

FSA Science Council Working Group on Risk and Uncertainty (Working Group 2)

Final Report and recommendations from the Working Group to the FSA

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This report was prepared by the Working Group and endorsed by the Science Council at its plenary meeting on 27 June 2018.

Question set by the FSA

At the first meeting¹ of the Food Standards Agency (FSA) Science Council on 16 June 2017 the FSA Chairman Heather Hancock introduced the main issues and challenges on which the FSA would like input from the Science Council over the next two years. A working group of the FSA Science Council was established to answer the following question from the FSA:

What does the Council advise to be best practice in establishing and communicating risk and uncertainty?

The FSA Chairman outlined the rationale for the question as follows. The FSA aims to make sure food is safe and what it says it is². In the future, the FSA needs to have established a strategic framework for making risk assessment and management judgments, and to be better at communicating risk and uncertainty to stakeholders, including the general public. Advice on this will enable the FSA to be more deliberate and clear in building consumer understanding about public health risks from food. It will also help the FSA to deal with the consequences of EU exit.

The Council Chair, Working Group Chair and FSA Chief Scientific Adviser (CSA) developed the Terms of Reference³ for the Working Group. The full terms of reference are on the Science Council website.

Approach taken by the working group

The Council established a Working Group to lead this task and the Working Group addressed the question in a phased approach. The first phase (by December 2017) considered the current FSA (and other relevant) approaches to establishing risk and uncertainty, and produced advice in the form of draft principles for best practice and what the FSA should do

¹ Meeting minutes can be found here: <https://science-council.food.gov.uk/sites/default/files/sciencecouncilminutes16june2017.pdf>

² This includes the risks from food and those arising from animal feed.

³ <https://science-council.food.gov.uk/science-council-subgroups/science-council-working-group-on-risk-and-uncertainty>

where any gaps exist or opportunities to improve arise. The second phase (by June 2018) built on this and considered current and best practice in communicating risk and uncertainty and any opportunities for the FSA to improve. It was useful for phase one to consider the key findings that need to be communicated *about*, to ensure these were covered in the approach to establishing risk and uncertainty.

The Working Group took an iterative approach working with the CSA and FSA officials, including FSA Risk Assessment Unit and Communications, Science and Policy teams. The Working Group consulted the FSA's other Scientific Advisory Committees on the principles (see ANNEX 3 for full list of acknowledgements).

The Working Group met on 4 October 2017 and 5 February 2018. It held interim teleconferences on 14 November 2017 and on 8 May 2018, and it also worked by correspondence. The details of its meetings are on the Science Council website⁴.

Conclusions and recommendations

Conclusions:

The Working Group noted that the FSA is already following globally recognised frameworks (notably the Codex Principles) but agreed there was a need to draw together an overarching FSA framework to show how it does this and demonstrate consistency in approach across different types of risks.

The Working Group concurred with the FSA view that its current system is not broken but that there is:

- an opportunity for continuous improvement and
- a need to ensure that the FSA's approach is clearly set out and formally documented.

Drawing up principles would make it evident that the approach has a sound basis in established good practice and help provide benchmarks against which FSA and others can assess how well it is performing in practice.

The scientific principles for risk assessment/risk analysis should be compatible with/have regard to and support the 5 principles of better regulation:

Proportionality; Accountability; Consistency; Transparency; Targeting. The Working Group would add Agility and Adaptability to these.

⁴ <https://science-council.food.gov.uk/science-council-subgroups/science-council-working-group-on-risk-and-uncertainty>

Recommendations:

The Working Group recommends that the FSA:

1. Adopts and publishes the principles on best practice on establishing risk and uncertainty tailored for the FSA, produced by the FSA with input from the Working Group (ANNEX 1).
2. Develops an overarching, harmonised approach to operationalising these principles in practice for food safety risk analysis, and asks its principal risk assessment Scientific Advisory Committees, COT and ACMSF, and others as appropriate, to work together to advise on this process.
3. Develops an appropriate form of documenting compliance with the overarching approach for establishing risk and certainty to ensure operational transparency, consistency and quality management.
4. Increases the frequency and depth of communication and iteration between risk assessors and risk managers.
5. Keeps under review the principles and the way the principles are implemented to ensure that they reflect changes in:
 - a. the state-of-the-art in approaches to risk analysis, both conceptual and technical;
 - b. the types of risk that need to be considered and the challenges these present such as increasing complexity;
 - c. the wider context in which the risk analysis takes place.
6. Looks beyond the application of the existing tools to the timely adoption of new innovations. Technical capabilities are always evolving and standard approaches may change. FSA needs capacity to monitor and adopt state-of-the-art approaches to risk analysis. This requires attention be given to maintaining a high level of technical competence.
7. Ensure activities relating to risk analysis are fully joined up across the FSA, including its advisory committees, for example by holding an annual workshop.
8. Consider types of risk other than those that directly relate to impacts on health (such as related to food authenticity and fraud) in the wider application of its advice and consider whether the principles for health risks might apply or be adaptable to these other risks.
9. Develops a framework for communicating risk and uncertainty that reflects the principles developed by the Working Group.
10. Understands that the risk analysis process will always be subject to challenge, even if procedures have been followed to the letter and that this should not prevent the FSA from communicating risk; FSA needs capacity to anticipate, prepare for and respond to such challenges.
11. Ensures that its risk communication framework is informed by an understanding of its audiences in terms of how they understand risk, what they want from risk communication, and what works best for risk communication with them. This

includes drawing on the evidence and expert advice on how people, businesses and others understand and accept risk and uncertainty and how this affects their decision-making.

12. Considers extending further its programme for testing approaches to risk communication with consumer focus groups, and with other stakeholder groups and audiences to inform its communication functions at a strategic level.
13. Considers consultation with the public (and/or other target audiences) on planned communications to improve communications and help to reach intended audiences.
14. Draws on other organisations' approaches and tools in considering its approach, and works with others in developing good practice. This should include:
 - i. Considering in detail the 'Defra Science Advisory Council Social Science Expert Group (SSEG) Task Group report: Communicating Risk⁵', in developing a practical risk communication framework for the FSA, including assessing the usefulness of a risk assessment checklist for FSA.
 - ii. Engaging with EFSA on its developing draft 'Guidance on Communication of Uncertainty in Scientific Assessments⁶' including through the public consultation by EFSA.
 - iii. Considering communications tools such as risk profiles.
15. Continues to develop its evidence base on trust so that its communications enhance trust in the FSA.
16. Ensures activities relating to risk communication are fully joined up across the FSA (drawing on relevant recommendations from Working Group 1 on use of science in FSA).
17. Asks the Advisory Committee on Social Science (ACSS) and other SACs to assist the FSA in responding to and implementing the Working Group recommendations.

⁵ <https://www.gov.uk/government/publications/science-advisory-council-communicating-risk-report>

⁶ <https://www.efsa.europa.eu/en/consultations/call/180504>

Annex 1: principles for establishing and communicating risk and uncertainty

Introduction

The principles are intended to be high-level and to capture best practice for the FSA and its Scientific Advisory Committees (SACs). Articulating them helps to demonstrate that the FSA approach follows best practice. The Working Group began with the assumption that the FSA and its SACs already follow globally recognised reference texts such as the Codex Alimentarius Principles for Risk Analysis, and will continue to do so. These (and similar guidance) provide useful general framing for the FSA's approach. The principles developed by the Working Group complement and build on these by highlighting aspects that are particularly important and relevant for the FSA and its work. The Working Group has highlighted specific features of these general approaches in these principles and in its recommendations to FSA for how it should operationalise them. The final principles bring together the conclusions from both phases of the Working Group's work.

The principles below have been co-developed by the FSA and the Working Group. They have been developed with reference to the sources listed and informed by consultation with FSA risk assessors and risk managers and the FSA's SACs.

- Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius⁷
- Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)⁸
- FSA 'Risky Food' Framework (Nov 2016)⁹
- POST Note on Communicating Risk¹⁰
- Defra Science Advisory Council - Social Science Expert Group (SSEG) Task Group Report: Communicating Risk¹¹
- EFSA Guidance on Uncertainty Analysis in Scientific Assessments¹²
- EFSA Public consultation on draft 'Guidance on Communication of Uncertainty in Scientific Assessments'¹³
- BfR (German Federal Institute for Risk Assessment) risk profiles¹⁴

⁷ <http://www.fao.org/docrep/006/Y4800E/y4800e0o.htm>

⁸ <http://www.fao.org/3/a-a1550t.pdf>

⁹ See Annex 2

¹⁰ <http://researchbriefings.files.parliament.uk/documents/POST-PN-0564/POST-PN-0564.pdf>

¹¹ <https://www.gov.uk/government/publications/science-advisory-council-communicating-risk-report>

¹² <https://www.efsa.europa.eu/en/efsajournal/pub/5123>

¹³ <https://www.efsa.europa.eu/en/consultations/call/180504>

¹⁴ http://www.bfr.bund.de/en/bfr_risk_profile-186391.html

Definitions

We use the following definitions taken from the Codex Principles for Risk Analysis¹⁵.

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

Risk Analysis: A process consisting of three components: risk assessment, risk management and risk communication as follows:

Risk Assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

Risk Management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

Risk Communication: 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.

In the context of these principles we have also adopted the following definitions.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

The Guide to Good Practice for Quantitative Veterinary Epidemiology provides these definitions¹⁶:

Verification: The process of determining that an analysis accurately represents the developer's conceptual description and specifications.

Validation: The process of determining that an analysis is acceptable for its intended use because it meets specified performance requirements.

The Committee on Toxicity (COT) and International Programme on Chemical Safety provide these useful additional definitions and commentary:

Variability: The observable diversity in biological sensitivity or response, and in exposure parameters.

Uncertainty: An estimate of the sum of the limitations in knowledge at the time of the risk assessment.

Uncertainty can be reduced with additional data. Variability cannot be reduced but may be better characterised with additional data. There is often uncertainty about the variability.

¹⁵ We note that different bodies may use other definitions of these terms.

¹⁶ <http://www.qve-goodpracticeguide.org.uk/guide>

General observations – risk analysis process

The FSA needs to assess risk and uncertainty in order to make sound decisions on which risks to prioritise and target and on how it addresses those risks that it has prioritised/targeted.

The assumption has been made that these principles apply to food-related health risks only (though they may also be relevant to animal feed), and will not cover the economic/trust impacts of fraud¹⁷.

The field of risk analysis is constantly evolving and the FSA should keep under review the principles and the way the principles are implemented to ensure that they reflect changes in:

- the state-of-the-art in approaches to risk analysis, both conceptual and technical;
- the types of risk that need to be considered and the challenges these present such as increasing complexity;
- the wider context in which the risk analysis takes place.

Risk assessors, managers and communicators need to be familiar with all steps in the risk analysis process and the principles are relevant to all involved.

¹⁷ Amendments to cover other kinds of risk (e.g. economic impacts, fraud) may be incorporated in the future.

Principles

Thematic Principle	Commentary
Governance of Risk Analysis	
<p>1. The overall objective of risk analysis applied to food safety is to ensure health protection.</p>	<p>Risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication - as defined by Codex), each component being integral to the overall risk analysis.</p> <p>The assessment of economic and/or social impacts associated with health risks may be necessary to inform appropriate risk management options.</p> <p>It may be possible (even desirable) to translate risk data into economic costs to facilitate decision-making or policy decisions.</p>
<p>2. There should be a functional separation of risk assessment and risk management.</p>	<p>This is important to:</p> <ul style="list-style-type: none"> • ensure the scientific integrity of the risk assessment; • avoid confusion over the functions to be performed by risk assessors and risk managers; • reduce any conflict of interest between the two roles.
<p>3. There should be effective dialogue between risk assessors, risk managers and risk communicators at all stages of the process, assuring a shared understanding of the question(s) to be addressed, and the planned outputs of the risk assessment.</p>	<p>The mandate given by risk managers to risk assessors should be as clear as possible.</p> <p>Risk analysis is an iterative process, and frequent interaction between risk managers, risk assessors and risk communicators is essential.</p> <p>The question to be addressed (the problem formulation) must be discussed and agreed at the outset by risk assessors, managers and communicators and appropriate deadlines agreed.</p> <p>Inputs and assumptions of the risk assessment and any associated uncertainties should be understood in advance of decision making by risk managers and communicators.</p> <p>Risk analysis should also involve dialogue with the public, industry and others who have an interest in and/or are affected by the conduct or the outcomes of the risk analysis.</p>

<p>4. The assessment, management and communication of risks should reflect the characteristics of the risks. The risk analysis will need to set out the relevant factors, conclusions and assumptions and uncertainties, and their effects, in order to inform this process.</p>	<p>There are a number of ways to characterise risk. One way of doing this that has been looked at across government is to consider how the risks arise such as:</p> <ul style="list-style-type: none"> i) urgent/emerging; ii) slow burn – evolving picture which acquires its own momentum; iii) Government/Agency/SAC initiated action to raise the profile of the issue. <p>The different characteristics of risk (and the fact that these may change over time) needs to be taken into account; for example an initial slow burn issue may become urgent.</p>
<p>Risk Assessment</p>	
<p>5. The primary objectives of risk assessment are to determine the nature of the risk, the magnitude of the risk, the comparative risk or to establish health based guidance values.</p>	<p>Risk assessment should incorporate an initial “statement of purpose” which should help in framing the scope of the risk assessment and the following four stages: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.</p> <p>Risk assessment may need to take into account assessment of positive effects on health or indirect effects on health of risk management options.</p> <p>In realistic circumstances where any possibility of exposure to a hazard cannot be excluded, although a risk assessment may indicate a very low risk it will not indicate zero risk.</p> <p>At a minimum, the risk assessment should follow the Codex process and describe any uncertainty, assumptions and variability in data, opinions or quality of evidence.</p> <p>There should be a structured approach to review the assessment approaches and the outcomes to ensure that the issue has been addressed correctly. This should include an approach for achieving closure and setting appropriate triggers for review.</p>
<p>6. The risk assessment should be fit for purpose. The risk assessment should be verified and validated. The entire process should be fully documented in a transparent manner.</p>	<p>Verification is the process of determining that an analysis accurately represents the developer’s conceptual description and specifications.</p>

	<p>Validation is the process of determining that an analysis is acceptable for its intended use because it meets specified performance requirements.</p> <p>As far as is legitimate, documentation should be accessible to all interested parties.</p> <p>A clear audit trail should be visible for all assessments and decisions, to ensure they can be adequately scrutinised. Scrutiny of the risk assessment should be followed by applying the FSA Science Checklist¹⁸.</p> <p>The risk assessment should be reviewed at appropriate intervals and updated if necessary.</p>
<p>7. A risk assessment should capture the implications of uncertainties on the conclusion of the assessment. Sources of uncertainty and variability, and any measures that could be taken to reduce uncertainty and/or better characterise variability, should be investigated and reported.</p>	<p>The consideration of uncertainty is an integral part of the risk assessment process.</p> <p>There are a number of dimensions to uncertainty, including the overall weight of evidence and gaps in evidence, and the robustness and applicability of the selected risk assessment methodology in any specific case.</p> <p>Expressions of uncertainty or variability in risk estimates may be qualitative or quantitative, and the tools and approaches used to characterise and express uncertainty or variability should reflect the needs of risk managers and risk communicators.</p> <p>The way uncertainty is expressed in formal or technical terms in a risk assessment (for example as a probability distribution of outcomes) may need to be translated into terms that risk managers can understand correctly and consistently and can act upon, in order to communicate messages effectively to different audiences (see risk communication principles below).</p> <p>Where a risk assessment is based on selected scenarios, uncertainties in the selection of scenarios should be clearly identified.</p>

¹⁸ FSA Science Checklist:

<http://webarchive.nationalarchives.gov.uk/20180411152907/https://www.food.gov.uk/science/sci-gov/science-governance>

Risk Management	
<p>8. The primary objective of risk management is the identification, appraisal and selection of options for intervention that deliver proportionate protection of consumers from the assessed risks, taking into account other legitimate factors. Actions proposed should be proportionate to the best available estimates of the risk and uncertainty regarding the risk.</p>	<p>Risk management should follow a structured approach and be transparent, consistent and fully documented in order to facilitate a wider understanding by all interested parties. Risk management should be a continuing process that takes into account all newly generated relevant information.</p> <p>The rationale for what is deemed ‘proportionate’ should be made explicit.</p> <p>There should be a structured approach for the evaluation of risk management options, implementation, monitoring and review.</p>
<p>9. The approach to considering acceptability of risk in risk management must be consistent and transparent, and needs to be clearly articulated.</p>	<p>An important element of implementing an approach is effective iteration between risk assessors and risk managers so that the overall risk management approach is both acceptable and proportionate and underpinned by an appropriate risk assessment. (An example approach is that set out in the FSA framework for risky foods – see ANNEX 2).</p> <p>Acceptability of risk is not a simple yes-or-no issue; that is, a risk may not always be acceptable or always be unacceptable. Clarity is needed as to how the FSA accommodates variations in what is considered acceptable risk amongst different stakeholders, such as the FSA itself, consumers and food businesses.</p> <p>The FSA’s approach to acceptability should reflect that although a risk assessment may indicate a very low risk, an expectation of zero risk is not usually realistic.</p>
<p>10. The risk manager should seek to understand, acknowledge and manage the potential emotional and value-driven responses to the risk management decision.</p>	<p>Adaptability should be built into the risk management approach to take into account a changing society and risk-benefit choices. It is important to establish and continue to build the evidence base for this – including consumer/stakeholder acceptability, media narrative and consumer/business behaviours.</p>
<p>11. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager. Risk</p>	<p>The consideration of uncertainty is an integral part of the selection of risk management options, and not an afterthought.</p>

<p>management should aim to take a balanced, proportionate approach when considering uncertainty in risk assessment and determining its impact on the selection of risk management options.</p>	<p>All types of uncertainty and variability should be handled according to a consistent, documented and transparent process, appropriate according to the level of assessed risk and the available risk management options. This consideration should address both the likelihood of different outcomes and the severity of those outcomes.</p>
<p>Risk Communication</p>	
<p>12. 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.</p> <p>Risk communication should be open, honest, transparent and fully consistent with the scientific evidence available. It should cover uncertainty and knowledge gaps.</p>	<p>FSA needs to be flexible in the way it communicates with different audiences (such as in the communication channels and tone used) – one approach does not fit all.</p> <p>It is important to take into account how different people and groups perceive risks and uncertainty in framing communication so that it achieves its intended outcome.</p> <p>One way to characterise audiences and to adapt messages is to look at degree of expert knowledge in the area (as in the three levels of ‘entry level’, ‘informed level’, and ‘technical level’ proposed by EFSA in its guidance). Another important grouping of audience is by role (e.g. risk manager, stakeholder expected to take action on the basis of the messaging, or citizen wanting basic understanding of the issue).</p> <p>FSA’s approach should be informed by an understanding of what terms like ‘honesty’ and ‘proportionate’ mean for FSA and for its different stakeholders and audiences.</p> <p>Where third party communicators (e.g. media) reflect risk communication messages accurately and proportionately this is a positive outcome, but third party communications are influenced by a number of factors that are not under the control of the risk communicator.</p>
<p>13. Risk communication should itself be evidence-based. This covers evidence informing the selection of the approach to communication and evidence on the success of the communication.</p>	<p>Communication professionals should be involved from the earliest opportunity.</p> <p>Changing behaviour through communication alone is not easy and where communication does affect behaviour this is often difficult to demonstrate clearly. However, FSA should be explicit in its</p>

	<p>objectives for communication and how it will assess their success.</p> <p>The selection of the approach to communication should be informed by evidence and expert advice on:</p> <ul style="list-style-type: none"> • the choice of mode of risk communication; • who the target audiences are; • how best to characterise uncertainty; • how people, businesses and others understand and accept risk and uncertainty and how this affects their decision-making. <p>Evidence on the success of a communication includes whether the target audiences have been reached and evidence of any behavioural changes that have resulted.</p>
<p>14. The communication of risk to interested parties should include transparent explanations of:</p> <p>i) any uncertainties in the risk assessment; and</p> <p>ii) the way that uncertainties were dealt with in the decision-making process.</p>	<p>The way that uncertainty is to be addressed in communication of risk should be considered from the outset.</p> <p>Where there are significant uncertainties in the risk assessment one aim of risk communication is to help people understand the range of possible outcomes and the balance of short-term and longer-term risks and opportunities.</p>
<p>15. Risk communication should always contribute to the FSA’s goal of being the primary source of trusted information about food risk.</p>	<p>Risk communication should have the effect of increasing trust in the FSA by the target audience and more broadly, and should enhance the FSA’s ability to communicate risk in the future.</p> <p>The possibility of unintended, negative consequences should be considered and mitigated throughout.</p>

Annex 2: FSA 'risky food' framework (November 2016)

The three 'zones of acceptability' of risk are taken from the FSA Board paper on risky foods¹⁹, presented in November 2016:

- i) foods for which the risk is so high they are always unacceptable (such as Specified Risk Materials under TSE controls) - the **red** zone;
- ii) foods for which the risk is low enough to be **broadly acceptable** and may be regarded as safe provided the usual controls and good practice for food production apply (many foods, such as bread or canned goods) - the **green** zone;
- ii) foods for which the risks exceed the nature or levels considered broadly acceptable by the FSA, but which some people may accept for other benefits, such as choice. These risks are **unacceptable unless** specific additional controls are designed and consistently applied - the **amber** zone.

Annex 3: Acknowledgements

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¹⁹ FSA Board paper on risky foods, November 2016
<https://www.food.gov.uk/sites/default/files/media/document/fsa161107%20%283%29.pdf>

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Advisory Committee on Microbiological Safety of Food

Advisory Committee on Novel Foods and Processes

Advisory Committee on Social Science

Committee on Toxicity

Committee on Mutagenicity

Committee on Carcinogenicity

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