Risk analysis: assurance

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Summary

1. The Board is asked to:
   - **discuss and agree** proposals for assurance of the risk analysis process;
   - as part of this, **discuss and agree** proposals for an FSA approach to the evidencing and consideration of an appropriately broad set of impacts in risk management;
   - specifically, **confirm** that the Board believes that its decisions on the risk analysis process, the assurance of this process, and the identification of the broad set of impacts to be evidenced and considered in risk management, together provide a robust basis for fulfilling the FSA's statutory duties to protect public health, whilst consistently taking appropriate account of broader consumer interests, risks, costs and benefits.

Introduction

2. 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.

3. 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 (see Annex B for risk analysis process map).

4. The Board asked the Executive to prepare a paper for discussion at its March 2019 meeting that reflected the approaches agreed in its previous discussions and proposed specific elements of assurance of the risk analysis process. This paper maps proposed assurance mechanisms that will apply through the stages of the risk analysis process and, as part of this, establishes an FSA approach to the evidencing and consideration of an appropriately broad set of impacts in risk management.

Strategic aims

5. Delivering an effective approach to risk analysis underpins the FSA's vision of being recognised as an excellent, accountable, modern regulator. We need to

have mechanisms that assure the outputs from risk analysis and establish an appropriate level of confidence that they deliver public health protection and take fully into account consumers' other interests in relation to food.

6. It follows that an important part of assurance in risk analysis is having confidence that we are consistently considering an appropriately broad set of impacts when framing risk management advice, and importantly that the identification and assessment of these impacts are supported by evidence.

7. This will allow FSA to demonstrably fulfil its statutory duty that "the Agency, in considering whether or not to exercise any power, or the manner in which to exercise any power, shall take into account (among other things) (a) the nature and magnitude of any risks to public health, or other risks, which are relevant to the decision (including any uncertainty as to the adequacy or reliability of the available information); (b) the likely costs and benefits of the exercise or non-exercise of the power or its exercise in any manner which the Agency is considering"[1] and demonstrate our statutory function of protecting consumers' other interests in relation to food.

8. The risk analysis process should have the capacity to provide for a 4-country model and deliver evidence-based food and feed safety risk management recommendations for the UK and individual countries where necessary 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 Food Standards Scotland (FSS).

Risk analysis: assurance roles

Delivering assurance on both routine and substantive issues

9. The Board agreed, in its September 2018 discussion of governance, that technical risk management advice on routine issues should be provided by the Executive to decision-makers. The elaboration of an appropriately broad set of impacts to be used when framing that risk management advice, and the opportunity for the Board to review this advice on a quarterly basis, would provide assurance in relation to technical risk management advice.

10. On more substantial and contentious risk management issues the Board agreed that it would provide risk management advice to decision-makers. We are proposing that the Board engages with these issues at an early stage, which will allow it to derive assurance directly that an appropriately broad set of impacts is being used when framing that risk management advice. This is an important step in the Board actively identifying the potential range of consumer interests and the public health aspects of the matter under consideration, including where further

[1] Section 23(2), Food Standards Act 1999.

evidence or science may be required. As a minimum, and by default in the course of open Board business[2]:

- the Board will be alerted to a substantial and contentious issue and would have an initial scoping discussion, without any decisions being made, at an early stage in the risk management process (step 8); and
- the Board would hold a substantive discussion to agree its risk management advice to decision-makers.

11. The Board may decide to engage in any risk management issue at other stages where this is justified by the nature of the risk or the complexity of its management. The timings of Board discussions on any risk management issue would be set in accordance with the Board meeting calendar, with the potential to convene extraordinary meetings of the Board at the discretion of the Chair, as provided for in the Board's Standing Orders.

Role of the Audit and Risk Assurance Committee in providing assurance on the risk analysis process

12. The Audit and Risk Assurance Committee (ARAC) provides scrutiny of the assurance, compliance and accountability systems and processes that the FSA uses to identify, manage and mitigate risk. ARAC's role in this regard is in providing assurance to the Board that the FSA is consistent in the application of risk analysis principles and in our consideration of an appropriately broad set of impacts when framing risk management advice. ARAC will not review individual risk management decisions.

Role of the FSA Chief Scientific Adviser and Scientific Advisory Committees in providing assurance on the risk analysis process

13. The September 2018 Board paper on risk analysis outlined the role of the Chief Scientific Adviser (CSA) in providing assurance to the Board on the completeness of the risk assessment and other evidence provided to risk managers, and that this evidence is used appropriately in the development of risk management recommendations. This assurance will be based on a level of oversight that is appropriate to the nature and complexity of the risk assessment and other evidence in each case. We are developing a system which allows the CSA to i) be assured that appropriate assurance processes have been followed, and ii) identify those issues that will require more direct personal input from the CSA in providing that assurance. This role was elucidated further through discussions at the December 2018 Board meeting.

[2] There could be a small number of circumstances in which this discussion would not be in the open - these are set out in the FSA Code of Practice on Openness.

14. The Chief Scientific Adviser will fulfil his assurance role through:
    - assurance of the completeness of problem formulation statements (step 3)
    - the oversight of quality assurance of the assessment of available evidence included in packages provided to risk managers, working with Scientific Advisory Committees and others (step 6)
    - assurance on the use and weighting of evidence in the development of risk management recommendations, including by the Advisory Forum on Food and Feed to which the CSA will have full access (steps 8-11)
    - assurance on the way uncertainties and their impacts have been identified, communicated and considered.

Risk analysis: ensuring we consider an appropriately broad set of impacts

Health-based risk assessments

15. Risk assessment is a scientifically based process which assesses the microbiological, toxicological, radiological and/or allergen risk associated with food or feed. The approach taken at the FSA is that recommended by Codex and consists of the following steps: i) Hazard identification; ii) Hazard characterisation; iii) Exposure assessment; and iv) Risk characterisation.

16. The FSA and its Scientific Advisory Committees have the capacity and capability to undertake risk assessments related to chemical, microbiological, radiological, allergenic and physical hazards in food and their impacts on human health. So that risk management is able to consider all relevant impacts, some types of risk assessment may from time to time need to be taken into account in the evidence base for which other government departments will either provide the lead or a contribution (e.g. in relation to risks to animal health) (See Annex A for further details).

Evidence relating to other impacts

17. Risk management decisions need to take into account an appropriately broad range of possible impacts in addition to the human health risk assessment. This is standard practice in risk management. We propose that, in order to deliver an appropriate level of rigour in our risk analysis processes, the other possible impacts informing our risk management advice should in each case be supported by evidence so that it is clear what factors risk managers have taken into account in arriving at any decision and how these have been weighed.

18. The factors which will come into play will differ on a case by case basis, taking into account the specific situation and local circumstances e.g. in considering the UK as a whole and/or issues related to individual countries. There are likely to be a consistent core of factors we would need to evidence and weigh in any risk

management considerations. There may also be more specific factors that may be relevant to some issues but not others. We anticipate that some of these will relate directly to consumers' other interests in relation to food, and some will relate to the broader range of costs, risks and benefits that we are bound by statute to consider.

19. It is not our intention to draw up an authoritative list of those other factors and possible impacts. This paper builds on the non-exhaustive list of factors set out in the December 2018 Board paper, which we will continue to develop over time. We have focussed on identifying core factors and establishing approaches that allow flexibility for us to identify, evidence and consider other issue-specific relevant factors.

20. The following factors have been identified as common ones we might consider (see Annex A for further details):
    - public health, safety and wellbeing;
    - wider consumer interests;
    - consumer habits, perceptions, acceptability and preferences;
    - economic impact;
    - technical/feasibility considerations.

21. These may not be applicable in all cases e.g. for regulated products the additional evidence requirements are included in the legislation so it is unnecessary to consider all those listed.

22. As well as the core factors above, we have also identified other factors that may require consideration including, the coverage and effectiveness of any non-legislative benchmarks in delivering substantially the same objective as government intervention; political change in trading partners; social economic factors; animal welfare; impact on trade; environmental impact. These factors will vary according to the issue under consideration.

23. We will evidence all factors and impacts used in the risk analysis process. However, they will reasonably have different weights and impact on the final risk management outcome and the FSA should retain sufficient flexibility to make the decisions that are most appropriate in any given circumstance. As noted earlier, the CSA will have a role in ensuring the different pieces of evidence are weighted appropriately during the analysis of risk management options and development of recommendations.

CONCLUSIONS

24. The Board is asked to:
    - **discuss and agree** proposals for assurance of the risk analysis process;
    - as part of this, **discuss and agree** proposals for an FSA approach to the evidencing and consideration of an appropriately broad set of impacts in risk management;

- specifically, **confirm** that the Board believes that its decisions on the risk analysis process, the assurance of this process, and the identification of the broad set of impacts to be evidenced and considered in risk management, together provide a robust basis for fulfilling the FSA's statutory duties to protect public health, whilst consistently taking appropriate account of broader consumer interests, risks, costs and benefits.

Annex A: Evidence to be taken into account in the development of risk management recommendations and advice

Health-based risk assessment

Risk assessment is a scientific process which assesses the risk associated with food or feed in relation to the following types of hazards:

- microbiological hazards
- toxicological hazards
- radiological hazards
- allergens.

Where required, risk assessment will be carried out by FSA in relation to these types of hazards to estimate:

- risk to consumers
- the reduction in human health risk that could be achieved by implementing particular risk management interventions.

In addition, some types of risk assessment may from time to time need to be taken into account in the evidence base for which other government departments will either provide the lead or a contribution, for example:

- worker health and safety
- animal health risk
- wildlife health risk or risks to wider environment
- plant health risk.

Evidence relating to other impacts

Core Factors

Public health, safety and wellbeing

I. nutrition, well-being of future generations[3], quality of life measures and impact on emotional and mental health.

Wider consumer interests

II. ethics, belief systems, labelling, informed choice, equity, impact on specific consumer groups (support for low income families) etc., food availability and food security.

Consumer habits, perceptions, acceptability and preferences

III. risk perceptions and likely consumer behaviours in response to risk (both inertia and over-reaction), emerging trends/current and future consumption habits and cultural/religious requirements and acceptability (of the risks and of the options for their management).

[3] For example, see Future Generations Wales

Economic impact (including the impact of this risk)

IV. the cost and resource of implementing risk management options and consideration of who will bear these costs, impact on domestic production, supply food chain and consumption, and consideration of consumers' willingness to pay for perceived benefits. Impacts of the actual risk could include lost work days.

Technical/feasibility

V. capability and capacity to implement risk management options, ability to enforce/verify controls are being applied, scientific/technological advances.

Issue Specific factors

As well as the core factors above, we have also identified other factors that may require consideration, including:

- the coverage and effectiveness of any non-legislative benchmarks in delivering substantially the same objective as government intervention;
- political change in trading partners;
- social economic factors - behaviours, habits, acceptability and preferences for other actors (industry, enforcement, third sector, etc.), time limits for implementation, different attitudes and risk adverse practices associated with different cultures and labour shortages;
- animal welfare - animal disease (exotic or endemic), animal welfare and efficacy of feed additives;
- impact on trade - the impact on public confidence in UK food, the impact on internal market framework, facilitation of trade and consideration of WTO rules;
- environmental impact - waste, recycling commitments and packaging, crop failures, climate considerations and CO_2 emissions equivalent, release of contaminants into the environment.

These factors will vary according to the issue under consideration.

Annex B Flowchart: FSA Food and Feed Safety Risk Analysis Process

This flowchart is provided separately.