Risk Analysis and Regulated Products Service Update

1. Purpose

1.1 This paper is the first in what will be regular updates on the progress of issues in the joint FSS and Food Standards Agency (FSA) Risk Analysis Process and GB Regulated Products Service.

1.2 The Board is asked to:

- **Note** the update on issues undergoing Risk Analysis and the status of the GB Regulated Products Service.

- **Provide a view** on the presentation of more detailed analysis of the work flowing through the risk analysis and regulated products service at future Board meetings.

- **Note** the challenges associated with resourcing and the volumes of applications in the system for regulated products.

- **Note** FSA work on Regulatory Reform and FSS involvement.

2. Strategic aims

2.1 The work of Risk Analysis and the GB 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 A key area of responsibility that FSS has undertaken since EU Exit is an increased role in food and feed safety risk analysis. FSS together with FSA has developed a process to consider issues where it is necessary to make a risk management recommendation. The aim of the risk analysis process is to provide confidence that FSS and FSA advice delivers public health protection; is informed by science and evidence; considers consumers' other interests in relation to food; and is independent. The process follows globally recognised frameworks for risk analysis, is open and transparent and provides for a four nations approach. It is used to assess the risks associated with food and animal feed, for example chemical, microbiological or allergen risks, to provide evidence-based advice to Ministers, business and consumers on safety risks.

3.2 Another key responsibility that FSS and FSA have undertaken since EU Exit is the GB Regulated Products Service (RPS). Applications are received

for regulated food and feed products, which require authorisation prior to entering the market. The approval process for applications comprises various stages before recommendations are made to Ministers in Scotland, England and Wales. A four nations approach to collaborative working is taken at all stages of the process. Where Ministers decide to authorise, the authorisation must be set out in secondary legislation before products may be placed on the market. For regulated products to be placed on the market in Northern Ireland (NI), in line with the NI Protocol, they must be authorised via the European Commission's authorisation process.

3.3 The Board has previously received updates on issues progressing through risk analysis and the RPS via the Chief Executives report. Going forward, it is the intention of the Executive to provide the Board with a more detailed analysis of the work flowing through the risk analysis process and the RPS. This can be presented as an Annex to this paper or as part of the broader FSS Performance Pack. A view from the Board on its preference is therefore requested.

4. Discussion

4.1 Risk Analysis Process status report: January 2023 – March 2023

4.2 Details of issues undergoing risk analysis are published to an online 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. The register provides information about issues that are being considered by FSS and the FSA through the food and animal feed risk analysis process. It includes a summary of each issue alongside its current status.

4.3 Four issues were added to the public register in the latest quarterly update in January 2023.

Issue	Description	Preliminary estimate of completion date
Risk assessment on Avian Influenza infection via the food chain.	Production of an updated risk assessment for Avian Influenza in food, triggered by changes to consumer advice regarding egg consumption and the geographically widespread nature of Avian Influenza generating over 100 confirmed cases in the 2021/22 Avian Influenza season. This work has been initiated to ensure risk management advice for the consumption of poultry, wild game and raw eggs remains appropriate and is supported by the latest evidence on risks associated with Avian Influenza, especially with respect to	Completion of the risk assessment (RA) Spring 23. Depending on the outcome of the RA further work on risk management (RM) may be required during 2023

	vulnerable groups, taking into account developments in the spread of Avian Influenza.	
Assessment of risk associated with tetra-methyl bisphenol F diglycidyl ether (TMBPF-DGE) used in can coatings.	Work to assess the safety of TMBPF-DGE, a substance used as a coating in metal food contact materials (e.g. aluminium food cans), is being undertaken to ensure its use in that context is appropriate in respect of the UK market. The assessment is being taken forward as TMBPF is considered as a potential alternative to bisphenol A (BPA), a substance that is more widely used in can coatings on the UK market but with specific restrictions in place.	The RA is expected to be completed in Spring 2023 with consideration of RM advice to follow later in 2023.
Assessment of the risk to vulnerable consumers from Listeria monocytogenes in blue cheese.	Assessment of the risk to vulnerable consumers from listeria monocytogenes in blue cheeses. There are inconsistencies in the advice provided by government partners to pregnant women on the consumption of blue cheese. A RA will assess the risk to vulnerable consumers. FSA and FSS are working together to present consistent RM advice underpinned by science and evidence.	Anticipate publication of a RA and RM advice in Spring 2023.
Assessment of the risk to vulnerable consumers from Listeria monocytogenes in smoked fish.	Assessment of the risk to vulnerable consumers, including pregnant women and people with weakened immune systems, from Listeria monocytogenes in smoked fish. This follows confirmation there has been an increase over the period 2020-22 in the number of cases of listeriosis linked to the consumption of smoked salmon by vulnerable groups. FSA and FSS are working with other Government departments to present consistent RM advice underpinned by science and evidence.	Anticipate publication of RA and RM advice in Spring 2023.

*Estimated completion dates are provisional at this stage and dependent on the progress of the RA phase and subsequent RM approach. Issues may be reprioritised if other issues emerge that take priority on public health grounds.

4.4 Work to assess the safety of Titanium Dioxide (E171) as a food additive continues, with the development of a risk assessment and economic impact assessment. The risk assessment is expected to be completed in early summer and, subject to the outcome the assessment, recommendations in relation to a regulatory approach will be developed during summer and autumn 2023.

4.5 To date, three issues are recorded as having completed in the public register:

- risk assessment work to support Defra's imported Products of Animal Origin (POAO) 2022 controls project
- review of controls on imports from Japan that were put in place following the Fukushima nuclear incident
- work with Defra to consider the risk associated with minced meat and meat preparations as part of a review of prohibitions and restrictions on imported EU foods.

4.6 Regulated Products Process (RPS)

4.7 The RPS has been running since January 2021. Year 1 included a peak of applications that were already progressing in the EU, and an influx of CBD applications. Since January 2022, a broader spectrum of applications has been received, and this has enabled a better understanding of the flow into the service. This confirms the likely mix of future applications, for example, that feed and food additive applications are likely to form a large proportion of the future flow and that around 150 applications each year can be expected on average. However, it is important to note that the flow of products into the system will vary from year to year, with peaks and troughs of applications depending on commercial cycles and when products come up for renewal.

4.8 In the first two years of live running, the use of 31 regulated products have been authorised under the GB system, improvements to processes have been put in place, problems with Retained EU Laws fixed (for example, changes to the regulations to make sure that lists of approved and prohibited products have legal force and are useable for industry and enforcement officers) and support provided to applicants help with the progress of applications. Over the next two years the number of authorisations will continue to increase and the peak of applications at pre-validation and in risk assessment from Year 1 is expected to reduce (many of these are paused awaiting further evidence before progressing).

4.9 Snapshot of applications received by GB Regulated Products Service

4.10 Details of validated applications going through the RPS are published in a public register. The register also shows the current stage of the application progress.

4.11 As of 31 January 2023, there are 424 applications progressing through the service which includes applications that have not yet been validated. Table 1 in Annex A shows the progress of applications per quarter, and the information below it explains the different stages. A detailed breakdown of the applications that are currently progressing is provided in Table 2 in Annex A.

4.12 As shown in Table 1 in Annex 1, there is a build-up of applications in the risk assessment phase (144). This is related to the large number of applications received in the first year of operation, comprising applications transferred from

the EU and CBD applications to meet the FSA's deadline of 31 March 2021. In the second year of operation, the flow of applications into risk assessment has been an average of 12 per month. There is not enough data yet to know if this will be typical.

4.13 Authorisations expected in the next 18-24 months

4.14 Applications are taken through the process in batches, enabling larger numbers to be authorised at the same time. The consultation on 11 Genetically Modified Organisms (GMO) applications closed in December. The legislation for these GMO authorisations should come into force across GB in April. The consultation on 2 Novel Foods, a food additive and a flavouring, also closed in December with legislation expected to come into force in May. The next batch for consultation will be 12 feed additives applications. The table below provides a summary for the next 18-24 months.

Description of applications	**(Estimated) erial decision**	**Estimate of Coming orce date (if ved by Ministers)**
8 GMO products and 3 modification of g GMO authorisation holders' detail	Q4 22/23	Q1 23/24
2 Novel food 1 Flavouring 1 Food additive	Q4 22/23	Q1 23/24
12 Feed additive	Q2 23/24	Q3 23/24
32 varying regimes TBC	Q3 23/24	Q4 23/24
First CBD authorisation(s)	Q4 23/24*	Q1 24/25

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

4.15 The progress of applications is subject to change, for example if additional evidence is required from an applicant.

5. Developments

5.1 Online application system

5.2 Development of a new Case Management System for regulated product applications is being progressed by the FSA. User testing commenced internally on the front end of the system at the end of last year and FSA have now commenced testing the system with external stakeholders, including Scotland, prior to launching it in Spring 2023. This will make major improvements to the application experience. It should improve the quality of dossiers received, provide a more informed journey for applicants and capture user feedback to help identify and address challenges in the system early in the process. FSS will

have full access to the system and is due to discuss training needs with the FSA shortly.

5.3 Regulatory Reform

5.4 In December the Board agreed the principles that will inform our discussions with UK Government departments on proposals for revoking and amending food and feed law using powers under the Retained EU Law (Reform and Revocation) Bill, and subsequent advice to Scottish Ministers.

5.5 Certain areas had already been flagged by both FSA and FSS as requiring review prior to the introduction of the REUL Bill. This included the need to consider changes to streamline the process for approving regulated products, and we recognise there is the potential to pursue this using powers in the Bill. These changes would involve considerable preparatory work and analysis to deliver, including detailed policy development and consultation. These discussions are ongoing with FSA.

5.6 FSS officials are also engaged in discussions with FSA on a review of the Novel Foods Regulatory Framework (based on Novel Foods Retained EU Legislation) which FSA have identified as a priority area for reform for which there has been a public commitment by the UK Government. This has ensured Scottish interests have been noted given the GB nature of the regulated products framework. The review will consider the national and international regulatory landscape, and present potential options for a Novel Foods Regulatory Framework. The project commenced on 5th January and aims to report in Spring 2023.

6.Resources

6.1 The first year of operation (Jan-Dec 2021) was not typical; as expected a large volume of applications were received into the GB process that were already progressing in the EU. Many CBD applications were also received to meet the FSA's deadline of March 2021 in England and Wales. This resulted in a significant volume of applications at the risk assessment stage. Over the next two years the build-up of applications in risk assessment, combined with the expected inflow of new applications over the course of the next 18 months, will continue to put pressure on the system.

6.2 To manage the growing workload, FSA are looking to increase its capacity across policy and science teams – in particular, risk assessment given it is the most resource intensive and takes the longest time to complete. As workload and FSA risk assessment capacity is being scaled up, it will be necessary to review how FSS science resource is most effectively allocated to maintain oversight of evidence and data relevant to Scotland. To date, our scientists have been actively involved in the delivery of a number of risk assessments on the risk analysis tracker and have provided technical support for the review of regulated products dossiers. However, resource constraints will limit our ability to keep pace with growing demand, requiring us to keep priorities, and our

scientific partnerships with the FSA under on-going review. In addition, although FSS has strong microbiological expertise (including at C1, C2 and CSA level), we have no senior level expertise to deliver or review toxicological risk assessment. Toxicological assessments form most issues progressing through both the risk analysis and regulated products processes.

In addition, consideration must be given to how the legislative aspects of regulated products authorisation are currently delivered by FSS, as both parties rely on partnership working to coordinate policy and authorisations across GB. There is a risk here that because of the lack of resource to deal with the full volume of EU work created by EU Exit, FSS is unable to meet the potential demand, particularly for regulated products, which may result in temporary regulatory divergence across GB, and discussions are taking place within the Executive about how this risk can be managed.

6.3 A review of the available data is underway and will build a more accurate model of the future demand on resources and the results of this analysis should be available for the next Board meeting; however, this will remain highly dependent on assumptions for future years. Forecasting remains challenging due to the uncertainty of the quantity and type of future applications which are influenced by commercial decisions and market trends. If there was a surge in applications, (similar to the peak of CBD applications in Year 1), pressures would emerge over the next 6 -12 months at the validation and risk assessment stage due to the scientific review requirements.

6.4 Close working relationships and engagement are in place between FSS and the FSA and the joint project management approach to regulated products applications is being enhanced. This will mitigate some of the risks to an extent, notwithstanding the risk highlighted above around resource within FSS to undertake this work fully in Scotland.

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/Recommendations

8.1 The Board is asked to:

- **Note** the update on issues undergoing Risk Analysis and the status of the Regulated Products Service.

- **Provide a view** on the presentation of more detailed analysis of the work flowing through the risk analysis and regulated products service at future Board meetings.

- **Note the challenges associated with resourcing and the volumes of applications in the system for regulated products**

- **Note** FSA work on Regulatory Reform and FSS involvement.

8.2 FSA have supported the drafting of this paper and will share a similar paper with their Board.

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Date **Annex A**

Progress and Breakdown of Applications in the Regulated Products Service

Table 1: Progress of applications per quarter

	Total Contacts	Incomplete Applications	Applications Progressing	Pre-Validation	Risk Assessment	Risk Management	Applications Completed
Jan-Mar 2021	989	782	182	103	69	10	25
Apr-Jun 2021	183	136	45	6	29	10	2
Jul-Sep 2021	105	82	23	6	9	8	0
Oct-Dec 2021	111	73	37	10	21	6	1
Jan-Mar 2022	108	82	23	16	7	0	3
Apr-Jun 2022	123	97	26	20	6	0	0
July-Sep 2022	113	90	23	20	2	1	0
Oct-Dec 2022	129	86	43	43	0	0	0
Total	1861	1428	402	224	143	35	31
Stop the Clock				94	27		

Key

- **Total contacts:** Number of submissions made on our application portal.
- **Incomplete Applications**: Submissions that do not pass initial administrative checks or are not applications. These also include applications that have been invalidated and applications that are withdrawn by the applicant.
- **Applications Progressing:** Number of applications that are progressing through the authorisation process. This does not include applications that have been authorised.

- **Pre Validation Stage:** Applications being reviewed by Policy and SERD before being deemed suitable for progress into risk assessment. Applications can be held here for some time as missing evidence is sought and provided. When information is requested, we apply stop the clock as we await the further evidence.
- **Risk Assessment:** Applications currently with SERD to develop a safety evaluation. The 'stop the clock' is used to allow us to gather further information from applicant.
- **Risk Management:** Applications that have been passed back to policy to consider risk management options.
- **Applications Completed:** Number of applications that have been completed.
- **Total Stop the Clock:** Number of applications where we have 'stopped the clock' whilst we await further information from the applicant (as at February 2023)

Table 2: Detailed breakdown of live applications in the Regulated Products Service as of 31 October 2022 and 31 January 2023.

Total applications as of 31st October 2022 / Total applications as of 31st January 2023

Breakdown of all applications by regime	Total no of applications progressing		No of applications at pre validation		No of applications at Risk Assessment		No of applications at Risk Management		No of applications at Authorisation		Applications completed	
Novel Food (Excluding CBD)	46	49	34	29	10	18	2	2	-	-	6	6
Novel Food CBD	128	129	115	116	13	13	-	-	-	-	-	-
Feed Additives	146	151	57	54	63	78	15	19	11	-	-	11
GMO	34	35	22	14	1	10	11	11	-	-	9	9
Novel Food Traditional	-	4	-	4	-	-	-	-	-	-	-	-
Food Contact Materials (Recycled)	8	11	3	6	5	5	-	-	-	-	-	-
Food Contact Materials (Plastics)	4	3	1	-	3	3	-	-	-	-	-	-
Extraction Solvents	1	-	1	-	-	-	-	-	-	-	-	-
Food Additives	17	17	5	5	11	11	1	1	-	-	-	-
Flavourings	8	10	4	6	2	2	2	2	-	-	-	-
Feed for Particular Nutritional Users (PARNUTS)	2	2	-	-	2	2	-	-	-	-	-	-
Novel Food Status	-	-	-	-	-	-	-	-	-	-	2	2
Smoke Flavourings	9	9	9	7	-	2	-	-	-	-	3	3
Food Enzymes	1	1	1	1	-	-	-	-	-	-	-	-
Other	2	3	2	3	-	-	-	-	-	-	-	-
Feed Detox	1	-	1	-	-	-	-	-	-	-	-	-
Food Contact Material (active)	1	-	1	-	-	-	-	-	-	-	-	-

Total	407	424	256	245	110	144	31	35	11	-	20	31