RISK ANALYSIS PROCESS: UPDATE

Report by Rebecca Sudworth

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1. Summary

1.1 The Board is asked to:

a) **Agree** proposals on the approach to:

- Prioritisation and triage of issues in the risk analysis process.
- Publication and consultation on issues in the process.

b) **Note** the progress on:

- Further developing and implementing the risk analysis process.

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 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.

2.4 This paper provides an update on the work we have undertaken to further refine the detailed operational procedures underpinning the process, with further detail for the Board to consider on our proposed approaches to prioritisation and triage of issues in the process, and approach to publication and consultation on issues in the process.

3. Approach to prioritisation and triage

3.1 The FSA's strategic direction is determined by the FSA Board. At an operational level there will be a need to ensure that as issues are fed into the

risk analysis process we allocate our science and policy resource appropriately. **Prioritisation** will indicate the overall sense of the importance of an issue relative to others, identifying what needs to be done more quickly and where resources should best be spent; **triage** will identify non-routine issues that need greater levels of scrutiny and assurance and consideration by the relevant officials and the FSA Board as appropriate. The regular Chair/CEO bilaterals will, as in other areas, ensure that this also takes into account the general position of the Board and identifies areas where further board engagement is required.

3.2 A consistent approach for prioritising and triaging issues in the process is required to ensure that:

- the correct priorities are identified from competing issues;
- the process operates efficiently, and resources are effectively deployed;
- issues transit through the process at the appropriate pace;
- the level of assurance is appropriate to the nature and complexity of the issue;
- the system can react quickly to reprioritise resources to higher priority issues where necessary.

3.3 In accordance with the international norms set in Codex, the primary objective of the risk analysis process is to ensure human health protection. The prioritisation and triage approach will reflect that.

3.4 Key elements of the proposed approach:

- Issues will be prioritised based on factors such as public health and consumer protection imperatives, our legal obligations, the potential impact on international trade, the relative ease or difficulty of resolving the issues, the level of political, public and stakeholder interest, and the extent to which the issue is aligned with the FSA's overall strategic approach.
- Issues will separately be triaged as "non-routine" if they meet one or more criteria, such as:
  - High level of political or ministerial interest.
  - High level of stakeholder interest.
  - High level of consumer interest.
  - Potential for undermining existing regulation or guidance rather than supplementing it.
- Resources for higher priority issues will be protected; and resources from lower priority issues will be redeployed as necessary to support higher priorities.
- The approach will support four-country working as far as possible. We are working with Food Standards Scotland to develop an operational approach that will function effectively for the FSA and FSS.
- A quarterly Prioritisation Programme Board will be established to track capacity in the system, take decisions on priorities overall, and provide assurance and challenge. The Board will report regularly to the Executive Management Team and the FSA Board the non-routine and high priority work going through the process.

3.5 In Northern Ireland, EU risk management decisions will apply for food and feed safety and consequently for any food that comes into the rest of the UK from Northern Ireland. How we consider EU risk management proposals within our UK risk analysis is a key consideration as it not only impacts on the FSA's approach (as the central competent authority in Northern Ireland) to engaging with standard setting in the EU but also impacts on our resources. In particular, there is a question on the extent to which EU regulations that will apply only in Northern Ireland under the Protocol go through the same prioritisation process as domestic measures that will apply in GB. As a general guide we propose that:

- for EU regulations assessed as routine at triage, we would manage their implementation in Northern Ireland but not undertake risk analysis additional to the analysis already undertaken by the European Food Safety Authority and Commission.
- EU regulations assessed as non-routine at triage would be prioritised for risk analysis as appropriate to the issue. This would provide evidence to underpin clear messaging on the scientific evidence in response to consumer concerns, for example, or to take action to protect consumer interests within the terms of the Protocol.

4. Publication and Consultation

4.1 The Board has made a commitment to publishing the advice we provide and the analysis and evidence on which that advice is based. Detailed proposals for what this means in practice for the risk analysis process have been further developed. The aim of this is to ensure that the FSA continues to fulfil its longstanding principles of openness and transparency and its commitment to publishing advice in a considered and consistent way. A communication plan proportionate to the issue will be drawn up in all cases, with issues considered non-routine requiring more detailed plans to be developed at an early stage.

4.2 As a minimum, for issues going through the risk analysis process, the following will apply:

- Issues under consideration will be published on an FSA webpage which will perform a similar function to the EFSA Register of Questions.
- Scientific Advisory Committees will continue to operate openly with agendas, papers and minutes routinely published unless there are specific reasons why an issue needs to be considered as reserved business in closed session (for example, where commercially sensitive confidential information needs to be considered).
- Meaningful consultation – i.e. consultation will be carried out before final decisions are taken and allowing appropriate time for response. A key opportunity for formal public consultation on risk management options and draft impact assessment is identified at Step 8 of the risk analysis process in order to inform the development of the risk management options.

- FSA Board discussions are held in open session and papers and minutes are published. On bigger issues the FSA Board is responsible for providing advice to others.
- Publication of our advice, and the analysis and evidence on which that advice is based, before it goes to Ministers, as is consistent with our established ways of working. The usual route for this will be the papers and discussion held in public by the FSA Board.
- For more routine, technical matters the Board has already agreed that it will receive a public quarterly update from the Executive in written form.
- Where legislation is required – consultation on the draft legislation.

5. Progress on implementing the risk analysis process

5.1 In January 2020 the Board received an update on implementation of the risk analysis process. Since then we have been continuing to develop and operationalise the process. More details are provided in Annex 1 and 2, including:

- An updated flowchart graphic (Annex 1).
- In line with the views of the Board in January 2020 and whilst it will remain as a future option, we no longer intend to convene the Advisory Forum for Food and Feed as part of the risk analysis process at this time. Its functions will be delivered effectively through other routes (Annex 1). It has therefore been removed from the flowchart graphic.
- How requirements of the Northern Ireland Protocol will be embedded into the existing process and supporting guidance on the risk analysis process.
- Ongoing stakeholder engagement.
- Testing capacity and resources.

5.2 We continue to work closely with FSS on developing and operationalising the risk analysis system so that it will work on a four country-basis.

6. Next Steps and Plans for Review

6.1 In the coming months our focus will continue to be on embedding the risk analysis process and 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:

Agree proposals set out in the paper on the approach to:

- Prioritisation and triage of issues in the risk analysis process.
- Publication and consultation on issues in the process.

Note the progress on:

- Further development of the operational detail and implementation of the risk analysis process.

ANNEX 1- Updated flowchart graphic

This Annex is provided separately.

ANNEX 2 - Progress on implementing 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 5.1 of this paper:

Advisory Forum on Food and Feed (AFFF):

The AFFF was established as an FSA committee by the Board in December 2018. The Forum was formed in anticipation of the FSA being delegated decision-making powers. The committee would therefore have composed not only FSA and FSS but also observers from other Government Departments (OGD) so they could assure themselves that, before any decision was taken by the FSA, that the FSA had fully considered their views. However, in January 2020 the FSA Board suggested that the Committee did not need to be stood up at present given that it had been confirmed that Health Ministers would be taking risk management decisions, based on FSA and FSS recommendations, after the transition period. Furthermore, the AFFF had been interpreted as a separate executive body that would form its own opinions and make decisions on behalf of the organisation. In fact, it had been intended as a consultative forum and part of the quality assurance system rather than a body forming its own view.

Nevertheless, we agree that the Committee does not need to form any part of the risk analysis process at present. The policy development process is already underpinned by collaborative working across FSA, FSS and other government departments as well as consultation with interested parties. Mechanisms are in place and being built in throughout the process to ensure FSA and FSS have opportunity to discuss risk management proposals (particularly those triaged as “non-routine”) and that other departments can raise relevant wider government initiatives early on in the process, so we can deliver risk management interventions that are effective for the UK as a whole or for individual countries as needed.

Northern Ireland Protocol and the Risk Analysis Process:

Under the Northern Ireland Protocol (NIP), Northern Ireland will have to comply with EU food and feed law, resulting in some different regulatory arrangements applying in NI than in the rest of the UK. In line with the overarching principles for the risk analysis process for a 4-country model, we will 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.

We would manage the implementation of routine EU regulations in Northern Ireland but not undertake risk analysis additional to the assessment already undertaken by the European Food Safety Authority and Commission. For non-routine issues, we will consider undertaking UK risk analysis. This will be prioritised against other

issues in the risk analysis process pipeline; the approach and criteria established for prioritising and triaging issues submitted for UK risk analysis will be followed.

We are ensuring that the risk analysis process, guidance and operational approaches reflect how the process will function for NI. We will also consider any NIP-specific training requirements and additional resources needed for undertaking risk analysis. We will also engage with and inform stakeholders of the proposed approach to risk analysis in NI.

Stakeholder engagement:
A stakeholder engagement plan on risk analysis has been developed to track engagement activity with key stakeholders to ensure that they are aware of and understand the risk analysis process, and the role of the FSA. We are also planning a series of events with domestic and international importers/exporters to explain the impact of the changes to them.

Testing capacity:
The FSA has increased its capacity and capability for assessing risks, providing advice, and managing those risks, so that we are able to deliver our new responsibilities and ensure that public health is protected. A significant amount of successful recruitment has taken place to meet our requirements and Scientific Advisory Committees and administrative support have been strengthened.
While trained staff are in place, capacity is currently being reviewed under different scenarios to identify any further resourcing or capacity needs that need to be addressed in preparation for the end of the Transition Period which will inform a bid in the Spending Review (SR20).