**FSA Science Council Working Group on Risk and Uncertainty (Working Group 2)**
**1st meeting Wednesday 4 October 2017**
**Conference Room 3, 4th floor, Aviation House, London**

**Attendees**

| Working Group | Secretariat | FSA |
|---|---|---|
| Mark Woolhouse (Chair) | Patrick Miller | Guy Poppy, Chief Scientific Adviser |
| Sandy Thomas | Gwen Aherne | Steve Wearne, Director of Policy |
| Sarah O'Brien (by telephone) | Emma Lamb | Mark Willis, Contaminants and Residues |
| John O'Brien | Rachel Mumford | Joanne Edge, Risk Assessment Unit |
| Mark Rolfe | | Barry Maycock, Chemical Risk Assessment Unit |
| Paul Turner | | |

**Agenda item 1 - Welcome and introductions**

1. Science Council Chair Sandy Thomas opened the meeting and Working Group (WG) Chair Mark Woolhouse welcomed the group and invited round table introductions.
2. Mark Woolhouse (WG Chair) noted that this was a closed session but a note would be prepared as background information to the Working Group's report to the Science Council on 13 December and published with it. The Chair invited frank and open discussion to support the Working Group in understanding how the FSA works and in order for the Working Group to develop useful recommendations for the FSA. He welcomed the openness FSA had shown in outlining areas of strength and weakness in the materials for the meeting.
3. Guy Poppy noted that an independent review of the FSA's Risk Assessment capability was completed in September 2017 and the FSA is currently considering the recommendations. The review report has been shared with the Working Group in confidence at this stage (this will be published at a later date). There are two high-level recommendations which are directly relevant to the role of this Working Group which relate to developing an overarching approach to risk assessment and a standardised framework for reporting risk assessments.
4. The working group asked about the FSA's current internal risk assessment and risk management capacity which Steve Wearne estimated as approximately 100 (around 25 people working in risk assessment; and some 70 in risk management – this refers to staff involved in developing policy risk management, and not inspection staff working on its enforcement and compliance.

**Agenda item 2 - Terms of Reference: SC WG2 papers 1-2 and 1-3**

5. Gwen Aherne introduced the draft Terms of Reference (paper 1-2) for the Working Group's consideration and provided an overview of the timeline and process for the Working Group's recommendations to the FSA (described in the process flow diagram, paper 1-3).
6. These had been developed by the Secretariat through iteration with Guy Poppy, Sandy Thomas and Mark Woolhouse and involved phasing of the work to answer the question set by FSA Chairman Heather Hancock at the Science Council meeting in June. The Working Group did not have substantive changes to the document and approved it as final.

7. The Working Group strongly supported the Secretariat's suggestion to invite early comment from the FSA's other Scientific Advisory Committees (SACs) on the draft principles on risk and uncertainty. The Working Group suggested there could be benefit in the FSA's two principle risk assessment committees, COT and ACMSF, working together to develop an overarching, harmonised approach to food safety risk assessment, drawing on the work each had done to systematise the approach to chemical and to microbiological risk assessment, respectively.

**ACTION 1 – Secretariat to invite comment from FSA SACs on the draft principles on risk and uncertainty in October, and add this step to the process flow diagram**

**Draft recommendation –** FSA to ask its principle risk assessment Scientific Advisory Committees, COT and ACMSF, to work together to develop an overarching, harmonised approach to food safety risk assessment.

**Agenda item 3 – Draft principles on risk and uncertainty: SC WG2 paper 1-4**

8. The first phase of the Working Group's work (to report 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.
9. Guy Poppy introduced the set of draft principles which had been prepared by the Secretariat as a starter for discussion by the Working Group. The Secretariat had developed these as a 'strawman' in consultation with FSA risk assessment and risk management colleagues, using the Codex risk analysis principles and other relevant materials.
10. The Chair invited the Working Group to comment on and critique the draft principles. Steve Wearne noted that the Codex principles were robust and globally recognised but invited the WG to consider whether they would be sufficient for FSA; he noted that they had been developed by risk managers, and there might be additional perspectives from risk assessment or communication which it would be helpful to capture in tailoring a version for FSA use. He noted that the process the FSA follows will be subject to increasing challenge outside the EU. Codex provides a baseline. The Codex approach allows for the consideration of 'other legitimate factors' (besides risk assessment) in risk management - such as social and cultural factors and acceptabilities, attitudes and preferences - and differences in how these are taken into account in different regions are behind some of the differences in risk management actions taken on the same risks around the globe.
11. The Working Group made the following comments and suggestions on the principles (these include comments made under agenda item 6):
    a. the working group would like the opportunity to provide further drafting suggestions after the meeting
    b. agreed that deviating from the Codex standard is not necessary or appropriate, and there could be a single overarching principle that commits the FSA to following the Codex principles; this is also an opportunity to tailor or supplement these to provide the FSA with its own set of high-level principles with extra detail or additional things it might want to include
    c. highlighted the need to consider how the principles will be used in practice

d. agreed 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 with a more standardised approach and terminology in some cases - so that it is clear the approach has a sound basis in established good practice
e. recommended that the principles should reflect the full extent of FSA's remit including authenticity as well as food safety - the text and draft principle should be revised to reflect this
f. highlight more explicitly the FSA Science Checklist (perhaps append in full rather provide a link to it) – a recommendation could be to review/update the Checklist as part of development of the overarching framework for establishing risk and uncertainty, to ensure it properly reflects the updated approach and supports its consistent use in practice
g. Principles 1,2,3 are similar to Codex, the WG did not see a need for significant changes, though the wording might be improved.
h. The Chair noted that the discussion flagged the need for better, iterative communication at each step of the risk assessment, risk management and risk communication cycle, internally and with external experts and stakeholders. This includes closer engagement of the SACs and their Chairs and a more coordinated approach to ranking and comparing risks. This discussion was mainly focused around Principle2 where it was noted we should add increased and more consistent/structured iteration between risk assessment and risk management.
i. Principle 4 should reflect FSA statutory requirements. Risk assessment should establish more than only the magnitude of the risk.
j. Principle 5 – it is not clear why the principles of risk analysis should be different for the 3 types set out, although the approach to implementing the principles would reflect the different characteristics of different types of hazard. Although consequences may differ, analysis would be the same. This should be made clearer in the wording. It could be helpful to develop a typology of risks that sets out the principal dimensions that affect, for each type what, when and how risk is communicated (this could be considered further in Phase 2).
k. Principle 6 – Acceptability of risk should not be a binary system (acceptable/not acceptable); the red/amber/green system used for example in the FSA's risky foods framework review is an alternative. The articulation of this principle needs further work but an important element of implementing it is effective iteration between risk assessment and risk management so that the risk assessment is able properly to support the assessment of acceptability using whatever framework is relevant in each case
l. Principle 7 on uncertainty needs to be elaborated on and made clearer what the intention is here to allow for robust commentary from the Working Group and others on the draft. It is not about 'acceptability' of uncertainty as such but the need to clearly establish and articulate the key elements of uncertainty in a way that is useful for the risk management and communication. This is probably the least formalised of the principles in terms of what FSA does at present and is subject to variabilities in approach/response of risk managers; further elaboration and standardisation with input from the WG would be useful; a number of important dimensions of uncertainty were

highlighted (including overall weight of evidence; uncertainty in the robustness and applicability of the established risk assessment methodology; sources of uncertainty and what and how they affect the risk assessment; implications of the uncertainties on the outcome and for the risk management decision; ways that uncertainty might be reduced)

**ACTION 2 – Secretariat to circulate the draft principles for the Working Group's comments and changes (the version to be circulated should have a more developed principle 7 on uncertainty)**

**Draft recommendation –** FSA should review and update its Science Checklist as part of developing an overarching framework for establishing risk and certainty

**Agenda item 4 - Presentation of FSA Case studies and discussion: SC WG2 papers 1-5 and 1-6**

12. The Chair noted that the aim of the FSA case studies was to help to illustrate for the Working Group how FSA works using real world examples. The Working Group could use this opportunity to explore and understand FSA approaches, challenges and opportunities and any strengths or areas for improvement, and test the draft principles against these cases.

**Acrylamide case study**

13. Mark Willis gave a presentation on the acrylamide case study. He provided an overview of the recent acrylamide consumer facing publicity campaign, and the evidence and rationale that underpinned this. This is a complex case as acrylamide is regarded as a genotoxic human carcinogen and is a naturally-forming contaminant in food. There is no dose-response relationship on which to base a safe level of exposure and the levels in food should be as low as reasonably achievable. EFSA and the FSA use the Margin of Exposure approach when assessing the risk of genotoxic carcinogens, which is the globally accepted tool to establish the level of concern about exposure where no health-based 'safe' level can be set. A communications initiative was launched in January 2017, informing consumers of practical steps they can take to reduce exposure to acrylamide during home cooking, and also setting out the action the food industry is already taking. Despite following the global standard, the MOE approach/concept was challenged by external risk experts in the media.
14. The Working Group explored the case in detail with the FSA officials present. Members advised there may be room for improvement in level and depth of communication between risk assessors and risk managers on the robustness and uncertainties with regards the risk assessment tools used, and in consideration of the risks compared to other genotoxic carcinogens; this is an area of uncertainty which needs to be considered explicitly but is perhaps not as obvious as other areas of uncertainty. The FSA may be able to learn from the approach in evidence based medicine on consideration strength of evidence (expert opinion versus RCTs).
15. The WG made a number of comments on risk communication - the Group were interested in whether the publicity material had been tested with consumers prior to publication. Members noted that media and other stakeholder challenge is always to be expected in response to a proactive campaign. The Working Group also discussed that the FSA's decision on route of communication (for example publishing advice on a website compared to a proactive consumer campaign) could be informed by i) the uncertainties and assumptions made in the risk

assessment tools and approaches ii) comparing to other risks. Communications could restate the scientific principles on which one bases the risk assessment and risk management. The Working Group was interested in how well the FSA is prepared to respond to challenge from external scientists in the media. These points can be picked up in phase 2 of the Working Group's work.

**Draft recommendation –** Put in place checkpoints between risk assessment, risk management and risk communication in order to increase the regularity and depth of communication and iteration between risk assessors and risk managers on the robustness and uncertainties with regards the risk assessment tools used, and in comparing/ranking risks to inform risk management and communication.

**Additional FSA Case Studies**

16. Additional shorter case studies on raw drinking milk and burgers less than thoroughly cooked were provided as a comparison to complement the acrylamide case as they involve different types of risks. In both cases the food is considered by FSA as a 'risky food' and the FSA Board has reviewed controls for these foods in light of new routes of sale and/or growing markets and consumption. Consideration of these two cases prompted the FSA to develop a *Framework for proportionate controls on risky foods* to help ensure that FSA could take a consistent, structured and transparent approach to identifying such foods and to developing proportionate controls for them.
17. In response to working group questions Steve Wearne highlighted that food law requires that the food business operator manages (rather than minimises) risks to health. The view of what level of risk is 'acceptable' may vary between the regulator, consumer and vendor. In some cases foods are banned (for example specified risk material – SRM) but in others, such as for raw drinking milk, although the FSA may consider that it is risky, some consumers want to have the choice to consume it, and so specific additional controls are put in place to minimise the risks. It was noted that these cases underline the need for improvement in the iteration between the risk assessors, including the SACs, and risk managers at regular stages of the process as the FSA executive develops its thinking and recommendations to its Board.

**Agenda item 5 Working Group case studies**

18. The Chair invited members to share additional examples to help broaden the discussion and draw on Members' own experience, and further test the draft principles against these cases. Working group members outlined examples of risk challenges in food and other areas. The key points made by the Working Group arising from discussions of these cases were –
    - The risk manager/communicator should consider how the intervention or policy will be implemented and what evidence/data and guidance would be helpful to provide to assist with this.
    - A lack of data can give the public a sense that there is a lack of a risk per se rather than that the controls in place to manage the risk are effective.
    - It is important to understand and to articulate the uncertainties associated with the robustness and applicability of the key reference points/assumptions in the risk assessment

methodology as well as in the outcome of its application in a specific case (e.g. the use of 10,000 as a guide for low concern in an MoE; minimum infective dose for a pathogen).

- Uncertainties in the evidence can give rise to varied interpretation of the results and conclusions. It is important to consider the consistency and reproducibility of evidence. Scientific Advisory Committees (SACs) are a good route to foster cross-departmental working given they are independent from government and can work across departments. Bringing SACs together means experts can more easily come to a consensus on the evidence. This has happened in several cases (such as risks and benefits of oily fish) but should occur more frequently.
- When considering risk we need to look at the whole picture/food. This is particularly relevant as food is a mixture which makes it more complex. Some benefits may give rise to risks eventually (for example degradation of a microbial control agent over time in food).

**Agenda item 6 - Revisiting Draft Risk & Uncertainty Principles**

19. The aim of this item was to reflect on any further changes to the draft principles in light of discussion of the case studies. The points raised are included in the notes on items 4 and 5 above. The Chair advised FSA should lead on drafting a framework that would expand on how the principles are/should be operationalised in FSA. The Working Group could advise on what the framework should seek to cover. This should feed into the FSA response to the independent review of its Risk Assessment capability (on the recommendations on developing an overarching approach to risk assessment and a standardised framework for reporting risk assessments).

**Draft recommendation -** FSA to develop a framework for how the principles are/should be operationalised in FSA. The Working Group will advise what this framework should cover.

**Agenda item 7 – Outputs and next steps Next steps**

20. The Chair led the discussion on the Working Group's outputs, way of working and agreed the following next steps:

- Secretariat to clarify principle 7 and circulate to SACs chairs, working group and internal FSA colleagues for feedback. These groups should be asked whether there should be additional principles as well as for comments on the seven principles in the current draft. **[ACTION 1 and 2]**
- Secretariat to develop with the WG Chair and the WG a report to the Council, providing context to the draft principles and other conclusions and recommendations the WG would wish to put to the Council **[ACTION 3]**
- Secretariat to organise a follow up teleconference for the Working Group early November to review the responses on the draft principles and any further updates to the principles. The WG could also consider its report to the Council. **[ACTION 4]**
- WG Chair Mark Woolhouse will report to the Science Council on the Working Group's recommendations on 13 December. There will then be an opportunity to reflect changes and comments in the WG's final report on Phase 1. Sandy Thomas will report on the Phase 1 recommendations to the FSA Board meeting in March.
- A WG meeting to progress Phase 2 could be scheduled for February. **[ACTION 5]**

**Meeting actions list**

| Action | Detail | Owner | Deadline |
|---|---|---|---|
| ACTION 1 | Invite comment from FSA SACs on the draft principles on risk and uncertainty in October, and add this step to the process flow diagram | Secretariat | End October |
| ACTION 2 | Secretariat to circulate the draft principles for the Working Group's (and FSA) comments and changes (the version to be circulated should have a more developed principle 7 on uncertainty) | Secretariat | End October |
| ACTION 3 | Secretariat to develop with the WG Chair and the WG a report to the Council, providing context to the draft principles and other conclusions and recommendations the WG would wish to put to the Council. | Secretariat | 2 November for first draft; 30 November for final draft |
| ACTION 4 | Secretariat to organise a follow up teleconference for the Working Group early November | Secretariat | Early November |
| ACTION 5 | A WG meeting to progress Phase 2 could be scheduled for February 2018 | Secretariat | |

**Draft timeline of next steps (developed by Secretariat after the meeting)**

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| 13 October | Secretariat to circulate: slightly revised version of principles (with no. 7 elaborated and contextual footnote at no. 1) and draft meeting note for WG comments and drafting suggestions; doodle poll for teleconference early November | Deadline for Working Group comments is 20 October |
| 13 October | Secretariat to share update with SAC Chairs on 3 Working Groups and invite comments on 7 draft principles | Deadline for SAC Chairs comments is 27 October |
| Early November date to be confirmed (aim to send 1 week before teleconference) | Secretariat to send agenda and papers to Working Group for the teleconference, including –<br>• Revised draft of principles with any additional commentary from the consultation with SAC Chairs and FSA staff<br>• Outline draft report from WG to Science Council 13 December meeting on powerpoint slides | |

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| T/C to be confirmed | Teleconference to discuss principles, report to Science Council, and plans for phase 2 | |
| Mid November | Further work on refining report to the Council including the principles/Circulate summary note of teleconference | |
| End November | Report to Science Council finalised/Plans for phase 2 in place/Publish background information on working group | Deadline for finalising report to the Council is end November |