Draft Risk and Uncertainty Principles

Background

At the first meeting of the Science Council on 16 June 2017[1] the FSA Chairman Heather Hancock introduced the main issues and challenges on which the FSA would like input from the Science Council in the next two years. This working group has been established to answer the following question:

> What does the Council advise to be best practice in establishing and communicating risk and certainty?
>
> Why – 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 help us to deal with the consequences of EU exit, and will enable us to be more deliberate and clear in building consumer understanding about public health risks from food

Approach

The Council has begun to address this question in a phased approach and has established a Working Group to lead this task (Annex 1). The first phase (by December 2017) has considered the current FSA (and other relevant) approaches to establishing risk and uncertainty, and advise on principles for best practice and what FSA should do where any gaps exist or opportunities to improve arise. The second phase will build on this and consider current and best practice in communicating risk and uncertainty and any opportunities for FSA to improve. However, it will be useful for phase one to consider the key things that will need to be communicated *about,* to ensure these are covered in the approach to establishing risk and uncertainty.

The principles are intended to be high-level and to capture current good practices within the FSA and its Scientific Advisory Committees (SACs). They are based on the assumption that the FSA and its SACs already follow globally recognised reference texts such as the Codex Alimentarius principles for Risk Analysis. The principles below are designed to make these more specific to the FSA, and, by articulating the high-level principles, help to demonstrate that the FSA approach follows best practice.

The Working Group has considered a range of materials and inputs. The principles below have been co-developed by the FSA and the Working Group. They have been developed from the sources listed and informed by consultation with FSA risk assessors and risk managers and the FSA's SACs.

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

- Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius
- FSA 'Risky Food' Framework (Nov 2016) [2]
- Cross government guidance

Definitions

As defined in the Codex principles for Risk Analysis (above):

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 is a process consisting of three components: risk assessment, risk management and risk communication as follows:

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

Risk Management: (RM) 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: (RC) 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 of food produced in the UK and UK consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions. This includes appropriate and helpful disclosure regarding uncertainty and knowledge gaps.

In the context of these principles we consider the following definitions:

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

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

Validation: means that an analysis is acceptable for its intended use because it meets specified performance requirements.

Uncertainty: Uncertainty is an estimate of the sum of the limitations in knowledge at the time of the risk assessment

[2] See Annex 2

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. The risk assessment should capture the implications of uncertainties on the conclusion of the assessment. Risk managers will need to understand the implications of uncertainty in the risk assessment to inform the consideration of options for risk management, and to understand how uncertainties might be reduced.

General Principles: 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 which it has prioritised/targeted.

The assumption has been made that these principles apply to health risks only, and will not cover the economic/trust impacts of fraud[3].

The following principles are intended to be a basis for discussion. They are by no means the finished article and will need to be further developed according to best practice guidance and further iteration with FSA risk assessment and risk management teams.

The FSA's default position is always to follow Codex risk analysis principles as a minimum requirement, some key elements of which are picked out in the principles below. Codex principles are the pre-eminent text and contain useful guidelines that all risk analysis actors should be aware of.		
Thematic Principle	**Stage(s) at which principle applies**	**Comments**
Governance of Risk Analysis		
1. There should be a functional separation of risk assessment and risk management	RA and RM	This is important to: • 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
2. There should be effective dialogue between risk	RA, RM and RC	Risk analysis is an iterative process, and interaction between risk managers, risk

[3] The principles as drafted are intended to apply to health risks only. Amendments to cover other kinds of risk (e.g. economic impacts, fraud) may be incorporated in the future.

assessment, risk management and risk communication, There should be shared understanding of the question, possible answers and possible consequences across risk assessors, managers and communicators		assessors and risk communicators is essential. The question to be addressed (the problem formulation) must be discussed and agreed at the outset by risk assessors, managers and communicators within an agreed timeframe. There should be a structured approach to review the assessment tools 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. Inputs and assumptions of the risk assessment and any associated uncertainties should be understood in advance of decision making by risk managers and communicators There should be a structured approach for the evaluation of risk management options; implementation; monitoring; and review.
3. The primary objective of the risk analysis process is the proportionate protection of health of consumers The primary objective of Risk Assessment is to determine the magnitude of the risk, the nature of the risk, the comparative risk or to establish health based guidance values	RA, RM, RC RA	The assessment of economic and/or social impacts associated with health risks may be necessary to inform appropriate risk management options. It may be possible (even desirable) to translate risk data into economic costs to facilitate decision making or policy decisions. Examples of health based guidance values include the acceptable daily intake (ADI) for food additives and pesticides, and the tolerable daily intake (TDI), provisional tolerable weekly intake (PTWI) and provisional tolerable monthly intake (PTMI) for food contaminants.
4. Different types of risks are managed and communicated	RA, RM and RC	Including, but not limited to: i) Urgent/emerging

differently, in line with guidance developed across government The management and communication of risks within the overarching framework of risk analysis will 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.		ii) Slow burn – evolving picture which acquires its own momentum iii) Government/Agency/SAC initiates action - Government/agency wishes to raise the profile of the issue This needs to be taken into account, for example, when assessing the urgency of assessing and responding to a given issue. The risk may inform which hazard or hazard combination to prioritise - the risk and uncertainty should be contextualised in terms of the hazard and specific situation under consideration.
Conduct of Risk Assessment		
5. Risk assessment, should be fit for purpose and the process should be fully verified, validated and fully documented in a transparent manner	RA	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. Risk assessment should take into account relevant food chain practices, sampling and inspection, and prevalence of specific adverse health effects. The risk assessment should follow as a minimum the Codex process and describe any uncertainty, assumptions and variability in data, opinions or quality of evidence. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties.

		In realistic circumstances, although a risk assessment may indicate a very low risk it will not indicate zero risk 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 Governance checklist[4]
Uncertainty & Acceptability in Risk Analysis		
6. FSA will handle all types of uncertainty according to a consistent documented process, appropriate according to the level of assessed risk and the available risk management options, and in line with agreed approaches.	RA, RM, RC	Uncertainty analysis will be developed to deliver better handling and quantification of uncertainty where appropriate. There are different elements of handling uncertainty for risk assessment, such as how to capture and articulate the uncertainty and what it means for the risk assessment and for risk management, to ensure the risk assessment is used appropriately.
7. The FSA articulates and follows a consistent and transparent approach to considering acceptability of risk in risk management.	RM	Acceptability of risk should not be binary system, in that it is not always acceptable or always unacceptable. An important element of implementing an approach is effective iteration between Risk Assessment and Risk Management so that the risk assessment is able to properly support the assessment of acceptability in the context of the agreed approach. Although a risk assessment may indicate a very low risk, there should be a consensus amongst stakeholders that zero risk is not realistic,

[4] https://www.food.gov.uk/science/sci-gov/science-governance

		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, food businesses. Adaptability should be built into this approach to take into account a changing society and risk-benefit choices An example approach is that set out in the FSA framework for risky foods (see Annex 2)

Annex 1 Risk & Uncertainty Working Group Membership

Working Group members	**Secretariat**	**FSA input**
Sandy Thomas	Gwen Aherne	Guy Poppy, CSA
Sarah O'Brien	Patrick Miller	Steve Wearne, Director of Policy
John O'Brien	Emma Lamb	Mark Willis, Contaminants & residues branch
Mark Woolhouse	Rachel Mumford	Joanne Edge, Microbiological Risk Assessment
Mark Rolfe		Barry Maycock, Chemical Risk Assessment
Paul Turner		

Annex 2

Three 'zones of acceptability' of risk taken from the FSA Board paper on risky foods[5], 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.

[5] https://www.food.gov.uk/sites/default/files/fsa161107.pdf