

RISK ANALYSIS PROCESS

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SUMMARY

1. The Board is asked to:
 - **discuss** the risk analysis process, presented in the flowchart at Annex A and **agree** the principles that govern each stage of the process;
 - **note** the plans to strengthen capacity and structures of FSA Scientific Advisory Committees for EU Exit at Annex B and **agree** these meet our best estimate on future needs;
 - **agree** proposals for establishing the Advisory Forum on Food and Feed including the Terms of Reference at Annex C;
 - **ask** the Executive to prepare a paper for discussion at the March 2019 Board meeting on assurance of the risk analysis process including the Board's role.

INTRODUCTION

2. The Board discussed papers on Risk Analysis and on Governance at its September 2018 meeting. It considered the approaches we are taking to evolve risk analysis processes, capacity and capability in preparation for EU Exit and agreed:
 - That we should continue to align our approaches and processes with international norms;
 - That when advising decision-makers we will observe the relevant principles and provisions in our long-standing Code of Practice on Openness;
 - The proposed high-level future governance and assurance arrangements for risk analysis.
3. The Board asked the Executive to prepare a paper for discussion at the December 2018 meeting on the process and principles that should be used at the different stages of risk analysis. This paper:
 - Explains the future process of risk analysis, the principles and frameworks that underpin this, and in an accompanying presentation to be given at the meeting, demonstrates how it will work in practice;
 - Sets out the plans to strengthen capacity and structures of FSA Scientific Advisory Committees for EU Exit; and
 - Presents our plans for establishing the Advisory Forum on Food and Feed (AFFF) including proposed Terms of Reference for this Forum.

4. We propose to prepare a more detailed paper for discussion at the March 2019 Board meeting on assurance of the risk analysis process including the Board's role in this.
5. The recommendations from the Science Council Working Groups on risk and uncertainty and on science capability and assurance are presented in other papers for this meeting and, as outlined in those papers, the recommendations are informing our approaches as they develop.

STRATEGIC AIMS

6. Delivering an effective approach to risk analysis underpins the FSA's vision of being recognised as an excellent, accountable, modern regulator. This paper provides an update on the developments we are making to risk analysis process in the FSA as part of our preparedness for EU Exit. The food and feed safety risk analysis process contributes to the FSA objective to ensure that the high standard of food safety and consumer protection we enjoy in the UK is maintained when the UK leaves the EU. These arrangements are required regardless of the outcome of ongoing discussions on the future relationship between the UK and the EU.

RISK ANALYSIS PROCESS, PRINCIPLES AND FRAMEWORKS

7. The FSA is already following globally recognised frameworks for risk analysis (notably the Codex Principles). As the FSA's role changes after EU Exit, we need to draw together an overarching FSA framework to show how we undertake risk analysis. An overview of the proposed FSA risk analysis process is presented at Annex A. This process map and its constituent elements represent the regime that will apply when the UK exits the EU. However, it should be noted that additional or adapted process and structures may be necessary depending on the outcome of future negotiations or common framework arrangements. This paper builds on the diagram in the September paper on risk analysis¹ that illustrated the flows and interrelationships between risk assessment, management and communication.
8. Risk managers will be alerted to the potential need for risk management intervention from a number of sources (Step 1). Following this, preliminary risk management activities will be carried out to determine whether action is needed (Step 2). If this identifies a need for action a risk assessment will be requested, the scope of that risk assessment defined, and any other evidence required to allow a decision to be made agreed (Step 3). The risk assessment and analysis of other evidence is completed, consulting external experts, Chief Scientific Adviser and the Scientific Advisory Committees as necessary (Steps

¹ https://www.food.gov.uk/sites/default/files/media/document/fsa-18-09-09-risk-analysis-process-governance-communication_1.pdf
<https://www.food.gov.uk/sites/default/files/media/document/fsa-18-09-09-board-risk-analysis-sep-18-amended-final.pdf>

4-6). The risk assessment and analysis of evidence is then presented to risk managers (Step 7). Risk managers will use this evidence to develop, analyse and identify risk management recommendations in consultation with other government departments and the Devolved Administrations (Step 8) which will be considered by an FSA advisory committee (Step 9) to develop advice (Step 10), that will be presented to the FSA Board as necessary (Step 11), Ministers and others (Step 12).

Overarching principles

9. The FSA's overarching principles for its risk analysis process are that:
 - The risk analysis process must be open and transparent. When advising decision-makers we will observe the relevant principles and provisions in our long-standing Code of Practice on Openness.² We will therefore publish the advice we provide to others and the analysis and evidence on which that advice was based;³
 - Advice and recommendations presented to Ministers will be risk, science and evidence-based and independent;
 - The risk analysis process should have the capacity to provide for a 4-country model and deliver, where appropriate to do so, unified food and feed safety risk management recommendations for the UK, as part of a UK-wide framework for food and feed safety and hygiene, proposals for which are being discussed and developed.
10. The best practice principles for establishing and communicating risk and uncertainty have already been described in Board paper 18-12-10⁴ and provide the structure for articulating our framework for risk analysis.

Operating procedures

11. Operating procedures for the risk analysis process are being developed and tested by FSA teams (including teams in Wales and Northern Ireland) in collaboration, where appropriate, with interested parties including FSS, DHSC, Defra and DIT and the Devolved Administrations.

² See

http://webarchive.nationalarchives.gov.uk/20090414091323tf/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 <https://www.food.gov.uk/sites/default/files/media/document/fsa-18-12-10-science-council-risk-uncertainty-final.pdf>
<https://www.food.gov.uk/sites/default/files/media/document/fsa-18-12-10-annex-fsa-science-council-wg2-risk-and-uncertainty-final-report.pdf>

12. The procedures will include: appropriate links to existing frameworks/guidance from our Scientific Advisory Committees (e.g. COT and ACMSF) and internationally recognised organisations; appropriate procedures for establishing priorities for risk assessment and risk management intervention; and the types of evidence that will need to be collated and assessed including the other legitimate factors⁵ that will be taken into account. Examples of other factors include animal health and welfare, health and safety, economic impact, environmental impact, trade distortion, impact on consumer choice, socio-economic factors, consumer perceptions, acceptability and preferences, including the wider interests of consumers.

Risk Communication

13. As reflected in the chart at Annex A, risk communication is integrated throughout the risk analysis process.
14. 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, the academic community and other interested parties, and to industry and consumers. It should include the explanation of risk assessment findings and the basis of risk management decisions, as well as use effective communications methods to achieve behavioural outcomes as part of a suite of risk management interventions.
15. Our approaches to risk communication and development of a practical risk communication framework are being informed by the Science Council Working Group's recommendations and principles and the FSA Advisory Committee on Social Science (ACSS) Risk Communication Working Group. This will include advice on developing and embedding operational procedures and learning from others who have operationalised such frameworks.
16. The ACSS Working Group recently discussed and provided a commentary on the Science Council Principles on Communicating Risk and Uncertainty which is helping the FSA develop its own practical risk communication framework.⁶

Risk Assessment and plans for strengthening our Scientific Advisory Committees capacity and structures.

17. The main elements of the FSA's risk assessment process are outlined in the flowchart at Annex A. Following agreement on the scope of the risk assessment and other evidence required, the process will involve the identification of approaches to gather and analyse evidence, and the production and

⁵ 'Other legitimate factors' is internationally accepted terminology for issues other than human health risk assessment that inform risk management and communication

⁶ The ACSS advice is published at <https://acss.food.gov.uk/>

presentation of risk assessment and other evidence supporting risk management and communication.

18. The FSA has four Scientific Advisory Committees (SACs) which provide independent expert advice on risk assessment. The FSA has developed its plans for strengthening capacity and structures of FSA SACs in preparation for EU Exit. These plans are outlined in more detail at Annex B. EU Exit will bring increases in the volume and range of independent expert advice we need on risk assessment to inform risk management at national level. The FSA will make the greatest possible use of the SACs and their sub-groups to advise on chemical, microbiological and radiological public health risks. We will recruit additional experts to the SACs to boost capacity and fill gaps in the parent SACs, and to populate new joint groups. We propose to review arrangements later in 2019 to identify any further changes needed to amend or formalise arrangements for the longer term.
19. The FSA will also continue to draw on other sources of scientific expertise including external technical expertise, internal expertise, and ad-hoc commissioned evidence generation, analysis and synthesis.

Risk Management and Advisory Forum on Food and Feed

20. The main elements of the FSA's risk management process are outlined in the flowchart at Annex A. The finalised risk assessment and other relevant evidence will be presented to risk managers who will use this to develop and analyse potential risk management interventions. They will identify the preferred option and develop risk management recommendations, which might include risk communication to key groups as part of a suite of interventions which will form the basis of advice to FSA Board, Ministers and others as necessary. The overarching principles that will govern the FSA's risk management approaches are outlined in Board paper 18-12-10.⁷

Advisory Forum on Food and Feed

21. The FSA Board has agreed in principle to establish⁸ an Advisory Forum on Food and Feed (AFFF) to provide, wherever appropriate, a cohesive UK risk management opinion on matters of food and feed, after considering risk management recommendations developed by the FSA and FSS, to assist those two organisations in delivering their core objectives to protect public health and

⁷ <https://www.food.gov.uk/sites/default/files/media/document/fsa-18-12-10-science-council-risk-uncertainty-final.pdf>
<https://www.food.gov.uk/sites/default/files/media/document/fsa-18-12-10-annex-fsa-science-council-wg2-risk-and-uncertainty-final-report.pdf>

⁸ Advisory Forum on Food and Feed is being established using provisions in Section 5(3) and Schedule 2 of the Food Standards Act 1999 which states that, after consulting the appropriate authorities, establish other advisory committees for the purpose of giving advice or information to the Agency about matters connected with its functions.

consumer interests in relation to food and feed safety. We are in discussions with FSS with regard to the AFFF, and it will be for the FSS Board and Scottish Ministers to agree the direction and approach for Scotland.

22. The AFFF will consider all food and feed safety issues⁹ where a risk management recommendation is required from FSA. It will not consider risk management advice provided to support operational management of routine food incidents. It will be established from 1 January 2019, running in pilot to test operational procedures so the Forum is fully functional from the end of March 2019. Proposed Terms of Reference for the Forum are presented at Annex C.

23. The main objectives of the Forum are to:

- Provide a mechanism for the development of unified UK risk management interventions, where appropriate, including those that may be required through any future food and feed safety and hygiene framework for the UK;
- Enhance trust and confidence in the UK's risk analysis processes by introducing greater transparency and extra rigour, once the UK is outside of the EU framework; and
- Ensure all relevant additional considerations are taken into account when forming risk management advice and recommendations. This will build on cross departmental and Devolved Administration engagement in order to ensure that relevant devolution issues and interests of other government departments with responsibilities for food and agriculture, health and trade are considered.

24. It is envisaged that the AFFF will consider risk management recommendations presented by risk managers and the evidence underpinning that recommendation. It will provide a view on whether the evidence supports a single UK risk management approach and/or different options for different countries where appropriate.

25. It is proposed that core membership of the Forum is drawn from officials in FSA (including officials leading for Wales and Northern Ireland) and FSS (subject to this being agreed as an appropriate mechanism for Scotland), with representation included as appropriate to cover all aspects of the risk analysis process. This is considered essential to deliver fully considered and objective risk management advice. Other departments, including DHSC, Defra, DIT and the Devolved

⁹ The AFFF will consider food and feed safety issues only from Day 1. Processes for managing development of FSA advice on other issues that fall within its remit in Wales and NI e.g. nutrition and food labelling will be considered as future operating capability taking into account mechanisms being established by other government departments to deliver repatriated functions.

Administrations should be invited to participate in the Forum given their potential interests in food and feed safety. This participation has been considered against the high-level principles and it is considered that full membership by other departments may introduce a risk to the independence of advice provided by food safety authorities. Participation as observers would protect the independence of the food safety authorities while still allowing departments to assure themselves that the necessary scientific and technical contributions to the risk analysis process gathered by FSA and FSS policy developers during earlier consultations with departments have been taken into consideration in reaching a recommendation.

GOVERNANCE AND ASSURANCE

26. The September Board papers on Governance¹⁰ and on Risk Analysis¹¹ outlined the governance and assurance framework for the FSA and proposed plans for development of appropriate assurance mechanisms that assure the outputs from risk analysis, their timeliness and their quality.
27. Further details on the FSA's plans for governance of science and a proposed framework for science assurance are covered in paper 18-12-09.¹²
28. The Executive proposes to prepare a more detailed paper for discussion at the March 2019 Board meeting on assurance of the risk analysis process and the Board's and Chief Scientific Adviser's role in this.

ENGAGEMENT WITH OTHER GOVERNMENT DEPARTMENTS

29. The FSA has been working closely with FSS, DHSC and Defra to develop its proposals for the risk analysis process. Proposals have also been shared with other departments including DIT, DExEU, Scottish Government, Welsh Government and NI Executive through a development group established to consider the AFFF and its operational procedures

DEVOLVED ISSUES/ UK FRAMEWORK

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

¹⁰ https://www.food.gov.uk/sites/default/files/media/document/fsa-18-09-08-governance-report_0.pdf

¹¹ https://www.food.gov.uk/sites/default/files/media/document/fsa-18-09-09-risk-analysis-process-governance-communication_1.pdf <https://www.food.gov.uk/sites/default/files/media/document/fsa-18-09-09-board-risk-analysis-sep-18-amended-final.pdf>

¹² <https://www.food.gov.uk/sites/default/files/media/document/fsa-18-12-09-sc-wg1-capability-assurance-final.pdf>
<https://www.food.gov.uk/sites/default/files/media/document/fsa-18-12-09-annex-sc-wg1-capability-assurance-final-report.pdf>

31. The FSA advises UK Government and the Devolved Administrations in Wales and Northern Ireland. Food Standards Scotland advises Ministers in Scotland. The proposed AFFF provides a mechanism for discussion and deliberation between food safety officials advising each of the four UK administrations.
32. Under the current devolution settlements, the devolved legislatures and administrations cannot act incompatibly with EU law. This has the effect, in policy areas where there is harmonised EU law (such as food and feed safety), of creating common UK-wide approaches - or 'frameworks' - even where these policy areas otherwise fall within devolved competence. In some policy areas, common frameworks will continue to be required after we leave the EU. Collaborative work is underway with colleagues from both UK Government and the Devolved Administrations to develop proposals for a framework for food and feed safety and good progress is being made. The principles agreed by the Joint Ministerial Committee (EU Negotiations) in October 2017 guide this work.
33. The risk analysis process and new structures being implemented to support risk analysis are being developed without prejudice to any future framework for food and feed safety. However, subject to agreement, the risk analysis process would provide a mechanism to deliver elements of the food and feed safety framework.

CONCLUSIONS

34. The Board is asked to:
 - **discuss** the risk analysis process, presented in the flowchart at Annex A and **agree** the principles that govern each stage of the process;
 - **note** the plans to strengthen capacity and structures of FSA Scientific Advisory Committees for EU Exit at Annex B and **agree** these meet our best estimate on future needs;
 - **agree** proposals for establishing the Advisory Forum on Food and Feed including the Terms of Reference at Annex C;
 - **ask** the Executive to prepare a paper for discussion at the March 2019 Board meeting on assurance of the risk analysis process including the Board's role.

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

This flowchart is provided separately.

Annex B: Plans to strengthen capacity and structures of FSA SACs for EU Exit

What we have now

1. The FSA has four Scientific Advisory Committees (SACs) which provide independent expert advice on risk assessment^{13, 14}:
 - Advisory Committee on the Microbiological Safety of Food (ACMSF)
 - Committee on Toxicity (COT)
 - Advisory Committee on Novel Foods and Processes (ACNFP)
 - Advisory Committee on Animal Feedingstuffs (ACAF)
2. Their current work focuses mainly on risk assessment to inform risk-based standards and controls. ACAF's work includes other areas including advice more related to risk management. Risk assessment for approval and review of regulated products is undertaken at EU level by EFSA (except for a small number of national assessments in limited areas carried out by ACNFP).

Why do we need to change?

3. EU Exit will bring increases in the volume and range of independent expert advice we need on risk assessment to inform risk management at national level. This presents two challenges:
 - i for **risk-based standards and controls**, we need to boost capacity to deliver more work at national level, including reviews of EU risk assessments from a UK perspective, and to support trade discussions. We also need to ensure the way we use the SACs shows a clear separation of advice on risk assessment from other advice informing risk management, in line with the principles for risk analysis.
 - ii for **regulated products** we will need to build capability for national risk assessments to inform approvals and post-market reviews of the safety of regulated products (currently almost all undertaken by EFSA).

What we are going to do by end March 2019?

4. To meet these demands, we will strengthen the structure and capability of the SACs as follows:
 - Advice on risk assessment, and technical advice directly relevant to risk assessment (such as migration of a chemical into food) will be delivered via the SAC model. Other advice informing risk management (such as whether

¹³ The FSA Science Council and Advisory Committee for Social Science provide advice on strategic science issues and FSA's use of science. These areas are not affected directly by EU Exit and they are not discussed further here.

¹⁴ The FSA also receives advice by SACs for which other Departments lead, including the Committee on Carcinogenicity (COC), Committee on Mutagenicity (COM), Scientific Advisory Committee on Nutrition (SACN) and Advisory Committee on Dangerous Pathogens (ACDP). These arrangements will continue after EU Exit.

- an additive is effective and is needed) will be provided via other routes such as internal expertise or commissioned external advice or research.
- For **risk-based standards and controls**, the existing SACs will continue to provide risk assessment advice (and if relevant risk assessment advice to inform discussions on trade agreements). This will be the main work of COT and ACMSF, with ACNFP and ACAF providing advice as needed.
 - For **regulated products**, three new joint expert groups will be established to take on the bulk of this work:
 - 1. Food contact materials
 - 2. Additives, flavourings, enzymes and other regulated products
 - 3. Animal feed and feed additives
 - The first two will be joint expert groups of COT and ACMSF, and the third will also be joint with ACAF, consistent with the existing remits of those three parent committees. ACNFP will provide advice on approvals of novel foods and GM (food and feed).
5. To help us deliver this work, we will recruit additional experts to the COT, ACMSF and ACNFP to boost capacity and fill gaps in the parent SACs, and to populate the new joint groups. To manage the demand on members' time, experts will take up one of two roles: working mainly in the parent SAC; or working mainly in a joint group, with some attendance at the other configuration in each case.
6. We will change the way we access ACAF's advice so that advice on risk assessment is clearly separate from other advice informing risk management. ACAF as a SAC will focus on risk assessment, mainly by asking certain ACAF members to join the new joint group on feed. We would also seek ACAF's advice on risk assessment for risk-based standards and controls, as needed. Where we want to seek advice from ACAF members on other issues informing risk management (such as industry practice and insight, guidance for industry) we would ask ACAF members provide this through new structures for advice on these issues, as we develop them.

Where we want to end up

7. We propose to review arrangements later in 2019, in light of experience with the demand and the way the arrangements are working, to identify any further changes needed to amend or formalise arrangements for the longer term.
8. As part of this review, we would consider the need for ACAF as a separate, FSA-led SAC. This would close off the outstanding Triennial Review action and would be done in consultation with the Board and with other departments with an interest in ACAF and their Ministers.

Annex C Proposed terms of reference for the Advisory Forum on Food and Feed ¹⁵

PURPOSE

1. The Advisory Forum on Food and Feed (AFFF) is a Food Standards Agency advisory committee established¹⁶ to assist UK food safety authorities (FSA and Food Standards Scotland (FSS)) in delivering its core objectives to protect public health and consumer interests in relation to food, helping ensure that the high standard of food safety and consumer protection we enjoy in the UK is maintained when the UK leaves the EU.

2. The AFFF will seek to provide, wherever appropriate, a cohesive UK risk management opinion on matters of food and feed after considering risk management recommendations developed by the FSA and FSS. This opinion will be taken into account by FSA and FSS risk managers as they formulate advice for Ministers and others.

3. The AFFF will consider food and feed safety and hygiene matters, including those issues considered and decisions previously taken by EU Institutions. It will formalise existing cross UK and government working that has previously underpinned preparation of UK positions for EU negotiations either in EU Council or Standing Committees.

4. The AFFF will achieve this by:

- (i) being open and transparent in how it has reached its risk management recommendations, upholding the public interest in relation to food and protecting public health and consumers' wider interests in food;
- (ii) reviewing risk management proposals in relation to food and feed safety, prepared by FSA or (subject to agreement) FSS in consultation with other interested parties as necessary, including but not exclusively flavourings, food contact materials, food enzymes, animal feed, food and feed additives, contaminants, allergens, novel foods, microbiological and chemical food safety;
- (iii) considering food safety aspects of related issues such as animal health and welfare, environmental and nutrition initiatives;

¹⁵ References here to Food Standards Scotland are dependent on this being agreed by Scotland as an appropriate means to give effect to a future UK-wide framework on food and feed safety.

¹⁶ The AFFF is being established using provisions in Section 5(3) and Schedule 2 of the Food Standards Act 1999 which states that, after consulting the appropriate authorities, establish other advisory committees for the purpose of giving advice or information to the Agency about matters connected with its functions

- (iv) considering risk assessment, scientific evidence, other legitimate factors and how these have affected the selection of risk management options including potential risk communication strategies to reach a view on proportional risk management interventions; and
- (v) providing advice that supports development of risk management recommendations by the FSA or the FSS in Scotland.

SCOPE

5. The AFFF will consider all food and feed safety issues¹⁷ where a risk management recommendation from FSA is required. This will include:

- (i) Risk management responses that flow from new national and international (EFSA, OIE, WHO/FAO) risk assessments; both new and amendments to EU Regulations and international standards;
- (ii) approvals for regulated products e.g. novel foods and food and feed additives;
- (iii) consideration of the food safety aspects of wider initiatives and developments on, for example, animal health and welfare, environmental, food supplements, nutrition and diet.

6. The AFFF will not consider risk management advice provided to support operational management of routine food incidents.

PROPOSED MEMBERSHIP (Subject to agreement)

7. The FSA and FSS will provide appropriate representation, taking into account the needs to represent interests of all 4 countries and expertise required to consider the food and feed safety matters under consideration. Other Government Departments, including the DHSC, Defra, DIT and the Devolved Administrations, will be invited to participate as observers.

<u>Members</u>	<u>Invited participants</u>
FSA Director of Policy (Chair)	Defra
FSA Head of Food Policy	DHSC
FSA Head of Science, Evidence and Research	DIT
FSA Veterinary Director	Northern Ireland Executive
FSA Director Wales nominee	Scottish Government
FSA Director NI nominee	Welsh Government

¹⁷ The AFFF will consider food and feed safety issues only from end of March 2019. Processes for managing development of FSA advice on other issues that fall within its remit in Wales and NI e.g. nutrition and food labelling will be considered as future operating capability taking into account mechanisms being established by other government departments to deliver repatriated functions

FSS nominee(s)	
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