

## FSA SCIENCE COUNCIL WORKING GROUP ON RISK AND UNCERTAINTY

### **Background**

At the first meeting of the Science Council on 16 June 2017 the FSA Chairman Heather Hancock introduced the priority questions on which the FSA needs input from the Science Council. 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.*

FSA needs to establish and communicate risk and uncertainty in relation to decisions on:

- prioritising risks and issues to consider.
- deciding how to tackle the risks we prioritise.
- balancing benefits of increasing confidence with the resource needed to reduce uncertainty.
- deciding what approach and resource is appropriate to achieve a specific level of risk.

The FSA does not believe its current system is broken but there is a sense it could be improved. It is currently done on an issue by issue basis and the FSA would benefit from articulating a framework of clear principles for establishing risk and uncertainty to provide more clarity and consistency in making decisions<sup>1</sup> and in communicating about risk.

There is increased urgency due to the fact that some decisions are taken at a European level but this may change in the future. The FSA needs to be confident that its approach works now and will work outside the existing regulatory framework. The Agency may face increased scrutiny for its decisions and it is vital we rise to this challenge in order to be an excellent, modern, accountable regulator.

For the Board, the key area to improve is in the extent to which the Board sees and understands the wider context of the risk, and consistency across different issues and types of risk and decision, rather than the specifics of assessing individual risks. The FSA also wants clear guidance on best practice to be in a position to demonstrate consistency in how

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<sup>1</sup> Decisions need to be made on a case-by-case basis as even similar cases are rarely identical. Understanding why these cases are different is essential

we've reached a decision with comparable discipline and rigour of thinking across different types of risks (e.g. microbiological, chemical, acute/chronic).

For risk assessors and managers in FSA (who have more day-to-day knowledge of risk analysis principles and practice) the key challenges are: how confident can we be that we are using the right approaches in the assessment and communication of uncertainty, and how can we ensure that this provides a sound basis for consideration of uncertainty in risk management?

This includes finding better ways to address uncertainty in terms of the timing/resource required to increase certainty for making decisions.

### **Approach and outputs**

The Working Group (WG) will advise the FSA on what is best practice in establishing and communicating risk and uncertainty.

It will take a phased approach. The first phase (by December 2017) will consider the current FSA approach to **establishing** risk and uncertainty, based on a framework or principles for best practice and what FSA should do where any gaps or opportunities to improve are identified, in relation to these principles and/or relevant practice elsewhere. The second phase will build on this and consider current FSA practice in **communicating** risk and uncertainty and any opportunities for FSA to improve, again with reference to the framework/principles and relevant insight or practice from elsewhere. 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 WG may wish to take a 'deep dive' into a particular issue that would serve as an example to illustrate a need to improve or how a recommendation would deliver a benefit.

An independent review of the FSA's Risk Assessment capability, commissioned by the FSA Chief Scientific Adviser, was completed in September 2017. The FSA is currently developing an action plan to implement its recommendations. This was mainly a capability review but there are a few recommendations which are directly relevant to the role of this Working Group (these relate to developing an overarching framework for risk assessments and a common format for reporting risk assessments). The Working Group will need to consider how its work in these areas will align with and inform the implementation of the review recommendations.

#### PHASE 1 (by December 2017)

- i. advising on a set of principles for best practice for establishing and handling risk & uncertainty, which will serve to structure the subsequent stages (the Science Council Chair advised the FSA to provide an initial draft as a starting point for discussion).

- ii. considering the current FSA approaches to establishing risk and drawing these together into a framework which address the Board's need to understand and communicate the FSA high-level approach and to assess options and proposals against it. (It is likely that much of the material for this exists already although it is not collated in one place or for this purpose.)
- iii. advising on any gaps or areas to improve FSA's approach, with reference to current FSA practice, the principles/framework, and relevant practice or insight from elsewhere; and what FSA should do to address these. This should include consideration of the following points:
  - a. What are the approaches we should use in the assessment and communication of uncertainty in risk assessment, and how can we ensure this allows for appropriate consideration of uncertainty in risk management?
  - b. How can we establish different types of uncertainty and articulate them in ways that are valid and defensible to scrutiny, comparable across different scenarios, and useful for decision-makers (internally and the FSA Board) both for individual assessments and the outcome of a risk assessment as a whole?
  - c. How can we assess and articulate the overall quality of evidence in ways that are scientifically valid and useful for decision-makers for example in terms of the overall confidence and the likelihood and extent to which it may change?
  - d. How can we help the Board understand this process?
  - e. How can we make sure the approach also allows us to weigh benefits against risks?

#### PHASE 2 (Spring 2018)

- i. Identifying any gaps or areas to improve FSA's approach to communication of risk and uncertainty, drawing on the outputs from phase 1, and with reference to current FSA practice, the principles/framework, and relevant practice or insight from elsewhere;
- ii. Advising on what FSA should do to address these. This will include:
  - a) considering cross government approaches and advise what is needed to make something specific/tailored for the FSA
  - b) possible additional input, such as inviting external speakers to a working group or holding a workshop with practitioners/those in academia with links to the FSA.
  - c) Possible input/joint working with WG1 who are addressing how we ensure the FSA Board have an overview of the correct evidence and are informed about any uncertainty, omissions or limitations. This overlaps with a WG objective to ensure the Board sees and understands the wider context of the risk, and consistency across different issues and types of risk and decisions, rather than the specifics of assessing individual risks.

**Timing**

- Heather Hancock’s original request was for advice within 6 months. The phased approach has been agreed with this in mind.
- Working Group meeting 4 October 2017 to critique/review draft principles for establishing risk and uncertainty.
- Recommendations to the Science Council’s second meeting 13<sup>th</sup> December 2017 on PHASE 1.
- 2<sup>nd</sup> WG meeting February/March 2018 (to be confirmed).
- Final recommendation to 3<sup>rd</sup> Council meeting (timing to be confirmed - May/June 2018).

**Membership:**

<b>Working Group members</b>	<b>Secretariat</b>	<b>FSA input</b>
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 (Chair)	Rachel Mumford	Joanne Edge, Microbiological Risk Assessment
Mark Rolfe		Barry Maycock, Chemical Risk Assessment
Paul Turner		

**With other inputs as needed:**

- i. As a first and ongoing task the Working Group will consider what other inputs it needs in terms of expertise/insight/commentary as well as of written material.
- ii. Consult with the FSA’s other Scientific Advisory Committees.
- iii. Input from Working Group 1 who are addressing how we ensure the FSA Board have an overview of the correct evidence and are informed about any uncertainty, omissions or limitations.