FSA 22-09-15 - Regulated Products Service: regular update to Business Committee

This paper provides a regular update on the on the current status of the regulated product service to ensure transparency on the progress of the service and proposes a set of key performance indicators to assist with measuring the performance of the service.

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1. Summary

1.1 The Business Committee is asked to note the current status of the Regulated Products Service.

2. Introduction

2.1 FSA and Food Standards Scotland (FSS) have been receiving applications for food and feed products which require authorisation prior to entering the market. The approval process for applications has various stages prior to recommendations being made to Ministers in England, Scotland and Wales. Where Ministers decide to authorise, the authorisation must be set out in legislation before products may be placed on the market within the nations. In order for regulated products to be placed on the market in Northern Ireland, they must be authorised via the European Commission's authorisation process.

2.2 As agreed with the FSA Chair and Chief Executive, starting in March 2022, this regular update is provided at each Business Committee. The accompanying performance pack provides detailed analysis of the work flowing through the service.

3. Snapshot of Applications Received by Regulated Product Service

3.1 As of 31st July 22, we have 381 applications progressing through the service. Fig. 1 shows the progress of applications per quarter, and the information below it explains the different stages. There is also a detailed breakdown of the applications we are progressing in Fig 2.

Figure 1 shows the to date progress of applications per quarter

Quarter	Total contacts	Incomplete applications	Applications progressing	Pre-validation	Risk assessment	Risk manageme

Quarter 4 2020/21	987	791	196	111	65	10
Quarter 1 2021	183	135	48	23	14	10
Quarter 2 2021	105	81	24	16	5	3
Quarter 3 2021	111	74	37	32	2	3
Quarter 4 2021	108	84	24	22	2	-
Quarter 1 2022	123	97	26	26	-	-
Total	1617	1262	355	230	88	26

Key

Total Contacts: Number of individual contacts received on the Regulated Products Application Portal.

Incomplete Applications: Number of contacts on the application portal, that were either not appropriate applications, had critical information missing for them to progress, or were applications that were subsequently withdrawn by applicants. All applicants are given an opportunity to provide the necessary information before we process as incomplete

Applications Progressing: Total number of live applications progressing through the service.

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.

Risk Assessment: Applications currently with SERD to formulate a risk assessment opinion.

Risk Management: Applications that have been passed back to policy to consider risk management options.

Authorisation: Applications where Ministers have agreed to authorise, but we need to complete the parliamentary Statutory Instrument process before the authorisations can be written into legislation.

Figure 2 Detailed breakdown of live applications in the Regulated Products Service as of end of July 2022

Breakdown of all applications by regime	Total number of applications progressing	Number of applications at pre-validation	Number of applications at risk assessment	Number of applications at risk management	Number of applications at authorisation
Novel food (excluding CBD)	32	20	10	2	-
Novel food CBD	133	122	11	-	-
Feed additives	135	68	45	11	11
GMO	29	17	1	11	-
Novel food traditional	3	1	2	-	-
Food contact materials (recycled)	7	2	5	-	-
Food contact materials (plastics)	3	1	2	-	-
Food additives	15	6	8	1	-
Flavourings	4	3		1	-
Feed for particular nutritional users (PARNUTS)	2	-	2	-	-
Novel food status	2	-	2	-	-

Breakdown of all applications by regime	Total number of applications progressing	Number of applications at pre-validation	Number of applications at risk assessment	Number of applications at risk management	Number of applications at authorisation
Smoke flavourings	9	9	-	-	-
Food enzymes	1	1	-	-	-
Other	5	5	-	-	-
Feed detox	1	1	-	-	-
Total	381	256	88	26	11

3.2 There are 256 applications at the pre validation stage, of which 122 are CBD applications. Following the publication of the CBD product list, resource is now being focused on progressing applications in this pre-validation stage of the process.

3.3 We have 88 applications progressing through Risk Assessment, which are for a range of different regimes. This stage is typically a significant contribution to the time to authorisation. We expect the number of applications in Risk Assessment will continue to grow during the first years of operation of the service as the service builds to a steady state.

3.4 For public transparency, we continue to update our Register of Regulated Product Applications, which lists the progress of applications once they have been validated.

4. Authorisations

4.1 A total of 18 applications, which includes Novel Foods, GMO and Smoke Flavouring products, have been approved and authorised by Ministers and the legislation has come into force in England, Wales and Scotland. We are also working on laying a Statutory Instrument for 11 Feed Additive applications, in September after the summer recess. The ministers have already confirmed their agreement to authorise those applications.

4.2 The next batch of potential authorisations will include 23 applications including GMO, Novel Food, Feed Additives, Food Additives and Flavouring products. Consultations on these applications will be launched shortly. Consultations will run for a period of 8 weeks, as the applications are considered routine. Recommendations will be made to Ministers once we have considered the consultation responses.

5. Online Application System

5.1 A new application system is being developed to replace the current application portal. As part of this work, we are reviewing the guidance we provide potential applicants to help them make appropriate applications at the right time. The new system will also reduce some

administrative tasks and provide better information to applicants on who is managing their application and the progress of it.

5.2 In order to provide the best possible product we will test the new application system with a range of users in October. Subject to the feedback we receive and further development of the system, we will provide continuous improvement over the coming months and the new application system is expected to go live before the end of the year.

6. Conclusions

The Business Committee is asked to **note** the current status of the Regulated Products Service.
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