Risk Analysis and Regulated Products Service: Regular Update to Business Committee

FSA 22-12-17 - This paper provides a regular update on the 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 22-12-17b Risk analysis and regulated products slides as PDF(Open in a new window) (429.32 KB)

1. Summary

1.1 The Business Committee is asked to:

- Note the update on issues undergoing risk analysis and the current status of the regulated products service
- Note the preliminary assessment of the impact of work to review Retained EU Law, which includes regulations governing the regulated products process

2. Introduction

2.1 The risk analysis process sets out the FSA's approach to its increased role in food and feed safety. A paper to the Business Committee in June recapped the objectives and core principles of the risk analysis process and contains links to the risk analysis process steps and previous board papers.

2.2 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 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. 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.

2.3 This regular update is provided at each Business Committee. The accompanying performance pack provides detailed analysis of the work flowing through the risk analysis process and regulated products service.

3. Risk Analysis Process

Risk analysis status report: September – December 2022

3.1 Details of issues undergoing risk analysis are published to an online register following initial consideration when it is confirmed that risk assessment or evidence is required, and the risk assessment stage commences.

3.2 Three issues were added to the public register in the latest quarterly update in October.

Table of risk analysis issues

Issue	Description	Preliminary estimate of completion date*
Review of T-2/HT-2 toxins in foods	Review of occurrence data for T-2/HT-2 toxins in cereals and assessment of the exposure of UK consumers to these toxins from cereals and cereal-based foods	End of 2023
Direct supply of meat (including offal) to the final consumer (potential cold chain disruption) (Qurbani meat and offal during Eid al-Adha)	The FSA is evaluating whether there is any additional risk to consumers as a result of the supply and consumption of less than fully chilled Qurbani meat and offal during Eid al-Adha	An interim approach is in place to protect consumers. A public consultation closed in September 2022. A decision about the future approach will be taken in 2023
Country Profiles - Imported Food of Non-Animal Origin (FNAO) Phase 1	The FSA Market Access Assurance Team will support the FSA Trade Risk Assessment Team in the production of Country Profiles for trading partners exporting food of non-animal origin (FNAO) to the UK. These profiles will assist the Market Access Assurance Team in monitoring the risk associated with each country and to inform on the need for follow-up action	Q1 2023

*Estimated completion dates are provisional at this stage and dependent on the progress of the risk assessment phase and subsequent risk management approach.

3.3 One issue has been designated as complete this quarter. This work had previously been considered ongoing, pending further work potentially being requested by Defra. We are now marking this issue as complete and any further work in the area will be considered as a separate risk analysis issue.

Completed Risk Analysis Issues

Issue	Description	Completion date
Risk Analysis of Minced Meat and Meat Preparations - Review of Prohibitions and Restrictions on Imported EU foods	FSA work with Defra to consider the risk associated with imported chilled meat preparations (all species), chilled minced meat (bovine, porcine, ovine and caprine) and minced meat (poultry)	August 2021

3.4 In line with our publication policy, the risk assessment for this issue has not been published at this time because it is material to ongoing policy development and contains sensitive information in relation to international trade.

4. Measuring performance and monitoring on Risk Analysis

4.1 In the previous paper to the Business Committee, we proposed a set of measures to monitor performance of the risk analysis process based on the underlying principles previously agreed by the Board:

- **Science and evidence-based:** a measure to provide assurance that our evidence is robust and follows best practice – our target for this measure is 100%.

- **Open and transparent:** a measure to demonstrate that we are following our publication policy and routinely publish evidence, and a full supporting information package. Exceptionally, and in line with our policy, we may not publish evidence, for example where this might prejudice policy development, ongoing scientific work, law enforcement, or the UK's position in international negotiations. This measure is therefore an indicator rather than a target.
- **Three- and four-country working:** a measure to demonstrate the effectiveness of our joined-up approach. We will report on whether a dispute has been raised about the process for engaging and involving devolved administrations. As this is not fully within the FSA's control, this measure is also an indicator rather than a target.

4.2 Only one issue has completed the end-to-end risk analysis so far, with two further risk assessments provided to Defra. This means we do not currently have sufficient baseline information to set performance targets relating to progress of issues in the risk analysis process. We intend to set targets in future once we have a robust baseline.

4.3 The proposed indicators are now incorporated into the combined regulatory services report which provides more detailed reporting of risk analysis issues, including statistics on issues in the process (slides attached).

5. Regulated Products Service

Snapshot of Applications Received by Regulated Product Service

5.1 Details of validated applications going through the regulated products service are published in a public register.

5.2 As of 31 October 22, we have 407 applications progressing through the service which includes applications that have not yet been validated. Table 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 Table 2.

Table 1: Progress of applications per quarter

Quarter	Total contacts	Incomplete applications	Applications progressing	Pre-validation	Risk assessment	Risk management	Applications complete
Jan-Mar-2021	989	782	192	104	68	10	25
Apr-Jun - 2021	183	136	46	10	25	10	2
Jul-Sep - 2021	105	81	24	10	10	4	0
Oct-Dec - 2021	111	72	38	25	7	6	1
Jan-Mar - 2022	108	82	23	21	2	0	3
Apr-Jun - 2022	123	97	26	26	0	0	0
July-Sep - 2022	113	90	23	21	1	1	0
Total	1732	1340	372	217	113	31	31

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 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.
Applications Completed: Number of applications that have been authorised. This column includes 11 applications where the authorisation will come into force by the end of November.

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

Breakdown of all applications by regime	Total no. of applications progressing (as of 31 Jul 2022)	Total no. of applications progressing (as of 31 Oct 2022)	No. of applications pre-validation (as of 31 Jul 2022)	No. of applications pre-validation (as of 31 Oct 2022)	No. of applications at risk assessment (as of 31 Jul 2022)	No. of applications at risk assessment (as of 31 Oct 2022)	No. of applications at risk management (as of 31 July 2022)	No. of applications at risk management (as of 31 Oct 2022)	No. of applications at authorisation (as of 31 July 2022)	No. of applications at authorisation (as of 31 Oct 2022)	Applications complete (as of 31 July 2022)	Applications complete (as of 31 Oct 2022)
Novel food (excluding CBD)	32	46	20	34	10	10	2	2	-	-	6	6
Novel food CBD	133	128	122	115	11	13	-	-	-	-	-	-
Feed additives	135	146	68	57	45	63	11	15	11	11	-	-
GMO	29	34	17	22	1	1	11	11	-	-	9	9
Novel food traditional	3	-	1	-	2	-	-	-	-	-	-	-
Food contact materials (recycled)	7	8	2	3	5	5	-	-	-		-	-
Food contact materials (plastics)	3	4	1	1	2	3	-	-	-	-	-	-
Extraction solvents	-	1	-	1	-	-	-	-	-	-	-	-
Food additives	15	17	6	5	8	11	1	1	-	-	-	-
Flavourings	4	8	3	4	-	2	1	2	-	-	-	-
Feed for Particular Nutritional Users (PARNUTS)	2	2	-	-	2	2	-	-	-	-	-	-
Novel food status	2	-	-		2		-		-		-	2
Smoke flavourings	9	9	9	9	-	-	-		-		3	3
Food enzymes	1	1	1	1	-	-	-		-		-	
Other	5	2	5	2	-	-	-		-		-	
Feed detox	1	-	1	-	-	-	-	-	-	-	-	-
Food contact materials (active)	-	1	-	1	-	-	-	-	-	-	-	-
Total	381	407	256	255	88	110	26	31	11	11	18	20

6. Applications in risk assessment

6.1 We have 110 applications progressing through risk assessment. As expected, the number of applications in risk assessment will continue to increase in the coming months as this is the stage that typically takes longest. It can also include ‘stop the clock’ periods if we need to work with applicants to address issues with the evidence provided.

6.2 We have 16 applications across the regimes where the outcome of the risk assessment is being drafted for quality assurance by the Science Advisory Committees. We continue to apply a continuous improvement approach looking to improve efficiency and our customer experience based on the experience of running the service. Concerted work has been undertaken in the last few months to develop the output format and publication process so that our stakeholders are clear about the nature of the assessment that has been undertaken.

7. Authorisations

Completed

7.1 Since January 2021, a total of 20 applications for GM, Novel Foods, and Smoke Flavouring products have been approved and authorised by Ministers and the legislation has come into force in England, Wales and Scotland. Statutory Instruments have been laid authorising 11 Feed Additive applications. The legislation will come into force on 24 November for Scotland and Wales, and 25 November in England.

Final stages (subject to final recommendations and Ministerial agreement)

7.2 In October we launched consultations on eight GM applications and two novel food applications, a food additive and a flavouring application. The consultation period will close in December, prior to us considering the responses and subsequently making recommendations to Ministers. We plan to launch consultations on 11 feed additive applications in January 2023.

8. Online Application System

8.1 Work on the new Case Management System for Regulated Product applications is progressing. User testing has commenced internally on the front end of the system. We are continuing to work with our contractor as they build and tailor the system, aiming for a live system for full user-testing by the end of the year.

9. Measuring performance and monitoring on Regulated Products

9.1 In June 2022, we proposed three performance measures for further development over the next six to twelve months:

- **Level of incomplete applications:** This is an indicator of the quality of our guidance and the pre-application support we provide. A large proportion of the contacts we receive through our application portal are not applications. This will be addressed by our new case management system where future applications will be uploaded, and the user guidance we provide at the front end of the service. As a reminder, since the opening of the service in January 2021 we have had 1,730 contacts on our application portal, with 371 being applications progressing at different stages of the process, and 31 applications have now been authorised. 1,340 contacts in the system amount to incomplete applications, of which around 500 related to CBD.

- **Applications taking longer than 2 months to validate:** Validation is the gateway to entering the full process and for the product to appear on the public register. It is important to applicants and is also an indicator of the efficiency and effectiveness of the FSA's internal processes. We will set targets once we have better baseline data.
- **Improved customer experience:** We are putting in place methods to measure customer experience. We will set targets for improvement once we have baseline data.

9.2 Detailed reporting of applications that are progressing through the Regulated Product service and data we are gathering on the applications, is incorporated into the combined regulatory services report (slides attached).

10. Impact of work on Retained EU Law on Risk Analysis Process and Regulated Products Service

10.1 Since March 2022, there have been several areas of work (either new or that have had an increase in scope) which place significant and unanticipated demands on key areas of the business, including work to deliver the Retained EU Law (Reform and Revocation) Bill. The FSA executive has reviewed all work and identified areas that must continue and areas that can be reduced, paused (to end of 2022/23 business year) or stopped.

10.2 Advising on food safety risks associated with regulated products, and the risk analysis to support this is one of our key statutory duties and has been identified as something important to protect. Our caseload is still growing as the flow of applications builds up now that we are outside the European Union, and we need to ensure we have the capacity to fulfil our obligations effectively.

10.3 However, certain aspects of our plans for the rest of this year will now change:

- We will slow down work on routine risk analysis issues (such as work on routine review and updating of permitted levels of additives and contaminants), which means accepting the risk that some products overshoot the planned timetable for authorisation.
- We will adjust our plans for a fundamental review of the regulated products service and focus on:

1. commissioning the novel foods framework review; and
2. looking for suitable opportunities to make improvements through the Retained EU Law work (see paragraph 11).

10.4 Further details on our prioritisation exercise and these changes can be found in FSA 22/12/05

11. Novel Foods Review

11.1 The invitation to tender for the external Novel Foods Regulatory Framework Review launched in early October. The closing date for bids was 8 November 2022 and applications are under consideration. The review will critically evaluate the current Novel Food Regulatory Framework (based on Novel Food Retained EU Legislation) and identify opportunities for potential reform.

11.2 The review will consider the national and international regulatory landscape, and present potential options for a Novel Foods Regulatory Framework assessing the benefits, limitations, risks, opportunities, resource and time implications as well as the impact on industry and consumers. The options presented in the output report will support the Food Standards Agency's internal thinking for potential reform of the regulatory framework for novel foods. While this

review is progresses, we will also look at the REUL Bill in parallel to ensure we identify any possible opportunities for making reforms that will make the current process more efficient and support business innovation.

12. Forward Look

12.1 In the next quarter we are expecting applications to be progressing through risk assessment for a range of regimes and this will include some new Novel Food dossiers which we will be putting through for committee review. Of particular focus are the batches of applications for the renewal of Smoke Flavourings and the CBD applications as more data becomes available to move the safety assessments forward.

12.2 In the early months of 2023, we plan to make recommendations to Ministers on the applications that we are currently consulting on. This will include 8 GM products, 2 Novel Foods, a flavouring and a food additive. Around this time, we will also be publishing 11 feed additive applications for consultation.

13. Risks

13.1 We are receiving a steady flow of applications into the service and acknowledge the risks around increased levels progressing at different stages of the authorisation process and the potential to build up in the system. In particular, at the risk assessment stage where typically applications spend most time.

13.2 More than half of the applications currently in risk assessment are for feed additives, which also account for most of the increase since the last report. Feed additives are a well-understood class of regulated products and applications are moving through the system, with legislation authorising 11 products coming into force at the end of November.

13.3 Other factors may also impact the pace at which we authorise including the involvement of legal resource on REUL bill work, maintaining a harmonised approach, where appropriate, across the four nations, and the complex system we have inherited post EU. Regulated Services Delivery is a priority for the FSA, and we understand our responsibilities in fulfilling our obligations to consumers and industry by processing applications efficiently to reduce unnecessary delays for products coming to market. We are continuing to expand as we recruit more risk assessors, risk managers and policy leads, to manage the demand. The development of performance indicators as we increase our baseline data, will also help our understanding of the scale.

14. Conclusions

14.1 The Business Committee is asked to:

- **Note** the update on issues undergoing risk analysis and the current status of the regulated products service;
- **Note** the preliminary assessment of the impact of work to review Retained EU Law, which includes regulations governing the regulated products process.