FSA 22-06-19b - 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 as requested at the March 2022 Business Committee meeting.

Report by Sukh Singh.

1. Summary

1.1 The Business Committee is asked to note the current status of the regulated product service, and to note the proposed performance measures.

2. Introduction

2.1 The Food Standards Agency (FSA) took the responsibility of managing risks in the food chain from the EU. We inherited a list of permitted regulated products (e.g., food and feed additives) which are in EU retained law. We are also responsible for assessing applications and making recommendations to Ministers for any changes or new authorisations in this area.

2.2 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 Northern Ireland, regulated products continue to be assessed and authorised by the EU.

2.3 As agreed with the FSA Chair and Chief Executive, starting in March 2022 we will provide this regular update at each Business Committee, to ensure greater transparency on the progress of the regulated products service.

2.4 At the March 2022 Business Committee, the Committee requested the Board receive a set of key performance indicators to assist with measuring the performance of the service. This paper proposes that performance indicators are used to monitor the quality of the guidance provided by the service, the timeliness of how long it takes for applications to progress through the service and the overall customer experience of the service we provide.

3. Snapshot of Applications Received by Regulated Product Service

3.1 We have 431 applications progressing through the service. We have now authorised nine Genetically Modified Organism (GMO) applications and the legislation on the products linked to

those applications has come into force.

3.2 Figure 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 Figure 2.

Figure 1 shows the to date progress of applications per quarter

Quarter	Total contacts	Applications progressing	Pre-validation	Risk Assessment	Risk Management	Authorisation	Completed
Quarter 4 2020 to 21	989	254	176	54	24	-	9
Quarter 1 2021	183	48	30	9	9	-	-
Quarter 2 2021	105	25	22	1	2	-	-
Quarter 3 2021	111	38	37	-	1	-	-
Quarter 4 2021 to 2022	108	29	25	1	3	-	-

Key

Pre-Validation Stage: Applications being reviewed by Policy and Science, Evidence and Research Directorate (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

Figure 2: Detailed breakdown of live applications on the regulated products service as of end of April 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	Applications completed
Novel food (non-CBD)	43	30	5	8	-	-
Novel food CBD	190	183	7	-	-	-
Feed Additives	121	63	36	22	-	-
GMO	24	15	1	8	-	9
Non-food traditional	3	1	1	1	-	-
Food Contact Materials (Recycled)	6	1	5	-	-	-
Food Contact Materials (Plastics)	3	1	2	-	-	-
Food Additives	15	8	7	-	-	-
Flavourings	4	4	-	-	-	-
Feed for Particular Nutritional Users (PARNUTS))	2	1	1	-	-	-
Novel Food Status	2	1	1	-	-	-
Smoke Flavourings	4	1	-	3	-	-
Food Enzymes	1	1	-	-	-	-
Other	4	4	-	-	-	-

3.3 Of the 292 applications at pre validation stage, 183 relate to ongoing Cannabidiol (CBD) applications that are currently being assessed by SERD for suitability. Figure 4 shows the overall snapshot of total applications. Figures 5 and 6 show the breakdown of CBD applications and non-CBD applications, respectively.

Figure 4: live applications

Figure 5: Live applications (CBD)

Figure 6: Live applications (non-CBD)

3.4 We have 66 applications that are progressing through Risk Assessment. Forty-two applications undergoing risk management. Nine have reached the stage where an opinion is being drafted.

3.5 We have now consulted on 31 applications, which include GMO, Novel Food, Smoke Flavouring and Feed Additive applications. All responses received from the consultations were analysed by our risk managers and considered in the subsequent advice we have provided to Ministers. Recommendations on those applications have now been made to Ministers.

3.6 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 We have nine GMO applications that have been authorised and the legislation has come into force in England, Wales and Scotland. The applications included eight Maize GMOs, four of which are renewal applications for products already authorised for the UK market. This also included a new authorisation of a soybean GMO.

4.2 The FSA made recommendations to Ministers to authorise five Novel Foods and make changes to five Smoke Flavourings authorisations (transferring the authorisations to new authorisation holders). Following agreement from Ministers, the legislation for those 10 applications was laid on 20 May 2022 and will come into force in June.

4.3 Recommendations will be made to Ministers to authorise 11 Feed Additives applications in June. If Ministers agree, the legislation for those applications will be laid and come into force after the summer recess.

5. Proposed Performance Measures

5.1 Three measures are proposed, with interim and long-term targets. The measures and targets will continue to be reviewed and developed over the course of the next six to 12 months, to allow an opportunity to gather more data on applications progressing through the service. At this stage, we have a group of 21 applications that are approaching the authorisation stages of the process, and nine GMO applications that have been authorised and the legislation has come into force. Once we have a larger set of end-to-end approval process data, we will develop a suitable performance indicator around the timeliness of the overall approval process.

5.2 Measure on quality of guidance

KPI: Percentage of applications which are incomplete when first submitted.

- current performance (Q1 2022): 72%
- year-end target (Q4 FY 2022/23): 25%
- long-term target: [To be confirmed informed by baseline]

What the measure is trying to achieve:

- as a measure of the quality of applications, we propose a measure to assess the number of ‘incomplete’ applications. While not entirely within the FSA’s control, a more user-friendly application system and enhanced guidance will help to drive up the quality of applications.

How we will meet our year-end target:

- the FSA is introducing a new case management system later this year, which should facilitate better quality applications.
- a review and revision of public guidance is also underway, with ‘application guidebooks’ and supplementary material to be produced later this year.

5.3 Measure on providing a timely service:

KPI: Percentage of applications taking longer than 2 months to validate

- current performance (Quarter 1 2022): 70%
- year-end target (Quarter 1 2023 / Quarter 4 FY 2022/23): 30%
- long-term target: [to be confirmed informed by baseline]

What the measure is trying to achieve:

- as a measure of the time taken to progress applications, we propose a measure to assess the length of time applications are held at the validation stage. Due to the surge of CBD applications in Jan 21 - Mar 21, and the poor quality of applications we have received, a backlog of applications held at validation stage has developed. By driving down the amount of time it is taking to validate applications, it will improve the customer journey and demonstrate that the FSA can progress applications for new products to enter the GB market in a timely manner.

How we will meet our year-end target:

- the FSA is introducing a new case management system later this year, which should facilitate better quality applications and will help save the amount of time it takes to complete validations assessments.
- once we have cleared the backlog of applications that developed following the CBD surge during Jan 21 - Mar 21, we will be in better position to validate applications in a more reasonable time.

5.4 Measure on improved customer experience:

KPI: Percentage of feedback surveys returned with positive experience

- current performance (Quarter 1 2022): No Data
- year-end target (Quarter 1 2023 / Quarter 4 FY 2022/23): [TBC informed by baseline]
- long-term target: [to be confirmed informed by baseline]

What the measure is trying to achieve:

- As a measure of how effective our service has been received throughout the authorisation process, we propose a measure to assess the user experience feedback we receive. We will frequently engage with applicants at different stages of their customer journey, for feedback on the service we provide.

How we will meet our year-end target:

- By providing good quality advice and guidance at the front end of the service and by keeping applicants well informed as their applications progress through the service.

6. Conclusions

6.1 The Business Committee is asked to note the current status of the regulated product service, and to note the proposed performance measures.