

## RISK ANALYSIS PROCESS: UPDATE

### Report by Rebecca Sudworth

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### 1. Summary

1.1 The Board is asked to:

- **Note** the progress on implementation of the food and feed safety risk analysis process and the high-level principles, governance and assurance arrangements agreed by the Board.
- **Note** the illustrative forward work plan for risk analysis, next steps and plans for review.

### 2. Introduction

2.1 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.

2.2 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.

2.3 This paper provides an update on implementation of the risk analysis process.

### 3. Strategic Aims

3.1 Delivering an effective approach to risk analysis underpins the FSA's vision of being recognised as an excellent, accountable, modern regulator. This paper provides an update on the progress we are making to implement the risk analysis process in the FSA as part of our preparedness for EU Exit. The food and feed safety risk analysis process will be central to everything we do and will contribute to the FSA objective to ensure that the high standard of food safety and consumer protection we enjoy in the UK is maintained when the UK leaves the EU.

- 3.2 The FSA already follows international best practice as it considers food and feed safety risks. In preparation for EU Exit we have developed our risk analysis process, improved our approaches, expanded our teams of experts and added increased rigour and transparency to allow the FSA to deliver its risk assessment and risk management functions. This will enable us to continue to protect consumers and provide independent and trusted advice.
- 3.3 The risk analysis process has been designed to be agile and flexible to meet requirements for individual issues and requirements when we exit the EU. The risk analysis principles, as agreed by the FSA and FSS Boards will apply when the UK leaves the EU and during the transition period. We will review and adjust the processes during that period so that the full risk analysis process transitions from shadow form to live operation by the end of the transition period.
- 3.4 We are building in a four-country approach as part of a UK-wide framework for food and feed safety and hygiene, proposals for which are being discussed and developed by FSA and FSS.

#### 4. Progress on Implementation of the Risk Analysis Process

- 4.1 The risk analysis process was agreed by the FSA Board in December 2018. The focus since March 2019 has been on refining the detailed operational procedures underpinning the process and adapting ways of working so that it is embedded and functions effectively within the organisation. The following key elements have been delivered (further details are in **Annex B**):
- A clear separation between our risk assessment and risk management functions.
  - An extensive programme of staff engagement and training and a package of staff guidance on the process which embeds the principles for risk analysis agreed by the FSA Board in December 2018.
  - Ongoing engagement with the FSA Scientific Advisory Committees (SACs) on their role in the risk analysis process.
  - The application process for regulated products including handling procedures for those dossiers within the EU authorisation process when we exit the EU.
  - A full internal resilience test of the high-level process and principles and detailed testing of individual steps.
  - Establishment of the Advisory Forum on Food and Feed to provide input to risk management advice.
  - Processes for embedding collaborative working across the four countries of the UK and with other government departments and devolved administrations, building on and formalising existing working arrangements.
  - A review of available risk communication guidance that is potentially applicable to food, and the current academic literature on risk communication.

- Publication of web pages describing the risk analysis process<sup>1</sup> including advice for stakeholders on the authorisation process for regulated products to support business readiness<sup>2</sup>.
- 4.2 The next challenge we are considering is how the three main likely calls on the use of the Risk Analysis process transit through the system. These are:
- 1) regulated products, perhaps the simplest as there is now a set UK process ready for EU Exit;
  - 2) how strategic and operational risks are prioritised within the FSA and how they feed into the process; and
  - 3) how the FSA deals with short term issues raised by other Departments or to which we need to respond quickly.

## 5. Forward Work Plan

- 5.1 The Board agreed, in its September 2018 discussion of governance, that technical risk management advice on routine issues should be provided by the executive direct to decision-makers. When we Exit the EU many of the issues that are likely to come to the risk analysis process for consideration first are routine technical issues, mainly regulated products for which applications for authorisation are already in the EU regulatory pipeline. In preparation for this, we have developed proportionate handling procedures for dealing with those applications. These will be adapted to take into account conditions applying during the transition period.
- 5.2 We have established processes to capture issues being considered through the risk analysis process including those currently in the EU pipeline and this will provide a basis for the forward look and updates to the FSA Board and to Ministers.
- 5.3 For the purposes of this paper we have provided an illustrative (non-exhaustive) workplan focussed on those issues currently at an advanced stage in the EU regulatory pipeline. This illustrates the range of routine technical issues that could be considered through the risk analysis process following the UK's exit from the EU. This is included in **Annex A**.
- 5.4 Looking ahead, it is intended that for each FSA Board meeting there will be a standing annex to the Chief Executive's report on progress which will summarise matters going through the risk analysis process, advice submitted to Ministers and Ministerial risk management decisions, initially set in the context of the transition period.

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<sup>1</sup> <https://www.food.gov.uk/business-guidance/food-and-animal-feed-safety-risk-analysis-after-brexit>

<sup>2</sup> <https://www.food.gov.uk/business-guidance/submitting-a-regulated-product-authorisation-application-after-brexit>

## 6. Next Steps and Plans for Review

- 6.1 For the next 12 months our focus will be on embedding the risk analysis process into the business, verifying the process is functioning effectively and fit for purpose for the environment we are working within. We will also actively manage the transition from the current operational readiness to live operation at the appropriate point.
- 6.2 The operation of the overall risk analysis regime, including risk assessment, risk management, risk communication and the advice and recommendations we put to Ministers, will be subject to a formal annual review by the FSA Board.

## 7. Conclusions

- 7.1 The Board is asked to:
- **Note** the progress on implementation of the food and feed safety risk analysis process and the high-level principles, governance and assurance arrangements agreed by the Board.
  - **Note** the illustrative forward work plan for risk analysis, next steps and plans for review.

## Annex A - Forward work plan

This Annex is provided separately.

## Annex B – Progress on implementation of the risk analysis process

This Annex provides further details on implementation of the risk analysis process and on the development of operational procedures as outlined in para 9 of this paper:

- We have delivered an extensive programme of **staff engagement** including a series of team briefings, workshops and other activities to raise awareness and test and embed the process.
- A package of internal **guidelines** for risk managers, risk assessors, analysts and risk communicators has been produced and is being used by officials. This includes overarching guidelines; guidelines for risk management steps; detailed guidelines for the risk assessment and evidence gathering steps in a number of tiers; and a risk communication framework. The guidelines were developed with a wide range of input and contributions from across the FSA and with FSS.
- High level guidelines were also shared and discussed with all the **FSA Scientific Advisory Committees** (in May/June) and the more detailed guidance on risk assessment was shared in September/October, with an opportunity for discussion. The risk communication framework has been agreed by our Advisory Committee for Social Science. Presentations on the risk analysis process were included in the FSA Discovery day for Scientific Advisory Committee members in June and the inaugural meeting of the Joint Expert Groups in October.
- The application process for **regulated products** is established and the platform for receipt of authorisation requests is ready to go live. UK handling arrangements for authorisations progressing through the EU authorisation process when we exit the EU have been agreed. These will be adapted to take into account conditions applying during the transition period.
- A full **resilience test** was completed 10 October with a wide range of representation from across the FSA to test the process and operational procedures. No major issues with the process were identified and the outputs are being used to refine our detailed operating procedures. This builds on detailed testing of individual stages.
- The **Advisory Forum on Food and Feed (AFFF)** has been established. The FSA Board held an initial discussion in June 2018 on the FSA's proposal to establish a regulatory forum to provide input to risk management advice. This was based on an assumption that the FSA would seek delegated powers for

risk management decision making on technical food and feed safety issues. Ministers would retain powers for decisions on more prominent issues with wider public policy implications. Ministers subsequently decided that while the FSA may in due course have responsibility for certain risk management decisions, until this time, on a transitional basis, all risk management decisions would be made by relevant health Ministers on the basis of FSA advice and in consultation with other Ministers as necessary. The timetable as reported to the Board in December 2018 was for the AFFF to be established from 1 January 2019, running in pilot to test operational procedures and to be fully functional from the end of March 2019. To this end a preparatory meeting was held February 2019. The timetable was subsequently adjusted in light of the ongoing EU Exit negotiations and the AFFF held its inaugural meeting in September 2019. A provisional forward schedule of monthly AFFF meetings is in diaries and these will be supplemented by monthly official level co-ordination meetings.

- We have implemented processes for embedding stronger **collaborative working** across the four countries of the UK and with other government departments and devolved administrations, building on and formalising existing working arrangements. A four-country liaison group has been established at official level to embed collaborative working on risk analysis across the FSA in England, Wales and Northern Ireland and with Food Standards Scotland. We are also putting in place a layer of regular working level co-ordination meetings with other departments (DHSC, Defra, DIT) and Devolved Administrations to support appropriate cross department engagement ahead of AFFF discussions. Officials from FSS and the FSA are engaged in discussions and continuing to develop arrangements that will allow the risk analysis process to function effectively within a 4-country model.
- We have conducted a review of the current state-of-play of available **risk communication** guidance that is potentially applicable to food, the current academic literature on risk communication and the extent to which current guidance reflects existing academic literature. The study has assessed the structure of risk communication guidance documents as well as the approach and level of detail provided on appropriate messaging and framing, channels for communication and how to approach different types of risk and audiences. Academic literature on risk communication has been reviewed and the state of evidence on different aspects of risk perception and communication has been summarised. The study has brought these two literatures together and identified where evidence is strongest, where there are still gaps and the extent to which risk communication guidance reflects the available academic evidence on risk communication. This will be published in due course, and we are about to begin qualitative research with consumers, journalists and communications practitioners to develop a practical risk communications toolkit for the FSA which reflects the latest thinking.

- We are implementing a supporting **communications plan** on the risk analysis process. Web pages describing the risk analysis<sup>3</sup> and regulated product authorisation<sup>4</sup> processes have been published, and we are continually looking for opportunities to share key messages on our risk analysis process with our stakeholders.
- We have developed internal systems for **tracking issues** in the risk analysis process. Live issues are being introduced to the process with new issues entering the early stages and ongoing issues being mapped on to the relevant step. This will provide a basis for the forward look and updates to the FSA Board and to Ministers.
- The Board agreed our commitment to **publishing** the advice we provide to others and the analysis and evidence on which that advice is based. Detailed proposals for what this looks like in practice for the risk analysis process are being developed through a cross FSA/FSS working group.

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<sup>3</sup> <https://www.food.gov.uk/business-guidance/food-and-animal-feed-safety-risk-analysis-after-brexit>

<sup>4</sup> <https://www.food.gov.uk/business-guidance/submitting-a-regulated-product-authorisation-application-after-brexit> and i