# Annual Review of Risk Analysis Process: Focus on Overall Performance and Risk Management

**Report by Rebecca Sudworth**

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## 1. Summary

1.1. The Board is asked to:

- **Review** the delivery of the FSA's risk analysis process in the first twelve months of operation since the end of the Transition Period in January 2021, focusing on overall performance and risk management;
- **Consider** the future plans for continuous improvement and longer-term regulatory reform, taking into account early lessons learned.

## 2. Introduction and background

2.1. A key, new, area of responsibility that the FSA has adopted since EU Exit is an increased role in food and feed safety risk analysis. This includes issues on which the FSA considers it necessary to make a risk management recommendation as well as the authorisation of substances allowed to be added to food and animal feed (see Annex A for process flow charts).

2.2. The Board agreed the risk analysis process in a series of discussions from 2018 to 2020 (a summary and links to previous papers are provided at Annex C). In June 2021 the Board reviewed the early delivery of the risk assessment function within the FSA and considered an outline of future priorities for the development of the regulated products service (as part of a wider forward look to future policy priorities).

2.3. This paper is the first annual review with the main focus of the operational and risk management elements of the risk analysis process post-Transition. Whilst we covered the risk assessment aspects of the process in June 2021, this paper also gives a brief update on this element in section 6.4. The paper sets out how the process has run in its first year of operation in 2021 and our plans for continuous improvement and longer-term reform, taking into account the early lessons learned. No issue has yet completed the full risk analysis process post transition; for this reason, our conclusions about the performance of the end-to-end process are early ones, and we will continue to gather

information and feedback as more issues reach the risk management stage. The first risk management recommendations to Ministers will be presented from February 2022 onwards, including a recommendation on the review of enhanced controls for products from Japan following the Fukushima nuclear accident.

## 3. Separation of risk assessment and risk management functions

3.1. It is a fundamental principle of accepted international standards in risk analysis that risk assessment (analysing the evidence and establishing risk) and risk management (making policy recommendations) are separate parts of the process. This ensures that risk assessment is based on science and evidence and not unduly influenced by political or other considerations. As part of our preparations for EU Exit, the FSA separated these functions internally and has embedded the principle of independent risk assessment into the risk analysis process.

3.2. Following an early review of risk assessment in June 2021, this paper focuses on the general performance of the system and, specifically on the risk management aspects. From 2023 onwards we will present an annual review of the combined process so the Board can consider all the elements of risk analysis as a whole – risk assessment, risk management and risk communication. The combined report will be prepared jointly by the FSA Directors with responsibility for risk assessment and risk management respectively.

## 4. Objectives and principles of the risk analysis process

4.1. The aim of the risk analysis process is to ensure formal mechanisms and approaches exist to assure the outputs and establish an appropriate level of confidence that they deliver public health protection and consider consumers' other interests in relation to food. The FSA follows globally recognised frameworks for risk analysis, notably the principles established in FAO/WHO Codex.

4.2. The FSA's overarching principles for its risk analysis process, agreed by the Board in December 2018 are:

- The risk analysis process must be **open and transparent**;
- Advice and recommendations presented to Ministers will be based on **consideration of risk, informed by science and evidence and will be independent**;

- The risk analysis process should have the capacity to provide for a four-country model and deliver, where appropriate to do so, **unified food and feed safety risk management recommendations for the UK**, as part of a UK-wide framework for food and feed safety and hygiene.

4.3. Since these principles were developed, we have further discussed with the Board how our commitment to working in a three- and four-country context needs adjusting in the light of more recent developments such as the Northern Ireland Protocol and the UK Framework Agreements. Our commitment to working constructively and collaboratively with the devolved administrations is unchanged; however, we are considering how to adjust this principle to take into account the new context.

4.4. This review considers how the FSA has put these principles into practice in the first year of running and sets out how we propose to develop future performance indicators and targets based on both qualitative and quantitative measures. Our thinking reflects our views not only on the process but also the optimal outcomes of our work, ensuring that consumers are protected.

## 5. Overview of progress and performance

5.1. The Board receives regular reports about issues currently progressing through the risk management process. The risk analysis process is the overarching framework that governs our approach. There are three broad categories of issue within the risk analysis process:

- 'Self-tasked' issues where the FSA identifies a food or feed safety issue for consideration – this can be proactive in response to changes in the food system, or reactive in response to an incident or new evidence.
- 'Externally requested' issues where the FSA is asked to provide risk assessment and/or risk management advice by Ministers or officials in other parts of government.
- Regulated Products, for specific categories of food and feed that must follow an authorisation process laid down in legislation.

5.2. In the first year of operation, the FSA has:

- Begun work on four issues as a result of new evidence and/or emerging changes in the food system.
- Received two requests from Defra to provide risk assessment and public health advice to support development of future borders policy (one has been completed; one is in progress).

- Progressed work on 428 live regulated products applications (see FSA 22/03/15 Business Committee paper on Regulated Products for more information)

5.3. As expected, **regulated products applications** represent the largest volume of work flowing through the system. Our planning assumptions, revised in 2020, suggested that the FSA could expect to receive around 350 regulated products applications each year. This did not take into account the impact of the regulatory approach to CBD, which led to a surge of applications around the March 2021 deadline. Other applications are in line with this planning assumption. Lessons learned from handling CBD applications are considered in more detail as a short case study in Annex B.

5.4. Time limits for each stage of the regulated products process are set out in regulations. These differ according to the type of regulated product. We are working hard to meet these timeframes, though on occasion, in common with other regulators, the work must be balanced and reprioritised in consideration of other emerging food/feed safety issues and changing priorities. The clock may also be stopped to allow the additional evidence to be obtained usually, though not always, because of omissions in the original application. This can lead to a longer time-period prior to a final decision.

5.5. Other than evidence requirements, there are two areas of the regulated products process where there is a risk that process-related delays could occur: the extensive existing legislative requirements which necessitate numerous steps in the engagement between officials and Ministers across the governments in the UK (this may be possible to streamline through regulatory reform, see section 8); and the requirement in UK law for product authorisations to come into force through legislation rather than automatically on a Ministerial decision. Both of these aspects are a result of translation of EU law into a UK context. The FSA is reviewing the process and will bring proposals to the Board before making recommendations to Ministers later this year about the potential for changes to streamline the process.

5.6. An overview of other issues in the regulated products service process is provided in the separate report to the Business Committee. As a former Member State of the EU, the UK has been actively involved in issues under consideration in Europe where work began before the end of the Transition Period and is building on already strong regulatory relationships with global regulators such as the US, Canada, Australia and New Zealand. The FSA's objective is to ensure that we lead, participate in and keep pace with developments in global food regulation and food system changes, providing

proportionate and timely risk management advice that prioritises food and feed safety whilst providing regulatory certainty and continuity to UK business and consumers.

5.7. Our approach to Titanium Dioxide is an example of this global interaction where we have shared views with other regulators. Titanium Dioxide has been under review in Europe since 2017; the EU announced a ban on the use of Titanium Dioxide in food in late 2021, to come into force after a short transition period. The FSA's scientific advisory committees conducted a review of the EFSA opinion in 2021; a joint statement was published in January 2022 stating that 'the weight of evidence did not support the conclusions drawn by EFSA'.

## 6. Meeting our core principles

### Transparency

6.1. The FSA is committed to ensuring that the risk analysis process is transparent. So far we have:

- Published two registers, regularly updated, which set out the applications in our regulated products service, and the issues going through the risk analysis process
- Run public consultations on several risk analysis issues and regulated products applications, including nine GMO applications and six novel foods applications
- Published a risk assessment on a review of imports from Fukushima, with more risk assessment publications to follow in the coming months
- Provided updates at each Board meeting on key issues in the risk analysis process, including through the Chief Executive's report
- Provided extensive training and support to industry in the run up to launch of the Regulated Products service, including a series of webinars. We also provided pre-application support and input for companies making applications for CBD products. We continue to have sustained dialogue with industry through a range of speaking engagements and other conversations.

6.2. Our future plans include:

- Providing new digital tools for stakeholders, including a new searchable database of CBD applications and associated products under consideration by the FSA, and a new, more user-friendly, application system for regulated products

- More structured and proactive engagement with industry through a suite of new industry engagement groups
- Development of additional 'application guidebooks' to ensure that legislative and other requirements are as clear and accessible as possible for industry.

**Evidence-based and independent**

6.3. The review of imports from Fukushima is our first high-profile issue going through the full post-exit risk analysis process. It showcases how we have followed the new process and principles to develop a UK risk management approach based on a fresh, independent, review of the evidence (see FSA 22/03/07). The quantitative risk assessment was published in December 2021.

**Risk assessment: developments since June 2021**

6.4. In June 2021 the Board received a paper on the **risk assessment** element of the risk analysis process. The key developments since then are:

- The 2021 cohort of staff has been trained to meet the quality standards required for routine assessments and deployed to address the significant number of requests received to date. Further capability building exercises are being planned for the 2022/23 financial year and the recruitment of the 2022 cohort of staff is well underway. This will bring the full complement of risk assessor posts to over 90.
- A key focus of our risk assessment team's activity has been working through the high volume of CBD applications, working closely with applicants to ensure they provide comprehensive evidence to meet validation requirements and thereby pass to the risk assessment stage. More detail on our approach to CBD is in the lessons learned section in Annex B.
- Devolved Ministers are about to be consulted by the Defra Secretary of State on transferring the responsibilities of the Advisory Committee on Animal Feedingstuffs to FSA. This is part of our continuing drive to make a consistent and harmonised UK food and feed committee structure.
- Some aspects of the later stages of the regulated product process are being tested for the first time. A continuous improvement approach has been utilised to identify efficiencies and best practices and ensure they are adopted quickly across the regulated product regimes. This will continue to be a key principle for the service going forward.
- We regularly review our regulated products processes in relation to risk assessment, to capture and implement lessons learned. Evaluation of demand will continue to make best use of the available resources to meet FSA priorities in this area.

**Working in a four-country context**

6.5. The FSA advises the UK Government and the devolved administrations in Wales and Northern Ireland; FSS advises Ministers in Scotland. Under provisional UK Frameworks and our risk analysis process we have mechanisms such as cross-government working groups in place to enable a four-nation approach, so we can deliver risk management interventions that are effective for the UK as a whole or for individual countries as needed. UK Frameworks include scope for inter-ministerial discussions on decisions if needed.

6.6. Under the Northern Ireland Protocol (NIP), Northern Ireland must comply with EU food and feed law, resulting in some different regulatory arrangements applying in NI than in the rest of the UK. We continue to consider the interests of consumers in Northern Ireland, whilst accepting that the NIP will restrict the decisions that can be taken in NI, in respect to UK risk analysis outcomes.

## 7. Measuring performance

7.1. As part of our plans for continuous improvement and development of the risk analysis process we intend to develop performance indicators and performance targets to provide a more objective measure of our performance. In doing so, we will consider the following issues:

- The perspective of different customers and stakeholders: for example, consumers may prioritise more extensive and comprehensive consultation whereas businesses may prioritise speed of decision-making;
- The timeframe for measuring impact: the effect of risk management decisions may not be apparent immediately and could require several years to evaluate;
- The need to design tailored measures for different elements of the system – risk assessment, risk management and risk communication;
- The need for both qualitative and quantitative measures, and putting in place new systems to collect and interpret data;
- Continued consideration of the potential for divergence and the mechanisms by which we can effectively handle this;
- Ongoing changes and developments as the risk analysis process beds in – for example, our plan to bring forward advice to Ministers this year about changes to retained EU law to reduce delays.

7.2. We propose to develop initial performance measures that will focus on:

- **Meeting our statutory timeliness targets in the regulated products process.** It is important that we meet our statutory commitments to consumers and to industry. In developing performance measures, we will

take into account the differences between regimes, the impact of 'stopping the clock' to seek additional evidence from applicants and the need, on occasion, to prioritise work on public health grounds to address new and emerging food safety issues. We will also consider indicators and targets for areas where there are no current statutory timeframes.

- **Supporting businesses** to improve the quality of applications to reduce delays: we will begin by developing two measures:
    - a measure of the quality of initial contacts to the regulated products service, to help us reduce and more appropriately direct general enquiries;
    - a measure of time that regulated product applications and other issues requiring evaluation spend in 'stop the clock' dialogue to help decide where we should focus additional support.

7.3. In June 2021 we informed the Board of our plan to conduct an external review of the regulated products process during 2022. We intend that this will focus on both current performance (looking at the running and performance of the process as is) and future reform (making recommendations for reform and improvements, drawing on examples of best practice in safety and product regulation domestically and globally). This will provide further evidence and recommendations about where to focus performance improvement efforts, and the best performance measures to adopt.

7.4. In the longer term we will develop additional measures to evaluate the performance of the whole risk analysis process with a view to further streamline, where possible. We can use the proposed measures above to monitor how long issues spend in each stage to help identify pinch points and ensure we have sufficient resource, focused in the right area.

## 8. Continuous improvement and future regulatory reform

8.1. The focus in 2022 will be on continuing to embed and deliver the service; we will sustain our continuous improvement and develop longer-term proposals for reform in accordance with four-country working, while ensuring that consumer safety remains the priority.

8.2. In the short term, we plan to commission a resources and workflow modelling tool. The model will enable us to better identify, allocate and deploy resourcing as dossiers move through the risk analysis process and, over time, forecast trends in the receipt of applications. In addition, we plan to conduct an in-house process review, taking an example product through the system to identify barriers and inefficiencies. We are also working on an improved Regulated Products Application IT system which will be more user-friendly.

8.3. Food and drink is featured prominently in the Government’s vision for a global trading nation with a commitment to do more to ensure the UK is at the

forefront of food innovation globally. In its Benefits of Brexit paper, published on 31 January 2022, there was a commitment by the Government to work with the Food Standards Agency to review the novel foods regulatory framework to create a transparent and effective system that is the best in the world for innovators, investors and consumers and encourages safe innovation in the sustainable protein sector. The external review planned for 2022/23 will support this thinking and enable us to draw on best practice from regulatory systems around the world in developing our ideas.

8.4. The Board is already aware of proposals by Defra to create a separate legal framework in England for gene edited products (discussed by the Board in September 2021), currently controlled by legislation on Genetically Modified Organisms (GMOs). This will impact on the FSA, as the regulatory body, alongside Food Standards Scotland, for the authorisation of GMOs. We will need to develop a new regulatory approach that provides assurance on safety, factoring in the need for coherence across the UK. We will present our proposals to the Board later this year.

8.5. Finally, there are different requirements and timeframes associated with the authorisation of different classes of food and feed substances. We are now considering, in the light of initial experience over the last year, the scope for regulatory reform to consolidate and simplify some of the processes, including those for novel foods. The extensive existing legislative requirements necessitate numerous steps in the engagement between officials and Ministers across the governments in the UK and there is opportunity to simplify and streamline the rules in this area.

## 9. Conclusions and next steps

9.1. The Board is asked to:

- **Review** the delivery of the FSA's risk analysis process in the first twelve months of operation since the end of the Transition Period in January 2021, focusing on overall performance and risk management;
- **Consider** the future plans for continuous improvement and longer-term regulatory reform, including the development of appropriate performance metrics.

## Annex A
## Risk Analysis and Regulated Products Flow Charts

https://www.food.gov.uk/sites/default/files/media/document/fsa-risk-analysis-flowchart.pdf

https://www.food.gov.uk/sites/default/files/media/document/fsa-regulated-products-flowchart.pdf

## Annex B
## CBD: lessons learned

As the Board knows, the FSA has taken a proactive and phased approach to the regulation of the Cannabidiol (CBD) market, to bring this part of the food industry into compliance with the law.

The approach balances legal compliance, consumer safety, the interests of consumers who take CBD products, and the desire to support innovation in the food industry. In the interests of consumer safety, in February 2020 we offered consumer advice, highlighting that none of the products currently for sale had been formally safety assessed. Further, if consumers were going to eat them, they should limit themselves to a maximum of 70mg a day, and we advised vulnerable consumers not to eat CBD products on a precautionary basis. We understand we were the first food regulatory agency in the world to do this.

To encourage the industry to become compliant, at the same time we set a deadline of 31 March 2021 for applications to be registered with the FSA so that CBD products could be taken through the usual novel foods assessment process. Having announced a deadline for applications to be received, the FSA has engaged extensively with industry, including through the provision of pre-application advice during 2020. The Chief Executive's report, and the report to Business Committee on Regulated Products, include further detail on the latest developments with processing CBD applications.

Our key learning points include:

> **The FSA acted early by publishing clear advice to consumers about risk based on a review of current available evidence.**

This was a good example of risk communication with recommendations for healthy adults and for vulnerable groups. We provided clear information about what is known about CBD and what is not known.

However, in providing this information there is a risk that some consumers wrongly believe that CBD has been authorised as safe by the FSA. We have been working with industry and retailers to make it clear that this is not the case, and no CBD products have yet been authorised. Additionally, where there is evidence of harm for any product we will take action.

**Setting a clear deadline for applications was necessary but drove a huge volume of applications and other contacts in the first quarter of 2021.**

The FSA responded by surging internal resource to cope with the demand, but we could have better anticipated that most approaches from companies would come in at the last minute and designed a more proactive handling approach. Our resource planning activities (outlined in section 8.2 above) will help to ensure we are better prepared for future peaks in workload, including as the large subset of CBD applications work through the remainder of the authorisation process.

**The FSA received a high volume of insufficiently complete applications which ultimately did not progress.**

Considerable staff time was spent sifting through these applications, and as such we are reflecting on more efficient IT processes to assist with application sifting, as well as ways to ensure that applicants have as much accessible information as possible, including the development of ‘application guidebooks’ referred to in section 6.2 above. This will include improving the navigability of the dossiers to ensure the key information and how it supports the safety of products can be identified quickly and easily.

In addition, we will look to encourage applicants to work more collaboratively and to submit applications based on the novel food seeking authorisation rather than the end products that contain them. Applications with the wrong focus or which have required consolidating has added to the review time at validity.

**CBD products are widely associated with health and wellness claims although no such claims have been authorised by the appropriate UK authorities.**

CBD products are an example of a global market where information about the claimed benefits of the product may come from a range of sources, often through peer-to-peer recommendations. Regulation and enforcement in this kind of market is challenging. Health claims are the responsibility of the Department of Health and Social Care and no health claims for CBD are currently authorised. The FSA will continue to work with DHSC and other regulators to improve coordination of regulatory approaches.

We will use these lessons learned to:

- Improve our engagement with industry and retailers when the FSA issues interim risk management advice;
- Improve our workflow planning, including better support for applicants particularly in new or emerging food sectors;
- Improve our cross-government working on borderline products where regulatory responsibilities can involve food, health and medical regulatory regimes.

## Annex C

## The design and development of the risk analysis process: links to previous Board papers

In September 2018 the Board discussed and agreed the governance and assurance framework for the FSA including the implications for the Board of the UK's exit from the EU and the proposed high-level future governance and assurance arrangements for risk analysis.

In December 2018 the Board discussed the risk analysis process in more detail and agreed the principles that we should apply at each stage of the process.

In March 2019 the Board discussed and agreed proposals for assurance of the risk analysis process; and as part of this, proposals for an FSA approach to the evidencing and consideration of an appropriately broad set of impacts in risk management.

In September 2019 the Board discussed the FSA's approach to uncertainty and risk in the context of the risk analysis process.

In January 2020 the Board was updated on progress on implementation of the risk analysis process and discussed the illustrative forward work plan for risk analysis and plans for review.

In September 2020 the Board considered the development and implementation of the risk analysis process and agreed proposals for prioritisation of issues and the approach to publication and consultation.