THE FSA’S APPROACH TO UNCERTAINTY AND RISK

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1. Summary

1.1 This paper forms part of the Board’s ongoing discussion of risk analysis principles and practice and underpins the FSA’s role in providing evidence-based risk management advice to Ministers taking risk management decisions.

1.2 The Board is asked to:

- **Set** its expectations about the way that uncertainty in risk assessment and other evidence in support of risk management should be expressed;
- **agree** that the Science Council and Advisory Committee on Social Science should continue to advise the FSA further in this regard;
- **note** that following the UK’s Exit from the EU, the FSA will be advising Ministers in relation to international negotiations which are governed by WTO obligations and **agree** that the consideration by the Board as risk manager of any uncertainty in risk assessment should follow relevant WTO reference texts; and
- **agree** that, when deciding to use the precautionary principle in formulating provisional risk management measures as part of its risk management advice, the Board should ensure that such measures are:
  - proportionate;
  - no more restrictive of trade that is required to achieve a high level of health protection;
  - informed by legitimate issues relating to technical and economic feasibility; and
  - reviewed within a reasonable period of time.

2. Introduction

2.1 Virtually all decisions related to complex systems – including those related to food and feed safety and consumers’ other interests in relation to food – are made in the presence of uncertainty due to lack of knowledge, and natural variability in outcomes. For example, there is often great uncertainty in estimates of the types, probability, and magnitude of health effects associated with a chemical agent, of the economic effects of a proposed regulatory action, or of the extent of current and possible future human exposures through multiple pathways. We often do not have the luxury of waiting for more evidence to emerge before taking action and, even where we do, uncertainty is often either irreducible or would take disproportionate resources to reduce. But by taking account of uncertainty and variability in an appropriate way, we can
make better, more transparent decisions about the proportionate control of risks to consumers and also consider the balance of risks and benefits in taking more time and using more resource to address sources of uncertainty.

2.2 This paper looks at a particular aspect of uncertainty – how it will be considered in line with the risk analysis principles and practice that the FSA will apply following the UK’s Exit from the EU\(^1\), when activities currently undertaken by the European Food Safety Authority and European Commission with respect to risk assessment and risk management of food safety and related issues will be undertaken in respect of the UK by the FSA. In particular, this paper sets out how the FSA should apply the precautionary principle, which will be converted into domestic UK law, when framing its risk management advice to Ministers.

2.3 One of the aspects of food safety on which the FSA will in future be advising Ministers is on food safety and related issues that arise in international trade negotiations. When advising Ministers, the FSA will need to bear in mind, among other things, the UK’s WTO obligations that national measures are based on risk assessment and constrain trade only so far as necessary to protect public health. The consideration of any uncertainty in the risk assessment should follow WTO reference texts, primarily the Codex Alimentarius Working Principles for Risk Analysis for Food Safety for Application by Government (CAC/GL 62-2007) see Annex 1, which were incorporated by the Science Council Working Group 2 into its recommended best practice principles, which were accepted by the Board in December 2018.\(^2\)

3. Discussion

Risk assessment

3.1 The presentation of risk assessment and other evidence to risk managers (Step 7 in the risk analysis process\(^3\)) will explicitly consider the degree of uncertainty and variability in the evidence that is available, and this will be quantified where possible and documented. Uppermost in the mind of the FSA executive when compiling this information will be the need to express the scientific uncertainty in a way that is useful to risk managers, including the Board, and that supports wider risk communication.

3.2 In terms of internal capability and capacity for risk assessment, these have recently expanded, following which we have a renewed focus on the development and application of risk assessment methods and associated staff training in qualitative and quantitative approaches to ensure the continued technical competence of our assessors. This internal resource is complemented by the FSA’s scientific advisory committees, whose membership has also recently expanded as part of our EU Exit readiness preparations.

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\(^1\) For previous Board discussions, see the minutes of Board meetings in September 2018, December 2018 and March 2019 and the supporting papers on Risk Analysis: Process, Governance, Communication (FSA 18/09/09), Risk Analysis Process (FSA 18/12/11), and Risk Analysis: Assurance (FSA 19/03/08).

\(^2\) See the minutes of the Board meeting in December 2018 and the supporting paper on Final Report from the Science Council Working Group on Risk and Uncertainty and FSA Response (FSA 18/12/10).

\(^3\) See Annex A to Risk Analysis Process (FSA/18/12/11).
3.3 In terms of internal assurance, we have current guidance on the assurance of these evidence packages, which has been developed iteratively through discussion between science and policy teams. Key to this is the role of the Chief Scientific Adviser in assuring the Board that due process has been followed and that uncertainties in the evidence base and their impacts have been identified, considered and communicated appropriately.

3.4 We aim to further develop our approach to the articulation of uncertainty in risk assessment over time, taking into account among other things:

- advice from the Risk Communication Working Group established by the Advisory Committee on Social Science at its first meeting in 2018;
- the results of further work commissioned in the light of advice from the Science Council Working Group on Risk and Uncertainty and the ACSS Risk Communication Working Group: a) a review of the frameworks used by other similar regulators; b) a review of the available literature on communicating risk and uncertainty; and c) primary research with consumers, risk managers, journalists, communications practitioners and other stakeholders to develop a practical risk communications toolkit for the FSA; and
- any further advice from the Science Council, as it discusses from time to time how it might add further value and assurance to the risk assessment work the FSA will undertake after the UK’s Exit from the EU.

**Risk management**

3.5 As set out in the recent paper on governance of risk analysis\(^1\), for material issues it will be for the Board to advise Ministers. Risk management is not a formulaic process and, in each instance, the Board will need to decide the approach it takes to risk management, including the impact of uncertainty on its risk management advice, while bearing in mind that risk analysis principles should be applied consistently and in a non-discriminatory manner.

3.6 One of the tools at the Board’s disposal will be the precautionary principle (see Annex 2). This is an aspect of EU food and feed law which will be converted into domestic legislation when the UK leaves the EU. The principle allows provisional risk management measures to be adopted in specific circumstances where, following an assessment of the available information, the possibility of harmful effects in health is identified but scientific uncertainty persists.

3.7 The precautionary principle appears in different formulations in different pieces of legislation and normative international texts, most notably the 1992 Rio Declaration on Environment and Development. The UK Government’s Inter-Departmental Group on Risk Assessment, of which FSA was a member, published a paper in 2002 on the application of the precautionary principle.\(^4\) This paper advised that the precautionary principle should be invoked when:

i) there is good reason to believe that harmful effects may occur to human, animal or plant health or to the environment; and

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ii) the level of scientific uncertainty about the consequences or likelihood of
the risk is such that the best available scientific advice cannot assess the
risk with sufficient confidence to inform decision-making.

3.8 The precautionary principle is therefore distinct from other drivers that require
cautions such as society’s view on the extent of protection afforded to children or
others considered to be vulnerable, or the wish to ensure that conventional risk
assessment techniques deliberately over- rather than under-estimate risk.

3.9 The precautionary principle is often selectively quoted. As a result, it is easy to
get the sense that the precautionary principle gives you one formula for how to
act, cost-benefit analysis gives you a different and conflicting formula, and it is
the job of the risk manager to arbitrate between these. But this is not the case.
The second part of the precautionary principle, often overlooked, makes clear
that when deciding to invoke the precautionary principle, and to take provisional
risk management measures, there is a duty on risk managers to ensure their
approaches are proportionate and no more restrictive of trade than is
necessary to protect public health. Therefore, precaution is not a
counterweight to science – in fact, in using it and applying judgement we have
to take into account the nature of the scientific evidence.

4. Conclusions

4.1 The Board is asked to:

- **Set** its expectations about the way that uncertainty in risk assessment and
other evidence in support of risk management should be expressed;

- **agree** that the Science Council and Advisory Committee on Social Science
should continue to advise the FSA further in this regard;

- **note** that following the UK’s Exit from the EU, the FSA will be advising
Ministers in relation to international negotiations which are governed by WTO
obligations and **agree** that the consideration by the Board as risk manager of
any uncertainty in risk assessment should follow relevant WTO reference
texts; and

- **agree** that, when deciding to use the precautionary principle in formulating
provisional risk management measures as part of its risk management advice,
the Board should ensure that such measures are:

  o proportionate;

  o no more restrictive of trade that is required to achieve a high level of
  health protection;

  o informed by legitimate issues relating to technical and economic
  feasibility; and

  o reviewed within a reasonable period of time.
RELEVANT PROVISIONS OF THE CODEX ALIMENTARIUS WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY FOR APPLICATION BY GOVERNMENTS (CAC/GL 62-2007)

SCOPE

1. The Working Principles for Risk Analysis for Food Safety for Application by Governments are intended to provide guidance to national governments for risk assessment, risk management and risk communication with regard to food related risks to human health.

GENERAL ASPECTS

2. The overall objective of risk analysis applied to food safety is to ensure human health protection.

3. These principles apply equally to issues of national food control and food trade situations and should be applied consistently and in a non discriminatory manner...

6. Risk analysis should be:
   • applied consistently;
   • open, transparent and documented; and
   • evaluated and reviewed as appropriate in the light of newly generated scientific data...

12. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. The assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard...

RISK ASSESSMENT

26. Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable...

28. The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.

29. The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers.
and made available to other risk assessors and interested parties so that they can review the assessment…

RISK MANAGEMENT

39. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. The relevance, effectiveness, and impacts of risk management decisions and their implementation should be regularly monitored and the decisions and/or their implementation reviewed as necessary…

RISK COMMUNICATION

43. Risk communication involving interested parties should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The decisions taken and the procedures followed to reach them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, and minority opinions that had been expressed in the course of the risk assessment (see para. 28).
ANNEX 2

THE PRECAUTIONARY PRINCIPLE

In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen may be adopted, pending further scientific information for a more comprehensive risk assessment.

Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.