# Risk Analysis and Regulated Products Service: Regular update to FSA Board

FSA 23-09-08 This paper has been prepared to update the Board on the performance of the FSA's Risk Analysis process and the Regulated Products Service (RPS).

## 1. Summary

1.1 This paper updates the Board on the performance of the FSA's Risk Analysis process and the Regulated Products Service (RPS). It provides an update on the progress made on continuous improvements to the current system and a high-level update on planning for future regulatory reform.

1.2 The Board will be asked to:

- **Review** the performance of the FSA's Risk Analysis process;
- **Review** the performance of the RPS;
- **Note** the progress made on continuous improvements;
- **Note** the update on longer term regulatory reform.

## 2. Introduction

2.1 This paper provides an update on activity since the June Board meeting. Background information about the Risk Analysis process and RPS has been provided in previous reports to the Board and is available on the FSA website.

2.2 This paper should be read in conjunction with the more detailed performance pack for Risk Analysis and the RPS in **Annex A**.

### Evidence and Discussion

### Current Performance

## 3. Risk Analysis

3.1 Risk Analysis issues that are being considered by the FSA and Food Standards Scotland ( FSS) through our food and animal feed Risk Analysis process are published to an online register. Issues are published to the 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.

3.2 As of 30 June 2023, there were 26 issues recorded on the public risk analysis register, 20 of which are actively progressing. As in the previous quarter, five of those issues have been identified as 'non-routine' and potentially requiring additional scrutiny by the Board in developing

Risk Management advice. Those five issues relate to the use of titanium dioxide as a food additive, bamboo-plastic food contact materials, ocean-bound plastic food contact materials, a review of the occurrence of the mycotoxin T-2/HT-2 in food, and substrates used to rear insects for animal feed.

3.3 Since our last Board update, there have been 4 new issues, which are:

1. Microbiological Risk Assessment to support development of advice and guidance to manage outbreaks of norovirus associated with consumption of raw oysters with respect to the amount of Norovirus contamination detected by real time reverse transcription polymerase chain reaction ISO 15216.
2. 2023 review of imported food and feed controls under Retained EU Commission Implementing Regulation 2019/1793.
3. Flexibility to increase the threshold for designation of low-capacity slaughterhouses.
4. Risk Profile to identify and characterise the hazards associated with oysters from different global regions.

3.4 There are 5 issues that have progressed to the development of Risk Management options (3 were previously undergoing Risk Assessment and 2 are new additions to the public register), and 1 issue no longer requires further risk analysis work. Annex A provides further details of all issues progressing through Risk Analysis.

# 4. Regulated Products Service

4.1 As of 30 June 2023, the caseload in the RPS was 426, this includes 23 new applications which are being progressed. We have continued to make steady progress with authorisations to date, meeting the expected timetables (allowing for ‘stop the clock’ periods where the FSA cannot progress applications until further evidence is provided by applicants). A further 16 applications have been completed since our June Board update, bringing the total number of completed applications to 50 since the service went live in January 2021.

4.2 We continue to project that we will deliver around 60 completed applications in 2023-24, and we have already completed 16. We have recently consulted on 12 Feed Additive applications, and there are 38 applications planned to transition from Risk Assessment to Risk Management by the end of September. As noted in our June Board paper, the main delivery risk is the availability of resources, particularly in Risk Assessment. We continue to mitigate this risk by batching applications by regime. The estimated earliest completion dates for applications can be found in the table at **Annex B**.

4.3 To support the assessment of CBD applications, a subgroup of both the Advisory Committee on Novel Foods and Processes (ACNFP) and the Committee on Toxicity (COT) has been formed to review the toxicological data that is key to the assessment of these applications. The subgroup is reviewing the studies in groups based on the composition of the product. They began with the products with 98% CBD or greater and this has allowed 3 applications from this group to complete the toxicological review within the assessment phase. These are scheduled for consideration by the ACNFP in September, including 1 with a draft assessment output for Committee consideration to progress their safety assessment. This subgroup is also reviewing the evidence provided to understand whether there is sufficient data to set safe upper intake levels for CBD as a substance and/or groups of CBD ingredients. It is expected that all applicants will receive a further update on the next steps for their application by the end of November.

### Continuous Improvement and Reform

# 5. Continuous Improvement

5.1 In our June Board paper, we outlined a set of continuous improvement measures we would put in place in the coming year.

5.2 The **Case Management System** (CMS) was successfully launched on 20 June 2023. We did not receive any applications on CMS in this reporting period (up to 30 June 2023), which covers the first few weeks of live running. Since 30 June, we have received a steady flow of applications and the limited evidence available is positive in terms of the quality of applications received to date. We believe this is due to the new guidance and additional information requested from applicants before a submission can be made. We are managing the legacy Application Service and CMS in tandem. This will ensure applications continue to be dealt with in date order and enables us to monitor application flow through the service.

5.3 One of the tools we believe will also support applications to flow through the service more efficiently is the **use of other regulators' opinions**. This would involve us validating the opinion of another regulator in specific and limited circumstances such as for the re-authorisation of products. We will be implementing this approach from the autumn as the first suitable applications reach the risk assessment stage. We will provide a further update in our December Board paper.

5.4 Our work to **focus Advisory Committee resource** on key issues and complex applications has a longer trajectory. This is dependent on successfully recruiting to senior science posts to help lead this work and the ongoing development of risk assessment skills, knowledge, and experience within FSA.

5.5 As set out in our June update, the **Policy and Science teams have expanded significantly** since the service began in January 2021, and as the workload has grown. Since our last Board update, the Risk Assessment team have increased by 1 full time equivalent (FTE), and now have 32 FTE staff in post and are recruiting for 4 FTE vacancies. The Regulatory Services unit who oversees the end-to-end delivery, have decreased by 1 FTE due to natural churn and now have 17 FTE in post and are recruiting for an additional 6 FTE vacancies. All teams are working collaboratively to ensure new entrants receive the necessary training required. In Risk Assessment, this on-the-job training takes time, especially for toxicology specialists, which is also a challenging discipline for recruitment. There are few experienced Risk Assessors to recruit, and training scientists can take up to 24 months to competently understand the regulations, science, and assessment processes, with support from experienced assessors.

5.6 We are continuing to work collaboratively with the team who are developing the regulatory framework for **Precision Bred Organisms** for food and feed to ensure its smooth transition into the business-as-usual RPS once it has been formally established in law. Further detail on Precision Breeding is provided in the separate Board paper (ref).

5.7 We have an active workstream focused on implementing the FSA approach to **cell-cultivated protein** reflecting the new challenges this technology poses for regulation. We are identifying and addressing issues that will need to be resolved to effectively assess and authorise applications for these products and engaging with international regulators and industry stakeholders.

# 6. Long-term Regulatory Reform

6.1 Following the discussion on longer-term reform at the June Board, we have now focused resource within the FSA to look at potential future options for more radical reform of the food and feed regulatory system. This work will include developing a set of reform principles and design features to guide options development as well as work to consider the external operating context.

6.2 The FSA continues to engage closely with other Government Departments on areas relevant to innovation and regulatory reform.  This includes participating in cross-government discussions to take forward the recommendations of the Council for Science and Technology (CST) on engineering biology and working closely with the Department for Science, Innovation and Technology (DSIT) on the recently launched call for evidence on engineering biology.

# 7. Conclusions

7.1 The Board is asked to review the performance of Risk Analysis and the RPS, to note the progress made on continuous improvement and our high-level update on planning for potential future regulatory reform.

# Annex A

Performance pack for Risk Analysis and the Regulated Products Service providing an update up to 30 June 2023.

# Annex B

Forward look for completing Regulated Products applications:

| Description of applications | Earliest estimate for Ministerial decision | Earliest 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 | Authorisations came into force across GB on 26 April. |
| 2 Novel food 1 Flavouring 1 Food additive | Q4 22/23 | Authorisations came into force across GB on 15 May |
| 12 Feed additives | Q2 23/24 | Q3 23/24 |

### 38 progressing to Risk Management

| Description | Earliest estimate for Ministerial decision | Earliest estimate of coming into force date (if approved by Ministers) |
|---|---|---|
| 4 Novel Foods | Q3 23/24 | Q4 23/24 |
| 4 Food Additives | Q3 23/24 | Q4 23/24 |
| 25 Feed Additives | Q4 23/24 | Q1 24/25 |
| 5 GMO | Q1 24/25 | Q2 24/25 |

### Future Planning

| Description | Earliest estimate for Ministerial decision | Earliest estimate of coming into force date (if approved by Ministers) |
|---|---|---|
| First CBD authorisation(s) | Q1 24/25* | Q2 24/25 |

* There is a dependency on the planned Home Office legislation on THC limits in consumer products.

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