RISK ANALYSIS: PROCESS, GOVERNANCE, COMMUNICATION

Report by Steve Wearne

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SUMMARY

1. The Board is asked to:

- **discuss** the approaches we are taking to evolve risk analysis processes, capacity and capability in preparation for EU Exit; and in particular:
- **agree** that we should continue to align our approaches and processes with international norms;
- **agree** that when advising decision-makers we will observe the relevant principles and provisions in our long-standing Code of Practice on Openness;
- **agree** the proposed future governance and assurance arrangements for risk analysis; and
- **ask** the executive to prepare a paper for discussion at the December Board meeting on the frameworks and principles that should be used at the different stages of risk analysis, informed by the Board's discussion of the current paper.

INTRODUCTION

2. In its discussion of planning and preparation for EU Exit in September 2017, the Board concluded that "it is important that there is a safe and effective unified system which encompasses a robust regulatory regime to maintain consumer confidence, to protect public health and the consequences of that for trade in food… that regime needs to encompass risk assessment and risk management."

3. The paper discussed at September 2017 Board meeting identified the basic elements of an effective regulatory regime, the first four of which are:

- to identify issues that might pose a threat to food safety (risk identification);
- to assess the scale of that threat (risk assessment);
- to inform others about that threat (risk communication); and
- to decide what, if any, action should be taken (risk management).

4. This paper sets out how these elements of an effective regulatory regime are being further developed in preparation for EU Exit.

5. The risk analysis function described in this paper will generate advice to decision-makers for UK Government and for the devolved administrations in Wales and Northern Ireland. As at present, Food Standards Scotland will have access to and will be able to commission risk assessments undertaken in the FSA, which will inform the advice they continue to provide to Scottish Ministers.

STRATEGIC AIMS

6. Having an effective approach to risk analysis underpins our vision of being recognised as an effective, accountable, modern regulator. This paper sets out the developments we are making to risk analysis in the FSA as part of the EU Exit programme.

DISCUSSION

7. Risk analysis is defined by the World Health Organization as a risk-based approach to the identification and management of public health hazards in food.[1] It is a key function of the FSA. It drives and informs interventions in order to reduce the risks to consumers from food and protect consumers' other interests in relation to food.

8. There is a range of long-standing, internationally recognised, normative texts which set out the constituent elements of risk analysis for food safety, the most significant of which are:

   - *Food Safety Risk Analysis: A Guide for National Food Safety Authorities* (Food and Agriculture Organization, FAO Food and Nutrition Paper 87, 2006);

   - *Working Principles for Risk Analysis for Food Safety for Application by Governments* (Codex Alimentarius, CAC/GL 62-2007); and

   - *Principles and Methods for the Risk Assessment of Chemicals in Food* (World Health Organization, Environmental Health Criteria 240, 2009)

9. We will continue to align our approaches and processes with these international norms in order to support both consumer protection and the facilitation of trade. We propose to return to the Board at its December meeting to propose principles which should inform our approaches to risk analysis, drawn from international normative texts and amplified by the FSA Science Council's Working Group on Principles for Establishing and Communicating Risk and Uncertainty, the report

[1] See http://www.who.int/foodsafety/risk-analysis/en/

from which, together with proposals from the executive for an action plan, will also be considered by the Board in December.

10. The outputs of the risk analysis process will, in general, be advice to decision-makers in relation to:

- risk-based standards and controls to ensure that food remains safe in respect of chemical, microbiological, radiological and allergen risks; and
- pre-market approvals and authorisations and post-market reviews of the safety of: food and feed additives; enzymes; flavourings; GM food and feed; and other novel foods.

11. In advising decision-makers we will observe the relevant principles and provisions in our long-standing Code of Practice on Openness[2], and in particular:

- we will publish any advice we provide to others[3], including any substantive advice we give to other Government Departments;
- we will explain the reasons for our decisions and advice to enable stakeholders to see the basis on which decisions have been made and to make an informed judgement about the quality of our processes and decisions; and
- we will provide information on the evidence and analysis[4] on which our decisions were made.

12. Annex 1 sets out a high-level process map for these elements of the effective regulatory regime that we are further developing in preparation for EU Exit.[5] Their delivery raises a number of issues, which are discussed below.

Capacity and capability for risk assessment and risk management

13. The delivery of an effective domestic regulatory regime will require an increase in the volume of risk analysis undertaken by the FSA post-EU Exit and to this end we have received additional funding from HM Treasury.

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[2] See http://webarchive.nationalarchives.gov.uk/20090414091323/http://www.food.gov.uk/aboutus/how_we_work/copopenbranch/

[3] For practical and legal reasons, there will be a small number of well-defined circumstances in which we will not release advice or information and these are set out in the Code of Practice on Openness.
[4] Evidence and analysis include, but are not limited to advice from our expert advisory committees and the results of research and surveys commissioned by us.

[5] This process map and its constituent elements represent the regime that will apply when the UK exits the EU. This does not exclude the possibility that we may further development these processes subsequently in the normal run of business. For example, we are considering the possibility of developing a website or journal where our syntheses of evidence are published, as several other food safety risk assessment bodies do.

14. In terms of our internal capacity and capability, we are in the process of recruiting 36 additional full time equivalent staff to our science and policy teams. We have received over 250 applications to date and the first tranche of new risk analysis staff are likely to join us in October 2018. One of our objectives in this recruitment activity is to bring in relevant skills and expertise that are currently underrepresented internally. We are also developing a programme of training to build and maintain capability.

15. In terms of ensuring that we can continue to access the science we need to support risk assessment, we are reviewing the structure, roles and governance of our Scientific Advisory Committees, sub-groups and other inputs from external expertise and how these work together. The FSA Science Council Working Group on Capability and Assurance has developed recommendations regarding, among other things, how we might ensure we work effectively with sources of external expertise. The report from the Working Group, together with proposals from the executive for an action plan, will be considered by the Board in December.

16. We will also continue our co-operation with international organisations and multilateral groups, and our bilateral relations with other national and supranational risk analysis organisations.

Risk communication

17. The primary goal of risk communication is to ensure the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions. As such, risk communication covers a wide range of activities, including the generation and use of evidence around how to communicate risk, and evaluating the impact of risk communication activity.

18. As now, the selection of risk communication approaches will be informed by, and proportionate to, the best available estimate and characterisation of the risk.

19. Our approaches to risk communication will be informed by the work of the Science Council Working Group on Principles for Establishing and Communicating Risk and Uncertainty, the report of which will be presented to the Board at its December meeting, and the Advisory Council on Social Science's Risk Communication Working Group, which has been established to advise the FSA on the development of a practical framework for risk communication. We envisage that a paper to the Board in December will propose frameworks and principles to be used at the different stages of risk analysis, which will be informed by the Board's discussion of the current paper. This will include in its scope a framework and principles for risk communication.

Regulated products

20. The FSA will have responsibility for the assessment of applications and the supporting dossiers of information on a range of regulated products[6], and for providing advice to decision-makers on approval or authorisation.[7] This work is not subject to our risk identification and prioritisation processes. It is driven by the applications received, the volumes of which are difficult to predict. For some categories of regulated products, overall timescales for the approval process and its constituent parts are set in EU legislation and will be transferred to domestic legislation. Once applications are received, the same processes of problem formulation, risk assessment, risk management, and provision and publication of advice will be followed as for risk-based controls and standards.

21. Regulated products will be subject to post-market review should, for example, new evidence emerge on the toxicity of their constituent chemicals which may necessitate a change to the stipulated conditions of use. Post-market review will follow the processes of risk identification through to provision and publication of advice as set out in Annex 1.

22. We will routinely require external advice in respect of regulated products, for either approval/authorisation or for post-market review. We therefore intend, in the first instance, to maintain our ability to call on the members of the Advisory Committee on Novel Foods and Processes and the Advisory Committee on Animal Feedingstuffs to provide expert advice. In the medium term, we would aim to review the scientific advisory committee structures that support the process of assessment of applications and supporting dossiers of information on regulated products, in the light of our experience in operating these processes. This would also allow us to close off the outstanding recommendation from the March 2016 triennial review of scientific advisory committees[8] relating to these two advisory committees.

Processes and information flows

23. The risk analysis process is a relatively mature and well-understood set of processes. The repatriation of responsibility for food safety risk analysis from EFSA and the European Commission to the UK is likely to lead to increases in the volume of work undertaken and the degree of scrutiny of our domestic processes. We have reviewed current risk analysis processes and identified developments that are needed in advance of EU Exit. We have designed these changes and are on track to deliver them by March 2019. Progress is overseen by the risk analysis project board, which reports to the EU Exit programme board of which the Chair is a member.

[6] Food and feed additives, enzymes, flavourings, GM food and feed and other novel foods
[7] Within a UK framework which will be agreed between the four UK administrations
[8] See http://www.food.gov.uk/sites/default/files/triennial-review-sac.pdf and https://www.food.gov.uk/sites/default/files/media/document/fsa160504%20%281%29.pdf

Organisational design

24. We are currently reviewing our organisational design to better position the FSA for a post-EU Exit world. This work will include the clear functional separation of risk assessment and risk management.

Governance and assurance

25. We need to have: appropriate governance mechanisms that ensure that our risk analysis processes deliver public health protection and take fully into account consumers' wider interests in relation to food; and appropriate assurance mechanisms that assure the outputs from risk analysis, their timeliness and their quality.

26. The table at Annex 2 proposes how the Board might discharge its governance and assurance responsibilities relating to the various stages of risk analysis, noting that additional assurance may be provided by the Chief Scientific Adviser and the Science Council. These are consistent with the proposals in the paper on FSA Governance (FSA 18/09/08) which is on the agenda for this meeting.

LEGAL/RESOURCE/RISK/SUSTAINABILITY IMPLICATIONS

27. Additional funding has been allocated by HM Treasury to the FSA for activity to prepare for EU Exit. This includes funding for additional staff for risk analysis, and for the development of new processes.

DEVOLUTION IMPLICATIONS

Risk assessment

28. The FSA undertakes risk assessment on its own behalf and on behalf of Food Standards Scotland. We envisage this arrangement continuing.

Risk management

29. The FSA advises UK Government and the devolved administrations in Wales and Northern Ireland. Food Standards Scotland advises Ministers in Scotland. There will be mechanisms for discussion and deliberation between food safety officials advising each of the four UK administrations, and an escalation mechanism on the relatively rare occasions where there is the possibility of different risk management approaches being taken in the different nations.

CONCLUSION AND RECOMMENDATIONS

30. The Board is asked to:

- **discuss** the approaches we are taking to evolve risk analysis processes, capacity and capability in preparation for EU Exit; and in particular:

- **agree** that we should continue to align our approaches and processes with international norms;

- **agree** that when advising decision-makers we will observe the relevant principles and provisions in our long-standing Code of Practice on Openness;

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ANNEX 1

HIGH-LEVEL PROCESS MAP FOR RISK ANALYSIS

The following pages set out a high-level process map for the constituent parts of risk analysis in the Food Standards Agency post-EU Exit:

- risk identification;
- risk assessment;
- risk management; and
- risk communication.

ANNEX 2 - GOVERNANCE AND ASSURANCE OF RISK ANALYSIS

<table>
<tr><td></td><td colspan="4">Stage of risk analysis</td></tr>
<tr><td></td><td>Risk identification, prioritisation and assessment</td><td>Risk management</td><td>Risk communication</td><td>Overall risk analysis</td></tr>
<tr><td>The FSA Board will deliver its governance responsibilities through:</td><td>Setting the framework and process for deciding priorities for risk assessment, informed by the relative impact and value of competing priorities</td><td>For routine, technical risk assessment advice to decision-makers: setting the risk appetite; ensuring an appropriate and consistent framework is approved by the Board, applied and regularly reviewed; agreeing the basis on which consumers' wider interests in relation to food are integrated into risk management

For more prominent issues, it will be the Board that provides formal advice to decision-makers on the basis of the risk analysis process described</td><td></td><td></td></tr>
<tr><td rowspan="2">The FSA Board will deliver its assurance responsibilities through:</td><td>The Chief Scientific Adviser, informed by the Science Council as appropriate, providing regular assurance reports on the extent to which our approach follows best practice and is resilient, including the capacity of our internal and external scientific and technical resource</td><td>For routine, technical risk assessment advice to decision-makers: the Board will receive a written summary at each Board meeting of: matters under consideration; advice formally submitted; and decisions made.</td><td rowspan="2">As for the most part risk communication is an operational process, assurance will be provided as part of the overall oversight of communications and of stakeholder management and engagement</td><td rowspan="2">Business Committee tracking implementation of risk management decisions taken by decision-makers

Audit and Risk Advisory Committee, reviewing relevant aspects of a number of risk analysis packages on technical issues, for example whether the comparative interests and needs of populations across all three nations were properly considered</td></tr>
<tr><td colspan="2">Advice from the Chief Scientific Adviser on the quality of communication between the risk assessment and risk management functions, and in particular whether the right questions are being consistently asked, with the right context explained, so that the evidence received is sufficiently comprehensive to address the risk in question</td></tr>
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