FSA Annual Report on Risk Assessment
Report by Julie Pierce, Director of Wales, Information and Science

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1. Summary

1.1 The Board is invited to:

- Review the delivery of the risk assessment function within the FSA in the six months after the end of European Union (EU) transition period.
- Consider the future steps proposed for the ongoing development of risk assessment in 2021 and beyond.

2. Introduction

2.1 In January and September 2020, the FSA Board noted the progress that had been made on arrangements for risk analysis (risk assessment, risk management and communication) required to be in place for the end of the EU transition period on 31 December 2020 and agreed that:

- we should continue our approach to the analysis of risk; and
- we should continue to be open and sharing with our science and evidence.

2.2 This report, presented six months post end of transition, provides details of the risk assessment work commissioned and outlines our ability to manage this demand, any challenges still to be overcome and areas of focus we plan in the next six months.

2.3 Finally, this report updates the FSA Board on the risk assessment proposals for the nutrition related labelling, composition, and standards (NLCS) assessments supporting delivery of FSA responsibilities in NI, and requests for risk assessment to support the policy remit of Other Government Departments.

3. Background

3.1 From the start of EU exit preparations, the FSA identified core aims to repatriate risk assessment functions from European Food Safety Authority (EFSA) and European Commission (EC) and deliver those functions from 1 January 2021. These were to have:

- Adequate processes in place to support the commissioning of work and problem formulation discussions (between risk assessors and risk managers).
- Capacity and capability to undertake, and communicate, the outcome of UK risk assessments for work we previously delivered (incident handling

and development of risk-based standards and controls) and to provide the risk assessment function for new requirements to support the GB market authorisations of regulated products and trade.

3.2 To achieve these aims, between 2018 and 2020, we implemented structural and procedural changes, including:

- functional separation of FSA staff between risk assessment and risk management roles;
- an expanded role for our Scientific Advisory Committees;
- the building of a new GB process for authorising regulated products;
- the development of technical guidance and IT platforms to smoothly communicate the application and progress of the Risk Analysis Process.

4. Discussion

Internal capacity and capability

4.1 In October 2018, the FSA had 20 dedicated risk assessors. Through investment and targeted recruitment, this number has increased, and we are predicted to have a headcount of 65 by early summer 2021. The most recent recruitment, starting in 2020, has been focused on building our capacity to assess the increased volumes of regulated products applications being made to the FSA as detailed in paragraph 4.13.

4.2 We have been running in-house risk assessment training programmes to train new staff in delivering Codex-aligned risk assessments (the international standard setting body), rapid risk assessments and risk profiles, with the next new programme being delivered from May 2021 for the latest cohort.

4.3 While overall recruitment has been successful this year; filling 20 of 23 recent posts, there have been challenges securing appropriately skilled toxicologists; a skillset that is becoming scarce. We are reviewing long term options to address this shortage, including engagement with others across government and academia, for example, exploring the potential for developing postgraduate apprenticeship training with relevant universities.

Risk assessment processes and procedures

4.4 Risk Analysis Guidelines were published on the Digital Workplace for staff to access in December 2020. These outline the procedures for commissioning, producing, quality assuring and disseminating the findings of risk assessments and reports on ‘other legitimate factors. Regular risk assessment-related training sessions have been provided.

4.5 New Fellows: Success in securing Strategic Evidence Fund (SEF) funding for 2 four-year FSA2020 Fellowships in computational toxicology and genomics/ bioinformatics to innovate risk assessment methodologies, making best use of sequence data available and in silico methods. Both fellowships have now

been awarded to successful applicant universities and the fellows are being recruited.

4.6 Improved data handling: working with colleagues in the FSA digital and data teams, we have developed a new system for indexing large reference sets to enable better systematic reviews, compiling reference lists.

4.7 Risk assessment webpages: in order to support better openness and transparency, work is ongoing to redesign the FSA science webpages in order to make our risk assessment publications more readily accessible.

Incidents handling and emerging risks

4.8 Incident risk assessment: in the past six months, the number of incidents which have required a risk assessment was 110. So far combined effects of the Covid-19 pandemic and end of the transition period have not affected the time needed to respond to requests.

Risk assessment to support risk-based standards and controls

4.9 Since 1st January 2021, the following food safety risk assessments to inform risk-based standards and controls have begun commissioning through the Risk Analysis Process:

- *Campylobacter* in small broiler slaughterhouses.
- Unchilled meat and offal.
- Bamboo composites used in biologically based food contact materials.
- Polycyclic aromatic hydrocarbons in tea.

4.10 Digital Risk Analysis tracker: the developed IT tracking and monitoring solutions, developed to serve a post exit minimum viable solution, are working well. There have been no significant issues associated with use of the Evidence Package Tracker which is the new repository of sharing evidence.

Regulated products risk assessment

4.11 Regulated products, such as additives, are those substances that require a pre-market safety evaluation and need to be approved by Ministers before they can be used. Online access to the GB FSA application service went live at the start of 2021. Progress is monitored via the Regulated Products IT software.

4.12 As of the end of April 2021, of 1079 regulated products applications that had been received, 423 have sufficient information to begin the validation process and of these 18 are actively in the assessment stage of the process. In 2020 the FSA estimated the number of dossiers expected in 2021 based on trends in the EU system. When the level of active dossiers are compared to these, and the surge in CBD (Cannabidiol) applications taken into account, the number received is largely in line with expectations. The proportion of flavouring and novel foods applications, other than CBD, is slightly lower than expected. We will continue to monitor this in the second half of the year.

4.13 To assist in our work in risk assessing future innovative food and feed applications, we have completed systematic reviews, providing extensive background data on the science and risks associated with three key new/emerging food technologies:

- Lab-grown/cultured meats.
- Gene edited/gene modified foods.
- Protein sourced from insects.

4.14 International collaboration: informal meetings have been held with several other regulators on how new food and feed products are assessed in other countries and regimes, for example cannabidiols and cultured meats.

4.15 Future resource planning: with the collection of real data since 1 January 2021, we are better placed to revisit our planning models and more accurately understand what will constitute sufficient capacity in this area, looking into the short-to-medium term.

4.16 In line with our commitment to share the evidence on which our risk assessments are based, the gene edited foods and insects reviews will be placed on the FSA website. The lab grown meat review is a summary of the current trends in the sector and identifies that the techniques are largely at the development stage with little information on any food safety risks, this will be used internally to identify data gaps.

Third Country market access requests

4.17 The second iteration of the Border Operating Model was published on 8 October 2020 with Defra the policy lead on this area, whilst FSA/FSS remain the competent authority for assessing the food and feed safety aspects of these products for consumers.

4.18 An initial process for third countries requesting market access via Defra UK Office of Sanitary and Phytosanitary Trade Assurance (UKOSPSTA) has been developed with the first point of contact for food safety to FSA Market Access Team embedded in Regulatory Compliance. To date, no market access risk assessment requests have been commissioned.

4.19 Working with Defra, we continue to address the challenges of implementing these new processes and ensure it is embedded and fully functional. A particular challenge is managing expectations on deadlines to complete complex risk assessments, the future publication policy for resulting risk assessments, and the mechanism of assuring public health still need to be fully developed and agreed with Defra and other Departments involved.

Supporting food and feed import risk assessment

4.20 To date, two import risk assessments have been commissioned by Defra to FSA. Both are associated with the assessment of food safety as a result of transferring statutory instruments:

- Import 2022 project: assessment of 19 categories of Products of Animal Origin (POAO) to support decision making on level of import checks that should be applied in England, Scotland, and Wales.
- Prohibitions & Restrictions meat products: food safety assessment of raw meat commodities imported from a range of EU and other 3rd countries to support decision making on prescribed transportation conditions (chilled or frozen).

4.21 Work has also started on one FSA commissioned risk assessment for the assessment of radiological risk to the UK consumer of radiocaesium for food imports from Japan. The risk assessment will be scientifically scrutinised by the Committee on Medical Aspects of Radiation in the Environment (COMARE) later in 2021 and the progress is tracked using the Evidence Tracker.

Other cross-government working

4.22 We are also working cross-government to provide new risk assessment requirements for other Departments. At this time, requests include:

- Assessing Reference Points for Action for non-permitted veterinary medicines for Veterinary Medicines Directorate (VMD). These are risk assessments to set limits for substances not authorised in the UK.
- The NLCS framework supports UK policy concerning nutrition and health claims. From a risk assessment perspective this includes advising on the addition of vitamins, minerals and other substances to foods, and the composition and labelling of certain foods (food supplements, food intended for infants and young children and foods for special medical purposes). The NCLS framework includes the ability to request assessment by expert committees on proposals to modify registers, lists, and schedules and policy proposals. Requests received to date relate to new nutrient sources and harmful natural components in botanical supplements. Requests on the allergenicity of infant formula are expected shortly.

4.23 We continue our participation as founding members of the Cross-government Risk Assessors Network (CRAN), with 8 other UK Departments / Executive Agencies members, which provides a forum for networking and discussing approaches to risk assessment to support consistency and understanding across UK government assessors.

Scientific Advisory Committees (SAC)

4.24 In the last 12 months, the FSA's SACs, sub-groups, and Joint Expert Groups (JEGs) have held 40 meetings to prepare and then operate outside of transition. These groups provide independent expert judgement and a key assurance mechanism to obtain external scientific scrutiny of risk assessments and technical advice before publication. Exceptions may include routine incidents and some entire risk assessments (although sections or approaches may still be reviewed).

4.25 Strengthen the role of our SACs: we have

- Upgraded all the SAC websites to requirements of the Accessibility Regulations 2018.
- Enabled the remote delivery of meetings and workshops with use of IT for externally accessed Teams site to enable electronic document sharing.
- Improved our efficiency in organising our SACs meetings through centralising our administrators in one hub across all SACs.
- Continued resilience and capacities of SAC experts through further recruitment campaigns. Twelve new SAC members were recruited in this year's campaign and 10 members were reappointed.

4.26 Third Party Evidence Review: in September 2020, the Science Council was commissioned to deliver a Rapid Evidence Review, aimed at providing guidance outlining how the FSA would review and consider un-commissioned third party evidence that it received, which sought to influence our policy and risk analysis (and as distinct to the structures in place for regulated product authorisation). The proposed framework, due to be published in Summer 2021, will:

- Emphasise the principles of quality, trust and robustness and seek to aid third parties in the consideration of scientific standards.
- Provide an internal resource to support consistency of best practice in the assessment of evidence.
- Be informed by and build on existing good practice within the FSA.

4.27 Register of specialists (RoS): we continue to use the register to support our work; for example, to commission external expert reviews. Created in 2019, the RoS currently has over 300 experts listed.

4.28 Future of the Advisory Committee on Animal Feedingstuffs (ACAF): One impact of the higher number of regulated product applications, has been the need to reconstitute ACAF, as a risk-assessment only SAC. Currently in abeyance, the FSA is working to reconstitute ACAF in this new model and is working with Defra to see if ownership of this committee can be fully handed over to the FSA (under current governance rules, it is a joint FSA-Defra SAC).

Northern Ireland (NI)

4.29 Under the NI Protocol, in NI businesses still follow EU rules for food and feed safety. Therefore, when we consider an issue through the UK Risk Analysis Process, in line with the four-country model, we still consider the risks to consumers in Northern Ireland, whilst accepting that the Northern Ireland Protocol (NIP) will restrict the decisions that can be taken in respect of NI.

4.30 Regulations that apply in NI under the NIP are generally not subject to risk analysis by the FSA in addition to the analysis carried out by the EFSA and EC. However, changes in NI assessed by the FSA as non-routine would be prioritised for UK risk analysis as appropriate to the issue.

4.31 When the need to assess non-routine changes occurs, as the FSA no longer has access to relevant EU databases, in the context of NI, this may create challenges when undertaking risk assessment.

5. Next Steps for the FSA Risk Assessment

5.1 Summary of the key areas of focus for the next 6 months (and potentially beyond):

- Further training of recently recruited staff to address the volume of applications submitted to the Regulated Products Service.
- Taking the first applications through the system and working with the Scientific Advisory Committees to refine working practices so that these receive a proportionate assessment while ensuring the system is efficient and ensuring there is sufficient capacity for feed additives via ACAF or an alternative committee.
- Contribute to discussions on information exchange with the EU in respect of NI to ensure the FSA has sufficient access to data for non-routine risk analysis issues affecting NI.
- Review the first 12 months of operation to identify any process improvements and inform planning on capacity and capability needed to meet the risk assessment function.

6. Conclusion

6.1 To prepare the FSA for EU Exit, we have taken significant steps to strengthen our risk assessment system. In addition to significantly building our capacity, both internally and within our expert Scientific Advisory Committees, we have built new capabilities (especially the new Risk Analysis Process), new enabling functions (e.g. IT systems) and made structural changes to the way we work (e.g. the separation of FSA science and policy functions). As a result, we were prepared for our minimum viable model as the UK ended the transition period.

6.2 However, challenges remain. In particular the volume of work being received in the area of regulated products in 2021 has exceeded earlier estimates. Having predicted an increase in 2020, we have been able to react and make further investments in our capacity. We will continue to monitor and evaluate the demand for risk assessment, and based on evidence, consider any further changes that might be required in the future.

6.3 The Board is asked to:

- Review the delivery of the risk assessment function within the FSA, made in the six months after the end of EU transition period.
- Consider the future steps proposed for the ongoing development of risk assessment in 2021 and beyond.