Regulated Products Service: Regular Update to Business Committee

Report by Sukh Singh
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1. Introduction

1.1 The Business Committee is asked to **note** the update.

1.2 Following the end of the transition period (31 December 2020) the 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.

1.3 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.

1.4 As agreed with the FSA Chair and Chief Executive, this regular update will be provided at each Business Committee, instead of being included as an annex to the Chief Executive's report (this was the reporting process during 2021). This is to ensure greater transparency on the progress of the regulated products service.

1.5 There are 4 key stages of the Regulated Products Service:

a) **Receipt of the application** and consideration as to whether sufficient information has been provided. Once an application has been submitted, the applicant has a window of seven days to upload documents. Once this window closes, the uploaded documents are subject to an initial sense check before being moved into the validation stage.
b) **The Validation stage** - consisting of two parts; an initial validation assessment by the FSA Policy team followed by a suitability check by the FSA's Science, Evidence and Research Directorate (SERD). Policy assesses whether the applicant has submitted the particular evidence required in legislation, whilst a more in-depth check by SERD ensures that suitable detail has been provided to compete a risk assessment. If information is insufficient, the FSA 'stops the clock' and pauses work on the application until the information is provided. Where lacking, it is deemed not to be able to move forward. Once sufficient evidence is

provided and deemed suitable, it then moves into the risk assessment phase.

c) **Risk Assessment and evidence gathering** – this is the consideration of the science and related evidence by SERD and will include, where appropriate, referral to the independent scientific committees for an opinion on safety. Other evidence, such as economic impact and consumer research may also be sought.

d) **Risk Management** – once the safety and other evidence has been collated and where appropriate assessed, this is passed back to risk managers who then consider a number of options based on that information as well as other factors. This is usually then subject to a public consultation, as appropriate. Matters identified as non-routine may be discussed by the FSA Board. Recommendations are then made to Ministers and based on their decisions, enabling legislation is drawn up.

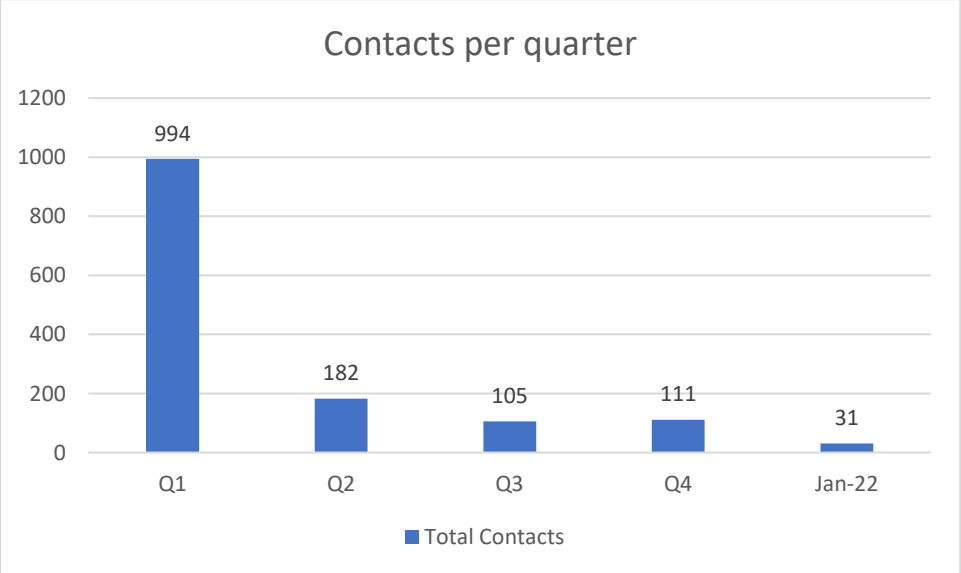
2. Headline Data and Commentary

Progress during 2021 and early 2022

2.1 Figure 1 shows the number of individual contacts made to the application service. In Q1, this number was very high due to a surge in CBD applications. There was also a high volume of contacts that failed to upload any documents and that could not be progressed any further, as well as contacts making general enquiries about regulated products (rather than making an application).

2.2 In Q1, a total of 396 contacts were considered incomplete and could not be progressed as applications; however, each of these contacts still had to be handled and processed as part of the initial receipt stage. From Q2 onwards, number of contacts began to stabilise at a much lower level.

Fig. 1: Contacts made to the application service (total per quarter)



2.1 Figure 2 shows the number of live applications in each quarter, that is, the number of applications at all stages in the process as a whole (steps a-d in para 1.5 above). The end of Q1 coincided with the FSA's deadline for the receipt of CBD applications, which explains the high level of progressing applications from Q1 onwards, rather than a steadier rise over time.

2.2 The number of live applications decreased in Q2 as applications that did not pass validation were filtered out. This continued throughout the year but was offset by new applications entering the system. By the end of 2021, 428 applications were progressing through the process. Also included is the live application figure for end-January 2022.

Fig. 2: live applications at all stages of the risk analysis process (cumulative figures) - breakdown in figure 3

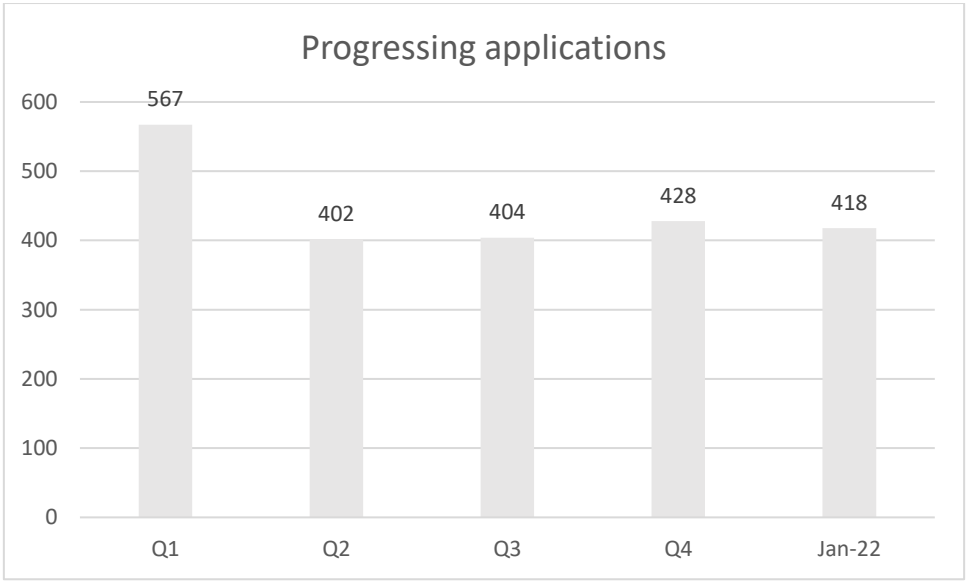
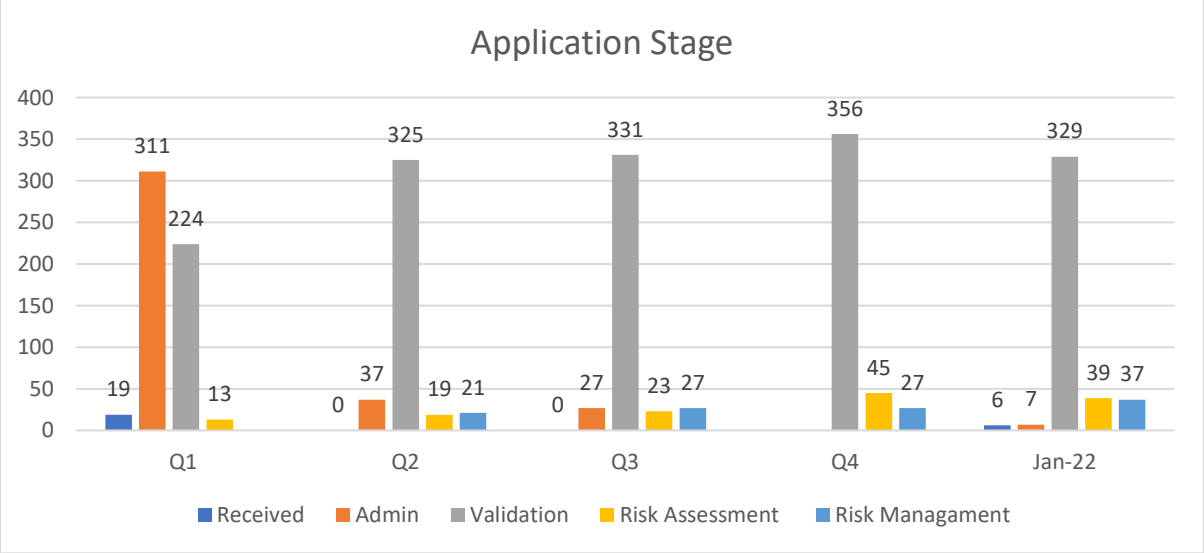


Fig 3: Progress of applications per quarter (cumulative):



Key

Received: Applications that have been submitted but the applicant's upload window is still open.
Admin Stage: Applications that are going through an initial "sense check" before being reviewed by policy at the validation stage.
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.

2.3 Figure 3, which is a breakdown of figure 2, highlights at what stage the applications are in the process. After the initial Q1 surge, most applications progressed to the validation stage. This figure has remained high due to applications being paused awaiting further information from the applicant.

2.4 27 applications had progressed to risk management by the end of Q3. These applications remained in risk management throughout Q4 as public consultations were launched to seek stakeholder feedback, with responses being analysed before advice can be put to Ministers.

2.5 The next stage is authorisation. Advice on nine Genetically Modified Organisms (GMOs) for food and feed uses will be given to Ministers in Q1 2022. This will be followed in Q2 2022 with a Statutory Instrument to bring forward the first GB authorisations in regulated products.

Snapshot of the current position

2.6 Cannabidiol (CBD) continues to account for most applications. There are currently 329 applications at validation stage. Of these, 191 relate to ongoing 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 7 shows the breakdown by regime of progress being made.

2.7 At the validation stage, 102 CBD applications and 18 non-CBD applications are currently paused awaiting further information from the applicant. These applications cannot be progressed further until the applicant has responded with the requested application.

Fig. 4: live applications as of 31 January 2022

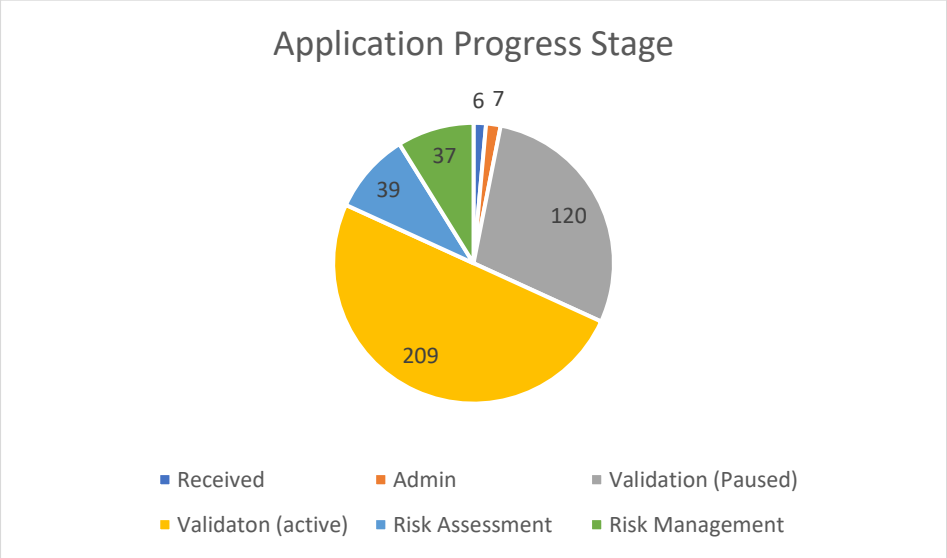


Fig. 5: Live applications as of 31st January (CBD)

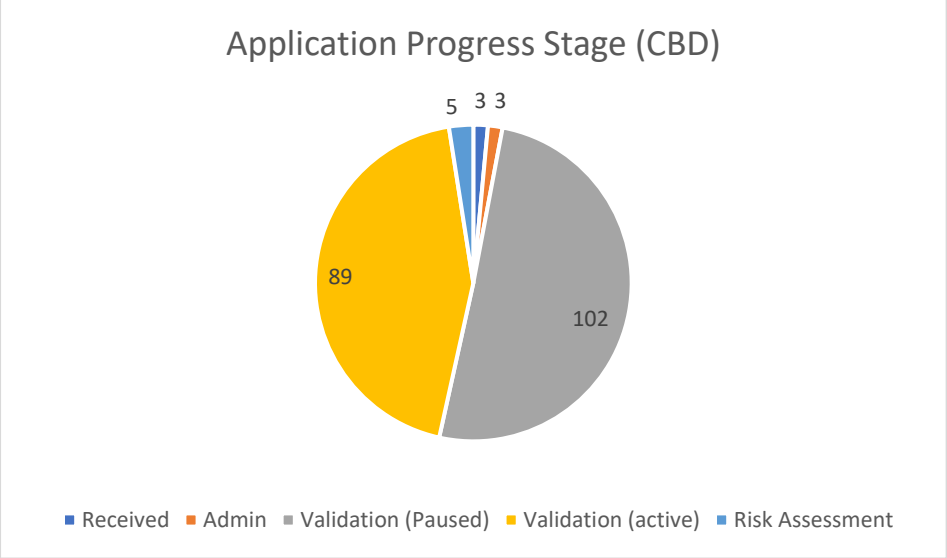


Fig. 6: Live applications as of 31st January (non-CBD)

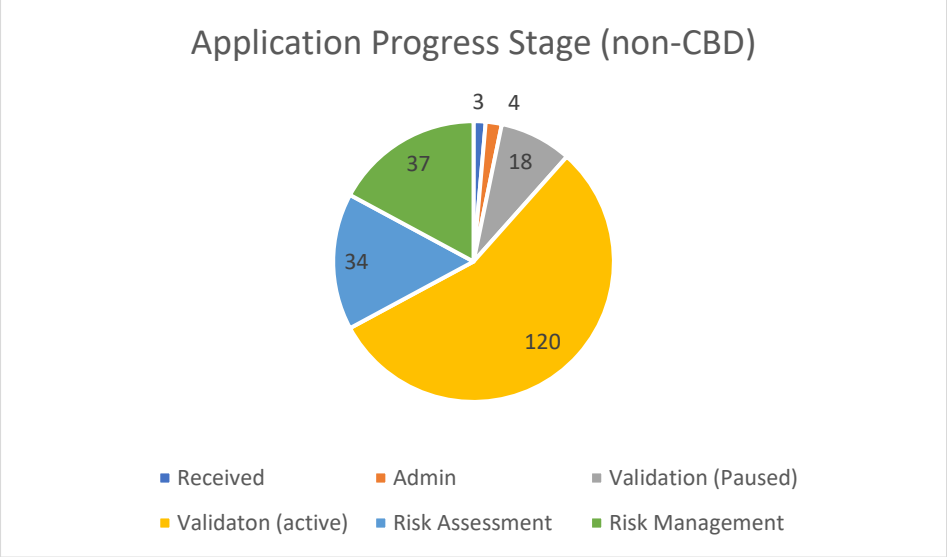


Fig 7: Detailed breakdown of live applications on the regulated products system

Year to date breakdown by regime	Total no of applications	No of applications Pre-validation	No of applications at Risk Assessment stage	No of applications at Risk Management
Novel Food	231	218	7	6
Feed Additives	110	69	20	21
GMO	31	21	1	9
Novel Food Traditional	2	1	0	1
Food Contact Materials (Recycled)	7	3	4	0
Food Contact Materials (Plastics)	3	2	1	0
Food Additives	14	9	5	0
Flavourings	3	3	0	0
Feed for Particular Nutritional Users (PARNUTS))	1	0	1	0
Novel Food Status	1	1	0	0
Food Enzymes	1	1	0	0
Other	1	1	0	0

2.8 In the case of applications also made to EFSA and in order to streamline the process as far as possible, applications that have had EFSA risk assessment opinions published are being reviewed by the FSA risk assessors without the necessity of a full new risk assessment. The applications at the risk assessment stage that are not being considered under this streamlined process (e.g., because they were not considered by EFSA) are being referred to and considered by relevant committees and Joint Expert Groups. 37 applications are under active consideration by the scientific committees. 11 have reached the stage where an opinion is being drafted.

2.9 **Novel Foods** had the highest percentage of applications to the Regulated Products Service in Q1 2021; the majority of these were CBD applications. The quality of the CBD applications was mixed; most of the new applications were deemed to be incomplete due to insufficient information being submitted.

2.10 The deadline for receipt of applications for CBD food extracts was 31 March 2021 and the observed reduction in applications for novel foods from Q2 onwards reflects this deadline.

2.11 Nevertheless, the surge in CBD applications created significant resourcing demands, impacting on the progression of non-CBD applications. As we move into 2022, the impact will soften as unsuitable applications are removed from the system and process.

2.12 Retained EU legislation (REUL) includes a renewal process for previously authorised substances under the GM, feed additive and smoke flavouring regimes. The review process for **feed additives** is required every ten years and while an ongoing process, a peak in applications is being experienced as it is now 10 years since the list was established. 44 applications have been received for feed additives before the required data submission date for the application and so these feed additives can continue to be marketed while the applications are reviewed.

2.13 We expect this number to increase significantly, as the review period starts to apply to a large number of feed additives. To manage this peak, steps are being taken to manage these efficiently through; effective triage and prioritisation, use of Secretariat lead assessments to focus Committee input on applications with greater complexity or changes in the risk and batching of similar additives to streamline committee consideration. Several of the renewals have already reached the opinion stage using this approach.

2.14 To manage the flow of opinions through the process while ensuring quality assurance, provisional agreement (pending formal approval from Devolved Administrations) has been reached with Defra Secretary of State to revive the Advisory Committee on Animal Feedingstuffs as a risk assessment Committee. This would lessen the burden on other committees currently providing quality assurance and reflects the significant number of dossiers expected for reauthorisation and in the longer term. Further information on this will follow as plans are implemented.

2.15 The 21 **feed additives** at risk management stage are a combination of substances, some of which are currently scheduled for public consultation around March with another planned later in the year.

2.16 The situation for **GM** is the same as for feed additives, in that there are a number of authorisations due for renewal. This number again is expected to rise, although not as sharply. A public consultation on the nine **GM** substances at risk management stage has now closed and recommendations will be made to Ministers in each of the nations imminently.

2.17 For public transparency, once applications are validated, brief details are published on the Register of Regulated Product Applications. The register is updated monthly and confirms at what stage of the process the applications are being held.

3. Consultations and progress to authorisation decisions

Regime	Consultation launch	Consultation closes	Expected time frame for advice to Ministers	Laying dates for Statutory Instrument to authorise[1]
GMO	30/11/2021	25/01/2022	28/02/2022	w/c 21/03/2022[2]
Novel Foods	17/12/2021	11/02/2022	28/03/2022[3]	TBC
Feed Additives	28/02/2022[3]	25/04/2022[3]	16/05/2022[3]	TBC

1: Should Ministers agree to authorise

2: Date confirmed with the Parliamentary Business and Legislation Committee

3: Expected dates (to be confirmed)

Commentary

3.1 Details of the latest and planned consultations is given in the above table along with timescales. These consultations are being run in parallel with Food Standards Scotland. Whilst Northern Ireland is still subject to EU legislation, the FSA and Food Standards Scotland are consulting on a four nations basis.

3.2 Consultations cover the following substances:

a) **GM:** Consultation covers eight Maize GMOs, four of which are new applications and four are renewal applications for products already authorised for the UK market. Consultation also covers an application for a new authorisation of a soybean GMO. The authorisations will be for import only, with no cultivation in the UK. Characteristics of the GMOs include products with genes which confer protection to the plant against pests and tolerance to glufosinate-ammonium based herbicides. Others have genes which confer tolerance to dicamba based herbicides. Some products have genes which aim to reduce yield loss caused by drought stress. Consultation can be found on the FSA website.

b) **Novel foods:** The substances covered by the consultation are to be used as components in infant follow-on formula. Three applications are for “human-identical milk oligosaccharides (HiMOs)”. The manufactured HiMOs are identical in structure to the same molecules present in breast milk. The other three applications are for Docosahexaenoic acid (DHA) rich oils derived from marine algae. DHA is mandatory in infant and follow-on formula under Regulation 2016/127. Consultation can be found on the FSA website.

c) **Feed additives:** The feed additives for consultation are a mixture of new authorisations, renewals and modifications of use. Substances cover a range of uses:
   - Nutritional feed additives to be used to provide essential micro-nutrients to animal diets.
   - Technological feed additives intended to improve the production; fermentation of, and/or aerobic stability of silage in the preparation of animal feed and not intended to be added to feed for direct consumption by the animal.
   - Zootechnical feed additives used to favourably affect the environment and/or the performance of animals.
   - Coccidiostats used to maintain the health of animals through the control of coccidiosis (an intestinal parasitic disease).

4. Conclusions

4.1 The Business Committee is asked to **note** the update.