Risk Analysis and Regulated Products Service: Regular Update to FSA Board

FSA 23-03-08 - This paper provides a regular update on the current status of the risk analysis and regulated product service to ensure transparency on the progress of the service.

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Gweld FSA 23-03-08a Risk analysis process and regulated products service report as PDF(Open in a new window) (414.62 KB)

1. Summary

1.1 The Board is asked to:

- **Note** the update on issues undergoing risk analysis and the current status of the Regulated Products Service (RPS)
- **Note** the summary of risks to delivery and mitigations
- **Note** the progress being made on Regulatory Reform

2. Introduction

2.1 This paper provides an update to the FSA Board about the progress of issues in the Risk Analysis Process and Regulated Products Service. FSA and Food Standards Scotland (FSS) receive applications 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 England, Scotland 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. In order for regulated products to be placed on the market in Northern Ireland (NI), in line with the Northern Ireland Protocol, they must be authorised via the European Commission's authorisation process. A paper to the Business Committee in June 2022 recapped the objectives and core principles of the risk analysis process and contains links to the process steps and previous board papers.

2.2 The accompanying performance pack provides detailed analysis of the work flowing through the Risk Analysis Process and the RPS.

3. Risk Analysis Process

Risk Analysis Status Report: January 2023 – March 2023

3.1 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 the FSA and FSS through our food and animal feed Risk Analysis Process. It provides a summary of each issue and its current status.

3.2 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 vulnerable groups, taking into account developments in the spread of Avian Influenza.	Completion of the risk assessment (RA) Spring 2023. Depending on the outcome of the RA further work on risk management (RM) may be required during 2023.
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.

3.3 Our work to assess the safety of Titanium Dioxide (E171) as a food additive continues, with the development of a RA and economic impact assessment. We expect the RA to be completed by the end of 2023 and, subject to the outcome of our assessment work, recommendations in relation to a regulatory approach will be agreed at the earliest by Q1 2024/25

3.4 Since the UK left the EU, we have recorded three issues as having completed on our public register. These are:

- RA 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; and
- 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.
- No additional issues have been designated as complete in the register since the last quarterly update to the Board.

3.5 The accompanying performance pack provides a summary of the number and type of issues progressing through risk analysis as well as indicators of performance against our objectives for transparency and quality. The content of the performance pack will remain subject to iterative development as the number of issues completing the end-to-end process increases.

4. Regulated Products Service (RPS)

Summary

4.1 The RPS has been running since January 2021. Year 1 included a peak of several hundred applications comprising those transferred to GB that were already progressing in the EU, and an influx of CBD applications to meet a regulatory deadline. Since January 2022, we have received a broader spectrum of applications, and this has enabled us to gain a better understanding of the potential future flow into the service. This confirms the likely mix of future applications, for example, that we might expect around 150 applications each year on average and that feed and food additive applications are likely to form a large proportion of the future flow. 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.

4.2 In the first two years of live running, we have authorised the use of 31 regulated products under the GB system, put in place improvements to our processes, fixed problems with Retained EU Laws (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 worked in partnership with applicants to support the progress of applications. Over the next two years the number of authorisations will continue to increase. We expect the peak of applications at pre-validation and in risk assessment from Year 1 to reduce (many of these are paused awaiting further evidence before progressing).

Snapshot of Applications Received by RPS

4.3 Details of validated applications going through the RPS are published in a public register.

4.4 As of 31 January 2023, we have 424 applications progressing through the service which includes a large number of applications that have not yet been validated and are paused awaiting evidence. Table 1 of Annex 1 shows the progress of applications per quarter, and the information below it explains the different stages. There is a detailed breakdown of the applications we are progressing in Annex 1 (Table 2).

4.5 As shown in Annex 1 (Table 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 our first year of operation, comprising applications transferred from the EU and CBD applications at our regulatory deadline of 31 March 2021. In our second year of operation, the flow of applications into risk assessment has been an average of 12 per month. We do not yet have enough data to know if this will be typical; a forward look and an assessment of future risks and mitigations is in section 5 below.

Authorisations expected in the Next 18-24 Months

4.6 In our first two years of operation, we have substantially increased resources in both Policy and our Science Evidence and Research Directorate (SERD) to deal with increasing numbers in the system. SERD are responsible for risk assessments and have a detailed workplan to manage the build-up of applications alongside new work. We will be introducing further process improvements in the coming year, for example a new Case Management System which will

streamline the process of submitting and validating applications, and an approach to making effective use of other regulators' opinions which will reduce the time spent in risk assessment. We have an established approach to taking applications through in batches, enabling larger numbers to be authorised at the same time. This gives us reasonable assurance that we will continue to make authorisations to the expected timescales over the next 12-18 months. In the longer-term we are considering regulatory reforms to further improve the efficiency of the RPS; details are in section 6 below.

Description of applications	(Estimated) Ministerial decision	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	Q1 23/24
2 Novel food 1 Flavouring 1 Food additive	Q4 22/23	Q1 23/24
12 feed additives	Q2 23/24	Q1 23/24
34 varying regimes TBC. This will include GMO, Novel Foods, a Food Additive and Feed Additives	Q2 23/24	Q1 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.

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

5. Forward look and risks to delivery

5.1 To manage the growing workload we continue to increase the resources in both policy and science teams: for example, the number of risk assessors has increased from five FSA employees in January 2021 to 30 in January 2023. Under current plans, the number of assessors will increase to 38 by the end of

2023. Risk Assessment is the stage of the process that is most resource intensive and takes the longest time to complete and therefore it is expected that there will be a larger stock of applications at this stage. This is the stage which carries most risk of building up a backlog if resources do not match demand as recruitment and training of risk assessors takes 9-12 months.

5.2 SERD has established a system to flexibly deploy resources in response to the dossiers received. Capacity to deliver risk assessments will continue to increase in the coming months as new risk assessors complete professional training and reach full capability. On current plans, we expect the caseload in risk assessment will reduce over the next two years once the peak in applications in the validation and assessment phases have moved through the system by 2025, and as long as we do not receive an unexpected surge in applications. We are using a number of levers to encourage recruitment, including online support sessions for applicants, career sites and use of professional networks and societies.

5.3 We are reviewing the available data to build a more accurate model of the future demand on resources and will provide the results of this analysis to the June Board; 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. Regulatory Reform

6.1 In the longer-term, opportunities for regulatory reform could bring significant benefits to applicants and the FSA by making the process more efficient and effective and enable consumers to benefit from new products more quickly. We are considering opportunities presented by powers created in the REUL Bill to streamline the process for approving regulated products. These reforms would involve considerable preparatory work and analysis to deliver, including detailed policy development and consultation, and therefore we assume that reforms could not be in place until 2026 at the earliest. Examples of the reforms under consideration are:

- A common application gateway, and standardised regulatory pathways through the different regimes;
- Shortening and streamlining the process through which authorisations come into force; and
- A more efficient process to update and publish the lists of which products have been authorised.

6.2 One of our priority areas of reform, and for which there has been a public commitment by the Government, is to review the Novel Foods Regulatory Framework (based on Novel Food Retained EU Legislation). We are evaluating the current framework and will identify opportunities for potential reform. The review is considering the national and international regulatory landscape and will present potential options for reform in spring 2023. Options will then be considered by FSA officials who will make recommendations to the FSA Board about the future strategy. This work is aimed at removing barriers to innovation; although options will focus on the effectiveness of the regulatory system overall, some (for example, enhanced pre-application support) would require additional resources for the FSA to deliver.

7. Conclusions

7.1 The Board is asked to:

- **Note** the update on issues undergoing risk analysis and the current status of the RPS.
- **Note** the summary of risks to delivery and mitigations.
- **Note** the progress being made on Regulatory Reform.

7.2 FSS has supported the drafting of this paper, and a version of it will also be shared with their board.

Annex 1: Progress and Breakdown of Applications in the Regulated Products Service

Table 1: Progress of applications per quarter

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-June 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 our 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, whilst we obtain the necessary information, required for Risk Assessment. 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 of February 2023).

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

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

Breakdown of all applications by regime	Total no. of applications progressing as of 31 Oct 2022	Total no. of applications progressing as of 31 Jan 2023	No. of applications at pre-validation as of 31 Oct 2022	No. of applications at pre-validation as of 31 Oct 2023	No. of applications as at risk assessment as of 31 Oct 2022	No. of applications as at risk assessment as of 31 Jan 2023	No. of applications at risk management as of 31 Oct 2022	No. of applications at risk management as of 31 Jan 2023	No. of applications at authorisation as of 31 Oct 2022	No. of applications at authorisation as of 31 Jan 2023	Applications completed as of 31 Oct 2022	Applications completed as of 31 Jan 2023
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	-	-	-	-	-	-

Breakdown of all applications by regime	Total no. of applications progressing as of 31 Oct 2022	Total no. of applications progressing as of 31 Jan 2023	No. of applications at pre-validation as of 31 Oct 2022	No. of applications at pre-validation as of 31 Oct 2023	No. of applications as at risk assessment as of31 Oct2022	No. of applications as at risk assessment as of31 Jan2023	No. of applications at risk management as of 31 Oct 2022	No. of applications at risk management as of 31 Jan 2023	No. of applications at authorisation as of 31 Oct 2022	No. of applications at authorisation as of 31 Jan 2023	Applications completed as of 31 Oct 2022	Applications completed as of 31 Jan 2023
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