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) risk analysis process and GB regulated products service. It also provides an update on progress made on continuous improvement to the current system and a high-level update on future regulatory reform.

1.2 The Board is asked to:

- **Review** the update on the performance of the risk analysis process and regulated products service.
- **Note** the progress made on continuous improvement.
- **Note** the update on longer term reform work.

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; 5 – FSS is trusted and influential. It also links to commitments made under 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 performance of the FSS/FSA risk analysis process since the June Board meeting. This includes applications progressing through the regulated products service, and issues that FSS/FSA has proactively chosen to consider.

3.2 Background information about the risk analysis process and regulated products service has been provided in the previous report to the Board in March 2023 and is available via this link on the FSS website.

4 Risk Analysis

4.1 Issues that are being considered by the FSS and FSA through our food and animal feed risk analysis process are published to an online register. Issues are published to the register 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 30 June 2023, there were 26 issues recorded on the public risk analysis register, 20 of which are actively progressing. As in the previous quarter, 5 of those issues have been identified as potentially requiring additional scrutiny by the Board in developing risk management advice. Those 5 issues relate to the use of titanium dioxide as a food additive, bamboo-plastic food contact materials, ocean-bound plastic food contact materials, a review of the occurrence of the mycotoxin T-2/HT-2 in food, and substrates used to rear insects for animal feed.

4.3 Changes in the register since the last update include the addition of 4 new issues:

- 3 issues having progressed to development and consideration of risk management options;
- 1 issue now requiring no further risk analysis work.

4.4 No additional risk analysis issues have been designated as complete in the register since the last quarterly update to the Board.

4.5 The Board may also wish to note publication of the smoked fish risk assessment in July, the first FSS-led joint risk assessment with FSA.

5 Regulated Products Service

5.1 As of 30 June 2023, the caseload in the regulated products service was 426. The Case Management System (CMS) was successfully launched on 20 June 2023. We did not receive any applications on the CMS in this reporting period (up to 30 June 2023), which covers the first few weeks of live running. Since 30 June we have received a steady flow of applications, indicating that the CMS is working as expected.

5.2 Steady progress has continued to be made with authorisations to date, meeting the expected timetables (allowing for ‘stop the clock’ periods where FSS/FSA cannot progress applications until further evidence is provided by applicants). A further 16 applications have been completed since the June Board update, bringing the total number of completed applications to 50 since the service went live in January 2021.

5.3 We are working with FSA towards an aspiration to deliver around 60 completed applications in 2023-24 and are currently navigating through the resource

challenges this presents, as set out in our June Board paper. We have already completed 16 this year and have recently consulted on 12 feed additive applications. We are also planning for and managing Tranche 3 applications (this consists of 38 applications across 4 different regimes) coming out of risk assessment into risk management. This is our biggest tranche to date and our planning has highlighted some delivery risks which we are working to mitigate. The estimated earliest completion dates for applications can be found in the table at **Annex A**.

5.4 The majority of the CBD applications have now provided their full data package for review with a few applications due to complete their submissions of missing data by the end of 2023. To support the assessment, a subgroup of both the Advisory Committee on Novel Foods and Processes (ACNFP) and the Committee on Toxicity (COT) has been formed to review the toxicological data that is key to the assessment of these applications. The subgroup is reviewing the studies in groups based on the composition of the product. They began with the products with 98% CBD or greater and this has allowed 3 applications from this group to complete the toxicological review. These are scheduled for consideration by the ACNFP in September, including 1 with a draft assessment output for Committee consideration. It is expected that all applicants will receive a further update on the next steps for their application in the Autumn.

6 Continuous Improvement & Reform

Continuous Improvement

6.1 In the June Board paper, we outlined a set of continuous improvement measures FSA/FSS intended to put in place in the coming year.

6.2 As noted above the CMS is now live, with 13 applications having been received in the system as of 31 July 2023. The limited evidence available to date is positive in terms of the quality of applications received. We believe this is due to the new guidance and additional information requested from applicants before a submission can be made. FSA/FSS are actively managing the legacy application service and CMS in tandem. This will ensure applications continue to be dealt with in date order and enables us to monitor application flow through the service.

6.3 One of the tools we believe will also support applications to flow through the service more efficiently is the use of other regulators' opinions. This would involve us validating the opinion of another regulator in specific and limited circumstances such as for the re-authorisation of products. We will shortly be issuing advice to Ministers on this approach, and subject to their views, would seek to implement this approach later this year.

6.4 Work to focus Advisory Committee resource on key issues and complex applications has a longer trajectory and is dependent on successfully recruiting to

senior science posts within FSA to help lead this work and the ongoing development of risk assessment skills, knowledge and experience.

6.5 We are also working closely with the FSA on the approach to cultivated meat and proteins, reflecting the unique challenges this technology poses for regulation. Respective FSS and FSA teams are working to identify and address key regulatory issues that will need to be resolved to effectively assess and authorise applications for these products and engaging with international regulators and industry stakeholders.

6.6 Finally, we also remain engaged on FSA's work to develop a regulatory framework for Precision Bred Organisms for food and feed in England. Our current focus however remains on working with the Scottish Government following publication of the European Commission's New Genomic Techniques (NGT) proposals in July, and any further assessment work that may need to be undertaken in Scotland.

Longer-term Regulatory Reform

6.7 As highlighted in the June Board paper, we are working with FSA to consider potential future options for longer-term reform of the food and feed regulatory system. This work is expected to include developing a set of reform principles and design features to guide options policy development, as well as Ministerial and stakeholder engagement.

6.8 This work is being progressed within our existing policy staff complement, and FSS capacity for continued delivery of core risk analysis and regulated products functions, alongside any regulatory reform that is agreed with FSA, remains challenging.

6.9 We will continue to provide the Board with updates via this regular report and will bring future proposals to the Board for agreement.

7 Equality Impact Assessment and Fairer Scotland Duty

7.1 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.

8 Conclusion

8.1 The Board is asked to:

- **Review** the update on the performance of the risk analysis process and regulated products service.
- **Note** the progress made on continuous improvement.

- **Note** that the update on longer term reform work.

Please direct queries to:

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Annex A

Forward look for completing Regulated Products applications:

Description of applications	**Earliest estimate for Ministerial decision**	**Earliest estimate of coming into force date (if approved by Ministers)**
8 GMO products and 3 modification of existing GMO authorisation holders' details	Q4 22/23	Authorisations came into force across GB on 26 April.
2 Novel food 1 Flavouring 1 Food additive	Q4 22/23	Authorisations came into force across GB on 15 May.
12 Feed additives	Q2 23/24	Q3 23/24
Tranche 3		
4 Novel Foods	Q3 23/24	Q4 23/24
4 Food Additives	Q3 23/24	Q4 23/24
25 Feed Additives	Q4 23/24	Q1 24/25
5 GMO	Q1 24/25	Q2 24/25
Future Planning		
First CBD authorisation(s)	Q1 24/25*	Q2 24/25

* There is a dependency on the planned Home Office legislation on THC limits in consumer products.

Progress of applications is subject to change, for example if new evidence is required from applicants.