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 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 FSS/FSA risk analysis process since the September Board meeting. This includes applications progressing through the regulated products service and issues that FSS/FSA has chosen to proactively consider.

3.2 Background information about the risk analysis process and regulated products service is available in the March 2023 report to the Board which can be accessed 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 September 2023, there were 29 issues recorded on the public risk analysis register, which includes issues completed. Of these, there were 22 actively progressing. Changes in the register since the last update include 3 new issues at the stage of Risk Assessment and evidence which are:

- the safety of the use of Titanium Dioxide as a feed additive;
- the safety of Bisphenol A (BPA) in food and
- the risk of allergic reaction from fortification of non-wholemeal wheat flour with folic acid

4.3 There are currently seven 'non-routine' issues, listed at **Annex A**.

4.4 The Risk Analysis issue relating to the assessment of the risk to vulnerable consumers from Listeria monocytogenes in smoked fish is now marked complete on the public register. FSS had a lead role in this work which in turn led to the updating of our advice to vulnerable consumers .

5 Regulated Products Service

5.1 As of 30 September 2023, the caseload in the regulated products service was 450. This includes 26 new applications in this reporting period with sufficient information to progress. In addition, one application was withdrawn and one application was invalidated in the Validation stage during this reporting period.

5.2 We have completed 16 applications relating to novel food, a food flavouring, a food additives and Genetically Modified products, since April 2023 and we have continued to make progress towards authorising 13 Feed Additive products. The consultation for these products closed in July and we issued advice to Ministers in September. On receiving agreement from Ministers, legislation authorising the additives was laid in the Scottish Parliament in November and will come into force in December, subject to parliamentary scrutiny.

5.3 Following a review of our forward timetable, we have identified that there will be a delay estimated to be between three and six months to the Risk Management stage (this covers the phase leading up to recommendations to Ministers) for the next batch of 33 applications. This delay is due to a combination of additional work, and aligning authorisation across England, Wales, and Scotland.

5.4 As discussed at the June Board meeting, there are resource pressures in all parts of the regulated products system. Since June, the extent of additional work on priority issues, and the subsequent impact on regulated products delivery has become clearer: this includes work to ensure the continued availability of Cobalt Salts as a feed additive and dealing with the first applications considered end-to-end since Brexit, without the benefit of previous work undertaken as part of the EU.

5.5 In addition to these resource pressures, the Risk Management and legislative drafting stage during tranche 2 took longer than expected, and this is a risk for tranche 3. The range and level of legal scrutiny and assurance essential to successfully drafting authorisations has taken longer to address than our planning

assumptions. We are therefore revising our assumptions about the time needed for this stage, which will ensure the accuracy of instruments in all countries, for applications due for authorisation within the next six months. Revised estimated dates of completion for applications in risk management are at **Annex B.**

5.6 As highlighted in previous reports, resource pressure remains the main risk to our delivery timetables particularly as new Risk Assessors and Risk Managers in the FSA are trained and upskilled. In FSS, we have also recently recruited a number of new staff to our Regulated Products Policy Team who are currently undergoing training. Regulated products service resourcing in the FSA has grown substantially since Brexit (but less so in Wales and FSS). However, given current financial and headcount constraints in FSS and FSA the opportunity for further expansion will be limited. This means the service will remain vulnerable to unexpected shocks (such as an unanticipated surge in applications), changes to priorities (such as requirements to adapt to new government policies) and additional, unforeseen work required for more complex applications (such as the authorisation of Cobalt feed additives). We are reviewing our longer-term forecasts in light of these risks and will report back to the Board in future reports.

5.7 CBD update – CBD applications continue to make up a significant proportion of our caseload. Since our report in September:

- FSS and FSA has published an Advisory Committee on Novel Foods and Processes (ACNFP) position paper on establishing a provisional Acceptable Daily Limit (ADI) for pure-form CBD, and updated consumer advice in response
- The ACNFP reviewed the first CBD applications at its September meeting, and considered one of these again at the November meeting
- The Home Office has published the Government's response to recommendations from the Advisory Committee on Misuse of Drugs on consumer CBD products, confirming it intends to bring forward legislation to prescribe the lawful amount of controlled Phytocannabinoids in such products. We welcome this and are liaising with the FSA as it works closely with the Home Office to ensure this legislation aligns with novel food regulations and provides clarity to industry. Without this change in the law, it will not be possible to authorise a substantial amount of CBD applications

6 Continuous Improvement and Reform

6.1 We are progressing continuous improvements, as set out below**.** These actions will reduce risk and enable us to increase delivery efficiency within existing resources. In addition, we are working with the FSA to consider how teams across England, Wales and Scotland could work more efficiently to reduce delays arising during the authorisation stage. This could include a streamlined process for dealing with requests for information from legal services and more central support with preparation of key documents and products required for the authorisation process.

6.2 Case Management System (CMS) - As of 30 September 2023, there have been 27 contacts on the new CMS resulting in 26 applications. This is in line with the GB planning assumption of 120 applications per year flowing into the service. To date, 97% of contacts have progressed to a full application demonstrating the added value of our new guidance and additional information requested from applicants before an application can be made. The FSA are continuing to develop the internal interface of CMS along with making other improvements to the service's usability in response to feedback from industry. The legacy Application Service and CMS are managed in tandem to ensure applications are dealt with in date order and enables us to monitor application flow through the service.

6.3 Use of other regulators' opinions - We have now notified Ministers of our intention to use other regulators' opinions, where we will validate the opinion of another regulator in specific and limited circumstances, such as for the re-authorisation of products. The process for implementing this approach has been developed, with pilot applications identified for consideration by an internal FSA panel to review the proposed conclusion. The first panel meeting took place at the end of November. The initial aim is to use this approach for renewal applications and this experience will be used to consider the opportunities to extend this option to other application types as part of our short-term improvements as well as work on longer-term regulatory reform.

6.4 Quality of applications - Poorer quality applications create delays in the risk assessment phase through requests for additional information to applicants and follow up questions where responses are not complete.

6.5 We are working closely with the FSA to improve pre-application engagement to enable applicants to understand data and evidence requirements, to be clear on the regime under which their product will be assessed and to submit good quality applications on the CMS. We are currently piloting enhanced pre-application engagement on a small selection of 'first of kind' applications using new and/or disruptive technologies, to inform our approach across regulated products. Our ambition is to improve the quality of applications which in turn will reduce the re-work required by applicants and the regulator in the early stages of the process. Whilst we can offer some limited improvements within current resources, we are also developing proposals for early engagement at the product development stage and a more comprehensive pre-application service as part of our longer-term reform work.

6.6 Precision breeding – This is the subject of a separate update paper for the Board.

6.7 Regulated products reform – In October, officials gave a presentation to the Board to update members and seek initial views on potential recommendations that could bring significant benefits to applicants and FSS whilst maintaining food and feed safety standards. These included some areas for priority attention and also consideration over the longer term.

6.8 Immediate reform - In line with the ambition to reform the regulated products service to reduce burdens on applicants and regulators and promote innovation

and growth, we have identified priority changes that we are looking to bring forward, reducing the risk of future delays to authorisations. These priority changes include:

- **A proportionate risk-based approach to the regulation of certain products requiring renewals**. Currently, legislation regarding GMOs, Smoke Flavourings and Feed Additives includes automatic requirements for periodic (e.g., 10-year) review and renewal of authorisation, regardless of whether evidence suggests that this is needed. To date, renewals have made up approximately 25% of all applications to the RPS. We will explore removal of these automatic requirements**,** utilising the appropriate legislative vehicle. This should release resource and time to consider new product applications, which could be considered higher risk than renewal applications (that have previously been assessed as safe). We will ensure there is adequate post-market surveillance and that we retain the ability to review authorisations in light of new evidence and act where necessary to protect public health and ensure food and feed safety.

- **A more efficient process for bringing authorisations into force following a Ministerial decision**. Currently, all regulated product authorisations are confirmed by secondary legislation which requires significant additional resource to prepare and lay and adds around 3-6 months to the time it takes for new products to gain market authorisation. This process is significantly longer than the process that applied when the UK was a member of the EU. This is an effect of the way the regulations were transposed into a UK context, with the Appropriate Authority (Ministers) being assigned the legislative steps previously completed by the European Commission. We will explore alternative options, such as bringing authorisations into force via publication to an official register following Ministerial approval, rather than through laying a Statutory Instrument.

- **Simpler, more transparent, and more accessible registers and lists of authorised regulated products**. The current methods for listing authorised products, which vary by regime, include lists in legislation or having separate pieces of legislation for each authorisation. This change would significantly streamline legislation and provide a more efficient process to record and communicate which products have been authorised, thereby enhancing transparency and accessibility, and reducing the regulatory burden associated with maintaining and using multiple, complex sources of essential information.

- We are also continuing policy development of a **Common Authorisation Procedure** to ensure a simplified process with a single 'front door' for applications.

6.9 Future Reform – The long-term strategy for delivering reform will focus on exploring options for fundamental changes across the regimes to further streamline and improve the process. This work will build on the priority reform plans and consider options to make the regulated product authorisation system as efficient as possible while being proportionate to risk. This will include investigating opportunities for

international collaboration, such as using other regulators' opinions, and opportunities to implement a triage structure for specific use cases and other authorisation factors.

6.10 We are committed to working with the FSA to develop a common approach to reform and mitigate any risk of divergence. Both FSS and FSA are broadly aligned in approaches and will work jointly on reform plans going forward. On 28 November, the FSS Chair wrote to inform Scottish Ministers of the approach set out above and undertook to write again when the proposals are more developed.

6.11 As a devolved policy area, all reform plans are subject to the open and transparent policy development process including impact assessments, public consultation and consultation with Ministers**.**

6.12 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.

6.13 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** the update on longer term reform work

Please direct queries to:

Stephen Hendry
Stephen.Hendry@fss.scot
SLT Sponsor – Garry Mournian
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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 (FCMs).
- Analysis of environmentally sourced recycled plastic in food contact materials (FCMs).
- 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.

Annex B

Forward look for Regulated Product applications in Risk Management as of October 2023

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