Additives	Q1 24/25	Q3 24/25

6. Regulated Products Priority Reform

The case for change

6.1 The current caseload of applications in the RP service is circa. 450. FSS and FSA have completed 63 applications to date, taking on average around 2.5 years from the submission of an application to completion. Although the rate at which products have been authorised is increasing, based on current inflows, resources and processes, the caseload is expected to grow from 450 in March 2024 to more than 570 by March 2026. Without action, we will be unable to keep pace with this growing caseload. 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.

6.2 In the December Board paper on the Regulated Products service, two initial reform measures were outlined that, taken together, would reduce our caseload and future inflows, and shorten the time taken to authorise. These reforms are intended to introduce a more proportionate, risk-based approach to the regulation of certain products requiring renewals, and a more efficient process for bringing authorisations into force following a Ministerial decision.

Proposed legislative reforms

Renewals of authorisations

6.3 For the majority of RP, once a product is authorised, the company that makes that product does not need to apply again for their authorisation to be renewed. FSS and FSA, through the joint risk analysis process, review any new information that emerges. If there are concerns about safety, we will independently assess any new evidence, and retain the ability to review existing authorisations and powers to take action to protect public health.

6.4 However, in line with assimilated law, authorisations for GM food and feed, feed additives and smoke flavourings must be renewed (usually) every ten years. Since 2021, when the GB RP service was implemented, there have been no rejections of renewal applications received. When new evidence about the safety of a product has emerged, FSS and FSA review existing authorisations. For example, titanium dioxide as a food and feed additive is currently being re-evaluated using the risk analysis process, based on new evidence.

6.5 Currently 22% of the RP service caseload is taken up with renewal authorisations. This significantly reduces capacity to deal with new product authorisations to a reasonable timeline. A significant number of feed additive renewal applications are expected in the run-up to renewal deadlines in 2027, meaning that by the end of 2027 over 50% of applications received into the service will have been renewal applications. Without reform this will put considerable strain on resources and could considerably impede the authorisation of new products.

6.6 Removing the renewals requirement essentially brings the regulation of these products in line with the regulation of other food and feed products. FSS and FSA retain the power to reconsider any product authorisation at any time. The way in which we do it would be risk-based, not time-based, and informed by independent assessment of new scientific evidence about a particular product or its use. Freeing up resource would also allow the approach to RA could be strengthened, building capacity for monitoring risks, horizon scanning and post-market surveillance.

6.7 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 initial EU authorisation. If new evidence emerges that requires a review of the decision, the evidence will be assessed and advice provided to Ministers to inform decisions regarding potentially modifying, suspending or revoking authorisations.

Removing the need for a Statutory Instrument

6.8 Following a risk management recommendation from FSS, Scottish Ministers decide whether or not to authorise a new regulated product in Scotland. FSA and Ministers carry out this same role in the rest of GB. Under the current legislative process, following Ministerial authorisation, a separate Statutory Instrument must be laid in Scotland, Wales, and England to prescribe the terms of authorisation in secondary legislation.

6.9 This reflects the way the assimilated law was repatriated at the point of EU Exit as part of the cross-government policy neutral deficiency fixing exercise to ensure legal operability and a functioning statute book. In making these legal fixes it was recognised that there is no direct equivalence between EU and GB regulatory and legislative processes, and associated public authority functions, and that a future review would likely be needed.

6.10 The GB process to prescribe the terms of authorisation in secondary legislation entails an active parliamentary scrutiny step, for which there is no direct parallel in the EU. The development and implementation of the required secondary legislation takes up to 6 months, including risk management development and legal drafting, which takes up considerable FSS and FSA policy and legal resource, as well as parliamentary time.

6.11 Removing the need for secondary legislation to authorise each individual regulated product and moving to an administrative-based approach, underpinned by a statutory duty to publish public lists of authorised products on the FSS and FSA websites along with their terms of authorisation, would bring greater efficiencies to the authorisation process. It would also allow authorised products to reach market faster, for the benefit of consumers and businesses. FSS and FSA resource would be freed up to focus on reducing the current caseload of applications within the service, while allowing a more agile and responsive regulatory approach.

6.12 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, so current levels of consumer and public health protection would be maintained.

Implementation

6.13 The FSA have sought agreement from the Department for Health and Social Care (DHSC) for these priority reforms to be taken forward by a GB Statutory Instrument using powers under the Retained EU Law (Revocation and Reform) Act 2023. The proposed legislative timeline is highly challenging with a proposed laying date in Westminster of July 2024.

6.14 This will require Ministerial agreement across the three nations, including the need to engage formal devolved consent mechanisms, and public consultation which is proposed to launch in April. We know that this work is of high interest to applicants and industry sectors and, subject to Ministerial agreement, will seek views from a wide range of stakeholders during consultation.

6.15 Working closely with the FSA in England and Wales, we are now preparing to provide advice to Scottish Ministers on these proposed reforms, and we will keep the Board informed of their decision.

Risks and mitigations

6.16 Completing policy development, legal drafting, and consultation across the nations, as well as fully respecting devolved consent mechanisms, within the above timeframe represents the most significant challenge to this work.

6.17 Removing renewals has a reputational risk as consumers may perceive this as reducing the level of FSS and FSA oversight. We will engage extensively with consumer representative groups to make sure consumer concerns are fully considered in any changes.

6.18 Whilst these reforms are being recommended on a GB-wide basis, as noted 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 the different nations.

7. FSA Board Sub-Group

Preliminary Recommendations

7.1 Given the growing caseload and 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 existing limited resources, taking into account the respective risk appetites of the FSA and FSS Boards. The preliminary

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

a. 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.

b. 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.

c. 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.

d. 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.

e. 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

7.2 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 and FSS are proposing to bring forward reforms to remove the requirement for renewal applications at set intervals, we will consider pausing work on renewal applications, for example the large number of routine animal feed additive renewals. This would release resources to focus on new applications so they can be brought safely to market more quickly.

7.3 Following the steer from the both Boards, and before final decisions are taken about the approach to managing the growing caseload (such as pausing work on renewals), FSS and the FSA will undertake further work on implementation. In all cases, we will work within the agreed principles, ensuring that the caseload management is designed to protect public health and ensure the best outcomes in the interests of consumers. We will engage with stakeholders and applicants before making any changes to the management of caseload or administrative changes to

the authorisation process, and ensure that all changes in approach are communicated clearly.

7.4 Because the RP authorisation process is highly integrated between England, Wales and Scotland, to reap the benefits of these proposed administrative reforms for consumers and applicants will require a three-nation approach. Subject to the agreement of the preliminary recommendations by both the FSA and FSS Boards, 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.

Use of other regulators opinions and decisions

7.5 FSA and FSS are seeking opportunities to expand work with food and feed regulators internationally to ensure that the process of authorising RP is proportionate and efficient. The aim will be 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 the intentions for international collaboration.

7.6 While we develop these longer-term approaches, we will continue to work proactively to ensure efficiencies are fully realised by using other regulators' opinions. FSA and FSS already make appropriate use of other regulators' risk assessments and risk management decisions 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, FSA and FSS scientists have been reviewing publicly available risk assessments relating to renewals, reducing our timing for this stage in the process from months to weeks.

8 Future Quarterly Reports

8.1 The Board is asked to endorse recommended changes to the reporting on the RA and RP processes. It is proposed that, to reflect the more operational nature of these services, this report will now be taken quarterly at the Finance and Business Committee (FBC) instead. This is a Committee of the Board established to give appropriate high-level oversight of financial and operational matters at Board level.

8.1 The Deputy Chair of the Board, as a non-executive member of the FBC, will provide verbal updates to Board meetings highlighting any issues arising in these reports. The Board will continue to take strategic papers on RA and RP on an ad hoc basis as required and to have the opportunity to consider risk management

recommendations for non-routine items progressing through the RA process. The Board will also receive separate papers on RP Reform as required, including on the proposals for any future reform.

9 Identification of risks and issues

9.1 In addition to the reputational risk and the risk of GB divergence set out in the Priority Reform Section (paragraphs 6.16 – 6.18). The Board will need to consider the resource implications of RP reform work and the risk associated with resourcing FSS involvement alongside FSA, as this draws on the same regulatory policy resource as that currently delivering core statutory regulated products responsibilities in Scotland.

9.2 The Board has previously indicated its risk appetite as HUNGRY to consider innovation with the potential to deliver improved efficiency and effectiveness. As has been highlighted one of the reasons for exploring RP reform is the significant resource pressures the inherited EU system places on both FSS and FSA. The reform proposals set out in this paper would meet this risk appetite and provide significant opportunities for streamlining the existing service.

9.3 The Board has agreed that priority reforms should be brought forward more quickly in 2024 to improve delivery of the current system whilst laying the foundations for the future. Noting the FSA Board sub-group preliminary recommendations will look to realise efficiency savings and allow both organisations to prioritise resource, achieving a system that protects consumers, speeds up authorisations and reduces the level of resource needed to deliver a high quality service can only happen (given current resourcing) if reforms result in a more efficient risk assessment process which is just as effective, a reduced caseload, and fewer steps to achieve authorisation.

10. Equality Impact Assessment and Fairer Scotland Duty

10.1 Equality Impact and Fairer Scotland Duty assessments are not considered necessary for this paper. The purpose of the paper is to provide an update on the issues going through the Risk Analysis Process and Regulated Products service.

11 Recommendations

11.1 The Board is asked to:

- **Note** the update on the performance of the risk analysis process and regulated products service (Sections 4 & 5)
- **Note and Comment** on our proposed priority reforms to the regulated products authorisation process, which are subject to agreement from Minister (Section 6)

- **Discuss and endorse** in principle, the preliminary recommendations arising from the FSA Board sub-group, subject to further work to develop a detailed implementation plan (Section 7)

- **Agree** the recommendation that future business as usual performance reporting on risk analysis and the regulated products service will go to the Finance and Business Committee (Section 8).

Please direct queries to:

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Date 13 March 2024

Annex A

List of Non-routine Risk Analysis Issues:

- Analysis of the safety of Titanium Dioxide (E 171) as a food additive
- Risk analysis of bamboo-plastic composite food contact materials
- Analysis of environmentally sourced recycled plastic in food contact materials
- Review of T-2/HT-2 toxins in foods
- Risk assessment of substrates used to rear insects for animal feed
- Analysis of the safety of Titanium Dioxide as a feed additive
- Assessment of Bisphenol A (BPA) in food