Risk Analysis and Regulated Products Service: Regular update

FSA 23-12-07 - This paper gives an update 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 forward look on plans for future regulatory reform, including 'quick wins' that could be implemented to deliver benefits more quickly. In future, reporting on Risk Analysis routine issues and the RPS will go to Business Committee.

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 forward look on plans for longer term regulatory reform;
- **Agree** the proposed reform principles for Regulated Products and;
- **Agree to progress** priority options for 'quick wins.'

2. Introduction

2.1 This paper provides an update on activity since the September 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.**

3. Evidence and Discussion

Current Performance

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 September 2023, there were 29 issues recorded on the public risk analysis register which includes issues completed. Of these, there were 22 actively progressing. Since our last Board update, there have been 3 new issues added to the public register at the stage of Risk Assessment and evidence. Those assessments relate to the safety of the use of Titanium

Dioxide as a feed additive, the safety of Bisphenol A (BPA) in food, and the risk of allergic reaction from fortification of non-wholemeal wheat flour with folic acid. There are currently seven 'non-routine' issues, listed at **Annex B**.

3.3 The Risk Analysis issue relating to assessment of the risk to vulnerable consumers from Listeria monocytogenes in smoked fish is now marked complete on the public register. Further analysis of all issues progressing through the Risk Analysis process and performance against Key Performance Indicators (KPIs) is in the accompanying performance pack at **Annex A**.

Regulated Products Service:

3.4 As of 30 September 2023, the caseload of applications in the RPS was 450. This includes 26 new applications in this reporting period with sufficient information to progress. In addition, one application was withdrawn, and one application was invalidated in the Validation stage during this reporting period. **Annex A** provides an analysis of all the applications currently in the RPS.

3.5 In our March and June Board papers we projected we would deliver around 60 completed applications by March 2024. We have completed 16 applications since April 2023, and we have continued to make progress towards authorising 13 Feed Additive products. The consultation for these products closed in July, and we issued advice to Ministers in September. On receiving agreement from Ministers, legislation authorising the additives was laid in November and will come into force in December, subject to Parliamentary scrutiny.

3.6 Following a recent review, we now expect there will be delays of around six months to the Risk Management and Authorisation stage of the next batch of 33 applications. This is due to additional work required to ensure the continued availability of Cobalt as a Feed Additive (prioritised on animal welfare grounds), pressure on resourcing in key teams, and the need to coordinate clearance and legislative processes in England, Wales and Scotland. Recent authorisations have taken longer than our planning assumptions to address legal and policy queries; we are therefore revising our assumptions about the time needed for this stage which will ensure the accuracy of instruments in all countries for applications due for authorisation within the next six months. This is also in the context of us taking through our first batch of authorisations that did not build on previous EU opinions; these have taken longer than expected. Revised estimated dates for completion are at Annex C. We have now built in additional review points for the future delivery timetable and will work with colleagues across FSA and FSS to consider further process improvements to reduce the impact of future delays.

3.7 As highlighted in previous reports, resource pressure remains the main risk to our delivery timetables. In the short-term we are mitigating this risk through continuous improvements that enable the current system to work more efficiently within existing resources, for example, making use of other regulators' opinions. In the longer-term we will bring forward plans for more radical reform, alongside 'quick wins' to streamline the system and reduce the burden on applicants and the regulator without compromising food safety. More detail about our programme of continuous improvement and plans for radical regulatory reform are in paras 3.9 below.

CBD Update:

3.8 CBD applications continue to make up a significant proportion of our caseload. Since our report in September:

- The FSA has published an ACNFP (Advisory Committee on Novel Foods and Processes) position paper on establishing a provisional Acceptable Daily Limit (ADI) for pure-form CBD, and updated consumer advice in response;
- The ACNFP reviewed the first CBD applications at its September meeting, and considered one of these again at the November meeting;

- The Home Office has published the Government's response to recommendations from the Advisory Committee on Misuse of Drugs on consumer CBD products, confirming it intends to bring forward legislation to prescribe the lawful amount of controlled Phytocannabinoids in such products. The FSA welcomes this and is working closely with the Home Office to ensure this legislation aligns with novel food regulations and provides clarity to industry. This change is necessary to support progress of CBD authorisations, which may be delayed or paused if the legislation is not in place.

Continuous Improvement and Reform

Continuous Improvement:

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

3.10 As of 30 September 2023, there have been 27 contacts on the new Case Management System (CMS) resulting in 26 applications. This is in line with our planning assumption of 120 applications per year flowing into the service. To date, 97% of contacts have progressed to a full application (compared to 24% on the legacy Application Service) demonstrating the added value of our new guidance and additional information requested from applicants before an application can be made. We are continuing to develop the internal interface of CMS along with making other improvements to the service usability in response to feedback from industry. The legacy Application Service and CMS are managed in tandem to ensure applications are dealt with in date order and enables us to monitor application flow through the service.

3.11 We have now notified Ministers of our intention to use other regulators' opinions, where we will validate the opinion of another regulator in specific and limited circumstances, such as for the re-authorisation of products. The process for implementing this approach has been developed, with pilot applications identified for consideration by an internal FSA panel to review the proposed conclusion. The first panel meeting took place at the end of November. The initial aim is to use this approach for renewal applications and this experience will be used to consider the opportunities to extend this option to other application types as part of our short-term improvements as well as work on longer-term regulatory reform.

3.12 Poorer quality applications create delays in the risk assessment phase through requests for additional information to applicants and follow up questions where responses are not complete. We have been generous to applicants in providing several chances to improve their dossiers and respond to information requests. Having kept this under review, this approach has not produced the benefits of improved applications or dossiers in the system and takes disproportionate resource, which has an adverse effect on workloads across the service. We have updated our letters to be explicit on the need for applicants to respond in full and by the agreed deadlines. Poor quality applications will either need to be updated quickly or be invalidated and will enable our limited resource to focus on progressing good quality applications. This new approach is being implemented already and external guidance is being updated to remind applicants of their responsibility to submit complete applications.

3.13 Resourcing remains a key risk for the RPS. Following further recruitment, numbers of vacancies in central policy and science teams have reduced. Given the context of a very tight cross-government funding position, we are planning the next financial years' service on the basis of current staffing levels, which means managing a growing caseload without growth in staff numbers. Our challenge, therefore, is to manage staff turnover and build capability and capacity as the service continues to develop. This is particularly pertinent for our risk assessors, as these skills are harder to recruit, and it takes longer for a risk assessor to reach full productivity. Our work on quick wins and on longer-term reforms remains essential to ensuring that the service is sustainable in the future.

3.14 We are improving our pre-application engagement to enable applicants to understand data and evidence requirements, to be clear on the regime under which their product will be assessed and to submit good quality applications on the CMS. We are currently piloting enhanced pre-application engagement on a small selection of 'first of kind' applications using new and/or disruptive technologies, to inform our approach across regulated products. Our ambition is to improve the quality of applications which in turn will reduce the re-work required by applicants and the regulator in the early stages of the process. Whilst we can offer some limited improvements within current resources, we are also developing proposals for early engagement at the product development stage and a more comprehensive pre-application service as part of our longer-term reform work.

3.15 On 22 November, the Chancellor announced in the Autumn Statement that the government will establish new regulatory sandboxes for novel industries, including the engineering biology industry. To enable this, the Department of Science, Innovation, and Technology has made £5 million available over three years and has asked regulators to bid for this money by pitching projects that would improve the regulatory service offered to engineering biology businesses to secure regulatory approval. We propose to submit a bid to run a sandbox on cell-cultivated products (cultured meat); if funding is available then we can use this opportunity to prepare for future growth in this market, improving the quality of future applications so they progress more smoothly.

Regulatory Reform:

3.16 We are working on proposals for longer-term reform of the RPS that will streamline the system and reduce the burden on applicants and the regulator without compromising food safety. We will bring forward detailed proposals for discussion in Spring 2024.

3.17 These proposals will build on the foundation for fundamental reform laid by the completion of the Novel Foods Regulatory Framework Review earlier this year. The review presented illustrative alternative approaches to reform ranging from adjustments within the scope of the current framework ('no-regrets' options) to more fundamental options such as triage-based regulation (grouping similar applications) and further work on recognising the evidence base or decisions of food regulators in other jurisdictions.

3.18 We aim to deliver some of the 'no-regrets' options from the Review in the immediate future, while preparing a long-term strategy to deliver fundamental reform options for all regimes.

3.19 To guide this work, we have developed a set of reform principles that are informed by and build upon the FSA seven guiding principles as presented in the 5-year strategy.

Reform Principles for Regulated Products:

3.20 These principles have been designed to guide the FSA Board in deciding which regulated product reform option(s) should be pursued in future. They should be applied to immediate reform activities and future reform activities. They will also be used to inform stakeholders and the public of how we want the future system to operate.

1. **We will protect public health.** There will be no reduction in food safety or standards as a result of our reforms.

2. **We will protect consumer interests**. Our new regulatory system will improve our ability to take consumer needs and preferences into account when making regulatory decisions.

3. **Decisions will be based on science and evidence**. We will continue to set high standards for evidence, working collaboratively with others on issues of mutual interest in order to maximise

efficiency.

4. **We will be open and transparent.** We will continue to publish our risk assessments and the basis for our regulatory decisions; we will maintain our focus on excellent risk communication for consumers and we will improve communication with applicants at all stages of the process.

5. **We will streamline our regulatory process**. We will design an agile, responsive and future-proofed system that allows us to be flexible, proportionate and proactive in our regulatory approach. Market access for safe products, processes and food technologies will be efficient, easy to navigate for businesses, and work for a UK context.

6. **We will facilitate innovation and enterprise.** Our regulatory environment will be able to evolve with the developing food system, respond to emerging technologies, and will make the UK a preferred destination for approvals for safe, innovative products.

7. **We will strive for four-country working**. We will minimise divergence within the UK and aim to have a common approach to regulatory reform with a framework that operates across the four nations.

3.21 Board to agree the proposed reform principles.

Immediate Reform Activity:

3.22 In line with FSA ambition to reform regulation to reduce burdens on applicants and the regulator and promote innovation and growth, we have identified priority changes that we are looking to bring forward, reducing the risk of future delays to authorisations. In addition to the FSA ambitions, this supports the UK government's Smarter Regulation programme. We aim to ensure a consistent approach across all four UK nations on these changes as far as possible, in line with our obligations under the provisional UK Common Framework. These priority changes include:

- A proportionate risk-based approach to the regulation of certain products requiring renewals. Currently, legislation regarding GMOs, Smoke Flavourings and Feed Additives includes automatic requirements for periodic (10-year, for example) review and renewal of authorisation, regardless of whether evidence suggests that this is needed. To date, renewals have made up approximately 25% of all applications to the RPS. We will explore removal of these automatic requirements, utilising the appropriate legislative vehicle. This should release resource and time to consider new product applications, which could be considered higher risk than renewal applications (that have previously been assessed as safe). We will ensure there is adequate post-market surveillance and that we retain the ability to review authorisations in light of new evidence and act where necessary to protect public health and ensure food and feed safety.

3.23 As previously outlined at the June 2023 Board meeting, we continue to develop policy on:

- A more efficient process for bringing authorisations into force following a Ministerial decision. Currently, all regulated product authorisations are confirmed by secondary legislation which requires significant additional resource to prepare and lay and adds around 3-6 months to the time it takes for new products to gain market authorisation. This process is significantly longer than the process that applied when the UK was a member of the EU. This is an effect of the way the regulations were transposed into a UK context, with the Appropriate Authority (Ministers) being assigned the legislative steps previously completed by the European Commission. We will explore alternative options, such as bringing authorisations into force via publication to an official register following Ministerial approval, rather than through laying a Statutory Instrument.

- Simpler, more transparent, and more accessible registers and lists of authorised regulated products. The current methods for listing authorised products, which vary by regime, include lists in legislation or having separate pieces of legislation for each authorisation. This change would significantly streamline legislation and provide a more efficient process to record and communicate which products have been authorised, thereby enhancing transparency and accessibility, and reducing the regulatory burden associated with maintaining and using multiple, complex sources of essential information.
- We are also continuing policy development of a Common Authorisation Procedure to ensure a simplified process with a single 'front door' for applications.

3.24 Board to agree to progress priority options for ‘quick wins.’

Future Fundamental Reform:

3.25 The long-term strategy for delivering reform will focus on exploring options for fundamental changes across the regimes to further streamline and improve the process. This work will build on the priority reform plans and consider options to make the regulated product authorisation system as efficient as possible while being proportionate to risk. This will include investigating opportunities for international collaboration, such as more comprehensive use of other regulators opinions, and opportunities to implement a possible triage structure in relation to the level of risk and other legitimate factors for different cases.

3.26 We are committed to working on a four-country basis to develop a common approach to reform and mitigate any risk of divergence and FSA and FSS are working jointly on reform plans going forward. We intend to engage with Ministers and the Permanent Secretary in Northern Ireland on potential legislative changes at the appropriate time.

3.27 As a devolved policy area, all reform plans are subject to the open and transparent policy development process including impact assessments, public consultation and consultation with Ministers and the Permanent Secretary in Northern Ireland, across all four nations.

4. Conclusions

4.1 The Board is asked to review the performance of Risk Analysis and the RPS, and to note the progress made on continuous improvement and our update on planning for potential future regulatory reform. The Board is asked to agree reform principles and agree to progress priority options for ‘quick wins.’

Annex A

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

PDF
Gweld FSA 23-12-07 - Risk Analysis and Regulated Products Performance Annex A.pdf as PDF(Open in a new window) (535.78 KB)

Annex B

List of Non-routine Risk Analysis Issues

RA ID number	Title of issue	Summary	Phase of risk analysis

G10000050	Analysis of the safety of Titanium Dioxide (E 171) as a Food Additive	On 6 May 2021, the European Food Safety Authority (EFSA) published an opinion on the safety of titanium dioxide (E 171) as a food additive. The EFSA panel concluded that E 171 can no longer be considered safe when used as a food additive. UK Scientific Advisory Committees will assess the EFSA opinion and any associated studies alongside the existing scientific evidence to provide a view on the safety of this permitted food colour. This will help inform what appropriate risk management action may be needed to safeguard consumers.	Risk Assessment and Evidence
G1000049	Risk analysis procedure for bamboo-plastic composite Food Contact Materials (FCMs).	Bamboo and similar plant-based materials are not considered to be authorised additives in plastic FCMs in accordance with Regulation 10/2011 (retained under domestic legislation in Great Britain), therefore a decision needs to be taken in respect of the GB market. The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) recently published their interim position statement on these articles.	Risk Assessment and Evidence
G1000057	Environmentally sourced recycled plastic in food contact materials (FCMs).	The FSA and FSS are aware of the use of recycled plastic in FCM products that are in part, or fully, fulfilled using plastic material that has been obtained from the environment (ocean, 'ocean-bound' or land). We are carrying out risk analysis to assess the safety of using these materials in food contact applications.	Risk Assessment and Evidence
G1000035	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.	Risk Assessment and Evidence
G1000069	Risk assessment of substrates used to rear insects for animal feed	The FSA has commissioned a comprehensive review of the safety of several currently non permitted substrates that could potentially be used to rear insect larvae for protein in animal feeds.	Risk Assessment and Evidence
G1000075	Titanium dioxide as a feed additive	On 16 June 2021, the European Food Safety Authority (EFSA) published an opinion on the safety of titanium dioxide (E171) as a FEED additive (EFSA No.6630). The Panel concluded that E171 can no longer be considered safe when used as a feed additive. This was followed by the publication of Regulation (EU) 2021/2090 of 25 November 2021 concerning the denial of authorisation of titanium dioxide as a feed additive for all animal species, which came into force in the EU on 20th December 2021, with sequential transition periods of up to 6 months (to 20 June 2022). A parallel safety assessment of titanium dioxide as a FOOD additive (G10000050) is ongoing. The safety risk assessment for titanium dioxide as a feed additive will consider the conclusions from the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) on the food additive prior to finalising the feed additive assessment.	Risk Assessment and Evidence

G1000084	Assessment of Bisphenol A (BPA)	Review of latest evidence relating to the safety of BPA in food. The European Food Safety Authority (EFSA) published its updated Opinion in April 2023 and recommended that the tolerable daily intake (TDI) be reduced to 0.2 nanograms per kilogram of body weight per day.	Risk Assessment and Evidence

Annex C

Forward look for applications in Risk Management as of October 2023:

33 applications	**Expected timeframe for consultation**	**Expected timeframe for coming into force date (pending ministerial and legislative timeframes)**
4 Novel Foods	Q4 23/24	Q3 24/25
3 Food Additives	Q4 23/24	Q3 24/25
26 Feed Additives	Q1 24/25	Q3 24/25