

STRATEGIC RISK MANAGEMENT

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1. Issue

- 1.1. The Board is asked to comment on the FSA's current approach to strategic risk management, our latest strategic assessment of potential concerns in the food system and in particular whether there are opportunities and the appetite for the FSA to more effectively manage the inherent food system risks.

2. Executive Summary

- 2.1. This is the third annual Strategic Risk paper to the Board. It sets out the FSA's approach to managing risk in the food system, as well setting out a summary of the outcomes of the Board's annual risk workshop, for formal approval by the Board.
- 2.2. All organisations should employ a range of approaches and actions for identifying and managing risk in relation to their strategic objectives and operational activities. The FSA is unusual in that its entire purpose is rooted in the management of risks in the food system: the department was formed in the aftermath of, and as a direct response to the incidence of BSE. It exists to tackle public health risks, as well as protecting consumers' wider interests in relation to food. That means that risk considerations are always front of mind, across the whole department. This paper reflects the FSA's strategic, corporate and management approaches to risk, including identifying which responsibilities lie at Board, ARAC or executive level, which were discussed in detail by the Board last year.

Risk in the food system

- 2.3. The food system is complicated, ever changing, and rich in potential risk. The FSA anticipates, identifies, assesses, prioritises and develops mitigations for risks in this food system, where those risks can impact public health in England, Wales and Northern Ireland. The FSA recognises that it can't directly manage all the risks in the food system and provides leadership in the system ensuring a comprehensive view of the risk landscape. It recognises the different actors in the system have responsibility for addressing certain risks. In particular, it is a Food Business Operator's duty to ensure that the food they provide is safe; Local Authorities (LAs) act as competent authorities in their own right to deliver local level controls; and consumers are encouraged to follow good hygiene practices in the home. In order to ensure that the controls in the food system are achieving the necessary outcome that food is safe the FSA monitors the levels of human cases of foodborne disease and

uses social science and surveillance to gain assurance these remain within acceptable levels.

COVID-19

- 2.4. When the FSA was presented by the unprecedented events of 2020 in relation to COVID-19, we reprioritised our work to provide an effective response - “FSA’s objectives throughout have been to ensure food safety, preserving the high level of consumer protection in the UK whilst supporting industry in maintaining the nation’s food supply”. In November the FSA instigated its incident management protocols on ‘winter planning’ which ensured readiness for the combined impact of the second wave of COVID-19 and the UK’s exit from the EU. Incident management protocols remained in place until February 2021 to ensure we were ready to meet the emerging risks with the necessary mitigating actions.
- 2.5. Despite these events, we have ensured our critical ‘business as usual’ work as a food regulator has properly managed these risks to properly protect consumers. During the COVID-19 pandemic FSA officials, like those in many organisations, quickly adapted their approach in order to maintain our reputation and relationships through both formal and informal virtual engagement.

The global food risk landscape

- 2.6. The FSA also recognises that the food system is global, and that it will play a different role now the UK is outside the EU. This presents opportunities for the FSA to influence directly how global food standards are set and for the UK to be an active member of Codex, the body which develops harmonised definitions and requirements for foods, in turn facilitating international trade. Also refer to Board Paper [EU and International Strategy Update](#).
- 2.7. We have streamlined how we monitor international developments, providing early intelligence and analysis on issues which could have an impact on food safety risks for consumers. This ensures that we can be proactive rather than reactive on the international stage. As outlined in the update to the [Board in November 2020](#) the FSA has established a flexible, responsive data-enabled Strategic Surveillance service to harness the power of data science to identify emerging risks before they become risks to public health, using a variety of data sources. In addition, as outlined in the September 2020 Annual Incidents Board paper the FSA is working closely with International Food Safety Authorities Network (INFOSAN) and their international membership and have developed a multi-country dedicated working group. This group brings together the INFOSAN members most frequently involved and engaged during international food safety incidents, with an overall aim to set and encourage development and sharing of best practice across the whole network to identify emerging risks. We have consolidated existing relationships and built our capability and resilience to collaborate and influence internationally. As Chair of the Codex electronic working group on the revision of the General Principles of Food

Hygiene and its Hazard Analysis and Critical Control Point (HACCP) Annex, we led on the development of revised text which has now been formally adopted by the Codex Alimentarius Commission. This key text lays the foundation for food hygiene, managing risk and facilitating consumers' access to safe food across the globe.

- 2.8. The FSA is leading work on precautionary allergen labelling as part of the International Social Science Liaison Group alongside Australia, New Zealand, the US, Canada, and the European Food Safety Authority. This innovative work will be the first-time social science evidence has fed into Codex Committee on Food Labelling.
- 2.9. From 1 January 2021, the UK will be undertaking food and feed responsibilities that were previously undertaken within various EU bodies. With responsibility for food and feed devolved across the four UK nations, the FSA is taking a consistent approach to the development of three common frameworks; Food and Feed Safety and Hygiene; Food Compositional Standards and Labelling; and Nutrition Claims, Composition and Nutrition Labelling. Also refer to Board paper [EU transition programme update](#)

FSA responsibilities and risk

- 2.10. The FSA has various levels of responsibility in its role to manage the risks in the food system. At the strategic level, the FSA acts as the Central Competent Authority (CCA) having ultimate oversight for the overall risk management and safety of the food system in England, Wales and Northern Ireland. We manage the risk of political divergence across the three nations through the UK frameworks. We consider the potential risks in the system, assessing and prioritising mitigating actions in terms of their potential impact on public health and consumer interests. In the recent '[Annual Surveillance Report](#)' the FSA set out how the FSA gathers information on risks from a wide variety of sources which allow it to best protect consumers now and in the future. Surveillance is a broad set of activities which includes horizon scanning, strategic surveillance, sampling, analytics, and social science. It also includes intelligence gathered from the FSA's Imports and LA Support teams all giving the FSA a deeper insight into the risks in the food system. The [National Food Crime Unit Annual Update outlines the risks of food crime, and the NFCU strategic threat assessment](#) aimed to broaden the dialogue around food crime, enhance visibility of the threat and, through this awareness, further mitigate associated risks and harms, with the support of our partners.
- 2.11. The FSA's sampling regime is a key aspect of our surveillance strategy and how we manage risk. We have completed phase one of the strategy developing our understanding of the current system and governance. Phase two will implement a new sampling framework, building on the resources and intelligence gathered within phase one. The approach ensures that food and feed sampling undertaken by the

FSA is informed by intelligence and integrates with the wider strategic surveillance and official sampling systems.

- 2.12. We have improved our capability to detect risk in imported food and feed which has allowed us to better target sampling activities, including the sampling programme undertaken in support of COVID-19.
- 2.13. The Risk Assessment team identify concerns such as microbiological risk, then use data to segment food businesses to support the Achieving Business Compliance (ABC) and Operational Transformation programmes (OTP) better target these risks.
- 2.14. We have focussed on the strategic priorities, e.g. provision of a capability to help mitigate the risks associated with leaving the EU and future changes in trade patterns, helping ABC and OPT better understand the businesses they regulate.
- 2.15. The FSA recognises the key role LAs play in the managing risk in the food system, as Competent Authorities in their own right. The FSA monitors the performance of the LAs, to set clear standards for the interventions needed including the levels and timeliness of inspection and enforcement activity. As well as performance management, the FSA as CCA gains assurance over LAs through its audit activity. These FSA's audits are prioritised using intelligence from FSA Policy teams and consider potential public health, financial and political impact. As outlined in the [LA delivery and performance update in December 2020](#) FSA guidance and advice to LAs changed during the course of COVID-19 to enable LA resources to be targeted at businesses posing the greatest risk to public health. The FSA has also temporarily paused its LA audit activity to allow the LA resources still working on food safety to be focused on high risk interventions.
- 2.16. Through the ABC Programme, we will focus more on outcomes, and work with businesses to draw assurance from their methods to reduce risk, rather than assuming assurance can only be provided by onsite inspection at establishment level. We will aim to target the scarce LA resources where we believe a premises-based inspection is the most effective way to mitigate risk, or where intelligence gathered requires a reactive LA response. We will explore how best to reduce interventions in low risk establishments so resource can be better targeted at those presenting the greatest risk and are non-compliant.
- 2.17. The focus of OTP is to modernise the areas of Official Controls delivered directly by the FSA Operations team acting as a Competent Authority, covering meat, dairy and wine inspection. Whilst the current model continues to ensure the required food hygiene and animal welfare controls are comprehensively delivered, there are some aspects that could be improved - being more risk based in our approach, improving value for money and assurance by aligning ourselves with the latest technological advances.

- 2.18. The OTP principles have been developed to help deliver transformational change whilst keeping consumer trust and safety at the heart of everything we do. Full transformational change is dependent on new legislation, and will therefore take time, nevertheless, this is our opportunity to shape meat regulation for the next generation of consumers.
- 2.19. The FSA's work on food hypersensitivity is a strategic priority for the FSA, driven by our ambition to reduce the risk in the food system for food hypersensitive consumers. In 2019 the FSA Board committed to making food hypersensitivity one of FSA's top priorities leading to the establishment of the Food Hypersensitivity Programme (FHS) to deliver this ambition. The FHS vision is; We want the UK to be the best place in the world to be a food hypersensitive consumer. We want to improve the quality of life for people living with food hypersensitivity and support them to make safe, informed food choices to effectively manage risk. We have progressed key areas of work including: developing a food allergy safety scheme to help consumers to make safe, informed choices when dining out; continued support to businesses and LAs in preparation for the Prepacked for Direct Sale labelling legislation that comes into effect in October 2021; an update of the online food allergy and intolerance e-training; the development of the Food Allergic Reaction Reporting Mechanism; and gaining input from food industry stakeholders of the causes and impacts of the increased usage of Precautionary Allergen Labelling. All these workstreams are designed to reduce risk for food hypersensitive consumers, as outlined in the last [Food Hypersensitivity programme update](#).

Corporate and delivery risk

- 2.20. The FSA Board has recognised that the rate of change in the food system is increasing. This alongside the fact the FSA's core purpose never changes means the FSA has moved to a three-year cycle for its strategy, from the five-year cycle it has previously worked to. It will also continue to prioritise its resources annually through its business planning and budgeting process to respond to emerging risks, as it has done for the 2021–2022 planning period.
- 2.21. The FSA Board agreed in January 2020, as outlined in ['FSA Strategic Objectives'](#) paper, that the vision remained: Food is safe; Food is what it says it is; Consumers can make informed choices about what to eat; and Consumers have access to an affordable diet, now and in the future. Our priority activity for 2021/22 remains: Response to COVID-19; Any residual EU transition work; and our three major programmes of work:
- Achieving Business Compliance Programme.
 - Food Hypersensitivity Programme.
 - Operations Transformation Programme (OTP).

2.22. In addition to identifying the strategic priorities for the FSA, the Board considers and monitors corporate risk (including impact on reputation, which in itself effects consumer confidence). In January, the Board held its annual risk workshop, to review and update as necessary the corporate risk register and our risk appetite. This is summarised at **Annex A**.

2.23. Adding to the Board's strategic and corporate risk roles, the Board's Business Committee has a key role in overseeing operational risk management, and the Audit and Risk Assurance Committee provides oversight of the effective application of appropriate controls and processes. The Chief Executive and Executive Directors hold responsibility for risk at the operational and delivery level.

Annex A
Corporate Risk Register

1. Failure to deliver Food we can trust

- 1.1. Risk is the core business of the FSA, and we were created off the back of a public health risk and amid concerns about food poisoning, intensive farming methods and Bovine Spongiform Encephalopathy (BSE).
- 1.2. The FSA's strategy and strategic plan articulate our purpose and mission and explain how that relates to the changing environment in which we operate. *Food is safe and what it says it is, and we have access to an affordable healthy diet, and can make informed choices about what we eat, now and in the future.* In addition, the FSA has a vision to be an '*excellent, modern, accountable regulator*'.
- 1.3. Throughout the COVID-19 pandemic our immediate objective has been to ensure food safety and support industry in maintaining the food supply chain. Supported through continued collaboration with Defra, a range of stakeholders and industry bodies. We have sought to ensure an effective yet flexible response whilst supporting our own key workers, putting their safety and wellbeing first throughout the outbreak, with food safety at the fore front at all times. The FSA has also drawn on the extensive expertise and support of our scientific advisory committees to determine that the risk of transmission of COVID-19 through consumption or handling of food, or handling of packaging, is very low.
- 1.4. Keeping people safe and reducing or eliminating food risk is a fundamental purpose of the FSA. Doing this relies on the FSA understanding the complex food landscape and the risks that may arise, having the scientific capability to make professional and timely risk assessments and the policy capability to provide appropriate risk management advice.
- 1.5. These capabilities and processes are captured in our 'risk analysis process', an end-to-end process by which a risk is identified through surveillance, assessed and mitigated (managed and communicated). Leaving the EU means that the FSA is now responsible for many of the combined risk analysis functions previously carried out by European Food Safety Authority and the European Commission. To ensure that the high standard of food safety and consumer protection is maintained our risk analysis process has undergone a complete review as part of our EU Exit preparations. We have conducted internal testing of the risk analysis process and the process responded well with no significant issues identified and as we start to use our new process it will be reviewed to ensure regulatory effectiveness.
- 1.6. Surveillance in general across the FSA remains critical to our role and therefore we have established a flexible, responsive data-enabled Strategic Surveillance service to harness the power of data science to identify emerging risks before they become risks to public health, using a variety of data sources.

2. Failure to maintain our Reputation / Credibility

- 2.1. Failing to influence and engage effectively with a wide range of stakeholders would risk our pledge to put consumers first in everything we do. Trust and confidence (of consumers, media, government, industry, partners) are central to us achieving our outcomes for consumers. One of the foundations of trust in the FSA is our use of evidence, openly published and well communicated.
- 2.2. Now we have left the EU we need to establish ourselves going forward to build credibility in our role to protect UK consumer interests and how our messages come across. Despite exiting, EU initiatives continue to have critical importance to UK consumer interests and there are challenges to sustaining the FSA's historically influential position. The FSA also has a new role to play in trade negotiations, both in discussions across Whitehall and in wider international forums. With the FSA Board setting out a clear approach to future trade negotiations and agreeing a clear set of principles to guide FSA officials.
- 2.3. There is a risk of detrimental impact on the FSA's reputation from potential pressure from other government departments making or changing policies, which could inadvertently have a detrimental impact on consumer safety or consumers' wider interest in relation to food. It is vital that we are able to influence Government effectively, in Westminster, Wales and Northern Ireland and in the EU, and beyond (e.g. in Codex).
- 2.4. With food hypersensitivity being identified as a significant food-related health issue in the UK, the FSA has set a long-term ambition that the UK should be the best place in the world to be a food hypersensitive consumer. Achieving this ambition has its own risks and will require a sustained and coordinated strategic approach over a long period of time. The FSA is recognised as a leader in the field and this brings an opportunity for us to use our capacity and experience to work in partnership with stakeholders inside and outside of government to achieve, what is hoped to be, a greater economic and financial impact than for all foodborne diseases. Also refer to the [Food Hypersensitivity programme update](#).

3. Failure of our Compliance / Legal / Regulation responsibilities

- 3.1. We face risks that arise because of external factors, such as changes in the global food system as they affect our jurisdiction. The challenge is to remain alive to this changing environment, which includes: the development of new technologies, an increasingly globalised food system, political uncertainty, and devolved Government's aspirations, and diminishing resources.
- 3.2. There continues to be growing challenges around safety, authenticity, as well as affordability, security and sustainability, especially operating outside of the EU. At the end of the transition period significant changes to the imports and exports of food and

feed came into effect. Many of these changes fall within Defra's remit, who lead on this area, whilst the FSA remain the competent authority for safety of these products.

- 3.3. To facilitate a smooth transition to the UK's new 'Import of products, animals, food and feed system' (IPAFFS), a phased approach is being taken for imports from the EU. Although the development of this system is being undertaken and led by Defra, the FSA has played a key role in ensuring that imported food and feed is safe. We have worked closely with Defra colleagues to develop IPAFFS and make available imminently. In preparing and contributing for business readiness the Imports Exports Team has contributed to central-government led activities through the Cabinet Office Border Protocols and Delivery Group. Also refer to the [EU Transition programme update](#)

4. Failure of our Operational / Policy Delivery

- 4.1. The strategic risk the FSA faces is our reliance on others to deliver many of our regulatory functions and need to closely work together to make sure we do not compromise current levels of service/consumer protection as new approaches are developed. Also, to protect UK consumers it is important to have effective mechanisms for collaboration both within the FSA and between the FSA and Food Standards Scotland and other government departments to deliver policies across the four countries taking into account potential different requirements or expectations across the 3 countries the FSA operates in. LAs have faced increased pressures during the pandemic, which has impacted resources and has highlighted challenges faced in meeting the FSA's expectations for delivery of food controls.
- 4.2. To maintain our operational delivery and consumer protection we implemented a risk based approach to audits of meat Food Business Operators and took actions to support the continued availability of Official Veterinarians and Meat Hygiene Inspectors to deliver Official Controls at meat plants through both FSA and it's delivery partner.
- 4.3. To ensure that there is minimal disruption to the food supply chain, we have introduced non-critical easements and flexibilities to support local and port health authorities by, for example, deferring some planned food hygiene, food standards and feed inspections. The guidance and advice we have given LAs is enabling them to be more responsive to changing risks across the business landscape and within individual businesses rather than prioritising planned interventions of businesses in the lower risk categories.
- 4.4. In the light of potential increased risk of food crime and adulteration, with fewer LA controls, the FSA increased its sampling of foodstuffs in July and August, on a regional basis. To date no serious non compliances have been found.
- 4.5. The FSA's National Food Crime Unit has been focussing on potential criminal activities arising from the COVID-19 pandemic. They are targeting for example, the illegal

substitution of ingredients for financial gain, the sale of unsafe or deceptive food supplements and the theft of animals for illegal slaughter.

5. Failure to secure and manage Resources and deliver Value for Money

- 5.1. Given the constraints on resource that faces all parts of government, and the importance of us maximising the benefits to consumers that we cause to be delivered and minimising the costs, we also place an even greater emphasis on the efficiency and effectiveness of our own work – including the policy processes that underpin our role as a Government department, our operational delivery activities, and the corporate resources that enable and support our work. Understanding how we are performing ensures that we are able to continuously improve the value for money of what we do.
- 5.2. In addition, the FSA has already identified the continuing resource pressure and challenges faced during the pandemic in LAs, who take front line responsibility for delivering inspections and enforcement of food and feed hygiene and standards. In addition to the modernisation work which seeks to find more effective and efficient ways to achieve public health objectives, including using data and technology to identify and focus on risk at the local level, the FSA is working towards more up to date methods of tracking LA resources and performance. The pandemic and our adjusted expectations of LAs since March have completely changed the delivery landscape of tracking the performance of LAs.
- 5.3. The need to reform the food hygiene delivery model, including the risk assessment scheme in the Food Law Code of Practice that drives planned intervention programmes, has now become urgent. Through the ABC Programme, we aspire to focus more on outcomes, and work with businesses to draw assurance from their methods to reduce risk, rather than assuming that in all cases assurance can only be provided by onsite inspection at establishment level.
- 5.4. This aligns with the National Audit Office 2019 report on the [Ensuring food safety and standards](#), where they highlight recommendations for the FSA as we take forward our plans to design a more flexible and risk-based regulatory system, acknowledging there are areas where we will need to work with ministerial departments to reach a government-wide view of how the regulatory system needs to respond to future challenges and risks.
- 5.5. As our approach becomes one which is about delivering impact from our expertise and influencing others, we become more and more dependent on the quality, skills, motivation and alignment of our people. We will continue to create an environment in which our people are highly capable, effectively supported, and consistently choose to make outstanding contributions to protecting, informing and empowering consumers.